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Menstrual health interventions to improve education and health outcomes among Ugandan students

Submission date
02/09/2021

Recruitment status
No longer recruiting

Registration date
16/09/2021

Overall study status
Completed

Last Edited
29/01/2026

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Many girls lack basic knowledge, facilities and/or materials for managing menstruation safely and with dignity. Improving menstrual health can lead to sustained long-term benefits to education, health and development. Many governmental and non-governmental organisations are interested in introducing interventions to improve menstrual health, including the UK Government Period Poverty Taskforce. However, there is a lack of evidence to guide policies and ensure interventions are effective.
Researchers have completed formative studies showing that poor menstrual health is a key factor associated with anxiety among girls and with missing secondary school or class in Wakiso District, Uganda. An effective intervention needs to address lack of knowledge of puberty and menstruation and the social environment (to reduce stigma), as well as practical methods to enable girls to better manage her periods (i.e. pad provision, education about effective pain management, and improvements to school toilet facilities). Studies suggest that an intervention addressing these elements can potentially improve education and mental health outcomes, but a randomised controlled trial is needed for definitive results to drive forward policy changes.
The aim of this study is to assess whether the intervention (MENISCUS) improves educational attainment, mental health symptoms, menstrual management and quality of life outcomes among girls in secondary school in Uganda.

Who can participate?
Secondary 1 students (mean age 15 years) in about 60 eligible secondary schools in Wakiso and Kalungu Districts in Uganda.

What does the study involve?
About 60 schools will be randomly allocated so that half receive the MENISCUS intervention in 2022 and the other half receive optimised usual care (provision of Government Menstrual Health guidelines and other relevant printed materials). The outcomes will be compared in secondary students between the two groups after 1 year, adjusting for baseline measures.
The primary outcomes are examination performance based on the curriculum taught during the intervention year; and mental health symptoms including emotional symptoms, attention and

peer relationship problems. The researchers will also assess the impact of the intervention on other outcomes including (in both girls and boys) menstrual knowledge and attitudes; and (in girls only) adequate menstrual practices (correct use of pads and/or menstrual cups), management of pain outcomes, self-efficacy (stigma and embarrassment around menstruation), quality of life, the prevalence of symptomatic urinary tract infections, school and class attendance during menses and overall, and confidence in maths and science. The main outcomes will be assessed in all students present in S3 at an endline survey. School and class attendance will be assessed in a sub-group of about 1500 girls.
The intervention has been designed to be culturally appropriate, aligned with Government guidelines, cost-effective, environmentally friendly and practically sustainable within the schools. The researchers will assess these elements through a process evaluation, health economics component and policy analysis.
At the end of the study, the schools in the control group will be offered the intervention package.

What are the possible benefits and risks of participating?
The benefits include improved self-efficacy to manage menstrual health. Risks include possible embarrassment in answering questions about genital symptoms or being asked to collect a urine sample. Participants will have an option to use a menstrual cup and may feel discomfort when inserting and removing the cup, and wrong placement may cause soreness until the participant becomes proficient in use.

Where is the study run from?
The London School of Hygiene & Tropical Medicine (UK), MRC/UVRI and LSHTM Uganda Unit, with implementing partner WoMena Uganda

When is the study starting and how long is it expected to run for?
November 2020 to August 2024

Who is funding the study?
The Department of Health and Social Care (DHSC) through the National Institute for Health Research (NIHR), Foreign, Commonwealth and Development Office (FCDO), the Medical Research Council (MRC), and the Wellcome Trust through the Joint Global Health Trials scheme

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MR/V005634/1

Study information

Scientific Title
Menstrual health interventions, schooling and mental health symptoms among Ugandan students (MENISCUS): a school-based cluster-randomised trial

Acronym
MENISCUS

Study objectives
The hypothesis is that the MENISCUS intervention will lead to improved educational performance, mental health outcomes and related health- and well-being outcomes among Ugandan secondary school girls. It is hypothesized that this will be achieved by improving self-efficacy for effective menstrual health (MH) in schools, through improving the MH social and physical environment, behavioural capability and observational learning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 26/05/2021, Uganda Virus Research Institute Research Ethics Committee (UVRI-REC, Uganda Virus Research Institute, Plot 51-59 Nakiwogo Road, Entebbe, PO Box 49, Entebbe, Uganda; +256 414 320 385; directoruvri@uvri.go.ug), ref: GC/127/21/05/819
2. Approved 14/07/2021, Uganda National Committee for Science and Technology (UNCST, Plot 6, Kimera Road, Ntinda, PO Box 6884, Kampala, Uganda; +256 414 705500; info@uncst.go.ug), ref: HS1525ES
3. Approved 03/08/2021, London School of Hygiene and Tropical Medicine (Keppel Street, London, WC1E 7HT, UK; +44 207 636 8636; ethics@lshtm.ac.uk), ref: 22952

Study design

Multicentre interventional single-blinded cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Menstrual health and education, health and well-being outcomes

Interventions
This study will be an open-cohort cluster randomised control trial with 60 schools (clusters) randomised 1:1 to two arms, with a mixed-methods process evaluation, and economic and policy analyses to evaluate the effectiveness and cost-effectiveness of a school-based MH intervention to improve education, health and wellbeing outcomes. The use of an open-cohort design allows students entering schools after baseline to participate in the endline survey.
The intervention will be implemented over the duration of 1 year in all intervention schools. At endline (2023), outcomes in all students in the class cohort who were present at baseline or joined during the intervention year will be assessed in a repeat of the cross-sectional survey. Selected secondary outcomes will be assessed in a randomly selected sample of approximately 1500 girls identified ahead of the endline survey to participate in a diary sub-study to assess associations of menstrual cycles and school attendance.

Control condition: Control arm schools will receive the MoES Guidelines on Menstrual Hygiene Management (MHM) in Schools (circular No. 1/2015) and the 2018 National Sexuality Education Framework (NSEF). Students will receive the Government Menstruation Management Reader. Control schools (n=30) will be offered the intervention after the endline evaluation is completed.

Intervention condition: Intervention arm schools will receive the control condition plus the MENISCUS intervention which comprises five components as follows:
1. Puberty Education Workshop: Train teachers of the participating students on how to deliver the puberty session to girls and boys. Teachers to develop an action plan, delivery of which will be overseen by a MH Leadership Group and the District Inspector of School.
2. Drama skit: MH drama skit developed by female and male students and performed at parents' day or another suitable occasion.
3. Provision of an MH kit: Distribution of a MH kit (reusable sanitary pads provided in a bag with underwear, a water bottle, soap and a towel) with the option to receive a medical-grade silicone, re-usable menstrual cup and a container for disinfection and storage. Teachers and prefects to train students to use the products. Training includes an education session on menstruation for girls and boys, and a gender-specific participatory session.
4. Pain relief: Information on effective period pain management, addressing common myths included in MH Training. Vouchers for analgesics will be included in the MH kit, each to be redeemed for six paracetamol or ibuprofen tablets per month from the school nurse or specified teacher.
5. Improving school WASH facilities: Improvements to school WASH facilities (fixing doors, providing locks, sanitary bins, toilet paper cages, water carriers, liquid soap (5L), and water (20L) containers) over seen by The MH Action Group, monitored by the District Inspector of Schools during routine termly school inspection visits.

Schools will be randomised 1:1 to intervention or control conditions in 3 batches, stratified by District (Kalungu) or sub-District (Wakiso). Restricted randomisation will be used to ensure good balance on key variables (i.e. school examination results, school type, mean SDQ score, current WASH facilities, and geographic area).

Intervention Type
Behavioural

Primary outcome(s)
Among all girls included in the endline survey:
1. Educational attainment of girls independently and objectively evaluated by endline perfomance in a bespoke examination set by the Uganda National Exam Board, which will assess the maths, English and biology curricula taught during the intervention implementation year, adjusted for baseline exam performance.
2. Mental health symptoms assessed in all girls using the Total Difficulties Scale of the Strengths and Difficulties Questionnaire (SDQ-25) adjusted for baseline

Key secondary outcome(s))
Current secondary outcome measures as of 18/12/2023:
1. Knowledge of puberty and menstruation; myths & attitudes towards menstruation (among all girls and a random sample of boys) reported by participants at endline measured by the number of knowledge items answered correctly (N=9) and myths/attitudes items answered correctly (N=3)
Among all girls:
2. Menstrual practices at last menstrual period (LMP) reported by participants at endline by direct questions (the odds of using only adequate menstrual materials that are appropriately cleaned or disposed of at LMP), and the mean score on the Menstrual Practice Needs Scale
3. Pain management during LMP reported by participants at endline by direct questions (the odds of using at least one effective pain management method and no ineffective methods)
4. Self-efficacy in addressing menstrual needs experiences at LMP measured using the mean score on Self-efficacy in Addressing Menstrual Needs Scale at endline
5. Quality of life reported by participants using the mean CHU9D score with Ugandan tariffs at endline
6. Symptomatic urinary tract infections (UTIs) measured as the odds of a positive test result from a urine sample if symptomatic at endline
Among sample of ~1500 girls:
7. School and class absence during menses measured as the odds of school days and classes missed during period-days compared with non-period days, measured from a daily diary for approximately 3 months prior to endline
8. School and class absence overall measured as the odds of all school days with school and/or class absence (regardless of menstruation) measured from a daily diary for 3 months prior to endline
9. Self-confidence in Mathematics and science abilities reported by participants at endline measured using the TIMMS confidence scale

Previous secondary outcome measures as of 08/08/2022:
1. Knowledge of puberty and menstruation; attitudes towards menstruation (among all girls and a random sample of boys) reported by participants at endline using a list of 9 questions that we have used previously
Among all girls:

2. Menstrual practices at last menstrual period (LMP) reported by participants at endline by direct questions and the mean score on the Menstrual Practice Needs Scale
3. Knowledge and practice of pain management during LMP reported by participants at endline by direct questions (e.g. the proportion knowing 4 or more effective pain management methods)
4. Self-efficacy in addressing menstrual needs experiences at LMP measured from the Mean score on Self-efficacy in Addressing Menstrual Needs Scale
5. Quality of life and happiness measured from validated tools at endline measured from the Mean CHU9D score and the single subjective wellbeing question "Overall, how happy are you with your life as a whole these day"
6. Prevalence of bacterial vaginosis (BV), vaginal yeast and urinary tract infections (UTIs) among symptomatic girls measured from self-taken vaginal swabs and a urine sample if symptomatic, at endline
Among sample of ~1500 girls:
7. Proportion of school days and classes missed during period-days after one year of the intervention measured from a daily diary for 3 months prior to endline
8. Proportion of all school days with school and/or class absence (regardless of menstruation) measured from a daily diary for 3 months prior to endline
9. Self-confidence in maths and science abilities measured using the TIMMS confidence scale

Previous secondary outcome measures:
1. Knowledge of puberty and menstruation; attitudes towards menstruation (among all girls and a random sample of boys) reported by participants at endline using a list of 9 questions that we have used previously
Among all girls:
2. Menstrual practices at last menstrual period (LMP) reported by participants at endline by direct questions and the mean score on the Menstrual Practice Needs Scale
3. Knowledge and practice of pain management during LMP reported by participants at endline by direct questions (e.g. the proportion knowing 4 or more effective pain management methods)
4. Self-efficacy in addressing menstrual needs experiences at LMP measured from the Mean score on Self-efficacy in Addressing Menstrual Needs Scale
5. Quality of life and happiness measured from validated tools at endline measured from the Mean CHU9D score and the single subjective wellbeing question "Overall, how happy are you with your life as a whole these day"
6. Prevalence of bacterial vaginosis (BV), vaginal yeast and urinary tract infections (UTIs) among symptomatic girls measured from self-taken vaginal swabs and a urine sample if symptomatic, at endline
Among sample of ~1500 girls:
7. Proportion of school days and classes missed during period-days after one year of the intervention measured from a daily diary for 3 months prior to endline
8. Proportion of all school days with school and/or class absence (regardless of menstruation) measured from a daily diary for 3 months prior to endline

Completion date
31/08/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/12/2023:
School-level inclusion criteria:
1. Mixed-sex secondary schools with S1–S4 classes

2. Day or mixed day/boarding schools.
3. At least minimal WASH facilities (including an improved water source and sex-specific sanitation facilities that are functional, usable, and accessible to female students at the time of the rapid assessment eligibility survey)
4. Estimated enrolment of 50–125 female S1 students in Wakiso and 40–125 female students in S1 in Kalungu, based on the 2019 report on the Master List of Education Institutions in Uganda

School-level exclusion criteria:
1. Schools that are currently participating in a menstrual health-related programme
2. Boarding schools with no day students
3. Single-sex schools
4. Schools exclusively for students with disabilities
5. Schools where more than approximately ~10% of students or parents of students do not understand Luganda or English

Participant-level inclusion criteria:
1. Female students in the class cohort of S2 in 2022 who were enrolled in a trial school at the time of the baseline and/or endline survey
2. Male students in the class cohort of S2 in 2022 who were enrolled in a trial school at the time of the baseline survey
3. For the diary sub-study, female trial participants were eligible if they reported having started menstruation at the time of the baseline survey

Previous inclusion criteria:
1. All female students starting Secondary 2 during 2021/2022 who are present and whose parents have given consent will be eligible for the baseline survey and to receive the intervention.
2. A simple random sample of ~15 male students (starting S2 during 2021) per school (900 total) who are present during Q4 2021 will be selected to participate in the baseline survey and asked to provide assent for data collection. The sampling will be done by the trial statistician using the random-number generator in Stata
3. The endline survey and assessment will be in Q1-2 2023, and all female students present and who have given consent/assent for the research will be eligible, as will the male students with baseline data

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
11 years

Upper age limit
21 years

Sex

All

Total final enrolment
5066

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
21/03/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Uganda

Study participating centre
MRC/UVRI and LSHTM Uganda Research Unit
PO Box 49
Entebbe
Uganda
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Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name

Foreign, Commonwealth and Development Office

Alternative Name(s)
Foreign, Commonwealth & Development Office, Foreign, Commonwealth & Development Office, UK Government, FCDO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. The London School of Hygiene and Tropical Medicne (LSHTM Data Compass). Website: https://datacompass.lshtm.ac.uk/). Data will be available after a 2 year embargo period from the end of the trial, and then available for 10 years. We proposed to offer controlled access to data, to ensure data is used in compliance with ethical conditions. Researchers will be invited to provide information on their aims and proposed analyses. The PI and Co-Is will evaluate each request and decide whether to grant data access. In line with the MRC/UVRI & LSHTM RDM policy, requests will only be turned down for justifiable reasons. Requests will be considered within 4 weeks. Participants will be asked consent for data sharing. Data will be anonymised. Data on very small focus group discussions where deductive disclosure can be performed will not be shared.

IPD sharing plan summary
Available on request, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/10/2024	17/10/2024	Yes	No
Results article		01/05/2025	28/04/2025	Yes	No
Results article	Secondary observation analyses	23/01/2026	29/01/2026	Yes	No
Protocol article		07/09/2022	08/09/2022	Yes	No
Other publications	Baseline data were used to assess factors associated with declining consent to receive a menstrual cup by parents and female students	05/12/2024	11/12/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical	version 1.2	16/01	22/01		

Analysis Plan		/2024	/2024	No	No
Study website	Study website	11/11 /2025	11/11 /2025	No	Yes