The Lancet Global Health

# Effects and costs of a multi-component menstrualhealth intervention (MENISCUS) on mental health problems, educational performance, and menstrual health in Ugandan secondary schools: an open-label, school-based, cluster-randomised controlled trial

--Manuscript Draft--

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| **Manuscript Number:** | LANGLH-D-24-01858R2 |
| **Article Type:** | Article (Original Research) |
| **Keywords:** | Adolescent Health; menstrual health; menstruation; Mental Health; Education; Randomized controlled trial; school health promotion |
| **Corresponding Author:** | Kate Andrews Nelson<br>London School of Hygiene & Tropical Medicine MRC International Statistics and Epidemiology Group<br>UNITED KINGDOM |
| **First Author:** | Kate A Nelson, MSc |
| **Order of Authors:** | Kate A Nelson, MSc |
| | Stephen Lagony, MPH |
| | Catherine Kansiime, PhD |
| | Belen Torondel, PhD |
| | Clare Tanton, PhD |
| | Denis Ndekezi, MPH |
| | Levicatus Mugenyi, PhD |
| | Ratifah Batuusa, BStat |
| | Christopher Baleke, MSc |
| | Katherine A Thomas, MSc |
| | Titus Ssesanga, BA |
| | Robert Bakanoma, MPH |
| | Prossy Namirembe, BA |
| | Aggrey Tumuhimbise, MMS |
| | Beatrice Nanyonga, BA |
| | Rodah Nambi, MPH |
| | Edward Obicho, BA |
| | Denis Ssenyondwa, PGCDH |
| | Daria Bucci, MSc |
| | Sophie Belfield, MSc |
| | Agnes Akech Ocen, BA |
| | Shamirah Nakalema, BA |
| | Connie Alezuyo, MSc |
| | Fred Matovu, PhD |
| | Stella Neema, PhD |
| | Nambusi Kyegombe, PhD |
| | Giulia Greco, PhD |
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|---|---|
| | John Jerrim, PhD |
| | Chris Bonell, PhD |
| | Janet A Seeley, PhD |
| | Helen A Weiss, DPhil |
| **Manuscript Region of Origin:** | UGANDA |
| **Abstract:** | Background<br><br>Menstrual health is a human rights issue, affecting mental health, wellbeing, and education. We assessed the effectiveness and costs of a school-based multi-component menstrual health intervention ("MENISCUS") to improve mental health problems and educational performance at individual level.<br><br>Methods<br><br>We conducted a cluster-randomised trial in Ugandan secondary schools, randomised 1:1 to the intervention or control condition (printed government menstrual health materials). The intervention included creating action groups, strengthening teacher-delivered puberty education, distributing menstrual kits, supporting student-led drama skits, providing pain-management strategies, and improving school water and sanitation facilities. Primary outcomes were mental health problems using the Strength and Difficulties Questionnaire (SDQ) Total Difficulties Score and independently-assessed educational performance at individual level. We estimated intention-to-treat intervention effects using mixed-effects models accounting for school clustering and adjusted for randomisation strata and baseline school-level means of outcomes. Registration: ISRCTN45461276.<br><br>Findings<br><br>We randomised 60 schools (30 per arm) and none withdrew. Between 21 March and 5 July 2022, 3841 female students participated in baseline assessments (89.7% of those eligible) and between 5 June and 22 August 2023, 3356 participated in endline assessments. At endline, there was no evidence of a difference in mental health problems (mean SDQ score: 10.8 vs 10.7 in intervention vs control arms; adjusted mean difference [aMD] 0.05, 95% CI -0.40 to 0.50) nor educational performance (mean z-score: 0.20 vs 0.12; aMD 0.05, 95% CI -0.10 to 0.19), despite improvements to menstrual health. The total incremental cost was US$85 per Senior 2 female student. One participant had a serious adverse event possibly related to the intervention.<br><br>Interpretation<br><br>Improving multiple dimensions of menstrual health in secondary schools in Uganda is important for health and human rights but is not sufficient to improve mental health or educational performance over one year.<br><br>Funding<br><br>UK Foreign, Commonwealth and DevelopmentOffice, Medical Research Council, Department of Health and Social Care, andWellcome. |

# Effects and costs of a multi-component menstrual health intervention (MENISCUS) on mental health problems, educational performance, and menstrual health in Ugandan secondary schools: an open-label, school-based, cluster-randomised controlled trial

Kate A Nelson*, Stephen Lagony*, Catherine Kansiime, Belen Torondel, Clare Tanton, Denis Ndekezi, Levicatus Mugenyi, Ratifah Batuusa, Christopher Baleke, Katherine A Thomas, Titus Ssesanga, Robert Bakanoma, Prossy Namirembe, Aggrey Tumuhimbise, Beatrice Nanyonga, Rodah Nambi, Edward Obicho, Denis Ssenyondwa, Daria Bucci, Sophie Belfield, Agnes Akech Ocen, Shamirah Nakalema, Connie Alezuyo, Fred Matovu, Stella Neema, Nambusi Kyegombe, Giulia Greco, John Jerrim, Chris Bonell, Janet A Seeley, Helen A Weiss

* Joint first authors

Affiliations:

1. MRC International Statistics and Epidemiology Group, London School of Hygiene & Tropical Medicine, London, UK (KA Nelson MSc, K Thomas MSc, Prof HA Weiss DPhil)
2. Medical Research Council/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit, Entebbe, Uganda (S Lagony MPH, D Ndekezi MPH, L Mugenyi PhD, R Batuusa Bstat, C Baleke MSc, T Ssesanga Kisa BA, R Bakanoma MPH, P Namirembe BA, A Tumuhimbise MMS, B Nanyonga BA, R Nambi MPH, E Obicho BA, D Ssenyondwa PGCDH, N Kyegombe PhD)
3. Africa Research Excellence Fund, MRC Unit The Gambia at London School of Hygiene & Tropical Medicine, Fajara, The Gambia (C Kansiime PhD)
4. Department of Disease Control, London School of Hygiene & Tropical Medicine, London, UK (B Torondel)
5. Department of Global Health and Development, London School of Hygiene & Tropical Medicine, London, UK (C Tanton PhD, D Bucci MSc, N Kyegombe PhD, G Greco PhD, Prof JA Seeley PhD)
6. WoMena Uganda, Kampala, Uganda (S Belfield MSc, S Nakalema BA, A Akech Ocen BA)
7. Ministry of Education and Sports, Uganda, Kampala, Uganda (C Alezuyo MSc)
8. Policy Analysis and Development Research Institute, School of Economics, Makerere University, Kampala, Uganda (F Matovu PhD)
9. Department of Sociology and Anthropology, School of Social Sciences, Makerere University, Kampala, Uganda (S Neema PhD)
10. Institute of Education, University College London, London, UK (Prof J Jerrim PhD)
11. Department of Public Health, Environments and Society, London School of Hygiene & Tropical Medicine, London, UK (Prof C Bonell PhD)

Correspondence to:

Kate A Nelson, MRC International Statistics and Epidemiology Group, London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT, UK. kate.nelson@lshtm.ac.uk

or

Prof Helen A Weiss, MRC International Statistics and Epidemiology Group, London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT, UK. helen.weiss@lshtm.ac.uk

# SUMMARY

## Background

Menstrual health is a human rights issue, affecting mental health, wellbeing, and education. We assessed the effectiveness and costs of a school-based multi-component menstrual health intervention ("MENISCUS") to improve mental health problems and educational performance at individual level.

## Methods

We conducted a cluster-randomised trial in Ugandan secondary schools, randomised 1:1 to the intervention or control condition (printed government menstrual health materials). The intervention included creating action groups, strengthening teacher-delivered puberty education, distributing menstrual kits, supporting student-led drama skits, providing pain-management strategies, and improving school water and sanitation facilities. Primary outcomes were mental health problems using the Strength and Difficulties Questionnaire (SDQ) Total Difficulties Score and independently-assessed educational performance at individual level. We estimated intention-to-treat intervention effects using mixed-effects models accounting for school clustering and adjusted for randomisation strata and baseline school-level means of outcomes. Registration: ISRCTN45461276.

## Findings

We randomised 60 schools (30 per arm) and none withdrew. Between 21 March and 5 July 2022, 3841 female students participated in baseline assessments (89.7% of those eligible) and between 5 June and 22 August 2023, 3356 participated in endline assessments. At endline, there was no evidence of a difference in mental health problems (mean SDQ score: 10.8 vs 10.7 in intervention vs control arms; adjusted mean difference [aMD] 0.05, 95% CI -0.40 to 0.50) nor educational performance (mean z-score: 0.20 vs 0.12; aMD 0.05, 95% CI -0.10 to 0.19), despite improvements to menstrual health. The total incremental cost was US$85 per Senior 2 female student. One participant had a serious adverse event possibly related to the intervention.

## Interpretation

Improving multiple dimensions of menstrual health in secondary schools in Uganda is important for health and human rights but is not sufficient to improve mental health or educational performance over one year.

## Funding

UK Foreign, Commonwealth and Development Office, Medical Research Council, Department of Health and Social Care, and Wellcome.

## PANEL: RESEARCH IN CONTEXT

*Evidence before this study*

Menstrual health, defined as complete physical, mental, and social wellbeing in relation to the menstrual cycle, is recognised by the World Health Organisation as a health and human rights issue. An integrated model of menstrual experience developed through a systematic review of qualitative studies illustrated pathways through which menstrual experience impacts on physical and psychological health, education, employment, and social participation. Two systematic reviews of the effectiveness of menstrual health interventions on i) health and social effects (2013) and ii) education and psychosocial outcomes (2016) collectively identified five randomised controlled trials. None of these trials tested interventions addressing both the physical and psychosocial aspects of menstrual health, and the reviews concluded that there was insufficient evidence that menstrual health interventions improve school attendance or psychological wellbeing. The authors called for more rigorous evaluations of multi-component interventions, based on theories of change with improved measurement of core concepts. A review published in 2020 of intervention effects on menstrual-related school attendance and educational attainment again found limited and heterogenous evidence, and called for studies addressing pain management, the major reason for menstruation-related absenteeism. We searched PubMed, with no language restriction, from 1st January 2015 (the end date of the 2016 systematic review) to 6th April 2024 for randomised controlled trials using the terms (menstrua* or menses or menarche) and (school or educ* or student). We identified two further school-randomised controlled trials (RCTs). One found evidence that providing menstrual cups to secondary-school students in Kenya reduced incident herpes simplex virus type-2 infection but not HIV, school dropout, or pregnancy; the other found no impact of menstrual pad distributions and/or reproductive health education on school attendance in Kenyan primary schools, but positive impacts on knowledge, attitudes, gender norms, and self-efficacy. Through colleagues, we identified three additional pre-prints of rigorous trials: an RCT in Bangladesh which found a positive impact of a multi-component menstrual health programme on menstrual health, school attendance and psychological wellbeing during menstruation (2021), an RCT in The Gambia which found no evidence of an impact on school attendance nor reproductive health outcomes (2023), and an RCT in Uganda which found no evidence of an effect on school attendance following distribution of pads and education (2018).

*Added value of this study*

This RCT adds to the limited evidence on the effectiveness of multi-component menstrual health interventions on educational and mental health outcomes and addresses priority research questions for improving menstrual health amidst growing global policy commitments. We found no evidence that the menstrual health intervention improved educational performance or reduced mental health problems among girls in secondary schools in Uganda, but found strong evidence that the intervention improved multiple dimensions of menstrual health, including menstrual self-efficacy and use of effective pain management strategies. We found a beneficial intervention effect on attitudes towards menstruation among male and female participants. Qualitative data suggested that the intervention was acceptable to, and valued by, participants. All resources used were costed to inform financial sustainability and cost-effectiveness analyses.

*Implications of all the available evidence*

Menstrual health is multidimensional, and multi-component interventions can lead to important improvements in the physical and social menstrual health environment in schools. Poor menstrual health is associated with poor mental health and school absenteeism, but menstrual health interventions may

not be sufficient to lead to measurable improvements in these outcomes, amidst many other stronger influences.

## INTRODUCTION

Menstrual health is defined as a state of physical, mental, and social wellbeing in relation to the menstrual cycle,[1] and is a recognised human right.[2] The definition reflects the multi-faceted nature of menstrual health, and the broad impacts it can have on individuals' health and wellbeing.[3] Achieving menstrual health is essential to meet multiple Sustainable Development Goals and while there is growing commitment to improve menstrual health, there is little evidence to guide effective intervention.[4]

Qualitative studies have highlighted possible consequences of poor menstrual health on education, employment, physical and psychological health, and social participation.[3] Shame, stigma, bullying, and distress during menstruation can contribute to reduced self-esteem, self-efficacy, and social participation, and to anxiety, depression, or conduct problems. Quantitative evidence for pathways linking menstrual health and mental health includes effects of menstrual-related hormonal fluctuations, dysmenorrhea, and access to menstrual products on psychological distress, anxiety, and depressive disorders.[5,6] Multiple aspects of poor menstrual health can lead to school absence, including fear of blood leakage and unsupportive physical and social school environments.[3] Interventions can improve menstrual-related knowledge and management, but few studies have quantified the impact of interventions on the socio-cultural context of menstrual experience, and educational, health, and wellbeing outcomes.[7,8]

In Uganda, only 35% of women aged 15-49 report having an adequate physical and social environment for menstrual management.[9] In 2016, our formative research in secondary schools in Wakiso District, Uganda showed that poor menstrual health was associated with school absenteeism and poor wellbeing.[10] We found a need for interventions to enable girls to better manage psychosocial and physical aspects of menstruation, and to include boys and teachers to improve the social environment. We then co-designed an intervention grounded in social cognitive theory ("MENISCUS" - Menstrual health Interventions, Schooling and Mental Health problems among Ugandan Students) with district and school-level stakeholders. We piloted the intervention in a pre-post study in two schools in Wakiso District, finding it feasible to deliver, acceptable, and valued by stakeholders. Following the intervention, there was improved school attendance and reduced mental health problems.[11]

Our hypothesis was that improved menstrual experiences and self-efficacy improves social participation, confidence, school engagement and attendance during menstruation, leading to reduced internalising and externalising mental health problems and improved educational performance. In this paper, we report the effectiveness of the MENISCUS menstrual health intervention on education and health outcomes in secondary schools in central Uganda.

## METHODS

### Study design and participants

We conducted a parallel-arm, cluster-randomised controlled trial in 60 secondary schools in Wakiso and Kalungu districts, Uganda, from 2021 to 2024 with a mixed-methods process evaluation and economic and policy analyses.[12]

Schools were eligible if they had male and female students, senior 1-4 classes, day or mixed day and boarding students, at least minimal water, sanitation, and hygiene (WASH) facilities, and estimated enrolments of 50-125 or 40-125 female Senior 1 students in Wakiso and Kalungu districts respectively. We excluded schools participating in existing menstrual health related programmes and those exclusively for students with disabilities. We assessed schools for eligibility using the government's 2019 master list of education institutions. We checked the eligibility of all government schools and a random sample of private schools through phone calls and visits.[13] We sought written, school-level consent from the headteacher or representative in 60 randomly-selected schools confirmed eligible and willing to participate.

We obtained enrolment lists from participating schools for the incoming Senior 2 class (academic year beginning January 2022; mean age approximately 15·5 years). All female students enrolled in Senior 2 in a trial school and present during the survey period were eligible. At endline, all female students present and enrolled in Senior 3, based on updated enrolment lists obtained as of 31 March 2023, were eligible for outcome assessments. We selected a simple random sample of 25 post-menarche female participants per school to self-complete a diary of their daily class attendance and menstrual cycle over approximately three months prior to the endline survey. If there were fewer than 25 post-menarche female participants, all were selected.

We selected a simple random sample of 15 male Senior 2 students per school to assess the intervention effect on knowledge and attitudes. Male participants enrolled in the same school at endline were eligible for outcome assessments. If there were fewer than 15 male students in a school, all were selected. Recruitment procedures occurred prior to random allocation.

Parents and guardians of eligible female students aged <18 years were invited to attend in-person meetings at school, where the research team explained the study procedures and sought written informed parental consent. We reached remaining parents/guardians through phone calls facilitated by the schools and documented verbal informed consent. We obtained a waiver of parental consent for male participants as the knowledge-based survey was deemed to carry minimal risk. We sought electronic written informed assent from students aged <18 years with parental consent and electronic written informed consent for those aged $\geq$18 years, immediately prior to the survey. Trial staff explained the study procedures in a classroom, after which students watched an informational video before deciding whether to assent. We sought separate parental consent and student assent to receive a menstrual cup, so that parents/guardians/students could choose to participate in all trial activities except for receiving a cup. Consent and assent were sought prior to endline for female students newly enrolled in a trial school post-baseline, using the same procedures in both arms.

Ethics approval for the trial was granted by the Uganda Virus Research Institute Research & Ethics Committee, the Uganda National Council of Science and Technology, and the London School of Hygiene & Tropical Medicine. Protocol amendments are detailed in the appendix (p2).

**Randomisation and masking**

After the baseline survey, we randomised schools 1:1 to receive the MENISCUS intervention or optimised usual care (printed government menstrual health materials). We stratified schools by district and baseline mean school examination score (above or below the median) and conducted covariate-constrained randomisation to minimise imbalance with respect to key factors: mean baseline examination score, past (2017-2019) school examination scores, government or private school, mean baseline score for mental health problems and menstrual practice needs, and school size (number of Senior 2 female students) (appendix p3). For each district, we generated all possible random allocations,

restricted to those meeting the specified stratification and balance criteria using the *cvcrand* R package, and then randomly selected 1000 of these allocations (LM and KAN).

We conducted one randomisation ceremony per district, where school representatives pulled three numbered balls from an opaque bag (with replacement), forming a three-digit number corresponding to the ID of one allocation. A fourth ball was selected to decide which arm would receive the intervention. Control arm schools were offered the intervention after completion of endline assessments.

Schools, participants, implementors, and most study staff including the study clinician who monitored adverse events could not be masked to allocation status. The PI (HAW), statistician (LM) and the Uganda National Examinations Board (UNEB) staff who independently administered the educational assessment were masked. To minimise assessment bias, surveys were self-completed by participants and co-ordinated by the research team, which was separate from the implementor (NGO WoMena Uganda).

**Procedures**

The MENISCUS intervention was developed following formative and pilot studies (2015-2018).[10–12] The theory of change (ToC) was grounded in social cognitive theory[14], with the intervention designed to positively reinforce observational learning and create a supportive environment for menstrual health, increasing participants' self-efficacy to address their menstrual needs, and supporting behaviour change through improvements to the social and physical school environments.

The intervention consisted of: i) training teachers to improve puberty education; ii) a student-led drama skit about menstrual health; iii) training selected students and teachers to deliver menstrual-health education sessions alongside the distribution of a menstrual kit containing reusable menstrual pads and an optional menstrual cup; iv) training on pain management, including provision of analgesics; and v) improvements to school WASH facilities (described previously[12]). In each school, a "Menstrual Health Action Group", consisting of teachers, students, and/or parents, was established to help coordinate and sustain the intervention.

We used a train-the-trainer model, with the implementor responsible for delivering central trainings to selected students and teachers who led school intervention activities. Following delivery of the intervention, it was expected that teachers would deliver puberty education sessions as part of the regular curriculum; students would perform the drama skit to the school community; menstrual health education sessions would be delivered with the kit distribution and repeated for students who were absent; participants would be able to access analgesics from the school nurse or designated teacher; and the Action Group would help maintain the WASH facility improvements.

We provided all schools with government guidelines on menstrual hygiene management and sexuality education, and all male and female Senior 2 participants with the government menstrual management reader.[15,16]

We conducted the endline survey approximately one year after baseline survey and randomisation. All surveys were self-completed by participants on tablets at their school. The research team offered support if requested but otherwise did not view responses. Data were synced daily to a secure ODK Central server.

Female students who newly enrolled in a trial school during the intervention year (identified through school enrolment lists as of 31 March 2023) completed a brief demographic survey at recruitment, prior to the endline survey.

We distributed booklets to diary sub-study participants approximately 12 weeks prior to the endline survey. We asked participants to complete them daily by shading boxes to answer six closed-ended

questions on their school and class attendance and menstrual flow. Trial staff visited schools every 2-3 weeks to collect completed pages. Participants were permitted to retrospectively complete the diary within the current week.

We assessed fidelity of implementation against pre-specified indicators. Schools that met each indicator, based on a combination of observations, implementor logbooks, minutes, and school self-report, were considered to have implemented the intervention to a minimum intended level.

As part of the process evaluation, we conducted in-depth interviews (IDI) with senior school staff members at baseline and endline (n=60), and with intervention implementors (n=8) and school menstrual health action group members (n=30) during intervention delivery and at endline. We selected four case-study schools with varied baseline educational performance, menstrual cup consent, and school size. In each case-study school, we conducted three IDIs with female students and teachers and three focus group discussions with female students, male students, and teachers respectively, during intervention delivery and at endline. Participants were purposively sampled to ensure variation in demographic characteristics and degree of engagement with the intervention. We used thematic analysis to understand the potential mechanisms of impact and their interaction with context.

We estimated all resources used for setting up and running each intervention component from a provider perspective, with a combination of top-down and micro-costing approaches. Financial and economic costs were identified and measured from project accounts and process evaluation data, and valued using an adapted costing tool.[17] Start-up costs were annuitized over their expected lifespans of 1.5 years and discounted at 7% and implementation costs discounted at 11% (the average interest rate during the start-up and implementation phases). Economic costs were used to reflect the value of non-financial costs (e.g. donated menstrual cups). Research costs were excluded. Unit costs were calculated as the total annual incremental costs per student in Senior 2. Costs were incurred in Uganda shillings, adjusted to 2023 prices and converted to 2023 US$. Further details and sensitivity analyses are reported in appendix pp16-18.

**Outcomes**

The primary outcomes were educational performance and mental health problems among all female participants at endline. Educational performance was independently assessed by UNEB over two days during the baseline and endline periods, following standard national examination procedures. The baseline assessment covered the mathematics and biology secondary school syllabuses taught pre-intervention, and the endline assessment covered the mathematics, English, and biology syllabuses taught in Senior 2-Senior 3. The outcome was the mean z-score for these subjects. Mental health problems were assessed using the Strengths and Difficulties Questionnaire (SDQ-25) Total Difficulties Score which is a dimensional measure of behavioural and emotional difficulties[18] and has been widely used among adolescents in Africa.[19] The possible range is 0-40, with higher scores indicating more problems.

Secondary outcomes included dimensions of menstrual health and school attendance (Table 1).

Serious adverse events (SAEs) were defined as death, life-threatening event, hospitalisation, or persistent or significant disability or incapacity, and were reported to the trial clinical officer by trained school designees. Schools reported SAEs from the date of randomisation until December 31$^{st}$ 2023.

**Sample size**

The sample size (60 schools) was estimated to provide 84% power to detect a target effect of a standardised mean difference (SMD) of 0·2 for continuous outcomes, assuming a harmonic mean of 60 female participants per school at endline, an intra-class correlation coefficient (ICC) of 0·05, and a two-

sided significance level of 0·05. The effect size was based on the pilot study findings.[11] Revised calculations were conducted in March 2022 to reflect smaller school sizes after COVID-related school closures. With 60 schools, a harmonic mean of 40 female students per school at endline was estimated to provide 80% power to detect an SMD of 0·2.

### Statistical analyses

The primary analysis was intention-to-treat, with schools analysed according to the arm they were randomised to, using individual-level data from endline participants. We adjusted analyses for randomisation strata and the baseline cluster-level mean of the outcome, where available, as fixed effects. All analyses accounted for clustering using a random effect for school.

For primary outcomes and continuous secondary outcomes, we estimated the intervention effect as the adjusted mean difference (aMD) and SMD at endline between arms using mixed-effects linear regression with 95% confidence intervals (CIs). For count and binary outcomes, we estimated adjusted incidence rate ratios (aIRR) and adjusted odds ratios (aOR) using mixed-effects Poisson regression and mixed-effects logistic regression, respectively.

We estimated the aOR for school absence using mixed-effects logistic regression with random intercepts for school and student, using the diary data. We estimated intervention effects for absence on 'period days' relative to non-period days as the interaction term between intervention arm and period day. 'Period day' was a binary variable defined a-priori as a day of menses or the day prior to first day of bleeding. We weighted this analysis by the inverse of the school-level sampling fraction, so results represent the female trial population.

We pre-specified use of the Benjamini-Hochberg procedure to adjust the type 1 error for the two primary outcomes.[22] For secondary outcomes, we made specific inferences for each individual null hypothesis and did not adjust the type 1 error.

We assessed effect-modification for primary outcomes by estimating p-values for interaction terms by subgroup and arm using the likelihood ratio test (LRT). Pre-specified subgroup analyses were district, school ownership and pre-defined binary categories of school-level variables (baseline educational performance score, school size, and proportion of boarding students), and individual-level variables (age group, day/boarding status, socioeconomic status, and median baseline SDQ/UNEB score respectively for primary outcomes).

For primary outcomes, we also estimated the intervention effect within the closed cohort of female participants at the same school at baseline and endline, hypothesising that the intervention effects may be stronger than for the primary analysis population. As sensitivity analyses, we estimated intervention effects using cluster-level analyses and using independent estimating equations with robust standard errors to minimise bias in the presence of informative cluster size.

Statistical analyses were conducted using Stata 18·0, and costing analyses using Excel. The trial was prospectively registered (ISRCTN45461276). An independent Trial Steering Committee provided scientific guidance and monitored the progress of the trial. The Independent Data Monitoring and Ethics Committee (IDMEC) reviewed the trial recruitment and safety data, and provided scientific guidance. The IDMEC approved the statistical analysis plan prior to the unmasking of trial data.

### Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

## RESULTS

We recruited 60 schools (Wakiso n=44; Kalungu n=16) from 67 schools confirmed eligible. Baseline participants were recruited from 21 March to 5 July 2022. Overall, 3841 (89·7%) of 4281 enrolled female Senior 2 students participated in the baseline survey (Figure 1). Of these, 1699 (44·2%) participants or their parents gave consent and assent to receive a menstrual cup. Female participants had a mean age of 15·6 years and 44·7% were boarding students. The mean baseline SDQ Total Difficulties score was 12·2 (SD 5·6; Cronbach alpha 0.71). Baseline school and participant characteristics and baseline measures of the outcomes were balanced across arms (Table 2; appendix p4).

All 60 schools participated in the endline survey (5 June to 22 August 2023). In total, 3356 female participants, including 310 who had joined since baseline and contributed to the endline assessments (control arm N=1666; intervention arm N=1690) (Figure **1**). The mean number per school was 55·5 (SD 28·2, harmonic mean 40·5) in the control arm and 56·3 (SD 30·4, harmonic mean 40·2) in the intervention arm. Of the 3841 female baseline participants, 2991 (77·9%) were seen at endline in the same school (closed cohort). A total of 312 female endline participants were missing UNEB assessment scores (9·3%) due to absence, 33 were missing a UTI test result (1·0%), and 4 were missing an MPNS score due to a survey error (0·1%). Of the 874 male baseline participants, 655 (74·9%) were seen at endline in the same school (appendix p8). Diary booklets were distributed to 1477 female participants from 3 April 2023. Of these, 1305 (88·4%) returned diaries, with a median of 69 school-days completed (IQR 61-77) (appendix p9).

We found no evidence for an intervention effect on the mean educational performance score or the SDQ Total Difficulties score. The mean z-score for the educational assessment was 0·12 (SE 0·02) in the control arm versus 0·20 (SE 0.02) in the intervention arm, with no evidence for a difference (aMD=0·05, 95% CI -0·10-0·19; SMD=0·06, 95%CI -0·12-0·24) (Table 3). The mean SDQ Total Difficulties score decreased from baseline to endline among participants in each arm (12·2 to 10·7 in the control arm; 12·1 to 10·8 in the intervention arm), with no evidence of a difference between arms at endline (aMD=0·05, 95% CI -0·40-0·50; SMD=0·01, 95%CI -0·07-0·09).

We found strong evidence of an intervention effect on most menstrual-related secondary outcomes, with small effect sizes (Table 3). Compared with control arm participants, those in the intervention arm reported greater knowledge about puberty and menstruation, more positive attitudes towards menstruation, greater use of effective pain management, fewer unmet menstrual needs, and greater self-efficacy to manage menstruation. We found no evidence of an intervention effect on adequate menstrual hygiene management, defined as exclusive use of adequate materials that were disposed or cleaned properly during their last menstrual period, and little evidence for an effect on the proportion with a symptomatic UTI. There was no evidence of a difference in female participants' confidence in mathematics or science. Results were similar when restricted to the closed cohort (appendix p12). In the diary sub-study, we found no evidence of an intervention effect on school or class attendance (on period days or overall) (Table 3).

Among male participants, we found evidence of a beneficial intervention effect on positive attitudes towards menstruation, and no evidence for an intervention effect on knowledge about puberty and menstruation (Table 3).

All findings were robust to the alternative estimation methods (appendix p12). We found no evidence that the intervention effects differed by the pre-specified subgroups (Table 4).

The implementor delivered all planned district-level training sessions within 3·5 months of randomisation, attended by 29/30 intervention schools. Menstrual health kits were distributed in all schools by 6 months after randomisation. The final implementor-led intervention activity (training of drama skit facilitators), was completed by 9 months after randomisation. Fidelity of school-led activities

varied across components (appendix pp13-15). Overall, 20/28 schools with complete process data implemented all intervention components to the minimum intended level (excluding the availability of analgesics, which we were unable to measure).

Qualitative findings indicated that the intervention was widely accepted among school communities and positively impacted menstrual experiences at school. Participants reported greater confidence in managing menstruation due to improvements to the social and physical school environments, such as the WASH facilities and access to menstrual products. Action Groups were reported to successfully engage the school community in activities (especially WASH and puberty education) and were perceived to be most successful when they had active student involvement. Staff turnover and motivation were challenging in some schools, affecting implementation. Provision of free reusable menstrual products alleviated participants' and parents' stress around acquiring disposable pads. Conversely, some participants reported not using the reusable products at school due to having to wash and dry them, with fears about washing menstrual blood and embarrassment around carrying a used pad. Education sessions, drama skits and distribution of analgesics were perceived to have normalised menstruation, provided information about pain and menstrual management, and addressed misconceptions about painkillers. Key challenges were maintenance of WASH facilities and access to painkillers. The central involvement of male students was seen as key to intervention success by improving interactions among male and female students, leading to more support from male students and reduced stigma.

The incremental cost of setting-up the intervention was US$40,990. The annual implementation cost was US$181,503, equivalent to a unit cost of US$6,050 per school, US$44 per Senior 2 student, or US$85 per Senior 2 female student. The largest cost drivers in the implementation were supplies (33%) and salaries (29%) (appendix p17).

Three participants in the intervention arm and two participants in the control arm had SAEs. One of the SAEs (severe anaemia secondary to excess vaginal bleeding, treated successfully) (appendix p11).

## DISCUSSION

This is one of the first RCTs to evaluate the impact of a multi-component menstrual health intervention on educational performance and mental health problems. We found evidence of effects on menstrual health outcomes including pain management, menstrual self-efficacy, and attitudes, but these were insufficient to impact the primary educational and mental health outcomes over one year.

Few evaluations of menstrual health interventions have included mental health outcomes.[8] The lack of impact of our intervention on mental health problems is consistent with results from a school-based RCT in Bangladesh, which found no intervention effect on psychological wellbeing measured by the Mental Health Index[23], and results from a quasi-randomised trial in Uganda which found no impact on psychosocial outcomes including the SDQ.[24]

The lack of intervention effect on mental health may be due to multiple factors. While we found strong evidence of an intervention effect on almost all dimensions of menstrual health measured, these effects were modest and may have been insufficient to lead to a measurable impact on mental health problems. A longer duration allowing for participants to have repeated positive menstrual experiences may also be needed to impact mental health. Given biopsychosocial links between menstrual health and mental health[5], the lack of effect likely also reflects the multiple causes of mental health problems among adolescents. A systematic review of brief, school-based counselling interventions which directly targeted mental health found heterogeneous but small positive effects on mental health or wellbeing, underscoring the challenge of improving mental health through school-based programmes generally.[25]

Finally, the improvement in mental health problems over time in both arms in our trial indicates a possible beneficial effect of participating in the research activities.

This is the first trial of a menstrual health intervention to include an educational performance outcome, in addition to absenteeism. We hypothesised that education performance would be improved by addressing menstrual factors associated with school absence and reduced engagement (pain, lack of menstrual products, poor WASH facilities, and stigma or behavioural restrictions).[3,12] The lack of evidence of an intervention effect on either absenteeism or performance adds to the limited body of evidence. A systematic review found moderate but non-significant effects on school attendance associated with menstrual product distribution interventions, and low levels of menstrual-related absenteeism overall,[8] and an RCT in Kenyan schools found no impact of providing menstrual cups and menstrual education on school absenteeism or dropout.[26] The lack of association may be partly due to the small number of school-days during menstruation (0-5 per month) and challenges measuring school attendance.[27]

The quality of school-led implementation was encouraging amidst COVID-related challenges and staff turnover. The lack of intervention effect is unlikely to be due to poor implementation given the adequate fidelity observed. Qualitative data showed the intervention to be highly valued by school staff and students. To our knowledge, 12/30 of the control schools reported some menstrual health-related activities such as pad distributions during trial follow-up. This may have attenuated the observed intervention effects on secondary menstrual health outcomes and demonstrates the added value of multi-component interventions that go beyond product provision.

A strength of our study is the alignment of the intervention and ToC with the definition of menstrual health[1] and integrated model of menstrual experience.[3] Our intervention was innovative in its focus on improving menstrual self-efficacy and the social environment, including attitudes among boys, and had an effect on almost all dimensions of menstrual health in the model.[3] The lack of effect on the proportion of participants reporting using adequate menstrual materials that were disposed or cleaned properly is consistent with our qualitative findings that reusable pads were less convenient to use at school than disposable pads. These findings highlight the importance of participant-centred interventions that improve perceived menstrual needs, beyond promoting objectively defined measures of 'good' menstrual management.

Additional strengths included a representative and heterogeneous sample of large schools in two Ugandan districts, supporting generalisability to this population. The acceptability of the intervention was also reflected in the minimal response bias with a high proportion of consent/assent at the school, parent and student levels. We minimised assessment bias with independent assessment of educational performance, self-completed surveys and collection of baseline data prior to randomisation. We minimised measurement bias using validated up-to-date tools for menstrual-related outcomes where these existed. Measuring school attendance is challenging and we used recommended data collection methods[27] validated in this setting against observational spot-checks for attendance.[11]

A limitation was the timing of the intervention rollout and endline assessment. The intervention took longer than anticipated to be fully delivered, with delays largely due to over-burdened schools following lengthy COVID-related school closures. These closures also meant that the school-led intervention implementation was split over two academic years, leading to interruptions during examination periods and holidays. Previous studies have shown that menstruators often take several months to become comfortable using the menstrual cup, so we may not have captured the full potential benefit.[28] The dynamic school environment, with students and staff leaving and joining throughout the academic year, meant that not all students received the full possible exposure to the intervention. Our trial design allowed us to capture the effects of an intervention when delivered in this real-world setting, but this

turnover has implications for longer-term sustainability of train-the-trainer intervention models which we will explore further in the process evaluation.

We used the SDQ to assess mental health problems due to its widespread use including among adolescents in sub-Saharan Africa. While it can be used to assess risk of emotional and conduct disorders, it may not directly capture some aspects of mental health problems relevant to menstrual health such as depression and anxiety.[19] However, there is a lack of alternative validated tools to assess mental health among adolescents at population-level in sub-Saharan Africa.[29] We similarly found no intervention effect on pre-specified exploratory outcomes of the SDQ internalising subscale (appendix p13), suggesting the lack of intervention impact on mental health is unlikely explained by these measurement limitations. It is possible that more targeted interventions are needed to address menstrual cycle disorders and severe dysmenorrhea, which may have stronger impacts on mental health.

The cost of the MENISCUS intervention per Senior 2 female student (US$85) exceeded that of a comparable trial in Kenya, in which the estimated annual cost of providing menstrual kits (cup or disposable pads and soap) and puberty education training was US$34 per direct recipient (appendix p18).[30] The higher cost of the MENISCUS intervention is likely attributable to the inclusion of additional components. Moreover, some intervention components were designed to benefit the entire school community, which would substantially reduce the cost per beneficiary if taken into account.

In a context of growing advocacy, policy, and public interest around menstrual health, it is critical to build the evidence base for what works to address substantial unmet menstrual health needs globally. We provide novel evidence for the effectiveness of a multi-component menstrual health intervention. While the intervention achieved modest improvements in multiple dimensions of menstrual health, these were not sufficient to impact mental health or educational performance as widely hypothesised. Further research is needed to strengthen interventions to improve adolescents' menstrual health as a human rights issue, and to directly address their mental health and educational needs.

**Contributors**

All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication. CBon, GG, JJ, CK, FM, JAS, CT, BT, and HAW conceptualised the research question, acquired the funding and designed the methodology. RBak, CBal, RBat, SB, CK, SL, SNak, PN, BN, RN, DN, SA, TS and AT conducted the investigation, under the supervision of CA, CBon, GG, JJ, NK, FM, SN, JAS, CT, KAN, KAT, BT and HAW. KAN, CK, SL and HAW undertook project administration. KAN, LM and HAW conducted the formal analysis. KAN, SL and HAW wrote the original draft and all authors critically reviewed the manuscript. HAW, KAN, and LM have directly accessed and verified the underlying data reported in the manuscript.

**Declaration of interests**

The authors declare no competing interests.

**Data sharing**

The de-identified individual participant data that underlie the results reported in this article are available indefinitely on request from the London School of Hygiene & Tropical Medicine Data Compass at https://doi.org/10.17037/DATA.00003822, along with the codebook, informed consent documents, and qualitative interview guides. Participants gave informed consent for their data to be published after de-identification. The statistical analysis plan is publicly available on the trial registration page: https://www.isrctn.com/ISRCTN45461276.

**Acknowledgements**

The MENISCUS Trial was supported by the Joint Global Health Scheme with funding from the UK Foreign, Commonwealth and Development Office, the UK Medical Research Council, the UK Department of Health and Social Care through the National Institute of Health Research (NIHR) and Wellcome (grant ref MR/V005634/1). We would like to thank the staff, students, and communities of participating schools for their engagement with the study; the stakeholders from the Uganda Ministry of Education and Sports and District Education Officers in Wakiso and Kalungu districts who generously offered their advice; and the members of our Community Advisory Boards for their valuable input. We thank the members of the Trial Steering Committee including Dr Nelly Mugo (Chair), Prof. Rashida Ferrand, Dr Cleophus Mugenyi, Prof. David Ross, Dr Marni Sommer, and Dr Emily Wilson-Smith, and the members of the Independent Data Monitoring and Ethics Committee including Prof. Penelope Phillips-Howard (Chair), Dr Laura Marsden, Dr Brenda Gati Mirembe, and Dr Brennan Kahan, for sharing their time and expertise with us throughout the trial. We would also like to acknowledge the many essential contributions from the entire MENSICUS research team including study administrator Alex Mutazindwa; the WoMena implementation team; and the late Dr George Miiro who led the formative work that underpins this study.

## LEGEND OF TABLES AND FIGURES

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Figure

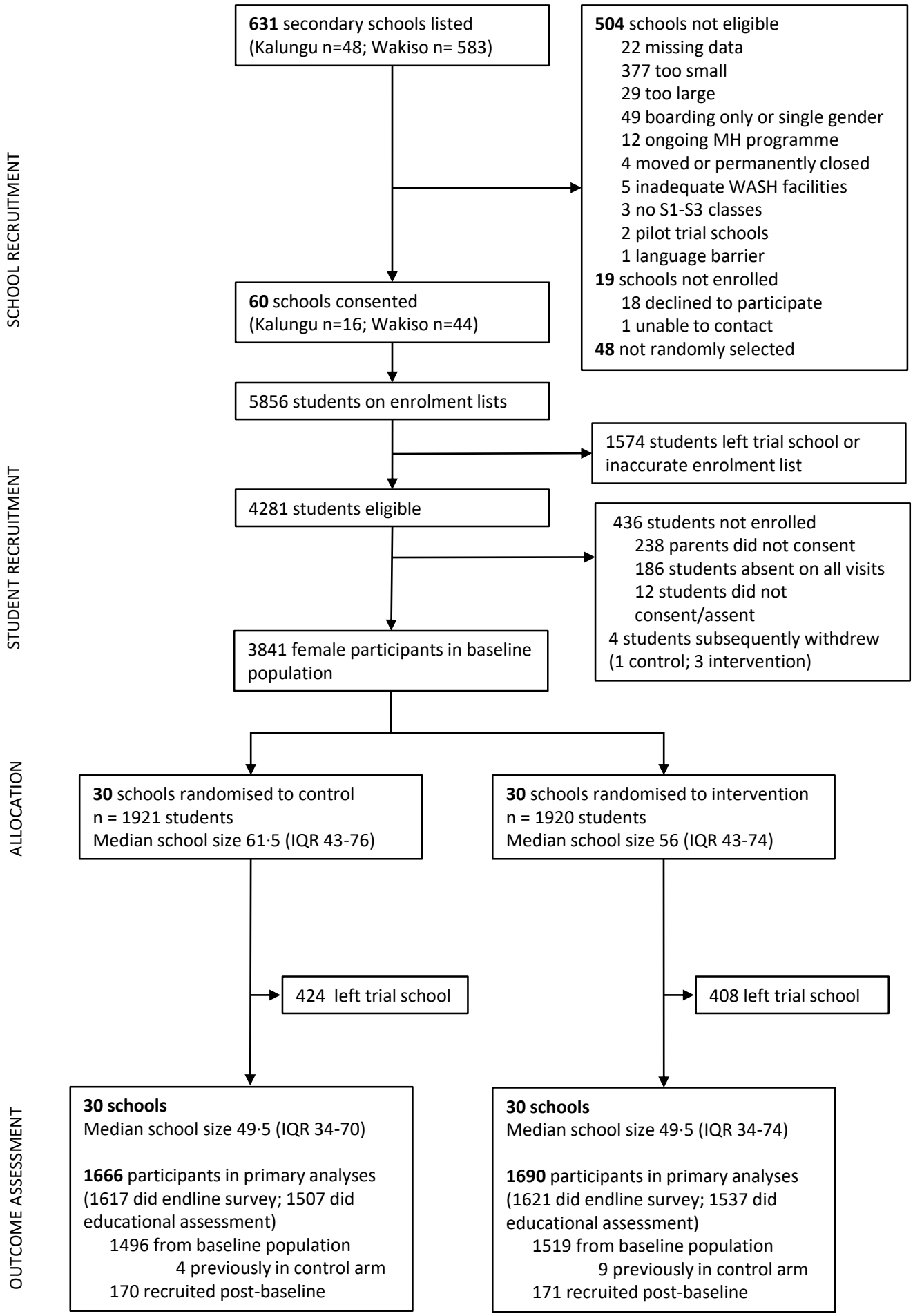
SCHOOL RECRUITMENT
631 secondary schools listed
(Kalungu n=48; Wakiso n= 583)
504 schools not eligible
22 missing data
377 too small
29 too large
49 boarding only or single gender
12 ongoing MH programme
4 moved or permanently closed
5 inadequate WASH facilities
3 no S1-S3 classes
2 pilot trial schools
1 language barrier
19 schools not enrolled
18 declined to participate
1 unable to contact
48 not randomly selected
60 schools consented
(Kalungu n=16; Wakiso n=44)
STUDENT RECRUITMENT
5856 students on enrolment lists
1574 students left trial school or inaccurate enrolment list
4281 students eligible
436 students not enrolled
238 parents did not consent
186 students absent on all visits
12 students did not consent/assent
4 students subsequently withdrew
(1 control; 3 intervention)
3841 female participants in baseline population
ALLOCATION
30 schools randomised to control
n = 1921 students
Median school size 61·5 (IQR 43-76)
30 schools randomised to intervention
n = 1920 students
Median school size 56 (IQR 43-74)
424 left trial school
408 left trial school
OUTCOME ASSESSMENT
30 schools
Median school size 49·5 (IQR 34-70)
1666 participants in primary analyses
(1617 did endline survey; 1507 did educational assessment)
1496 from baseline population
4 previously in control arm
170 recruited post-baseline
30 schools
Median school size 49·5 (IQR 34-74)
1690 participants in primary analyses
(1621 did endline survey; 1537 did educational assessment)
1519 from baseline population
9 previously in control arm
171 recruited post-baseline

Table (now with tracked changes removed)

**Table 1. Definitions of secondary outcomes**

| Secondary outcome | Definition | Analysis population |
|---|---|---|
| Knowledge of puberty and menstruation | Number of factual items correct out of 9 | All male and female participants (separately) |
| Attitudes and myths towards menstruation | Number of items with positive responses out of 3 | All male and female participants (separately) |
| Adequate menstrual hygiene management | Use of only adequate menstrual materials that were appropriately cleaned or disposed of during last menstrual period (LMP)* | Female participants who reported menstruating in the past six months |
| Menstrual experience | Menstrual Practice Needs Scale[20] (MPNS) score (higher score indicate fewer unmet menstrual needs) ** | Female participants who reported menstruating in the past six months |
| Effective pain management | Use of at least one pre-defined effective pain management method and no ineffective methods during LMP | Female participants who reported menstruating in the past six months and reported pain during LMP |
| Self-efficacy to address menstrual needs | Self-efficacy in Addressing Menstrual Needs Scale[21] (SAMNS) (higher scores indicate greater self-efficacy) | Female participants who reported menstruating in the past six months |
| Symptomatic urinary tract infection (UTI) | One or more urogenital symptoms reported plus leucocyte esterase and/or nitrates with a urine Multistix 8 dipstick result (test done if 1+ symptom reported) | Female participants who reported menstruating in the past six months |
| School and class absence during menses | Odds of missing a full school day or lesson, respectively, on period-days relative to non-period days, with period days defined as the days with flow plus day prior | Diary sub-study participants (female only) |
| School and class absence overall | Odds of missing a full school day or lesson, respectively, on a school day | Diary sub-study participants (female only) |
| Confidence in mathematics and science | Mean scores on the Trends in International Mathematics and Science Study (TIMSS) confidence in mathematics and science scales | All female participants |
| Quality of life | Child Health Utility 9D Index (not included in current paper) | All female participants |

*Defined as using a disposable pad or tampon that is always able to be immediately disposed; a reusable pad, cloth/towel, or homemade pad that is washed with water and soap and dry before use; or a menstrual cup that is boiled during or just before/after LMP; and no inadequate materials reported.

** The MPNS score is calculated as the weighted average of i) the core items and school-specific items (given 75% weight) and ii) the relevant material-specific items (given 25% weight), since participants answer a different number of items depending on the materials reported.

**Table 2. Characteristics of participants enrolled in a trial school at baseline by arm and gender**

| | Female participants | | Male participants | |
|---|---|---|---|---|
| | **Control** | **Intervention** | **Control** | **Intervention** |
| Number of participants | 1921 (50·0%) | 1920 (50·0%) | 429 (49·1%) | 445 (50·9%) |
| District | | | | |
| Kalungu | 409 (21·3%) | 450 (23·4%) | 118 (27·5%) | 119 (26·7%) |
| Wakiso | 1512 (78·7%) | 1470 (76·6%) | 311 (72·5%) | 326 (73·3%) |
| Age in years | 15·5 (0·9) | 15·6 (1·0) | 16·0 (1·1) | 16·2 (1·2) |
| Age group | | | | |
| <15 years | 190 (9·9%) | 186 (9·7%) | 28 (6·5%) | 24 (5·4%) |
| 15 years | 786 (40·9%) | 757 (39·4%) | 117 (27·3%) | 103 (23·1%) |
| 16 years | 702 (36·5%) | 689 (35·9%) | 137 (31·9%) | 150 (33·7%) |
| 17 years | 186 (9·7%) | 222 (11·6%) | 109 (25·4%) | 118 (26·5%) |
| ≥18 years | 57 (3·0%) | 66 (3·4%) | 38 (8·9%) | 50 (11·2%) |
| Student type | | | | |
| Day | 1058 (55·1%) | 1066 (55·5%) | 249 (58·0%) | 254 (57·1%) |
| Boarding | 863 (44·9%) | 854 (44·5%) | 180 (42·0%) | 191 (42·9%) |
| Religion | | | | |
| Catholic | 593 (30·9%) | 626 (32·6%) | 154 (35·9%) | 145 (32·6%) |
| Protestant, Born Again, Seventh Day Adventist | 719 (37·4%) | 772 (40·2%) | 151 (35·2%) | 179 (40·2%) |
| Muslim | 597 (31·1%) | 517 (26·9%) | 122 (28·4%) | 119 (26·7%) |
| None/Other | 12 (0·6%) | 5 (0·3%) | 2 (0·5%) | 2 (0·4%) |
| Ethnicity | | | | |
| Muganda | 1327 (69·1%) | 1310 (68·2%) | 310 (72·3%) | 300 (67·4%) |
| Non Muganda | 594 (30·9%) | 610 (31·8%) | 119 (27·7%) | 145 (32·6%) |
| Primary caregiver* | | | | |
| Mother | 1117 (58·1%) | 1141 (59·4%) | 211 (49·2%) | 240 (53·9%) |
| Father | 472 (24·6%) | 461 (24·0%) | 168 (39·2%) | 155 (34·8%) |
| Self | 5 (0·3%) | 9 (0·5%) | 3 (0·7%) | 7 (1·6%) |
| Other | 327 (17·0%) | 309 (16·1%) | 47 (11·0%) | 43 (9·7%) |
| Caregiver's education level | | | | |
| Primary or less | 447 (23·3%) | 457 (23·8%) | 111 (25·9%) | 110 (24·7%) |
| Secondary or more | 1156 (60·2%) | 1121 (58·4%) | 269 (62·7%) | 277 (62·3%) |
| Don't know | 318 (16·6%) | 342 (17·8%) | 49 (11·4%) | 58 (13·0%) |
| Household size | | | | |
| 0-5 people | 560 (29·2%) | 619 (32·2%) | 125 (29·1%) | 143 (32·1%) |
| 6-7 people | 630 (32·8%) | 613 (31·9%) | 138 (32·2%) | 151 (33·9%) |
| ≥8 people | 731 (38·1%) | 688 (35·8%) | 166 (38·7%) | 151 (33·9%) |
| Meals eaten previous day | | | | |
| Three or more | 599 (31·2%) | 608 (31·7%) | 151 (35·2%) | 157 (35·3%) |
| Two | 955 (49·7%) | 993 (51·7%) | 226 (52·7%) | 233 (52·4%) |
| One or fewer | 367 (19·1%) | 319 (16·6%) | 52 (12·1%) | 55 (12·4%) |
| Socioeconomic position** | | | | |
| Lowest | 642 (33·4%) | 654 (34·1%) | 144 (33·6%) | 149 (33·5%) |

| | | | | |
|---|---|---|---|---|
| Medium | 615 (32·0%) | 659 (34·3%) | 141 (32·9%) | 149 (33·5%) |
| Highest | 664 (34·6%) | 607 (31·6%) | 144 (33·6%) | 147 (33·0%) |
| Educational assessment z-score[†] | -0·25 (0·61) | -0·22 (0·62) | .. | .. |
| SDQ total difficulties score | 12·17 (5·60) | 12·14 (5·61) | .. | .. |

Data are mean (SD) or n (%); *Participants were asked to select one primary caregiver, 'Other' includes grandmother, grandfather, aunt, uncle and other small categories. **Socioeconomic position was derived using principal components analysis of participants' self-reported household assets and utilities. [†]n = 422 participants missing a baseline educational assessment score. SDQ = Strengths and Difficulties Questionnaire

**Table 3. Intervention effects on primary and secondary outcomes, intention to treat analysis of endline population**

| | Control arm | | Intervention arm | | Effect estimates | | |
|---|---|---|---|---|---|---|---|
| | N | Mean (SE)/ n (%) | N | Mean (SE)/ n (%) | Adjusted* effect estimate (95% CI) | p value | SMD (95%CI) |
| **Primary outcomes** | | | | | | | |
| Educational assessment z-score | 1507 | 0·12 (0·02) | 1537 | 0·20 (0·02) | aMD: 0·05 (-0·10, 0·19) | 0·56 | 0.06 (-0.12, 0.24) |
| SDQ total difficulties score | 1617 | 10·73 (0·14) | 1621 | 10·80 (0·14) | aMD: 0·05 (-0·40, 0·50) | 0·84 | 0.01 (-0.07, 0.09) |
| **Female secondary outcomes** | | | | | | | |
| Knowledge score (out of 9) | 1617 | 5·61 (0·03) | 1621 | 6·15 (0·03) | aIRR: 1·10 (1·07, 1·13) | <0·001 | ·· |
| Attitudes score (out of 3) | 1617 | 1·84 (0·02) | 1621 | 2·20 (0·02) | aIRR: 1·20 (1·14, 1·26) | <0·001 | ·· |
| Adequate MHM | 1502 | 835 (55·6%) | 1482 | 797 (53·8%) | aOR: 0·91 (0·76, 1·08) | 0·27 | ·· |
| MPNS Score | 1503 | 2·28 (0·01) | 1482 | 2·34 (0·01) | aMD: 0·09 (0·05, 0·13) | <0·001 | 0·18 (0·09, 0·27) |
| SAMNS score | 1506 | 64·08 (0·47) | 1483 | 68·48 (0·48) | aMD: 4·95 (3·31, 6·59) | <0·001 | 0·27 (0·18, 0·36) |
| Effective pain management | 1268 | 845 (66·6%) | 1219 | 919 (75·4%) | aOR: 1·50 (1·25, 1·80) | <0·001 | ·· |
| Symptomatic UTI | 1486 | 323 (21·7%) | 1470 | 253 (17·2%) | aOR: 0·74 (0·54, 1·00) | 0·06 | ·· |
| Confidence in mathematics | 1617 | 1·60 (0·02) | 1621 | 1·61 (0·02) | aMD: 0·01 (-0·05, 0·07) | 0·77 | 0·01 (-0·08, 0·10) |
| Confidence in science | 1617 | 1·99 (0·02) | 1621 | 2·01 (0·01) | aMD: 0·02 (-0·03, 0·08) | 0·44 | 0·04 (-0·06, 0·13) |
| **Male secondary outcomes** | | | | | | | |
| Knowledge score (out of 9) | 314 | 5·44 (0·08) | 341 | 5·73 (0·07) | aIRR: 1·04 (0·97, 1·11) | 0·27 | ·· |
| Attitudes score (out of 3) | 314 | 1·17 (0·06) | 341 | 1·69 (0·06) | aIRR: 1·44 (1·26, 1·64) | <0.001 | ·· |
| **Diary sub-study outcomes** | | | | | | | |
| School absence** | 36035 days | 10·5%† | 36777 days | 10·5% | aOR: 0·95 (0·73, 1·24) | 0·69 | ·· |
| Days with class absence | 36035 days | 15·3% | 36777 days | 14·4% | aOR: 0·90 (0·71, 1·16) | 0·70 | ·· |
| School absence during menstruation | 5886 period days | 13·5% | 6246 period days | 11·2% | aOR: 0·81 (0·62, 1·05) | 0.11 | ·· |
| Days with class absence during menstruation | 5886 period days | 15·5% | 6246 period days | 14·4% | aOR: 0·97 (0·77, 1·22) | 0.77 | ·· |

aMD = adjusted mean difference, aOR = adjusted odds ratio, aIRR = adjusted incident rate ratio, SMD = standardised mean difference, CI = confidence interval, SDQ = Strengths and Difficulties Questionnaire, MHM = menstrual hygiene management, MPNS = Menstrual Practice Needs Scale, SAMNS = Self Efficacy in Addressing Menstrual Needs Scale, UTI = urinary tract infection. Intracluster correlation coefficients: educational assessment = 0·12; SDQ total difficulties = 0·01*Adjusted for district, high/low school educational score, and the baseline cluster-level mean of the respective outcome measure where available (not included for symptomatic UTI and school/class absence outcomes; adequate MHM adjusted for use of only adequate material at baseline). **Diary days from n=651 intervention arm participants; n=652 control arm; † Diary sub-study prevalences weighted by inverse school-level sampling fraction.

**Table 4. Effect-modification of intervention effect on primary outcomes, intention to treat analysis of endline population**

| | **Educational performance** | | **Mental health problems** | |
|---|---|---|---|---|
| **Subgroup** | aMD (95%CI) | $p_{interaction}$ | aMD (95%CI) | $p_{interaction}$ |
| By district | | | | |
| Wakiso | 0·15 (-0.15, 0.46) | 0·45 | 0·56 (-0·37, 1·48) | 0·22 |
| Kalungu | 0·01 (-0·17, 0·19) | | -0·11 (-0·61, 0·40) | |
| By ownership | | | | |
| Private | -0·03 (-0·30, 0·24) | 0·47 | 0·19 (-0·56, 0·95) | 0·69 |
| Government | 0·09 (-0·10, 0·28) | | -0·004 (-0·56, 0·55) | |
| By school size | | | | |
| Below median | 0·10 (-0·11, 0·32) | 0·53 | 0·33 (-0·41, 1·06) | 0·36 |
| Above median | 0·01 (-0·20, 0·21) | | -0·11 (-0·67, 0·44) | |
| By proportion boarding | | | | |
| <50% boarding participants | 0·08 (-0·12, 0·27) | 0·72 | -0·15 (-0·75, 0·45) | 0·31 |
| ≥50% boarding participants | 0·02 (-0·20, 0·24) | | 0·32 (-0·35, 0·98) | |
| By age | | | | |
| <16 years | 0·07 (-0·09, 0·23) | 0·45 | -0·25 (-0·86, 0·37) | 0·18 |
| ≥16 years | 0·03 (-0·13, 0·19) | | 0·28 (-0·30, 0·86) | |
| By student type | | | | |
| Boarding | 0·05 (-0·11, 0·22) | 0·79 | -0·29 (-0·91, 0·33) | 0·33 |
| Day | 0·04 (-0·13, 0·20) | | 0·13 (-0·54, 0·79) | |
| By socioeconomic position | | | | |
| Below median | 0·05 (-0·11, 0·22) | 0·81 | -0·09 (-0·71, 0·52) | 0·51 |
| Above median | 0·04 (-0·13, 0·21) | | 0·17 (-0·41, 0·74) | |
| By baseline educational assessment score | | | | |
| Below median | 0·05 (-0·13, 0·22) | 0·94 | .. | .. |
| Above median | 0·05 (-0·12, 0·22) | | .. | |
| Baseline SDQ total difficulties score | | | | |
| Below median | .. | .. | -0·08 (-0·71, 0·56) | 0·63 |
| Above median | ... | | 0·10 (-0·45, 0·64) | |

aMD = adjusted mean difference; SDQ = strengths and difficulties questionnaire. Subgroups for school size, age, socioeconomic position, educational assessment score, and SDQ determined by the median value.