

Menstrual Solutions Study

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| Submission date 09/12/2014 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 16/12/2014 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 04/10/2022 | Condition category Other | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Adolescent schoolgirls in Kenya consider managing their menstrual cycle as a main causes of stress with many using unhygienic items such as old cloth, paper and grass throughout their period. The difficulties they experience due to their menstrual cycle can result in them missing lessons at school or even dropping out together. However, there is currently a lack of research looking into the full impact of menstrual difficulties on these young women's lives and there is little in the way of available tools and data methods to investigate it. One solution is the menstrual cup. This is a silicone bell-shaped container that is placed into the vagina to collect menstrual flow, emptied and reinserted, then cleaned at the end of each menstrual cycle. Cups can last up to 10 years, have been available since the 1930's and are available internationally, including in Kenya (but not in impoverished rural communities). There have been some small studies that have tested the menstrual cup among schoolgirls but reliable data on how acceptable their use is, how safe they are and measurable outcomes remain scarce. Here, we want to determine the acceptability, use and safety of menstrual cups compared with other menstrual products. The results will help with the development of a large-scale field trial.

Who can participate?

Schoolgirls in rural primary schools in western Kenya, living in a demographic health and surveillance system site, aged 14-16 years of age and have started having menstrual periods.

What does the study involve?

Each school participating in the study is randomised into one of 3 groups. Girls attending schools in group 1 are given menstrual cups (Mooncup®). Girls attending schools in group 2 are given sanitary pads (Always®); two packs (16 pads) are provided per cycle. Girls attending schools in group 3 continue using traditional menstrual items (which could include some use of sanitary pads if privately purchased). All participants are given soap for hand-washing and soap is given to all the schools taking part to encourage hand-washing among their pupils. The study looks at cultural acceptance, use, satisfaction, costs and safety of menstrual cups, compared with sanitary pads and 'usual practice', and assesses school, sexual and reproductive health, and wellbeing.

What are the possible benefits and risks of participating?

All participants benefit from being given education on puberty, training on using a computer, nurse screening, soap for hand-washing and screening (and free treatment) for reproductive

tract infections. Girls in the two intervention groups benefit from being given free menstrual products (menstrual cups, or sanitary pads) that help them to better manage their menstrual cycle. Girls may risk physical or personal difficulties associated with using menstrual products, of most importance is contamination of cups due to unclean environments and toxic shock syndrome. Girls may be embarrassed or feel shame discussing menstrual management problems.

Where is the study run from?

Conducted within a health and demographic surveillance system, the field site for the Kenya Medical Research Institute (Kenya).

When is the study starting and how long is it expected to run for?

From March 2012 to April 2014.

Who is funding the study?

Joint Global Health Trials scheme – Medical Research Council (UK)

Who is the main contact?

Dr Penelope A Phillips-Howard

Contact information

Type(s)

Scientific

Contact name

Dr Penelope Phillips-Howard

ORCID ID

<https://orcid.org/0000-0003-1018-116X>

Contact details

Department of Clinical Sciences
Pembroke Place
Liverpool School of Tropical Medicine
Liverpool
United Kingdom
L3 5QA
+44 798 543 1005; +254 702 126 188
Penelope.Phillips-Howard@lstmed.ac.uk

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Menstrual solutions in adolescent schoolgirls in western Kenya: a cluster randomised controlled acceptability, feasibility and safety study

Acronym

MS Study

Study objectives

Provision of modern menstrual hygiene management to schoolgirls increases girls chances to engage, attend, and complete school, and decreases their sexual and reproductive health risks.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Kenya Medical Research Institute Ethics Review Committee, 05/07/2012, ref. 2198
2. Liverpool School of Tropical Medicine Research Ethics Committee, 12/07/2012, ref 12.11

Study design

Single-site, 3-armed, open cluster randomised controlled feasibility study.

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

School, social, and health outcomes associated with menstrual hygiene management in schoolgirls

Interventions

1. Arm 1 - menstrual cups, one cup size B for girls. Mooncup (R) brand used, as FDA approval, and tested among girls and women in low income countries
 2. Arm 2 - sanitary pads, 2 packs (16 pads) provided per cycle at time of routine nurse screening, Always(R) brand used as the most well known and common type
 3. Arm 3 - usual practice (control), girls continue using traditional menstrual items (which could include some use of sanitary pads if privately purchased).
- Small stationary item such as biro provided at screenings to equilibrate provision between study arms. Participants in all arms received soap for hand-washing, provided at each nurse screening. Detergent soap provided to all study schools throughout study to support handwashing.

Intervention Type

Mixed

Primary outcome(s)

Prevalence of cumulative school attrition over one school year per arm: Nurse screening of all participants twice termly identified girls missing from school. Using geo-location data from health and demographic surveillance system, field staff (village reporters) visited homes to confirm if participants had dropped-out of school, and reasons for this, or if drop-out was due to migration out of the study area, or transfer to another school. Data capture has been throughout study, with endpoint confirmation through household visits to all homes of participants in 2014.

Absence from school (note absenteeism is difficult to measure, so different methods adopted to

determine which generates precision data): collected from monthly menstrual calendars provided to participants, from school registries compared against twice termly unannounced school visit headcounts, and girls separate private screening surveys.

Key secondary outcome(s)

1. Feasibility of conducting a menstrual solutions study among primary schoolgirls: proportion of schools agreeing to participate, proportion of parents and target aged girls agreeing to participate, proportion of girls withdrawing from participation - generated from baseline records and ongoing screening, and study supervisors survey lists.
2. Effect of knowledge, attitudes, and practices to menstruation and menstrual hygiene management: conducted among participant girls, parents, and school teachers, through focus group discussions generating qualitative data, at baseline, mid-study, and end-study, on cultural social and schooling factors influencing study and study outcomes.
3. Prevalence of reproductive tract infections per study arm: generated as an endpoint using self-completed (nurse assisted) vaginal swabs conducted through cross-sectional survey of participants at closure of the study . This includes non-sexual (candida albicans, bacterial vaginosis), and sexual (trichomoniasis vaginalis, chlamydia trachomatis, and neisseriae gonorrhoea)
4. Prevalence of staph aureus in participants, and prevalence of toxic shock syndrome toxin-1 in positive staph aureus participants, per study arm: measured through self-conducted vaginal swabs during repeat cross sectional survey at beginning and mid-point in study.
5. Proportion of participants using allocated intervention: generated from twice termly nurse screening checks consisting of face to face interview with participants, plus parallel separate girls' survey where girls reported confidentially using netbook computer. In addition, girls in the cup arm were requested to bring cup each screening, for nurse assessment of cup viability (defined use was change in colour associated with menstrual blood). Girls in pad group also answered question on how many pads they used per menses. Girls in usual practice (control) reported what items they had used.
6. Wellbeing of participants: measured at baseline, then quarterly to measure indicators of wellbeing - using the PEDSQL instrument.
Cup contamination: a random sample of cups were switched for new ones among recorded users, representing varying duration of use; these were tested to detect presence of e. coli contamination (by duration of use).
7. Girls menstrual hygiene: generated from nurse screening and girls personal surveys, twice termly, on Handwashing, use of soap, cleaning of menstrual products.
8. Water, sanitation, and hygiene (WASH) conditions in study schools: repeat cross-sectional surveys conducted through unannounced spot checks by trained WASH field team through physical observation, followed by informant interview, to evaluate WASH standards at baseline, and longitudinally 1-2 times per term over study, by study arm.
9. Direct and indirect costs incurred by study arm: ongoing collection of cost data for all elements of the study, generated from financial records, invoices of intervention costs, discussion with field staff, records of study activities with estimates of time spent by participants, beneficiaries and staff.
10. Safety of menstrual solutions (physical or personal problems with using items; toxic shock syndrome, reproductive tract infections): nurse screening of participants twice termly with ongoing teacher and field staff vigilance in case of an event; ongoing review of all death reports in the area through health and demographic surveillance system, liaison with health services, and a review of health clinic registers.

Completion date

01/04/2014

Eligibility

Key inclusion criteria

1. Primary school girls, in classes 5 upwards
2. Attend a study school
3. Reached menarche, experienced a minimum of three menses
4. Are aged 14-16 years at enrolment
5. Resident in the health and demographic surveillance system study area
6. Parents/guardian provided written informed consent
7. Participating girl provided written informed assent

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Child

Lower age limit

14 years

Upper age limit

16 years

Sex

Female

Key exclusion criteria

1. Not attending primary school, or below class 5
2. Not reached menarche or experienced minimum of 3 menses
3. Are outside the study age (14-16 years at enrolment)
4. Not resident in health and demographic surveillance system study area
5. Do not attends one of the study schools
6. Parent/guardian refused informed consent
7. Participant refused informed assent
8. Participant declares presence of an intrauterine device;
9. Participants has a severe physical / learning disability preventing informed consent or ability to participate
10. Participant has suffered from toxic shock syndrome;
11. Participant is pregnant pre-intervention (determined through observed/declared pregnancy, and birth; not through pregnancy testing)

Date of first enrolment

15/08/2012

Date of final enrolment

30/08/2013

Locations

Countries of recruitment

Kenya

Study participating centre

Center for Global Health Research

Kenya Medical Research Institute

Kisumu

Kenya

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Sponsor information

Organisation

Kenya Medical Research Institute

ROR

<https://ror.org/04r1cxt79>

Funder(s)

Funder type

Research organisation

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

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 are/will be available upon request

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|--|--------------|------------|----------------|-----------------|
| Results article | results on Prevalence of reproductive tract infections and the predictive value of girls' symptom-based reporting | 01/06/2016 | | Yes | No |
| Results article | results on Menstrual cups and sanitary pads to reduce school attrition, and sexually transmitted and reproductive tract infections | 23/11/2016 | | Yes | No |
| Results article | | 15/09/2022 | 04/10/2022 | Yes | No |