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Menstrual Solutions Study

Submission date
09/12/2014

Recruitment status
No longer recruiting

Registration date
16/12/2014

Overall study status
Completed

Last Edited
04/10/2022

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

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 measure
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.

Secondary outcome measures
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 albucans, 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.

Overall study start date
01/03/2012

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

Age group
Child

Lower age limit
14 Years

Upper age limit
16 Years

Sex
Female

Target number of participants
750 (3 arms, target of 250 per arm)

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

Sponsor details
PO Box 1578
Kisumu
Kenya
401000

Sponsor type
Research organisation

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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Intention to publish date
30/06/2015

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