



Does Menstrual Hygiene Matter?

Investigating the Impact of a Menstrual Hygiene Program (Reusable Sanitary Pad and Menstrual Health Education) on Rural Ugandan Girls' School Absenteeism: study protocol for a cluster randomised control trial. SCHARR Report Series (31) School of Health and Related Research, University of Sheffield, ISB 1 900752 29 8

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The University Of Sheffield.

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General Information

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1. Abstract

This study builds on the pilot work of the Irise research group to investigate the impact of menstrual hygiene interventions on East African girls' school attendance, achievement and self-esteem. A step wedge, cluster design will be utilised and 40 schools in total will be recruited to the intervention and control arms. Schools will receive a menstrual hygiene programme, including the distribution of reusable sanitary pads and menstrual health education. The impact of the program on girls' school attendance will be monitored using the validated Irise questionnaire and school registers. The impact of the program on activities of daily living during menstruation and self-esteem during menstruation will also be measured using the Irise Questionnaire and explored using focus groups.

2. Research Aims and Objectives

Aims

- To assess the impact of a Menstrual Hygiene Management (MHM) Program, based around the distribution of reusable pads and the delivery of health education in schools, on East African schoolgirls.

Objectives

- To explore initial (baseline) MHM practices and knowledge
- To assess school absenteeism during the study period
- To assess the impact of menstruation on activities of daily living at baseline , 6 and 12 months into the study
- To assess girls' self-esteem during menstruation at baseline , 6 and 12 months into the study

3. Background

3.1 Irise International

Irise International, a UK registered charity (registration number: 1157722) was founded in response to the concerns of women and girls about the impact a lack of support for Menstrual Hygiene Management (MHM) was having on their lives. It is run by young professionals from Uganda and the UK in close collaboration with the women and girls who participate in the programmes. Irise is currently working to develop a replicable MHM package through the set-up of local social enterprises producing reusable sanitary products and the delivery of menstrual health education through a cascade training approach.

The initial research of Irise, collaborating with disadvantaged women and girls to identify their concerns, concluded that a lack of support for MHM was acting as a barrier to their empowerment through an insidious impact on their ability to engage in education and make good decisions about their reproductive health. Further discussions revealed that this issue includes systemic misinformation and stigma around women's reproductive health ranging from doctors teaching that sex is the only cure for period pain to the belief that menstruating women are dirty and can contaminate others. This poor information

environment is further disempowering due to lack of an affordable sanitary product, forcing girls to use unhygienic and inadequate alternatives like dirty rags and corn husks.

Our surveys of 1,193 girls across the Great Lakes Region suggest that this issue is widespread¹:

Proportion of girls who report missing school because of menstruation	53%
Mean days missed because of menstruation	1.5
Range of days missed because of menstruation	0-11
Proportion of girls using cloths/rags some or all of the time	71%
Proportion of girls who believe menstrual pain is a sign of illness	61%

3.2 Pilot work

Irise undertook a pilot study in Kisumu Kenya. Groups of 30 girls from 10 schools were randomly allocated to control or intervention groups. The intervention group received training on how to make a reusable pad and enough equipment to make three. Data was collected at baseline and at one month using a questionnaire. The mean number of days girls reported missing school specifically due to menstruation was 1.66 with responses ranging from 0-11. Figure 1 provides a breakdown of how girls rated the effect of menstruation on school attendance; 35.5% of girls reported missing school once or twice during menstruation and 17.25% reported missing school several times. Overall 5 in 10 girls reported missing some school because of menstruation compared to just 1 in 10 in the UK.

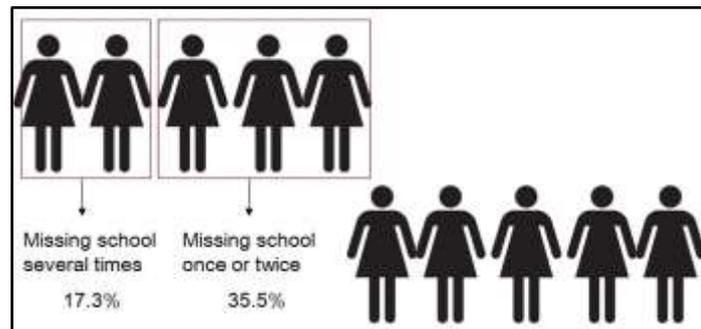


Figure 1: Proportion of girls missing school due to menstruation

After one month follow-up, absenteeism was reduced, on average, by 1.5 days in the schools that received the intervention. A covariate adjusted t-test of group mean number of days missed, control group vs intervention group, showed the result was close to the 5% significance level the difference between groups in mean days missed be 1.48 days; $P=0.077$; 95% CI -3.17, 0.21).

For all schools in the intervention group the mean number of days of school missed decreased or stayed constant; schools in the control group either stayed constant or increased². The results for each school for this measurement are shown in figure 2 and the mean results are visually represented in figure 3.

3.3 Preliminary work

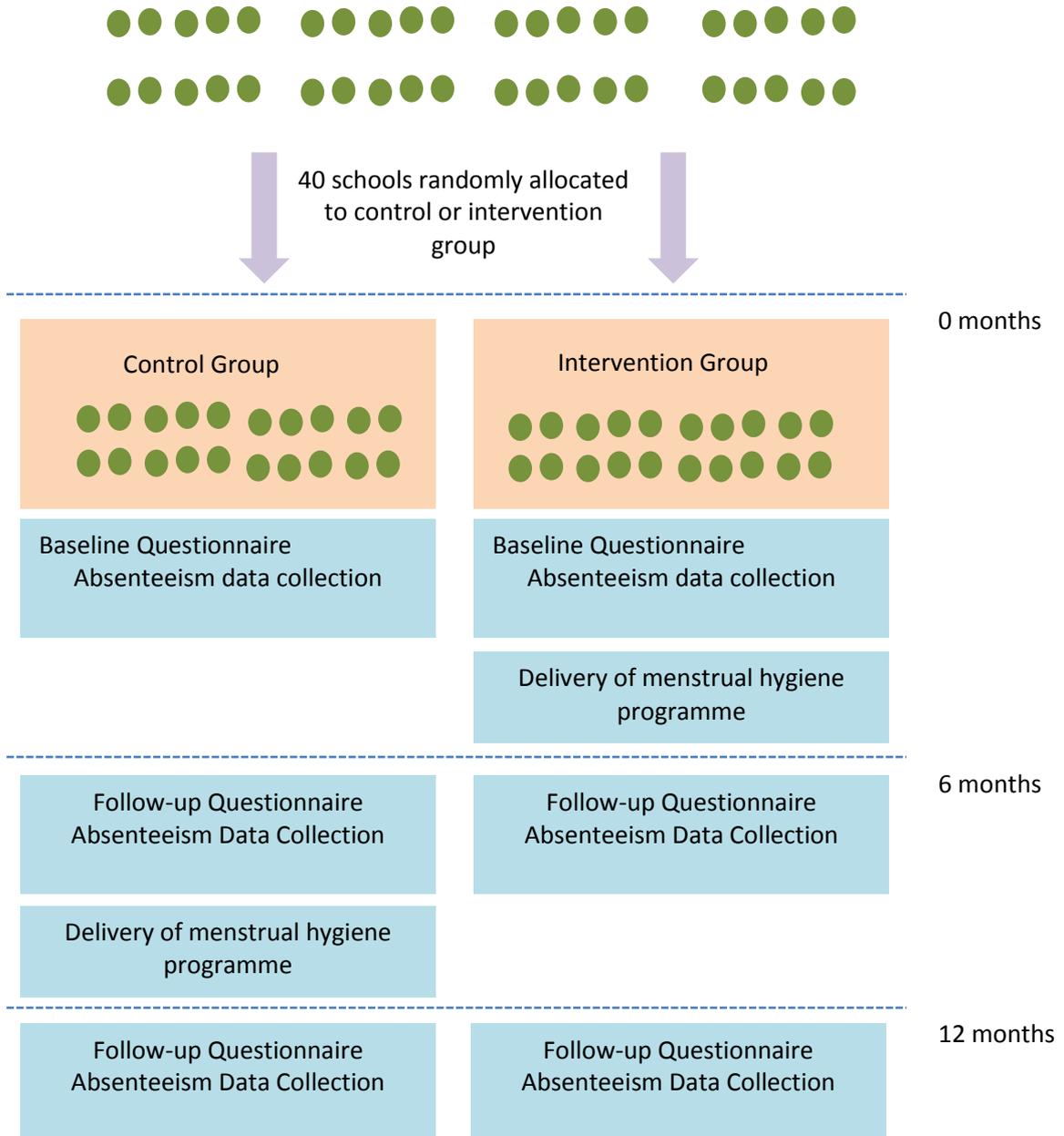
A preliminary round of data collection took place in June and July 2013 in 30 schools through the delivery of a questionnaire¹. A more detailed investigation using interviews was carried out in a select number of schools in order to understand local menstrual hygiene practices in more depth and collect context specific information relevant to the delivery of a menstrual hygiene program. This work was used to inform the development of this protocol.

4. Research methods

4.1 Design

A step wedge design was chosen to provide a control group for 6 months but to allow all girls enrolled in the study to receive the intervention at 12 months. We will also be able to see if the effect of the intervention in the intervention group is replicated in the control when they receive the intervention at six months. **Thirty girls aged between 14-18 from each school** will be enrolled in the study and will receive pads and menstrual health education. Each school will be treated as a cluster. Schools will be selected a predefined distance apart in order to minimise the effect of girls from different schools talking to one another. At baseline half the schools will be randomly allocated to receive the intervention and while the other half will act as a control group. After six months the remaining schools will also be given the intervention and all schools will be followed up for the remainder of the study period. Focus groups and structured interviews will be carried out in randomly selected schools after the questionnaire throughout the research period in order to explore the girls' answers in more depth.

4.2 Flow Diagram



Target population and setting

The target population will be rural Ugandan schoolgirls between the ages of 14-18. The setting will be Primary Schools in Western Uganda.

4.3 Recruitment of schools

Forty schools in Western Uganda will be recruited through local Irise partner, LuYoDeFo and through contacts at Kampala International University and the Department of Health. These Irise partners and contacts will provide a list of schools in the areas selected to take part in the research. These schools will then be visited by an Irise researcher and will be given information about the study. They will have the opportunity to opt in or out at this point. Written informed consent will be obtained from the head teachers of the schools and from the girls themselves.

4.4 Planned Inclusion/Exclusion Criteria

Girls from schools who have not previously been recipients of a menstrual hygiene program between the ages of 14-18 from participating schools will be included in the study.

4.5 Planned Intervention

During the first 6 months 20 schools will receive menstrual health education and an Easy Pad Kit (containing 6 reusable pads and a storage bag) from a local social enterprise set-up as part of Irise's project work in Uganda. During the second 6 months the remaining 20 schools will receive menstrual health education and all girls will receive an Easy Pad Kit from the local social enterprise.

4.6 Proposed Sample Size

Based on the results of a pilot study school absences were reduced by 1.5 days in a month with a standard deviation (SD) of 3.691 and an intra-class correlation (ICC) of 0.173. We postulate that the intervention may have a similar monthly effect over 6 months thus, the effect size is 1.5 days per month. The expected average class size is 30 school girls.

To detect a difference of 1.5 days with a SD 3.691 days with 80% power and two-sided significance level of 5%, with an ICC of 0.173 to account for clustering we require 20 schools per arm with 30 girls in each school. A total sample size of 40 schools would equate to approximately 1200 school girls. In total 42 schools were recruited to allow for possible school dropout.

5. Proposed Outcome Measures

5.1 Primary Outcome Measure

- The mean number of days of school missed per month (absenteeism).

5.2 Secondary Outcome Measures

- Knowledge of Menstrual Hygiene
- Impact of menstruation on activities of daily living
- Self-esteem during menstruation

5.3 Measurement of Outcomes

Baseline data will be collected via the validated Irise questionnaire. Absenteeism data will also be collected from school registers. Teachers will receive training on the importance of keeping an accurate register. Registers will be audited every 1-2 months through unplanned visits to the schools to compare the register to the actual attendance. Self-reported data on school absenteeism, the effect of menstruation on activities of daily living and self-esteem will also be collected at 6 months and 12 months using the Irise questionnaire. Focus groups will also be conducted in randomly selected schools.

We aim to conduct at least 10 focus groups in 5 intervention and 5 control schools which are randomly selected from the sample. There will be 4-6 discussants for each focus group session, which will last 45-60 minutes. The focus groups will be conducted in Runyankole by a local research assistant, who was previously trained by the researcher. The researcher will be present to observe the discussion. Furthermore, 10-15 in-depth interviews with randomly selected girls will be conducted in the same ten schools. Finally, the researcher will conduct short interviews with the educators involved in the study/intervention to find out more about their perspectives on/experiences with the program. Some discussions will be recorded and transcribed. Some the focus groups will involve activities and the data will be collected in the form of photographs.

6. Statistical Analysis

The primary endpoint (days per month missed) will be analysed by analysis of variance in which the covariates will include the individual's age; number of days missed the previous 6 months; the trial arm (intervention or control) and distance from a highway (a stratifying variable); and the design/cluster effect of school as a random effect.

Quantitative data will be analysed using SPSSR under the supervision of Steven Julious, Professor of Medical Statistics at The University of Sheffield.

7. Qualitative Analysis

A grounded theory approach will be applied to the qualitative data collected using the focus groups and structured interviews. The analysis will be conducted by two researchers separately. They will then meet and discuss their analysis in order to triangulate the findings.

Qualitative data will be analysed with advice from Dr Lata Narayanaswamy at The University of Leeds.

8. Ethical Arrangements

Ethics for this study has been granted by The University of Sheffield's School of Health and Related Research (Ethics reference number: 0677/KW). Ethics approval has been obtained locally from Makerere University School of Public Health and the trial will be registered with The Ugandan National Council for Science and Technology (UNCST). The trial has also been registered with Clinicaltrials.gov and the protocol will be published online on the White Rose Consortium.

9. Expertise

The study will be supported by academics from Sheffield School of Health and Related Research, Sheffield Institute of International Development and Kampala International University. Both East African and UK students will be involved in data collection and analysis.

Dr Emily Wilson-Smith, Dr Calum Wilson-Smith and Dr Josephine Reeve founded the Irise research group in 2011 and worked on the INSPIRES study and the Irise Questionnaire Validation Study together. They have also supervised women's health research in Madagascar and Uganda involving 9 students in 2013.

Professor Steven Julious is a Professor in Medical statistics, works part time in the Clinical Trials Research Unit and has been an Irise advisor since 2011. Steven has 20 years of clinical trials experience in both academic and commercial settings. He has a research interest in the epidemiology of asthma, clinical trials and health services research.

10. References

1. *Guerry E (2013) An Assessment of Baseline Menstrual Hygiene Practices and Absenteeism in Western Uganda.* Irise. [Online] Available: www.irise.org.uk/online-womens-health-library/learn/.
Prestwich G (2013). An exploratory study into Menstrual Hygiene Management amongst rural, primary schoolgirls in Uganda: what implications does menstrual related absenteeism have for future interventions? Irise. [Online] Available: www.irise.org.uk/online-womens-health-library/learn/.
Wilson E. et al. (2014) Education. Period. Developing an acceptable and replicable menstrual hygiene intervention. *Development in Practice*. Vol 24; 1: 63-80.
2. Irise 2011. INSPIRES: Investigating a reusable sanitary pad intervention in a rural educational setting - evaluating the acceptability and short term effect of teaching Kenyan school girls to make reusable sanitary towels on absenteeism and other daily activities: a partial preference parallel group, cluster randomised control trial. [Online] Accessed: 11/11/12 Available at: <http://eprints.whiterose.ac.uk/43906/>

9. Summary of Protocol Amendments and Administrative Changes to the Protocol

9.1. Amendments to the Protocol

Text revisions resulting from the protocol amendment are incorporated in the text of Protocol. The changes to the protocol are summarised below.

1. Section 4.1
2. Section 4.4

9.2. Administrative changes

The following changes were made

1. Section 3.2 the text was edited to clarify the treatment effect previously observed
2. Section 4.6 the sample size calculation was edited so the correct ICC and standard deviations were given
3. Section 5.3 additional details about the qualitative component of the study were added
4. Section 7 the text was edited to specify that grounded theory will be used to analyse the qualitative data