

Part I: Information about this study

Introduction

You have already agreed for your daughter to take part in the MENISCUS trial, which is led by scientists at the London School of Hygiene & Tropical Medicine, MRC/UVRI and LSHTM Uganda Research Unit, with our partner WoMena Uganda.

We would now like to explain an additional, optional part of the study. This is the offer for your daughter to receive a menstrual cup, and have training on how to use it. If your daughter receives the cup or not, she will still receive the reusable pads and all parts of the intervention.

We invite your daughter to be part of this research. It is optional for you to choose whether or not you want her to participate in this research.

Procedures

As part of the menstrual kit that your daughter will receive, she will also receive a menstrual cup (called the Ruby Cup). This is an alternative to pads to manage periods. The cup is a soft silicone cup which is folded and inserted into the vagina to collect the menstrual fluids and can be worn during the day and overnight without concern of leaking. The cup must be emptied once it is full, then it will be rinsed and reinserted again if necessary. Most girls/women need only to empty it in the morning and again in the evening. By experience, your daughter will know how often to empty it according to her specific needs.

Your daughter will be asked to participate in a session led by a teacher or peer who has been trained by an expert trainer in menstrual health, the menstrual cup and re-usable pads. They will show your daughter how to use the menstrual cup and re-usable pads, and will discuss any concerns you might have about this. your daughter will be asked to use the menstrual cup and/or re-usable pads for the next year, until she is in S3, if she feels comfortable doing so. At the end of this time, your daughter may be asked about her experience using the cup and re-usable pads. If she is experiencing any problems using the cup, she will be able to discuss it with the trained team leader.

Risks and discomfort: Is this bad or dangerous for you?

Menstrual cups have been used widely in many countries, including Uganda, and have few health risks. your daughter will be taught how to insert it. Once the cup is inserted, most girls find it painless, even if they have never had sexual intercourse. However, your daughter may feel some discomfort when she inserts and removes it (especially the first few times), and she may also feel embarrassed or may be afraid of inserting the cup into the vagina.

There is a risk of an allergy to the material that is used to make the menstrual cup (silicone), but this is very rare. If your daughter experiences pain, burning, irritation, inflammation in the genital area or discomfort during urination, she must remove the cup and contact the school study nurse or study coordinator immediately. The menstrual cup has been used by many millions of women around the world, and there has been one documented case of a woman becoming ill with toxic shock syndrome after using a menstrual cup called the DivaCup. It causes high fever, flu-like symptoms, dizziness, and can rapidly lead to severe illness. Toxic shock syndrome is very rare, and it has not been reported with RubyCup, which is the cup that we are offering. However, if your daughter experiences these symptoms during her periods, then she should remove the menstrual cup immediately, go to the local health clinic for a check-up, and contact our study coordinator by phone. If she has suffered from toxic shock syndrome previously, it is recommended not to use any internal form of sanitary protection, including menstrual cups or tampons. Your daughter will be taught how to clean the cup. There is a risk of infection or irritation if the cup is not cleaned properly.

Benefits: Is there anything good that happens to you?

Sharing the Findings: Will you be told the study results?

When this research is completed, we shall inform you and your daughter about the results obtained. Then we shall share the research results with authorities at the school, municipal and national levels, including what we have learnt.

Afterwards, we will be telling other people, scientists, health workers and others, what we found. We will do this by writing and sharing reports and by going to meetings with people who are interested in this work. The research findings will be published in international science journals and electronic websites so that other people may learn from us. However, the results will never be reported in a way that allows anyone except members of the research team to know what your daughter specifically told us or any of the individual results we obtained from her. Data may be made available in the public domain via the London School of Hygiene and Tropical Medicine data repository. This means that it may be used for further analyses. All data will be anonymised i.e. it cannot be linked to your daughter.

Who to contact: Who can you talk to or ask questions about this study?

You can ask us questions now or later by telephone, e-mail, post or at the physical addresses indicated on the assent/consent form to be given to you. If you are nearby, you can come and see us.

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