

Information and consent form for parents/guardians of female students (or the respective school head teacher or their authorized designate in the absence of a Parent) for the MENISCUS trial.

Summary (What you should know about this study):

The aim of the

Part I: Information about this study

Introduction

The MENISCUS trial 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 are carrying out research to guide our secondary schools to identify practical ways of helping girls to become and stay healthier and complete studying at school through improved management of menstrual periods. We have received permission to conduct this research from your school administration, the district, the Ministry of Education and Sports, and the Research Ethics Committees of the UVRI, LSHTM and Uganda National Council of Science and Technology (UNCST).

We invite your daughter to be part of this research. It is optional for you to choose whether or not you want your daughter participate in this research. If you agree to allow your daughter to participate, we shall ask your daughter for approval as well. Both of you have to approve before your daughter can be involved.

Please feel free to ask us questions now or later using our contact information which is indicated below. We will take time to explain to you.

Purpose

The purpose of the MENISCUS study is to see whether a health promotion intervention in secondary schools improves menstrual health (i.e. how girls manage their periods safely and confidently). We want to learn whether the package is likely to improve education, health and well-being outcomes among girls, and menstrual health knowledge and attitudes towards periods among boys. If the intervention is successful, it could be introduced in other schools in Uganda.

Selection

We request your daughter to participate in this research because she is a female secondary school student starting Form 2 in one of 60 schools chosen for this study. We are seeking your consent because you are the parent/guardian of your daughter.

Voluntary Participation

It is optional for your daughter to participate in this research. You or she can choose to say no. That decision shall not affect any services that you and your family receive at the secondary school and/or health facilities. You can ask as many questions as you like and we shall be available to answer them. You don't have to decide today. You can think about it and tell us what you decide later. You can agree that the school head teacher or authorized designate shall provide exceptional signed consent on your behalf if you are not available or accessible for documented reasons.

Procedures

There are 60 schools in the trial. Of these, half (30) will be randomly selected to receive the MENISCUS intervention. In these 30 schools, all pupils in Form 2 at the start of 2022 will receive education about puberty and menstruation, improvements to school toilet facilities, and will have the option to participate in a drama skit relating to menstrual health. Your daughter will also sit two independently administered educational assessments covering wil,

5) Genital symptoms and self-collection of vaginal swabs

In the questionnaire at endline, your daughter will be asked about how she cleans her genitals and any current urogenital

find out more about her health information and service needs. We hope that these will help all the relevant people to meet those needs better in the future. Taking part in this research may also remind her to think deeply about her health and her future.

Reimbursements: Will your daughter receive anything for being in the study?

You will be given 10,000 shillings to compensate for your time and effort. Your daughter will not be paid to take part in this research. However, she will be given a pen, a hardcover note book and a soft drink to compensate for her time and effort.

Confidentiality: Is anybody going to know about this?

We will not tell other people that your daughter was involved in this research. We shall not share personal information that identifies her to anyone who does not work in this research. Any information about her will have a study number on it instead of her name. However, her data may be seen by auditors.

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

When this research is completed, we shall inform your daughter, her peers and parents/guardians about the results obtained from the trial. The results will never be reported in a way that allows anyone except members of the research team to know what you specifically told us or any of the individual results we obtained from you. We will also share the research results with authorities at the school, district 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. Data may also be made available in the public domain via the London School of Hygiene and Tropical Medicine. 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.

You can contact any of the following about this research

Dr. Catherine Kansiime, MENISCUS Trial Manager

PART 2: PARENTAL CONSENT (VERSION 1.3 NOVEMBER 2021)

By signing below I consent for my daughter to participate in the study as described above, including for:

My daughter to self-complete the two study questionnaires

My daughter to receive a menstrual management kit

My daughter to self-collect two vaginal swabs, one of which will be stored and may be shipped overseas

My daughter to participate in group discussions or interviews and complete a daily diary on school attendance and menstruation, if selected for these activities

All anonymised data collected to be used as part of the research and shared with other researchers