

Information sheet for **women participating in menstrual monitoring** part of
“The Low birth weight South Asia trial: a study into cost-effective interventions”
(to be translated into Nepali and Maithili)

You will be given a copy of this information sheet.

Title of Project: **The Low birth weight South Asia trial: a study into cost-effective interventions**

This study has been approved by the UCL Research Ethics Committee (Project ID Number: 4198/001) and by the Nepal Health Research Council (Project ID Number: 108/2012).

Details of the study

We are doing a research study in your district and we would like to invite you to participate. You do not have to take part if you don't want to.

The research is being done by Mother and Infant Research Activities (MIRA), led by Prof DS Manandhar, and Prof Anthony Costello and Dr Naomi Saville from University College London in the UK. MIRA has an office at Ramanand Chowk in Janakpur. The main office is in Kathmandu.

What is the research?

We are contacting 17 000 pregnant women to compare different ways to make their babies healthier. We hope to improve the weights of babies in Dhanusha and Mahottari districts. We think that this might make them healthier, improve their growth and help them to do well in school. A good way of making babies healthier might be to make sure that their mothers have good diets during pregnancy. It isn't clear what the best way to do this is: we want to find the best means of improving babies' weight, so we are going to compare different ways of helping mothers to have better diets.

We are going to try out 4 ways of improving mothers' diets in Dhanusha and Mahottari.

1. In 20 VDCs we will work with women's groups organised by Female Community Health Volunteers and with other community members. The groups hope to improve women's eating during pregnancy so that they increase their intake of nutritious food. In these areas we will give Rs1000 to women who take part in the trial after they deliver their baby.
2. In 20 VDCs we will work with women's groups and give pregnant women a food supplement.
3. In 20 VDCs we will work with women's groups and give pregnant women money to help them eat more nutritious food.
4. In 20 VDCs we will support existing Government of Nepal programmes and give Rs1000 to women who take part in the trial after they deliver their baby.

In all 179 health facilities of Dhanusha and Mahottari, we will provide training on mothers' and babies' nutrition, and on caring for small babies, for health workers in government facilities. Which group your VDC belongs to has been decided by a lottery system.

Who are we inviting to participate?

You can take part if you are a woman aged 13 to 49, live permanently in the study area, and could become pregnant.

What will happen if you agree to take part in checking of whether you are pregnant or not?

If you agree, we will check whether you might be pregnant every month. We will start to do this in Shrawan 2070 and will carry on until about Asad/ Shrawan 2072. Our ward *ganak* will record your name and address so we know who you are and where you live. Then she will visit you at home every month to check whether you might be pregnant by asking about your periods. She will keep what you say confidential and won't tell your family members or neighbours anything you share with her.

If you think you might be pregnant, a MIRA team member will ask you to give a urine sample and will arrange a pregnancy test. If you turn out to be pregnant, we will give you a photo ID card to show that you are involved in the study. Then we will ask you questions and weigh and measure you and your baby several times. We will tell you more about this in more detail if you become pregnant.

What will you get if you take part in checking on your periods?

As we said, there are 4 sorts of VDC. Your VDC is one that gets *[delete those that do not apply]*

Government programmes only



- Women's group only** ☐
- Women's groups and food** ☐
- Women's groups and cash** ☐

If you do not become pregnant you will not get payments or food, but if women's groups are working in your area you are welcome to attend. Women who become pregnant will all get some benefit, of either money or food, from participating.

Are there any risks if you participate?

We do not think that any harm will come to you but it is possible that you might find sharing information about your periods or pregnancy uncomfortable or upsetting. You don't have to continue to take part if you don't feel like it. If you would like to talk to someone about the feelings generated by the questions, please contact a member of MIRA staff or Dr Saville.

Your information will be confidential

All information you share with MIRA *ganaks* or interviewers will be kept confidential, which means that they are not allowed to tell anyone what you have told them. The information will be recorded either on paper or entered onto mobile phones. The kind of information we will keep about you will include your name, age or date of birth, address and the answers to questions that we ask you. The information will be stored in registers and on computers, but they will be protected so that only authorised people will be allowed to look at them.

Ethical approval

The Nepal Health Research Council (NHRC) and University College London Research Ethics Committee have approved the study.

Agreeing to take part

Your participation is voluntary. If you don't want to take part, you can refuse without any problem. If you agree to participate and then change your mind at any time, please tell us and we will stop visiting you. If you decide to take part you will be given this information sheet to keep.

More information

You should feel free to discuss the study with other people or ask us any questions.

If you have any more questions, you can contact Mr Bhim Prasad Shrestha, Trial Manager, Mother and Infant Research Activities (MIRA), Ramanand Chowk, Janakpur, Dhanusha. Tel 041-523371.

or

Dr Naomi Saville, Senior Research Associate, University College London Institute for Global Health and Technical advisor to Mother and Infant Research Activities (MIRA), YB Bhawan, Thapathali (behind Imperial Finance building), GPO Box 921, Kathmandu Nepal. Tel: + 01-4101546.