

Information sheet for **pregnant women who are residents of**
Women's group and Cash Payment areas of the research study
“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. Everyone will benefit from taking part.

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 in monitoring during pregnancy and after delivery?

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

What will happen if you agree to take part?

Now that we have confirmed that you are pregnant by taking a pregnancy test, the ward *ganak* will carry on visiting you, and we will arrange 4 things:

1. First, we will measure your height and weight and ask some questions about you and your household, previous pregnancies or children, what you have been eating, what you tend to buy, where you will be later in pregnancy, and where you think you will have the baby. We would also like to weigh and measure your youngest child under 5 years at this time (if you have one).
2. Towards the end of your pregnancy we will weigh you again and talk to you about what you have been eating, what you have been buying, what you have been doing during your pregnancy and where you plan to be for your delivery. We would also like to weigh and measure your youngest child under 5 years at this time (if you have one).
3. When your baby is born we will either visit you at a health facility or at home. We will weigh and measure your baby within 3 days of delivery and ask you some questions about your delivery.

4. About one month after the birth of your baby we will visit to ask you about your baby's health, and weigh and measure you and your baby.

Sadly, and rarely, some babies do not survive. If this happens, we will try to understand what happened by talking to you and your family. You don't have to agree to this, but if you do the information we collect will help us to understand more about how these unfortunate things happen so as to try to develop ways of preventing them in the future.

What will you get if you take part?

As we said, there are 4 sorts of VDC.

Your VDC is one that gets **women's groups and money during pregnancy**.

VDC with women's groups and money during pregnancy

We will visit you during and after pregnancy. We will invite you to take part in monthly meetings of the women's groups. The meetings will be a chance to discuss issues that affect the health of you and your baby, to learn new things and to make friends with other women. You do not have to attend the meetings, but if you choose to during your pregnancy you may benefit by learning new things about nutrition and health and by being better prepared for the birth of your baby.

We will give you a monthly payment of NPR 750, up to 7 times. You will be advised to use the money to buy special food for your own consumption during your pregnancy, to help you to improve your diet and your and your baby's health. In order to get the full amount you need to make sure that the *ganak* is aware of your pregnancy as early as possible. You can get the money any time after 8 weeks of pregnancy (which is usually after you have missed 2 periods), after you have completed your pregnancy test and interview. The money is available for a month, so you won't get it after the month has ended. If you move somewhere else where the money is available, you will continue to receive it. If the money isn't available in the new place, you won't get it unless you move back here.

Are there any risks if you participate?

We do not think that any harm will come to you. However, we will see you regularly to check that you are well, and if there is cause for worry we will stop the study. It is possible that you might find sharing information about your periods or your pregnancy uncomfortable, or that you might find answering some of the questions about your pregnancy, delivery or antenatal care embarrassing or upsetting. You don't have to answer any questions 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. When experts are looking at the information to work out which approach is the best for improving babies' weight and health, they will not be able to identify you individually. We will tell people what we find, though both meetings and reports that we make. These people include you and your family, your VDC representatives, government health workers and senior people, and experts worldwide.

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. Antenatal, delivery or postnatal care at government health facilities will not be affected in any way, whether or not you decide to take part. 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 and be asked to sign or give a thumbprint on a form to say that you agree.

If you agree to take part you may be asked whether you are happy to be contacted about participating in future studies. Your participation in this study won't be affected if you choose not to.

More information

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

Remember, it is up to you to decide whether to take part or not. Choosing not to take part will not disadvantage you in any way. If you do decide to take part you are still free to withdraw at any time and without giving a reason.

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.