



Your invitation to join

## **The MAMMI Study**

A study to find out more about the health and health problems of first-time mothers during pregnancy and during the first year after the baby's birth.

The MAMMI study has been approved by the Research Ethics Committees of the Coombe Women and Infants University Hospital (CWIUH) and the Faculty of Health Sciences, Trinity College Dublin. MAMMI stands for **Maternal health And Maternal Morbidity in Ireland.**

If you have any questions about this study, please contact any researcher from the MAMMI team at 087 2290989.

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## **Why have I been given this booklet?**

You were given this booklet because you are having your first baby. This booklet tells you about the MAMMI study and what it means if you decide to take part.

## **What is the MAMMI study?**

MAMMI stands for **M**aternal health **A**nd **M**aternal **M**orbidity in **I**reland. It is a study to look into the health and health problems of first-time mothers during pregnancy and during the year after the birth.

## **Why are you doing this study?**

We want to find out:

- what health problems, if any, women experience during pregnancy and after the birth of their first baby;
- what health services, if any, pregnant women use; and
- how to improve women's health during and after pregnancy.

## **What sort of questions will you ask me?**

We will ask you about:

- your general health and whether you have any medical conditions or have had any operations;
- what you eat and the type of activity and exercise, if any, that you do (in survey 1A)
- any problems you have passing urine (water);
- any problems you have with your bowel movements such as soiling yourself or passing wind when you don't mean to;
- any problems or pain you may have during sex;
- your relationship with your partner and if you are worried about or experiencing violence in the home;
- how often you talk to a doctor, nurse or midwife about your health problems;

- your work or study;
- the type of flat, apartment or house you live in; and
- your thoughts on some issues.

### **Who else is taking part in this study?**

We are inviting women, aged 18 and over, who are having their first baby to take part in the study. Women who have had miscarriages or abortions before this pregnancy are welcome to take part. Altogether, we are asking 2,600 women, 600 women attending the Coombe Hospital, to take part.

### **What does taking part in the study mean for me?**

We are asking you to complete **six** surveys please. You should fill out the first survey (which came with this booklet) while you are pregnant and the second antenatal survey, 1A, when you are about 7 or 8 months pregnant (about 28 to 36 weeks) (we will post this one to you closer to the time). The other four surveys you will be completing at 3, 6, 9 and 12 months after you have given birth. We will post these surveys to you closer to the time also. The surveys are also on the website, [www.MAMMI.ie](http://www.MAMMI.ie). Each survey takes about 45 minutes to complete.

If you decide to take part in the study, we will ask you to:

- sign the consent form which came with this booklet;
- fill out the survey form that came with this booklet while you are pregnant and a second one, two months later (about your diet and physical activity);
- complete four surveys about your health and health problems at 3, 6, 9 and 12 months after your baby's birth; and
- agree to let the research team have access to your and your baby's medical records held by the Coombe Hospital.

## **Are there any risks for me or my baby?**

We do not see any risks with taking part in this study. However, if we find out during the study that a woman or her baby is being harmed or that there may have been a problem with the care a woman received, we must tell the Study Conduct Monitoring Group.

## **What is the Study Conduct Monitoring Group?**

The Study Conduct Monitoring Group (SCMG) has been set up to:

- guide the research team;
- manage any problems that may arise during the study; and.
- deal with complaints.

If you raise a serious complaint, the group will discuss it. They won't know who you are. If they decide that your complaint should be brought up with midwives or medical regulatory authorities, they will ask your consent to share your personal details but can no longer protect your identity. The regulatory bodies need to know who they are representing.

The group is made up of senior staff from the Coombe Hospital and Trinity College Dublin.

## **Are there any benefits for me or my baby?**

The study will not benefit you personally. The information you give will be pooled with the information given by all the other women in the study. This will help us to better understand some of the health problems that women experience during pregnancy and after birth and what can be done to help them.

By taking part in the study you will be helping other mothers and their babies in the future.

## **Can anyone take part in the study?**

To take part in the study you must be aged 18 or over and able to read and understand English.

## **How will you protect my personal information?**

- We will keep all the information you give us private and confidential.
- We will give your survey information a unique number (a code). We will also remove your personal details from the first survey. This means that your answers will not be linked to your personal details.
- We will store your personal details and your code number securely and separately from the completed surveys. They will be kept in a locked cabinet, in a locked office in an area where few people have access.
- Paper copies of the information you give on the surveys will be identified by your code.
- We will keep an electronic version of the information you give us on a computer. Only the research team will have access to this information. We will use passwords, encryption (special software to scramble the information so it cannot be read) and anti-virus software to protect the information on the computer.
- If we do a face-to-face interview with you, we will record the interview. We will make a paper copy of the recording and show it to you so that you can confirm it is an accurate copy of the interview. We will transfer the audio recording to a secure hard disk, and then destroy the recording. We will use your code number to identify you on the paper copy. We will store the paper copy in a locked cabinet, in a locked office in an area to which few people have access.

- All members of the study team who have access to your information must sign a confidentiality agreement form.
- We will only disclose your personal details in **exceptional circumstances** for example if you or your baby is being harmed or you complain about the researchers (for more information see 'What is the Study Conduct Monitoring Group' on page 6).

### **What happens to the information at the end of the study?**

We will publish the findings from the study and may give talks about the findings at healthcare conferences. It will not be possible to identify you or your answers in these publications or talks.

The information from the surveys may also be used in future research projects. However, the **researchers will not contact you unless you give your consent** to future contact. This is explained below.

### **What do the options on the consent form mean?**

The consent form asks you to sign your name to show that you agree to take part in this study.

The consent form also asks you to agree to the following options:

- **Paragraph 5** lets you say if you want a member of the research team to call you after your baby's birth. If you say yes, they will contact you and invite you to take part in an interview.
- **Paragraph 9** lets you agree to information collected from you as part of this study being used for future research studies.
- **Paragraph 10** lets you say if you want your personal details such as your name and address to be destroyed after stage 1 of this research. If you



say yes, the research team will not be able to contact you when this stage of the research is over.

- **Paragraph 11** lets you agree to us keeping your personal details for five years after the end of the first stage of this research. If you say yes, the research team will contact you and invite you to take part in future studies.

Remember, **you do not have to agree to any of these options.** However, if you do agree, you will help us to continue our study of the health problems of pregnant women, mothers and their babies.

### **What do I do next?**

1. Sign the consent form.
2. Keep a copy for yourself.
3. Post the original signed consent form and your completed survey form using the stamped address envelope that came with this booklet.

### **Can I leave the study?**

Taking part in the study is voluntary. You can withdraw from the study at any time without giving a reason. This will not affect the care you or your baby receives.

### **How can I get in touch with you?**

You can get in touch with any member of the MAMMI team, Deirdre Daly, Sunita Panda, Jamile Marchi, Deirdre O' Malley and Francesca Wuytack, by texting or calling 087 2290989.

You can also get information on our website, [www.mammi.ie](http://www.mammi.ie).





