

## Participant Information Sheet

We would be very grateful if you would consider taking part in this study. Please read the following participant information sheet. Do feel free to ask if anything is unclear.

### **What is the purpose of the study?**

We know that many mothers who formula-feed their babies would like to have more information and support. We have developed a programme to help mothers feed the correct amounts of formula so that babies have a healthy pattern of growth. By healthy growth we mean not too fast and not too slow.

The purpose of this study is to test whether following our programme leads babies to a more healthy pattern of growth and development.

### **Why have I been invited to take part?**

You have been invited to take part because your baby is having some formula-milk feeds. This may be in combination with breastfeeding.

### **Do I have to take part?**

No, you do not have to take part. If you decide not to take part, we will respect your decision. This decision will not affect the healthcare that you or your baby receives in any way. If you do decide to take part, you will be asked to sign a consent form at your first study visit. Although we would like you to complete the study, you are free to withdraw at any time, without giving a reason, and this will not affect the healthcare that you and your baby receive.

### **What will happen if I take part in the study?**

If you decide to take part, you will be put into one of two groups. One group will be given standard advice about formula-feeding and weaning (standard advice group). The other group will be given help and support to follow the Baby Milk feeding programme (new programme group). Which group you will be in is purely down to chance, hence you have an equal (or 50:50) chance of being in either group. We will compare the growth of babies in the two groups. We will ask you not to discuss the advice that you have been given with other mothers in case they are in a different group. You can of course discuss the advice with your GP or Health Visitor who will be aware of this study.

If you are put in the **standard advice group** you will have 3 meetings (at roughly 2, 6 and 12 months) and 3 telephone calls (at 3, 4 and 5 months).

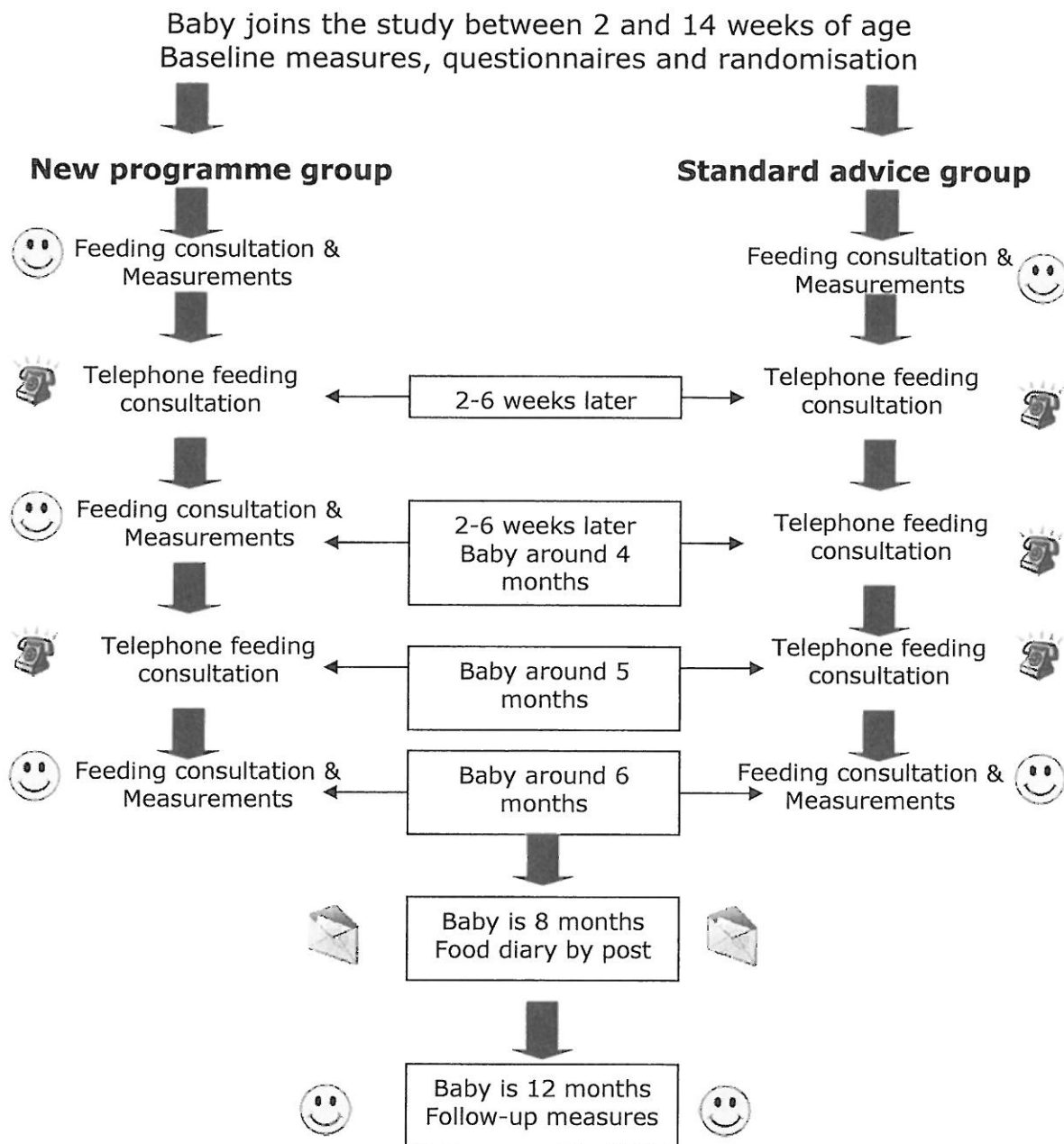
If you are put in the **new programme group** you will have 4 meetings (at roughly 2, 4, 6 and 12 months) and 2 telephone calls (at 3 and 5 months).

Meetings will take place at a specially designed research facility in Cambridge, Ely, Wisbech, Huntingdon, or if you prefer, at your home.

Both groups will be asked to fill out a 4-day diet diary when their baby is 8 months old and will receive a phone call around this time to check whether they have any questions.

Travel costs for all visits will be reimbursed.

**Study flow chart**



At each visit we will monitor the growth of your baby and discuss your baby's feeding and growth with you. At the 12 month visit we will measure your baby's abdominal (tummy) fat by using an ultrasound device similar to that used during pregnancy. We will measure your height, weight and percentage body fat at the first visit. We encourage you to attend visits with your partner and/or other

members of the family involved with feeding your baby. The visits will last about one hour. Before each visit we will send you one or two questionnaires to fill out. The questionnaires will take around 30 minutes to fill out each time and will ask you questions about your baby's feeding.

Telephone calls will last for about 15 – 20 minutes and we will talk to you about your baby's feeding and growth. For training and quality control purposes the telephone calls and face to face contacts may be recorded. The study staff will notify you prior to recording each contact to ask if you are happy for this.

We will give you a free telephone number to call if you have any questions between contacts.

### **What are the possible benefits of taking part?**

Your participation may help you make better decisions on how to feed your baby. You will also learn how to monitor the growth of your child and we will try to answer any questions you have about your baby's feeding and growth. Please note that these visits are additional to your usual healthcare and you will still need to attend routine NHS checks with your GP or Health Visitor.

The results of the study will help us understand the links between feeding practices and your baby's behaviour, appetite and growth. This information will help policy makers to decide whether to adopt the new programme in the UK.

### **What are the possible risks of taking part?**

The risks to you and your baby are negligible, as we will be monitoring the growth of your baby closely. The study materials (leaflets and questionnaires) have been prepared after consultation with paediatricians (children's doctors), GPs, health visitors, midwives, dieticians, psychologists and, most importantly, other mothers.

Further information regarding this particular research study may be obtained by contacting the study information line on Freephone 0800 756 0878 or emailing us at [babymilkstudy@mrc-epid.cam.ac.uk](mailto:babymilkstudy@mrc-epid.cam.ac.uk).

If you are interested in obtaining independent advice or information regarding your rights as a research participant, you can contact Christopher Hampson, the Patient Advice and Public Engagement Co-ordinator at Cambridge Community Services NHS Trust on Freephone 0800 0132511.

### **Will my taking part be kept confidential?**

Other than informing your GP, your participation in this study will be kept strictly confidential. However, as with anyone else who works with children, we have a responsibility in relation to safeguarding children, which includes a duty to disclose to the relevant authorities any instance of reasonable evidence of non-accidental child suffering. This would not occur without prior consultation with our trained clinical staff.

### **Who will have access to my information?**

All information that is collected about you and your baby during the course of this research will be kept strictly confidential. Information will be stored anonymously, using a study identification (ID) number, by the Medical Research Council (MRC) Epidemiology Unit and its collaborators, which includes the University of Cambridge and the University of East Anglia. Codes connecting your individual identity to the stored data records will be kept separately. The

database containing personal information will be stored on a secured drive, password and firewall protected, on computers in the MRC Epidemiology Unit.

If you wish to withdraw from this study any data collected up to your withdrawal date will be retained and safely stored, but your contact details will be removed.

**What will happen to the study results?**

The study results will be published in scientific journals and presented at conferences both nationally and internationally. You will not be identified personally in any report or publication.

**Who is organising and funding the study?**

The study is organised and funded by the Medical Research Council (MRC) Epidemiology Unit in collaboration with the UKCRC Center for Diet and Activity Research (CEDAR) and the University of East Anglia (UEA). The MRC is funded by the UK Government and is the major national organisation that supports high quality medical research with the aim of improving human health. The UKCRC Center for Diet and Activity Research (CEDAR) is one of 5 Centres of Excellence in Public Health Research and is based at the University of Cambridge. The University of East Anglia is a well renowned University based in Norwich.

**Who has reviewed the study?**

All research involving the NHS is looked at by an independent group of people, called a Research Ethics Committee, who protect your safety, rights, well-being and dignity. This study has been reviewed and given favourable opinion by the East of England: Cambridge South Research Ethics Committee.

**What should I do next?**

If you would like to take part, please contact our study line on Freephone **0800 756 0878** or email us at [babymilkstudy@mrc-epid.cam.ac.uk](mailto:babymilkstudy@mrc-epid.cam.ac.uk). Alternatively you can fill in the reply slip below and post it to us using the Freepost address provided. Once we receive your reply slip, we will contact you by telephone and arrange an appointment to see you and your baby.

**Thank you for considering contributing to our study.**