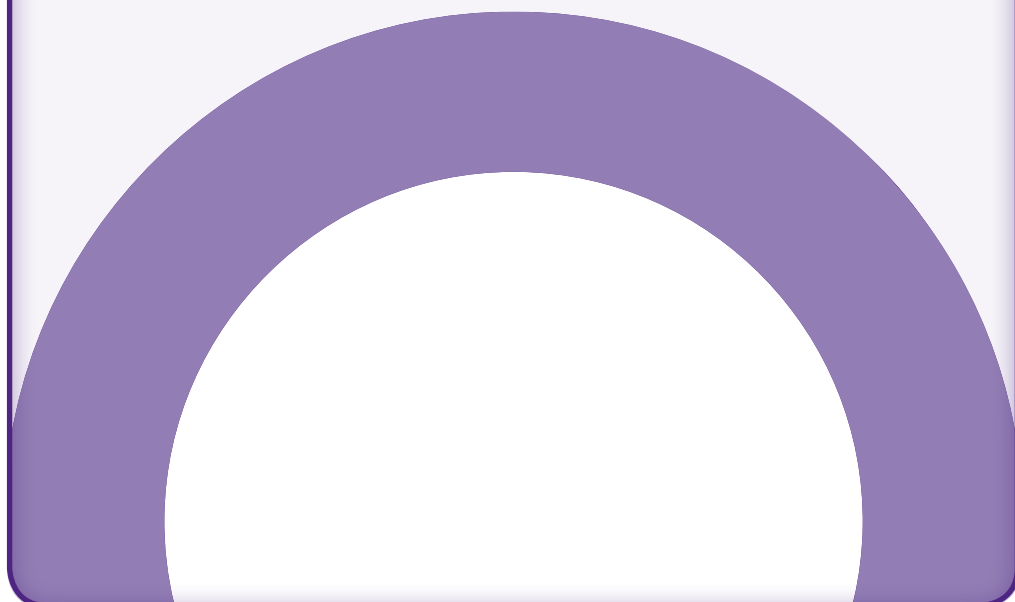




Speed of increasing milk feeds

Parent Information Leaflet



REC Reference: 13/EM/0030

ISRCTN: 76463425

Clinical trials.gov: NCT01727609

SIFT Study – Speed of Increasing milk Feeds Trial

We understand this is a difficult time for you and your family and it may not seem a good moment to be talking about research. However, we think it is important to tell you about a study this hospital is taking part in for babies who have been born early.

○ What is the purpose of this study?

When babies are born early they cannot feed for themselves and we give them their milk down a tube into their stomach. We start with a small volume and we gradually increase the amount of milk as long as the baby is well. We are trying to find out the best way to feed babies to keep them healthy in the long term. We want to know whether they do better if we feed them a little faster or a little more slowly. This study is taking place in neonatal units all over the UK. We want to include about 2,800 babies so that we can find out which speed of feeding is best.

○ Why have I been invited to take part?

We are inviting parents of babies born more than 8 weeks early or weighing less than 1,500g to allow their babies to take part in this study. Some babies born this early can develop complications, including infection in the blood and a bowel disease called necrotizing enterocolitis (NEC). These complications can be serious and can have long term effects on development. We want to find ways of making the risk of these complications as low as possible. We are carrying out this study to see whether the risk of complications is lower with a faster or a slower rate of increasing the milk.

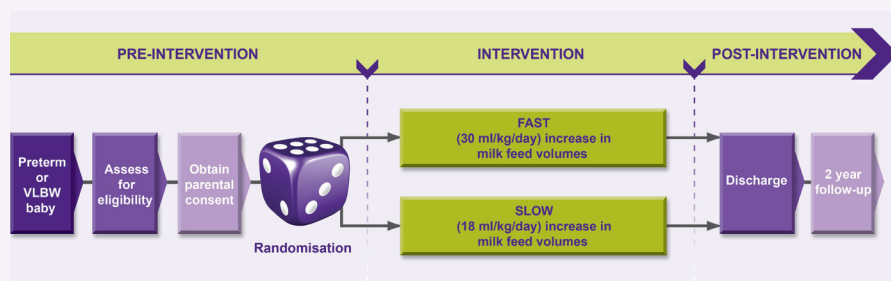
○ Does my baby have to take part?

Whether or not your baby takes part is completely up to you. A doctor or nurse taking care of your baby will discuss the study with you and answer any questions. Your baby's care will not be affected in any way if you decide you do not want your baby to take part in the study.

If you decide you would like your baby to take part, you can change your mind at any time and withdraw your baby from the study without giving a reason.

○ What will happen if my baby does take part?

If you agree to your baby taking part, we will ask you to sign a consent form. All babies start off on very small amounts of milk, which is then increased until they get all of their feeding as milk. When the team caring for your baby are ready to start increasing the milk we will tell them whether the milk should be increased at a faster or a slower rate. The decision to use the faster or the slower milk feed increase will be decided randomly for each baby (rather like a toss of a coin). The daily decisions about feeding will still be made by the nurses and doctors caring for your baby, and feeds will only be increased if the baby is well. Both ways of feeding are typical of those used by different hospitals in the UK, so neither is new. But by comparing different speeds of increase in this way, we can find out which speed helps achieve the best outcomes for babies born early. This flow chart shows what will happen if you decide to let your baby take part in the study:



Babies in this study will not have any extra tests and the rest of your baby's care will be exactly the same as routine care for babies born early. When your child is two years old we will contact you again. We will send you a questionnaire that will ask how your child is developing. This is a really important part of the study. Some babies who are born

early can have problems later as they grow and develop. If we make any change to the care that newborn babies get, we want this to give them the best chance of a good long-term outcome. Before you sign the consent form, please think about whether you are happy to give us this information in two years' time.

○ What milk will my baby receive?

Whether or not you take part in the trial, you will choose the type of milk your baby will be given after talking with the doctors and nurses. Although we know breast milk is best for babies, formula milk can also be used during the trial. If you are expressing breastmilk you will be supported with this.

○ Are there any risks, benefits or side effects for my baby?

We believe that there are no disadvantages for your baby in taking part in this study. All babies will be monitored very closely throughout the study by the staff on the Baby Unit. If your baby is unwell, the doctor in charge will discuss this with you and help you decide whether or not to continue to feed your baby according to the study.

○ What if relevant new information becomes available?

We will inform you if any important new information becomes available during the course of the study that might make you change your mind about your baby's involvement.

○ Will my taking part in this study be kept confidential?

Your GP will be told that your baby took part in this study.

We will collect some information about you and your baby; the details will be kept securely and will only be seen by study organisers, the research sponsor and NHS Trusts who ensure that studies such as these are carried out safely. They may also look at your baby's notes to check that the study is being carried out correctly.

We will keep your name, address and other contact details. The Health and Social Care Information Centre and other central UK NHS bodies will be used to keep in touch with you and provide information about your baby's health status.

○ What will happen to the results of the research study?

At the end of the study, the results will be analysed and published in a medical journal. We will send you a summary of the final results of the study. A copy of the full journal article can be requested from the National Perinatal Epidemiology Unit. You and your baby will not be identified in any report or publication about the study. Unidentifiable data from this study may be shared with other groups who are carrying out similar work.

We may seek to follow up the study by contacting you to find out how your child is at school age. If we do this, we will contact you through the Health and Social Care Information Centre.

○ Who is organising and funding the research?

The study is being run by the National Perinatal Epidemiology Unit at the University of Oxford. The study is funded by the Health Technologies Assessment programme within the National Institute for Health Research [<http://www.hta.ac.uk>].

○ Who has reviewed the study?

All research that involves NHS patients has been approved by an NHS Research Ethics Committee before it goes ahead. Approval means that the Committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given sufficient information on which to make an informed decision to take part or not. The East Midlands - Nottingham 2 Research Ethics Committee has reviewed and approved this study.

○ **What happens in the event that I have a complaint to do with my baby taking part in this study?**

If in the unlikely event your baby has been harmed by taking part in this study, you may have grounds for legal action and could seek compensation through the Research Sponsor, the University of Oxford, who has appropriate insurance-related arrangements in place. If your baby is harmed and it is due to any routine clinical treatment or negligence then the NHS indemnity arrangements will apply. If you wish to complain about any aspect of the way you or your baby has been treated you may use the normal NHS complaints procedures; the Patient Advice and Liaison Services at your hospital will advise you about this (their contact details are on the back page of this leaflet).

○ **What if there is a problem?**

If at any stage you have any concerns about this study or the way it has been carried out, you should contact the Principal Investigator or Neonatal Nurse (their names and contact details are on the back page of this leaflet). Information is also available on the study website [www.npeu.ox.ac.uk/SIFT].

If you would like to contact an independent organisation to discuss the inclusion of babies in research studies generally we suggest that you contact Bliss, a special care baby charity. Their contact details are on the back page.

Thank you for reading this leaflet – please discuss this study with the doctor or nurse who is looking after your baby if you have any questions.



for babies born too soon,
too small, too sick

Chapter House, 18-20 Crucifix Lane, London SE1 3JW

Free phone Family Support Helpline: 0500 618 140

Local contacts

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This study is being organised by the National Perinatal Epidemiology Unit (NPEU) CTU at the University of Oxford. The Unit is dedicated to improving the care provided to women and their families during pregnancy, childbirth and the period after birth, as well as the care provided to the newborn.

www.npeu.ox.ac.uk

