

## Parent Information Leaflet

**Full Title:** Development and evaluation of a parenting intervention to promote motor development in infants born very preterm

**Short title:** Helping Our Premature infants ON to better motor skills (HOP-ON)

### Local Study Team:

Dr Helen Budge – Nottingham University Hospitals

Dr Joe Fawke – University Hospitals Leicester

Dr John McIntyre – Derby Hospitals

**Researchers:** Professor Cris Glazebrook, Professor Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Dr Helen Budge, Sarah Westwater-Wood, Professor Heather Wharrad, Anita Hughes, Katy Allen

### Invitation

You are being invited to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully, and talk to others

about it if you wish. This information sheet tells you the purpose of this study, what will happen if you take part and about the conduct of the study.

Please feel free to ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

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

Research has shown that infants who are born very prematurely (less than 32 weeks) may have a greater risk of problems associated with motor skills (movement development). This can lead to difficulties with handwriting and sport which may be seen during school years. This study aims to show parents how to help their premature infant learn movement (motor) skills from an early age. Information will be provided to parents in a programme which we have called HOP-ON. HOP-ON uses film clips, simple text, diagrams and photos to show parents how to interact with their infants and how to encourage their child's motor skills. The information will be provided as an interactive computer program in two volumes, one around discharge from hospital and a second volume at about 3 months after discharge. The information will also be provided on a DVD and information booklet for parents who do not have access to a computer. At 12 months parents will be given details of a HOP-ON website which will provide suggestions of activities for you to do with your child up to the age of three years.

We wish to look at how parents follow the guidance in the HOP-ON programme, and whether this leads to better movement (motor) skills for their infants.

To do this, we will give some parents the HOP-ON CD or DVD and information booklet (intervention group), and some parents a similar CD or DVD and information booklet called

SMILES (control group). SMILES has useful information and guidance on interacting with your premature infant, but not the information about specific motor skills.

### **Why have I been invited?**

You have been invited as you are a parent of a premature infant born 32 weeks gestation or less, who has been cared for in one of five participating hospital, and your infant has either just been discharged from hospital or will be discharged within a few weeks.

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

No, participation in this research project is entirely voluntary. It is up to you to decide. If you are interested we will arrange for our researcher to describe the study to you and go through this information sheet, which we will then give to you. If there is anything you do not understand please ask the researcher or contact a member of the research team (information below). If you agree to take part we will then ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason. This would not affect the standard of care you receive, or your legal rights.

### **What will I have to do and what will happen to me if I take part?**

If you decide to take part, you will be asked to complete an expression of interest form and consent form and return it to the researchers in the stamped addressed envelope provided. You will then either be given HOP-ON or SMILES packs, but you will not be able to choose which version you are given. The version you get will be decided by random allocation, like tossing a coin. The allocations will be hidden in sealed envelopes so that no one will know in advance which version

any participant will get. You will be given or sent a pack which contains a CD or DVD and information booklet prior to, or following your infant being discharged from hospital. The pack will also contain letters to pass on to your health visitor, and your GP to let them know about the study too.

When your infant is 3 months old you will be sent a pack of questionnaires asking about you and your infant's health and well-being. At 12 months a researcher will contact you to arrange a visit at your home. This visit will involve an assessment of your infant's movements and include details of their weight and length. To assess their movement, three motor assessments will be conducted by a trained professional, and with your permission these assessment will be video recorded. This recording would respect your infant's dignity and a code given to avoid the use of names. Once the video has been assessed it will be stored securely. Some parents may, at a later date, be asked whether they would give their permission for the video to be used as an educational tool, but again no names would be used. The video recording is to check the quality of the data and aid the development of a quality of movement scale. However, the recording is entirely voluntary, and would not affect your participation in the study. During this visit, you would be asked some questions regarding your infant's development and will be given an evaluation form to find out your experience of using the CD or DVD and information booklet. If you are allocated to the HOP-ON group, you will also be given the opportunity to take part in a telephone interview to discuss the use of the HOP-ON CD/DVD. This will be audio-recorded.

At the 12 month visit you will be asked if you are interested in participating in any follow up studies, and if so to confirm that we can hold on to your contact details for this purpose. If you have consented to having the assessment of your infant recorded, you will be asked whether you would like a copy posting to you.

Prior to sending the questionnaire packs we would check your child's health records to ensure that questionnaires are not sent out if it is not appropriate. If at any point the information from the study gives rise to concerns regarding your or your infant's health and wellbeing, we would provide you with information regarding appropriate support. For example we might suggest that you contact your GP, health visitor or other support services.

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

If you take part in the study you will receive CD or DVD and information booklet based information about caring for your premature infant, which you can keep. There is no guarantee however, that these will benefit your infant. You will also be offered information about your infant's performance on tests of physical and mental development at 12 months, and if you agreed to the recording then you will also be sent a copy of the film of your infant participating in the study. You will also be given access at the end of the study to a website which will give you suggestions for activities with your infant up to the age of three years.

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

The main disadvantage will be giving up your time, as you will be involved in the study for approximately 18 months.

### **What will happen if I do not want to carry on with the study?**

Your participation in the study is voluntary and you are free to withdraw at any time, without giving a reason and without your legal rights or medical care being affected. If you withdraw the

information collected up to that point cannot be erased and this information may still be included in the findings.

### **Will my taking part in the study be kept confidential?**

Yes. Ethical and legal practice will be followed, and all information including videos will be stored in a locked cupboard in the Department of Community Health Sciences, at the University of Nottingham. The videos of the motor assessment will be anonymised. They will only be viewed by the research team listed above. However, we will ask some parents if their infant's video can be used for educational purposes, such as presentations at conferences. If your infant's video is chosen for this purpose we will ask for your consent separately to the consent for this study.

### **What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers (Katy Allen or Anita Hughes) who will do their best to answer your questions, or you can speak to Professor Cris Glazebrook tel: 0115 8230420. However, if you are still unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

### **Who is organising and funding the research?**

This study is being organised and sponsored by the University of Nottingham and is being funded by The Henry Smith Charity and Action Medical Research UK.

### **What will happen to the results of the research study?**

The results will be presented in a report to Action Medical Research UK, and will be written up as academic articles in journals. A summary of the findings will be sent to all participants. The movement assessment part of the study is being carried out as an educational qualification, so will be submitted in a study report (thesis) to the University of Nottingham. We may wish to use some direct quotes in the publications, from the evaluation forms received from parents. However, these would be anonymised.

### **Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and agreed by Nottingham 1 Research Ethics Committee prior to the research being conducted.

### **Contact details**

If you have any further enquiries about this research, please do not hesitate to contact the researchers:

Katy Allen: 0115 8230431 or Anita Hughes: 0115 8230983  
or the Chief Investigator: Professor Cris Glazebrook on 0115 8230420

Or another member of the research team:

Professor Sarah Redsell	Tel: 0115 8230809
Dr Samantha Johnson	Tel: 0116 2525444
Dr Charlotte Beer	Tel: 0115 8230410
Dr Helen Budge	Tel: 0115 8230611
Sarah Westwater-Wood	Tel: 0115 8231793
Professor Heather Wharrad	Tel: 0115 8230909

**Thank you for taking the time to read this information sheet.**