

# DOLFIN



## DOLFIN Study Parent Information Leaflet

(For babies born less than  
28 weeks of gestation)

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## Introduction to the DOLFIN Study

The DOLFIN study aims to find out if adding a daily nutrient supplement to a baby's usual milk and weaning food can help improve their neurological child development.

Babies born very early have a higher risk of problems with neurological child development (e.g. how they think, communicate, play, and interact with others) than babies born close to their due date.

A small UK study using the same supplement showed it was safe, and that it may improve neurological child development, but we need to find out more. We'd like to invite you and your baby to take part in a new study using the supplement to help us find out more.

### Your baby's involvement

Babies taking part will receive either a nutrient treatment supplement or a control supplement. You cannot choose which supplement your baby will receive. So that we can properly measure whether there is any difference between the effects of the treatment and control supplements, you and your health professionals won't know which supplement your baby is receiving.

### What is the supplement?

The supplement is a powder which is mixed with your baby's usual milk or weaning foods, and is given every day for around one year. It can be given alongside any medication, fortifiers or vitamins your baby is receiving.

The treatment supplement contains nutrients needed for healthy brain development, within Recommended Daily Amounts. The control supplement contains most of the same nutrients as the treatment supplement but in much smaller amounts.

### Taking part

While your baby is in hospital, the staff caring for your baby will give the supplement and then help you to do this. You will need to continue the supplement at home.

We will ask you to tell us how much supplement you have given your baby each week using the DOLFIN study app, by text or email, or using a paper diary. There are short questionnaires to fill out when your baby joins the study, at hospital discharge, and during the next two years.

We have a video about the study on our website.

To watch follow the link ([www.npeu.ox.ac.uk/dolphin](http://www.npeu.ox.ac.uk/dolphin)) or use this QR code



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# DOLFIN Study – Developmental Outcomes of Long-term Feed Supplementation in Neonates

We know this is a difficult time for you and your family but we think it is important to tell you about a study this hospital is taking part in for babies who have been born very early.

## What is the purpose of this study?

This study is designed to find out whether adding a daily nutrient (food) supplement to the usual milk and weaning foods of babies born very early can help improve their brain development, and their neurological child development (such as how they think, communicate, play and interact with others).

To find out if the supplement is helpful, we will compare the neurological child development of children who received the nutrient treatment supplement with children who received a control supplement. Half the babies will receive the treatment supplement and half the babies will receive the control supplement.

## Why have I been invited to take part?

We are inviting you to take part because your baby was born more than 12 weeks early. The risk of problems with neurological child development are higher for babies born very early than for babies born near their due date.

## What is the supplement?

The supplement is a powder that is mixed with your baby's usual milk or weaning foods. The supplement can be given once a day or split across more than one feed.

The treatment supplement contains nutrients that occur naturally in a healthy diet. These are long chain polyunsaturated fatty acids, uridine-5'-monophosphate, cytidine-5'-monophosphate, and choline, and vitamins and trace elements. Supplement nutrient levels are within Recommended Daily Amounts. The nutrients come from fish and egg sources. The supplement also contains very small amounts of cow's milk protein. The control supplement is a well-balanced nutritional product that contains much smaller amounts of most nutrients in the treatment supplement.

Your baby can continue their usual medication, vitamins and fortifiers when taking the supplement.

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## How is the supplement given? Does it matter how my child is fed?

The supplement can be given in your baby's usual milk feed. Babies who are being breastfed, babies feeding from a bottle (any milk of your choice), and babies receiving milk via a feeding tube can take part.

Staff on the Neonatal Unit will help you find the best option for you, and support feeding. When you go home, feeding support will be available through your local NHS clinical team. If needed, the local NHS clinical team can also get advice from the DOLFIN research team which includes experts on infant feeding. We will provide you with a range of materials to support you to give the supplement including information leaflets, instruction videos and helpful links. These are also available on the DOLFIN study website <https://www.npeu.ox.ac.uk/dolphin/parents>.

If you are bottle feeding your baby, or your baby is having their milk through a feeding tube, Neonatal Unit staff will help you learn to give the supplement so you can continue this when you go home. We will also give you written information showing you how to give the supplement, and details of online information and materials (e.g. videos showing how to mix and give the supplement).

## What will happen if my baby and I do take part?

- If you agree to take part, we will ask for your consent. A computer will decide if your baby will receive the nutrient treatment supplement or the control supplement. Your baby will have a 50% chance of receiving the treatment supplement and a 50% chance of receiving the control supplement. You cannot choose which supplement your baby receives. Neither you nor the staff caring for your baby will know which group your baby is in.
- While in hospital the staff caring for your baby will give the supplement, and then help you to become confident to do so. You will need to continue the supplement at home until the date your baby would have turned one if they'd been born on their due date. Supplement cannot be provided beyond this period.
- The research team will send you reminders to give the supplement via the DOLFIN study app, or via text messaging or email, if you prefer. Some reminders can be switched off or sent less frequently if you would like them to be.
- We will ask you to tell us how much supplement you have given your baby each week using the DOLFIN study app, or by text message or email, or by filling out a paper diary – you can use whichever method you prefer.

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- You will need to have your baby weighed monthly so that the amount of supplement can be increased as your baby grows. We will support you to give the correct amount of supplement for your baby's weight.
  - There are no additional blood tests or other tests required for this study and all other aspects of your baby's care will be the same as usual care for babies born very early.
  - We will ask you to complete a questionnaire when your baby joins the study, at hospital discharge, and at 3, 6, 12, 18 and 24 months of age (based on your baby's original due date). The questionnaires will gather information about your family circumstances, quality of life, how you are finding giving the supplement, unplanned hospital admissions, and about your baby's neurological child development. This information is very important as it will tell us whether the supplement improves neurological child development, and if the supplement has a wider effect on you and your family. You can complete the questionnaires online (we will send a link via text message or email) or as a paper version (whichever you prefer). We will monitor your baby's health and wellbeing throughout the time your baby is having the supplement.
  - When you need more supplement, it will be delivered direct to your home address or another place you choose, by a distribution courier. If you miss the delivery, you can rearrange the delivery for another day to suit you. This is all provided free, at no cost to you.
  - Throughout the study you will be able to contact your local NHS clinical team or the DOLFIN study team with any questions you may have. Contact details can be found on the back of this leaflet.

### **Are there any potential benefits for my baby?**

If the supplement is shown to be effective, your baby's neurological child development (such as how they think, communicate, play, and interact with others) may be improved. The results of the study may also help guide treatment for babies in the future. If the supplement is effective, organisations such as the National Institute for Health and Care Excellence (NICE) can decide if it should be offered through the NHS.

- We will share the results from the neurological child development questionnaire at 24 months of age with your NHS team, so they can discuss the results with you, and use the information to help plan any care and support that your child may need.

Participants who take part to the end of the trial when their child is age 24 months will receive a £25 voucher as a thank you.

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## Are there any potential risks or side effects for my baby?

The supplement has been used in a smaller study of around 100 babies and infants without any problems or side effects.

As well as asking you to let us know about any unplanned hospital admissions, your local NHS clinical team will also let us know about this. We will use this information to identify any unexpected side effects.

If your local NHS clinical team need to know whether your baby is receiving the treatment or control supplement for clinical reasons, they can find out from the DOLFIN study team.

If your baby develops an allergy to cow's milk protein, egg, or fish, you may be asked to stop the supplement while this is assessed.

## Does my baby have to take part?

It is your choice whether to take part or not. 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 if you decide not to take part. If you decide you would like to take part, you can change your mind at any time. You can withdraw from the study without giving a reason and this will not affect your baby's care.

## Who is producing the supplement?

The supplement has been developed and provided free of charge to the study by Nutricia, Netherlands. Nutricia makes foods for medical nutrition. You can find out more about Nutricia on their website, <https://www.nutricia.co.uk/>. Nutricia is the only supplier of this supplement. Nutricia were not involved in the design of the study, and will not be involved in the collection or analysis of study data.

Nutricia will only be able to see the results of the study when they are publicly available unless they agree to pay the NHS for the results at the end of the study. Nutricia will not be given your personal details.

## Are the supplements kosher, halal, and vegan?

Some of the nutrients come from fish and egg sources. The supplements contain small amounts of cow's milk protein.

The supplements contain small amounts of cow's milk protein. The supplements do not contain pork or meat products but are not certified kosher and halal compliant. You may wish to discuss this further with your local NHS clinical team or religious leaders.

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## Can my baby take part if they are already taking part in another study?

You can choose whether your baby takes part in any study they are invited to join. If your baby is already taking part in another study, or there is another study your baby could join, a doctor or nurse taking care of your baby will discuss both studies with you. They will let you know if your baby can't take part in both studies.

## What if relevant new information becomes available?

We will keep up to date with any relevant studies and look closely at their results. We will inform you if any important new information becomes available during the study.

## Will you contact me in the future about any longer-term effects of the supplement on health and learning?

To look at the long-term health and learning effects from this study, we would like to collect future information about babies who have taken part. We will ask for your consent to collect this information. If you don't want to do this, you can still take part in the DOLFIN study.

If you do agree for us to contact you in the future, we ask for your permission to keep your personal identifiable information and to share this (including your baby's name, date of birth, address, sex and healthcare number) with national databases via NHS Digital or equivalent UK NHS bodies, and the National Pupil Database held by the Department for Education.

We plan to collect information about long-term health and learning effects in three different ways:

1. When your child is pre-school age we may contact you to ask you to complete some additional questionnaires about their neurological child development.
2. When your child is older, we may contact you to invite them to take part in a follow-up study.
3. We plan to look for differences in children's health, and their learning at school.

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## You and your data, including personal information

### What information will be collected about us during the study?

If you do consent for your baby to take part, we will collect personal information about you and your baby.

This includes name, date of birth, NHS number, contact details, and NHS data about your baby's birth, and their feeding and health. We will also ask you to give us some information about yourself and your family.

### How will we use information about you and your baby?

We would like to use information about you and your baby during this study, and also use information about your child when they are older. This section tells you about that:

People involved with the study may use this information to check your records and make sure that the research is being done properly – this includes authorised staff from the research team, regulatory bodies, and your local hospital. Your GP and Health Visitor will also be told that your baby is taking part in this study.

### Who will have access to our data?

We will only collect and use information that we need for the research study. We will only let people who need to know your name and contact details have this information. You and your baby's data will have a study ID instead of using a name. We will always write our reports in a way that no-one can work out that you or your baby took part in the study.

Nutricia (the company providing the supplement) will not have access to any of your personal information. Anonymised information about the safety of the supplement will be shared with Nutricia during the study.

To send you the supplement, your name, address, email address, phone number and your baby's name will be shared with the company sending the supplement to you at home and their courier.

If you are using the study app, your name, email address, mobile phone number and your baby's name and date of birth will also be shared with the digital app supplier, Newcastle University.

### How will you keep our data safe?

We will keep your data safe and secure, and follow all privacy rules, including the General Data Protection Regulation (GDPR) and the Data Protection Act in its current form. We will keep all information about you safe and secure at



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the National Perinatal Epidemiology Unit Clinical Trials Unit at the University of Oxford, the Newcastle upon Tyne Hospitals NHS Foundation Trust, and Newcastle University.

At the end of the study, the research team will keep identifiable information about you and your baby from this study for 25 years after the study has finished in case we need to check it.

Information that doesn't identify you or your baby from this study may be shared with other groups who are carrying out similar research.

If you agree, we will keep some of the data so we can check the results. If you agree, we will keep your contact details so we can get in touch with you about your child's neurological development when they older.

For more information on how we process and protect you and your baby's data, please see our website: [www.npeu.ox.ac.uk/ctu/privacy-notice](http://www.npeu.ox.ac.uk/ctu/privacy-notice)

You can also contact the Data Protection Officer within the Sponsor's office at Newcastle upon Tyne NHS Foundation Trust: [nuth.dpo@nhs.net](mailto:nuth.dpo@nhs.net) or you can contact the Information Commissioner's Office (ICO) ([www.ico.org.uk](http://www.ico.org.uk) or 0303 123 1113). You can find out how research uses NHS patient data by reading:

Patient Data and Research leaflet – Health Research Authority ([hra.nhs.uk](http://hra.nhs.uk)).

### **What if I change my mind about taking part?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your child's health from central NHS records/ your hospital. If you do not want this to happen, tell us and we will stop.

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

At the end of the study, the results will be published in medical journals and presented at scientific conferences. A summary of the results will also be published on the DOLFIN trial website ([www.npeu.ox.ac.uk/dolphin](http://www.npeu.ox.ac.uk/dolphin)). We will send you a summary of the results written for parents, and a link to the full copy of the journal article. Parents from the research team, charities and support groups will help us tell people about the findings. We will make sure no-one can work out who you or your baby are from the reports we write.

Due to the long-term nature of the study we will not let you know which supplement your baby received until all follow-up has been carried out, including any future follow-up studies – this is to avoid biasing the results.

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## Further information

### Who is organising and funding the research?

This study is being sponsored by The Newcastle upon Tyne Hospitals NHS Foundation Trust (sponsor). The study sponsor has responsibility for the study.

The National Perinatal Epidemiology Unit, Clinical Trials Unit (NPEU CTU) at the University of Oxford, in partnership with Newcastle University, are coordinating and managing the study on behalf of the sponsor.

The study is funded by The National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) programme – the NHS research funder.

### Who has reviewed the study?

All NHS research is assessed by an independent group of people called a Research Ethics Committee to protect the interests of the people taking part in it. This study has been reviewed and approved by the Central Bristol Research Ethics Committee.

### 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 can contact your local NHS clinical team at your Neonatal Unit, or the DOLFIN study team (their contact details are on the back of this leaflet).

If you wish to complain about any aspect of the way you or your baby has been treated you can also use the normal National Health Service complaints procedures. The Patient and Liaison Service (PALS) at your hospital will advise you about this (their contact details are on the back page of this leaflet).

In the case of any harm to participants arising from the management or conduct of the research the NHS indemnity scheme applies. In the case of harm arising from the design of the research then Newcastle University insurance applies.

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## Where can I find more information about the study?

If you have any questions or would like further information about the study please speak to your baby's nurse or doctor on the Neonatal Unit. They can discuss the study further with you, or arrange for a research nurse to meet with you to give further information and answer any questions you may have.

You can also contact the DOLFIN study team using the contact details on the back of this leaflet. Information and resources can be found on the DOLFIN website [www.npeu.ox.ac.uk/dolphin](http://www.npeu.ox.ac.uk/dolphin)).

If you would like to contact an organisation to discuss the inclusion of babies in research studies generally, we suggest that you contact Bliss, the charity for premature and sick babies.

Their contact details are:



### **Bliss**

Fourth Floor, Maya House, 134-138 Borough High Street, London SE1 1LB

Website: [www.bliss.org.uk](http://www.bliss.org.uk)

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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.

## Local contacts

**Principal Investigator**

**Nurse/Dietitian/  
Lactation consultant**

## Contact address:

NPEU Clinical Trials Unit  
National Perinatal Epidemiology Unit (NPEU)  
Nuffield Department of Population Health  
University of Oxford, Old Road Campus, Oxford OX3 7LF

**T:** 01865 617919

**E:** [dolphin@npeu.ox.ac.uk](mailto:dolphin@npeu.ox.ac.uk)

**W:** [www.npeu.ox.ac.uk/dolphin](http://www.npeu.ox.ac.uk/dolphin)

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](http://www.npeu.ox.ac.uk)

REC Reference: 22/SW/0009    ISRCTN:62323236

This project was funded by the National Institute for Health and Care Research Health Technology Assessment (HTA) Programme. (Project number NIHR 130925).