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# Parent Information Leaflet

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This Easy Read document has been written in partnership with Sunderland People First. It is an Easy Read version of the DOLFIN Parent Information Leaflet





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## GETTING IN TOUCH WITH US



If you have any questions or want to discuss this study more please speak with one of the doctors or nurses looking after your baby.

If you are already at home please contact your local NHS clinical team.



You can also email the DOLFIN study team at: [dolphin@npeu.ox.ac.uk](mailto:dolphin@npeu.ox.ac.uk)

Or call us at: 01865 617919

## DOLFIN STUDY



You and your baby are invited to take part in a research study called DOLFIN.



You don't have to take part – it is your decision.



This study may help your baby and other babies in a similar situation.

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## WHAT IS THE DOLFIN STUDY ABOUT?



The DOLFIN study is aiming to find out if a nutritional (food) supplement can help child development.

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The research team carried out a small study using the supplement. This showed the supplement is safe, and may help child development. Now we need to do a bigger study to find out more.

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We will look at whether the supplement helps with things like how a child thinks, communicates, and plays.

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If the study shows that the supplement helps child development, it might be given to other babies in the future.

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This leaflet will tell you more about the study.

If you would like to watch a video about the study, follow the link ([www.npeu.ox.ac.uk/dolphin](http://www.npeu.ox.ac.uk/dolphin)), or scan the QR code.

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## WHY HAVE I BEEN INVITED TO TAKE PART?



You have been invited to take part because you are the parent of a baby who was born early or had difficulties around birth.



Babies born early or who have difficulties around birth have a higher risk of child development problems.

## WHAT WILL I HAVE TO DO IF I DECIDE TO TAKE PART?



You will be asked to give the supplement to your baby daily for one year after their original due date.



We will ask you to fill out a questionnaire:

- when your baby joins the study
- when your baby leaves hospital
- at 3, 6, 12, 18 and 24 months after your baby's original due date.



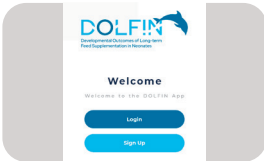
We can send you the questionnaire by text or email. Or you can fill in a paper form. You can choose.



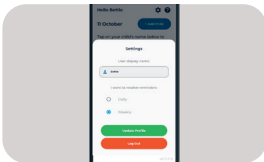
Your local NHS clinical team and the DOLFIN study team can give you help to complete the questionnaires.



You will be given contact details for your local NHS clinical team. The contact details for the DOLFIN study team are at the beginning of this leaflet.



During the study the research team will ask you about the supplement you have given using the study app, or by text or email. You can use a paper diary if you prefer.



We can give you help to use the study app and change settings. For example if you want to have fewer reminders about giving the supplement this can be changed.



The research team will also send reminders to fill out the questionnaires using the study app, or by text or email if you prefer.



Your baby will not need any extra tests as part of the study.



If you take part until your child reaches 2 years old, you will receive vouchers worth £25.

## INFORMATION ABOUT THE SUPPLEMENT



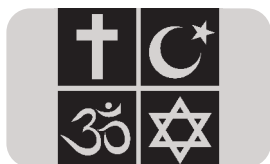
The supplement contains nutrients which are included in a healthy diet.



The supplement contains small amounts of fish and cow's milk.



It does not contain pork or other meat. The supplement is not halal or kosher compliant.



If your baby has restrictions to their diet for religious reasons, you may want to take advice from a faith leader.



## WHICH SUPPLEMENT WILL MY BABY GET?



Half of the babies will be given the treatment supplement and half will be given a dummy (control) supplement.



The control supplement contains most of the nutrients in the treatment supplement but in much smaller amounts.



You cannot choose which supplement your baby will get. A computer will decide.



The treatment supplement and the control supplement look and feel the same.



It is very important for the study that parents, health professionals looking after your baby, and researchers are not told which supplement your baby is getting.



The research team will compare results of babies who have received the treatment supplement with those who received the control supplement.

## DOES IT MATTER HOW I FEED MY BABY?



You can take part in the study whichever way you are feeding your baby:

- Breastfeeding
- Bottle feeding
- Tube feeding



If you decide to change the way you feed your baby during the study, you can still take part.



There are different ways to give the supplement depending on how you are feeding your baby.

## WHO IS DOING THE RESEARCH?



Newcastle University Hospitals NHS Foundation Trust is leading the study.



The study is funded by the NHS Research Funder - The National Institute for Health and Care Research (NIHR).



The Research Team includes doctors and dietitians from the NHS, and researchers from the University of Oxford and Newcastle University.

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## WHO MAKES THE SUPPLEMENT?



The supplement is made by a company called NUTRICIA. NUTRICIA make foods for special medical purposes.

NUTRICIA is the only company producing the supplement.



NUTRICIA also make sure the supplement is safe for use, but are not involved in any other part of the study.

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## WHO ELSE WILL KNOW MY BABY IS TAKING PART IN THE STUDY?



We will let your GP and Health Visitor know that you are taking part in the study.



This will help them to keep a check on your baby's progress and give you support.



Taking part in the study will not affect your baby's medical care.

## WHAT IF I CHANGE MY MIND ABOUT TAKING PART?



If you decide to take part and then change your mind you can stop at any time. It is important you let us know. You do not need to give a reason.

## WHAT INFORMATION WILL BE COLLECTED ABOUT ME AND MY BABY?



We need your consent to take part in the study. To give consent you will also need to read the main Parent Information Leaflet.



We need some personal information from you and your baby as part of the study.



We will collect some information from your baby's NHS records.



If you stop taking part in the study, we will use the information we have already collected.



If you do not want us to keep collecting information about you and your baby, please tell us and we will stop.

## INFORMATION WE COLLECT



You and your baby's NHS number.



You and your baby's name and date of birth.



The address to send the supplement when your baby is home from the hospital.



Your email address if you have one.



Your mobile telephone number if you have one.



Information about family life.



Information about your baby's feeding and any health conditions your baby has.

## KEEPING YOUR INFORMATION SAFE



By law we need to keep your private information safe.



We will only collect and share information we need as part of the study.



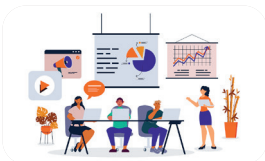
For example, your address will only be given to the company who delivers your supplement.



People will not know who you or your baby are from the study results.



We will keep your information for 25 years in case we need to check it during this time.



The DOLFIN study team can tell you more about how your information is used.

## SHARING INFORMATION ABOUT YOU AND YOUR BABY



We will share results about your child's development when they reach 2 years old with your hospital doctor or GP.



We will share information about you taking part in the study with the NHS so that we can find out about your child's health.



If you agree we will also share your information with the Department of Education so that we can find out how your child is doing in school. You do not have to agree to this to take part in DOLFIN.

## MAKING SURE THAT THE STUDY IS CARRIED OUT PROPERLY



An independent group makes sure that the study is carried out properly. The name of the group is the Central Bristol Research Ethics Committee.



If the doctors looking after your baby need to know which supplement your baby is taking, they can find out.

## RESULTS OF THE STUDY



The results of this study will be published in a medical journal.



A medical journal keeps health professionals like doctors up to date with new information.



We will send you a link to the results.



The report will also be available on our website: [www.npeu.ox.ac.uk/dolfin](http://www.npeu.ox.ac.uk/dolfin)

## AFTER THE STUDY



If you give us permission, we might ask you more questions after the study has ended. This will be before and after your child starts school.



## OTHER RESEARCH



Other research teams may be doing similar studies to the one we are doing.



We will let you know of any new information from these studies.

**Bliss**  
for babies born  
premature or sick

You can find out more about research into sick and premature babies by visiting the Bliss website: [www.bliss.org.uk](http://www.bliss.org.uk)

## IF YOU HAVE ANY CONCERNS



If you are not happy about something to do with the study you can contact us, or you can contact the Patient Advice and Liaison service (PALS) team at your local hospital.

## IF YOU HAVE ANY QUESTIONS



If you have any questions or want to discuss this study more please speak with one of the doctors or nurses looking after your baby.

If you are already at home please contact your local NHS clinical team.





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## Local contacts

**Principal Investigator**

{PI }

**Nurse/Dietitian/  
Lactation consultant**

{ C2 }

{ C3 }

{ PALS Name }

{ PALS }

### 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)

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