

Parent Supplement Training

It is the responsibility of the site staff at Neonatal Units (NNUs) to train parents how to prepare, administer, store and dispose of the supplement.

Training is considered complete when site staff are confident that parents can undertake supplementation without supervision. **Parents should be instructed not to start administering supplement themselves before training.**

Parent training in making up and administering the supplement should be provided as soon after randomisation as is appropriate, in case of transfer, with a refresher later if required.

If an infant is transferred or discharged prior to training being completed, or an infant is consented post-discharge, it is a site decision how best to manage parent training. Sites should arrange for training to be completed as soon as possible, either in-person or remotely (e.g. via telephone or video call). Training may include parents watching the DOLFIN supplementation videos (available on the DOLFIN website www.npeu.ox.ac.uk/dolphin); parents observing clinical team giving supplement; parents giving supplement themselves in hospital with guidance from clinical team.

Key points training should cover:

- Parents are aware how to mix and administer the supplement (in both milk and weaning foods)
- Parents are aware of how to store and dispose of the supplement
- Infants will be able to have all medicines and supplements they would normally have.
- Parents are aware of the need to regularly weigh their baby to ensure the correct dose of supplement is given (parents are asked to report weights once monthly for the first 6 months post-discharge).
- The DOLFIN app is downloaded (if being used) and that parents are aware of how to use it, or an alternative method of reporting agreed e.g. paper diary.
- Parents know how they will receive more supplement and how to get in touch if they have an issue or need replacement supplement.
- Parents know who to contact for queries relating to the trial, and who to contact for clinical queries.

See **Guidance Sheet 4a & 4b: Study Intervention** for further details on supplement storage, dosing, preparation and administration.

Parents should contact the recruiting site if they require further supplement training or guidance and can also be signposted to the DOLFIN website which includes a number of resources including videos showing how to give supplement, supplement guidance leaflets and dosing charts (www.npeu.ox.ac.uk/dolphin).

Documenting Parent Training

Sites should document that training has taken place in the infant's medical notes and on the DOLFIN randomisation system.

- On the randomisation website click 'Recruitment List'

Menu

Latest 3 participants		
Study no	Date randomised	Time since randomisation
10691	20/07/22 16:40	about a day
10686	18/07/22 16:43	3 days
10675	13/07/22 17:07	about a week

Please select one of the following options:

1. Randomise infant
2. Randomise infant with random data
3. Login packs
4. Pack list
5. Pack list (detailed)

- Find the study ID for infant you would like to add contact details for and click 'Edit'

Study no	Recruiting centre	Time randomised	Pack	Print	Edit contact details
12715	Leicester Royal Infirmary	30/10/23 11:53	C2279	<input type="button" value="Print"/>	<input style="border: 2px solid red;" type="button" value="Edit"/>
12704	Addenbrooke's Hospital, Cambridge	26/10/23 13:51	C6595	<input type="button" value="Print"/>	<input type="button" value="Edit"/>

- At the bottom of the page select 'Yes' for 'Parents have completed supplement training' (this will be default No)

Parent prefers to report by

Mobile app (recommended) Online forms (OpenClinica Participate)

Parents have completed supplement training

Yes No ←

Support for families post-discharge

Parents should be advised that supplementation may be temporarily paused if an infant is transferred to a hospital that is not part of the study (although the DOLFIN study team will try to obtain local approvals wherever possible). This is outlined in the Parent Information Leaflet (PIL).

If approvals cannot be obtained, parents should resume or start giving the supplement as soon as possible, either once they are transferred to another participating site or once discharged home.

Please continue to support these families to ensure supplementation continues and parents remain engaged.

It may be required to offer additional or refresher parent supplement training.

At discharge, ensure parents are given the **DOLFIN Parent Discharge Pack** containing:

- A supply of supplement, scoops and sachet closing clips.
- Written support materials and resources (sites can also signpost to the DOLFIN study website (www.npeu.ox.ac.uk/dolphin) for online resources and supplement administration videos:
 - **Parent Information for Supplement Use Leaflet** - how to mix and give the supplement
 - **DOLFIN Supplement Use Info Breastfeeding Babies Leaflet** (*if applicable*)
 - **DOLFIN Quick Supplement Guide**
 - **DOLFIN Supplement Dosing Charts**
 - A personalised study timeline (on reverse of **DOLFIN Thank you Card**)
 - Contact information for their local NHS clinical team and DOLFIN study team (on back of Parent Information for Supplement Use Leaflet)
 - Health Visitor Letter (**please update this locally with the participant's details and add to the Discharge Pack**)
 - A paper adherence diary for recording supplementation (if using this as alternative to study app)
 - **Easy Read Supplement Leaflet** (*if applicable*)

Parents should be signposted to online information and videos including supplement administration for different feeding methods on the DOLFIN website www.npeu.ox.ac.uk/dolphin.

Families will be supported throughout the trial by their local NHS clinical teams as per usual care. This may include the neonatal team, paediatricians, dietitians, lactation consultants and health visitors. The recruiting site are responsible for supporting an infant throughout the trial, including when an infant is at a Continuing Care Site (CCS).

Parents should be provided with information on who to contact with trial-related queries; this should be either the local research nurses or the local post-discharge clinical team, depending on local set up. The DOLFIN study team at the NPEU CTU can respond to direct queries from parents relating to trial processes, data collection or resupply of supplement; but they are unable to become involved with queries relating to the clinical care of an infant. These queries need to be directed to the local neonatal and local post-discharge clinical teams as appropriate.

Parents should ideally contact their local NHS clinical team in the first instance (using the details on the back of the **DOLFIN Parent Information Leaflet** and **DOLFIN Parent Information for Supplement Use Leaflet**) but parents can also contact the DOLFIN study team at any time.

Letters

Electronic versions of the GP letter and Health Visitor letter are provided to sites. Please update these with the participant's details and send to both parties. The Health Visitor letter should also be included in the Discharge Pack.

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Study app

The DOLFIN study app can be used by parents throughout the study period to:

- Report supplement adherence (whether they have given supplement);
- Record infant's weight (to ensure correct supplement dosing);
- Report unplanned hospital admissions (so sites can check if they require SAE reporting).

The DOLFIN study app is the preferred method for parents to record trial information where possible. If parents are not able to, or do not wish to use the study app, there are agreed alternative methods for reporting this information. **Please ensure option preferred by parents is recorded on the Contact Details Form.**

The app is not used for re-ordering supplement or for completing questionnaires.

Parents sign up to the app using their email address. **This must be the one that was entered on the contact details form at randomisation.** Once a parent has created their profile on the app, they can add their baby or babies to it using their infant's unique study ID. Parents can each use the app on separate handsets for the same infant.

Parents and sites can refer to the **DOLFIN study app user guide** for further information on downloading the app and registering an infant (available as hardcopy from sites, or electronic via email or downloaded from DOLFIN website). Parents or site should report any problems or queries relating to the study app to the DOLFIN study team.

Infant weights

Parents are asked to report monthly weights for their infant during the supplementation period (12 months EDD) to ensure that they receive the correct supplement dose.

Options for reporting infant's weight:

1. Use DOLFIN study app (preferred option wherever possible)
2. Complete forms on OpenClinica (receiving links in text messages/emails as they will for parent questionnaires)
3. Complete paper **DOLFIN Adherence Diary** (daily or weekly) and post back to the DOLFIN study team in a FREEPOST envelope

Parents using the study app will receive monthly prompts to report weight. When they report a weight, there is a field to enter how many scoops of supplement they are giving. The app does not calculate this; parents should use the dosing chart to see how much supplement they should give.

Parents using OpenClinica will receive reminders by text/email to report weights via the link. Parents using paper diaries will receive reminders by text/email and should record weights in the relevant section of the DOLFIN Adherence Diary.

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Parents will be reminded that the **DOLFIN Supplement Dosing Charts** are available online at <https://www.npeu.ox.ac.uk/dolphin/parents/resources>, so they can check the number of daily scoops if they need to. The **DOLFIN Supplement Dosing Charts** are also included in the **DOLFIN Parent Discharge Pack**.

For the first 6 months, the local research nurse should contact parents monthly to confirm the correct dose and the infant's current weight. If parents are confident of the dosing method, dose confirmation calls can cease thereafter.

Parent adherence reporting

Parents will be asked to report whether they have given the supplement to their child once their infant has been discharged from hospital. If parents are giving the supplement to their infant in hospital prior to discharge home this would ideally be reported by the parents (if it is not being recorded on the **Daily Dosing Log**). Parents can report via the app before the baby has been discharged home. If they are not using the app but are giving supplement prior to discharge, they can record this on a paper adherence diary (even if they will be using the OpenClinica links after discharge).

- Parents will be asked to report on a **daily** basis for the first one month (28 days) from their baby's discharge from hospital whether they have given their baby the supplement.
- After 1 month parents will be asked to report on a **weekly** basis, reporting once per week for the previous 7 days. Parents can only report for the previous 7 days, earlier days cannot be reported.

Options for reporting supplement adherence:

1. Use DOLFIN app (preferred option wherever possible).
2. Complete forms on OpenClinica (receiving links in text messages/emails as they will for parent questionnaires)
3. Complete paper **DOLFIN Adherence Diary** and post it back to the DOLFIN study team in a FREEPOST envelope
4. Site staff can complete adherence data provided by the parents (e.g., in a phone call) on behalf of the parents via OpenClinica

The DOLFIN Study team will send reminders to parents to report the adherence data (either via study app prompts for parents using the study app, or via text/email for parents using DOLFIN Adherence Diary or OpenClinica link via text/email).

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Parents cannot choose whether to report daily or weekly, but they can choose whether to receive daily or weekly reminders to give supplement:

- Parents using the study app can switch reminders at any time in the Settings section of the app – see **DOLFIN study app user guide**),
- For parents using the paper **DOLFIN Adherence Diary** or links via text messages/email, parents or sites should email the DOLFIN study team at dolphin@npeu.ox.ac.uk.

Supplement should be given daily, only reporting and reminders change.

If parents are regularly not reporting this data, site staff may be asked to follow up with the parents to see if they are having any issues.

Parents will receive a notification when it is 12 months from their infant’s EDD to let them know that they can stop giving the supplement.

If an infant discontinues the supplement, they should be advised to uninstall the app / disable notifications. Parents who have discontinued supplement may still receive text / email messages from the DOLFIN study team prompting them to report unplanned hospital admissions and complete questionnaires (depending on the nature of their change of consent).

Reporting unplanned hospital admissions

Parents are asked to report any unplanned hospital admissions for the period of supplementation (until 12 months of age EDD plus 2 weeks). Parents only need to report unplanned hospital admissions that they have not already informed the recruiting site of.

Parents using the study app can report unplanned hospital admissions for their infant through the app (sites and the DOLFIN study team will receive a notification), or directly to their local clinical team. Parents using OpenClinica or paper diaries should report unplanned hospital admissions to their local clinical team.

Parents receive reminders via text message/email to report any unplanned hospital admissions.

Sites should confirm whether the unplanned hospital admission requires reporting as a Serious Adverse Event (SAE) (see **Guidance Sheet 9 – Safety Reporting**).

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Site checklist for transfer/discharge of infant

- Complete **Transfer/Discharge Form**
- For transfers, notify DOLFIN study team as soon as you are aware of transfer. See **Guidance Sheet 7 – Transfer of infants**
- Confirm contact details. Remind sites to notify sites of any change of contact details
- Agree on making contact at month 1, 2, 3, 4, 5 and 6 after discharge (to confirm weight/dosing)
- App downloaded and set up, or alternative agreed for adherence reporting (ensure preferred option is recorded on the **Contact Details Form**)
- Trained on supplement administration or a plan agreed for training (remote or in-person) and importance of daily dosing
- Aware of correct storage and disposal of supplement
- Discuss importance of weighing baby regularly to ensure correct supplement dosing
- Received guidance on different options for feeding and who to contact for support
- Received guidance or signposted to breastfeeding specific resources (if applicable)
- Parents know how they will receive resupply of supplement and who to contact if they need more supplement or they have an issue
- Complete participant timeline (on reverse of **DOLFIN Thank you card**)
- Remind parents about completion of parent questionnaires and confirm how parent wishes to complete the questionnaires
- Ensure parents know how to access support if needed, and have local clinical team contact details
- Parent training has been documented by site in infant's medical notes and on the **DOLFIN randomisation website**
- Provided with **DOLFIN Transfer Pack** and/or **DOLFIN Discharge Pack**
- Send patient localised GP letter and Health Visitor letter

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