

# The **DREAM** Study

Information Leaflet



A study for infants  
with **cow's milk**  
**allergy**

**The DREAM Study is running across the UK looking at treating infants with cow's milk allergy**

**You have been given this information because your child may be eligible to take part in this study**

### **Cow's Milk Allergy**

Cow's milk allergy (CMA) is one of the most common food allergies in children, affecting 2-7% of infants in the UK. The current way to manage CMA in children is to avoid all products containing cow's milk, use special 'hypoallergenic' (unlikely to cause an allergic reaction) formulas, and wait for children to outgrow the allergy. However, this method does not always work, and many children remain allergic, even as adults. Cow's milk avoidance is difficult and accidental reactions, even severe ones, are common.

### **Why are we doing this study?**

The study will compare two different types of formulas (control and intervention). We want to know if one of these formulas will help more infants overcome their allergy after one year.

Please note, breastfeeding is the optimal food choice for the first year of life and we will only recruit children who are already receiving a hypoallergenic formula for the management of cow's milk allergy.

The results from DREAM will help doctors and patients decide how they should or should not manage infants with CMA.

### **What happens in DREAM?**

If your child takes part in DREAM, blood tests and 'milk challenges' will be carried out to confirm their allergy. We will then use a computer to decide at 'random' which formula milk your child is given. This is called

“randomisation”. In DREAM, there is an equal chance of receiving either of the two milk formulas. We will then provide the allocated formula and instructions for feeding for the next 12 months. You will also be required to complete a short, daily diary to record how much formula your child is given. In most cases, feeding will be free (depending on your child’s appetite). If your child does not tolerate a full feed, a prespecified, smaller quantity may be given.

In this research study we will use information from your child’s medical records. We will only use information that we need for the research study. We will let very few people know yours or your child’s name or contact details, and only if they really need it for the study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study, we will save some of the data in case we

need to check it and for future research. We will make sure no one can work out who you or your child is from the reports we write.

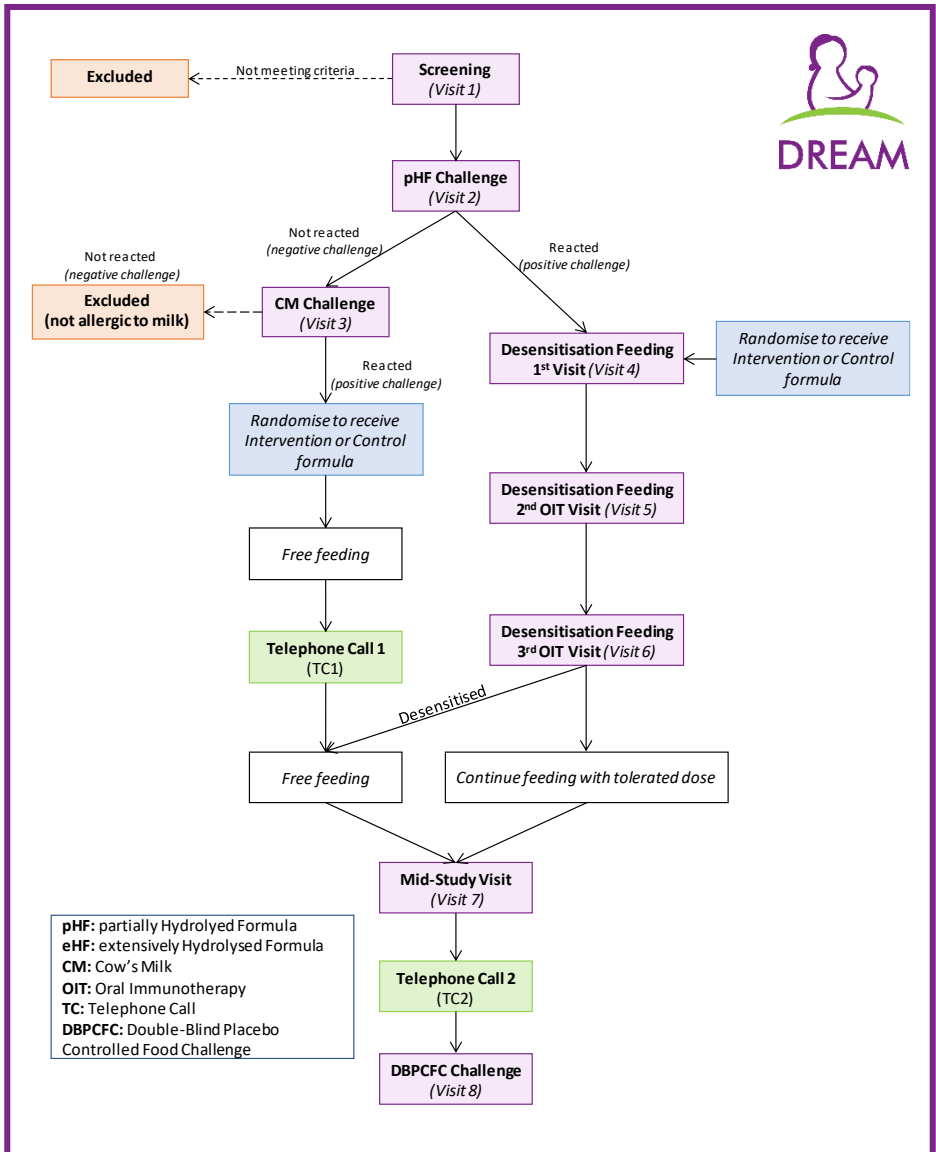
### **Do you and your child have to take part?**

No, you do not have to take part. However, before you make a decision, we would suggest that you find out more about the study by visiting the website below or speak to your child’s doctors or nurses.

You can also learn more about the DREAM Study on our website:

[www.dream-trial.org.uk](http://www.dream-trial.org.uk)





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