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Baby Milk Study: establishing a healthy growth trajectory from birth

Submission date
03/11/2010

Recruitment status
No longer recruiting

Registration date
13/01/2011

Overall study status
Completed

Last Edited
23/07/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The number of children who are obese (very overweight) has increased rapidly over the past two decades. Children who are overweight are likely to be overweight as adults which may cause problems both in the short term and in the long term. National surveys show that more than one in five children are already overweight (13%) or obese (10%) when they start school. Hence any efforts to prevent obesity must start early. The Foresight Report and the Healthy Weight Healthy Lives strategy have highlighted the importance of preventing childhood obesity by focussing on the early years. However, to date there is little evidence on which to develop effective preventive strategies. Infancy is a period of rapid growth and weight gain and obesity prevention during this period may be effective. Nutrition and growth during infancy may also have long term effects by altering eating behaviours and risks of obesity and obesity-related disorders in later life. UK Infant Feeding Surveys show that at birth one in three (35%) babies receive formula-milk and this number increases to almost all babies (92%) at 6 months of age. So, in addition to promoting breastfeeding, it important to optimise the growth of formula-milk fed babies. Previous research shows that parents who give their babies formula-milk as part of their everyday diet need more information and support. Researchers at the Centre for Diet and Activity Research (CEDAR) and MRC Epidemiology Unit in Cambridge have been working with mothers and healthcare professionals to develop a feeding programme which aims to avoid formula-milk fed babies putting on too much weight. The programme developed for this study aims to support parents who feed their babies formula-milk to achieve a healthy pattern of growth and weight gain.

Who can participate?
Mothers with formula-milk fed babies aged between 2-10 weeks.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are given advice and support to follow the new feeding programme. Those in group 2 are given routine advice about formula-milk feeding and weaning. The growth of babies in the two groups are then compared during the first year of the babies lives. This comparison is important to test whether the new feeding programme is effective in preventing the babies from gaining too much weight and become obese in later life.

What are the possible benefits and risks of participating?
Participants will get information about infant feeding and growth which may help them make better decisions. Participants in both groups will be sent regular newsletters to inform them of the emerging findings. There are no risks of taking part as decisions are made by mothers.

Where is the study run from?
MRC Epidemiology Unit, Cambridge (UK)

When is the study starting and how long is it expected to run for?
January 2011 to December 2015

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Rajalakshmi Lakshman

Study website
http://www.mrc-epid.cam.ac.uk/research/studies/babymilk/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R090204/123

Study information

Scientific Title
Establishing a healthy growth trajectory from birth: a randomised controlled trial of a theory-based, multi-component intervention to reduce formula-milk intake and prevent excess weight gain during infancy

Study objectives
Research question:
Is it feasible and acceptable to reduce formula milk intake (as per 2004 World Health Organization [WHO] recommendations for energy requirement) and prevent excess weight gain during infancy using a theory-based, multi-component intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 4 Research Ethics Committee, 30/04/2010, ref: 10/HO305/9

Study design
Single (assessor) blind parallel-group individually randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please email babymilkstudy@mrc-epid.cam.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Public health, obesity prevention

Interventions
We have developed an intervention to support mothers to feed their babies appropriately based on 2004 WHO recommendations for energy requirement. The intervention consists of three components:
1. A motivational component based on Social Cognitive Theory
2. A component to help translate motivations into actions (including goal setting, action plans and self-monitoring)
3. A component to help mothers to cope with barriers
The intervention comprises 3 x 30 - 45 minute face-to-face contacts (at baby's ages 2, 4 and 6

months) and 2 x 15 - 20 minute telephone contacts (at 3 and 5 months) in addition to theory-based intervention leaflets (at 2 and 4 months).

The control group (usual care) will have the same number of contacts as the intervention group during which general information about formula-milk feeding and infant health will be discussed and continued participation in the study will be encouraged.

Intervention Type
Behavioural

Primary outcome measure
Change in weight standard deviation score from birth to age 12 months

Secondary outcome measures
Secondary objectives of the trial are to quantify the effects of the intervention on:
1. Infant energy intake and diet at age 8 months
2. Changes in infant adiposity during the first year of life
3. Health service utilisation during the first year of life
4. Maternal wellbeing
5. Maternal body composition

We will test the hypothesised mechanism (based on Social Cognitive Theory) underlying any effect of the intervention on behaviour. Data from the trial will also allow cohort analyses to:
1. Quantify the associations between the underlying psychological correlates, such as parental attitudes about growth, intentions, confidence (self efficacy)and outcome expectancies (constructs of the Social Cognitive Theory), and feeding behaviour and weight gain. We will perform qualitative studies to explore how parents make feeding decisions during the first year of a baby's life.
2. Understand where parents get information and advice about formula-feeding and what advice they follow
3. Quantify the association between formula milk intake and infant weight gain, length, body mass index (BMI), abdominal circumference and adiposity in the first year of life
4. Quantify the associations between infant temperament, sleep and eating behaviour on infant growth and feeding

In order to assess cost-effectiveness we will measure the costs of delivering the intervention and model the reduction in the burden of obesity if we are successful in preventing rapid weight gain (a difference of 0.67 standard deviation score or one centile line between the groups).

Overall study start date
01/01/2011

Completion date
28/12/2015

Eligibility

Key inclusion criteria
Participants will be male and female babies aged 2 - 10 weeks at recruitment, and their parents. All healthy, singleton, term infants who are already receiving some formula-milk will be eligible to participate.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
700

Total final enrolment
669

Key exclusion criteria
1. Low birth weight (less than 2,500 g)
2. Pre-term infants (less than 37 weeks gestation)
3. Infants with major malformations, hormonal or metabolic diseases which might interfere with nutrition or growth

Date of first enrolment
01/01/2011

Date of final enrolment
28/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Epidemiology Unit
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Medical Research Council (MRC) (UK) - Epidemiology Unit

Sponsor details
c/o Dr Rachel Curran
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Sponsor type
Research council

Website
http://www.mrc-epid.cam.ac.uk/

ROR
https://ror.org/052578691

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council - National Prevention Research Initiative (Grant no. MR/J000361/1)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The main trial results paper will be published later in 2016. There are plans to publish a paper from the qualitative study nested within the trial and the cost-effectiveness paper. All papers will be uploaded to the study website.

Intention to publish date

31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/10/2015		Yes	No
Statistical Analysis Plan	version v1	30/07/2015	27/05/2016	No	No
Results article	results	18/10/2018		Yes	No
Results article	results	01/11/2018	23/07/2019	Yes	No