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PROmotion of Breastfeeding Intervention Trial

Submission date
25/02/2005

Recruitment status
No longer recruiting

Registration date
09/09/2005

Overall study status
Completed

Last Edited
03/06/2021

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
The Promotion of Breastfeeding Intervention Trial (PROBIT) is a study in the Republic of Belarus involving 31 maternity hospitals and affiliated clinics across the country. The study was designed to help scientists, health care providers, and the general public understand the effects of infant feeding on child health and development. In 1995, 16 hospitals and clinics were randomly allocated to a breastfeeding promotion intervention based on World Health Organization materials and procedures, while 15 continued breastfeeding practices in place at the time of random allocation. Mothers and babies were recruited from June 1996 to December 1997. In total, 17,046 mothers and their babies were recruited into the study. Of these, 16,492 (97%) were followed at regular intervals until the infants were 12 months of age. Detailed information was recorded at each follow-up visit about infant feeding, digestive and lung infections, and rashes. When PROBIT children were six and a half years old, 13,889 (81%) were examined for height, weight, body fat, blood pressure, behaviour, dental health, intelligence quotient (IQ), asthma and allergy. At age 11 and a half years, 13,879 (81%) were again examined for height, weight, body fat, blood pressure, and also had blood tests to measure diabetes and heart disease risk factors. Currently we are seeing the children at age 16 years.

Who can participate?
Mothers and their babies joined the study during their delivery hospital stay. Mothers could take part if they started breastfeeding, and they and their baby were healthy.

What does the study involve?
At the current visit, when the child is 16, the pediatrician:
1. Measures the childs height, waist, blood pressure, weight and body fat.
2. Tests the child's vision by asking him/her to read letter charts. A small number of children are also tested using an instrument that assesses whether they need glasses.
3. Examines the childs skin for rashes.
4. Tests the childs lung health by asking him or her to blow into a tube three to eight times to measure the capacity of the lungs.
5. Asks the child to take a computer-administered test of brain development (including memory, ability to solve problems, attention, perception, verbal skills, information processing and motor skills).
6. Administers a questionnaire to assess other aspects of the childs health and physical development.

What are the possible benefits and risks of participating?
The lung function assessment involves blowing hard into a tube several times. Repeated blowing may cause some people to become wheezy. The pediatrician has asthma medication on hand to relieve these symptoms if they occur. None of the other measures or tests carries any risk to the child. As a result of the examination, the pediatrician may identify previously undiagnosed eye, lung or blood pressure problems in the child, which will then be followed up appropriately.

Where is the study run from?
The study is run from the The National Research and Applied Medicine Mother and Child Centre (Minsk, Belarus), in collaboration with the School of Social and Community Medicine, University of Bristol (Bristol, UK), Departments of Pediatrics and of Epidemiology, Biostatistics and Occupational Health, McGill University Faculty of Medicine (Montreal, Canada), and Harvard Medical School and Harvard Pilgrim Health Care Institute (Boston, USA).

When is the study starting and how long is it expected to run for?
The study started in January 1995 and is expected to run until December 2015. We hope the study will extend beyond this time as we intend to look at the childrens health over many years.

Who is funding the study?
This study is supported by a grant from the Canadian Institutes of Health Research (CIHR) and the US National Institutes of Health (NIH). The study has previously been funded by the National Health Research and Development Program (NHRDP) Health Canada, European Unions project on Early Nutrition Programming: Long-term Efficacy and Safety Trials, the Thrasher Research Fund (USA), the United Nations Childrens Fund (UNICEF), and the European Regional Office of the World Health Organization (WHO).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT01561612

Protocol serial number
MOP-53155

Study information

Scientific Title
Breastfeeding duration and exclusivity: impact on child health and development

Acronym
PROBIT

Study objectives
Current study hypothesis as of 11/03/2009:
Experimental intervention will lead to increased exclusivity and duration of breastfeeding, and hence to improved infant and child health.

Initial information at time of registration:
Experimental intervention will lead to increased exclusivity and duration of breastfeeding, and hence to reduced infection and eczema in infancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of McGill University Health Centre, 28/11/2001
Added 02/09/2013: Research Ethics Board of McGill University Health Centre, 18/06/2012, ref: 11-190-PED

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Healthy, full-term, breastfed infants

Interventions
Experimental group: breastfeeding promotion intervention at maternity hospitals and affiliated polyclinics
Control group: continuation of maternity hospital and polyclinic practices existing at time of randomisation

Intervention Type
Behavioural

Primary outcome(s)
One or more episodes of gastrointestinal infection in first 12 months of life.

Key secondary outcome(s))
Current secondary outcome measures as of 09/01/2013:
1. Respiratory infections in first 12 months
2. Atopic eczema in first 12 months
3. Weight, length, and head circumference at 1, 2, 3, 6, 9, and 12 months
4. Blood pressure (BP) at age 6.5 and 9 years
5. Asthma, hay fever, atopic eczema, and allergy skin tests at age 6.5 years
6. Intelligence quotient (IQ) and behaviour at age 6.5 years
7. Oral/dental health at age 6.5 years
8. Anthropometry, lipoproteins, glucose, insulin, adiponectin, and IGF at age 11 years
9. Maternal height and weight at 6.5 and 11.5 years postpartum
10. Maternal body composition at 11.5 years postpartum
11. Maternal blood pressure at 11.5 years postpartum
12. Child metabolic syndrome at age 11.5 years
13. Eating attitudes at age 11.5 years
14. Child blood pressure at age 6.5, 11.5 and 16 years
15. Child body composition at age 11.5 and 16 years
16. Eczema, asthma, cognition, vision and lung function at age 16 years
17. Length/height and weight throughout childhood

Amended as of 11/03/2009:
8. Anthropometry, lipoproteins, glucose, insulin, adiponectin, and IGF at age 11 years

Initial information at time of registration:
1. Respiratory infections in first 12 months
2. Atopic eczema in first 12 months
3. Weight, length, and head circumference at 1, 2, 3, 6, 9, and 12 months
4. Blood pressure (BP) at age 6.5 and 9 years
5. Asthma, hay fever, atopic eczema, and allergy skin tests at age 6.5 years
6. Intelligence quotient (IQ) and behaviour at age 6.5 years
7. Oral/dental health at age 6.5 years
8. Lipids, lipoproteins, glucose, insulin, and HbA1c at age 9 years

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Birth weight equal and above 2500 g, either sex
2. Gestational age equal and above 37 weeks
3. Maternal intention to breastfeed

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Neonatal disease or condition contraindicating breastfeeding
2. Neonatal disease or condition making breastfeeding difficult or impossible
3. Maternal psychosis
4. Maternal human immunodeficiency virus (HIV) or active tuberculosis (TB)
5. Maternal chemotherapy or radioisotopes

Date of first enrolment
01/01/1995

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Belarus

Canada

Study participating centre
The Montreal Children's Hospital
Montreal
Canada
H3H 1P3

Sponsor information

Organisation
McGill University (Canada)

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (ref: MOP-53155)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
UNICEF

Alternative Name(s)
United Nations Children's Fund, United Nations Children's Emergency Fund, United Nations International Children's Emergency Fund, Fonds des Nations Unies pour l'enfance, Fondo de las Naciones Unidas para la Infancia, ,

Funding Body Type
Government organisation

Funding Body Subtype
International organizations

Location
United States of America

Funder Name
Thrasher Research Fund (USA)

Alternative Name(s)
The Thrasher Research Fund, Thrasher Research, TRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
National Health Research and Development Program (NHRDP) - Health Canada (Canada)

Funder Name
European Union (EU)

Funder Name
National Institutes of Health (NIH) (USA)

Alternative Name(s)
US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/10/2007		Yes	No
Results article	results	01/12/2007		Yes	No
Results article	results	01/03/2008		Yes	No

Results article	results	01/05/2008		Yes	No
Results article	results	01/12/2011		Yes	No
Results article	results	13/03/2013		Yes	No
Results article	results	01/07/2013		Yes	No
Results article	results	21/01/2014		Yes	No
Results article	results	01/07/2014		Yes	No
Results article	results	01/08/2014		Yes	No
Results article	secondary analysis results	03/07/2017		Yes	No
Results article	secondary analysis results	01/04/2018		Yes	No
Results article	secondary analysis results	01/02/2019	29/01/2020	Yes	No
Results article	secondary analysis results	01/09/2019	15/09/2020	Yes	No
Results article		23/01/2021	03/06/2021	Yes	No
Other publications	cohort profile	01/06/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes