

PROMotion of Breastfeeding Intervention Trial

Submission date 25/02/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 03/06/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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 child's 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 child's skin for rashes.
4. Tests the child's 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 child's 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?

Prof. Michael S Kramer
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Study website

<http://www.bristol.ac.uk/social-community-medicine/projects/probit/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01561612

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

One or more episodes of gastrointestinal infection in first 12 months of life.

Secondary outcome measures

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

Overall study start date

01/01/1995

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

Age group

Neonate

Sex

Both

Target number of participants

17046

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)

Sponsor details
845 Sherbrooke Street West
James Administration Bldg., Suite 429
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H3A 2T5

Sponsor type
University/education

Website
<http://www.mcgill.ca/>

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, 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, 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)

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)

Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

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
Other publications	cohort profile	01/06/2014		Yes	No
Results article	results	01/07/2014		Yes	No
	results				

Results article		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