

**PROMOTION OF BREASTFEEDING
INTERVENTION TRIAL II**

PROBIT II STUDY

Manual of Procedures

Manual of Procedures – General Considerations

1. DESCRIPTION OF THE STUDY

1.1 Summary presentation of patient follow-up

Children were included from 31 selected maternity hospitals and followed for 1 year (12 months) at one polyclinic affiliated with the maternity hospital in **PROBIT**. During the initial one-year period, information was collected at six different times: when the child was 1, 2, 3, 6, 9 and 12 months. **PROBIT-II** is a follow-up of these children at 6½ years of age.

1.2 Information to be collected

During the interview, the information collected will be include:

- 1) measurements of weight, standing and sitting height, head, waist, hip, mid-thigh and mid-upper arm circumferences; triceps and subscapular skinfolds; blood pressure; age at weaning (for children still breastfed at 12 months of age), early psychological development, marital status and relationship, thumb sucking, pacifier use and dental maturity; and pets at home;
- 2) skin-prick tests for allergies;
- 3) current and recent symptoms of asthma, hay fever, and atopic eczema will be based on the ISAAC questionnaire;
- 4) Wechsler Abbreviated Scale of Intelligence (WASI);
- 5) Strengths and Difficulties Questionnaire (SDQ) completed by both the mother and the child's teacher.

The polyclinic chart will also be reviewed to collect information on past heights, weights, and head circumferences; visits and prescriptions of medications for asthma, allergic rhinoconjunctivitis (hay fever), and atopic eczema; age at weaning (if still breastfeeding at 12 months); and any hospitalizations (and the reason for those hospitalizations) since the age of 12 months.

Objective of the study: The principal objective of the proposed study is to examine whether the experimental breastfeeding promotion intervention introduced in Belarus in 1996-1997 has effects detectable at 6½ years of age on atopic disease, cognitive development, behaviour, growth, obesity, and blood pressure. The comparison of the experimental and control groups, when analyzed by intention to treat, will allow the most rigorous examination to date of the causal relationship between prolonged, exclusive breastfeeding and these important health outcomes.

1.3 Logistics and roles

Polyclinic coordinator: In each polyclinic, the polyclinic coordinator will be in charge of:

- Verifying that each child included in the study is followed according to the protocol. The main role will consist of identifying mother and children and asking them to come, or if they cannot or will not, collecting some follow-up by telephone. This task is very important for the study.
- The polyclinic coordinator will also verify that for each study child, the appropriate information (PROBIT Interview and Chart Review Questionnaire, and SDQ questionnaire) is collected. This information will be sent every week to the Data Centre in Minsk.

- The polyclinic coordinator will also complete the correction forms when errors or missing information have been identified by the Data Centre.

Data Centre: The Data Centre is responsible for data entry and data management. It will receive the forms on a weekly basis from each of the participating polyclinics and proceed to data entry. The Data Centre will generate, on a weekly basis, the list of errors identified on the forms that have been entered. There are two types of errors:

- missing value
- incorrect value (incompatible with what is expected)

The polyclinic coordinators will be contacted to correct the errors. The corrections will then be sent back to the Data Centre to be entered into the database.

For the polyclinics with more than (900) children expected to participate in PROBIT-II, a second pediatrician will be named to assist the polyclinic coordinator and participate as an investigator in all aspects of PROBIT-II.

2. ORGANIZATION OF THE STUDY

2.1 Locating the children

During the fall of 2002, children will be located by the pediatrician of each polyclinics and document if child is potentially reachable for PROBIT-II study.

2.2 Visit

The polyclinic coordinator (and assistant) will receive the data booklets just after the training workshop in Minsk.

Children will be examined and mothers interviewed by the polyclinic coordinator, who will:

- 1) ensure that children come to the polyclinic visit
- 2) ensure that PROBIT data forms are completed
- 3) send copies of data forms to the Data Centre on a weekly basis
- 4) correct or complete information when errors are detected

3. INTERVIEW, EXAMINATION, AND QUESTIONNAIRES

1. Ask mother to sign consent form.
2. In the waiting room, the mother should complete the Child Behaviour Questionnaire-Parent Version.
3. During the interview, follow the order of the questions in the questionnaire.
4. When the questionnaire is completed, give the gift to the child.
5. Complete the Chart Review Questionnaire by consulting the child's polyclinic chart.
6. Ask the parent the name of the child's school and teacher, and write them on the Child Behaviour Questionnaire-Teacher Version.
7. Once a week, send data forms to the Data Centre in Minsk.
8. Every 1-2 months, distribute Child Behaviour Questionnaire-Teacher Version to each teacher named by study parents: one questionnaire per study child. A teacher may have several study children in his/her class, or even the entire class. Do not write in the teacher's ID number at the top of the questionnaire. These numbers will be assigned by the Data Centre in Minsk.
9. Every school year, distribute Teacher Classroom Questionnaire (one per teacher, not for each child) to each teacher named by study parents. Do not write in the teacher's ID number at the top of the questionnaire. These numbers will be assigned by the Data Centre in Minsk.

N.B. Please indicate in the margin when data are missing. This will reduce the number of queries from the data management centre.

Interview Questionnaire

SECTION 1: IDENTIFYING INFORMATION

1.1-1.2: Child's last and first name:

Write in order: last name, then first name.

1.3 Hospital No:

Each hospital has a number from 01 to 34. This number must be reported on each questionnaire, because it is essential to identify children in the study.

1.4 Subject No:

Each child has a subject number from 001 to 9999, which was assigned at the maternity hospital for all children whose mothers agreed to participate. This number is also part of the identifier that serves to identify each child in the study. It is therefore necessary to report this number on all data forms. It is crucial to keep the same subject number to ensure a link between the two databases (PROBIT-I and PROBIT-II).

1.5 Date form completed:

This is the date on which the information is collected. DD-MM-YY

SECTION 2: MATERNAL HISTORY AND SYMPTOMS

2.1 to 2.8: Check the appropriate box.

For question related to the duration of breastfeeding, to the nearest completed month

SECTION 3: CHILD'S BEHAVIOURAL DEVELOPMENT

3.1 to 3.7: Check the appropriate box.

N.B. Question 3.7 (if applicable) is answered by the pediatrician, not the parent, based on the parent's responses to questions 3.3 to 3.6 and the pediatrician's knowledge of the child.

SECTION 4: ASTHMA AND ALLERGIES

4.1 to 4.24: Check the appropriate box.

For questions: 4.12.1-4.12.12 and 4.22-4.23, check all that apply.

SECTION 5: CIGARETTES AND ALCOHOL CONSUMPTION

5.1 to 5.2 Check the appropriate box (one box only).

5.3 to 5.4 Drinking vodka, wine, or beer: how often?

This question relates to the average frequency at which the mother or father currently consumes vodka, wine, or beer. If mother or father drinks more than

one kind of alcoholic drink, you should count the total number of drinks. Use the highest category for the total (one box only).

5.5 to 5.6 Drinking vodka, wine, or beer: how much?

This question relates to the average quantity of vodka, wine, or beer the mother or father currently consumes when s/he has a drink. If a mother or father consumes more than one kind of alcoholic drink, you should check the total equivalent quantity (one box only). **Note: if the mother or father does not drink, you should check the box 0-50 ml vodka (0-100 ml wine, 0-200 ml beer).**

SECTION 6: MARITAL STATUS AND FAMILY RELATIONSHIPS

6.1 to 6.4 Check the appropriate box.

SECTION 7: BLOOD PRESSURE (1)

Systolic and diastolic blood pressure will be measured in duplicate in the right arm in the sitting position using the automated (digital read-out) Omron M1 device: once (first) after the interview (but before the anthropometric measurements) and a second time (see Section 9, blood pressure (2)) after these measurements.

SECTION 8: ANTHROPOMETRIC MEASUREMENTS

It is important to use standardized procedures consistently. The video cassette demonstrates the anthropometric procedures used to obtain body measurement reference data for the third U.S. National Health and Nutrition Examination Survey.

8.1 Weight:

Record the weight in kilograms to the nearest 0.1 kg.

8.1.1-8.1.2 Child: Measure the weight two times. If the measures differ by > 0.1 kg, take a third and fourth measurement, if necessary.

8.1.3 Record the mother's weight, reported verbally.

8.1.4 Record the biologic father's weight as reported by the mother (or the parent accompanying the child).

8.2 Standing height:

Standing height is measured with a fixed stadiometre with a wall-mounted stadiometre with a movable headboard. Hair ornaments, jewelry, and braids should be moved or removed from the top of the head in order to measure height properly. The child stands with the heels of both feet together touching the base of the wall. The toes are pointing slightly outward at approximately a 60-degree angle.

The pediatrician should check the position of several points of body contact with the wall. The first contact point is the heels, followed by the buttocks, the scapular or shoulder blades, and finally the back of head. Depending upon the overall body conformation of the child, all points may not touch. The trunk of the body should be positioned vertically above the waist with the arms and shoulders relaxed. The head should be aligned in a Frankfurt horizontal plane. The head is in a Frankfurt plane when the horizontal line from the ear canal to the lower border of the orbit of the eye is parallel to the floor and perpendicular to the wall.

Many children will assume this position naturally, but for some it might be necessary to make a minor adjustment. If required, the pediatrician may gently tilt the head up or down until a proper alignment is achieved with the eyes looking straight ahead. Once correctly positioned, the headboard is lowered, and the child is instructed to take a deep breath and stand as tall as possible. A deep breath allows the spine to straighten, yielding a more consistent and reproducible height measurement. The headboard is positioned firmly on top of the head with sufficient pressure to compress the hair. The measurement is read in centimetres and recorded to the nearest millimetre (0.1 cm). The child then relaxes and steps away from the stadiometre.

Record the height in centimeters to the nearest 0.1 cm.

8.2.1-8.2.2 Child: Measure the height two times. If the measures differ by > 0.5 cm, take a third and fourth measurement, if necessary.

8.2.3 Record the mother's reported height.

8.2.4 Record the biologic father's height as reported by the mother (or the parent accompanying the child).

8.3 Sitting height:

Sitting height is a measure of the length of the trunk of the body from the buttock to the top of the head when a subject is sitting upright. To record this measure, a stadiometre and a box or stool of known height are used. The child sits on the box with the posterior aspect of the buttock, the shoulders blades and the back of the head touching the wall. Similar to the procedure followed for standing height, the head is positioned in the Frankfurt plane. The child is instructed to take in a deep breath and sit up as tall as possible. The head piece of stadiometer is lowered to the top of the head and the hair is compressed. The reading is taken to the nearest millimetre (0.1 cm).

Measure sitting height twice to the nearest 0.1 cm. If the measures differ by > 0.5 cm, take a third and fourth measurement, if necessary.

8.4 Head circumference

A plasticised cloth tape is used to measure head circumference. Any hair ornaments or any hair arrangements such as braids that may interfere with the accuracy of the measure should be removed. The pediatrician stands to the right side of the child. The tape is placed around the head. On the face, the lower margin of the measuring tape is placed just above the eyebrows. On the side of the head the tape extends above the ears to the back of the skull, where it is centred over the occipital prominence. While holding the tape in place over the eyebrows, the tape is moved up or down as necessary on the posterior aspect of the skull. The objective is to locate the maximal circumference of the head at the occipital prominence. The two ends of the measuring tape should be pulled firmly to compress the hair and the underlying soft tissues. The measurement is recorded to the nearest millimetre (0.1 cm).

Record head circumference twice to the nearest 0.1 cm. If the measures differ by > 0.5 cm, take a third and a fourth measurement, if necessary.

8.5 Waist circumference

To define the level at which the waist or abdominal circumference is measured, a bony landmark is first located and marked. The child stands and the pediatrician, who is positioned to the right of the child, palpates the upper hip bone to locate the right ilium. Just above the uppermost lateral border of the right ilium, a horizontal mark is drawn and then crossed with a vertical mark on the mid-axillary line. The pediatrician places the measuring tape around the trunk at the

level of the mark on the right side. The pediatrician then inspects all sides to make sure the measuring tape is at a level horizontal plane. The tape is then tightened slightly, but without compressing the skin and underlying subcutaneous tissues. The measure is recorded to the nearest millimetre (0.1 cm).

Record waist circumference twice to the nearest 0.1 cm. If the measures differ by > 0.5 cm, take a third and fourth measurement, if necessary.

8.6 Hip circumference

The child is asked to stand upright with feet together and weight evenly distributed. The pediatrician is positioned on the right side with eye level at the hip region of the child. The cloth measuring tape is placed around the hip and anchored at the maximum protuberance of the buttock. The measuring tape is held snugly but not pulled tight, and the measure is recorded to the nearest millimetre (0.1 cm).

Record hip circumference twice to the nearest 0.1 cm. If the measures differ by > 0.5 cm, take a third and fourth measurement, if necessary.

8.7 Mid-upper arm circumference

To locate the middle of the upper arm, the child should stand with the right arm flexed 90 degrees at the elbow. The palm faces up and the fingers tips point straight ahead. The pediatrician stands behind the subject. The uppermost edge of the posterior border of the acromion process is located on the right scapula, and a horizontal line is drawn at this point. The zero end of the measuring tape is held on this mark. The tape is extended down the midline on the posterior surface of the arm to the tip of the olecranon process at the elbow. The distance between the mark at the acromion and the tip of the olecranon is divided by two. A horizontal mark is made at the mid-point on the posterior aspect of the arm before the measuring tape is removed. This marked is then crossed with another line extending from the acromion to the olecranon. This point defines the site at which both mid-upper arm circumference and the triceps skinfold is measured.

Arm circumference is measured with the child standing and the right arm hanging loosely and relaxed. It is important to be certain that the muscle of the arm is not flexed or tightened, which could yield a larger and inaccurate reading. The pediatrician stands to the right side of the child and places a measuring tape around the upper arm perpendicular to the long axis of the arm at the marked point. The measuring tape is held gently on the skin surface. The two ends of the measuring tape are pulled together, using care not to compress the skin and underlying subcutaneous tissue. The arm circumference is recorded to the nearest millimetre (0.1 cm).

Record mid-upper arm circumference twice to the nearest 0.1 cm. If the measures differ by >0.5 cm, take a third and fourth measurement, if necessary.

8.8 Mid-thigh circumference (cm)

To measure upper leg length, the child sits on an examination table. The lower part of the right leg hangs freely over the edge of the table, and the right knee is positioned at a 90-degree angle. The zero end of the measuring tape is placed at the inguinal crease just below the anterior superior iliac spine. The measuring tape is then extended along the anterior midline of the thigh to the top of the mid-point of the patella. To check the proper location of the zero end, the technician should firmly place the middle finger over the measuring tape at the site and then instruct the child to raise the thigh slightly. If positioned correctly, a tightening of the muscle tendon will be clearly felt. A reading is then taken from the measuring tape to the nearest millimetre (0.1 cm). This distance is divided by two, which

indicates the mid-point of the thigh. A mark is made on the skin at this mid-point before the measuring tape is removed. This mark is then crossed with another mark that extends on a line between the anterior superior iliac spine and the middle of the patella. This point defines the site at which the mid-thigh circumference is measured.

For thigh circumference, a standardized position is required. The child is instructed to step back with the left foot. This shifts the body weight to the left leg. The right leg is in front and bends slightly at the knee. The soles of both feet are flat on the floor. The right (forward) foot is used mainly to assist with balance but should not bear the weight of the body. The pediatrician is positioned to the right of the child and places the measuring tape around the thigh at the mid-point previously marked for upper leg length. The measuring tape is positioned on the skin perpendicular to the long axis of the thigh. The two ends of the overlapping tape are pulled together, using care not to compress the skin and underlying subcutaneous tissue. The thigh circumference measurement is recorded to the nearest millimetre (0.1 cm).

Record mid-thigh circumference twice to the nearest 0.1 cm. If the measures differ by > 0.5 cm, take a third and a fourth measurement, if necessary.

8.9 and 8.10: Skinfolds

Prior to measuring the skinfolds, each site is carefully marked on the right side of the child's body. For each site, the skinfold is lifted up at a location 2 cm above the point at which the caliper tips will be placed. The thumb and index fingers separate the subcutaneous fat from the underlying muscle. Just the skin and adipose tissue are taken up to form a distinct fold. The jaws of the caliper are placed perpendicular to the length of the fold while the pediatrician continues to hold the skinfold. The actual measurement is read from the caliper dial 2-3 seconds after the caliper tips are applied to the skin, and the tension is then released from the caliper handle.

The skinfold thickness is measured in millimetres to the nearest 0.5 millimetre. On some individuals it is not possible to separate the fat from the muscle tissue. When a distinct fold of skin and subcutaneous fat cannot be made with confidence, an appropriate note should be added on the data form, and the measurement value should not be recorded.

8.9 Triceps skinfold

The triceps skinfold is measured on the right upper arm at the point previously marked for the mid-upper arm circumference. The child stands upright with feet together, shoulders relaxed, and the arms hanging loosely at the side. The pediatrician stands behind the child and gently lifts the triceps skinfold with finger tips just above the mark. The triceps skinfold is held parallel to the long axis of the upper arm. The tips of the caliper jaws are placed perpendicular to the line of the fold, 2 cm from the fingertips and centred over the mark point.

After a 2-3 second equilibration period, measure the right triceps skinfold twice to the nearest 0.5 mm. If the measures differ by > 1 mm, take a third and fourth measurement, if necessary.

8.10 Subscapular skinfold

The subscapular skinfold is measured with the child standing upright, shoulders relaxed, and arms hanging loosely at the side. The pediatrician stands behind and gently palpates the inferior angle (lower-most tip) of the right scapula. A

mark is made on the inferior angle of the scapula. The pediatrician gently lifts a fold of skin and subcutaneous adipose tissue with the index finger directly above and medial to the mark at the inferior angle of the scapula, and with the thumb reaching toward the spine. The skinfold forms a line extending diagonally toward the right elbow. The jaws of the caliper are placed perpendicular to the length of the fold, 2 cm from the fingertips, with the tip of the caliper jaw directly on the mark at the inferior angle of the scapula.

After a 2-3 second equilibration period, measure the right subscapular skinfold twice to the nearest 0.5 mm. If the measures differ by >1 mm, take a third and fourth measurement, if necessary.

SECTION 9: BLOOD PRESSURE (2)

See Section 7.

SECTION 10: SUCKING BEHAVIOUR

10.1 to 10.3 Check the appropriate box. For questions 10.2.1 to 10.2.4, check all that apply.

SECTION 11: WASI

See WASI Manual and scoring sheet.

SECTION 12: SKIN-PRICK TESTS

Skin-prick tests will be used to assess hypersensitivity to house dust mite, cat, birch pollen, mixed northern grasses, and *Alternaria*. Controls include 1% histamine sulfate (positive control) and glycerosaline diluent (negative control). After cleansing the skin with a gauze square moistened with alcohol, the tests are performed by placing a drop of each antigen on the volar surface of the forearm, and gently pricking the skin through the drop using a solid-bore needle held at a 45-degree angle. The skin should be lifted very slightly with the prick, but not deeply enough to puncture the skin or cause bleeding. One needle is used for the 5 test antigens, in the order shown on the Interview Questionnaire: house dust mite, cat, birch pollen, mixed northern grasses, and *Alternaria*. The needle is then thrown away. A second needle is then used for the saline and histamine controls, following which it too is thrown away. This same sequence should be followed for all children starting near the antecubital fossa and working distally down the forearm.

The longest and orthogonal (perpendicular to the longest) diameters of the wheal and flare of all positive reactions are measured to the nearest mm 15 minutes after the test and reported on the data form. In addition, for independent and blinded verification, each positive wheal or flare is outlined with a black ink pen on the arm. One pen can be used for approximately 10 children. The paper tape is placed on the arm, with the sticky side touching the skin. It is important to rub the tape before removing it and pasting it onto the data form (page 6) for measurement by the Data Centre in Minsk.

If the size of the wheal and/or flare exceeds the width of the tape, use two strips of tape stuck together, and paste it on the **back** of the data form. Near the tape, indicate which test it represents. Write a note in the data form box to indicate that the reaction size was too big to fit in the box.

Polyclinic Chart Review Questionnaire

SECTION 1. HISTORY OF HEIGHTS, WEIGHTS, AND HEAD CIRCUMFERENCES SINCE 12 MONTHS OF AGE

1.1 Weights

Record the child's weight in kilograms to the nearest 0.1 kg for all weights measured since 12 months of age.

1.2 Heights

Record the child's height in centimeters to the nearest 0.1 cm for all heights measured since 12 months of age.

SECTION 2: MEDICATIONS

Check all that apply.

SECTION 3: WEANING

Age at weaning (complete cessation of breastfeeding), to the nearest completed month.

SECTION 4: HOSPITALIZATIONS

Transcribe the dates of all hospitalizations since the age of 12 months, related to gastrointestinal infection, pneumonia, asthma.

SECTION 5: TOOTH EXAMINATION

These data are to be extracted directly from the dentist's examination recorded in the polyclinic chart.

5.1 to 5.3: Total number of teeth, teeth with caries, and teeth with fillings.

5.4 Condition of teeth: Complete the table for each of the 8 incisors (central teeth). For each tooth, circle the number corresponding to whether it is a baby tooth (11, 12, 21, 22, 31, 32, 41, 42) or adult tooth (51, 52, 61, 62, 71, 72, 81, 82). If the tooth has been shed or extracted, circle the number corresponding to the baby tooth. Then write in the letter (one only) in the table that corresponds to that tooth.

A = healthy

B = one or more caries

C = extracted or shed

D = one or more fillings

E = erupting adult tooth

N.B. If a given tooth has one or more caries and one or more fillings, code it as B.

5.5 Data of the dentist's examination.