

For Mrs. Abdullah
as reviewer Date _____
ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Dr. Rukhsana Haider Trainee Investigator (if any) _____
 Identification No. 92-015 Supporting Agency (if Non-ICDDR,B) _____
 Title of Study "Promotion of Exclusive Breastfeeding in Infants aged 1-10 weeks in a diarrhoeal disease hospital: how effective can it be?" Project status:
 New Study
 Continuation with change
 No change (do not fill out rest of form)

- Circle the appropriate answer to each of the following (If Not Applicable write NA).
1. Source of Population:
 - (a) Ill subjects Yes No
 - (b) Non-ill subjects Yes No
 - (c) Minors or persons under guardianship Yes No
 2. Does the study involve:
 - (a) Physical risks to the subjects Yes No
 - (b) Social Risks Yes No
 - (c) Psychological risks to subjects Yes No
 - (d) Discomfort to subjects Yes No
 - (e) Invasion of privacy Yes No
 - (f) Disclosure of information damaging to subject or others Yes No
 3. Does the study involve:
 - (a) Use of records, (hospital, medical, death, birth or other) Yes No
 - (b) Use of fetal tissue or abortus Yes No
 - (c) Use of organs or body fluids Yes No
 4. Are subjects clearly informed about:
 - (a) Nature and purposes of study Yes No
 - (b) Procedures to be followed including alternatives used Yes No
 - (c) Physical risks Yes No **NA**
 - (d) Sensitive questions Yes No **NA**
 - (e) Benefits to be derived Yes No
 - (f) Right to refuse to participate or to withdraw from study Yes No
 - (g) Confidential handling of data Yes No
 - (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure Yes No **NA**
 5. Will signed consent form be required?
 - (a) From subjects Yes No **NA**
 - (b) From parent or guardian (if subjects are minors) Yes No
 6. Will precautions be taken to protect anonymity of subjects Yes No
 7. Check documents being submitted herewith to Committee:
 - Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
 - Protocol (Required)
 - Abstract Summary (Required)
 - Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
 - Informed consent form for subjects
 - Informed consent form for parent or guardian
 - Procedure for maintaining confidentiality
 - Questionnaire or interview schedule
- * If the final instrument is not completed prior to review, the following information should be included in the abstract summary:
1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
 2. Examples of the type of specific questions to be asked in the sensitive areas.
 3. An indication as to when the questionnaire will be presented to the Cttee. for review.

We agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects before making such change.

R. Haider
Principal Investigator

Trainee

SECTION 1 - RESEARCH PROTOCOL

1. TITLE : Promotion of exclusive breastfeeding in infants aged 1-10 weeks in a diarrhoeal disease hospital: how effective can it be?

2. PRINCIPAL INVESTIGATOR : Rukhsana Haider MBBS, MSc

CO-INVESTIGATOR : Asma Islam, MBBS, MPH

CONSULTANT : Prof. Demissie Habte

3. ANTICIPATED STARTING DATE : July, 1992

4. COMPLETION DATE : December, 1993

5. TOTAL DIRECT COST : US\$ 39,280.00

POSSIBLE SOURCE OF FUNDING : WHO/ ICDDR,B

6. SCIENTIFIC DIVISION : This protocol has been approved by the Clinical Sciences Division



Signature of the Associate Director,
Clinical Sciences Division

Date: _____

ABSTRACT SUMMARY:

In Bangladesh, as in other developing countries, mothers are adding breast milk substitutes by 1-12 weeks of age, and shortening the duration of breastfeeding. One of the consequences of this detrimental practice, is that the number of younger infants with diarrhoea is steadily increasing. To minimize the feeding of breastmilk substitutes in these young infants, we plan to promote and emphasize exclusive breastfeeding when they attend a diarrhoeal disease hospital for treatment. A randomized controlled clinical trial will be carried out, by providing intensive educational messages and lactational support in the hospital cases. The mothers of these infants will be followed up monthly for six months (when these messages will be reinforced), to see whether the changed practice is sustained at home. Hospital controls, who will only receive the usual encouragement for breastfeeding as part of other ongoing health education messages, and not the intensive breastfeeding promotion messages, will be selected for comparison of feeding patterns and nutritional status. Neighbourhood controls for determining feeding practices in non-diarrhoeal patients of the same age group will also be studied. Pre- and post promotion questionnaires on knowledge, attitude and practice of breastfeeding, administered to the mothers of the patients on admission and completion of study, will be used for assessment of acceptability and impact of the educational messages.

REVIEWS:

- a) Chairman, Research Review Committee
- b) Chairman, Ethical Review Committee
- c) Director, ICCDR, B

SECTION II - RESEARCH PLAN

1. INTRODUCTION

1.1 OBJECTIVES :

The objective of this study is primarily to assess whether breastfeeding promotion can be done effectively in infants aged 1-10 weeks attending a diarrhoeal hospital. Other objectives will include development of appropriate tools and methods for breastfeeding promotion, and resultant impact on nutritional status.

1.2 BACKGROUND

Over the last decades, the trend towards decreasing breastfeeding and increasing bottle feeding was seen first in the developed countries followed by the developing countries¹. As more extensive use of breast milk substitutes continue, the total duration of breast feeding is being reduced drastically. This tendency is spreading from the privileged to the less privileged classes especially in towns². Breastfeeding is seen to be decreasing rapidly in urban areas as mothers migrate from the villages and lose contact with established traditional customs of their village culture. In the developed countries however, a reversal of this trend, towards increased breastfeeding has been achieved mainly by intensive breastfeeding promotion through health education courses^{3,4} and breastfeeding mothers support groups⁵.

An exclusively breastfed infant is defined as an infant who is given no other liquid or solid^{6,7}. Unfortunately, the practice of exclusive breastfeeding is still very unusual. The significant benefits of exclusive breastfeeding over other forms of feeding in which the infant is given water, tea, or juice in addition to breastmilk have only recently been documented as reports of recent studies are being made available. In Lima, Peru, the diarrhoea prevalence rates doubled with the addition of these other fluids⁸.

Although previous studies in Bangladesh^{9,10} have shown 95-98% of the rural infants to be breastfed, recent studies in urban areas have confirmed the observation that most of the babies receive additional food early in life. A study of clinic and home delivered infants in Dhaka city in 1986 showed only 49% to continue exclusive breastfeeding upto the age of 4 months in the home delivered babies and 33% in the clinic delivered babies¹¹.

Another study from Dhaka and Narayanganj in 1989 reported that only 7% of the mothers had been advised by a doctor to exclusively breastfeed their infants upto 5 months age before starting complementary feeds, whereas 82% had actually been advised otherwise¹².

In some of the Dhaka slums, one study showed only 22% of infants aged 0-5 months to be exclusively breastfed during a 3 months survey, and powdered milk started in 32% of infants within 6 months of age¹³, and another study showed the mean age of the children who stopped breastfeeding to be 3.69 ± 1.75 months¹⁴.

The latest information from an ongoing study, following neonates from Holy Family Red Crescent Hospital and Dhaka Shishu Hospital¹⁵, has shown a complementary feeding rate of 88% by 14 weeks of age.

The reasons for not starting breastfeeding or for the early cessation of breastfeeding seem to be similar to those in other countries viz: insufficient breastmilk, urbanization, promotion of commercial formulas, working mothers, lack of family support, inappropriate health practices after delivery, status symbol etc¹⁶.

The consequences of decline in breastfeeding and the increasing use of formulae have been extensively documented^{17,18}. Breastfeeding promotion programmes which have focused on maternity services during the last weeks of pregnancy, and after delivery, including education of mothers and hospital staff, and change in hospital practices, have been successful upto some extent¹⁹. The results of the Brazilian Breastfeeding Promotion Campaign using mass media, showed a rise in breastfeeding rates from 38% at onset to 65% at the peak of the programme³⁴.

However, the percentage of women especially those from the lower socio-economic class having access to such facilities is extremely low. Home deliveries are still the norm even in the urban areas of Dhaka. There is thus no way to reach this group of women unless they are visited in the community, or if they themselves attend a health facility.

There is now conclusive evidence that breastfeeding confers significant protection against illness and death associated with diarrhoea, and minimizes its adverse nutritional effects. Breastfeeding promotion has been demonstrated to be an efficient measure for preventing diarrhoea, and has many other important social, economic and health benefits²⁰.

Evidences of the protective effect of breastfeeding against morbidity due to some infectious diseases, especially diarrhoea are considerable. A review of 35 studies from 14 countries revealed the following: 83% of studies found that exclusive breastfeeding was protective compared to no breastfeeding, and 76% that partial breastfeeding was protective compared to no breastfeeding. The same review also highlighted that breastfeeding promotion can reduce diarrhoea morbidity rates by 8-20% and diarrhoea mortality rates by 24-27% in the first 6 months of life²¹.

A study in Brazil has documented that non breastfed infants had 14.2 and 3.6 times the risk of death from diarrhoea and respiratory

infections compared to breastfed ones²². When infants with partial breastfeeding were compared with those on exclusive breastfeeding in a study in Ethiopia, a relative risk of 5.2 for developing diarrhoea was obtained²³. In a study from urban Iraq, bottle-fed infants aged 2-3 months were 55 times more likely to be hospitalized for diarrhoea than exclusively breastfed infants of the same age²⁴.

In Bangladesh breastfeeding has also been associated with a substantial reduction in the risk of severe cholera and shigellosis^{25,26}. Other data suggest that continued breastfeeding may protect against diarrhoeal morbidity and mortality well into the third year of life: the protection does not, however, appear to continue after the cessation of breastfeeding²⁷.

Evidence also exists that breastfeeding can protect against the adverse nutritional effects of diarrhoea^{28,29}. In the Gambia, diarrhoea had no significant effect on the growth of exclusively breastfed infants, whereas it was one of the two major causes for growth faltering in the others. Growth velocity was also seen to be normal in the second year of life in the breastfed infants despite continuing infections²⁸.

The probable cost-effectiveness of breastfeeding promotion as an intervention for the control of diarrhoeal disease has also been calculated. For the least expensive package of interventions (at about US\$1.00 per mother), the cost per diarrhoea case averted was less than US\$15, and that of diarrhoea death averted was US\$400 or less, even for low impact programmes in settings with a low level of exclusive breastfeeding³⁰. In developing countries, various health service needs have to be satisfied, but owing to manpower, budgetary and other resource constraints, it is necessary to select those few that meet the priority health needs and are at the same time, affordable³¹.

1.3 RATIONALE

- Exclusive breastfeeding during the early months of life protects against infections and has marked nutritional, psychological, contraceptive and economic advantages.
- Although Bangladeshi mothers still breastfeed in the beginning, a vast majority is adding other fluids or foods much earlier than recommended, thus increasing the chance of gastrointestinal infections.
- Since most of the deliveries still take place at home, only a small proportion of mothers can be contacted at the maternity hospitals or centres for the promotion of exclusive breastfeeding.
- Using the concept of missed opportunity to implement exclusive breastfeeding at birth, we wish to evaluate the role of intensive promotion during the early weeks of life, using a point of contact at a diarrhoeal treatment centre in changing the practice towards exclusive breastfeeding, and its impact on morbidity.
- When mothers see their infants diarrhoea properly treated, they might be more receptive to educational messages which may prevent further episodes of diarrhoea.
- The Control of Diarrhoeal Diseases Programme (CDD) at the WHO is looking at ways to prevent diarrhoea and has identified breastfeeding as an important factor, and trials of intervention promoting breastfeeding as one of its research priorities³².
- UNICEF and WHO have now launched the "baby friendly hospital initiative" on a global scale, to convince hospitals, health services and parents that breastfeeding gives babies the best possible start in life³³. This research will help in understanding some of the problems in establishing a hospital as "baby friendly".
- Breastfeeding promotion has been successful in increasing the number and duration of breastfed infants in other countries³⁴ and can produce the same results in Bangladesh if designed and implemented properly.

1.4 SPECIFIC OBJECTIVES:

PRIMARY:

To assess whether effective promotion of exclusive breastfeeding can be carried out in infants aged upto 10 weeks of age, admitted in a diarrhoea treatment centre, and whether the change in feeding practice can be sustained at home if follow up is provided for six months.

SECONDARY:

1. To develop and test appropriate tools and messages for promotion of exclusive breastfeeding.
2. To assess the impact on nutritional status following intensive breastfeeding promotion in these infants.

2. STUDY DESIGN

1. Randomised prospective intervention trial starting in the hospital with community follow-up.
2. Case control study with additional community control to define the study population.

Hospital Cases: Hospital patients who will receive the breast-feeding promotion messages during hospital stay and reinforcement of these messages on monthly follow up at home.

Hospital controls : Hospital patients who will receive the usual health education messages including breastfeeding encouragement during hospital stay only.

Community control : Feeding pattern and anthropometric measurements will be recorded on the first and last follow-up visit in a neighbouring infant of the same age group, without diarrhoea.

2.1a Inclusion criteria:

Infants aged 1-10 weeks

Sex- male and female

History of diarrhoea (watery or invasive) not more than 7 days

Feeding status - infants on all modes of feeding

Location of residence - within 12 km of Dhaka city to facilitate follow-up

2.1b Exclusion criteria:

Infants of mothers with inverted nipples, working full time, and unwilling to change feeding pattern, will not be included in the study.

Infants with history of persistent diarrhoea, and presence of life threatening infections will also be excluded because of other confounding variables which will influence the outcome of the study.

2.2 SAMPLE SIZE ESTIMATE

At present about 70% of urban infants are partially breastfed. We expect to reduce this figure to 50% by successfully influencing at least 20% of the mothers to breastfeed exclusively for 5 months.

Using the formula (35)

$$n = \frac{p_1(100-p_1) + p_2(100-p_2)}{(p_1-p_2)^2} * f(\alpha, \beta)$$

($\alpha = 0.05$, $\beta = 0.2$)

the sample size obtained is 92.

Calculating for a dropout/migration rate of 20%, the expected sample size is 110 in each group.

2.3.1 ENROLMENT OF SUBJECTS

A register will be maintained at the Triage Area of the Outpatient Unit to record attendance of all infants aged 1-10 weeks. This will provide the sampling frame from which patients who fulfil the study criteria will be selected for the study, and randomised accordingly.

The patients will be enrolled in the study after receiving an informed consent according to the requirements of the Ethical Research Committee.

2.3.2 ALLOCATION TO TREATMENT GROUP (RANDOMISATION)

Random permuted blocks of variable length will be used for preparation of the randomisation code. Individual patient assignments, case or control, corresponding to the randomisation list, will be placed in a series of sealed envelopes. Each patient selected for the study during the day (8.30 am - 3.00pm) will be allotted to the case or control group according to the numerical sequence on the envelopes.

2.3.3 STANDARD CASE MANAGEMENT

A baseline history and examination of the patient will be carried out to collect all relevant present and past information on feeding. Necessary investigations and treatment of infection will be carried out according to usual hospital practice in ICDDR,B during their hospital stay.

Anthropometric measurements which will be carried out on admission after correction of dehydration, on discharge and on monthly follow-up are:

- * Body weight (using the NNC (National Nutrition Council) bar scale which has a sensitivity of 25g and is easy to carry on home visits.
- * Length (to the nearest 0.1 cm) using a standardised locally made measuring board.
- * left mid-arm circumference (to the nearest 0.1 cm) using a measuring tape.

The anthropometry will be performed by trained health assistants, and an average of three measurements will be considered as the observed value.

3. Plans for Breastfeeding promotion:

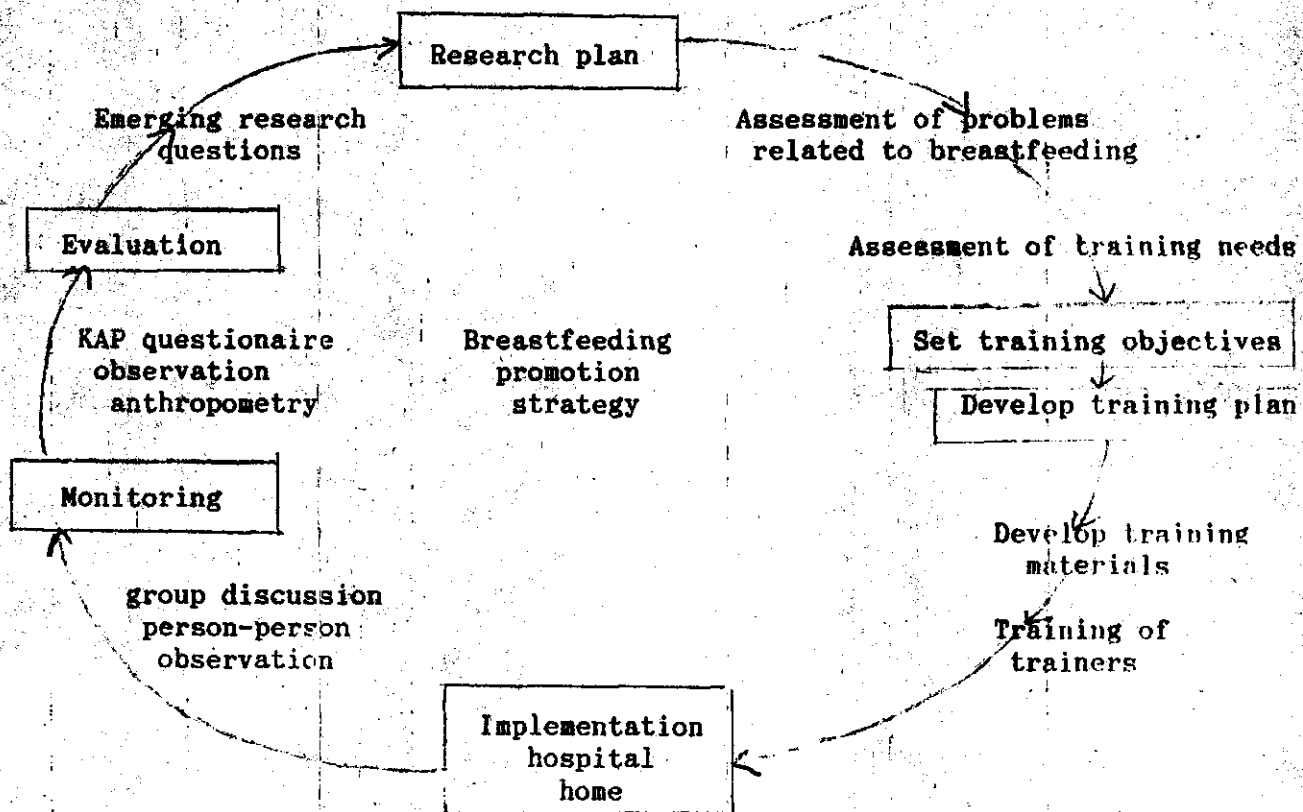


Fig 1. Schematic outline of the breastfeeding promotion strategy

3.1 Trial Organization

3.1.1 Development of Training Materials and Pretesting

- Pre-testing of breastfeeding promotion education messages - 1 week (App-6)
 - Pre-testing of data recording forms - 1 week (App-2)
 - Pre-testing of KAP questionnaire - 1 week (App-3)
- } completed
- Review and adaptation of the above - 2 weeks

The above will be done before onset of hospital phase of study

3.1.2. Formation of study team

- Principal investigator - MSc Human Nutrition
+ Training in Lactation Management
- Co-investigator - MPH in maternal and child health
with experience in imparting training
to mothers
- Medical Officer (1)
(MO) - MBBS, to be trained in research
- Health assistants (4)
(HA's) - graduates with background in
sociology/ nutrition and some
experience in delivering health
education at the community level
- Health workers (4)
(HW's) - Class VIII and above with
experience in health care

3.1.3 Training of study personnel

Research medical officer, health assistants and health workers (all female) will be oriented by the investigators with regard to the meaning and importance of exclusive breastfeeding. They will also be made familiar with the physiology and mechanics of breastfeeding (Fig-2), psycho-social influences, possible difficulties and how to overcome them. The importance of mother's nutrition for successful breastfeeding will also be emphasized. The essential messages about breastfeeding as outlined by the Campaign for Protection, Promotion and Support of Breastfeeding in Bangladesh (CPPBF) and WHO³⁶ will be specially stressed (Appendix-6), and bottlefeeding discouraged by pointing out the disadvantages.

Development of positive attitude towards breastfeeding is essential for its promotion and can only be achieved after the team members attain an understanding of its incomparable advantages.

For this purpose the following schedule will be followed over two weeks:

- Materials and lesson plan developed by CPPBF for training of MO's and HW's will be utilised.
- Day 1 - orientation - to research project and hospital
Pre-test using KAP questionnaire to be used for mothers

- Day 2 - lecture and discussion in the morning (1 and 1/2 hr) techniques for conversing with mothers in the afternoon
- Day 3 - same
- Day 4 - Show educational material to be used for mothers video, flipcharts followed by discussion for clarification
- Day 5 - practical demonstration of correct breastfeeding techniques and use of "nursing supplementer"
 - anthropometric measurements
- Day 8-13 - revision, clarification, discussion of educational messages and data collection foras, anthropometry
- Day 14 - post-test

3.1.4 Training of Mothers

These breastfeeding education messages will be transmitted by the HAs to the mothers of the hospital cases on admission, discharge and monthly followup for 6 months as out lined in the responsibilities of team members (appendix-1). Attempts will be made to include grandmothers, as well as fathers in these sessions as far as possible.

3.1.5 Training Media

- Flip charts showing simplified illustrations (eg. Fig 2 & 3 and others from the Manual by FS King³⁷) to explain the physiology and mechanics of breastfeeding will be used.
- Bengali video on Breastfeeding being used since last two years for training of health workers will be shown.
- Group discussions will be encouraged following these sessions and mothers will be encouraged to question for clarification of educational messages and ask for practical help at any time.

Time allocated for these sessions will be approximately 30-40 minutes.

3.1.6 Additional tools

- Efforts to be made to initiate breastfeeding after admission if not given previously, using nursing supplementer³⁷ and metachlorpromide, which helps to increase prolactin levels in the blood³⁸. This process will also be applied in

mothers who had breastfed previously but stopped later on. At the same time, extra diet will be provided for the mothers as per hospital practice (Appendix-5).

- Mothers will be repeatedly reassured about their lactational capacity and encouraged through conversations with mothers who were successful in breastfeeding. Photographs showing successful re-lactation after using "nursing supplementer" will also be shown (Fig 2). Demonstration of maintenance of weight initially and then achievement of weight gain on exclusive breastfeeding will further help to convince the mother about the sufficiency of her breast milk.
- In addition there will be demonstration of proper techniques for holding and breastfeeding the baby and mothers will be actively assisted to do so by the principal investigator who will be trained in lactation management.
- Conversion to predominant--exclusive breastfeeding will be achieved in the hospital, by first decreasing frequency and then gradually stopping intake of formula /other foods.

4. Evaluation of training

All study personnel will be pre and post-tested after training which will help firstly to identify messages which may need further clarification or simplification, and secondly, to assess the impact of training. The questionnaire used will be the same as that provided for the mothers (Appendix-3).

5. FOLLOW-UP:

All the study patients will be followed up each week at home for six months. Collection of feeding and morbidity data will be done weekly (Appendix-4) by a health assistant accompanied by a health worker. Containers for collection of diarrhoeal stool will be left with the mother enabling her to show it to the health assistant or to bring it to the hospital for laboratory tests if required. Weekly visits will also provide an opportunity to check on the actual feeding practices at home. ORS packets will be distributed by the health workers, but for treatment of infection patients will be encouraged to consult a physician, preferably in the ICDDR,B hospital.

Anthropometric measurements will be carried out monthly in both the groups at home. Breastfeeding promotion messages will be reinforced only to the mothers of the hospital cases on monthly home visits till the end of the study.

For each case, an age matched neighbourhood control without diarrhoea will be visited at the onset and completion of study to assess the breastfeeding practice and for anthropometric comparison.

6. MONITORING

The study will be monitored by the PI by unscheduled home visits. This will also help to identify and solve problems being faced by the health workers in the field.

Withdrawals from the study will be due to noncompliance of the parents, or due to migration out of the follow-up area.

7.1 Data Collection and Management

recruitment of patients - 5 patients per week will be needed
12 months for hospital part of the study

follow-up of last case for six months - 18 months

All information will be obtained in pre-coded forms which are being pre-tested. These include baseline data, KAP questionnaire for mothers, weekly feeding, morbidity and anthropometry data forms (App-2 to 4).

Data forms will be checked by the medical officer and then by the investigators. Consistency of the data will be checked through logical and range checks in the data base program. System files will be created using SPSS PC+ software for analysis.

7.1.1 RESPONSE VARIABLES

- * Number and % of infants being breastfed (exclusively, predominantly, or partially) at onset of the study and at 5 months of age.
- * Difference between cases and controls regarding change in feeding practices
- * Growth patterns and nutritional status in the above groups
- * Impact of breastfeeding promotion messages on the mothers by change in knowledge, attitude and practices, and assessment of preferences of media- face to face discussions, flip chart, video etc.

Failures- infants of mothers who consistently refuse to make any change in feeding practices and avoid followup- will be analysed separately .

7.1.2 Data analysis

After evaluation of the baseline data for comparability in the case and control groups, the outcome variables will be compared by appropriate parametric and non parametric tests on raw data. Confounding variables will be controlled for, and dichotomous outcome variables will be compared by chi-square test or Fisher's exact test as required.

Data analysis and report writing will take approximately 3 months

8. Final evaluation and recommendations for future action

The results of the study will be important in identifying whether:

- a) the right measures were undertaken to implement the research plan
- b) the objectives were attained
- c) the strategy and method were appropriate given the circumstances
- d) aspects which could be improved are identified
- e) implications for application of breastfeeding promotion and support strategies in the community are assessed
- f) areas for further research are identified

DEFINITIONS

We will follow the definitions laid down by the WHO

Exclusively breastfed

Infants receiving only breast milk (no water, juice, etc).
Drops, syrups (vitamins, minerals, medicines) accepted.

Predominantly breastfed

Breastmilk being the predominant source of nourishment along with liquids (water, fruit juice, medicines etc)

Complementary feeding

Breastmilk and solid or semi-solid foods. May include non-human milk.

Partially breastfed

Infants receiving breast milk but most of the calories coming from animal milk/other foods (i.e. breastmilk given less frequently than other milk/food).

Non-breastfed

Not receiving any breast milk

Bottle feeding

Any liquid or semi-solid food from a bottle with nipple/teat.

Diarrhoea

Defined as following for different age groups⁸.

For < one month age - more than 5 stools/day

> 2 months age - more than 4 stools/day

3 months and above - more than 3 stools/day

For exclusively breastfed infants however, the definition will also include that "mother also considers it to be an episode of diarrhoea". Duration of a diarrhoeal episode will be defined as beginning from the first 24 hour period that meets the definition of diarrhoea and ending with the last diarrhoeal day when stool becomes soft. This will have to be followed by at least 2 full consecutive days that do not meet the definition of diarrhoea.

PROPOSED STUDY BUDGET (18 months)

	US\$
1. LOCAL SALARY	
Dr.R. Haider 10%	1500
Dr. Asma Islam 5%	1080
2. New Recruitment (Training)	
(1) Research fellow 100%	
(4) Health Assistants 100%	18000
(4) Study Worker(UV) 100%	
3. Local Travel (patient follow-up)	3000
4. Supplies & materials including drugs	6100
5. Print and publication	900
6. Interdepartmental services including laboratory	5700

	36280
7. Capital expenditure	3000

	39280
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APPENDIX - 1

Responsibilities of Team Members

Medical Officer

1. Patient selection
2. Filling of baseline information data forms and questionnaire on admission and completion of study.
3. Supervision of HA's and HW's
 - schedule timing for imparting breastfeeding education in the hospital for mothers of hospital cases.
 - observe performance of HA's and HW's in rendering delivery of breastfeeding promotion messages through video, flip chart and interpersonal communication with mother.
 - schedule follow-up visits
 - treat for any ailments on follow-up visits of mother and child.
4. Data entry.

APPENDIX-2

BASELINE DATA FORM

- 1. ID no. _/_/_/

- 2. Residence _/_
 - 1= village
 - 2= periurban
 - 3= urban slum
 - 4= town

- 3. Age in weeks _/_

- 4. Sex _/_
 - 1= female
 - 2= male

- 5. Weight in kg _/_.__/_

- 6. Length in cm _/_.__/_

- 7. MUAC in cm _/_.__/_

- 8. No. of children in the family _/_

- 9. Birth order of the child _/_
 - first = 1
 - second = 2
 - third = 3

- 10. Born in _/_
 - home = 1
 - hospital = 2
 - clinic = 3

- 11. Breast feeding _/_
 - 0= never
 - 1= continuing
 - 2= stopped

- 12. If this baby is breastfed, is it _/_
 - 1= exclusive (only breast milk)
 - 2= breast milk plus water/juice
 - 3= breast milk plus formula
 - 4= breast milk plus solids
 - 5= BM + solids + formula

13. Was Colostrum given

1= no
2= yes

/

If yes, within how many hours?

/ /

14. Pre lacteal feed given

1= no
2= yes

/

If yes, what ?

How many times?

_____ day

_____ night

15. Period exclusively breast fed

in days

/ / /

16. If other milk /fluid/food started

at what age (days)

/ / /

17. Breast fed for total days

/ / /

18. Why was breast feeding stopped?

1= no milk

/

2= insufficient milk

/

3= nipple problem

/

4= baby refused BM

/

5= mother started working

/

6= mother became sick

/

7= another pregnancy

/

8= during diarrhoea

/

9= baby was sick

/

10= others

/

11= +

/

12= +

19. No of days with diarrhoea _/_
20. Last episode of diarrhoea
how many days ago? _/_
21. Mother's age in years _/_
22. Mother's weight _/_._/
23. Mother's height _/_/_._/
24. Mother's MUAC _/_._/
25. Mother's education
-
26. Mother's occupation _/_
 1= housewife
 2= labourer
 3= factory worker
 4= service
 5= student
 6= others
27. Mother's income _/_/_/_/_/
 (monthly in takas)
28. Father's education
-
29. Father's occupation _/_
 0= unemployed
 1= labourer
 2= rickshawpuller
 3= shopkeeper
 4= odd jobs
 5= service
 6= business
 7= other (specify)
30. Father's income _/_/_/_/_/
 (monthly in takas)
31. Father not supporting _/_
 1= died
 2= left

32. Construction of house

a. Roof

1= straw, 2= tin, 3= wood, 4= concrete,
5= leaves, 6= plastic, 7= others (specify)

b. Walls

1= katcha (mud), 2= leaves, 3= bamboo,
4= wood, 5= tin, 6= brick,
7= others (specify)

c. Floor

1= Katcha (mud), 2= bamboo, 3= wood
4= brick/concrete, 5= others (specify)

d. electricity

1= no 2= yes

e. No. of rooms for sleeping

33. Total household members

34. No. of persons in child's family per room

35. Type of toilet

1= open
2= common latrine katcha
3= common latrine pucca
4= private latrine katcha
5= private latrine pucca
6= common sanitary
7= private sanitary

36. Water source for washing

1= pond
2= tubewell
3= piped water (common)
4= piped water (private)

37. Water source for drinking
(code as above)

APPENDIX-3

QUESTIONNAIRE FOR MOTHERS
(On admission and after completion of study)

1. Do you breastfeed your baby ? Yes ___/ No ___/
If yes, how many times ? _____ per day
_____ per night
2. When should other foods be added to baby's diet ? _____
3. Are you giving any other fluid as well? Yes ___/ No ___/
If yes, which fluid are you giving? (specify) _____
If yes, how many times are you feeding? _____ per day
_____ per night
What amount? ----- spoons per day
_____ cups per day
4. Are you giving any other food as well? Yes ___/ No ___/
If yes, which food are you giving? (specify) _____
If yes, how many times are you feeding? _____ per day
_____ per night
What amount? ----- spoons per day
_____ cups per day
5. Do you think colostrum should be given? Yes ___/ No ___/
6. If so, why ? _____
7. Do you know when after birth a baby should be put to the breast? _____
8. Is the timing important ? Yes ___/ No ___/

9. Should anything else be fed before starting breastfood?

Yes ___/ No ___/

10. Do you think you need extra food to produce more milk?

Yes ___/ No ___/

11. Which food/drink?

12. Do you think breastmilk can protect your baby against any illness?

Yes ___/ No ___/

13. If yes, what type of illness?

14. Is breastmilk cheaper than other milk?

Yes ___/ No ___/

15. Is breastfeeding good for the mother?

Yes ___/ No ___/

16. If yes, why?

17. Did anyone encourage you to breastfeed: If yes, who?

Yes ___/ No ___/

18. If you have problems with breastfeeding do you consult with anyone?

Yes ___/ No ___/

19. If so, with whom?

20. When diarrhoea started, did you breast feed

as usual?
breast feed less?
breast feed more?
change the diet?
stop breastfeeding
if yes, why?
if no, why?

Yes ___/ No ___/

Yes ___/ No ___/

Yes ___/ No ___/

Yes ___/ No ___/

Yes ___/ No ___/

21. For how many days or months should a baby be given only breast milk?

22. How long should breast feeding be continued?

APPENDIX-4

WEEKLY FEEDING FOLLOW-UP

1. Are you breast feeding this baby now? _____
2. If yes, how many times? _____ times/day
_____ times/night
3. Any other fluid/milk/food given? _____
4. Specify: _____
5. Why? _____
6. How many times? _____ times/day
_____ times/night
7. Given by: _____ cup/spoon
8. Any problems with breast feeding? _____

9. If baby had diarrhoea how did you feed your baby? _____ less
_____ usual
_____ more
_____ change of diet

Observation:

1. Did you see mother breast feeding her baby while you were there? ___/ yes ___/ no
2. Did you see any feeding bottles in the house? ___/ yes ___/ no
3. Was baby being looked after by person other than mother? ___/ yes ___/ no
4. Did you see mother feeding the baby with other foods? ___/ yes ___/ no
(Specify) _____

WEEKLY MORBIDITY

1. Does your baby have diarrhoea ? Yes ___/ No ___/
2. Since how many days? _____ days
3. Is it watery ? Yes ___/ No ___/
Mucoid Yes ___/ No ___/
Blood + mucus Yes ___/ No ___/
4. Does he/she have cold ? Yes ___/ No ___/
cough ? Yes ___/ No ___/
fever ? Yes ___/ No ___/
5. Since how many days? _____ days
cold? _____ days
cough? _____ days
fever? _____ days
6. Does your baby have any other ailments? Yes ___/ No ___/
7. If so, please specify _____
8. Did you give any medicine for these ailments? Yes ___/ No ___/
9. If yes, please specify _____

MONTHLY ANTHROPOMETRY

- a) Body weight ___/___/___/
- b) Length ___/___/___/
- c) MUAC ___/___/___/

APPENDIX-5

Breastfeeding management in the hospital

Day-1

- collection of baseline data (app-2)
- administration of KAP questionnaire (app-3)
- if infant is not breastfed, metachlorpropamide to be started 1 tab (10 mg) thrice daily and continued for 7 days as is the present hospital practice in ICDDR,B.
- extra diet for the mothers in the form of milk suji, khichuri and sweet puffed rice (muri) providing extra 1100 kcal to the usual "attendant" hospital diet of 1500 kcal.
- continuation of formula feeding 1-2 hourly depending upon age of infant.
- If baby is on breastmilk as well as on complementary feeds, this will be given 4 hourly with encouragement for frequent suckling in between.

Day-2

- educational session on breastfeeding with the help of video in the morning (20 - 30 min) followed by further explanations with the help of flipcharts and group discussion in the afternoon. These will be repeated on discharge.
- if non-breastfed, baby will be helped to suckle at the breast with the aid of a "nursing supplementer". In this method, a piece of a thin nasogastric tube is attached to the breast with one end dipping into a cup containing milk formula and the other end along the nipple, so when the baby sucks, milk enters the tubing from the cup. As he/she sucks harder, it stimulates the nipple which starts production of the milk³⁴ and Fig-3. This process will be continued for a few more feedings the next day as well till the breastmilk production is well established. (This is being successfully implemented by the investigator in the hospital since the last 2 months.

Day-3

Frequency of formula feeding will be further decreased. Individual interaction of the mothers with the investigators to establish rapport, identify and solve problems regarding breastfeeding.

Group discussion with HA's in the afternoon to:

- answer mothers queries
- take help of mothers who have been convinced to exclusively breastfeed, or have initiated lactation after coming to hospital, to interact with the other mothers who are enrolled in the study.

Day-4 onwards

- only breastmilk to continue till the stool become soft and the infant is ready to be discharged from the hospital.

However, the time required for conversion to predominant and then to exclusive breastfeeding may vary, depending upon mothers' lactational capacity and ability of the baby to suck. Interaction with the HA's will be continued as described before, till discharge.

APPENDIX-6

Breastfeeding Related Educational Messages (CPPBF & WHO)

1. Breastfeeding provides ideal food for the healthy growth and development of all infants.
 2. Exclusive breastfeeding (i.e. only breast milk- no water, milk or solids) should be continued upto 5 months* of age by giving day and night and on demand.
 3. Colostrum should be fed immediately after birth as it provides nutrition, baby's first immunization, and prevents disease. Water, sugar-water, milk etc should not be given (unless medically indicated).
 4. Pregnant and lactating mothers should be given an extra amount of usual home food, during each meal.
 5. Mother's anxiety, stress and lack of confidence in her ability to breastfeed, are the usual reasons for milk insufficiency. Emotional support will strengthen women's confidence to breastfeed successfully.
 6. Breastmilk protects babies from getting diarrhoea, respiratory infections, colic, allergies and eczema, and thus prevents malnutrition.
 7. Mother benefits by breastfeeding because
 - she regains her figure quickly
 - exclusive breastfeeding provides contraception in most cases upto first 6 months
 - there is no blood loss, so it prevents anaemia and improves mother's health
 - lowers risk of developing breast and ovarian cancer
 - saves mothers time and needs no separate utensils or fuel for its preparation
 - mother - baby bonds are strengthened
 8. Breastmilk does not have to be bought and so saves money for the family as well as the country.
 9. Breastmilk should continue for at least 2 years of age with addition of home cooked energy dense foods after 5 months, even if baby has diarrhoea or other illness.
- * 5 months agreed by CPPBF



Fig. 2. Physiology of breastmilk production

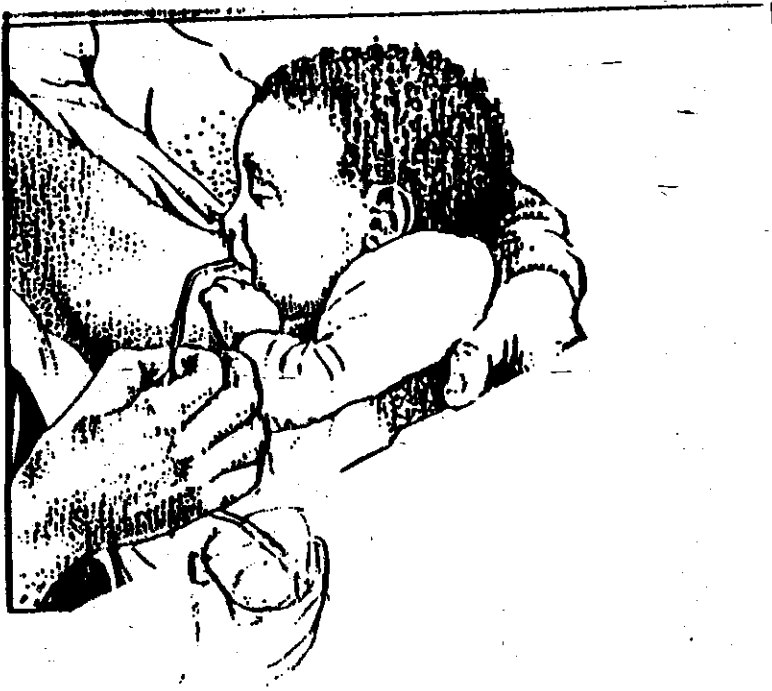


Fig. 3. Helping to feed with 'nursing supplementer'

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

1. To minimize the feeding of breastmilk substitutes in infants aged 1-10 weeks, we plan to promote exclusive breastfeeding when they attend diarrhoeal hospital for treatment. Two hundred and forty infants aged 1-10 weeks suffering from acute or invasive diarrhoea will be selected and categorized to cases and controls for intensive education on breastfeeding and lactational support. They will be followed up weekly, monthly for six months after discharge, for feeding practices, anthropometry and reinforcement of educational messages. Neighbourhood, non-diarrhoeal control infants will be selected for feeding patterns, and nutritional status on admission and completion of study.
2. There is no risk to the patient.
3. The patient will receive the routine treatment as practised at ICDDR,B for the management of diarrhoea
4. All the records will be kept confidentially by the investigators. Only identification number of the patients will be used during data analysis.
5. Informed consent (signed or thumb impression) will be obtained from the patient's mother after full explanation of the procedure of the study in Bengali by the investigators.
6. Interviews will be obtained with regard to the knowledge attitude, and practise of breastfeeding in the hospital before intervention of educational message on promotion of breastfeeding and on completion of the study to assess the change in behaviour and practice of exclusive breastfeeding. In addition female health assistant and health worker will be visiting the patients house weekly/monthly for knowing the breastfeeding and other feeding practises of the mothers, occurrence of any illness and weighing the infant to observe the growth pattern. The interview will take about 10-20 minutes.
7. The patients will benefit from the treatment of diarrhoeal illness. Exclusive breastfeeding will decrease the morbidity of the infant and will also improve the nutritional status. There is no risk involved in breastfeeding infants.
8. The activity will not require hospital records or any other body fluids.

CONSENT FORM

The addition of other milk/foods to breastfed babies less than 5 months old can increase the babies chances of getting more illnesses like diarrhoea, cold, cough, fever etc. It also leads to decrease in mother's milk and so decreases the total duration of breastfeeding .

We would like to help you to exclusively breastfeed your baby upto 5 months of age by gradually decreasing the feeding of breastmilk substitutes. In the hospital the baby will get the necessary treatment, and if required you may need to attend sessions on benefits of breastfeeding and how to improve it.

After discharge we will visit your baby weekly at home to see whether there are any illness or feeding problems and to take weight & height to see if he/she is growing well.

You can withdraw your child from the study any time. He/she will receive equivalent hospital care and medical treatment even if you do not agree to participate in the study.

If you are willing to participate in this study, please sign or put your left thumb impression below:

Signature of the P.I.

Signature or LTI of the mother

অম্মাতি শাস্ত্র

শাস্ত্র মায়েব- দম বয়মেব- বাচ্চাদের- বুকের- দুধেব
মায়ে অন্য- দুধ- দিচ্চেনা- খাবার- খাওয়ালে- শিশুর- জায়গিয়া-
ঠাণ্ডা, দাৰিমা- এবং- ছুর- হওয়াব- মত- বিভিন্ন- অসুস্থতায়-
ভোগায়- সম্ভাবনা- বৃদ্ধি- পায়। ইহা- মায়েব- দুধেব- পরিমাণ-
নিম্নে- দেয়- এবং- সেই- মায়ে- বুকেব- দুধ- খাওয়াব- সম্ভ-
সীমাস্ত- দম- যায়।

আমরা- ধীরে- ধীরে- আপনাব- বাচ্চাকে- ৫ মাস- বয়স-
পর্যন্ত- অন্যান্য- খাবার- নিম্নে- দিয়ে- শুধুমাত্র- বুকেব- দুধেব-
উপর- নির্ভরশীল- করে- রাখতে- চাই। হামসাতালে-
শিশুকে- প্রয়োজনীয়- চিহ্নগুলো- দেওয়া- হবে- এবং- যদি-
প্রয়োজন- হয়- তবে- আপনাকে- বুকেব- দুধেব- উন্নতির- এবং-
উন্নতি- সম্ভারিত- আলোচনা- অনুষ্ঠানে- যোগ-দিতে- হতে- পারে।

হামসাতাল- মেছে- ছুটির- পর- প্রতি- মাসে- আমরা-
আপনাব- শিশুর- অসুস্থতা- এবং- খাদ্য- সম্ভারিত- সমস্যা-
সম্বন্ধে- খোঁজ- নিতে- যাবো- সেই- মায়ে- আপনাব- শিশু- সঠিক-
বৃদ্ধি- পাচ্ছে- কিনা- দেখাব- জন্য- ওজন- এবং- লম্বা- মাপবো।

আপনি- যে- কোন- সমস্যা- আপনাব- শিশুকে- এ- জায়গায়- মেছে-
প্রত্যাহার- করে- নিতে- পারেন। আপনি- যদি- জায়গায়- অংশ-
নিতে- সম্মত- না- হন- তর্পি- আপনাব- শিশু- হামসাতালেব-
যথায়- চিহ্নগুলো- এবং- যত্ন- পাবে।

আপনি- যদি- জায়গায়- অংশ- নিতে- রাজী- থাকেন- তবে-
নিচে- প্রাক্কর/বামহাতেব- বৃদ্ধাধুর্নীক- ছাপ- দিন।

বুকের দুর্ঘ-মঙ্গলিক-শিখা-বার্তা :

- ১) বুকের দুর্ঘ মঙ্গল শিখর-লুপ্তা-এবং উন্নতির-জন্য
স্বাস্থ্য-আদর্শ-যাদ-।
- ২) কেবলমাত্র বুকের-দুর্ঘ (সাগিন, দুর্ঘ-অথবা সাত-যাবার-
ব্যতীত কেবলমাত্র বুকের-দুর্ঘ) দিন-বুকের-চর্চনা
অনুযায়ী ৫ মাস-সময়-আওয়ালো-উচিত-।
- ৩) মায়ে-শালন দুর্ঘ (সুখম দুর্ঘ) শিখর-কয়েক-সর-যত
ভাড়াভাড়া-মুখ-শিখরে-আওয়ালে-হবে-। ইহা শিখর-
সুস্থ, সুখম-বোজ-স্মৃতি-বোধ-কমতা-এবং-বোজ-
স্মৃতি-বোধ-হও-।
- ৪) স্মৃতি-বেলায়-যাদ-সুখম-অথবা-সুখম-সুখম-এবং
দুর্ঘ-মাত্রে-অতিরিক্ত-সময়-যে-আওয়ালো-দেওয়া
উচিত-।
- ৫) মায়ে-দুর্ঘ-অপ্ত-অপ্ত-^{সাধারন}-কারন-হচ্ছে-মানসিক
উদ্ভিগ্নতা-এবং-দুর্ঘ-আওয়ালোর-নিজস্ব-সামর্থ্য-উপর-
আওয়ালো-অভাব-। মানসিক-দুর্ঘ-অপ্ত-অপ্ত-আওয়ালোর-
দুর্ঘ-আওয়ালোর-বাপারে-মায়েদের-আওয়ালে-মহুত
হও-।
- ৬) বুকের দুর্ঘ শিখরে-ডাম্বিয়া, স্বাম-স্বাম-কমিত
মঙ্গলম-বোজ-সেই-সময়ে-সঙ্গিক, চর্ম-বোজ-ও
সুস্থ-শীত-যে-কিনা-হও-।

৭) মা বুকের দুধ খাওয়ানোর মাধ্যমে উদ্ভূত হয়
জরন :-

- মে তার- পূর্বের- প্রাচ্য- এবং টেদহিড- গঠন
পুনরায় ফিরে যায়।

- শিশুরো ও মাম সর্ষনু শুধু মায়- বুকের- দুধ-
খাওয়ালে ইহা মায়ের গর্ভ-নিয়ন্ত্রণে সহায়ক হয়।

- গতে দেহান বকের- অপচয় হয় না, তাই ইহা-
রক্ত-শূন্যতা সৃষ্টিবোধ- করে- এবং মায়ের স্বেচ্ছের উন্নতি
ঘটিত।

- বুকের জাঙ্কার- এবং গর্ভাঙ্গায়ের জাঙ্কার-
অম্লাননা হয়।

- মায়ের অময় বাঁচায় এবং দেহান স্থলানী- কিংবা
স্বার্থে বামন-মায়ের- স্বেচ্ছা হয় না।

বাতল খাওয়ানোর- অসুবিধা- সমূহ :-

- ক্রাম-বহুল

- সর্ষিড- ঘনত্ব- এবং নিরাসাদভাবে দুধ স্বেচ্ছিত- অসুবিধা-
সমূহ

- শিশু বেতনের- নিগল- এবং মায়ের দুধের নিগলের মধ্যে-
সামর্থ্য- বুঝতে না পারায় দুধ খাওয়ার- ইচ্ছা কম যায়।
ফলে মায়ের বুকের দুধের পরিমাণও কম যায়।

- স্বেচ্ছা-শূন্যতা, জাঙ্কার- এবং স্বেচ্ছার- স্বেচ্ছা বৃদ্ধি-
পায়।

৮) বুকের দুধ- দেহান- স্বেচ্ছা- হয় না। ফলে অতিবক্ত-
খরচ বাঁচায়।

৯) শিশুকে দুই বছর পর্যন্ত বুকের খাওয়াতে হবে
প্ৰথমই মায়ে ৫ মাস পর হতেই প্ৰয়োজ্য
বান্ধবা শাক-সবুজ খাবার খাওয়াতে হবে।
শিশু কামৰিয়া-দিক্ৰবা-অন্যদেহন অশুদ্ধতাম
আক্ৰান্তি ব্ৰনেও বুকের দুৰ্গ খাওয়ানো চৰ্চনিয়ে
হেতে হবে।

