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Memorandum

12 March 2000

To : Dr. S. K. Roy
Clinical Sciences Division

From : Professor Mahmudur Rahman
Chairman, Ethical Review Committee

Sub : Approval of protocol # 99-041

This has reference to your memo of 8th March 2000 attaching a modified copy of your protocol # 99-041 entitled "Feasible means to address moderately malnourished children within BINP Communities". I am pleased to inform you that the protocol is hereby approved upon your appropriate addressing of the issues raised by the Committee made its meeting held on 23rd February 2000.

Thanking you and wishing you success in running the said study.

cc: Division Director
Clinical Sciences Division



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Date : 8th March, 2000

To : Professor Mahmudur Rahman
Chairman, Ethical Review Committee, ICDDR,B.

From : Dr. S. K. Roy
Scientist, Clinical Science Division, ICDDR,B. 

Sub : Response to ERC comments on " Feasible means to address moderately malnourished children within BINP Communities". Protocol # 99-041

Thank you for considering the protocol entitled " Feasible means to address moderately malnourished children within BINP communities" in the ERC. We have modified the protocol according to the comments of ERC in your letter dated 29th February, 2000 as following. Hope this will satisfy the comments of the ERC and receive your approval.

Changes made

- a) Hypothesis and objectives of the protocol have been re-written for making it more understandable (page:6)
- b) The specific conditions for referral of subjects to THC has been clearly mentioned. (page: 21)
- c) Mildly malnourished children without growth faltering are acceptable to this protocol because this group of children will be under preventive approach of the protocol to study whether Less Intensive Nutrition Education (LINE) can effectively prevent malnutrition.
- d) Compliance of nutrition education will be measured and analysed (included in Data analysis section on pages 28)
- e) The consent form has been modified with a statement 'you will decide for participant of your child in this study. If your child does not participate in this study, she/he will still receive the standard services from us (consent form Bangla and English version).
- f) The Bangla consent form has been made to conform with the English version.
- g) Spell checking has been done.

Thank you very much.



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Memorandum

29 February 2000

To : Dr. S. K. Roy
Clinical Sciences Division

From : Professor Mahmudur Rahman *Mahmudur*
Chairman, Ethical Review Committee

Sub : Protocol # 99-041

The Ethical Review Committee met on 23rd February 2000 to consider your protocol # 99-041 entitled "Feasible means to address moderately malnourished children within BINP communities". After thorough review and discussion on the protocol, the Committee made the following observations to be addressed in your protocol:

- a) 'hypothesis' and 'objectives' parts of the protocol should be re-written for making it more understandable.
- b) as the study subjects are both moderate and mildly malnourished, you should clearly mention at what point and at what conditions, the subjects will be referred to THC. In addition, you should also mention how the cases of mild-moderate malnutrition with an infection will be taken care of.
- c) ^{P1} you should clarify whether the statement 'mildly malnourished without growth faltering' (in Table 3 at page # 18) is acceptable for a research protocol.
- d) ^{P1} you should mention when the compliance of the nutrition education be measured (ref: page # 19). Will there be any changes between groups of education if compliance is not up to the mark in the less intensive group? Will this create a bias? How will this be taken care at the time of analysis?
- e) the consent form should include a statement to the effect that service facility shall not be denied to any one in case of his/her unwillingness to participate in the study or subsequent withdrawal from the study.

- f) the Bangla consent form should conform to the English version.
- g) typos should be corrected.

The Committee, therefore, requests you to incorporate the above observations in the protocol and resubmit a modified copy of it for consideration of the Chair.

Thank you.

cc: Division Director (A)
Clinical Sciences Division

(FACE SHEET)

ETHICAL REVIEW COMMITTEE

APPROVED COPY

Principal Investigator: Dr.S. K. Roy

Trainee Investigator (if any): _____

Application No. 99-041

Supporting Agency (if Non-ICDDR,B) _____

Title of Study Feasible means to address moderately Project Status:

malnourished children within

BINP communities.

 New Study Continuation with change No change (do not fill out rest of the 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) Minor or persons under guardianship Yes No

5. Will Signed Consent Form be Required

- (a) From subjects Yes No
- (b) From parents or guardian Yes No
(if subjects are minor)

2. Does the Study Involve:

- (a) Physical risk to the subjects Yes
- (b) Social risk Yes
- (c) Psychological risks to subjects Yes
- (d) Discomfort to subjects Yes
- (e) Invasion of privacy Yes
- (f) Disclosure of information damaging to subject or others Yes

6. Will precautions be taken to protect anonymity of subjects Yes No

3. Does the Study Involve:

- (a) Use of records (hospital, medical, death or other) Yes
- (b) Use of fetal tissue or abortion Yes
- (c) Use of organs or body fluids Yes

7. Check documents being submitted herewith to Committee:

- ____ Umbrella proposal - Initially submit an with 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*

4. Are Subjects Clearly Informed About:

- (a) Nature and purposes of the study Yes
- (b) Procedures to be followed including alternatives used Yes
- (c) Physical risk Yes
- (d) Sensitive questions Yes
- (e) Benefits to be derived Yes
- (f) Right to refuse to participate or to withdraw from study Yes
- (g) Confidential handling of data Yes
- (h) Compensation & or treatment where there are risks or privacy is involved in any particular procedure Yes NA

- * 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. Example 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 Committee for review

We agree to obtain approval of the Ethical Review Committee before making such change:

any changes involving the rights and welfare of subjects

Principal Investigator

Trainee

S.K. Roy
7/3/2000

RESEARCH PROTOCOL

FOR OFFICE USE ONLY

Protocol No: 99-041 Date:

RRC Approval: (Yes) Date: 30.01.2000

ERC Approval: Yes/No Date:

1. Title of Project (Do not exceed 60 characters including spaces and punctuation's)
Feasible means to address moderately malnourished children within BINP communities.

2a. Name of the Principal Investigator(s) (Last, Middle, First) Dr. S.K.Roy	2b. Position / Title Scientist	2c. Qualifications MBBS, MSc Ph D(Nutr)
--------------------------------------------------------------------------------	-----------------------------------	--------------------------------------------

3. Name of the Division/ Branch / Programme of ICDDR,B under which the study will be carried out.
Clinical Sciences Division

Contact Address of the Principal Investigators
4a. Office Location: Clinical Sciences Division ,
ICDDR,B

4b. Fax No: 883 116
4c. E-mail: skroy@icddrb.org
4d. Phone : 8811751-60

5. Use of Human Subjects 5a. Use of Live Animal
Yes Yes
No No

5b. If Yes, Specify Animal Species

6. Dates of Proposed Period of Support
(Day, Month, Year - DD/MM/YY)

7. Cost Required for the Budget Period
7a. 1st Year (\$): 109,454 2nd Year: 54727

7b. Direct Cost (\$) 142,766

Total Cost (\$) 164,181

8. Approval of the Project by the Division Director of the Applicant

The above-mentioned project has been discussed and reviewed at the Division level as well by the external reviewers. The protocol has been revised according to the reviewer's comments and is approved

Name of the Division Director


Signature

27/12/99
Date of Approval

9. Certification by the Principal Investigator

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application

10. Signature of PI

Date :

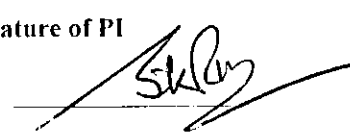

27/12/99

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List of Acronyms

ALRI	:	Acute Lower Respiratory Tract Infection
BINP	:	Bangladesh Integrated Nutrition Project
BRAC	:	Bangladesh Rural Advancement Committee
BCC	:	Behaviour Change Communication
BBS	:	Bangladesh Bureau of Statistics
CBNC	:	Community Based Nutrition Centre
CNC	:	Community Nutrition Centre
CNO	:	Community Nutrition Organizer
CNP	:	Community Nutrition Promoter
CARE	:	Christian Association for Relief Everywhere
Co PI	:	Co-Principal Investigator
CF	:	Complementary Feeding
FGD	:	Focus Group Discussion
FWC	:	Family Welfare Centre
GMP	:	Growth Monitoring Promotion
GOB	:	Government Of Bangladesh
HA	:	Health Assistant
INE	:	Intensive Nutrition Education
IEC	:	Information Education Communication
ICDS	:	Integrated Child Development Service
KAP	:	Knowledge Attitude and Practice
LINE	:	Less Intensive Nutrition Education
MUAC	:	Mid Upper Arm Circumference
NCHS	:	National Centre for Health Statistics
NGO	:	Non Government Organization
PEM	:	Protein Energy Malnutrition
PQLI	:	Physical Quality of Life Index
QC	:	Quality Control
SF	:	Supplementary Feeding
TOT	:	Training of the Trainers
UNICEF	:	United Nations Children Fund
VNMC	:	Village Nutrition Management Committee
VNC	:	Village Nutrition Committee
VDG	:	Vulnerable Group Development
WG	:	Women Group

PROJECT SUMMARY: Describe in concise terms, the hypothesis, objectives, and the relevant background of the project. Describe concisely the experimental design and research methods for achieving the objectives. This description will serve as a succinct and precise and accurate description of the proposed research is required. This summary must be understandable and interpretable when removed from the main application. (TYPE TEXT WITHIN THE SPACE PROVIDED).

Principal Investigators Dr. S .K. Roy

Project Name: Feasible means to address moderately malnourished children within BINP communities.

Total Budget: \$ 156,291 **Beginning Date:** as soon as possible **Ending Date:** 18 months after start

The Bangladesh Integrated Nutrition Project (BINP) of the Government of Bangladesh has started showing reduction in malnutrition of women and children under two years of age in last 3 years of it's activities. Moderately malnourished children form a large proportion of children in the community. With success of the BINP this proportion is farther increasing as severely malnourished children are improving and "graduating" to the moderately malnourished category. Recent operations research of BINP shows that it is possible to reduce moderate malnutrition substantially through a specific package of intensive nutrition education. (INE). That was a demonstration study to test the efficacy of the approach on a relatively small number of children with intensive intervention. There is now an urgent need to define an effective and feasible means applicable in a larger population in the country. A study will be therefore conducted in 4 division of BINP thanas of Bangladesh over an 18-month period. Moderately malnourished children will be in management intervention and mildly malnourished and well-nourished infants will be in preventive intervention group. For management intervention, a total of 750 moderately malnourished will be randomized to receive either intensive nutrition education or less intensive education. For preventive purpose, 380 mildly malnourished children of 6 months to 2 years of age and 100 well nourished infants of 6 to 9 months of age will receive either less intensive education or no education. Infants between 6 to 9 month ages will be brought under less INE to ensure their complementary feeding practice. Care givers of one group of mildly malnourished children and one group of 6-9 month old infants will not receive any education to serve as controls. Focus Group Discussion (FGD) based INE will be conducted taking into consideration of geographical variation for an in-depth understanding of culture. Focus group discussion will be held with mothers to discuss beliefs, food habits and feeding practices of these children. An anthropologist and a nutritionist will jointly develop the nutrition education package. INE on child caring and on food security and disease control. Mothers of the first intervention group will receive intensive nutrition education and motivation for childcare, complementary food demonstration, and household food mobilization for child feeding twice weekly for first three months, which will be then reinforced once in a week for the last three months of intervention. The less intensive intervention group will receive nutrition education with the same components twice a week for the first month then once a week for two months and then twice monthly for the last three months of intervention. INE will be given for a total of 6 months. An observation will be done to identify for sustainability effect for an additional period of 6 months. Their weight and length gain will be recorded. The Community Nutrition Promoter (CNP), Community Nutrition Organizer (CNO), women's group and village nutrition committee will be involved in motivating and

ensuring child caring practices. Data on morbidity will be collected and necessary medical advice for referral to the health centre will be given equally to each group. The CNP and CNO's time will be mapped and will be asked to adopt study messages to examine the practicality. Data collection, counseling on child caring practice, food demonstration and nutrition education using IEC will be organized and supervised by project staff. It is assumed that if the intervention is successful, and once the nutritional status improves, they are likely to maintain good health. The IEC on dietary practice will be communicated to the VNMC (village nutrition management committee) members for further preventive measures. Data on cost effectiveness of the nutrition education strategies will be collected by a health economist. Data will be analyzed for change in nutritional status from moderate to mild malnutrition or normal nutrition and proportions of children continuing complementary feeding will be compared between the intensive and less intensive intervention and control groups. It is expected that the results of the study will help define the effectiveness of our nutrition education package to prevent and reduce moderate malnutrition existing in large proportion of children in setting with different geographical, and cultural and feeding practices.

KEY PERSONNEL (List names of all investigators including PI and their respective specialties)

Name	Professional Discipline/ Specialty	Role in the Project
1. Dr. S.K.Roy	Scientist, ICDDR, B	Principal Investigator
2. Prof. G.J. Fuchs	Director, CSD, ICDDR,B	Co-Principal Investigator
3. Dr. S.M.Akramuzzaman	Senior Medical officer ICDDR, B	Co-Investigator
4. Dr. Zeba Mahmood	BRAC, Bangladesh	Collaborative investigator

DESCRIPTION OF THE RESEARCH PROJECT

Hypothesis to be tested:

Concisely list in order, in the space provided the hypothesis to be tested and the Specific Aims of the proposed study. Provide the scientific basis of the hypothesis, critically examining the observations leading to the formulation of the hypothesis.

Hypothesis

- a. Less intensive nutrition education including food demonstration at the community level will be equally effective as intensive nutrition education for the prevention and reduction of moderate malnutrition.
- b. The effect of less intensive nutrition education given over a period of 6 months will sustain during the following six months without any intervention.

Specific Aims:

Describe the specific aims of the proposed study. State the specific parameters, biological functions/ rates/ processes that will be assessed by specific methods (TYPE WITHIN LIMITS).

Objectives:

The major overall objectives of the study are to determine feasible and effective means to prevent and reduce the proportion of moderately malnourished children through the identification of effective family level changes in feeding and nutrition behavior.

Primary:

- a. To compare the efficacy of intensive nutrition education with less intensive nutrition education including food demonstration for 6 months for the prevention and reduction of the moderate malnutrition in children of a 6 to 24 months of age.
- b. To examine the differences in IEC components for nutrition education in different geographical region.
- c. To define specific culture based nutrition education for the prevention of moderate malnutrition, which are feasible and sustainable.

Secondary:

- a. To measure the improvement of behavioral change communication (BCC) of mothers/care-takers and correlate this with improvement of nutritional status of their children.
- b. To assess the cost-effectiveness of the strategies for nutrition education.

Background of the Project including Preliminary Observations

Describe the relevant background of the proposed study. Discuss the previous related works on the subject by citing specific references. Describe logically how the present hypothesis is supported by the relevant background observations including any preliminary results that may be available. Critically analyze available knowledge in the field of the proposed study and discuss the questions and gaps in the knowledge that need to be fulfilled to achieve the proposed goals. Provide scientific validity of the hypothesis on the basis of background information. If there is no sufficient information on the subject, indicate the need to develop new knowledge. Also include the **significance and rationale** of the proposed work by specifically discussing how these accomplishments will bring benefit to human health in relation to biomedical, social, and environmental perspectives. (DO NOT EXCEED 5 PAGES, USE CONTINUATION SHEETS).

Bangladesh has the highest proportion of malnourished children in the world. The infant and child mortality are also among the highest in south Asia. In Bangladesh, about two thirds of all childhood deaths are associated with underlying malnutrition (Fauveau et al 1991). The Government of Bangladesh has been trying different ways for reducing childhood malnutrition. Such programs include the Vulnerable Group Development (VGD) Project, vitamin A distribution project, iodine deficiency disorder control program, iron supplementation program and improving food availability for the underprivileged sections of the society. Despite these, not enough improvement has been observed in the field of nutrition. In review of the past fifty-year's information of dietary intake and growth, it has been observed that food intake has substantially decreased and growth faltering in children has worsened (Roy et al 1988). Maternal malnutrition is evidenced by low weight, short stature and anemia in pregnant and lactating women. Micronutrient deficiencies are evidenced by prevalence of xerophthalmia, iron deficiency anemia and iodine deficiency disorders. The effects of childhood under nutrition, begin with a low birth weight (estimated to occur among 35-50% of births in Bangladesh) (Hasan et al 1995) and continue into adulthood.

The prevalence of PEM among children is very high, and has remained almost the same for the last decade. Thirty percent of all children under six years of age are severely stunted and another 31.2% are moderately stunted (BBS 1995). As many as 68.3% of the total children are under-weight and 16.7% are wasted, the highest rates are in Asia (BBS 1995). Given the greatly disadvantaged start by the way of a low birth-weight followed by inadequate breast-feeding by their undernourished mothers, average Bangladeshi infants are already below the lower end of the range of anthropometric values found among western babies during the first three to six months. The late and insufficient introduction of complementary feeding further retards the infant's growth; usually the child do not pick up its pace of growth before two years of age. By then, it is too late to reverse the early growth lag, which persists throughout the life, and similarly some of the damages done to mental development are irreparable. The weight for age curve of Bangladeshi children continues to lie below the third percentile of the NCHS Standard, though it runs roughly parallel to the standard from around the second year of life onward; the older children cope better with the adverse milieu of food-insecure and unhealthy household, while being unable to regain lost ground.

Definition of moderate malnutrition:

According to the Gomez classification Grade II or moderate malnutrition is defined when the weight for age of a child is 61-75% of the 50th centile of weight of the National Centre for Health Statistics

(NCHS) data.

Understanding of malnutrition:

The understanding of the particular causes of malnutrition has been revolutionized in recent years, but these advantages of knowledge are inadequately translated into new policies. Briefly, it is now established that the majority of malnourished children (other than those born with low birth - weights) become malnourished in the period from birth to the age of two years, and that the way forward must be through prevention based on what are now recognized as the essential elements of good nutrition - adequate health, both of which depend on well informed and well supported care of the young child. Yet, still today, the majority of efforts to combat malnutrition, on which tens of billions of dollars are spent worldwide, are based on feeding program for those children who are over three years of age. India's Integrated Child Development Service (ICDS) program, for example, is reaching two thirds of the nation's children in an attempt to improve their health, nutrition and development, but it benefits mainly children between the ages of three and five and has, therefore, had little nutritional impact (CARE 1994). All existing program specifically aimed at improving child nutrition should now recognize that the task is to prevent a child from becoming malnourished before he or she reaches the age of two year.

This new knowledge and understanding of nutritional issues must be translated into a wide understanding - among government ministries, planners of health services, communities, and parents. Without such a consensus on the causes of malnutrition, it is unlikely that there will be a consensus on the specific priority actions that are required. Given progress towards equality for women, those priority actions could begin to make a significant difference in the years immediately ahead. They could include, for example, a major effort to ensure that all families and health workers know the importance of better diet and more rest in pregnancy, of exclusive breast feeding during the early months of life, and of introducing the right kind of complementary foods in the right way and at the right time. Similarly, if people are to be seen as the key actors in the process of improvement, then another obvious priority must be to increase access to today's information about how to protect normal growth.

BINP project and its three main components.

In view of wide spread malnutrition, the Government of Bangladesh (GOB) has initiated Bangladesh Integrated Nutrition Project (BINP) to address this problem. The Ministry of Health and Family Welfare has initiated the project with the financial assistance from the World Bank. The project is the first major initiative of the GOB. It has been initiated with the view that investment in the nutrition sector will make an important contribution to the development of human resources of the country. This project is the beginning of the long-term effort of the Government aspirations expressed at the International conference in Nutrition (ICN, Rome) of 1992 and the World Summit for children of 1990. The main conceptual basis of the project is threefold: Food availability, good health, and caring practices specially targeted to children and women. The main goals of the project are to improve nutritional status of the people, national capacity building, and community

empowerment for action against malnutrition and to achieve measurable nutritional impact in the project areas.

Following are three major areas of BINP:

1. National level nutrition activities with sub components of program development and institution building. Information, education and communication (IEC) development, strengthening of existing nutrition activities and project management, monitoring and evaluation.
2. Community based nutrition component (CBNC) to focus on growth monitoring and promotion activities and motivation of individuals for supplementary feeding at village level, and
3. Inter-sectoral nutrition program development to improve nutrition through efforts beyond the scope of CBNC, through the emphasis of nutritional aspects of existing activities in various sectors (e.g. agriculture) and the support of innovative actions with potential nutrition impact. Sub-project proposals from government and non-government organizations are financed from inter-sectoral fund.

The project has initially been implemented in six thana in the first year and more thirty-four thana by 2 years for completion of BINP by 2001. The main beneficiaries of this project are women of childbearing age and children under two years of age.

The Government aims to establish an effective national nutrition program to improve child survival, strengthen the demand of services, prevention of malnutrition in children, improve low birth weight, increase learning capability of children, to have healthier and more productive future generation.

Results from the initial study at Shahrasti:

In the BINP project there was a recognition that a very large proportion of under two children are moderately malnourished. Yet experience compared to intervention severe malnourished children there was no definitive intervention to improve the situation in moderately malnourished children, as there was little worldwide successful. Therefore an operations research was commissioned by BINP to investigate effective means to address moderately malnourished children (weight for age between 60-75% median NCHS standard). Care givers of one group received intensive nutrition education (INE) for three months, the second group received intensive nutrition education plus daily 300 Kcal food supplementation (SF) of BINP (INE+ SF), and the third group as control received the standard BINP intervention of two weekly education by the implementing NGO CNP's. The study subjects were observed for an additional period of three months after intervention. Significant improvement in nutritional status was evident with intensive nutrition education in 3 months. The results show that the nutrition education reduced 37% of moderate malnutrition, whereas added with food supplements, nutrition education reduced 47% and there was 18% reduction in the control

group. Net weight gains (g) over the three months intervention period were 436 Vs 320, 688 Vs 334, 910 Vs 636 grams at the end of the 1st month, 2nd month and 3rd month of intervention in education Vs control group. The weight of the group receiving both supplementation and education were even higher i. e 487g at 1st month, 763g at 2nd month and 1061g at 3rd month respectively. The rates of weight gains (g/kg BW) in 3 months were 104g, 154g and 182g in control, education and SF+ education group respectively.

Substantially greater reduction of moderately malnourished children indicates the potential of intensive education and education plus SF for reduction of childhood malnutrition.

(Detail results of Shahrasti field project given in the Annex 3, page –42.)

Current state of nutrition

In Bangladesh, a recent base line study of 44 BINP thanas shows that about 5% children are severely malnourished, 37.4% are moderately malnourished, 43.7% are mildly malnourished and 13.7% are normally nourished (by Gomez classification) under two years of age. Marked reduction in severe malnutrition has been reported as a result of the BINP supplementation program. This resulted in a relative increase in moderately and mildly malnourished children. There is also a growing concern that in spite of reduction in severe malnutrition, a net increase in second-degree malnutrition will continue to affect the quality of life. Therefore, there is an urgent need to find an effective and feasible means to address this large segment of child population to restore a better nutritional status i.e. improvement to mild or normal nutritional status. Once children are improved into that level, it needs to be maintained. The proposed operations research will involve BINP area and explore effective and feasible interventions. The existing growth monitoring program uses GMP cards upon which weights are plotted monthly and can be easily used for identification and learning by the mothers and community members. The results of the recently completed operations research show that it is possible to reduce moderate malnutrition significantly by some effective means with intensive measures within a relatively short period of time. Yet it is important to find a practical and an optimal education package to achieve a desired reduction of moderate malnourished children.

Significance of the study

Introducing appropriate complementary feeding at 6 months can prevent growth faltering in early infancy. The study proposes both preventive and management approach, which may rapidly reverse the present situation of malnutrition. Appropriately introduced complementary feeding will protect healthy infants from falling into malnutrition. Mildly malnourished children (43.7% now) will be prevented to fall into moderate malnutrition and moderately malnourished children will improve to better nutrition. Moderately malnourished children often reflect chronic malnutrition and slow growth. As the proportion of moderately malnourished children make up a large population of children (37.4%) under two years of age, it will be most important to target these children to ensure a healthier child with normal nutrition (13.4% now). Recently completed study shows that there is effective means to address them. But it is important to find a feasible means to make a program

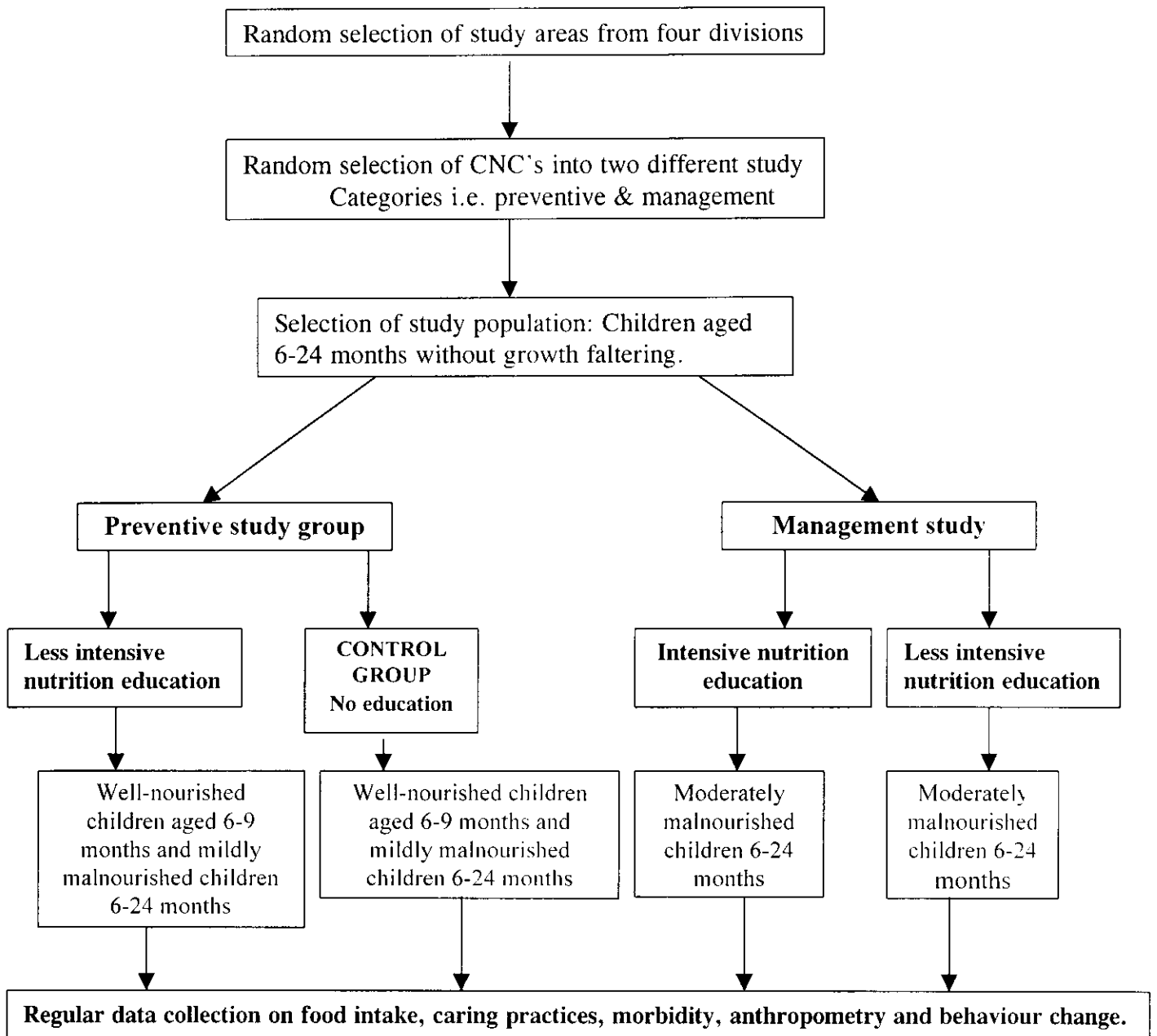
implementable and sustainable in context of resource constraints.

The present study will be conducted in four administrative divisions with less intensive nutrition education for management as well as preventive purposes. It will try to determine an effective and feasible strategy that can be implemented by the community to reduce moderate malnutrition. If the study results are found successful, there will be rapid improvement of the nutritional status of children. The results of this study will help undertaking intervention programs to prevent and reduce child malnutrition and related consequences.

Conceptual frame work:

On the basis of the knowledge from the recently conducted study, it would be appropriate to identify the specific causes and design the remedial measures accordingly. Genesis of moderate malnutrition may be seen as a growth faltering of well nourished children when food security, disease control and caring practices may be inadequate and thereby children can get into the cycle of malnutrition. It is known that food security in young infants means appropriate breast-feeding and timely introduction of appropriate complementary feeding. Therefore the study can have a two prong approach: one is the preventive measure through intensive nutrition education to the healthy and mildly malnourished children and the other is management approach i.e. identified moderately malnourished children can be managed at their home. Monthly GMP sessions at CNC's can provide earlier weight change of moderately malnourished children, but it may not be able to identify the cause of genesis of moderate malnutrition. Difference in cultural practices, child-feeding behavior, caring of children, and attitudes to food in different geographical areas will be assessed through anthropological study. Following issues will be explored through anthropological tools. These issues are, past illness, birth history, plan for child feeding, knowledge on child feeding and dietary preparation, allocation of time for child care, breast-feeding frequency, complementary feeding, religious influence on feeding practice, frequency of feeding, gender bias on feeding practice and practice of medical care. Moreover willingness to change for improving child nutritional status will be focused. The initial results will help to develop area specific messages and means of intensive nutrition education components. Giving appropriate complementary food and prompt action on disease control will be regarded as important determinants of child's nutritional status. Counseling will be done to family heads and decision-makers. The experience from the recent study at Shahrasti shows that once mothers are convinced about the benefits of intensive feeding to improve the health of their babies, they can convince their husbands to support their initiatives for improvement of child health. The moderately malnourished children will be under INE or less intensive education (LINE) with a management approach. The mildly malnourished children will be similarly approached to prevent falling into moderate malnutrition. Further, well nourished infants between 6 and 9 months of age will be included in less intensive group to benefit from introduction and maintenance of appropriate complementary feeding to prevent the fall to malnutrition.

Conceptual frame work



Research Design and Methods

Describe in detail the methods and procedures that will be used to accomplish the objectives and specific aims of the project. Discuss the alternative methods that are available and justify the use of the method proposed in the study. Justify the scientific validity of the methodological approach (biomedical, social, or environmental) as an investigation tool to achieve the specific aims. Discuss the limitations and difficulties of the proposed procedures and sufficiently justify the use of them. Discuss the ethical issues related to biomedical and social research for employing special procedures, such as invasive procedures in sick children, use of isotopes or any other hazardous materials, or social questionnaires relating to individual privacy. Point out safety procedures to be observed for protection of individuals during any situations or materials that may be injurious to human health. The methodology section should be sufficiently descriptive to allow the reviewers to make valid and unambiguous assessment of the project. (DO NOT EXCEED TEN PAGES. USE CONTINUATION SHEETS).

Material and methods:

A two-prong nutrition intervention study will be conducted in four administrative divisions of Bangladesh. One strategy will include nutrition education for prevention of malnutrition and other will include nutrition education for management of moderate malnutrition in 6-24 months old children using UNICEF guidelines of food security, disease control and caring practices. The approach will include anthropological and nutrition skills to educate mothers on specific knowledge skills.

The village nutrition management committee will be met at the onset of the study to discuss the objectives of the study, the level and types of input and cooperation that can be mobilized will be planned. A local volunteer will be identified to work for the project selected by the village nutrition committee. Village women's group will meet to plan their time and availability for demonstration and advocacy of measures undertaken for the research projects. The proportion of activity that can be channeled through the CNP and time available for the CNP will be determined. Normally nourished 6-9 month old infants, mild and moderately malnourished children less than 2 years will be taken from the CNP registrar and GMP cards. The proportion of moderately malnourished children with growth faltering and who are receiving supplementary feeding will be excluded from the study. It is known that in health intervention, there is visit effect, where regular visits of health workers indirectly influence caregivers to ask about child's well being and seek advice. To minimize the effect all groups will receive same number of visits for information collection.

Design of the project:

This will be a prospective longitudinal intervention study. The study will have

- a) a management approach and
- b) a preventive approach.

Management approach study groups

- (1) One intervention group of moderately malnourished children without growth faltering will

receive **intensive nutrition education** (INE) and demonstration of appropriate complementary feeding at home in same intensity of recently completed study at Shahrasti thana in Chandpur district. The education will include food demonstration, specific education on diet, components of caring practices, and disease control linking to the referral system.

- (2) The second intervention group will be moderately malnourished children without growth faltering who will receive **less intensive nutrition education** (LINE) food demonstration and specific education on diet, components of caring practices, and disease control linking to the referral system.

Preventive approach study groups

- (3) The third group will be the preventive group with mildly malnourished children and well-nourished 6-9 months aged infants who will receive less intensive nutrition education same as the second group of moderately malnourished children
- (4) The fourth group will be controls for the preventive group with mildly malnourished children and well nourished 6-9 month aged infants who will not receive any education.

Moderately malnourished children will be included to improve their nutritional status into better nutrition and well nourished and mildly malnourished children will be included to prevent their fall as well as improve in nutrition status.

Details of the nutrition counseling and demonstration of food are given in annex 1.

There will be modification of nutrition education after baseline FGD studies on food perception. The base line weight and length of each child will be recorded. Weight and length will be taken each month for a period of 6 months. Project workers will also take information on anthropometry from the GMP sessions. The main responsibility of education will remain with the health assistant. CNP timing will be mapped and their special training manual will be prepared. They will be trained in different sessions to educate the mothers groups. The sessions with moderately malnourished children and their parents will be organized in consultation with village nutrition management committee (VNMC). The counseling will be based on pictorial or written script in Bangla. Required number of sessions will be planned for increasing the ability to recognize moderately malnourished children. The feasibility will be seen through exploratory meeting with VNMC and moderately malnourished children's mothers.

In the intervention area, **complementary food** will be prepared and demonstrated by the nutritionist and health assistants. Feeding will be encouraged in groups at the community level for initial one month and then it will be encouraged to do at home with supervision of the women support group and health assistants.

Sample size calculation:

Sampling frame: The study subjects will be under 2 years of age and will be recruited from the growth-monitoring program at CNC. Of the total population about 4.5% are under 2 years at a given time. From this population about 10% show growth faltering and come to the CNC for supplementary feeding as the part of the BINP activities. About thirty eight percent children under 2 years of age suffer from moderate malnutrition, about 43.7% are mildly malnourished and about 13.7% are normal according to recent baseline report of BINP.

Sample size for management study group:

In each CNC about 20 children are expected to suffer from moderate malnutrition.

The study hypothesis is that there will be no difference in improvement between intensive nutrition education group and less intensive education group in proportions improving from moderate malnutrition receiving nutrition education. The study will disprove the hypothesis if a 15% difference is detected with statistical significance.

$$\text{Using formula } n = \frac{p_1(1-p_1) + p_2(1-p_2)}{(p_1 - p_2)^2} (z_{\alpha} + z_{\beta})^2$$

(Reference: G W Snedecor and WG Cockran. Statistical Methods in Medical sciences. Oxford Publications 6th edition 1968, pp 111-114). Where p_1 is proportion of reduction of moderate malnutrition in intensive nutrition intervention group and p_2 is reduction in proportion of malnutrition in less intensive education group and $(z_{\alpha} + z_{\beta})$ is the function of level of significance and power of the statistical test.

$p_1=0.5$ and $p_2=0.35$

where z_{α} = level of significance at 5%, =1.96

and z_{β} = power of the study 90%, =1.28

where $(p_1 - p_2)$ = difference of proportion moving to mild malnutrition between control and intervention group.

$$n = \frac{0.5 \times 0.5 + 0.35 \times 0.65}{(0.15)^2} \times 10.5 = 222.$$

Taking a cluster effect of the design as the children will be selected from CNC s this is increased to $222 \times 1.5 = 333$. with a drop out possibility of 10%, it will be about 366 children in each group.

Total sample size will be $366 \times 2 = 732$ or 750 subjects.

Sample size for preventive study group:

Assumption is that mildly malnourished children will usually slip into moderate malnutrition without any nutrition education but with less intensive nutrition education, they will not slip into malnutrition. The study will be interested to detect a difference of 20% with a 5% probability and

90% power.

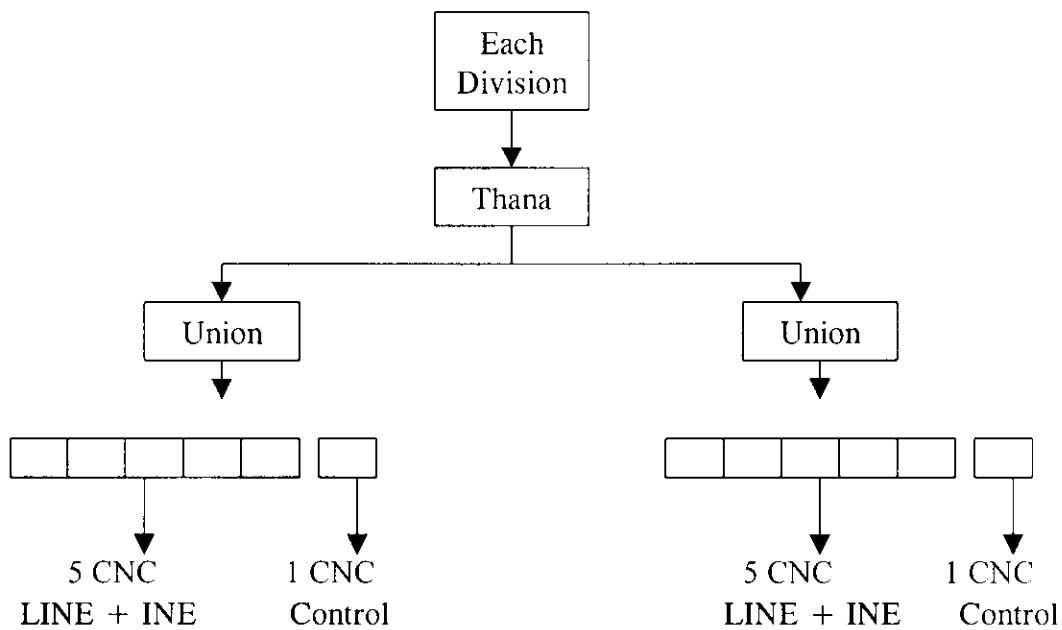
To detect this 20% difference the number of mildly malnourished children in two study groups will be $(121 \times 2) = 242$. The cluster effect of randomization by CNCs will be controlled by multiplying the number by a factor of 1.5 i.e. $242 \times 1.5 = 363$ for mildly malnourished groups and possible drop out (10%) can be covered with a total number of $(190 \times 2) = 380$ subjects.

As almost 80% of the 6-9 month old infants will be included in mild and moderate groups, rest 20% who are well nourished will be studied with less intensive education for preventive approach. There will be $(50 \times 2) = 100$ infants in 6-9 month old group to receive either less intensive education on complementary feeding or no education. These well nourished infants will be analyzed separately to see if less intensive education on complementary feeding prevents them from falling to mild or moderate malnutrition.

Selection and randomization procedure: (Tables 1,2,3)

For management approach the number of subjects will be 375 in each group and a total of 750 children will be selected from 40 CNCs from 4 divisions. One thana will be randomly selected from each Division, and two unions will be randomly selected from each thana, and 5 CNS will be randomly selected from each union. From a total of $(5 \times 2 \times 4) = 40$ CNCs, 20 will be allocated for intensive education and 20 will be randomly allocated for less intensive education.

To avoid contamination for the control groups with no nutrition education in the preventive approach, 8 additional CNCs will be randomly selected one from each union of the four divisions. Finally in each union 5 CNCs will be under either intensity of education and one CNC will be with no education. A diagram is given below:



LINE : Less intensive nutrition education, INE : Intensive nutrition education

Table 1

Sample selection

Subjects	Intensive education	Less intensive education	No education	Total
Moderately malnourished	375	375	---	750
Mildly malnourished	---	190	190	380
6-9 months old infants	---	50	50	100
CNCs	20	20	8	48

Table 2

RANDOMIZATION PROCEDURE

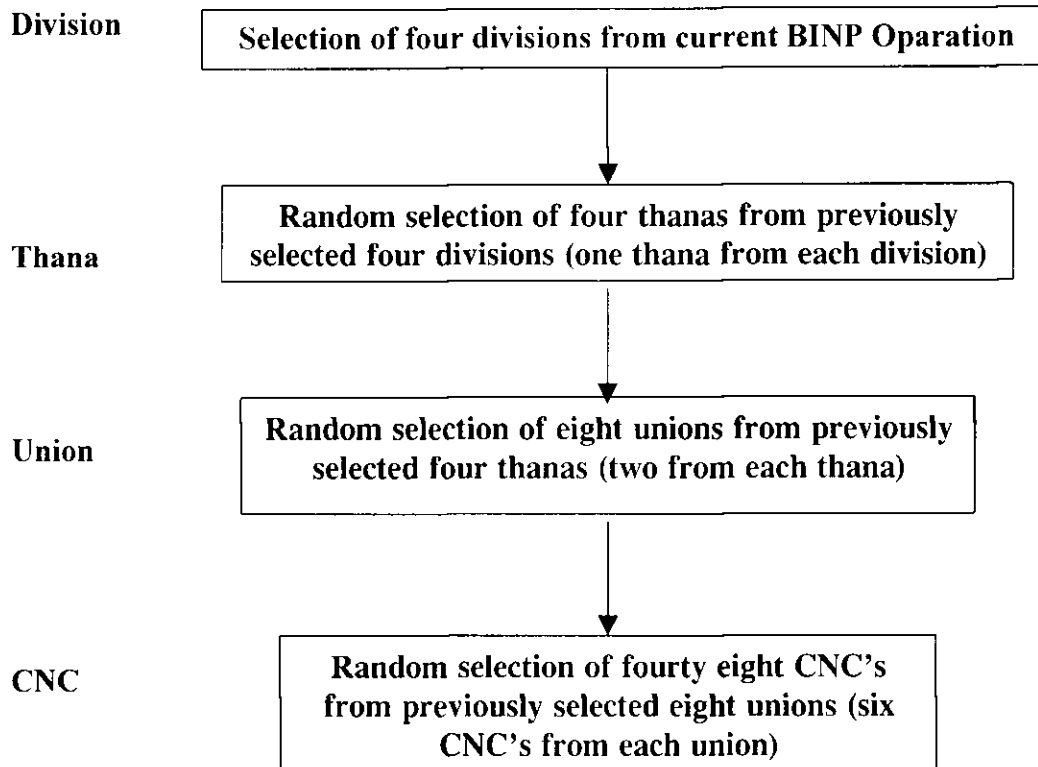
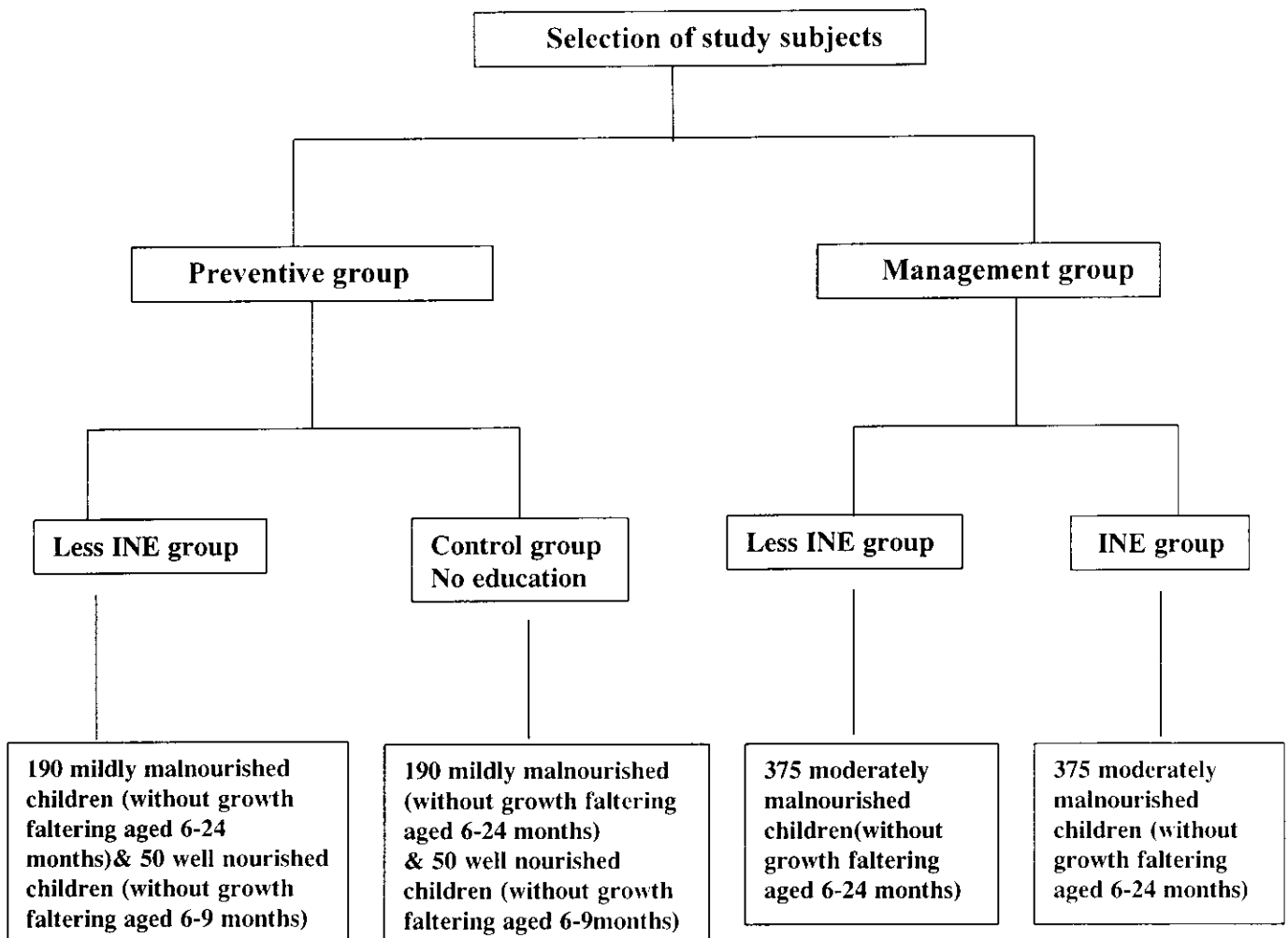


Table 3

Selection procedure



Randomization procedure:

(a) Total number recruited moderately malnourished children are 750. They will be selected equally from 40 CNC's in two study groups. Individual child will not be randomized but the children in each CNC as a group will be allocated randomly to either of the two study groups according to a random number table. Identified 5 CNC's in each union will be randomly allocated by their identification numbers to one of the two study groups.

(b) In the preventive group, mildly malnourished children will be randomized by CNCs for less intensive nutrition education or no nutrition education.

(c) Another preventive group of well-nourished 6-9 month aged infants for complementary feeding will be randomized by CNCs into either to less intensive nutrition education or no nutrition education.

Staff training:

A staff-training curriculum will be developed on the basis of the experience of the recently completed operations research at Shahrasti. A module of training manual will also be produced to fulfill the adaptation need of the CNP/CNO's with newer findings of the project. Staff training will be at Dhaka. Another training manual will be prepared for mothers according to earlier study and FGD reports.

Quantitative data collection

One health assistant (preferably graduate level having recognized ability to communicate with village mothers) will be appointed to provide nutrition education and collection of data in the area covered by 3 CNCs. There will be one supervisor with nutrition background to train the health assistants and organize and supervise nutrition education on child feeding and caring practices. Investigators will train and guide the health assistants. An anthropologist and a nutritionist will participate in counseling on child feeding and caring practices.

Anthropometric data will be collected monthly from the GMP sessions with accuracy ensured. Accuracy of weighing scales will be tested against a known weight by health assistants. The project nutritionist will also standardize the weighing method. Separate study data will be collected if the quality of anthropometry of CNPs is not acceptable. A project physician will record a base line clinical assessment of deficiency signs of micronutrients. Weight will be taken using salter scale (UK) (sensitivity 100g). Length will be measured by a locally constructed length board with precision of 1mm. Staff will be trained by Investigators and nutritionist. MUAC- data will be collected with TALC (Teaching Added at Low Cost)(UK) tape with causes of 2 mm.

Data on compliance level of nutrition education will be collected during 2 weekly observation period. Data on causes of noncompliance will be also recorded. Changes in child feeding frequency and changes in dietary composition will be recorded

Referral system and disease control

A project medical officer will educate on timely referral to Thana Health Complex (THC) or FWC during illness of the child. A communication with THC medical officer will be strengthened for BINP initiatives for malnourished children.

Collection of morbidity data:

Morbidity information will be collected at two weekly home visits during study period using pre-tested questionnaire.

Operational definition

Fever: If the temperature is more than normal, that is above 38.5⁰ C is called fever.

In the field level:

1. When mother tell about her child suffered from fever that lasted for 1 day, a physician will examine the child and child will be treated at home for mild fever.
2. When mother will tell that her child has fever lasting for two to three days, it will be regarded it as moderate fever.
3. Mother will tell that fever lasts for more than three days, he will be examined and regarded as sever fever.

Diarrhoea: An episode of diarrhea is defined as the passage of three or more loose or watery stools within 24 hours. Records will be collected on consistency and the number of stools per day.

1. A child passing loose, liquid or watery stool more than three times per day will be called acute diarrhoea.
2. Presence of blood with stool will be define as invasive diarrhea.
3. When a single episode of diarrhea lasts for more than two weeks, it will be called persistent diarrhoea.

Ear Infection: A child will have pain in ear, fever, with watery or purulent secretion from one or both ear will be diagnosed as ear infection.

Lower respiratory tract infection: When a child suffering from cough and fast breathing more than 50 per minute, fever, or chest indrawing will be defined to have lower respiratory tract infection (LTRI).

Upper respiratory tract infection: A child suffering from cough and cold without sings of LRTI will be diagnosed as upper respiratory tract infection (URTI).

Skin infection: A child suffering from skin disease with impetigo or skin infection or scabies will be define have skin infection.

Sore on Tongue: Ulceration or fissure on tongue or palate will be identified as sore tongue.

Angular stomatitis: Any child having signs of ulceration or excoriation in angle of mouth will be diagnosed to have angular stomatitis.

Xerpthalmia : Conjuntival haziness & corneal haziness will be diagnosed as Xerophthalmia.

The subjects will be referred to THC by interviewers during two weekly home visits if following conditions develop:

Referral will be done accordingly to IMCI criteria in the following ways:

1. Pneumonia: After 2 days of first time of antibiotic therapy:

Check the child for general danger signs.

Assess the child for cough or difficult breathing.

Ask:

- Is the child breathing slower?
- Is there less fever?
- Is the child eating better?

Treatment:

- If chest indrawing or a general danger sign, give a dose of second-line antibiotic or intramuscular chloramphenicol. Then refer URGENTLY to THC.

2. Diarrhoea:

After 5 days:

Ask:

- Has the diarrhoea stopped?
- How many loose stools is the child having per day?

Treatment:

- If the diarrhoea has not stopped (child is still having 3 or more loose stools per day), do a full reassessment of the child. Give any treatment needed. Then refer to THC.

3. Dysentery:

After 2 days:

Ask:

- Are there fewer stools?
- Is there less blood in the stool?
- Is there less fever? Is there less abdominal pain?
- Is the child eating better?

Exceptions- If the child:

- is less than 12 months old, or
- was dehydrated on the first visit, or
- had measles within the last 3 months. Then refer to THC.

4. Ear-Infection:

After 5 days:

Ask:

- Is there ear pain?
- Is there ear discharge? If yes, for how long?

Look and feel:

- Look for pus drawing from the ear.
- Feel for tender swelling behind the ear.

Treatment:

- If there is tender swelling behind the ear or high fever (38.5°C or above), refer Urgently to THC.

5. Fever:

Ask:

- For how long?
- If more than 7 days, has fever been present every day?
- Has the child had measles within the last 3 months?

Look and feel:

- Look or feel for stiff neck.
- Look for runny nose

Look for signs of measles

- Generalized rash and
- One of these: cough, runny nose, or red eyes.

Treatment:

- Very severe febrile (high fever 38.5°C for above), then refer urgently to hospital.
- If fever is present every day for more than 7 days, refer for assessment.

Qualitative data collection methods

The baseline data will be collected through:

1. Survey
2. Focus group discussion
3. Participant observation:

Each method of data collection is elaborately mentioned bellow.

1. **Survey:** Information of socio economic condition of the respondents will be collected through direct questionnaire. These answers will cover the issues of family income, food status, education, occupation of the parents and also the size and type of the family.

2. **Participant Observation:** Participant observation will be conducted to explore basic feeding

pattern at home like breast feeding frequency, complimentary feeding, frequency of feeding, gender bias on feeding practice and allocation of time for child care. Anthropologist or nutritionist will observe 10-15 mothers of moderately malnourished children. Mothers will be observed from morning till evening. Data collected through participant observation will validate the data of focus group discussion.

3. Focus group discussion (FGD):

It is necessary for the immediate care givers of children, mothers or guardians to be involved in the problem and to initiate remedial measures with the help of their own resources that they can obtain from their environment. From FGD of mothers and caregivers we expect to learn and use information to develop appropriate culturally based practical nutrition education messages for the following issues:

1. Perceptions on causes and possible consequences of malnutrition from mothers that they experience in their day to day life.
2. Ideas on the management of the nutritional problem and its preventive measures.
3. The perceptions on food security.
4. Feeding practice of children and pattern and frequency of breast-feeding.
5. Mothers' perceptions about initiation of immunization.
6. Mothers beliefs on foods for child health, feeding requirement and appropriateness of food.
7. Food taboos and practices in diseases.
8. Perceptions and practices on healthy food and non-healthy food at different ages of a child.
9. Perceptions on growth and their responsibility on caring practice and complementary feeding.

The views expressed by the mothers through Focus Group Discussion on possible causes of malnutrition and their suggestion on the preventive and management measures will be used as base line data to prepare the material for counseling mothers on nutrition related behavior change.

FGD will be conducted on mothers in 6 groups each from 3 CNC's (1 control and 2 study areas). There will be 6-8 mothers of moderately malnourished children in each Focus Group Discussion. This is expected to be more or less homogenous, since mothers having young children in the villages are of similar age FGD will be conducted by the anthropologist. Moderator will play the role of guiding the group on the right topic by putting them on the track. The research personnel will facilitate discussion but they will not influence the discussion. A tape recorder will be used to record the discussion. One facilitator will take notes. Obtained data from FGD will be analyzed manually by using coding.

The FGD will be conducted again to evaluate the change in behaviour and the process indicators. The method indicated above will be followed in the later part of the study.

A pre-test on knowledge of child feeding practice will be done and will be repeated with same the questionnaire after the diet counselling sessions with the mothers. Data on feeding frequency, preparation of information on child feed, dietary ingredients, frequency of feeding and constraints will be recorded at two weekly intervals in study groups. Post test will be conducted at the end of

nutrition education period.

The health assistants will be pre-testing the nutrition knowledge of the mothers and mothers will be observed before actual training is given. These subjects will not be included into study. This will reduce observer bias of the health assistants.

Outcome variables:

1. Mothers understanding and ability to identify moderate malnutrition in children.
2. Mothers understanding on consequence of moderate malnutrition.
3. Change in knowledge of mothers in feeding practices.
4. Frequency of home feeding (Breast-feeding and supplementary feeding).
5. Frequency of seeking medical care during illness, referral, incidence, duration of illness.
6. Adequacy of child feeding, frequency & type of feeding.
7. Weight gain, weight for age and weight for height at the end of intervention.
8. Proportion of complementary feeds in 6-9 months age group.
9. Nutritional status of children at various phases of intervention and observation.
10. Adaptation level of nutrition education program by CNP, CNO.
11. Constant of not practicing education knowledge.

Secondary outcome variables: -

1. Incidence and prevalence of diarrhoea and ALRI
2. Referral success and failure
3. Resistance to education
4. Food insecurity for child
5. Mothers time constraint for CF preparation
6. CNP time constraints for INE

Process indicators:

5. Number of counseling sessions
6. Proportion of attendance by mothers to counseling session
7. Proportion of attendance of supplementary feeding demonstration session
8. Number of home visits of by Health assistants
9. Use of IEC materials in sessions.
10. Number of community sessions with mothers groups, women's group, and VNMC.
11. Proportion weighing sessions.
12. Member of VNMC meetings.
13. Percent of feeding frequency change.
14. Record of referral.
15. Feeding related behaviour.

Quality control measures:

Quality assurance will include questionnaire development, FGD, intensive staff training, standardization of study procedures, which will be written in detailed manuals, regular staff meetings and supervision by the investigators. The project investigators in 15% random samples will directly supervise systematic data collection. Anthropometry will be standardized at the beginning of monthly sessions by trained nutritionist. External validation of anthropometry will also be done. Validation of nutrition education will be done by attending the sessions by supervisors during group with a check list education and with separate interview. Cross check with mothers for preparation of feeds and feeding frequency will be done by nutritionist. Feeding frequency will be rechecked after the day of interview in 15% of the randomly selected sessions at the household levels. Investigators will make random spot checks and will re-interview at least 15% of mothers on child morbidity on the same day using the same questionnaire. With identification of any discrepancy, the data will be informed to the respective health workers and corrections will be done by supervisor's assistance. Each child will have a record file of important events such as migration, referral, and death and will be kept with project office. The field activity will be communicated to PI by the project supervisors and senior staff by phone or fax in between the visits in the field. Data will be checked by running checking program in computer after collection and before analysis.

Adaptation process of the Community Nutrition Promoters (CNP's) and Community Nutrition Organizer (CNO's):

CNP and CNO's will be asked for their time to learn the specific nutrition education that has proven to be successful for improving nutrition status and they will be involved to pick up the work schedules of the research team. After the first three months of study, adaptation process will begin. If time is available CNP's will take over the health assistant's work and CNO's will take over supervisor's work by end of 6 months and will replicate in more CNC's.

Time will be planned with CNO and CNP's to define their role in nutrition education. The current

study with knowledge of the previous one will identify specific knowledge base that helps behavior change communication of mothers in feeding appropriate food and frequency, referral during illness, and caring practices. A review of the BINP training manual will be done to find adjustment of the specific messages based on our messages on the preventive and management approaches for introduction of complementary feeding. An initial standardization of CNP sessions with mothers will be done with project investigators and field staff. Supervisory level adaptation of monitoring the quality of CNP and CNO work will be planned and accommodated. It remains to see the actual operations taking place in context of time constraint of CNP's in their daily work schedules. The details on following areas will be worked out with the NGO implementing in Thanas before planning of adaptation can be actually begun.

1. Availability of CNP and CNO time
2. Training of CNP and CNOs
3. Monitoring / Supervision
4. Evaluation of the work

Cost Effectiveness of the Alternative Strategies to address moderately malnourished children

Add in specific objective section the following:

5. To assess the cost-effectiveness of the two alternative strategies to prevent and reduce moderate malnutrition in 6-24 months old children.

Add in the conceptual framework section:

In order to assess the cost-effectiveness of the two alternative strategies, the costing of the intervention activities will be undertaken.

To ensure that all relevant resources used for the alternative intervention strategies, it will be necessary to observe outputs (effectiveness measures) being produced and then try to link the inputs/resource used in the production of specific outputs.

Data will be collected to determine the following costs while undertaking the intervention.

The costing will be done from providers'/programme perspective and will include the identification of the following:

Capital costs will include values of setting up (building, furniture, equipment, vehicles), and training (non-recurrent). *Recurrent costs* will include personnel (salaries and benefits), training (recurrent), rent and utilities, equipment and supplies (operation and maintenance), building (operation and maintenance), vehicle (operation and maintenance), head office (HO) logistic and management support, and supervision (HO and regional quality control). Attempts will be made to identify the

cost, which are only the research components. The incremental costs of adopting the alternative strategies will be analyzed.

Relevant data for this part of study will be collected simultaneously with the main part of study. Additional tools will be developed to collect data.

The emphasis of the economic evaluation through cost-effectiveness analysis will be to evaluate the direct and indirect cost for each type of output measures. The main indicators of effectiveness (output) measures will include:

- proportion of mothers understanding the consequences of moderate malnutrition
- proportion of mother with improved knowledge in feeding practices
- proportion of child with improved nutritional status at various phases of intervention

Add in the personnel requirements:

This part of the activity will include involvement of one Senior Operations Researcher and Senior Field Research Assistant from the Health Economics Program. It is suggested that about 10% of Senior Operations Researcher's time will be needed for 18 months. He/she will mainly provide the guidance in designing the data collection instrument and analyzing the data. A full time Senior Field Research Assistant for 12 months, who will report to the Senior Operations Researcher of the Health Economics Programme, will be needed to supervise the field data collection and the interviewers to be assigned for collecting cost information.

Facilities Available

Describe the availability of physical facilities at the place where the study will be carried out. For clinical and laboratory-based studies, indicate the provision of hospital and other types of patient's care facilities and adequate laboratory support. Point out the laboratory facilities and major equipment that will be required for the study. For field studies, describe the field area including its size, population, and means of communications. (TYPE WITHIN THE PROVIDED SPACE).

Site selection:

This research project will be conducted in 4 thanas in four Divisions, one in Khulna, one in Dhaka, one in Rajshahi and the other in Chittagong. Four thanas that are under CBNC activities will be randomly selected from each division. These are NGO run thanas where the NGO's are implementing the project activity with the help of Government or vice versa in the Government run thana. Then eight unions will be selected from these four thanas. That means two unions will be selected from each thana by using simple random sampling. Again by using simple random sampling six CNC's (Community Nutrition Centre) will be selected from each union. The basic information, already existing in the registrar (e.g. anthropometry) of the CNP will be reviewed.

Data Analysis

Describe plans for data analysis. Indicate whether data will be analyzed by the investigators themselves or by other professionals. Specify what statistical software packages will be used and if the study is blinded, when the code will be opened. For clinical trials, indicate if interim data analysis will be required to monitor further progress of the study. (TYPE WITHIN THE PROVIDED SPACE).

Data will be double entered in a microcomputer within a week of data collection. The field supervisors will visually check data before sending for entry into the computer. Any error, discrepancy or omission found during data entry will be reported to the investigators without delay. Data will be entered into microcomputer using SPSS Windows's program. Data on weight gain, frequency and introduction of complementary feeding will be compared between experimental groups. Complementary feed introduction and regularity will be compared among 6-9 month age groups in education and control groups. Comparability between intervention and control groups will be assessed by baseline characteristics such as age sex, nutritional status, socioeconomic characters, feeding practices, etc. Continuous variables will be assessed for normal distribution. T test will be performed to compare data of normal distribution; otherwise non-parametric test will be used. Chi-squared test will be performed for categorical variables, Multiple regression analysis will be done with weight gain as dependent variable and intervention and potential confounding variables such as age, sex, SES, baseline nutritional status, infection as independent variables. Separate analysis will be performed for periods of intervention, reinforcement and observation.

Compliance of nutrition education will be measured at 2 weekly observation period (already mentioned). Compliance will be measured as process indicator. Comparison of compliance will only

be done at the end of the study so that the investigators will have no idea about which group is more a less compliant. Therefore, these will be little change of introduction of bias due to non-compliance, effect of intensive or less intensive nutrition education will be compared as a whole. So complain will be seen as a factor of nutrition education with given intensive. Analysis of compliance data will be done by relating to the outcome effect of nutritional status and can be compared between two education groups.

Analysis of qualitative data

Data collected from the focus group discussion and observation will be ordered, reduced and coded according to the qualitative data analysis method (Applied health Research Manual: Anthropology of Health & Medical Care: report- International Congress in Anthropology of Health and Health care). All sorts of qualitative data will be summarized and a detailed report will be presented. Emphasis will be given on change of KAP (Knowledge, attitude and practice), BCC (Behavior change communication) among the participants. Statements about various important issues and graphical presentation of the reason behind the issues and socio-economic cycle behind the important issues will be presented. Matrix, diagram and flow chart will be presented as the reason / origin (both socio-economical and bio-medical) behind malnutrition, failure to improve nutritional status by the study subjects. Conclusion will be drawn based on the data, matrix, diagram and flow chart and possible causes will be explained. Recommendations will also be given on this connection. The qualitative data will help mainly to explain in-depth believes and thoughts behind food and health behavior and will identify changed perceptions on BCC. This information will explain more the process of change to link with frequency of performance or absolute terms of weight gain or improvement of nutritional status. Qualitative data will help to identify the cultural background of nutrition that will be employed in developing curriculum/package of nutrition education.

Investigators experience

The investigators will be from ICDDR, B and BRAC that will help operation of the project. The investigators are experienced with recently completed operations research project on "Effective means to address moderately malnourished children", BINP community based nutrition component (CBNC) and knowledgeable on the current operation at the Thana level. The experience on requirement and effectiveness of training components of intensive nutrition education will guide the most economic way to find the feasible means. The collaboration with BINP and partner NGOs includes assistance in training, and IEC distribution, organization of local support groups, regular monitoring and quality control.

Ethical Assurance for Protection of Human Rights

Describe in the space provided the justifications for conducting this research in human subjects. If the study needs observations on sick individuals, provide sufficient reasons for using them. Indicate how subject's rights are protected and if there is any benefit or risk to each subject of the study.

There will be no ethical problem as there will not be any risk or harm to the children. Parental consent will be taken after informing them the objectives and procedures of the study. It may be necessary to give medical treatment for severe illness; children will be referred to local health care system. All mothers of children with moderate malnutrition will receive nutrition education. Which will improve the nutritional status as seen in our previous project.

Use of Animals

Describe in the space provided the type and species of animal that will be used in the study. Justify with reasons the use of particular animal species in the experiment and the compliance of the animal ethical guidelines for conducting the proposed procedures.

No animals will be used in this study

Literature Cited

Identify all cited references to published literature in the text by number in parentheses. List all cited references sequentially as they appear in the text. For unpublished references, provide complete information in the text and do not include them in the list of Literature Cited. There is no page limit for this section, however exercise judgment in assessing the "standard" length.

References:

1. Ahmed K and Hasan N. Nutrition survey of Rural Bangladesh 1981-82 edited by Institute of Nutrition Food Science 1983.
2. BBS. UNICEF, Progotir Pathey, 1995.
3. BBS. Statistical Pocket Book Of Bangladesh, 1994
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5. Begin ID, Viteri FE. Nutritional rehabilitation centers-an evaluation of their performance. *J Trop Pediatr* 1973 19:404-16.
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11. Hasan KZ, Sack RB, Siddique AK, Roy E. Factors influencing birth weight in a rural community of Bangladesh (Abstract). *J Diarrhoeal Dis Res*. 1995, 13(1):71-2.
12. Fauveau V, Briend A, Chakraborty J & Sarder AM. The contribution of severe malnutrition to child mortality in rural Bangladesh: Implication for targeting nutritional interventions.

Food and Nutrition Bulletin 1990; 12:215-219

13. G W Snedecor and WG Cockran. Statistical Methods in Medical Sciences. Oxford Publications 6th edition 1968, pp 111-114,
14. Lofti M, Manson JB. Direct intervention programs to improve infant & child nutrition. In Infant & Child Nutrition Worldwide: issue the perspectives. Falkner F. ed. CRC press.
15. Maria T Bredow, Alan A Jackson. Community based effective. low cost approach to the treatment of severe malnutrition in Jamaica. Arch. Dis Child 1994; 71:297-303.
16. Roy SK, Haider R. Is Nutritional Status Deteriorating in Bangladesh? Health policy and planning 1988;3:325-328.
17. Roy S K, Rahman M, Mitra A K, Ali M, Alam A. N, Akbar MS. Can mothers denitrify malnutrition in their children? Health policy and Planning 1993;8(2):143-149.
18. World summit for children, world declaration on the survival, protection and development of children. United Nations, New York. September 1990.
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Dissemination and Use of Findings

Describe explicitly the plans for disseminating the accomplished results. Describe what type of publication is anticipated: working papers, internal (institutional) publication, international publications, international conferences and agencies, workshops etc. Mention if the project is linked to the Government of Bangladesh through a training programme.

The results will be immediately used by the National Nutrition Program (NNP) of the Government of Bangladesh and the rest of the developing world who needs it. The result of this study will be disseminated in the following way:

1. The results will be disseminated in national and international seminars and will be published in peer-reviewed journals for sharing within the scientific community.
2. Results will be presented in workshops
3. Results will be used to improve management protocols for moderately malnourished children and will help program managers nationally and internationally as required.
4. Results will help reposition strategies using Nutritional Anthropology as an efficient instrument for BCC for reducing moderate malnutrition in children.

Collaborative Arrangements

Describe briefly if this study involves any scientific, administrative, fiscal, or programmatic arrangements with other national or international organizations or individuals. Indicate the nature and extent of collaboration and include a letter of agreement between the applicant or his/her organization and the collaborating organization. (DO NOT EXCEED ONE PAGE)

This study is a collaborative study between ICDDR,B and BRAC, Bangladesh.

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

Principal Investigator

Name	Position	Date of Birth
Dr. S. K. ROY	Scientist, Clinical Sciences Division, ICDDR,B	November 12, 1950

Academic Qualifications (Begin with baccalaureate or other initial professional education)

Institution and Location Study	Degree	Year	Field of
Dhaka Medical College. University of Dhaka, Bangladesh	MBBS	1973	
London School of Hygiene and Human Nutrition Tropical Medicine, UK	M.Sc	1984	Nutrition
University of London	Ph. D		Nutrition

Research and Professional Experience

Concluding with the present position, list, in chronological order, previous positions held, experience, and honours. Indicate current membership on any professional societies or public committees. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. (DO NOT EXCEED TWO PAGES, USE CONTINUATION SHEETS).

1. 1992-Present Scientist, Clinical Sciences Division, ICDDR,B
2. 1987-92 Associate Scientist, Clinical Sciences Division, ICDDR,B
3. 1981-87 Senior Medical Officer, ICDDR,B

Bibliography

1. **Roy SK**, Chowdhury AKMA, Rahaman MM. Excess mortality among children discharged from hospital after treatment for diarrhoea in rural Bangladesh. *Br Med J* 1983;287:1097-9.
2. **Roy SK**, Chowdhury AKMA, Rahaman MM. Excess mortality among children discharged from hospital after treatment for diarrhoea in rural Bangladesh (letter). *Br Med J* 1983;287:1553.
3. **Roy SK**, Rabbani GH, Black RE. Oral rehydration solution safely used in breast-fed children without additional water. *J Trop Med Hyg* 1984;87:11-3.
4. **Roy SK**, Speelman P, Butler T, Nath S, Rahman H, Stoll BJ. Diarrhoea associated with typhoid fever. *J Infect Dis* 1985;151:1138-43.
5. **Roy SK**, Haider R. Is nutritional status deteriorating in Bangladesh? *Health Pol Plann* 1988;3:325-8.
6. **Roy SK**. The importance of zinc. *Food Laboratory Newsletter* (Stockholm, Sweden) 1988;133:11-2.
7. **Roy SK**, Shome GP, Alam AN, Haider K. Chloramphenicol resistant *Salmonella typhi* (Case report). *J Diarrhoeal Dis Res* 1988;41-2.
8. **Roy SK**, Alam AN, Majid N, Khan AM, Hamadani J, Shome GP. Persistent diarrhoea: a preliminary report on clinical features and dietary therapy in Bangladeshi children. *J Trop Pediatr* 1989;35:55-9.
9. **Roy SK** and Tomkins A. The effects of severe zinc deficiency on growth, food intake, diarrhoea and pathological changes in intestinal tissue. *Bangladesh J Nutr* 1989;2:1-7.
10. **Roy SK**, Akramuzzaman SM. Understanding and management of persistent diarrhoea. *Bangladesh Priv Med Pract J* 1990;1:25-33.
11. **Roy SK**, Haider R, Akbar MS, Alam AN, Khatun M, Eeckels R. Persistent diarrhoea: clinical efficacy and nutrient absorption with a rice based diet. *Arch Dis Child* 1990;65:294-7.
12. **Roy SK**, Akramuzzaman SM and Akbar MS. Persistent diarrhoea: total gut transit time and its relationship with nutrient absorption and clinical response. *J Pediatr Gastroenterol Nutr* 1991;13:409-14.

13. **Roy SK**, Akramuzzam SM, Haider R, Majid N, Khatun M, Akbar MS, Alam AN. Persistent diarrhoea: factors affecting absorption and clinical prognosis during management with a rice-based diet. *Acta Pediatr* 1991;81 (suppl 381):139-43.
14. **Roy SK**. Effect of zinc supplementation in patients with acute and persistent diarrhoea. *Glimpse (ICDDR,B Newsletter)* 1991;13:3.
15. **Roy SK**, Behrens RH, Haider R, Akramuzzaman SM, Mahalanabis D, Wahed MA, Tomkins AM. Impact of zinc supplementation on intestinal permeability in Bangladeshi children with acute diarrhoea and persistent syndrome. *J Pediatr Gastroenterol Nutr* 1992;15:289-96.
16. **Roy SK**, Rahman M, Mitra AK, Ali M, Alam AN, Akbar MS. Can mothers identify malnutrition in their children?. *Health Pol Plann* 1993;8:143-9.
17. **Roy SK**, Akramuzzaman SM, Haider R, Khatun M, Akbar MS, Eeckels R. Persistent diarrhoea: efficacy of a rice-based diet and role of nutritional status in recovery and nutrient absorption. *Br J Nutr* 1994;71:123-34.
18. **Roy SK**, Tomkins AM. Zinc diarrhoea link. *Dialogue on Diarrhoea* 1994;56:7.
19. **Roy SK**. Zinc Supplementation in the treatment of childhood diarrhoea. *Indian J Paediatr.* 1995;62:181-193.
20. **Roy SK**, Tomkins AM, Akramuzzaman SM. Current management of persistent diarrhoea and malnutrition in developing countries. *Hong Kong J Paediatr.* 1995;1(suppl):100-113.
21. **Roy SK**, Haider R. Persistent diarrhoea: Appropriate dietary management. *Dialogue on Diarrhoea*, issue 37, June 1989.
22. **Roy SK**, Islam A, Molla A, Akramuzzaman SM, Jahan F, Fuchs G. Impact of single megadose of vitamin A at delivery on breastmilk of mothers and morbidity of their infants. *Eur J Clin Nutr* 1997;51:302-307.
23. **Roy SK**, A M Tomkins S M Akramuzzaman, R H Behrens R Haider, D Mahalanbis, G Fuchs. Randomized controlled trial of zinc supplementation in malnourished Bangladeshi children with acute diarrhoea. *Arch Dis Child* 1997;77:196-200.
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25. **Roy S.K.** Complementary feeding in children of South Asia. UNICEF Special Publications. Regional Office of South Asia, Kathmandu, 1997.

26. **Roy S.K.**, Islam A, Ali R, Islam K.E, Khan R. A, Ara S. H, Saifuddin N.M, Fuchs G.J. A randomized clinical trial to compare efficacy of erythromycin, ampicillin and tetracycline in the treatment of cholera in children. Trans. Royal. Soc. 1998 Vol;92: 460-2.
27. **Roy S.K.**, Childhood Diarrhoea. In : Child Health Dialogue. AHRTAG. 1998
28. **Roy S.K.**, Tomkins A.M., Akramuzzaman S.M., Haider R, Behrens R.H., Fuchs G. Impact of zinc supplementation on persistent diarrhoea in malnourished Bangladeshi Children. Acta Paediatrica. 87;1235-9:1998.
29. **Roy S.K.**, A.M. Tomkins, R. Haider, R.H. Behrens, S.M. Akramuzzaman, D.Mahalanbis, G.J. Fuchs. impact of zinc supplementation on subsequent growth and morbidity in bangladeshi children with acute diarrhoea. European Journal of Clinical Nutrition 53:529-34:1999
30. Roy S.K. , A.M. Tomkins, R. Haider, R.H. Behrens, S.M. Akramuzzaman, D. Mahalanbis, G.J. Fuchs. Impact of zinc supplementation on subsequent growth and morbidity in Bangladeshi children with acute diarrhoea. European Journal of Clinical Nutrition. 1999.

PAPERS PUBLISHED AS CO-AUTHOR

1. Butler T, Islam M, Islam MR, Azad AK, Huq MI, Speelman P, **Roy SK**. Isolation of *Yersinia enterocolitica* and *Y. intermedia* from fatal cases of diarrhoeal illness in Bangladesh. Trans R Soc Trop Med Hyg 1984;78:449-50.
2. Butler T, Knight J, Nath SK, Speelman P, **Roy SK**, Azad MAK. Typhoid fever complicated by intestinal perforation: a persisting fatal disease requiring surgical management. Rev Infect Dis 1985;7:244-56.
3. Akbar MS, **Roy SK**. Combating nutritional disorder: what promises? Dhaka Shishu Hosp J 1988;4:18-25.
4. Khatun F, Nahar N, **Roy SK**. Acute diarrhoea: an evaluation of non-host factors in children of Bangladesh. Bangladesh J Nutr 1989;2:26-35.
5. Haider R, **Roy SK**. Persistent diarrhoea: appropriate dietary management. Dialogue on diarrhoea 1989:37.
6. Behrens RH, Tomkins AM, **Roy SK**. Zinc supplementation in diarrhoea: fortification

against malnutrition (letter). Lancet 1990;336:8712.

7. Akbar MS, **Roy SK**. Persistent diarrhoea and its management. Touch 1991; 10:69-71.
8. Akbar MS, **Roy SK**, Banu N. Persistent diarrhoea: management in algorithmic approach using a low cost rice based diet in severely malnourished Bangladeshi children. J Trop Pediatr 1993;39:332-7.
9. Rahman M, Mitra AK, Ali M, Alam AN, Akbar MS, **Roy SK**. Maternal Health as a determinant of the nutritional status of the child. J Trop Pediatr 1993;39:86-8.

Co-Principal Investigator

Name	Position	Date of Birth
George J. Fucfs	Director, Clinical Sciences Division, ICDDR,B	November 3, 1951

Academic Qualifications (Begin with baccalaureate or other initial professional education)

Institution and Location	Degree	Year	Field of Study
University of Missouri-Columbia	B.A	1974	
University of Missouri-Columbia	M.D	1980	

Research and Professional Experience

Concluding with the present position, list, in chronological order, previous positions held, experience, and honours. Indicate current membership on any professional societies or public committees. List, in, chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. (DO NOT EXCEED TWO PAGES, USE CONTINUATION SHEETS).

Internship/Residency:		Year	specialty
Institution			
Good Samaritan Hospital Phoenix, Az	Internship	1980	Intern Med
Phoenix Hospitals Affiliated Program Phoenix, Az	Internship	1981	Pediatrics
Tufts-New Engl Med Ctr Boston, MA	Residency	1981-1983	Pediatrics

Clinical/Research Fellowships:

1983-1984 Geographic Medicine and Ped GI/Nutrition eEngl Med Ctr	1984-1985 Ped Infect Dis University of Texas Health Science Centre At Houston	1985-1986 Ped GI/Nutrition University of Texas Tufts-New Health Science Centre At Houston
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Positions:

1995-Present	Director, Clinical Science Division, ICDDR,B Dhaka, Bangladesh
1992-Present	Associate Professor of Pediatrics LSU Medical School, New Orleans, LA
1990-1994 Jan-Mar 1990	Visiting Scientist Research Institute of Health Sciences Chiang Mai University (Thailand)
1990-1992	Acting Chief, Division of Gastroenterology and Nutrition LSU Medical School, Director of GI/Nutrition, Children's Hospital, New Orleans, LA
1986-1992	Assistant Professor of Pediatrics, LSU Medical School, New Orleans, LS

Board Certification:

National Board of Medical Examiners (1981)
FLEX (1985)
American Board of Pediatrics (1986)
Pediatric Gastroenterology (ABP), (1991)

Society Memberships:

North American Society for Pediatric Gastroenterology and Nutrition (1986)
Infections Disease Society of America (1986)
American Academy of Pediatrics (1987)
American Gastroenterology Association (1989)
American Society for Clinical Nutrition (1994)

Publications (10 selected):

1. Fuchs G.J. ,Mobassaleh M, Donohue-Rolf A, Montgomery RK, Grand RJ, Keush GT. Pathogenesis of Shigella diarrhoea:rabbit intestinal cell microvillous membrane site for shigella toxin. *Infect Immun* 53:372-377,1986.
2. Fuchs G.J, Culbert S, Pickering LK. Acinobacter calcoaceticus sepsis in children with malignancies. *Pediatr Infect Dis* 5:545-549, 1986.
3. Klein K, Fuchs GJ, Kulapongs P, Mertz G, Suskind RM. Endotoxemia in protein-calorie malnutrition. *J Pediatr Gastroenterol Nutr* 7:225-228, 1988.
4. Fuchs GJ, Ruiz-Palacio G, Pickering LK. Amebiasis in the pediatric population. In: Amebiasis: Human infection by Entamoeba histolytica. Ravdin JI (ED), Jone Wiley and Sons, Inc., New York, 1988.
5. Fuchs GJ, Dewier M, Hutchison SW, Sundeen M, Schwartz S, Suakind RM. Gastrointestinal blood loss in older infants: Impact of cow's milk versus formula. *J Pediatr Gastroenterol Nutr*. 16:4-9, 1993.
6. Fuchs GJ, Farris RP, Dewier M, Hutchison SW, Warriar R, Doucet H, Suakind RM. Iron status and intake of older infants fed cow's milk with cereal versus formula. *Am J Clin Nutr* 58:343-348, 1993.
7. Fuchs GJ, Ausayakhun S, Ruckphaopunt S, Tansuhaj A. Relationship between vitamin A deficiency, malnutrition and conjunctival impression cytology. *Am J Clin Nutr*. 60:293-298, 1994.

8. Fuchs GJ, Tienboon P, Linpisarn S, Nimsakul S, Leelapat P, Tovanabutra S, Vanida Tubtong, DeWier M, Suskind RM. Nutritional factors and thalassaemia major. *Arch Dis Child* 74:224-227, 1996.
9. Faruque ASG, Fuchs GJ, Albert J. Changing epidemiology of cholera due to *Vibrio cholera* O1 and O139 Bengal in Dhaka, Bangladesh. *Epidemiol Infect* 116: 275-278, 1996.
10. Teka T, Faruque ASG, Fuchs GJ. Risk Factors for death in under-five children attending a diarrhoea treatment centre. *Acta Paediatr*. 85: 1076-1079, 1996.

Detailed Budget for New Proposal

Project Title: Feasible means to address moderately malnourished children within BINP communities.

Name of P.I.: Dr. S.K. Roy

Protocol Number: 99-041 **Name of Division:** Clinical Sciences

Funding Source: World Bank **Amount Funded (Direct):** \$ 142,766

Indirect: \$ 21,415 **Amount (Total):** \$ 164,181

Starting date: As soon as possible **Closing date:** 18 months after start

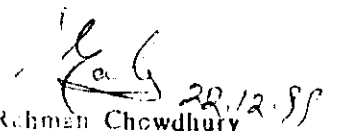
Categories	Level	Position	No.	Rate/ Month	%	US Dollars
1) Personnel:						
Dr. S. K. Roy		Principal Investigator	1	1,800	25%	8,100
Prof. G. Fuchs		Co-principal Investigator	1			
Dr. Investigator	NO-A		1	650	100%	11,700
Dr. Akramuzzaman		Co-Investigator	1	1,106	20%	3,982
Sr. Operation Researcher	NOB		1	758	10%	1,364
Anthropologist	GS-6 (CSA)		1	355	100%	6,390
Nutritionist	GS-6		1	465	100%	8,370
Medical Officer	NO-A (CSA)		1	492	100%	8,856
Sr. Field Res. Asstt.	GS-4 (12 months)		1	278	100%	3,336
Supervisors	GS-4 (CSA)		4	206	100%	14,832
Health Assistants	(CSA)		20	102	100%	36,720
Clerk	(CSA)		1	80	100%	1,440
Sub-total						105,090
2) Consultant :						
Collaborative Consultant (Dr. Zeba Mahmood)				600	10%	1,080
Communication Specialist (Anish Barua)				600	20%	2,160
Sub-total						3,240
3) Travel:						
Local Projects						4,000
Dhaka and project site						3,500
International						4,500
Field visit honorarium						1,800
Sub-total						13,800
4) Supplies						
Office supplies						2,000
Medical supplies						1,000
Office furniture, cabinet etc.						2,000
Sub-total						5,000

5) Other Expenses :

Phone & fax	2,316
Printing and publication	1,440
Microcomputer & data analysis	3,000
Office rent	2,880
Dissemination seminars	2,000
Support for local community	2,000
IEC Materials	2,000
Sub-total	15,636

Total Direct Cost	142,766
Indirect Cost @ 15%	21,415

Total Project Cost US\$ \$ 164,181


M. Rahman Chowdhury
Senior Budget & Cost Officer
ICDDR, B, Mohakhali
Dhaka-1212, Bangladesh.

Budget Justifications

Please provide one page statement justifying the budgeted amount for each major item. Justify use of man power, major equipment and laboratory services

PI: The principal Investigator will spent 25% of his time for the study and will be responsible for overall designs, monitoring of progress, quality control for whole research work and administration at every step.

Co-Principal Investigator: The co-principal investigator will help with design, decision making and actual planning of study (no funds).

Co-Investigators: Two ICDDR, B Co-investigators and one investigator for partner NGO, BRAC would be needed to make visits in 4 divisions and training of the senior level staff and their expertise would be as used in the project.

Senior Operation Researcher's: The Senior Operation Researcher will be necessary to assess the cost-effectiveness of the nutrition education strategies. He/She will mainly provide the guidance in designing the data collection instrument and analyzing the cost-effective data. His time will be needed for 18 months.

Communication Specialist: A Communication expert will help with training plan for health education and the strategy for implementation. Discussion structure would be developed for breast-feeding and other training issues. He will supervise strategies and IEC materials.

Nutritionist: A Nutritionist will be needed for developed lesson plans for the training of health assistants, training anthropometry, and other nutritional issues to the health assistants, intensive health education to the mothers, Visit food demonstration sessions and complementary feeding sessions, giving easy nutrition education to the mothers.

Anthropologist: An anthropologist will be needed to conduct Focus Group Discussions, conduct intensive training sessions for the health assistants, assuring quality of the data collected by the health assistants, and help with Nutritionist for FGD based health education training plan.

Senior Field Research Assistant: The Field Research Assistant will be assigned for collecting cost information, who will report to the Senior Operations Researcher of the Health Economics Programme, will be needed to supervise the field data collection and will be needed for full time for 12 months.

Supervisors: One in each division will supervise field work and maintain quality control for Health Assistants at field level for education, training and data collection.

Communication: Field visits from Dhaka to 4 divisions would be necessary to supervise monthly evaluation and progress of work at the field level. There will be transportation need; this will be for study area and for bringing staff and data to office and as necessary in community.

Dissemination: Dissemination will be done by seminar, productions of reports and publication in national and international nutrition and policy related journals. The results are expected to benefit developing countries in a unique and potential way. Which will be communicated through internal policy and program in the conferences.

Facilities: Analysis of data would require a microcomputer and other logistics would be required for running of the project.

Other Support

Describe sources, amount, duration, and grant number of all other research funding currently granted to PI or under consideration. (DO NOT EXCEED ONE PAGE FOR EACH INVESTIGATOR)

Time frame of the study

Months	1	2	3	4	5	6	7	8	9	10	12	13	14	15	16	17	18
Initial set up	■	■															
Staff training			■														
Operations Intense				■	■	■											
Operations Reinforce							■	■	■								
Observations										■	■	■	■	■	■		
Analysis																■	
Manuscript Writing																	■

Training plan:

In this study there will be three tiers of training sessions:

(A) A special core training session for project Nutritionist, Anthropologist, Medical Officer and field supervisors will conducted by Principal Investigator and co- Investigators.

Duration: 8 hours/day for 10 days.

Venue: ICDDR,B, Dhaka.

(B) A special core trainer session for health assistants will conducted by Medical Officer, Nutritionist, and Anthropologist.

Duration: 8 hours/day for 10 days

Venue: ICDDR,B, Dhaka.

(C) Training session¹ on the nutrition knowledge for the mothers':

Participants : Recruited subjects' mothers who will participate in FGD session.

Trainer : Health Assistants

Number of participants: Ten to twelve mothers in a group

Duration : Two hours

Sitting arrangement:

CNC areas with one or two mats for trainee mother /caretakers and a tool for trainer and a table for demonstration of complementary food preparation at the household level and discuss their new knowledge with each other.

Steps of the training session:

First steps: Current issue of social events.

Duration: Minimum 5 minutes.

Procedure: The trainer Health Assistants first introduces herself with all trainee mothers/caretakers and asks the participants to introduce themselves. Then the trainer will speak with all trainee mothers about current nutritional status for their children. Then the trainer will speak on about training issues.

Duration: 20 minutes.

Materials:

1. Colored IEC materials, Philip chart, posters on different nutrition items.

Topics: The trainer gives identified essential messages about breast feeding, weaning food items, complementary food preparation, child nutrition, caring practice, personal hygiene and sanitation according to the knowledge gap of the mothers/caretakers, found from FGD session.

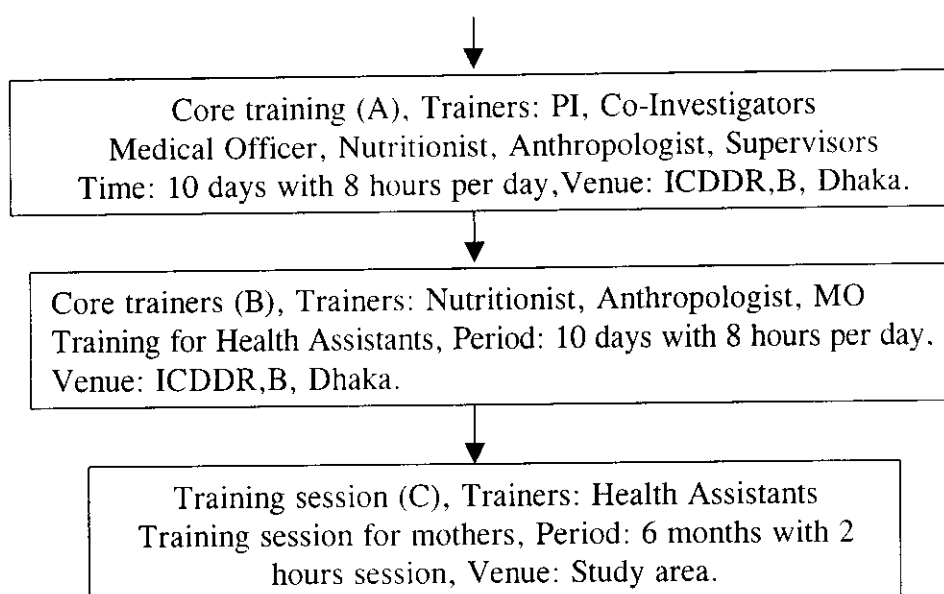
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About two hour later trainer will take feedback from the trainees about training session.

Participation in training sessions will be recorded.

¹ A bangla curriculum has been developed for the health assistants to the trainee mothers

Diagram reflection the communication strategy



Frequency and intensity of the two intervention groups

A. Intensive Nutrition Education

Topic	3 mon. Intervention (Frequency/week)	Number of training sessions	3 mon. Reinforcement: (Frequency/week)	Number of training sessions
Nutrition concept on diet	2 per week	24	1per week	12
CP, BF & Hygiene	1per week	12	1per 2week	6
Food Demonstration & House hold food mobilization	1per week	12	1per month	3
Referral/ Disease control	1per week	12	1per month	3

B. Less intensive Nutrition Education

Topic	3 mon. Intervention: (Frequency)	Number of training sessions	3mon. Reinforcement: (Frequency)	Number of training sessions
Nutrition concept on diet	2 per wk for 1 m.	8	1per week	4
	1per wk for next 2 m.	8	2 per month	4
CP, BF & Hyg	1per 2 week	6	1per month	3
Food Demonstration	1per 2week	6	1per month	3
HH Food mobilization	1per 2week	6	1per month	3
Referral/ Disease control	1per2week	6	1per month	3

আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র
মহাখালী, ঢাকা - ১২১২

সম্মতি পত্র

গবেষণার নাম : মাঝারি মাত্রার অপুষ্টি শিশুদের অপুষ্টি নিবারণের জন্য বাস্তবধর্মী পদক্ষেপ নির্ণয়

মাঝারি মাত্রার অপুষ্টিতে আক্রান্ত শিশুর পুষ্টি অবস্থা উন্নতিকল্পে এবং এক বছরের কম বয়সের শিশুর অপুষ্টি প্রতিরোধে গ্রহণযোগ্য এবং কার্যকরী উপায় খুঁজে বের করার জন্য বাংলাদেশ সমন্বিত পুষ্টি প্রকল্পের আওতায় আমরা একটি গবেষণা কার্যক্রম হাতে নিয়েছি। শিশুর স্বাস্থ্যগত অবস্থা উন্নতির জন্য এই গবেষণা কার্যক্রমটি পরিচালনা করা হচ্ছে এবং এইজন্য আমরা আপনাকে এই গবেষণায় অংশগ্রহণে আমন্ত্রণ জানাচ্ছি। আমরা শিশুর স্বাস্থ্য বিষয়ে কিছু তথ্য আপনার কাছ থেকে জানব এবং কিভাবে শিশুর স্বাস্থ্য ও পুষ্টি অবস্থার উন্নতি করা যায় সে বিষয়ে আমরা আপনাকে বলব, যা আপনি আপনার শিশুর ক্ষেত্রে কার্যকরী করতে পারবেন।

যদি আপনি এই গবেষণায় অংশগ্রহণে সম্মত হন তাহলে আপনার এবং আপনার শিশুকে নিম্নলিখিত কার্যক্রমে অংশগ্রহণ করতে হবে :

- ১) সম্পূরক খাবার (খিচুড়ী) এবং বাড়ীতে রান্না করা খাবারগুলো মিশিয়ে শিশুর জন্য পুষ্টিকর খাদ্য তৈরী করার ব্যাপারে আপনাকে বিশদ পুষ্টি শিক্ষা অথবা স্বল্প পুষ্টি শিক্ষা দেয়া হবে।
- ২) শিশুর যত্ন সম্পর্কে আপনাকে বিশদ শিক্ষা দেয়া হবে এবং বাড়ীতে শিশুকে কিভাবে খাওয়ানো উচিত সেই ব্যাপারে আপনার চিন্তাধারা এবং শিশুর যত্ন ও খাদ্য সম্পর্কে আপনার ধারণা আপনি আমাদেরকে বলবেন।
- ৩) এক বছর যাবত প্রতি পনের দিন পর পর শিশুর অসুস্থতার বিষয়ে আমরা খোঁজ নেব।
- ৪) এক বছর যাবৎ প্রত্যেক মাসে একবার করে আপনার শিশুর ওজন ও উচ্চতা পরিমাপ করা হবে।
- ৫) এই গবেষণায় আপনার শিশু অন্তর্ভুক্ত হবে কিনা, তা আপনার সিদ্ধান্ত। গবেষণা চলাকালীন সময়ে আপনার শিশুকে প্রত্যাহার করলেও আপনার শিশু আমাদের নিয়মিত সেবা থেকে বঞ্চিত হবেনা।

আপনি যদি এই গবেষণায় অংশগ্রহণে রাজী থাকেন তাহলে এই সম্মতি পত্রে স্বাক্ষর/টিপসই দিন।

গবেষকের স্বাক্ষর

সাক্ষীর স্বাক্ষর

মাতা/পিতা/অভিভাবকের স্বাক্ষর

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International Centre for Diarrheal Disease Research, Bangladesh

Consent Form

Title of the Research Project: Feasible means to address moderately malnourished children within BINP communities.

Principal Investigator: SWAPAN KUMAR ROY

Before recruiting into the study, the study subject must be informed about the objectives, procedures, and potential benefits and risks involved in the study. Details of all procedures must be provided including their risks, utility, duration, frequencies, and severity. All questions of the subject must be answered to his/ her satisfaction, indicating that the participation is purely voluntary. For children, consents must be obtained from their parents or legal guardians. The subject must indicate his/ her acceptance of participation by signing or thumb printing on this form.

We have undertaken a research project to find out feasible and effective means to improve nutritional status of moderately malnourished children and prevent infants from malnutrition within Bangladesh Integrated Nutrition Project (BINP) communities. The research work is being conducted to improve the health of the children and therefore we are inviting you to take part in this research. We shall ask you some information about child health and we shall also tell you how to improve child health and nutrition, which you can also practice for your child. If you agree to take part in this study then you and your child will have to go through the following procedures:

- 1) You will receive either intensive nutrition education or less intensive nutrition education on preparation of complementary feeding (Khichuri) and mix of cooked food for feeding your child.
- 2) Intensive counseling on caring practices will be given to you as well as you will tell us how you think your child should be fed at home and your views about his food and health care should be given.
- 3) You will be asked about your child's illness at fortnightly intervals for a one year period.
- 4) Weight and height of your child will be measured once in a month for a period of one year.
- 5) You will decide for participation of your child in this study. If your child does not participate in this study, she/he will still receive the standard services from us.

If you agree to take part in this study please put your signature/thumb impression in this consent form.

Signature of PI
Name

Signature of witness

Address

Date:

Date:

Signature/thumb impression
of guardians
Address

Date

Annexure-1

1: Nutrition and health education:

Malnutrition is not a medical and or a health problem alone. It is not a food scarcity and or a poverty problem either. It is rather a social problem stemmed out of ignorance, defective food habit, mistaken status identity, and related others. Addressing the issue of malnutrition thus demand interventions geared to behavior change which requires structured awareness building and educational efforts on nutrition and health.

1.a. Nutrition & Health Education Strategy.

A Nutrition & Health Education Strategy will be developed at the very beginning of the project based on the following considerations:

- that the project is an educational intervention;
- that less intensive education is to have greater focus over high intensive education to test its effectiveness for a nation-wide replication;
- that the audience (subject) will primarily cover illiterate/semiliterate women/families with some emphasis on local elite for their supportive and promotional roles;
- that the project is aim at sustainable behavioral change related to dietary practices, food preparation and consumption patterns and basic health care especially of your children, pregnant/lactating mothers and family members;
- that there will be set messages and tested food items for promotion;
- that there will be grassroots workers to reach the audience and their families; and
- that there be an in-built mechanism for monitoring of the effects leading to impact.

The Strategy will encompass the following specific activities :

- a. A review of existing information and knowledge regarding subject's (audiences') health and nutritional practices;
- b. Development of specific and alternative (to suit area/seasonal variations) messages related to different food items and its ingredients;
- c. Selection and training of health & nutrition workers on communication and motivational skills and on selected food items with their preparation based on set manual(s) and discussion guidelines;
- d. Appropriate supportive visual aids, samples/models will also be developed for interpersonal, organizational and community media;
- e. HNWs will then organize and conduct educational and motivational sessions with mothers, community members at individual and group levels;
- f. Localized advocacy efforts will also be initiated to mobilize support of local elite and community members; and
- g. Certain reminder materials like poster-calendars for families, booklets/leaflets for students and elite/leaders, flags for static centers, etc. will also be developed and used.

1.b. The Discussion Guidelines

Training of NHWs on Communication and Motivational Skills will be crucially important. These NHWs will eventually organize and conduct discussion sessions with mothers and others food items, its preparation and consumption. Accordingly, Manuals with lesson plans and discussion guidelines respectively will be developed to prepare and equip NHWs for the task.

The Discussion Guidelines for the NHWs to conduct the discussions with mothers will be based on the following steps :

- a. exploration of the subject's present practices with reasons;
- b. introduction of alternative practices and or food items as potentially better;
- c. presentation of economic, health and other benefits of the alternative(s);
- d. solicitation of subject's acceptance to test the alternative; and
- e. description and demonstration of its preparation and administration/
consumption.

This has to be followed by the subject's testing or trial to extend psychological support, responding to her/his additional queries and building faith and confidence in changing her/his behavior and practice.

A sample Discussion Guideline of shown below -

Session Title: Breast Feeding

Objectives : After the session, the participating mothers will be able to

- a. Identify Breast Milk as the best gift of nature/God to a mother and a child;
- b. Describe (some) the feeling while breast feeding their children;
- c. Explain the advantages and benefits of breast feeding;
- d. Describe the importance of colostrum and its administration; and
- e. Narrate the ideal breast feeding practices.

Duration : 120 minutes

Lesson Plan:

Objectives: Process	Content Points	Materials	Time
1. - Greet and welcome the participants			3m
- Introduce yourself and get others			7m
- Explain the objective and duration of the session	- Exchange experiences and new ideas on breast feeding	- Cards	2m
	- 90m		
- Share the importance of openness and participation	- Learning & help others to learn	- Illustration	5m

2. – Ask, what is the God’s/Natures’ best gift to a mother and a child ? - Probe and process the responses	- Views from participants - Mother’s milk	- Poster - Picture	5m 5m
3. - Ask, what are the present practices regarding breast feeding ?	- Views on colostrum, starting, frequency, duration, other foods, etc.	- Poster/ Picture	8m
4. – Synthesize and summarize		- Poster	5m
5. – Ask, what are your feelings while breast feeding your child ?	- Expressions of participants		10m
6. – Appreciate the expressions and note down the important points	- Important points	- Poster	5m
7. – Ask, what are the advantages and benefits of breast feeding ?	- Points from Participants	- Poster	10m
8. – Probe, process and present	- natures best gift and inexpensive - readily available in sufficient quantities - it is fresh and does not need worming - children love it and it bonds - it has preventive and anti-infective properties - it supplies essential nutrients ideal for child’s growth	- Poster	15m
9. – Add the following messages with explanation	- Colostrum must be fed to children as soon as child’s birth - Exclusive breast-feeding should be continued up to the age of six months. - Breast-feeding should be continued up to two years - Children should be fed with breast milk as many times as possible. - Learn about best practices about breast feeding for your and child’s benefit.	- Poster/Picture	15m
10. – Summarize the basic points to remember and thank everyone.			10m

Similar discussion structure will also be developed for other issues.

2. **Khichuri** will be explained and demonstrated how to prepare at home of a study subject.

Food ingredient	Quantity
Rice	2 fistful (65g)
Pulse	1 fistful (27g)
Oil	5 teaspoon full (30ml)
Potato	large (Hugh), small one piece (40g)
Sweet guard	small one piece (15g)
Green leafy vegetables	1 teaspoon after (15g)
	Cooking
	Egg/meat/fish 1piece (55g)
Water	4 glasses

Procedure:

900 k.cal (55g protein)

Required amount of rice, pulse and oil to be boiled in a container. After some times, potatoes are mixed and then sweet pumpkins to be added. Green leafy vegetables to be added 5 minutes after boiling of rice and to cover the container is to be covered for 25 minutes to cook the 'khichuri'.

After cooking the khichuri, its weight to be about 850 gram. Mothers' were advised to cook in her time preferably in the morning and feed. Khichuri in 5-6 schedules in a day.

The following procedure shown to prepare home made feeding for children:

3. Food cooked in the family are to be taken together such as cooked rice, dhal potato, vegetable fish or egg as available, thoroughly mixed and extra oil about 5-67 teaspoonful is added and feed to the child 4-5 times a day.
4. To show the mothers how to prepare a supplementary feeding packet at home, which was essentially the same as given in CNC by CNP. Roasted rice powder (40 g) roasted pulse powder (20 g) molasses (10g) and 6 g of oils about one teaspoonful. At the time of thoroughly mixing these ingredients, water has to be added to make consistency from thick to liquid according to the preference of child. Older child likes more thick and younger one likes more liquid.

About vegetables:

5. Vegetables are very important part of the diet. They are rich in β -carotene and vitamin C and contain significant amount of calcium, iron and other minerals.

6. Dark Green leafy vegetables (DGLV) are the most valuable because they contain more β -carotene and vitamin C, more calcium and iron, than pale green leaves and other vegetables.
7. Amaranth is much superior to cabbage or lettuce as it contains vitamins and mineral.
8. A green leafy and other vegetable play a major role in reducing vitamin A deficiency, and contribute to lessening the prevalence of iron deficiency anemia.
9. Dietary deficiency of vitamin A affects the eyes and it can lead to blindness.
10. The nutritive value of different seasonal fruits is their contents of vitamin C, B and energy.
11. Zinc is present in most foods of animal origin. Good sources include chicken, beef, mutton, sea fishes, legumes and wheat. Zinc deficiency has decreased efficiency of food utilization, poor growth, depressed gonadal functions, and frequent diarrhoea and other infection.

Iodine salt:

12. Only iodized salt should be used in the household food preparation. Adequate dietary iodine improves growth and increases intelligence and its absence cause growth failure, failure in life skills.

About egg:

13. Each egg contains a high proportion of essential amino acids necessary for growth, is rich in fat and contains very good quantities of calcium, iron, zinc, vitamin A and D and also thiamin and riboflavin.

About fat:

14. Fat is important because it has more than twice (9 Vs 4 kcal per gram) as much energy as carbohydrates, or protein. Thus it can reduce the bulk of the diet. Child need more energy in small amount of diet as his stomach is small. It issues vitamin in body and adds good taste to diet.

About caring practice:

15. Caring practice would include washing and bathing as required. It included encouragement to the child to play and have attentions as soon as child demands. Other members of the family should give attention to child if he demands anything.

About personal hygiene:

16. Cleaning and identifying a feeding plate for the child would be necessary, as quantity of food will be known when a child has been give food in a defined container. A child needs adequate food for growth satisfactory.

Disease Control:

17. Mothers would be given counseling on disease control, such as advice on immunization at time, referral to health family in illness. Preventive care for cold, and taking to FWCs for ARI, high fever, and diarrhoea frequent is necessary.
18. Counseling will be done how to identify moderate degree malnutrition. GMP card available in family or CNC will used. Counseling will be given on consequence and risk of malnutrition from disease or inadequate feeding of a child.
19. Village Nutrition Management Committee (VNMC) will be given regular orientation during monthly meetings to accept the philosophy that children of their own village should be healthy and they can remove child malnutrition from their village if they follow and guide a few simple principles about child care and feeding.

Annexure 2

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

1. In this operations research project, we are proposing a community trial in 4 of the BINP thanas in 4 divisions to address the effective and feasible means to prevent and reduce moderately malnourished children and under two years. The Bangladesh Integrated Nutrition Project (BINP) is an initiative of the Government of Bangladesh to reduce severe malnutrition and growth faltering of infants, children under two, and malnutrition in pregnant and lactating women. A recent operations research in Shahrasti thana of Chandpur district has demonstrated significant implementation of moderate malnutrition with intensive nutrition education. It is therefore important to study the feasible means to replicate the nutrition education program for large-scale improvement. To address this issue, an operations research will be undertaken in one thana in each of 4 divisions over an 18-month period. A total of 750 moderately malnourished children will be studied in intensive and less intensive nutrition education groups from 48 community nutrition centers. A group of 380 mildly malnourished children and another group of 100 well nourished 6-9 months old infants will be studied in two groups of less intensive education or no education for preventive effect of nutrition education. The mothers of the first intervention group in moderately malnourished group will receive intensive nutrition education on child feeding, complementary food preparation, and preparation of mixed food household food for first 3 months then will be reinforced for next 3 months. The second intervention group will receive a less intensive education for 3 months then will be reinforced for next 3 months. CNP, CNO s and women group and village nutrition committee will be involved in the process for adoption of the nutrition education for regular program.
2. There is no potential risk to the subject. No blood will be drawn for study purpose.
3. Medical advice will be given to subjects of all groups in the form of enhancing referral to THC of FWC.
4. Privacy of the subject will not be interrupted. All the information will be kept with investigators and will not be available to others.
5. Signed consent form will be obtained from the mothers after explaining them the procedures of the study. The objectives and benefits of the study will also be described to them.
6. Mothers will be interviewed for their knowledge and practices of child feeding and caring. Morbidity history of children will also be recorded. This interview will require 10 to 15 minutes. This will not reduce their normal activity for practical significance.
7. It is assumed that if the intervention is successful, improving nutritional status the knowledge of mothers about child feeding will benefit individual child. Benefits to society will be reflected by overall improvement in nutritional status. The IEC on dietary practice and nutrition education will

be communicated to the village members and village nutrition management committee for their use. The study is likely to give a long-term benefit to the society. It is expected that the results of the study will demonstrate how to reduce moderate malnutrition in large proportion of children. This will also reduce the risk of developing severe malnutrition.

8. No hospital records including treatment, birth or death will be required. Only children's body weight and length will be measured or recorded from GMP cards. No organ, tissue, or body fluid will be used.

Annexure 3

Detail discussion on malnutrition

Role of morbidity in causing malnutrition:

UNICEF has popularized the concept that there are three determinants of malnutrition namely

- a) lack of food security,
- b) lack of disease control and
- c) lack of caring practices.

Increased illness is known to be significantly related to genesis of malnutrition. Malnutrition in children continues in a vicious cycle of infection---malnutrition--infection. Studies reported from Bangladesh and other countries have shown that frequent diarrhoea causes malnutrition and invasive diarrhoea is responsible for stunting in children. (Henry FT 1993) It is known that severely malnourished children have associated infections, many of which are sub clinical. It is also possible that moderately malnourished children have reduced immunity compared to well nourish children and this would increase risk of infections.

Role of food insecurity in causing malnutrition

A child needs adequate amount of food with necessary nutrients for regular growth, health and development. Growth of young children is faster and after six months of age, only breast-feeding can not support adequate growth. Therefore appropriate complementary feeding needs to be provided by caregivers. Young infants and children have limitation of stomach capacity and quality of food with adequate nutrient density and frequent feeding is necessary. There are different concepts of mothers and caregiver on child feeding. Frequent cause of child malnutrition has been identified as not giving enough energy, protein and minerals and vitamins during fast growth. A common finding has been feeding of cereal-based porridge of diluted milk formula when requirement for adequate growth is not met. Traditionally in Bangladesh good practice of appropriate complementary feeding is almost absent due to absence of such food or food mixes. Therefore a child is often given less energy dense food and at a frequency as given to adults e.g. three times a day. This gives an energy deficit condition leading to slower growth. After exclusive breast feeding, growth faltering occurs in most of the children due to inadequate complementary feeding. A traditional practice of child feeding is mainly responsible for malnutrition of children in Bangladesh, virtually there is no culture of giving right kind and timely introduction of complementary feeding. A major part of intervention of child malnutrition and ensuring adequate growth would be therefore to help mothers and care givers with empowerment with teaching how to prepare and feed appropriate complementary feeding. It is important to note that infantile malnutrition begins soon after exclusive breast-feeding and therefore any child at risk shows signs of growth retardation within one year of age. Unfortunately, in Bangladesh, infants grow with insufficient breast milk and insufficient complementary feeding at a period of rapid growth. It is an important strategic consideration to start appropriate complementary feeding at right age. If all infants after 6 months and possibly within 9

would be a radical reduction in rate of malnutrition in young children. It is appropriately suggested by UNICEF to reach every child before one year of age in regard to identify and ensure good practice of feeding. Every child has to be exclusively breast fed up to 6 months of age. But soon after this period, they need to be adapted with non-breast milk complementary food including ingredients of family food. The properties of a complementary feed for young children at the young and fast growing stage should be easily available, cheap, able to support growth with adequate energy and nutrient density as well as adequate micro nutrients. Home based diet should be ideally promoted to help nutritional catch up or maintenance of good health. Food security at household level is vulnerable to family's ability to produce or buy and therefore extreme poor houses are under some process of food insecurity. Linking them with BINP inter-sectoral sub projects, as nutrition gardening or poultry may help it. BINP has inter-sectoral sub projects such as poultry, pisci-culture, nutrition garden that can be utilized by the vulnerable families.

Role of caring practices in child nutrition

Mother and the care givers of a child need to ensure caring the child in providing adequate feeding by appropriate breast feeding such as exclusive breast feeding up to six months of age, and continue for 2 years, provide appropriate complementary feeding after six month of age. Often, the traditional culture and food taboos pose obstacles for giving timely complementary feeding. Good complementary feeding would mean to ensure quantity and quality of feeding. Caring practice would include child stimulation by playing, and giving encouragement to the child. Giving immunization and adopting with other health care program such as vitamin A capsules and providing care for environmental health hazards. Young children frequently suffer from illnesses due to under-developed immune system. It is important to give early medical services to reduce suffering and cut the cost of diseases. In doing so appropriate referral system is to be ensured and availed. Mothers should be equipped with knowledge about the harmful effect of the diseases for child growth and mortality. Women empowerment with ability to feed the child properly and take medical care adequately is likely to ensure the caring ability of the mother. Early detection of learning disability and responding to the environment and emotional need is also essential part of caring practices.

Importance of appropriate breast-feeding practices:

It necessary to ensure exclusive breast feeding from birth to 6 months. At present, only 15% of children are exclusively breast-fed. Therefore it is a big challenge to get 100% exclusive breast-feeding. The infants should get appropriate complementary feeding from 6 months to 24 months. In this period family food need to be introduced. There is a need to caution that even children up to 24 months are rapidly growing, they are not adults, they need more than 3 times a day frequency of complementary feeding and they do not get food outside home like the adults.

Prevention of malnutrition:

The preventive approach would essentially address the determinants of malnutrition from early infancy.

Complexity of malnutrition

Malnutrition in the children is the results of long sequence of inter-linked events. Inadequate dietary intake and diseases are the most immediate cause of malnutrition. Diseases, especially infectious diseases affect dietary intake and nutrient utilization. The underlying causes can be numerous and usually inter-related. Child-care can be reduced due to maternal illness and maternal malnutrition. Direct effect is reduced breast-feeding and lack of energy and initiative for childcare. Maternal malnutrition and close gap between pregnancies, unsafe water for drinking and washing, lack of environmental sanitation, overcrowding, absence of proper hand washing after defecation, lack of immunization, helminthes infestations, unequal distribution of food and resources, communicable and non communicable diseases, major micro nutrient deficiencies and lack of proper facilities to treat common disease of childhood by qualified physicians and many other factors are responsible for the risk or cause of malnutrition in childhood. Four countries in Asia, namely India, Indonesia, The Philippines and Thailand provide good examples of nutrition intervention programs to tackle PEM in young children (Lofti et al, 1990). The interventions include (De Onis et al, 1993) growth monitoring and promotion (BBS, 1992); breast feeding and supplementary feeding (World Summit for Children, United Nations, 1990); health and nutrition education and health services for severe nutritional deficiencies (Maria et al, 1994); food demonstration and home gardening (Cook et al, 1971); family planning services (Beaudry et al, 1973); immunization. (Beghin et al. 1973); supply of micro-nutrients. Malnutrition is a result of intertwined political, socioeconomic, cultural and health relationships in a given situation. A multi-sectoral, integrated" bottom up' approach involving the community in all community intervention programs including problem identification, intervention planning, implementation, monitoring and evaluation has been emphasized for success of such programs.

It is conceivable that genesis of moderate malnutrition may be the growth faltering of well-nourished children. The second mechanism may be the shifting of severely malnourished children into moderately malnourished groups as they improve. The consequence of malnutrition in childhood is very significant. Childhood retardation in growth affects cognitive development, thereby schools performance and quality of life. Malnutrition of moderate grade is less obvious to identify and is given less attention. Moderately malnourished children are also compromised in host resistance; therefore frequent suffering from disease is usual. That has economic and social cost on the family and country as a whole. Malnourished children grow into malnourished adults who are in disadvantaged situation compared to healthy nations. Economic growth, physical quality of life indexes (PQLI) and progress is therefore largely dependent on nutritional status in early childhood.

Understanding of malnutrition by mothers:

A recent study done in Bangladesh showed that about 80% mothers could correctly identify malnutrition of their children (Roy et al 1993). It has been shown in that study that 66% of the uneducated (education 0 year), 74% of less educated (education 0 - 5 years) and 69% of better educated (> 5 years) mothers correctly detected under nutrition. When weight for height (wt/ht < 80% median NCHS) was used as an indicator of malnutrition, mothers correctly identified malnutrition with a specificity of 79%.

Annexure 4.

Results from the initial study at Shahrasti:

The objective of the study was to find an effective means to reduce the proportion of moderately malnourished children by one-third of the existing level in a short period. The study was initiated by stratified random sampling of alternately situated CNCs in 15 of 3 Unions in Shahrasti Thana. In all 15 CNCs were randomly selected in three study groups. 5 CNCs a total of 282 moderately malnourished subjects aged 6 months to 2 years. Subjects who were given supplementary feeding for growth faltering were excluded from the study.

Three study groups were studied of which the control group received the standard BINP advice on nutrition and health education twice in a month. Mothers of the second group received a more intensive nutrition education on food security, disease control and caring practices. Mothers of the third group received intensive education and their children received an additional supplementary feeding of BINP packets of 300 kcal daily for 6 days a week. The intervention was continued for a period of three months and subjects were observed for a period of a further three months. The research team in the field was composed of a medical officer, a nutritionist, an anthropologist, two supervisors and 8 health assistants, selected from the local community. The village nutrition management committee (VNMC) was involved in monthly meetings for motivation of parents, two of the women's support groups assisted in assembling the mothers of the children for weekly nutrition education. A baseline survey was conducted on childcare, feeding, demographic and socioeconomic status. Focus group discussion at baseline was done by the anthropologist on perceptions on child feeding, food taboos, use of growth enhancing food, function of food for child growth, caring practices during illness on health seeking behavior. Nutrition education package was developed with the help of the knowledge gained from FGD. Mothers' points of resistance were identified and messages and explanations were built for necessary improvement in behavior change communication (BCC).

Nutrition education was given to mothers on selected issues:

- 1) Instruction of preparation of an energy dense, protein adequate convenient food from household ingredients namely Khichuri (Annexure-1) which can be prepared in the morning and can be fed to child for 5-6 times a day to give approximately 750 kcal per day. The recipe ensures essential amino acids from a reference protein source and adequate energy from oil source as well as mixes of vegetables.
- 2) To prepare complementary feed from household cooked foods with addition of extra oil. Other snack foods were demonstrated to feed in between. Breast-feeding was also appropriately promoted.

Data collection on anthropometry e.g. weight, length and mid upper arm circumference was done by the health assistants at two weekly intervals, morbidity at weekly interval, food intake and feeding practices at weekly intervals on pre-designed questionnaire. Point prevalence survey was conducted to find the practices of mothers on child feeding behavior. The study subjects were followed up for observation for a period of three months in absence of intervention.

There was significant improvement in nutritional status with intensive nutrition education in three months time. The results show that the nutrition and other education reduced 56% of moderate malnutrition, supplementary feeding and nutrition education reduced 64% and there was 30% reduction in the control group.

Net weight gain (grams) over three month's of intervention was 436 Vs 320, 688 Vs 334, 910 Vs 636 grams at one month, 2 months, and 3 months of intervention in education Vs control group respectively. The weight gain in group receiving both supplementation and education was even grater, 487g at 1 month, 763g at 2 month, and 1061g at three month respectively. The rate of weight gain in 3 months was 104, 154 and 182 g/kg in control, education and SF+ education group respectively ($p < 0.001$). There was substantial improvement in complementary feeding frequency (average 5.3 from 2.5 times per day) associated with nutrition education compared with the control group.

Weight gain was correlated negatively with age of the child, and body weight but positively height. Weight gain was negatively associated with prevalence of diarrhoea and febrile episode, blood in stool when controlled for other factors. There was no significant difference in net weight gain between the education and supplemented groups ($p < 0.1$). There was change in behaviour related to home feed preparation and identifying specific foods for child feeding in groups reducing nutrition education. There was a seasonal effect on disease pattern. At certain times, most of the children had suffered from fever and diarrhoea, which was followed by faltering body weight. Incidence of diarrhoea was 13/100-child month, 19/100-child month and 16/100-child month in control; education and supplementary feeding group respectively. Incidence of acute respiratory tract infection (ARI) was 10/100 child month, 3/100 child month and 2/100 child month during intervention in control, education and supplementary feeding group respectively. It was found that mothers did not have special idea on the quality and quantity issue of a complementary food for the child or recognizing a special need during rapid growth. Their practice of child feeding in time or frequency was traditional. Some mothers had idea that disease of a child is a God's will and they would take him to a local hekim for purified water or kabiraji treatment. Some mothers had strong belief that expensive foods or fruits like grapes, apples etc. form blood. They had believes on hot and cold food and practice of with holding food during illness was common. Food items such as oil and egg were considered to be too strong, gas producing and indigestible for young children. There were complaints of not getting attention in Thana Health Complex when they visited for treatment of their children.

Follow up FGDs at the end of three months intervention were conducted and showed significant important in negative ideas on adding oil to children's feed and addition of eggs in home made complementary feed cooked "Khichuri". Referral to medical service centres remained a problem of not getting service from the thana health centres during that need.

For preparation of food and taking care of the child, mothers' time was critically important e.g. during harvesting period, mothers could find little time for cooking supplementary food as well as make the child feed by herself. Mothers cooked extra khichuri for children on 3-4 days a week. Alternate food mixes taught by health assistants were given from family pots during the weekdays. Many of the poor families could manage only one meal a day and could not afford to buy varieties and ideal ingredients to prepare complementary food. With frequent nutrition education, parents purchased dietary items which mothers

initially resisted because they perceived not essential for better child growth. Mothers reported that with the improvement in nutritional status of moderately malnourished children, their husband took more initiative to buy more special foods for their children. These items included soybean oil (usually cooking was done with mustard oil), eggs, lentils/dhal and different colored vegetables. Superstitions and food taboos on some food items were almost removed in the intervention groups.

Some improvements were also observed in the control group, which attributed to all or some of the following reasons: a) Two weekly nutrition education was given to mothers of the moderately malnourished children by CNPs and CNOs of the implementing NGO. b) The NGO workers (CNO/CNP) adopted and used specific messages from instruction of our health assistants at the field level. C) The baseline data on prevalence of malnutrition was collected immediately after the flood and therefore there was natural recovery in the first month in all the study groups after flood period. D) The study period covered the harvesting season enabling a better food intake in all groups.

Children from all groups were followed up for an additional period of 3 months after the intervention. The improvement weight gain continued steadily only in the intervention groups.

We concluded that, the substantial reduction in moderately malnourished children through nutrition education and SF has significant potential to reduce this staggering problem. Further research is needed to define the intensity of education needed to achieve sustained improvement.

S.A., Hope this is helpful!

Reviewer - I

Best,
Jim

May 1999

TO: S.K. Roy

FROM: Jim Levinson

SUBJECT: Your O.R. Draft on Feasible Means to Address Moderately Malnourished Children

Bondhu, I'm so delighted to see that you and ICDDR,B are taking this moderate malnutrition issue so seriously. On the basis of your earlier study and this one, I would imagine we can develop the basis for reducing moderate malnutrition significantly in BINP and the NNP.

Since this clearly is a major study, I would hope we could utilize it to provide the most crucial information we need on the moderate issue for BINP and NNP. I've offered 6 major suggestions below, and then some minor points.

Major Suggestions:

1. I thought the first study idea of doing the O.R. jointly with BRAC was excellent. I'd suggest the same in your Phase 2 study so that you can have the advantage of working with a group on the ground, can have the advantage of on-the-spot reality and feasibility checks, and to assure that results will translate into action quickly.
2. I'm not sure that the cohorts as you have them will be most helpful in filling information gaps. We already have some experience, for example, with less intensive nutrition education since, in fact, this is what BINP has been doing. Instead, how about the idea we discussed with George and Kabir, namely comparing as cohorts: (a) behavioral change communications in the context of feeding for all 6-9 month olds, and (b) behavioral change communications carried out at the household level (which might involve carrying around to each home some well-prepared complementary food in a tiffin carrier to help facilitate complementary food introduction at 6 months.)
3. There is some very specific information we need from this study, beyond the cohort effects, to inform BINP and NNP operations. This includes
 - a. the specific messages being disseminated, and the constraints and resistance points faced; our information from BINP is that a number of messages also have to be disseminated to husbands and mothers-in-law - this should be documented.
 - b. the specific behaviors which have changed as a result (we must be sure not to jump from intervention to anthropometry without checking the behaviors per se.)
 - c. the sustainability of these behavioral changes (do they remain changed 6 and 12 months later?)
 - d. is food necessary to make these changes happen (i.e. to get overworked mothers to devote this amount of time on counseling.)
 - e. is the counseling best done in a group setting or in the home?
 - f. what CNP training is necessary to make this happen?

The very most important behavioral change for children of this age would seem to be timely introduction of complementary food. It would be good to know before and after the intervention, what proportion of infants are receiving complementary food at 6 months, 7-9 months, 9-12 months, and over 12 months.

To make sure we don't duplicate BINP work already done, you should be sure to look carefully at the pre-BINP formative research carried out on behaviors. (You can get from Kabir). It's quite thorough as to constraints and resistance points.

4. In the study as presently designed, you look carefully at two of the determinants of malnutrition (caring practices and morbidity) but not at food security information, i.e. economic status. Let me suggest that we profile right at the outset all the moderates by economic status (using the groupings already on the registration form (at least in Phase 2 thanas), and also by gender, and that we organize our results, accordingly by economic status and gender. In terms of the former, this would allow us to ask the question of whether the moderates from poor families will benefit as much from this intervention as moderates from households economically better off.¹
5. Why use mildly malnourished kids as a control group, when it would be perfectly ethical to use moderates in other areas experiencing the normal BINP intervention? Using "milds" as a control group would certainly bias the results, yes?
6. You seem to want to introduce different systems to deal with morbidity. Why not leave everything except the behavioral change the same as BINP so that results will be fully applicable?

Minor Points

Page 7 - Your discussion under food security seems to apply more to caring practices.

Page 12 (middle) - UNICEF is now suggesting that reaching a child before age 1 is yet better.

Page 16 - Note my comments #1 and 2 above.

Page 17 - Second full sentence: I've never seen such evidence.

How do you explain the 30% reduction in the control group?

Last full sentence: It would be useful to indicate more about the data used to assess complimentary feeding frequency. A recent BRAC study found that time constrained women rarely have the time to provide as many daily feedings as BINP suggests, particularly if this requires even one more cooking operation per day.

Page 18 (last four lines) - It would be useful to know how this compares and how it differs from what BRAC does now - another reason for doing the research together.

Page 29 (comment about project physician) - see my comment #6 above.

Page 31 (outcome variable #2) - Do we really care about her ability to identify "moderate" malnutrition. (I'm not sure I could do it!) I would think her ability to identify malnutrition period would be adequate.

(outcome variable #6) - Looking again at comment #6 above, how much "medical" care is a child in BINP likely to get.

I share your high expectations for this study and what it can provide. I'm sure you'll do another great piece of work.

¹ If you have birthweight data - which you might for children under 2 in BINP thanas - it also would be terrific to group the moderates by low or adequate birthweight, and see whether the interventions benefit each equally.

Response to reviewer's comments on " Feasible means to address moderately malnourished children within BINP Communities"

Reviewer-1.

Major suggestions

1. BRAC has been taken as a collaborating partner.
2. Suggestion taken. 6-9 months old infants are now in study and control groups for comparing behavioral change communication.

It is passive and appears as an impractical approach to move house to house with Khichuri/CF and feed each eligible child, but may be interesting.

3.
 - a. Specific messages developed from earlier study at Shahrasti will be used in this study and many information will be generated from this study to develop specific messages for mothers and decision-makers of the families.
 - b. Specific behavior changes which has made difference has been available from the earlier study and has been given in Background section and in appendix.
 - c. Sustainability of behavior change for a period of 6-12 months; this will be answered from the present study. Earlier study has shown a 3-month period sustainability during the observation period.

d. Is food necessary for this change?

The study will test the effect of nutrition education on behavior change leading to change of nutrition of a child without outside supplementation. Food security for a child is a precondition for adequate growth. Home based feeding is sustainable and cost effective solution which the study will explore at various setting.

e. Is the counseling best done in a group setting or at home?

The earlier study used a small group setting for education and in exceptional case individual counseling. Both were effective but former is better in terms of time, manpower and building group confidence in new believes.

f. What training is necessary for CNPs?

The study protocol has provision to work out this in details with implementing NGO at a stage when project has established smooth operation.

Duplication of BINP work has been avoided. The formative research already done has been considered during development of this project.

4. What is the differential impact of this approach on children from lower or better socioeconomic status?

The study will have a cross section of all children and impact will be analyzed by socioeconomic strata. Earlier study has shown no significant impact of economic status except very exceptionally poor and disadvantaged house holds. It will be considered with other confounding variable of growth as food security, disease control and caring practice all are considered together for growth performance.

5. Why use mildly malnourished children as controls?

Mildly malnourished children will be in education and no education to see the preventive effect of the nutrition education. They will match as perfect control for comparison. They will not be compared with moderately malnourished group.

6. Why introduce different system to deal with morbidity?

No additional efforts will be made for morbidity control as suggested by reviewer. Referral system is yet to take a momentum to address morbidity in BINP beneficiaries.

Minor points:

These have been addressed as suggested.

INSTITUTE OF NUTRITION, MAHIDOL UNIVERSITY

Phuttamonthon 4, Nakhon Pathom 73170, Thailand

Phone: 66 (02) 4419035 to 9 Fax: 66 (02) 4419344

Fax Cover Sheet

URGENT

DATE: ~~29 July 1999~~ | October 1999

TO: Dr. S.K. Roy PHONE: 880-2-871751-60 FAX: 880-2-883116
28D DR, B DHAKA, BANGLADESH 880-2-888050

FROM: Enam Wasantwatt PHONE: (662) 4419740
871568
871686

RE: Proposal Review

Number of pages including cover sheet: 5

Message Dear Roy : As you've requested AGA?
Any questions, please E-mail me.
Best Regards,
Enam

BINP/OPRP PROPOSAL EVALUATION SCORING FORM (1)

TH

1002

2/5

BINP/OPRP PROPOSAL EVALUATION SCORING FORM (1)

Please score on a 1-5 scale: 1 = very bad - 5 = very good

Project Proposal Title "Feasible means to address moderately malnourished children within BINP communities" by S.K. Roy et al.

		SCORE
1	Background	3
2	Description of objectives	2
3	Description of hypotheses or conceptual framework	3
4a	Design: Definitions of key concepts and variables	3
4b	Design: Sample size and sampling strategy	4
4c	Design: Clarity of analysis plan	3
4d	Design: Feasibility of proposed methods	3
4e	Design: Adequacy of any interview form or laboratory methods	3
5	Feasibility of time schedule	4
6	Adequacy of budget	3
7	Research capacity	4
TOTAL SCORE		35

8	Appropriateness toward answering research question Please Comment	Yes	No
	The study design and methods, if appropriately conducted should be able to answer the main research question. Certain clarity on objectives are needed. (see weaknesses in 10.)	/	

2/5

BINP/OPRP PROPOSAL EVALUATION SCORING FORM (2)

9.	Please describe ethical considerations, if any None
10.	In summary please describe a. the strengths of this proposal <p style="text-align: center;">See attached page</p> b. the weaknesses of this proposal <p style="text-align: center;">See attached page</p>

CONCLUSION	
(please tick)	
<input type="checkbox"/>	support the application
<input type="checkbox"/>	a. without qualification
<input type="checkbox"/>	b. with qualification
<input type="checkbox"/>	do not support the application

PROPOSAL : FEASIBLE MEANS TO ADDRESS MODERATELY MALNOURISHED CHILDREN WITHIN BINP COMMUNITITES

BY S.K. ROY et al

10. SUMMARY

10a. Strengths of the proposal

The proposal addresses an important issue to explore a feasible and effective approach to reduce moderate malnutrition in young children. Based on the preliminary findings, the investigators propose to investigate the effect of less intensive nutrition education as the practical means for intervention as well as prevention purposes. The study outcome should be applicable to the nationwide program to improve nutritional status of infants and preschool children.

10b. Weaknesses of the proposal

The proposal on an overall basis, needs readjustment. Certain sections are too lengthy and some parts should be elaborated. Specific comments are as follows:

Terminology: The word "curative" is misleading and implies medicinal approach with therapeutic treatment at hospitals or health centers and is NOT appropriate to be used with a nutrition education and/or food-based approaches which are "preventive" in nature.

1. A list of abbreviations used in the proposal should be provided.

Background: This section is way too long (16 pages!!) and tends to be repetitive, the focus areas can be highlights on BINP which contains the malnutrition status in young children and major determinants, preliminary findings in Shahrasti and finally, the rationale leading to this study which at the present stage is unclear and should be linked to the preliminary study in Shahrasti. One caution: the investigators mentioned the term "sustainability" of the procedure, if this is to be tested, evaluation of sustainability must be included in the specific objectives and design. Appropriate references need to be added to this section

Objectives: The section containing hypothesis, conceptual framework and objectives should be rewritten. The objectives lack clarity and focus and are not in agreement with the design. Conceptual framework should be drawn as diagram.

Materials and methods: Some revision is needed. This section will be more clearer if the content can be grouped, for example, SITE SELECTION, SAMPLE SIZE CALCULATION, SUBJECT SELECTION AND RANDOMIZATION, INTERVENTION, PERIOD OF STUDY (justification on seasonal effect).

In regard to the method used, why not involve the assessment of Knowledge

there is NO component to evaluate sustainability or cost-effectiveness, the investigators must decide whether to include these components or not.

6. Another point that needs clarification in the METHOD section is about WHO, HOW and HOW FREQUENT the intensive or less intensive Nutrition education will be carried out. Some information is provided in Annex 1 which should be included in the METHOD. Data management should consider that certain incomplete data may be corrected in the field and NOT to wait for reporting to the investigators which could be too late!

7. Significance of the study: The design of this study at present does not address SUSTAINABILITY. Another issue of strengthening health supportive system and personnel needs to be brought up which is not within the scope of this study but may affect the study results.

8. Investigators's experiences: It is not clear and does not reflect research experiences of the principle investigators and team.

Budget: this part should be grouped for clarity. Salary and honorarium should be justified. I question the "International travel" as relevant at this point. What about field operation expenses besides personnel like per diem, fuel and driver, vehicle rent, living expenses or subsidization for field workers?

Reviewer 2

Q.1. Terminology: The word “curative” is misleading and implies medicinal approach with therapeutic treatment at hospitals or health centers and is NOT appropriate to be used with a nutrition education and/or food-based approaches which are “preventive” in nature.

Ans.1. The word “curative” is omitted from the text and has been corrected accordingly.

Q.2. A list of abbreviations used in the proposal should be provided.

Ans.2. The list of abbreviation used in the proposal are given on **page 3**.

Q.3. Background: This section is way too long (16 pages!!) and tends to be repetitive, the focus areas can be highlights on BINP which contains the malnutrition status in young children and major determinants, preliminary findings in Shahrasti and finally, the rationale leading to this study which at the present stage is unclear and should be linked to the preliminary study in Shahrasti. One caution: the investigators mentioned the term “sustainability” of the procedure, if this is to be tested, evaluation of sustainability must be included in the specific objectives and design. Appropriate references need to be added to this section.

Ans.3. Background section has been reduced, focussed and sustainability is omitted on **page 7**.

Q.4. Objectives: The section containing hypothesis, conceptual framework and objectives should be rewritten. The objectives lack clarity and focus and are not in agreement with the design. Conceptual framework should be drawn as diagram.

Ans.4. a . Hypotheses and objective is modified on **page 6**.

b. Conceptual framework has been given as diagram on **page 12**.

Q.5. Materials and methods: Some revision is needed. This section will be more clearer if the content can be grouped, for example, SITE SELECTION, SAMPLE SIZE CALCULATION, SUBJECT SELECTION AND RANDOMIZATION, INTERVENTION, PERIOD OF STUDY (justification on seasonal effect).

Ans.5. Material and methods has been grouped and made clearer on **page 13**.

In regard to the method used, why not involve the assessment of Knowledge Attitude and Practice or KAP? Based on the proposed method and design as such, there is NO component to evaluate sustainability or cost-effectiveness, the investigators must decide whether to include these component or not.

The design will fully permit KAP result in beginning & all end of the study. Cost effectiveness study is not a direct objective of the study.

Q.6. Another point that needs clarification in the METHOD section is about WHO, HOW and HOW FREQUENT the Intensive or less intensive Nutrition education will be carried out. Some

information is provided in Annex I which should be included in the METHOD. Data management should consider that certain incomplete data may be corrected in the field and NOT to wait for reporting to the investigators which could be too late!

Ans.6. WHO, HOW and HOW FREQUENT the intensive or less intensive nutrition education will be carried out have been mentioned in the method section (**page:13**).

Q.7. Significance of the study: The design of this study at present does not address SUSTAINABILITY. Another issue of strengthening health supportive system and personnel needs to be brought up which is not within the scope of this study but may affect the study results.

Ans.7. Sustainability is not included in the objectives. But 6 months of observation will allow measuring it to a greater strength the adoption of the nutrition education by CNP will test more of sustainability through regular counseling.

8. Investigator's experience: It is not clear and does not reflect research experience of the principle investigators and team.

Ans.8. The research experience of the principle investigators and team is reflected in the previous study of "Shahrasti project" and CV is attached.

9. Budget: this part should be grouped for clarity. Salary and honorarium should be justified. I question the "International travel" as relevant at this point. What about field operation expenses besides personnel like per diem, fuel and driver, vehicle rent, living expenses or subsidization for field workers.

Ans.9. Budget has been grouped and justified and given on **page 44**.

Check List

After completing the protocol, please check that the following selected items have been included.

1. Face Sheet Included
2. Approval of the Division Director on Face Sheet
3. Certification and Signature of PI on Face Sheet, #9 and #10
4. Table on Contents
5. Project Summary
6. Literature Cited
7. Biography of Investigators
8. Ethical Assurance
9. Consent Forms
10. Detailed Budget