

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigators: Francoise Moonens Trainee Investigator (if any) Joan Fleischman

Application No. 86-001 Supporting Agency (if Non-ICDDR,B) _____

Title of Study Assessing the Efficacy of a Nutrition Rehabilitation Centre on Improved Nutritional Status Project status:
() New Study
() Continuation with change
() No change (do not fill out rest of form)

Circle the appropriate answer to each of the following (If Not Applicable write NA).

- 1. Source of Population:
 - (a) Ill subjects Yes No
 - (b) Non-ill subjects Yes No
 - (c) Minors or persons under guardianship Yes No

- 2. Does the study involve:
 - (a) Physical risks to the subjects Yes No
 - (b) Social Risks Yes No
 - (c) Psychological risks to subjects Yes No
 - (d) Discomfort to subjects Yes No
 - (e) Invasion of privacy Yes No
 - (f) Disclosure of information damaging to subject or others Yes No

- 3. Does the study involve:
 - (a) Use of records, (hospital, medical, death, birth or other) Yes No
 - (b) Use of fetal tissue or abortus Yes No
 - (c) Use of organs or body fluids Yes No

- 4. Are subjects clearly informed about:
 - (a) Nature and purposes of study Yes No
 - (b) Procedures to be followed including alternatives used Yes No
 - (c) Physical risks NA Yes No
 - (d) Sensitive questions NA Yes No
 - (e) Benefits to be derived Yes No
 - (f) Right to refuse to participate or to withdraw from study Yes No
 - (g) Confidential handling of data NA Yes No
 - (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure Yes No

- 5. Will signed consent form be required:
 - (a) From subjects Yes No
 - (b) From parent or guardian (if subjects are minors) Yes No

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

7. Check documents being submitted herewith to Committee:

- ___ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
- ___ Protocol (Required)
- ___ Abstract Summary (Required)
- ___ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
- ___ Informed consent form for subjects
- ___ Informed consent form for parent or guardian
- ___ Procedure for maintaining confidentiality
- ___ Questionnaire or interview schedule

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:

- 1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
- 2. Examples of the type of specific questions to be asked in the sensitive areas.
- 3. An indication as to when the questionnaire will be presented to the Cttee. for review.

(PTO)

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

F. Moonens
Principal Investigator

Joan Fleischman
Trainee

ABSTRACT SUMMARY

1. See materials.
2. None - only invasion of privacy
3. Data will be maintained using code numbers.
4. None.
5. a) As most patients are illiterate, a verbal explanation will be made.
b) NA
c) NA
6. Interviews will be conducted in the homes.
7. See significance section.
8. NA

SECTION-I: RESEARCH PROTOCOL

- 1. Title: Assessing the Efficacy of a Nutrition Rehabilitation Centre on Improved Nutritional Status
- 2. Principal Investigators: Francoise Moonens
Bonita Stanton
- Trainee Investigator: Joan Fleischman
- 3. Starting Date: 1 March, 1986
- 4. Completion Date: 31 August, 1986
- 5. Total Direct Cost: US\$ 5,397.00
- 6. Associate Director for CSR Program:

This protocol has been approved by the Community Services Research Working Group.

Signature of the Assoc. Director for CSR Program: _____

Date: 29.12.85

7. Abstract Summary:

The evaluation of supplementary feeding programs has been mandated in recent reviews. Controlled, long term studies are necessary to clarify whether programs are effective in improving nutritional status. 85 children have been treated at Kaliganj Nutrition Rehabilitation Centre and followed at regular intervals for 6 months after discharge. Anthropometric measurements have also been collected at regular intervals for children in the non-intervention area of the Water and Sanitation project. Cases can be matched with controls of the same sex, age, nutritional status, and socioeconomic status at time of admission to the feeding centre. The analysis will determine whether the weight differential established during attendance at the centre is maintained 6 months after discharge.

8. Reviews:

- (i) Ethical Review Committee: _____
- (ii) Research Review Committee: _____
- (iii) Director: _____

SECTION-II: RESEARCH PLAN

INTRODUCTION

a) Objective

To evaluate the efficacy of a community-based Nutrition Rehabilitation Centre on long term sustained improvement in nutritional status.

b) Background

An estimated 227 million U.S. dollars is spent on supplementary feeding programs per year [1], comprising approximately 95% of the total budget for nutrition in developing countries [2]. The most effective way to provide supplementary food is undetermined; and the broader question of whether these programs actually improve the nutritional status of children remains unanswered. There are presently disputes over how long to provide supplementary nourishment; which children benefit from these programs; what type of food is most appropriate, and whether education or infectious disease control should necessarily accompany feeding [1, 3, 4, 5].

The effectiveness of supplementary feeding programs is also highly controversial [6]. In fact, there is some evidence to suggest that programs can be detrimental to the targeted individuals [1, 7]. In Beaton and Ghassemi's review of over 200 evaluations and program reports of nutrition rehabilitation centers, take home feeding programs, feeding centers, and other

food distribution programs the authors stated, "We remain unconvinced that either the true effects or the full benefits of food distribution programs have been measured...." Currently available program reports have limitations which include insufficient details for analysis, lack of baseline data, inadequate statistical testing, subjective conclusions, lack of controls, and inadequate follow-up [1]. Additional evaluations are needed to identify which programs are most successful, and to determine whether supplementary feeding is an effective treatment of malnutrition.

✓ Nutrition Rehabilitation Centres offer advantages over other food distribution programs since they attempt to treat malnutrition through education of mothers and the use of low cost locally available foods [4]. They are usually staffed by local people and located in buildings comparable to village homes [3]. Although these centers are believed to effect nutritional improvement on a long term basis, there is little evidence to support this. Beaton and Ghassemi cited only three controlled studies among all the nutrition rehabilitation centre evaluations reviewed [1]. (In two of these nutritional status was measured during attendance at the clinic ~~but not~~ ^{and} after discharge. Both concluded that there was significant improvement [8, 9].) The other study took one set of anthropometric measurements 9-15 months after discharge and concluded that the centers' effect on weight gain was insignificant. However, the control group used consisted of children who had attended the center for less than one month, creating an obvious bias [3].

The Kaliganj Nutrition Rehabilitation Centre has been operating for 9 months with a followup system incorporated into the program design. 85 children (age range between 18 months and 4 years with an arm circumference smaller than 11.5 cm.) have completed a 3-5 week course during which they are given four meals per day and their mothers are given one. Mothers are required to be present at the centre every morning for a cooking demonstration and a lecture-discussion on nutrition. (For details of this program see "A Manual for Nutritional Rehabilitation Day Care Centre" available upon request.) The mean weight for height percentage averages 78% on admission, 85% on discharge and 89% 12 weeks after discharge.

c) Rationale

The Kaliganj Nutritional Rehabilitation Centre (KNRC), an example of a community based supplementary feeding program, has been managed for 9 months by local volunteers who maintain the daily curriculum, recruitment of patients, community relations, and an effective follow up system. Anthropometric measurements are being taken throughout childrens' stay at the centre, and 2 weeks, 6 weeks, 3 months, 4 1/2 months, and 6 months after discharge. Short and long term improvement in nutritional status can be evaluated using a control group selected from children in the non-intervention area of the Water and Sanitation Protocol No. 84-023, available on request.

SPECIFIC AIMS

1. To determine if children who attend the KNRC weigh more than control children at the time of discharge.
2. To determine if children who attend the KNRC weigh more than controls six months after admission.
3. To identify factors which predict which children are most likely to benefit from a Nutritional Rehabilitation Centre.
4. To determine the influence of other sociodemographic and health variables on the effectiveness of the program.
5. To determine which aspects of nutritional behaviour (hygienic, feeding practices, food preparation, etc.) are different between families whose mothers have attended the KNRC versus those who have not.

METHODS AND PROCEDURE

Kaligani Nutrition Rehabilitation Centre: (See Pilot Protocol No. 85-005(P)). All children who have attended the centre for more than 3 weeks will be included in the study.

Control group: (See Water and Sanitation Protocol No. 84-023). Controls will be selected from the non-intervention area, where 950 families have been monitored for nutritional status in the past year. From the approximate 1100 children less than 6 years in this area, we shall select control children matching for sex, age within 3 months, weight for height within 5 percentage points, and, if possible, estimated monthly per capita income within 100 Tk. To control for seasonality, control children will be selected within 2 months of the admission. One, and if possible two, controls will be selected for each study subject.

Data collection: Height to the nearest cm. and weight to the nearest .1 kg. continue to be collected every three months for control children. For study subjects, height and weight have been measured during attendance at the Nutrition Rehabilitation Centre, and continue to be measured at 2 weeks, 6 weeks, 12 weeks, 18 weeks, and 24 weeks after discharge. Measurements will also be taken 9 months after discharge for the 55 first children. Census enumeration forms and socioeconomic status forms (see Attachment 1 and 2) will be completed on every family. A 24 hour feeding recall, and a one-month morbidity recall (number of days of illness, hospitalisation) are collected at 3 months, 6 months and 9 months after discharge (See Attachment # 3).

Observations: A random 25% sample of study subjects and controls will be observed for prolonged periods of time for practices covered in the health education including food preparation, consumption of balanced meals, hand washing procedure, and the storage and covering of cooked foods and water (See Attachment # 4). In addition, a case control study will be conducted to compare children who succeeded in maintaining improved nutritional status at 6 months after discharge to those who did not. This will assist in specifying which are the determinant factors of success after leaving the centre.

Analysis: The percent of cases versus controls achieving a 5 and 10% increase in weight/height from admission to discharge,

(short term benefit) and at 3, 6, and 9 months follow-up (long-term benefit) will be compared. Analysis will be performed by using a chi square test, a Fisher exact test, and a Mann Whitney-U test (for non-parametric data.) From the results of our pilot study, we can expect more than 60% of our intervention group and less than 20% of our control group to achieve a 10% increase in weight for height from admission to 3 months after discharge. The sample size of 85 is big enough to give us a power of 0.9. Other nutritional indices and variables to compare the intervention group and the control group might be selected during the analysis, to be best adapted to the results. The importance of initial nutritional status, change in nutritional status during the stay in the Feeding Center, family size, crowding and seasonality on improved weight for height will be analysed. The cost per child for attendance at the KNRC will be determined.

SIGNIFICANCE

The KNRC is a feasible model for treating malnutrition through a community based supplementary feeding program. It is maintained by local staff and is supported by the village. In addition, it uses local food, educates mothers in nutrition and sanitation, and is run at low cost. If shown to be successful it could be easily duplicated. The evaluation will provide information on program efficacy to similar centres operating in Asia, Africa, and Central America.

FACILITIES REQUIRED

1. Office - no additional
2. Laboratory - no additional
3. Logistic -- increased computer time (personnel is already available).
4. Equipment - length board
5. Field space - provided by the community.

REFERENCES

1. Beaton GH, Ghassemi H. Supplementary feeding programs for young children in developing countries. *Am J Clin Nutr* 1982; 35: April.
2. Berg A. The nutrition factor. Washington D.C.: Brookings Institution, 1973; 160-79.
3. Darisme MB, Latham MC. Nutritional rehabilitation centers - an evaluation of their performance. *J Trop Pediatr Env Child Health* 1973;19:299-332.
4. King KW, Fougere W, Webb RE, Bergren G, Bergren WL, Hilaire A. Preventive and therapeutic benefits in relation to cost: performance over 10 years of mothercraft centers in Haiti. *Am J clin Nutr* 1978;31:679-90.
5. Beghin I, Viteri F. Nutritional rehabilitation centers: an evaluation of their performance. *J Trop Pediatr Env Child Health* 1973;19:404-16.
6. Scrimshaw NS. Myths and realities in international health planning. *Am J Public Health*, August, 1974.
7. Henry FJ. Failure of a supplementary feeding program to improve the health of young children. *Ecology of Food and Nutrition* (In press).
8. Devi SY, Pushpamma P. Rural creche: a longitudinal study, Hyderabad, India: Indo-Dutch project for child welfare, Agricultural University, 1978. [cited by Beaton and Ghessemi (1)].
9. King KW, Beghin ID, Fougere W, Dominique G, Grinker R, Foucauld J. Two-year evaluation of a nutritional rehabilitation (mothercraft) centre. *Arch Venez Nutr* 1968;18:245. [cited in (4)].

SECTION-III: BUDGET

A) DETAILED BUDGET

	<u>% Effort</u>	<u>Amount in US\$</u>
<u>Personnel:</u>		
Pediatrician	-	-
Program Evaluators	-	-
Francoise Moonens	-	-
Joan Fleischman	-	-
Nursing (Mrs. Z. Gafur)	100	1,404
Community Health Workers	100	500
Interviewer (for 3 months)	100	500

		Sub-total: 2,404
<u>Supplies and Materials:</u>		
Food - 250 Tk/day x 6 days x 25 weeks		1,293
Measuring board, office supplies		300

		Sub-total: 1,593
<u>Travel:</u>		
Local transport		900
Computer Costs		500

		Grand Total: 5,397
		=====

B) BUDGET SUMMARY

<u>Category</u>	<u>Amount in US\$</u>
1. Personnel	2,404
2. Supplies & materials	1,593
3. Travel	900
4. Computer cost	500

=====
Grand Total: 5,397
=====

Fund have been provided for this analysis by UNICEF and UNDP.

আমি _____ ব্যক্তিগত _____ কাজের মত _____

IDH $\frac{0}{1}$ _____
12

তারিখ- _____
13 - 14

স্বাক্ষর-বিধি প্রথম নিবন্ধ-কাজী :

আমনি যে কাজীতে আছেন ১) হ্যাঁ ২) না ৩) অনিশ্চিত _____
এই বিধি আদেশের নিবন্ধ- _____
19

প্রথম বিধি আদেশের কাজী- ১) হ্যাঁ ২) না ৩) অনিশ্চিত _____
20

আমনি যে বিধি স্বাক্ষর করেছেন
(যে কোন স্বাক্ষর) ১) না ৩) অনিশ্চিত _____
২) < প্রকৃ সফর _____
৩) > প্রকৃ সফর- _____
21

নীচের নিবন্ধসমূহের ক্ষেত্রে তথ্য (কোনটি) আদেশের কাজীতে
আছে।

যা আছে তার 0-5 = 0-5

৬ অর্থসংগ্রহ (স্ব) = 6

অনিশ্চিত = 7

22

23

২৩

২৪

আমনি যে কাজীতে আছেন (সেইজন বিধি নীচের- নিবন্ধসমূহের-
আছে।

স্বাক্ষর ১) হ্যাঁ ২) না ৩) অনিশ্চিত _____
24

অনিশ্চিত- কোন অর্থসংগ্রহ উভয় ১) হ্যাঁ ২) না ৩) অনিশ্চিত _____
25

অনিশ্চিত- অর্থসংগ্রহ ১) হ্যাঁ ২) না ৩) অনিশ্চিত _____
26

ಪ್ರಥಮ ಮಾಪನ

1) 28 2) 29 3) ಅನಿಗಮಿತ 27

ದ್ವಿತೀಯ ಮಾಪನ

1) 28 2) 29 3) ಅನಿಗಮಿತ 28

ತೃತೀಯ ಮಾಪನ

29

ಚತುರ್ಥ ಮಾಪನ

30

- 1) ವ್ಯಾಜ 2) ಗೌಮ 3) ಗೌಮ 4) ಅನಿಗಮಿತ
- 5) ಕಾಡೆ 6) ಪೊದಾ 7) ಅನುಮ

ಪಂಚಮ ಮಾಪನ

2 - 9 = 1 - 5 ಅನಿಗಮಿತ = 7
3 2 3 4 5 6 7 8 9
31

ಷಷ್ಠ ಮಾಪನ - ಪರಿಮಾ (32 ಅನುಮಾನಿತ ಅಥವಾ ಸಂಪೂರ್ಣ)

32 - 36

ಪ್ರಥಮ ಮಾಪನ

37 38

ದ್ವಿತೀಯ ಮಾಪನ

41 42

ತೃತೀಯ ಮಾಪನ

39 40

ಚತುರ್ಥ ಮಾಪನ

43 44

FOLLOW UP VISIT SHEETID: 1 2 3 4 5 6 7 8 9 10 11 12 13 14Name: 15 16 17 18 19 20 21 22 23 24 25 26Date of visit: D 27 28 M 29 30 Y 31 32Number of weeks since discharge: 33 34Name of interviewer: 35 36 37 38 39 40 41 42 43 44 45 46

Presence: 47 present = 1
 absent but will return = 2 (+ date)
 absent but will not return = 3
 absent, do not know if will return = 4

Weight in Kg.: 48 49 50Height in Cm: 51 52

Breastfeeding: 53 Yes = 1
 No = 2

Is there uncooked rice stored in the house: 54 No = 1
 Yes, less than 1 sheer = 2
 Yes, more than 1 sheer = 3

Is the mother present? 55 Yes = 1
 No = 2

(If no who is taking care of the child)

How many times did your child eat yesterday (meals and snacks) 56

What did he/she eat (per each meal)

1.

2.

3.

4.

5.

6.

Was the child ill last month? 57

No = 1
Dysentery = 2
Watery diarrhoea = 3
Temp. + cough = 4
Other = 5 (describe)

Was the child admitted to a hospital? 58

Yes = 1
No = 2

How many days was your child ill: 59 60

Are there stools around the house? 61

Yes = 1
No = 2

Is there uncovered food? 62

Yes = 1
No = 2

If there is food, what is in the pot? 63

Rice = 1
Dal = 2
Vegetable = 3
Chapati = 4
Khichuri = 5
Rice-Niramish = 6
Other = 7 (describe)
No food stored = 8

Is there uncovered garbage? 64

Yes = 1
No = 2

Is there uncovered drinking water? 65

Yes = 1
No = 2

Are there chicken 66

Yes = 1
No = 2

Are there vegetables growth? 67

Yes = 1
No = 2

Does the mother use a cooking box? 68

Yes = 1
No = 2

Was there a major change in the composition of the household since your stay in the feeding centre?

- No = 1
- Death= 2 (who?)
- Birth= 3
- New marriage = 4
- New cohabitant = 5
- Person who left = 6 (who?)

69

Please write the month when it happened

Was there a major change of income since your stay in the feeding centre?

70

- No = 1
- Loss of a job = 2
- Additional job = 3

Other⁺ - 4

Other⁻ - 5

How many times did you change of house?

71

Is your house better than the one you had at the time of your stay in the feeding centre?

72

- Same house = 1
- Yes = 2
- No = 3
- Other house equivalent = 4

Please specify what is different

How many weeks have you been away from Keraniganj since your stay in the feeding centre?

73 74

FOLLOWUP VISIT SHEET

ID: _____

NAME: 1 2 3 4 5 6 7 8 9 10 11 12 13 14

DATE OF VISIT: 15 16 17 18 19 20 21 22 23 24 25 26

NUMBER OF WEEKS SINCE DISCHARGE: 27 28 29 30 31 32 33 34

NAME OF INTERVIEWER: 35 36 37 38 39 40 41 42 43 44 45 46

উপস্থিতি : উপস্থিত = 1
 অনুপস্থিত, কিন্তু ফিরিয়ে = 2 (DATE) 47
 অনুপস্থিত, ফিরিয়ে না = 3
 অনুপস্থিত, ফিরিয়ে আনবে কিনা জানা নেই = 4

ওজন (কিলোগ্রাম): 48 49 50

উচ্চতা (সেন্টিমিটার): 51 52

স্বাক্ষর দুই-খাওয়ালো: হ্যাঁ = 1
না = 2 53

কত ডায় চার্জল বাড়ীতে অস্থায়িত? না = 1 54
হ্যাঁ, ১ অথবা ২ কক্ষ = 2
হ্যাঁ, ৩ অথবা ৪ কক্ষ = 3

স্বাক্ষর উপস্থিতি : উপস্থিত = 1 55
 অনুপস্থিত = 2
 [এক মিনিটের সময়কাল পর্যন্ত কক্ষ

কতদিন আপনার নিম্নে ক'বাব (যেহেতু ? (উত্তী ও শনকা খাবাব)

এ কি (যেহেতু) (প্রত্যক খাবাব)

- ২.
- ২.
- ৬.
- ৪.
- ৫.
- ৬.

গত সাতটা আপনার নিম্নে কি অসুস্থ হয়েছিল ?

৫৭

না = ১

আম্মাকার = ২

পাভনা পায়খানা = ৩

জ্বর + কামি = ৪

অন্যান্য = ৫ [বর্ননা সত্র]

কতদিন অসুস্থ ছিল ?

৫৪ ৫৯

শরমসাতলে গিয়েছিল কি ?

হ্যা = ১

না = ২

না = ২

বাড়ীর আলো পালো তামব অল আছে কি ?

হ্যা = ১

না = ২

না = ২

চাকনা ছাড়া খাবাব আছে কি ? হ্যা = ১

যদি থাকে তবে

হাত = ১

ডাল = ২

আক =

চালনি

হি

কেন্দ্র হতে মায়ার পদ আপনার অংশের কোন অধীন পরিবর্তন এছাড়া কি? 6

- = 1
- = 2
- = 3
- বিবাহ = 4
- নতুন অদ্য = 5

[চার্ট প্রাকলন দয়া করে সেই আয়ের নাম জানান।]

অন্যান্য বিদায় গ্রহন = 6 [ক?]]

কেন্দ্র হতে মায়ার পদ আপনার আয়ের কোন পরিবর্তন দাঁড়াবে কি? 70

- = 1
- অতি = 2
- চাকুরী = 3

অন্যান্য⁺ = 4
অন্যান্য⁻ = 5

{ বিস্তারিত

কেন্দ্র হতে মায়ার পদ কত বার বাকী বদলিয়েছেন? 71

আমাকালীন যে বাকীতে ছিলেন তার মধ্যে কি আপনার বাকী উত্তর

- বাকী = 1
- = 2
- সমা = 3

বাকী পরিবেশ = 4

[করে পরিবর্তনটা বলুন।]

কেন্দ্র থেকে মায়ার পদ বত সপ্তাহ মাঝে কেন্দ্রীয়পন্থা থেকে দূরে আর