ETRICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigators: 
Francoise Moonens
Patricia Stanton

Application No. 86-004

Title of Study Assessing the Efficacy of a Nutrition Rehabilitation Centre on Improved Nutritional Status

Trainee Investigator (if any) 
Joan Fleischman

Supporting Agency (if Non-ICDDR,B)

Project status: 
( ) New Study
( ) Continuation with change
( ) No change (do not fill out rest of form)

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

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

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

4. Are subjects clearly informed about:
   (a) Nature and purposes of study  Yes No
   (b) Procedures to be followed including alternatives used  Yes No
   (c) Physical risks  Yes No
   (d) Sensitive questions  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  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:
   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.
   Examples of the type of specific questions to be asked in the sensitive areas.
   An indication as to when the questionnaire will be presented to the Ctte. for review.
   
We agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects before making such change.

Principal Investigator

Trainee Investigator

JAN 16 1986
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$ 5,597.00

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: [Signature]
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 Kaligani 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 [11]. 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 and during attendance at the clinic but not 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 follow-up 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


### SECTION-III: BUDGET

#### A) DETAILED BUDGET

<table>
<thead>
<tr>
<th>Personnel:</th>
<th>% Effort</th>
<th>Amount in US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatrician</td>
<td>100</td>
<td>1,404</td>
</tr>
<tr>
<td>Program Evaluators</td>
<td>100</td>
<td>500</td>
</tr>
<tr>
<td>Françoise Moehans</td>
<td>100</td>
<td>500</td>
</tr>
<tr>
<td>Joan Fleischman</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Nursing (Mrs. Z. Gafur)</td>
<td>100</td>
<td>1,404</td>
</tr>
<tr>
<td>Community Health Workers</td>
<td>100</td>
<td>500</td>
</tr>
<tr>
<td>Interviewer (for 3 months)</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

Sub-total: 2,404

#### Supplies and Materials:

- Food - 250 Tk/day x 6 days x 25 weeks: 1,293
- Measuring board, office supplies: 300

Sub-total: 1,593

#### Travel:

- Local transport: 900

#### Computer Costs: 500

Grand Total: 5,397
### B) Budget Summary

<table>
<thead>
<tr>
<th>Category</th>
<th>Amount in US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Personnel</td>
<td>2,404</td>
</tr>
<tr>
<td>2. Supplies &amp; materials</td>
<td>1,593</td>
</tr>
<tr>
<td>3. Travel</td>
<td>900</td>
</tr>
<tr>
<td>4. Computer cost</td>
<td>500</td>
</tr>
</tbody>
</table>

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Grand Total: 5,397
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Fund have been provided for this analysis by UNICEF and UNDP.
WATER & SANITATION PROJECT
SOCIO-ECONOMIC STATUS

Form 80

Thana ______________________ Comm ______________________

ID # 0/1/2/3/4/5/6/7/8/9/10/11/12

Date ______________________

Month ____________ Day ____________ Year ____________

Does the head of house hold own:

The house you live in 1) Yes 2) No 7) Uncertain

Some other house 1) Yes 2) No 7) Uncertain

Land (anywhere) 1) No

2) ≤ 1 acre 7) Uncertain

3) 1 acre

How many of the following are owned by your household:

Radio ) exact # 0 - 5 = 0 - 5

Watch ) 6 or more = 6

uncertain = 7

Do you have in your house where you are living now:

Electricity 1) Yes 2) No 7) Uncertain

Water tap or tubewell 1) Yes 2) No 7) Uncertain

Sanitary Latrine 1) Yes 2) No 7) Uncertain

Pit Latrine 1) Yes 2) No 7) Uncertain

Hanging Latrine 1) Yes 2) No 7) Uncertain

The roof of your house is predominantly

The outside wall of your house is predominantly

1) Thatch 2) Bamboo 3) Tin 7) Uncertain

4) Wood 5) Pucca 6) Other

How many rooms in your house

1 - 5 = 1 - 5

6 or more = 6

Uncertain = 7

Approximate income of household last month

Interviewer # ____________ DCA # ____________ Form # ____________
১. হেলার তথ্য

২. আহ্লাদের মাধ্যমে

৩. সুলভ বিষয়ের জ্ঞান

৪. ধারণার প্রতি সচেতনতা

৫. প্রশ্নের উত্তর দেওয়া

৬. ধারণার প্রকাশ

৭. অন্যান্য প্রশ্ন


dh ১


dh ৩


dh ৫


dh ৭


dh ৯


dh ১১


dh ১৩


dh ১৫


dh ১৭


dh ১৯


dh ২১


dh ২৩


dh ২৫


dh ২৭
প্রথম অনুভূতি
1) জান 2) জান 3) জানতে

প্রথম অনুভূতি
1) জান 2) জান 3) জানতে

অবশেষে বিভাগ সাধন কর্মকর্তা
1) শেষ 2) শেষ 3) শেষ 4) শেষ 5) শেষ 6) শেষ

জনপ্রচার - অনুপ্রাণিত অনুপ্লাশ তিন মাস

3 - 5 = 1 - 5, মানোর্ণতা = 7

32 - 36

1) 37 2) 36 3) 41 4) 42

39 40 8 43 44
<table>
<thead>
<tr>
<th>Individual Serial Number</th>
<th>Spouse Serial No</th>
<th>Mother's Serial No</th>
<th>Names of All Members of the Household</th>
<th>Are the members of household physically present at 45</th>
<th>Relation to Head of Household</th>
<th>Age (Completed years)</th>
<th>Date of Birth of the Children under the age of 6 years</th>
<th>Sex</th>
<th>Marital Status (Married/Living as married/Divorced/Separated)</th>
<th>Year</th>
<th>Month</th>
<th>Maid Occupation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>20-44</td>
<td>Yes/No</td>
<td>48-49</td>
<td>48-49</td>
<td>50-51, 52-53</td>
<td>54</td>
<td>Unmarried/Living as married/Divorced/Separated</td>
<td>58</td>
<td>54</td>
<td>58-57</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other Page Used Then</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Total Member in the Household:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Second occupation of head of house:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>How many pregnancies has the first wife of the head of household:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>How many pregnancies have resulted in a live birth:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>How many of those children are still alive:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Is mother nursing any children now Yes-01 No-02 NA-06:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Spot Checked/Reinterviewed:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Edited: 74 75</th>
</tr>
</thead>
</table>
FOLLOW UP VISIT SHEET

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

Name: 15 16 17 18 19 20 21 22 23 24 25 26

Date of visit: D 27 28 M 29 30 Y 31 32

Number of weeks since discharge: 33 34

Name 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 50

Height 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?

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

Was the child admitted to a hospital?

Yes = 1
No = 2

How many days was your child ill?

Are there stools around the house?

Yes = 1
No = 2

Is there uncovered food?

Yes = 1
No = 2

If there is food, what is in the pot?

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

Is there uncovered garbage?

Yes = 1
No = 2

Is there uncovered drinking water?

Yes = 1
No = 2

Are there chicken

Yes = 1
No = 2

Are there vegetables growth?

Yes = 1
No = 2

Does the mother use a cooking box?

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?)

Please write the month when it happened

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

No = 1
Loss of a job = 2
Additional job = 3
Other+ = 4
Other- = 5

How many times did you change of house?

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

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?
FOLLOWUP VISIT SHEET

ID: 1 2 3 4 5 6 7 8 9 10 11 12 13 14
NAME: 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: 33 34

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

এপি: এলেক্ট্রোলেটিক 1

অ্যাপ্লাসিয়া, লেটের অগ্রিং: 2 (DATE)

অ্যাপ্লাসিয়া, সিস্টেমের আস্ত: 3

অ্যাপ্লাসিয়া, নিউরো অ্যান্টিস্ট কোর্স টেন্ডি: 4

অ্যাপ্লাসিয়া (কিলো পার্শণ): 48 49 50

উল্লেখ (প্রক্রিয়া সম্পন্ন): 51 52

হাসপাতাল তথ্য আর্মিনী: 53 1

নো: 2

কে অন্য চেষ্টা করেছে অপুষ্টতা? 54 1

আসা ২ অন্য ভর্তি: 2

সহায় ২ অসুখের বেগুনি: 3

আলোর এপি: এলেক্ট্রোলেটিক 1

অ্যাপ্লাসিয়া: 2

[ঐক্যের সিঞ্চন সম্পূর্ণ হওয়ার পরে]
তাকে আপনার কিছু কথা ভুলে যেও না? (কিন্তু আলোক থাকবে)
যা কি ঘোষণা? (অত্যন্ত থাকবে)

1.
2.
3.
4.
5.
6.

গুরু আপনি আপনার কিছু কথা ভুলে যেও না? ৫

না = ১
আলোক = ২
পাশাপাশি গাঁথানা = ১
কাঁটা + কাঁটা = ৫
অন্যান্য = ৫  

কে কি আমার হয়ে দিল?

না = ১
আলোক = ২

শাসনালী গাঁথানা কি?

না = ২

সাধুর আপনি যাঁকে অল্প করে আশায় কি? এখা = ১

না = ২

চাকরা হাজি মাথায় আস্ত কি?  এখন=

না = ১
আলোক = ২
ardware=

চাকরা থাকে অল্প করে আলোক এখন না হাসি?
কেন্দ্র হত মায়ার পড়া আপনার আমার কাছ হাতে অবরোধ কি?

ঝামে আকালে হরা কাদে কেই আবার নাম জানা।

কলা নম্বর আদায় = 5

কে আচরণ বিদায় শ্রদ্ধা = 6 [কে?

কতটা হত মায়ার পড়া আপনার আমার কাছ পরিবর্তন হলে কি?

= 1

পুরুষ জ্ঞান = 2

কোন কাঠামো = 3

কেন্দ্র হত মায়ার পড়া কত সাদা পাথরি বসানো হয়?

= 1

অন্যান্ত $+$ = 4

অন্যান্ত $-$ = 5

কেন হতে মায়ার পড়া কত সাদা পাথরি বসানো হয়?

= 1

পুরুষ = 2

মাধ্যম = 3

কেন্দ্র পরিবর্তন = 5

কে করে পরিবর্তন করেন?

কতটা হতে মায়ার পড়া কত অপসার মায়ার কগারীগুলো রয়ে দুর্বল অস্ত্র