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Principal Investigator Dr. A.N. Alam

83-002(P)

Trainee Investigator (if any)

Title of Study Wheat Syrup as a caloric Supplement for improving the rate of weight gain in children

Supporting Agency (if Non-ICDDR,B)

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 NA
   (c) Minors or persons under guardianship — (Yes) No

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

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

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

5. Will signed consent form be required:
   (a) From subjects — Yes No
   (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 Committee:
   ✓ Umbrella proposal - Initially submit overview (all other requirements wil be submitted with individual studies
   ✓ Protocol (Required)
   ✓ Abstract Summary (Required)
   ✓ Statement given or read to subjects nature of study, risks, types of que ions to be asked, and right to refus to participate or withdraw (Required)
   ✓ Informed consent form for subjects
   ✓ Informed consent form for parent or guardian
   ✓ Procedure for maintaining confidentia ity
   ___ Questionnaire or interview schedule *

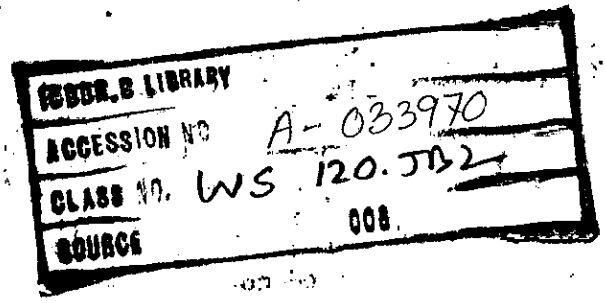
* If the final instrument is not completed prior to review, the following informati should be included in the abstract summa
   1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
   2. Examples of the type of specific questions to be asked in the sensitiv areas.
   3. An indication as to when the questio naire will be presented to the Cttee. for review.

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

Principal Investigator

Trainee

REF
WS 120.JB2
A 318w
1983



83-00-3(P)
20/1/83

SECTION I - RESEARCH PROTOCOL

1. Title: Wheat Syrup as a Caloric Supplement for Improving the Rate of Weight Gain in Children

2. Principal Investigator: Dr. A.N. Alam

   Co-Investigators: Dr. H. Rahman, Dr. Sultana Khanam

   Consultant: Dr. M. Mujibur Rahaman

3. Starting Date: February 15, 1983

4. Completion Date: May 15, 1983

5. Total Direct Cost: U.S.$ 1200

6. Scientific Programme Head:

   This protocol has been approved by the Nutrition Working Group.

   Signature of Scientific Programme Head: M A Rahman

   Date: 9/11/1983

7. Abstract Summary:

The effect of different levels of calorie and protein intake on the weight gain of twenty severely malnourished children 2-6 years of age and the feasibility of using wheat syrup as a caloric supplement will be evaluated.

8. Reviews:

a) Research Review Committee: _____

b) Ethical Review Committee: _____

c) Director: _____

d) BMRC: _____

e) Controller/Administrator: _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION:

1. Objectives: The aim of this limited study will be to assess the rate of weight gain in malnourished children offered a high energy diet ad libitum during the early phase of rehabilitation.

2. Background: Childhood malnutrition is a widespread problem in the developing countries including Bangladesh and is one of the leading causes of morbidity and mortality. Malnourished children who are acutely ill need immediate resuscitation on admission to hospital. Initiation of cure is usually accomplished within a week of admission. The next period of rehabilitation, however, could be as long as 4-6 weeks or even longer. The primary aim at this stage is to achieve rapid weight gain. The rate of weight gain in children recovering from malnutrition is much more significantly influenced by the level of calorie intake than by that of protein. This is because of the high energy cost of new tissue synthesis, both as stored energy and as energy consumed in oxidative synthetic process[2]. In order to achieve a rapid 'catch-up' growth, ad libitum feeds have been advocated[3] during the rehabilitation phase so as to provide high energy intake (about 150-200 Kcal/kg body wt/day) and a relatively modest protein-intake (about 3-4 G/kg/day)[4]. This will ensure a rapid weight gain of 10-15 times the normal rate and an early discharge from the hospital decreasing the hospitalisation cost and allowing an efficient use of the scarcely available hospital beds. Rapid recovery will also lessen the risk of cross infection of vulnerable underweight children and emotional stresses of separation from their families. The most important problem faced by the nutritionists is the inability of the malnourished children to consume enough quantities of food to meet the body demands due to the bulk of the foods[5] and limitations imposed by the stomach size[6]. Starch-based diets like cooked rice or wheat products traps almost twice their dry weight of water which "dilutes" the calorific value of the food making it necessary to administer frequent feeding. For example, an infant at one year of age has to consume about 2 kg of boiled rice to meet the calorie needs of normal growth. One must also be careful not to overload the gut as the intestinal mucosa in malnourished children is thinned with marked flattening and broadening of the Villi[7] and digestive enzymes are reduced. Addition of fat reduces the dietary bulk, but it is not desirable as many malnourished children do not tolerate it well due to secondary lipase deficiency.

Processing of cereal-based foods like wheat, rice etc by enzyme treatment, precooking, high pressure extrusion can reduce the dietary bulk. By using such appropriate enzymes (α-amylase and protease which are available in commercial quantities), a highly palatable carbohydrate nutritive syrup has been prepared from powdered wheat grain[8]. A preliminary study was conducted by us[9] where the acceptability and digestibility of the syrup was evaluated in a group of malnourished children during recovery and the net absorption of carbohydrate, nitrogen and calories derived from the product was determined. It was observed that the syrup was avidly accepted by all children except one with evidence of positive nitrogen balance. Such results have encouraged us to propose further study in order to ascertain the feasibility of using the syrup as a caloric supplement for improving the rate of weight gain in a group of malnourished children.

The method of preparation, composition and the advantages of the syrup have previously been described (Protocol No. 82-011 P).

3. Rationale: The study, if successful and if wheat syrup is available in plenty, should pave the way for reducing the cost and the period of hospitalisation and early rehabilitation of malnourished children by achieving rapid weight gain.

Rice could be equally substituted for wheat. The process of enzymatic extraction is relatively simple if appropriate enzymes (α- amylase and protease now made and available in commercial quantities) are available. Therefore, if the results prove to be encouraging further steps may be taken in promoting its manufacture in the country on a cottage industry scale like the soya milk. As a matter of fact the soya milk is produced from imported beans whereas the syrup could be made from either wheat or rice. Further studies will be planned on the basis of this initial trial.

B. SPECIFIC AIMS

(1) To ascertain the rate of weight gain in malnourished children during the study period.

(2) To compare the daily calorie and protein intakes in the two groups of patients and to determine their relation to the observed rate of weight gain.

C. METHOD OF PROCEDURE

Twenty malnourished children, between 3-6 years of age, who are recovering from malnutrition in the Children's Nutrition Unit (CNU), Dhaka will be recruited for the present study. An attempt will be made to exclude patients with oedema, systemic infections, metabolic disease or on antibiotic or chemotherapy. Informed consent will be obtained from their parents or guardians before entering them to the study. No antibiotics will be administered to the children till the study is completed. However, vitamins and mineral supplements will be given to the patients.

Twenty patients recruited early in the rehabilitation phase (usually the beginning of 2nd week), will be divided into two equal groups. The first group will be offered, ad libitum, highly nutritious CNU diet spaced between six meals. No additional dried skimmed milk will be allowed to these children. The second group, matched for age and weight as closely as possible, will receive wheat syrup (approx. 1.5 Kcal/ml) ad libitum in addition to usual CNU diet. The syrup will be offered in between the meals. The dietary calorie and protein intake from each item of food will be calculated. Any left over from different items of food will be weighed and their nutrient value will be calculated. Each child will be weighed to the nearest 1_G everyday in the morning using a Toledo scale. The study will be carried out for a period of two weeks. The study patients will be discharged when they reach their expected weight for height (75-80% wt. for ht. Harvard standard). At this point most children diminish their food intake and the 'catch-up' growth is exceedingly low[6].

D. FACILITIES REQUIRED:

Children patients in Nutrition Unit, Dhaka will be studied.

E. COLLABORATIVE ARRANGEMENTS

This will be a collaborative study between ICDDR,B & Children's Nutrition Unit (CNU). The wheat syrup will kindly be provided by Prof. A. Dhalqvist from Sweden.

F. Analysis of Data: Rate of growth will be computed for each group of patients using usual regression technique (regressing weight gain against time). Rate of weight gain in two groups receiving two types of food will be tested by students' T test.

Calorie and Protein Values of Diets/100 Gms to be Offered to the Study Patients

	Calories	Protein (Gms)
1. Rice Pudding	68	1.94
2. Rice, Meat and Vegetables	80	4.33
3. Rice and Dal	77	2.92
4. Wheat Syrup	399	11.5

REFERENCES

1. Waterlow, J.C. (1961). J. Trop. Pediatr. 7:16

2. Kielanowski, J. and Kotarbinski, M (1969). In proceedings of the Eighth International Congress of Nutrition, Amsterdam p. 742.

3. Ashworth, A (1974). Br. J. Nutr. 31:109.

4. Ashworth, A (1980). J of Human Nutr. 34:360

5. Hellstrom et al (1981). J Trop. Pediatr. 27:127.

6. Ashworth, A (1979) Proc. Nutr. Soc. 38:89.

7. Gracey, M.S. (1981) Br. Med. Bull. 37:77.

8. Dahlqvist, A. et al (1978) A Nutritive Syrup from grains Background paper for 5th Int. Congress on Food, Science and Technol., Kyoto.

9. ICDDR,B Research Protocol: Acceptability and digestibility of a wheat syrup: Alam A.N. et al. (No. 82-011 P).

SECTION III - BUDGET

A. DETAILED BUDGET

1. PERSONNEL SERVICES

Name	Position	% of Effort	Project Requirement	
			Tk.	Dollar
Dr. A.N. Alam	Principal Investigator	20	14,000	
Dr. H. Rahman (CNU)	Co-Investigator	-	No cost to ICDDR,B	
Dr. Sultana Khanam	"	-	"	
Dr. M.M. Rahaman	Consultant		-	

2. SUPPLIES & MATERIALS

Wheat syrup		800
Equipment	N i l	
Hospitalisation cost	N i l	
Outpatient care	N i l	
ICDDR,B Transport		200
Rent, Communication	N i l	
Printing		200
Travel	N i l	
Contractual Services	N i l	

Tk. 14,000 + $ 1200

(US $ 1 = Taka 20) = Tk. 14,00 = 700 $

GRAND TOTAL = $ 1200 + $ 700 = $ 1900

Incremental cost = $ 1200

Abstract Summary for Ethical Review Committee

1. This limited study aims at achieving a rapid weight gain during early rehabilitation of recuperating malnourished children in Bangladesh. Malnutrition is the biggest contributor of childhood mortality in developing countries. Rehabilitation of malnourished children is an expensive and long-protracted undertaking. One of the principal difficulties encountered during nutritional rehabilitation of children is the bulk of the food that could supply adequate amount of calories needed. In almost all types of diarrhoea, which is the principal factor associated with childhood malnutrition in developing countries, absorption of carbohydrates have been found quite satisfactory. Thus a soluble carbohydrate, preferably a polyglucose, should make it possible to concentrate considerable amount of calories in a small volume of water. The nutritive syrup prepared from powdered wheat grain is such a carbohydrate, which is easily dissolvable in small volume of water, free from lactose and is quite palatable. The syrup will be offered in addition to usual diet to ten malnourished weaned children between 3 to 6 years of age who are recovering in the Children's Nutrition Unit in Dhaka.

2. There are no potential risks involved in this study.

3. Though there are no potential risks involved, the patients will be under consistant observation of physicians and will get optimum care and management.

4. During data analysis, only the case number will be used.

5. Informed consent in a consent form will be obtained from the authorised legal gardian or the parents of the patient before being included in the study.

6. A brief interview will be taken only to obtain the clinical history of the disease.

7. The patient will get proper treatment and care during the study period, and if successful, will make early recovery. If the wheat syrup proves to be successful then it should pave the way for reducing the period of hospitalisation and early rehabilitation of malnourished Bangladeshi children.

8. Hospital records will be required.

সম্মতি পত্র

আমি, মি, ডি, ডি, আর, বি এবং মি, এম, ইউ একযোগে পুষ্টিহীনতা রোগের উন্নততর চিকিৎসা উদ্ভাবনের চেষ্টা করছে। পুষ্টিহীনতার সঠিক চিকিৎসা করার বিভিন্ন সমস্যা আছে। তার মধ্যে একটা অন্যতম সমস্যা হচ্ছে কি ভাবে পরিমানমত খাদ্যের মধ্যে বেশী পরিমাণ ক্যালোরি দিয়ে ওজন বৃদ্ধি করানো যায়। আমরা গবেষণা করে এমন একটি নতুন ধরনের পুষ্টিকর, সুস্বাদু এবং বিরাদদ খাদ্য বের করেছি যা দিয়ে চিকিৎসায় ব্যবহার করতে ইচ্ছুক। আমরা খোলাকার্ড শিশু এই গবেষণায় অংশ নেবে।

খোলাকার্ড যদি রাজী থাকেন তাহলে নিম্নলিখিত ব্যবস্থাদি নেয়া হবে।

১। খোলাকার্ড শিশুকে সর্বোত্তম চিকিৎসা দেয়া হবে।

২। এই পুষ্টিকর বিস্কুটটি আগামী ১৫ দিন খোলাকার্ড শিশুকে খাবারের আগে আগে দিনে চারবার করে খেতে দেয়া হবে।

৩। সম্পূর্ন আরোগ্যলাভের পর খোলাকার্ড শিশুকে ছুটি দেয়া হবে। ছুটির সময় আবশ্যকমত ঔষধ দেয়া হবে।

৪। খোলাকার্ড যে কোন সময় এই গবেষণা থেকে খোলাকার্ড শিশুকে প্রত্যাহার করে নিতে পারেন। খোলাকার্ড এই গবেষণায় অংশগ্রহণ না করলেও খোলাকার্ড শিশুর সুচিকিৎসার কোন ক্রটি হবেনা।

খোলাকার্ড যদি এগুলায় রাজী থাকেন, তাহলে নীচে খোলাকার্ড স্বাক্ষর/বুদ্ধাংগুলির ছাপ দিন।

গবেষকের স্বাক্ষর ও তারিখ

অভিভাবকের স্বাক্ষর/ছাপ

CONSENT FORM

The ICDDR,B and CNU are jointly trying to find out better ways of treatment of malnutrition in children. There are different problems involved in treatment of malnutrition. One of the main problem is how to supply adequate amount of calories for rapid weight gain during early rehabilitation. In order to achieve this goal, we wish to try a new food, extracted from wheat, which is nutritious, harmless and palatable. We would like your child to participate in our study.

1. Your child will get proper treatment.

2. The nutritive wheat syrup will be offered to your child, 4 times a day, in between the usual nutritions diet for a period of two weeks.

3. Your child will be discharged when recovered completely. If necessary, medicines will be given at the time of discharge.

4. You can withdraw from the study at any time. Even if you do not participate, the treatment of your child will be hampered.

If you are willing to let your child participate in this study, then please put your signature or left thumb impression below.

_____ _____

Signature of Investigator

Signature or left thumb impression

Date:_____

Relation with the patient_____