

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Dr. L. T. Khan
 Application No. 85-016
 Title of Study Clinical Trial of
Plantain (green) Banana-based ORS in the
Treatment of acute Diarrhoea in Children

Trainee Investigator (if any) _____
 Supporting Agency (if Non-ICDDR,B) Aga Khan Health
 Project status: Services, Tanza
 New Study
 Continuation with change
 No change (do not fill out rest of form)

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

1. Source of Population:
 - (a) Ill subjects Yes No
 - (b) Non-ill subjects Yes No
 - (c) Minors or persons under guardianship Yes No
 2. Does the study involve:
 - (a) Physical risks to the subjects Yes No
 - (b) Social Risks Yes No
 - (c) Psychological risks to subjects Yes No
 - (d) Discomfort to subjects Yes No
 - (e) Invasion of privacy Yes No
 - (f) Disclosure of information damaging to subject or others Yes No
 3. Does the study involve:
 - (a) Use of records, (hospital, medical, death, birth or other) Yes No
 - (b) Use of fetal tissue or abortus Yes No
 - (c) Use of organs or body fluids Yes No
 4. Are subjects clearly informed about:
 - (a) Nature and purposes of study Yes No
 - (b) Procedures to be followed including alternatives used Yes No
 - (c) Physical risks Yes No
 - (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 a overview (all other requirements will be submitted with individual studies)
 - Protocol (Required)
 - Abstract Summary (Required)
 - Statement given or read to subjects of 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 (itec) 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

85-016
28/5

SECTION 1 - RESEARCH PROTOCOL

1. TITLE: CLINICAL TRIAL OF GREEN BANANA
(PLANTAIN) BASED ORS IN THE
TREATMENT OF ACUTE DIARRHOEA
IN CHILDREN.
2. PRINCIPAL INVESTIGATOR: Dr. L.T. Khan
- COLLABORATIVE INVESTIGATOR
AND CONSULTANT: Dr. A.M. Molla
- CO-INVESTIGATOR: One physician (to be named)
3. STARTING DATE: 15th March 1985
4. COMPLETION DATE: 14th March, 1986
5. TOTAL DIRECT COST: Tanzanian Sh. 504,500
US \$ 25,000
- AVAILABILITY OF FUNDS: The Aga Khan Health Services,
Tanzania.
6. SCIENTIFIC PROGRAMME: This protocol has been approved
by the Nutrition Working Group.

K. M. S. Azizi
Signature of ^{the} Head, Nutrition Working Group
Date: *May 28, 1985*

7. ABSTRACT SUMMARY:

The advantages of a rice-based ORS over the standard WHO/UNICEF ORS in terms of acceptability, calorie supplementation, reduction in vomiting and stool output have already been established in ICDDR,B and other Centres. However, rice is not a staple diet in Tanzania, where green bananas and maize constitute the two major staple foods, used by most Tanzanian. One clinical and a field trial on Maize ORS is currently being proposed in Kenya. Green banana (plantain) is used extensively as a staple food in many African countries, West Indies and Middle and South Americas, and all along the tropical belt. In view of the above facts a three cell clinical trial is being envisaged - Maize ORS, Banana ORS and the comparison as WHO/UNICEF ORS. In the Banana-based ORS, potassium supplement will not be added due to the high indigenous levels of potassium in Banana. A total of 150 children between the ages of 4 months and 59 months with acute diarrhoea will be studied in paediatric ward. During the first 24 hours, children will be served with only ORS. Breast fed children will not be included in this study. The ORS intake, urine output, stool output, serum specific gravity and gain in body weight will be taken as the criteria to determine the efficacy of the ORS. The result obtained will help us recommend the use of Banana and Maize ORS in appropriate areas at clinical and home levels and further the possibility of a field trial for plantain-based ORS in Tanzania and elsewhere where it is used extensively. $\frac{1}{2}$ litre of ORS will be prepared by adding either 30 g of Maize flour or one plantain (~100 gm) and 1.75 gm sodium chloride ($\frac{1}{2}$ T.S.F.)

8. REVIEWS:

- (a) Research involving human subject - ICDDR,B: -----
- (b) Research Review Committee - ICDDR,B: -----
- (c) Director - ICDDR,B: -----
- (d) Chairman - Aga Khan Health Services, Tanzania: -----
- (e) Medical Research Council - Director, Tanzania: -----

SECTION II - RESEARCH PLANA. INTRODUCTION:1. Aim of the study (Objective):

The aim of this study in a clinical set up is to evaluate the relative efficacy of a green banana (plantain) salt ORS (without any other electrolytes), and also maize salt ORS, compare to the WH/UNICEF ORS, for oral rehydration of children with acute diarrhoea, in Dar-es-salaam, Tanzania.

2. Specific aim:

To study the efficacy of green banana (plantain) salt ORS in terms of change in haematocrit, electrolyte balance, weight gain, reduction in vomiting, duration of diarrhoea, stool volume and compare them with the Maize-salt ORS and the standard WHO ORS.

3. Background:

Diarrhoea constitutes a major health hazard to children in the developing countries, including Tanzania. It is amongst the first five important deadly diseases of children in Tanzania. The efficacy of ORT in replacing the loss of fluid and electrolytes in watery diarrhoea has been well-established (1-4). Oral rehydration therapy has in recent years reduced this toll and has extensively eliminated the need of I.V. fluid therapy except in most severe cases. The discovery of glucose facilitated transport of sodium and water in the small intestines led to the use of glucose electrolytes solution for effective therapy of

rehydration of patients with acute watery diarrhoea (14). The ORT at the same time is cheap and comfortable for the patient. Since glucose is not universally available and expensive in some countries, it was replaced by sugar (16). In further simplification Gur and Molasses has been used in place of sugar (15). Recently the Cereal (rice powder) has been used with improved results (6-7). The results of Rice ORT (6-7) using 50 gm or two fistful showed to reduce (i) stool output and ORS intake by 50% (8), (ii) vomiting by 80% and (iii) compared to the glucose ORS, it has 2½ times more calories and rehydrates more efficiently as shown by gain in weight and serum specific gravity. It is effective in correcting biochemical abnormalities and maintaining them within normal limit.

Plantain or green banana cooking is grown very widely in the tropical belt all over the world. In most of the African, Caribbean and Middle and South American countries, it is extensively used as a staple diet (9), as well as a fruit.. Hence the green banana is not only highly valued but also readily available in these countries. In Tanzania, the most thickly populated areas of the north and along the great lakes use banana as the major staple diet. With the constant flow of migration to cities and urban areas, the banana staple people are seen in most areas of Tanzania. Hence besides maize, banana plays an equally important role in some parts of Tanzania where it is used as a staple diet.

Green banana-based ORS would have manifold advantages compared to glucose/sucrose ORS.

1. Being a food, it will be readily acceptable in Tanzania.
2. It is readily available all the year round.
3. Relatively cheap
4. Being available at home (especially in the backyard, where it is grown in Tanzania), it would eliminate the storage and transport of ORS packets - attaining a certain level of self-sufficiency.
5. Hypothetically the green banana starch like the starch of other cereals being digested by intraluminal enzymes, liberates glucose molecules slowly into the intestinal lumen and at the mucosal surface (14).
6. And for the same reason would not cause rise of osmolality. Therefore, a higher level of carbohydrate could be used in the ORS to provide more calories.

Green banana contains sufficient potassium and some antidiarrhoeal elements like pectin, and lignin and hydroxy-tryptamin making it potential diarrhoea therapy.

Repairing the plantain for ORS use entails boiling the plantain intact with skin for 10-15 minutes and then mixing it with water, forming a homogenous solution. This requires time and fuel, but should be seen in light of the advantages of food based ORS. In any case, in Tanzania cooking banana (plantain) is always cooked before consumption. Therefore, boiling the banana for the preparation of ORS would not be considered a hindrance. The boiling of banana is necessary to soften

it, to hydrate the starch (10) and ease the hydrolysis of disaccharides which is completed at the mucosal surface. Unhydrolysed polysaccharides reaching the colon often inter-act with bacteria producing degradation products causing fluid secretion, increased motility, cramps, irritation and distension. Hence full hydration of starch by boiling e.i. dehydrate.

In Tanzania and many African countries it is a routine to prepare maize or banana porridge as a weaning food for children, and as breakfast for others. Hence the fuel cost and time used in the preparation of maize and banana ORS may not seem out of place, and would be acceptable as routine procedure. However, the cost and logistics of the food based ORS must be weighed against its benefits like reduction in the duration of diarrhoea, stool output, increased calorie content and lower risk of contamination, and above all bringing the diarrhoea treatment to the door-step of the mother.

Criteria for selecting possible cereals/food for trial clinically:

In order to quantity for being used in ORS, the cereal/food concerned must be:

1. Available and cheap.
2. Easily digestible
3. Easy preparation for using the ORS
4. Must be accepted by the target population.
5. Should be used by a large number of population as staple food.
6. Biochemical composition must be satisfactory.
7. Must be free from side effects or stigma in the community.

The plantain qualifies for the above criteria.

Composition of differene cereals to be used for trial:

Table 1 shows the composition of the different food proposed to be used in this trial. Both maize and banana have adequate carbohydrate and in right proportion and should work as glucose substitute in the ORS. ORS prepared from plantain and maize were tested and in a preliminary study, for their acceptability by 10 doctors of the ICDDR,B and 20 OPD patients. All of them accepted them well. Africans should accept them even better because of their traditional use. In vitro hydrolysis carried out in ICDDR,B. ICDDR,B showed the glucose content of maize to be 70% and plantain as 16.4 gm %. The plantain has high content of potassium as compared to maize. Lebanthal et al (14) in their studies showed that 85% of young children (12 months) recovering from acute diarrhoea can tolerate and absorb glucose explained starch from corn syrup (14). Evidences exist that plantain was used for nutritional management of premature infants (). These information support that maize and banana have been the theoretical qualification to work in ORS. The biochemical composition of the plantain as carried out in ICDDR,B is presented in Table II. Based on the glucose content of different cereals the composition of the proposed ORS per 500 ml is shown in Table III.

Food prepared from green babana and maize in Tanzania:

1. Mashed (steamed) green banana (MATOKE):

The raw green banana is peeled, salted, covered in a layer of banana leaf and steamed in a cooking pot. After steaming, it is eaten along with boiled meat or fish or vegetables.

2. Green banana and meat (NDIZI NYAMA):

Pieces of peeled green banana along with meat, salt and tomatoes are cooked in water. Eaten as a main meal. In the coastal regions coconut milk is added along with spices and green chillis to give added flavour. This preparation is used extensively by many Asians and Africans especially in the holy month Ramzan.

3. Raw banana crisps:

Like potato crisps this is prepared in the urban areas. They are salted and delicious.

4. Maize meal (UGALI):

Boiling water and maize flour with added salt to taste. Consistency semi solid. Used as cereal diet with vegetables or meat.

5. Maize and banana porridge (UJI):

Used extensively as weaning food for children, and breakfast for adults and older children. For breakfast milk and sugar may be added. Traditionally these preparation are commonly used during diarrhoea.

6. Roasted maize and banana:

Maize or banana are roasted on grill and served with salt.

RATIONALE:

- (a) Rice powder ORS has proved its superiority over WHO/UNICEF ORS. Banana being a major staple diet in Tanzania and it is desirable to use this as a trial for food based ORS.
- (b) Because of its composition banana could be effectively used to replace the glucose in ORS.
- (c) Banana has high potassium content and it will eliminate the need for adding the additional potassium into the ORS. Therefore in spite of it being a banana salt ORS, it will have adequate potassium content which is so appropriate in the developing country where both hypokalaemia and malnutrition are rampant. Thus an expensive, and superior home made ORS will be made available to the target population. Traditionally in many African, Asian and also other plantain eating countries. Banana is used as adictary therapy during diarrhoea and after recovery. Therefore the proposed ORS will be an acceptable ORS and it will possibly increase the use rate of ORS in the countries concerned.
- (d) Before widely recommending Banana ORS it is essential to test its efficacy in a well controlled set up in a country like Tanzania where it is a staple diet for a large number of people.
- (e) In Tanzania maize is the other major stable diet and maize fulfills the criteria for being used as a glucose substitute in ORS. Thus the proposed two types of ORS based on plantain and maize if found successful will help reducing the diarrhoea related mortality in Tanzania and propagate home made ORS at the community level.

METHODS AND PROCEDURES:

1. Preparation and composition of the $\frac{1}{2}$ litre oral rehydration solution to be used in the study.

(a) One plantain will be boiled (intact with skin) for 10-15 minutes in sufficient water. 100 gm of boiled peeled banana (approximately one banana) will then be mashed and added to 500 ml of the already boiled water and mixed. 1.75 gram of salt (NaCl) will be added and stirred. It is then served to the patients.

(b) Maize flour 30 gm (readily available in the market) is boiled in 550 mls (to allow for evaporation) of water for 5-7 minutes and cooled. After adding the 1.75 gm of salt the ORS is stirred and served to the patients. Once prepared the different ORS will be labelled as follows in the study:

1. Plantain ORS
2. Maize ORS
3. WHO/UNICEF ORS

2. Selection of patients:

Patients will be selected according to the following clinical criteria:

- (a) Diarrhoea will be defined as three or more loose stools in 24 hours.
- (b) Table IV represents the criteria for selection of patients.

Owing to the difficulty in collection of urine, in females, only male patients will be selected. Urinary bag prepared with surgical gloves will be used for collection of urine. Patient with a history of systemic illness, dysentery or severe malnutrition will not be included in the study. Stool on admission will be sent for microscopic examination. Because of non availability of facilities in Tanzania, no attempts will be made to isolate micro-organisms from the patients with acute diarrhoea. The study procedure will be fully explained to the parents or guardians of the patients and will only be admitted after the informed consent is obtained. Cases of suspected shigella with pus cells 20/hpf or toxemic signs clinically, will be excluded for the study. Antibiotics will not be prescribed during the study and those needing antibiotics on clinical grounds will be taken out of the study.

3. Sample size:

We are hoping to achieve at least 30 percent reduction in the stool output by the proposed banana salt and maize salt ORS. Based on the result of the rice ORS in ICDDR,B it has been calculated that at least 50 patients will be required in each group to be of statistical significance. The distribution of the patients is shown in table V.

4. Randomization procedure:

The study will be randomized but can not be blinded because of the distinctive colour and consistency of the solutions. A random table will be prepared with same numbers of patients for each of the food based and control ORS. Then a small ticket for each patient will be made and inserted into a box.

When a patient is admitted, the nurse on duty will pick up one ticket from the box and assign the patient to the study group accordingly.

5. Laboratory investigations on admission and during the trial study:

The laboratory investigations include CBC, Hematocrit, serum electrolytes, urine for routine microscopic analysis and stool for microscopic analysis for puscells, ova or cysts etc. No attempts will be made for isolation of the causative organisms.

6. Initial clinical procedure:

Height or length and weight of the patients will be taken on admission. The study physician or the investigator will thoroughly examine the dehydration state of the patient and exclude any serious systemic illness. Severely dehydrated patient will be treated by intravenous route using half strength Darrow's solution. The initial replacement will be done calculating on the basis of body weight and severity of dehydration according WHO guidelines and the required amount of fluid will be given within 4 hours after admission. After the initial rehydration clinical reassessment will be made to start the ORT. Moderately dehydrated patients will start ORT immediately. Thus in severely dehydrated patients ORS will be used only to maintain the on going losses in stool, urine and vomitus which will be collected individually and measured eight hourly.

The following measurements will be carried out during the clinical trial for 72 hours after inclusion into the study.

- a. Measurement of weight and height on admission.
- b. Weight gain every day until discharge from the hospital.
- c. Pulse, respiration and temperature on admission and 8 hourly until 72 hours.
- d. Hydration state and clinical assessment 8 hourly upto 72 hours.
- e. Blood for Hb%, Sp. gr. and serum electrolyte on admission and after the first 24 hour.
- f. Intake/output every 8 hourly upto the 72 hours.

ORS will be measured accurately and given to the mother or attendants to feed the patients under close supervision of the study nurses. Measured quantity of plain water will be allowed to each child. Clinical evaluation of skin elasticity, mucous membrane and sign of over hydration will be assessed. Constant observation of the patient will be done by study nurse and clinical officers assigned to the project by the investigators. In first 24 hours children will be given only ORS but no food will be offered otherwise the glucose released from the food will participate in transporting sodium and water. Subsequently ORS, as practiced in the hospital ward, food and measured quantity of plain water will be allowed. Study will be continued until the 72 hours after inclusion of the patient into the study.

7. Clinical failure and indications for discontinuation of the study:

- a. Excessive vomiting - making the patient unable to drink.
- b. Weight loss more than that of admission i.e. negative balance and reappearance of severe dehydration.
- c. Signs of electrolyte imbalance e.g. lethargy, restlessness ect.

When all or any of the above signs are present, the investigator will re-examine the patient, take body weight, blood for serum electrolyte and sp. gravity, and the patient will be declared as therapeutic failure and sent for usual clinical care.

DATA ANALYSIS:

Flow sheets for the study will be prepared and filled in for each patient. Information will be analysed and paired t-test will be done between the results among the patients receiving the two types (control versus food) of ORS. Table will be prepared to compare the results of the therapy of the ORS type used.

From the results, calculation will be made to assess the following aspects for all types of ORS.

- a. Effect of therapy on weight gain, stool output, change in serum specific gravity, urine output.
- b. Biochemical parameters like serum electrolytes and serum glucose.
- c. Net stool output at 8 hour interval.

8. Significance:

The results will provide valuable information regarding the efficacy of green banana (plantain) ORS, as well as maize ORS. This will simplify treatment of diarrhoea and bring it to the home level at low cost and even reduce the nutritional effect of diarrhoea in countries where plantain is a staple.

9. Facilities required:

- a. Laboratory facilities - exist for biochemistry and clinical pathology.
- b. No new office space is required.
- c. Hospital resources - 4 patients will be selected from OPD and started at a time, with experience the number will be increased.
- d. statistical data analysis - will be managed in Dar-es-salaam.
- e. Deep freezer - available.
- f. Weighing scale - available
- g. Animal resources - will be necessary for E. coli toxin assay and will be done in Nairobi, Kenya (if possible).

STATISTICAL ANALYSIS:

The following variables will be considered during analysis:

- amount of intake of ORS
- amount of output of (a) stool, (b) vomitus, (c) urine at different interval of time after the administration of ORS
- duration of diarrhoea after administration of ORS
- gain in body weight
- change in serum specific gravity and haematocrit since admission.

This means all of these variables for each type of ORS will be compared with those of standard WHO ORS using the t-statistics. While comparing the proposed ORS taking at a time, F-statistics can be used.

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

1. Taken from P 1 - Abstract summary.
2. There is no significant risk. The food used in the study is a staple food in various parts of Tanzania. The carbohydrates are adequate and is not likely to produce hypoglycaemia.
3. The study will be carried out at the Aga Khan Hospital, Dar-es-salaam, Tanzania. Patients will be screened before admission for any possible disease or any other complications and will remain under constant supervision of a nurse, clinical officer and a medical officer. Appropriate measure will be taken whenever any complication arises.
4. Only hospital in patient number of the patient will be used during the analysis of the data.
5. Informed consent will be obtained from the guardian of the patient after full explanation of the procedure in the local language.
6. No detailed interview except relevant history of illness.
7. All patients benefit from study, ORS with glucose is used as a standard diarrhoea therapy all over the world. It is anticipated that the group of patient treated with food based ORS will be provided with effective rehydration and also supply adequate extra calories which might help and early nutritional rehabilitation.
8. Hospital records and body fluids like stool, urine vomitus and 3 ml of blood will be required.

SECTION III - BUDGETA. Personnel:

	<u>% effort</u>	<u>Salary annum TSH</u>	<u>Allowance and/ or transport TSH</u>	<u>Project requirements TSH</u>
Principal Investigator		96,000.00	-	-
Co-Investigator		-	20,000.00	-
Medical Officer		72,000.00	-	-
Microbiologist		72,000.00	-	-
Lab. Technician		24,000.00	-	-
Nurses (5)		72,000.00	-	-
Cleaners		12,000.00	-	-
Cook/Utensil/Bottle cleaner		30,000.00	-	-

Total = TSH. 378,000.00

<u>B. Supplies and Materials:</u>	TSH
Stationary goods	1,000.00
Urine bag	500.00
Buckets	500.00
Beds	2,000.00
Makintosh, Blanket & Others	1,000.00
Cereals	500.00
Utensils	1,000.00
Electrolytes	1,000.00

TSH = 8,000.00

<u>C. Equipment:</u>	
Measuring scale	1,000.00
Weighing scale	500.00
Measuring jars	500.00
Disposable gloves	500.00
Pocket computer	1,000.00

TSH= 3,500.00

D. Patients Hospitalization:

	<u>TSH</u>
Total no. of patients	150
Average hospitalization days	3
Total no. of hospital days	450
Cost per day	200.00
 Total hospitalization cost	 <u>90,000.00</u>
	TSH=90,000.00

E. Laboratory:

Deep freezer	500.00
Incubator	500.00
Laboratory supplies	5,000.00
	<u>6,000.00</u>
	TSH=6,000.00

BUDGET SUMMARY

		<u>T S H</u>
A. Personnel	..	378,000.00
B. Supplies and materials	..	7,000.00
C. Equipment	..	3,500.00
D. Patients hospitalization	..	90,000.00
E. Laboratory	..	6,000.00
F. Consultants' visits	..	20,000.00
		<hr/>
	TOTAL:	TSH = 504,500.00

CONSULTANTS VISIT DURING THE STUDY PERIOD:

The collaborative co-investigator or consultant will be visiting the Kakamega Hospital Project in Kenya. Collaborative arrangement will be done to bring them to Tanzania to supervise the study. A return air ticket, Kakamega to Dar-es-salaam, will be provided and all necessary expenses in Tanzania will be paid during their stay. The investigator will spend enough time according to the availability of his/her time.

Consent form

The Aga Khan Hospital, Dar-es-salaam is carrying out research to find out simple, effective and inexpensive treatment for diarrhoeal diseases. A cereal (rice) based oral rehydration solution in which the grain powder instead of glucose has been used with superior results to the standard oral rehydration solution (ORS). AKH would like to carry out further research on oral rehydration solution made of 100 gram plantain or 30 gram of maize flour along with the WHO recommended electrolytes in half litre of water. We would like you to allow your child to participate in this study. The study will last for 3 days or earlier and during this period your child will be treated with either glucose electrolyte solution or one of the newly proposed oral rehydration solution. In addition to the measurement of stool, urine and vomitus, 3 mls of blood will be drawn on admission and at the end of 24 hours of treatment. The results of blood test will be mainly used to evaluate the effect of treatment. Your child will be allowed to go home after diarrhoea has stopped and other necessary treatments are completed. You may choose not to participate in this study and in any case appropriate treatment of diarrhoea as available in this hospital will be provided to your child.

Finger print/signature of the patient/guardian.

Date: -----

Signature of the Investigator

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TABLE I
COMPOSITION OF RIPE BANANA AND CORN FLOUR PER 100 GRAM (13)

Food	Calorie	Protein	Fat	Mineral	Fibre Crude	Carbohydrate	Energy	Calcium	Phosphorus	Iron	Carotene	Thiamine	Riboflavin	Niacin	Vit. C	Potassium	Sodium
	mg	gm	gm	gm	gm	gm	K.cal	mg	mg	mg	mg	mg	mg	mg	mg	mg	mg
Ripe Banana	109	1.15	0.18	0.83	0.62	23.3	100	8.7	28	0.55	0.23	0.04	0.06	0.65	12	393	1.0
Corn flour		8.95	2.82	1.16	1.47	73.6	376	18	256	24.0	0.3	0.44	0.13	1.93	0	120	0.7

TABLE II

COMPOSITION OF 100 GM OF COOKED PLANTAIN AS HAS BEEN ANALYSED IN ICDDR,B

Protein gm%	Fats gm%	Glucose		Total Calorie K.Cal/gm	Potassium mmol	Sodium mmol	Chloride mmol
		Pre-hydration	Post-hydration				
0.33	0.05	0.097 gm%	16.4 gm%	102	10.7	0	20

TABLE III

COMPOSITION OF PROPOSED ORS IN $\frac{1}{2}$ LITRE (500ml)

Food used (25 gm rice equivalent)*		Electrolyte gm/ $\frac{1}{2}$ litre		
		NaCl	NaCHO ₃ / NaCitrate	KCl
Green banana	100 gm	1.75 gm	1.25 gm	Nil
Maize flour	30 gm	1.75 gm	1.25 gm	0.75 gm
Water	$\frac{1}{2}$ litre			

* Amount fixed on the basis of glucose content after in-vitro hydrolysis.

TABLE IV

DISTRIBUTION OF PATIENTS TO DIFFERENT FOOD BASED ORS

Food	No. of patients
Plantain based ORS	50
Maize based ORS	50
Glucose ORS	50
Total: Three Groups	150

TABLE V

CRITERIA FOR SELECTION OF STUDY PATIENT

Particulars	Selected	Excluded
Age (months)	4 months - 59 months	Less than 4 months and greater than 59 months
History of diarrhoea	Upto three(3) days	Greater than three days
Sex	Male	Female
H/O antibiotics	No antibiotic	Antibiotic
Blood count	Normal WBC Normal differential count	High count (greater than 15,000) Shift to the left
Dehydration	Moderate to severe	Mild
Weight/Height	≥ 70	≤ 70
<u>Stool examination</u>		
Pus cells	Upto 20/HPF	Greater than 20

TABLE VI

COMPARISON CHARACTERISTICS OF THE STUDY PATIENTS (MEAN \pm SEM)

Criteria	Food ORS	WHO ORS	P
Age (months)			
Adm. weight (Kgm.)			
Adm. Hct			
Adm. Hb			
Adm. Ser. Spgr.			
During illness (prior to adm.)			
Dehydration status			
Mild			
Moderate			
Severe			
Serum Electrolytes	On admission		24 hours
Na ⁺ mmol/Lt.			
K ⁺ mmol/Lt.			
Cl ⁻ mmol/Lt.			
TCO ₂ meq/Lt.			
Serum glucose			

TABLE VII

TABLE TO COMPARE THE EFFICACY OF THE FOOD BASED ORS WITH
STANDARD WHO/UNICEF ORS (MEAN \pm SEM)

Parameters	Food ORS	WHO ORS	P
<u>Stool output</u>			
a. Total volume (litres)			
1st 24 hrs.			
2nd 24 hrs.			
b. ml/kg/day			
1st			
2nd 24 hrs.			
<u>Vomitus (ml/kg/day)</u>			
1st 24 hrs.			
2nd 24 hrs.			
<u>Intake of ORS (ml/kg/day)</u>			
1st 24 hrs.			
2nd 24 hrs.			
<u>Intake by I.V. route (ml/kg/day)</u>			
1st 24 hrs.			
2nd 24 hrs.			
<u>Intake of plain water (ml/kg/day)</u>			
1st 24 hrs.			
2nd 24 hrs.			

Continued

TABLE VII (CONTINUED)

Parameters	Food ORS	WHO ORS	P
<u>Combined intake</u> (ORS, IV, Water) ml/kg/day			
1st 24 hrs.			
2nd 24 hrs.			
<u>Urine output (ml/kg/day)</u>			
1st 24 hrs.			
2nd 24 hrs.			
Gain in body weight (% of adm. wt.)			
Failure, No. and %			