A COMMUNITY BASED RANDOMIZED TRIAL OF THREE MODES OF ORAL REHYDRATION THERAPY

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Befekadu Teferedegn, M.D.

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by

Dr. Befekadu Teferedegn

DEPARTMENT OF COMMUNITY HEALTH,
FACULTY OF MEDICINE

Approved by the Examining Board.

Adanetch Kidanemariam, CNM.MPH.MSPH.Dr.PH _____
Chairman, Department Graduate Committee

Dr. C. Larson _____
Advisor

Dr. S. Shapiro _____
Examiner

Prof. A. Segall _____
Examiner

Prof. N. Cunningham _____
Examiner

Dr. Gebre Selassie Okubagzhi _____
Examiner

Dr. J.Pickering _____
Examiner

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ABSTRACT

A randomized field trial of the relative efficacy of three oral rehydration therapies (ORT) was carried out in 18 rural peasant associations of Adamaboset district, Ethiopia. The three ORTs were pre-packaged glucose oral rehydration salt (GORS) solution (n= 153), home made cereal based oral rehydration pre-packaged salt (CBORS) solution (n=154), and home made cereal and salt based oral rehydration therapy (CBORT) solution (n=156).

CBORT was superior ($p<.01$) to GORS and CBORS in terms of mean weight gain and diminished stool frequency at 24, 48, and 96 hours following onset of therapy. Analysis of hydration status indicated a higher proportion of children receiving CBORT were found in both the deterioration and improvement categories at 4 hours, but mean dehydration status at 4, 24, 48 and 96 hours was no statistically different among ORT groups. Mothers' compliance was significantly ($p<.05$) higher and children's acceptance not statistically different between those receiving CBORT when compared to GORS and CBORS. The non-packaged CBORT therapy was found to be as or more efficacious than GORS or CBORS in the treatment of acute childhood diarrhoea. On the basis of these findings it is recommended that replication studies of the relative effectiveness of CBORT, particularly in comparison with CBORS, be done with the view of eventually adding CBORT to ORT programs.

INTRODUCTION

Diarrhoeal disease is a major public health problem in developing countries. It is among the leading causes of mortality and morbidity and results in substantial economic and social burden to families. The Ministry of Health of Ethiopia (MOHE) currently estimates that there occur, on average, 4.8 episodes of diarrhoea per year in children under 5 years of age (1). In Adamaboset District, the district in which this study was carried out, acute diarrhoeal disease is the second most common cause of morbidity among all age groups seen in health institutions.

The immediate consequences of acute diarrhoea are dehydration followed by death. An estimated 4 to 5 million diarrhoea associated deaths occur annually in the world (2). In Ethiopia surveys have reported a wide range of diarrhoeal disease mortality rates among children under five. Estimates range from 1.3 to 27 deaths per 1000 children under five per year (3,4). Latest national estimates indicate that for every 1000 children under 5 years there are 9.2 annual deaths due to diarrhoea and 46% of all under-five deaths are due to diarrhoea (1).

Another consequence of acute diarrhoeal disease, in particular following repeated episodes, is malnutrition (5). Repeated episodes occurring in early childhood, a

critical period of growth, will also contribute to growth retardation (5).

There are primary and secondary preventive strategies. Primary preventive measures would include improved access to safe water supply and proper waste disposal; particular emphasis has been given to the disposal of infants' faeces. Generally good sanitary and hygienic conditions, proper nutrition, and vaccination are included in primary prevention strategies. Vaccination for rota virus is on trial in Burma (6). Substantial protection against cholera which can be achieved by oral immunisation has been shown to be effective in volunteer studies and field trials (7,8,9). Research on the development of a vaccine for shigellosis is also ongoing (10).

Secondary preventive strategies, of which this study is concerned, aim to prevent or minimize the immediate and longer term consequences of acute diarrhoeal disease. These strategies include oral rehydration therapies of varied content. The relative effectiveness of alternative formulations of oral rehydration therapy remains controversial. Increased family awareness of the usefulness of early fluid and caloric replacement in acute diarrhoeal disease are also among the secondary preventive strategies. Another important factor is the close accessibility of health services through which

acute diarrhoeal disease can be managed early.

There are several alternative oral rehydration solutions which have been formulated and tested. The best known and most thoroughly tested are the pre-packaged oral rehydration solutions. These can be divided into glucose containing and cereal (rice, wheat, millet, sorghum, potato, maize) based oral rehydration solutions. Alternatively, home made oral rehydration solutions made with materials readily available in the home are now being advocated and tested.

Each of the oral rehydration therapies presently in use is associated with certain advantages and disadvantages which address issues related to their relative efficacy and effectiveness. Considerable controversy exists as to the relative merits of each choice. Most importantly for home made formulations is the question whether or not people can be taught to safely prepare ORS in the home. Other questions include the relative merits of alternative salt and carbohydrate ingredients.

The present policy of the MOHE natinal control of diarrhoeal disease program (CDD), regarding oral rehydration solutions, is to give pre-packaged glucose-oral rehydration salt (GORS) solution to children who attend health institutions. These packets are to be distributed and dispensed by health institutions

(hospitals, health canters, health stations, drug shops and health posts). It is recommended that GORS be given to any child with acute childhood diarrhoea and mild to moderate dehydration (11). In all health institutions except health posts, GORS demonstration "corners" are to be established and caretakers are instructed in how to prepare and give the solution at home. The CDD has stated in a circular no other form of oral rehydration solutions are to be given.

The statement of the policy is mainly for the sake of the uncertain safety and relative efficacy and effectiveness of oral rehydration therapies other than the glucose oral rehydration salt (GORS) solution. As a result, the different oral rehydration solutions particularly the non-packaged which can be made with home available materials remains subject to study.

REVIEW OF LITERATURE

Oral rehydration solution for diarrhoea started as early as the beginning of the 1830's, when salt water was used in the treatment of acute diarrhoeal disease (12). At that time, it was concluded that an oral salt water solution given to an adult patient actually worsened the disease (13).

Renewed attention in the potential efficacy of oral rehydration salt solution began in the 1950's. The interest in oral rehydration therapy developed when glucose was added to salt water solution. There was a significant absorption of water and electrolytes in animal experiments (14). This then led to several clinical trials. The major question was, can rehydration be achieved orally?

Early clinical trials resulted in successful oral rehydration which was as good as intravenous rehydration in cholera patients (15). Thereafter the application of oral rehydration to all acute diarrhoeal disease became an issue of interest to public health personnel.

GLUCOSE ORAL REHYDRATION SALT (GORS) SOLUTION

After the theory concerning glucose co-transport of sodium and water absorption along the intestinal wall was developed, more studies were conducted on GORS efficacy and effectiveness. GORS was found effective for rehydrating people irrespective of age and cause (16,17). It has also drastically reduced the diarrhoea related deaths in epidemic situations (18,19) and in clinical settings (20,21).

Most importantly community based studies were conducted on the effectiveness of glucose oral rehydration salt (GORS). The effectiveness of GORS in

reducing diarrhoea related death among children below the age of six years was evaluated in a rural community of Haryana, North India (22). The glucose oral rehydration salt was implemented in 25 villages by the state health workers (study area A), and in 22 other villages by the unpaid literate village volunteers (study area B). A group of 22 villages served as control in which GORS was not provided from the project area. The case-fatality rate was found to be significantly lower in study area A and B compared to the control area.

Finally after a number of animal laboratory experiments, and some clinical and field trials, agreement was reached to add glucose or sucrose to oral rehydration solutions. This was recommended by WHO and pre-packaged GORS was prepared as pre-packaged WHO/UNICEF ORS and began to be advocated worldwide.

GORS has played a major role in replacing intravenous rehydration in favor of oral rehydration. It is also after this advocation of ORT that the use of oral antibiotics were strongly discouraged for most cases of diarrhoea. The low cost of producing and packaging ORS, the simplicity of and ease of taking the substance orally made it readily accessible. However, disadvantages of GORS were also found. GORS does not convince mothers because it does not reduce stool volume. Too much glucose is also known to lead to an osmotic penalty which

results in more fluid and caloric loss. Glucose is also expensive and not commonly available in the third world. These limitations led to interest in another option, particularly cereal based ORS.

CEREAL BASED ORAL REHYDRATION SALT SOLUTION (CBORS)

In CBORS, the electrolytes sodium chloride, potassium chloride and bicarbonate are used as in GORS, in terms of quantity and preparation (see Appendix A). The difference is that glucose is replaced by cereals. The cereal is mixed with water and the mixture is stirred continuously during boiling. It is then taken off the heat and the electrolyte added.

Considering the cereal based solution, rice ORS began to be tested in the early 1980's and evaluated as a traditional treatment in many parts of Asia and later on in India and some African countries (23,24). The comparative and controlled trials conducted in institutions in the 1980's, initially replacing glucose of GORS by rice and later on by other cereals, found that in comparison to GORS there was lower stool output, shorter duration of illness, smaller intake of rehydration fluid, less vomiting and better weight gain (25-30).

One of the initial comparative studies was between rice ORS (study group) and glucose ORS (control group) in

children between 3 months and 5 years. Lower rates of stool output, shorter duration of diarrhoea, and better absorption of rehydration fluid was found in the study group (25). Another similar comparison done on infants under six months yielded the same results (26).

Usage of other cereals began by replacing glucose with wheat flour and found wheat flour ORS to be superior to GORS in rehydrating children (27) in terms of weight gain at four hours. A Kenyan study utilizing maize showed that the cereal-prepackaged ORS was as efficacious as GORS (28). A study was also done to know the relative efficacy of oral rehydration solution made from partially hydrolysed wheat grain, cooked rice powder, or glucose. Using measures similar to the above study, ORS made from hydrolysed wheat grain and cooked rice powder was found to be better than glucose ORS (29). Rice, maize, sorghum, millet, wheat and potato ORS were also compared and found better than glucose ORS (30).

Giving additional food and either glucose or rice ORS were studied in children with moderate and severe dehydration (31). Initial rehydration was begun using intravenous fluid and subsequently the oral rehydration solution. Stool output differences were seen in the first 24 hours. Boiled rice and chicken was given in the study institution. Stool output was less with glucose, significantly at 8 hours, but not significantly after

starting food.

Less is known about what the outcome will be in a community based situation if mothers are told to give any type of diet to the child in addition to ORS. What will be the relationship between the outcome and the quantity/frequency of additional food? One might expect that the mother would give less additional food if the treatment contains cereal than if it contains no cereal and looks like fluid only. Considering the above factor, it is important to do a cereal and non-cereal comparison in a community based situation.

Following the efficacy studies, effectiveness was also studied in rural Bangladesh (32). Rice based ORS was found to be superior to glucose ORS and to a third control group where drugs were given in that mothers followed used the ORT most if they were in the rice ORS group. Mothers in the control group used ORT the least. Duration of diarrhoea differed significantly between the groups, being lowest for the rice ORS users. After two years of study, complete data on anthropometric measures were obtained for 474, 516 and 606 children respectively in the rice ORS cell, glucose ORS cell and the cell with no intervention (control cell). Children suffering from four diarrhoeal episodes who received rice ORS gained weight significantly more rapidly than those receiving GORS or mainly drugs.

From the above studies CBORS appears to be superior to GORS in terms of efficacy and effectiveness. Yet the difficulties still exist in packaging costs, technique and manufacturing including storage of pre-packaged salt, distribution and availability to families. The presence of cooking facilities in the home is another limiting factor in the use of CBORS.

Rehydration using simple home available materials is another possibility, for which safety, relative efficacy and effectiveness need to be studied.

CEREAL BASED ORAL REHYDRATION THERAPY (CBORT)

Home available fluid was recommended under the principle that it is best to give more fluids during early home treatment (33). Both cereal and salt (NaCl) are commonly available in most households.

In central Ethiopia, North Shoa Administrative Region, CBORT was described during health education sessions. Only 54% of the women were able to measure salt in the safe and effective range using a single three finger pinch after verbal instructions only were given (34). Later on, verbal instructions and a practical demonstration were given. A follow-up survey in 20 communities with 1493 women revealed that 89% of the women knew exactly how to made CBORT solution (35).

Another issue of CBORT is its content. The content of cereals include potassium and chloride. Some amount of replacement of potassium and chloride can be obtained naturally from the cereal in the CBORT and from some additional foods because it is a rule to continue feeding in addition to giving the rehydration fluid (see table 1). Replacement of potassium is a slow process that may take 14 weeks, once potassium supplement is started (36). No obvious ill effects due to hypokalemia by itself in acute diarrhoeal disease dehydration were seen even in one patient who developed a serum potassium level of less than 2 mmol/litre. The results of a study done to compare packed glucose oral rehydration solution and Cereal package oral rehydration salt (30) showed mean potassium level of admission and after 24 hours of potassium replacement to be similar.

It has been shown that solutions without bicarbonate are satisfactory, (37) particularly in mild and moderate dehydration. Assuming salt in the home is 100% NaCl then 5.265 grams of salt are needed in one litre of water to make a solution that is 90 meq./litre (the recommended WHO formula). Solutions above 120 meq/litre are thought to be too high and potentially harmful. A wide range of sodium is found to be effective in rehydrating children - as low as 30 meq/litre to as high as 120 meq/litre (38-41).

Accessibility and distribution of ORS packages have an influence both on impact (in terms of mortality and morbidity) and usage rates. If the ORS packet is available within 4 km. radius from the home, the diarrhoea related morbidity is 2-3 times greater than when it is within 2 Km. However within 5 km. distance of ORS distribution, the health delivery site may have no effect on diarrhoea related mortality (42).

If it is a possible to use oral rehydration methods without relying upon packaged ORS, there will be considerable potential benefit, in terms of reducing mortality and morbidity. Oral rehydration methods using home available materials are accessible at almost every house.

Table 1: Caloric and mineral content of commonly used foods in 100 grams of food.

Items	Energy Value (K.cal.)	K+(mg.)	Cl-(mg)
Cow's Milk	65	150	95
Human Milk	60	58	42
Row Carrots	23	220	61
Barely	360	120	110
Bread Whole Meal	216	220	860
Flour Whole Meal	318	360	38
Lentils	304	670	64

There would seem to be hypothetical benefit of non-packaged home available CBORT in terms of efficacy and effectiveness. Safety has been shown to be acceptable in one study cited above. However studies of efficacy, effectiveness, and particularly safety, must be done in community based situations.

SUMMARY STATEMENT

The pre-packaged GORS, which is still the recommended ORT in Ethiopia, has in most studies been found to be inferior to CBORS in terms of efficacy and effectiveness. With either of these choices, diarrhoea continues to account for several million deaths and much more morbidity in the developing world. Why? Part of the problem may lie in the manufacture and distribution of pre-packaged ORT's. In this regard, the non-packaged, home made CBORT deserves careful study.

OBJECTIVES

To compare the relative efficacy of three alternative oral rehydration therapies in the treatment of acute diarrhoeal disease in children under five years of age. The three therapies are:

i. GORS: Pre-packaged glucose + salt oral rehydration solution,

ii. CBORS: Home made cereal (cereal based) + pre-packaged salt oral rehydration solution, and

iii. CBORT: Home made cereal (cereal based) + home made salt oral rehydration therapy.

Efficacy is measured in terms of duration and frequency of diarrhoea, state of hydration, change in weight, mothers' compliance, and children's acceptance. (refer to appendix A for a detailed description of these solutions/ therapies)

HYPOTHESIS

1. There is statistically significant difference (two tailed), in the relative efficacy of the three oral rehydration therapies as measured by:

1.a. mean duration of illness

1.b. mean frequency of stool

1.c. proportion with improved or adequate rehydration

1.d. mean weight gain

1.e. proportion of mothers complying with oral rehydration therapy instructions

1.f. proportion of children "accepting" therapy.

METHODS

STUDY DESIGN

This is a pragmatic, experimental, randomised field trial comparing the relative efficacy of three alternative oral rehydration therapies in the treatment of acute childhood diarrhoea. The study was carried out in the Adamaboset district of the East Shoa region of Ethiopia. The general architecture of the study is summarized in figure 1.

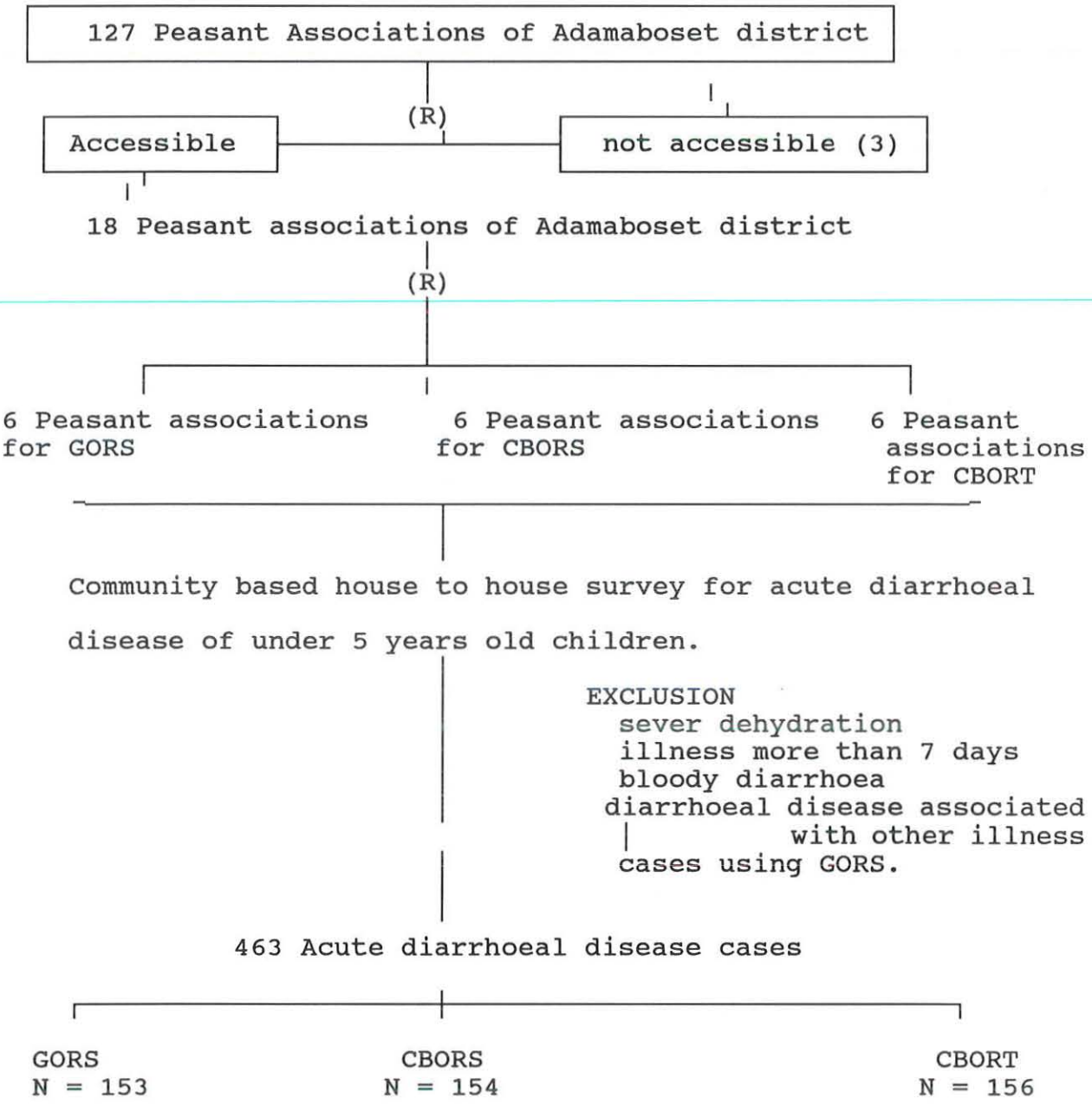

Figure 1: Entrance into study

POPULATION

Source Population. The source population was any child under 5 years of age living in any of the 127 rural peasant associations (PA) of Adamaboset District. At the time of the study the total population of these PA's was estimated to be 106,000. Given an approximate under-five proportion of .20, an estimated 22,000 children were living in 127 peasant associations at the time of the study. Based upon statistics from the National Control of Diarrhoeal Diseases Program (CDD), the 2 week period prevalence for acute childhood diarrhoea (ACD) in this age group is .16 (3). One could then expect about 3,500 cases in total or 28 cases per peasant association per 15 days.

Sample size and power calculations. The formula applied to estimate the sample size requirements for the comparison of two independent means was as follows .

$$N/\text{ group} = Sd.^2\ (Z\ \text{alpha}/2 + \text{beta})^2/\text{delta}^2$$

Setting the alpha error at 0.05, beta error at 0.05, estimating the standard deviation in the mean weight gain to be 330, and wishing to detect a main group difference in mean weight gain of as small as 100 grams, the projected sample size per group was 142.

Study population. Given the need for 150 cases of ACD x three treatment alternatives a total of 450 study subjects were sought. Based upon the above occurrence

projections for ACD, 18 PA's were randomly selected from a table of random numbers. Then by lottery, six PA's and six students were assigned to each of the treatment groups.

Twice a week trained research assistants systematically went house to house to identify active cases of ACD. A maximum of 4 cases per visit were entered and at the next visit they continued where they had left off. At each house the assistants introduced themselves (details in Appendix B) and inquired if there was child under five in the household. Next they identified those who were sick at the time and among those, children with ACD. ACD was defined as three or more loose stools over the past 24 hours and of 7 or less days duration. Among these children a further history was taken, they were then weighed and examined. Those found to be severely dehydrated (refer to Appendix C), those with bloody diarrhoea, and or those with concurrent illness were immediately given oral rehydration and referred to the nearest health centre. These children were seen again at 4 and 24 hours to determine if they had complied with referral and ORT instructions.

Caretakers of children with no to moderate dehydration were told a study was being conducted on treatment of ACD in the district and were asked consent to participate in this study and to instruct them in the

treatment their PA had been assigned. Over a nine week period 463 cases were identified and all consented to participate. The breakdown was as follows; GORS (n = 153), CBORS (n = 154), and CBORT (n = 156).

INTERVENTION

A description of the three alternative oral rehydration therapies to which subjects were assigned follows.

GORS. (refer to appendix A for detailed description of contents) For children who were randomized to GORS, caretakers (almost always mothers) were explained the preparation and shown how to mix 1 sachet in one litre of boiled water. The quantity of GORS mothers were instructed to give was based upon the WHO, dehydration specific, guidelines found in rehydration charts 1 and 2 of appendix D.

CBORS. (refer to appendix A for detailed description of contents) The caretakers of children who were randomized to CBORS, mother or guardian, were asked what cereals (wheat, barely or oat) were available in the home. If not available, cereal was provide. Next instruction was given to measure one handful of cereal flour (50 to 60 grams) with 1.1 litter of water. The latter quantity was measured in a home cooking container and a mark made on a stick corresponding to 1.0 and 1.1 litres. Caretakers were told to continuously boil and

stir the mixture for 10 minutes or to the point it had boiled down to the 1.0 litre mark. This was followed by cooling. A pre-packaged salt mixture of potassium chloride, sodium chloride and tri-sodium citrate (see Appendix A) was then added. The amount of rehydration solution given was according the rehydration charts 1 and 2 in appendix D.

CBORT. (refer to appendix A for details of contents) Children who were randomized to the CBORT group received instructions regarding cereal preparation which was identical to the CBORS group. Instead of the pre-packaged salt electrolytes, one pinch of (three finger up to the first cursor) home salt (NACL) was added. The rehydration solution was given in a similar manner to that of GORS and CBORS, as per charts 1 and 2 in appendix D.

At the end of the demonstration, caretakers were informed they would return in about 4 hours.

MEASUREMENT

Determinant and base line measurement. Demographic data was initially obtained by interview of the caretakers. Then an initial child weight to the nearest 10 grams was taken using a baby scale (Detecto baby scale).

Stool frequency for the past 24 hours was recorded

as reported. The interviewer recorded the output as mild (3 times in 24 hours), moderate (4 to 10 times), and severe (greater than 10 times). Assessment of dehydration was made by the interviewers who were trained to use the WHO assessment chart for dehydration (see Appendix C). This included symptoms reported by the mother such as frequency of diarrhoea, vomiting, thirst, and urine output; signs observed by the interviewer from examination of the eyes, mouth, tongue, respiratory rate, and skin elasticity. According to the dehydration chart, children were then categorized no dehydration, some/ moderate dehydration, or severe dehydration.

Frequency of vomiting as reported by the mother was also recorded according to the categories of none or some (less or equal to 3 in 24 hours), frequent (4 to 7 times in 24 hours), very frequent (greater than 7 times in 24 hours).

Outcome measurement. Following rehydration, measures were taken at four time intervals; 4, 24, 48 and 96 hours. Weight, frequency of stool output (taken at 24, 48, 96 hours only), hydration status, and frequency of vomiting were recorded as described previously, except that the none to mild category of stool frequency was 0 to 3.

The mother's compliance with the instructions to prepare and give the rehydration fluid was assessed by

asking her directly and recording her answer as Yes or No. A Yes answer indicate partial or full compliance. Child acceptability was measured according to the mother's report of whether the child took the fluid very well, moderately well, or refused. Mothers were also asked if they gave additional food and their response was scored as yes or no. These variables were measured after 4, 24, 48 and 96 hours.

DATA COLLECTION

18 recent high school graduates with good grades were selected in collaboration with the high school director. Theoretical and practical training was given in class and in the field over 15 days.

Questionnaires were prepared and the pretested over a one week period. Modifications were then made. Students were then paired and assigned PA. The pairs covered the same PA's throughout the duration of the study. The time sequence and planned field activities are as shown in table 2.

Table 2. Field Activities and the time sequence.

Serial time	Day	Activity
Time 0	Monday or Thursday morning	Identification of 4 study cases, complete questionnaire 1 and apply intervention
Time 1	Monday or Thursday afternoon	1. Outcome measurement and completion of questionnaire 2. 2. Supervision and evaluation of active cases.
Time 2 24 hrs. later	Tuesday or Friday	Outcome measurement and filling out questionnaire 2.
Time 3 48 hrs. later	Wednesday or Saturday	1. Outcome measurement and filling out questionnaire 2.
Time 4 96 hrs. later	Friday or monday	1. Out come measurement and filling out questionnaire 2. 2. Evaluation and supervision of outcome measurements

ANALYSIS

Change in three major outcome indices from baseline were calculated in the following manner.

Weight change. Mean weight change by treatment category at each follow-up time was determined. Statistical differences were tested for (F statistics).

Weight change was also categorised into weight loss, weight maintained and weight gain; weight loss = 0, weight maintained =1, weight gain =2. A mean weight change score for each treatment group was compared at 4, 24, 48 and 96 hours. Finally the relative risks of weight loss vs. weight gain and their 95% confidence intervals were calculated to asses the strength of association between rehydration therapy group and weight outcome.

Change in state of hydration. Dehydration change was scored 0 to 4 according the following criteria.

0 = A change from no dehydration to moderate or severe dehydration. 1 = No improvement in moderate dehydration status.

2 = No change in no dehydration status.

3 = A change from moderate dehydration to no dehydration.

The proportion of subjects by therapy group in each category over time was calculated. Mean group scores at each follow-up interval were computed and F statistics

used to detect if there was a significant difference. Finally the relative risk of deterioration to moderate/severe dehydration or remaining so, by group was calculated.

Stool frequency. Change in stool frequency was scored according the following criteria.

0 = Frequency increased

1 = Frequency remained the same

2 = Frequency decreased from moderate or severe to none or mild.

The proportion of subjects deteriorated, the same, or improved by group was calculated. Mean therapy group scores were computed and F statistics calculated for main group differences.

Mother's compliance. The relative risk between treatment groups of mothers' not preparing and giving the rehydration fluid at any time during 4, 24, 48 and 96 hours computed.

Child acceptance. Scores were given for child acceptability; 0 if rejected, 1 = moderately taken and 2 = very well taken. 4, 24, 48 and 96 hour scores were summed and a mean score calculated. Also the relative risk of rejecting at any time was also computed.

RESULTS

A total of 463 under 5 year-old children with acute diarrhoeal disease were found over the 9 week duration of the trial. Main group assignment numbers were as follows 154 CBORS , 156 CBORT and 153 GORS.

Baseline Descriptive Findings

Age, initial mean weight, dehydration status, and frequency of stool output and vomiting in the three rehydration groups are summarised in tables 3 and 4. There were no statistically significant ($p < 0.05$) between group differences, except stool frequency which was higher in the CBORT group.

Missing subjects at each data collection time during follow-up are as shown in table 5. Missing child or mother, restless child during weight measurement and difficulty with stool frequency estimation were reasons for missing data in the follow up measurements.

Main Group Effects

i. Weight Change. Mean weight change at 4, 24, 48, and 96 hours following onset of therapy by rehydration therapy group is summarised in table 6. It can be seen there is a statistically significant greater weight gain in the CBORT group at each time interval when compared to GORS and CBORS. The proportion of children experiencing weight loss, weight maintained, and weight gain over 96

hours is as summarised in table 7 and in figures 2.a and 2.b. From figure 2.a it can be seen that a greater proportion of children in the CBORT group experienced early weight gain (<24 hrs). The proportion experiencing weight loss is highest in the GORS and lowest in CBORT group at all follow-up times.

Mean score for weight change category over time for the three groups was; CBORS 6.26, CBORT 5.96, and GORS 5.25. These differences were statistically significant, at $p < 0.01$. Finally, the relative risk for weight loss vs weight gain in each group and their 95% confidence intervals were calculated. These results are found in table 8. In terms of relative risk, statistical differences ($p<0.05$) at all times between CBORT and GORS were found, but none were found between CBORT and CBORS.

Multiple liner regression was performed to determine the effect on weight change of initial weight in comparison with rehydration group. Initial weight, entered first, made no significant contribution to the outcome.

ii. Dehydration Status. The proportion of subjects with deteriorated and improved dehydration status by treatment group is as shown in table 9 and in figure 3. A higher proportion of deterioration in hydration status among children receiving CBORT was found at 4 and 24 hours. Paradoxically, it is the CBORT group which also

shows the highest proportion improved at 4 hours. The GORS is lowest at all time intervals. The mean dehydration category scores at 4, 24, 48 and 96 hours are as shown in table 10. There is no statistical difference ($p > 0.05$) in mean scores.

There is also no statistically significant difference ($p > 0.05$) in the relative risk of becoming moderately to severely dehydrated, as shown in table 11.

iii. Stool Frequency. Stool frequency category by rehydration group over time is as summarized in table 12 and Fig 4. Mean treatment group scores were computed and differences tested for their significance as shown in table 12. CBORT was found to be better in improving stool frequency ($p < 0.01$) at all time intervals. The mean summated stool frequency category for the duration of follow-up by rehydration group was as follows; CBORT (5.23), CBORS (4.33) and GORS (4.21).

iv. Mothers' Compliance. The crude relative risks of not complying (i.e. not preparing and/or not giving the rehydration fluid) by treatment group is as summarized in table 13, with 95% confidence intervals and p-values included. These relative risk calculations indicate that mothers using CBORT were much more compliant.

TABLE 3. AGE GROUP DISTRIBUTION OF CHILDREN BY TREATMENT GROUP

AGE (MONTHS)	REHYDRATION GROUP		
	CBORT N(%)	GORS N(%)	CBORS N(%)
6-11	43(27.6)	35(22.9)	29(18.8)
12-23	71(45.5)	48(31.4)	70(45.5)
24-35	21(13.5)	29(19.0)	20(13.0)
36-47	11(7.1)	19(12.4)	18(11.7)
48-56	10(6.4)	22(14.4)	17(11.0)
TOTAL	156(100)	153(100)	154(100)

TABLE 4. BASE LINE HISTORY AND PHYSICAL EXAMINATION.

	REHYDRATION GROUP			
MEASUREMENT	CBORT	GORS	CBORS	P-VALUE
1. MEAN WEIGHT (GRAMS)	9444	9123	9185	NS
2.PROPORTION WITH MODERATE DEHYDRATION	.47	.55	.46	NS
3.PROPORTION MODERATE TO SEVER STOOL FREQUENCY	0.85	0.45	0.54	> 0.05
4. MEAN SCORE OF VOMITING	1.01	1.04	1.00	NS

TABLE 5. MISSED CASES DURING FOLLOW-UP

ORT GROUP	4 HOURS		24 HOURS		48 HOURS		96 HOURS	
	HX*	O\E+	HX*	O\E+	HX*	O\E+	HX*	O\E+
GORS	0	3	3	2	4	2	4	6
CBORS	0	4	5	4	5	4	6	4
CBORT	0	1	0	1	0	2	2	1
TOTAL	0	8	8	7	9	10	12	11

* = HISTORY
\+ = ON EXAMINATION

TABLE 6. COMPARISON OF THE MEAN WEIGHT CHANGE AMONG THE REHYDRATION GROUPS OVER TIME.

	REHYDRATION GROUP MEAN WEIGHT CHANGE (GRAMS)				
TIME HOURS	CBORT	GORS	CBORS	F STATISTIC	P-VALUE
4	105	82.4	37.7	2.34	<0.05
24	259	88.0	86.3	11.3	<0.01
48	303	144	163	4.78	<0.01
96	371	186	162	8.52	<0.01

Change in weight categories

Figure 2A. weight gain

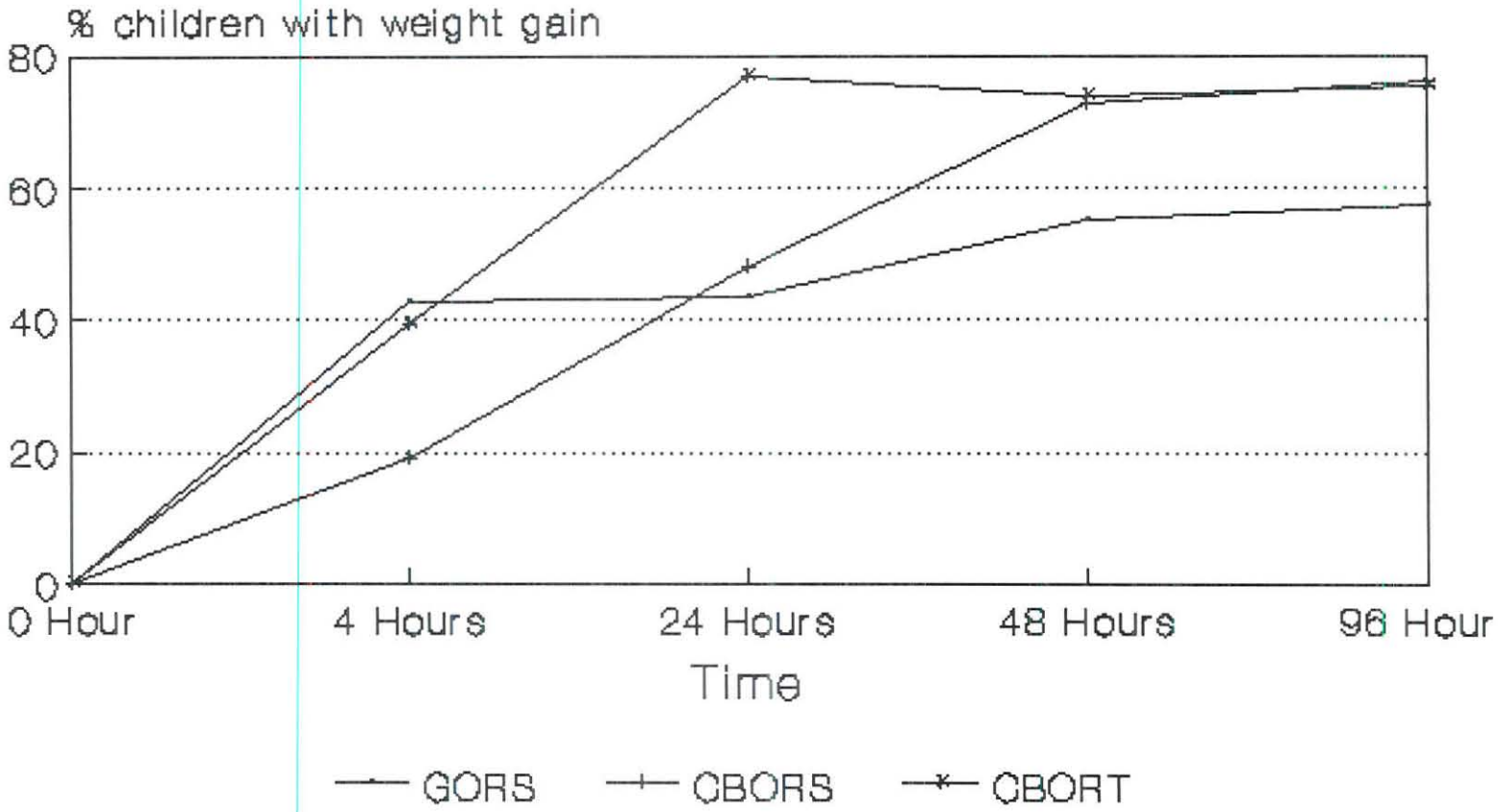

Figure 2. CHANGE IN WEIGHT CATEGORIES
OVER TIME BY ORT GROUP

Change in weight categories

Figure 2b- weight loss

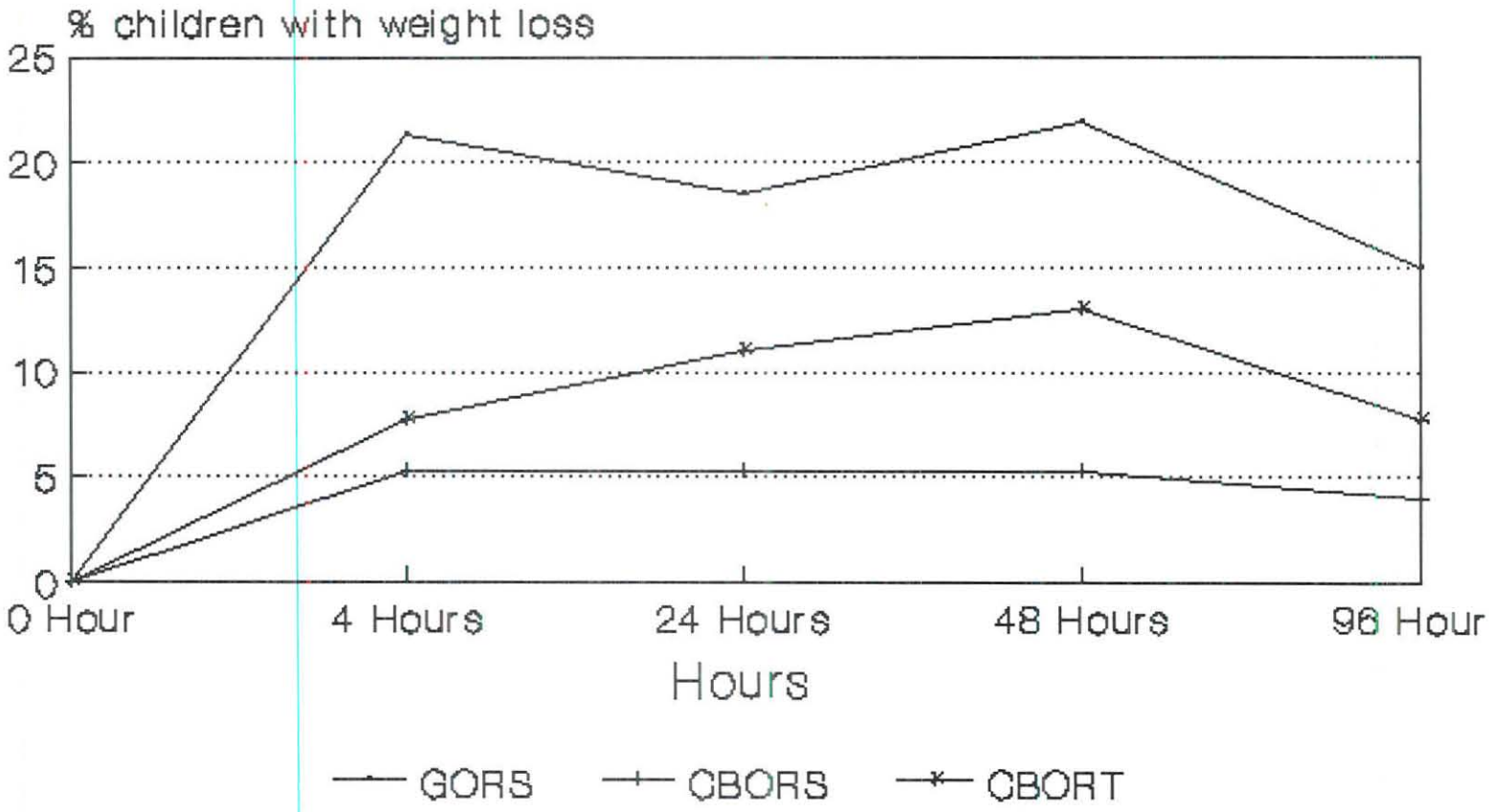

Figure 2. CHANGE IN WEIGHT CATEGORIES
OVER TIME BY ORT GROUP

TABLE 7: CHANGE IN WEIGHT CATEGORIES AMONG TREATMENT GROUPS AT FOLLOW UP INTERVALS

TIME	4 HOURS			24 HOURS			48 HOURS			96 HOURS		
REHYDERATION GROUP	CB-ORT	GORS	CB-ORS	CB-ORT	GORS	CB-ORS	CB-ORT	GORS	CB ORS	CB ORT	GORS	CB ORS
WEIGHT LOSS %	12 7.7	32 21.3	8 5.3	17 11	28 18.5	8 5.3	20 13	33 21.9	8 5.3	12 7.7	22 15	6 4
WEIGHT MAIN-% TAINED	82 52.9	54 36	113 75.3	19 12.3	57 37.8	70 46.7	20 13	35 23.2	33 22	26 16.7	41 27.9	30 20
WEIGHT GAIN %	61 39.4	64 42.7	29 19.3	119 76.8	66 43.7	72 48	114 74	83 55	109 72.7	117 75.5	84 57.5	114 76
TOTAL %	155 100	150 100	150 100	155 100	151 100	150 100	154 100	151 100	150 100	155 100	147 100	150 100

TABLE 8: CRUDE RELATIVE RISKS OF WEIGHT LOSS VERSUS WEIGHT GAIN BY REHYDRATION GROUP

TIME (HOURS)	REHYDRATION GROUP	OUTCOME		RELATIVE RISK	95% CI	P-VALUE
		WEIGHT LOSS	WEIGHT GAIN			
4	1. CBORT	12	61			
	GORS	32	64	2.03	1.12-3.66	0.021
	CBORS	8	29	1.32	0.59-2.93	0.686
24	2. CBORT	17	119			
	GORS	28	66	2.38	1.39-4.10	0.002
	CBORS	8	72	0.8	0.36-1.77	0.738
48	3. CBORT	20	114			
	GORS	33	83	1.91	1.16-3.13	0.014
	CBORS	8	109	0.46	0.21-1.00	0.067
96	4. CBORT	12	117			
	GORS	22	84	2.23	1.16-4.20	0.022
	CBORS	6	114	0.54	0.21-1.30	0.287

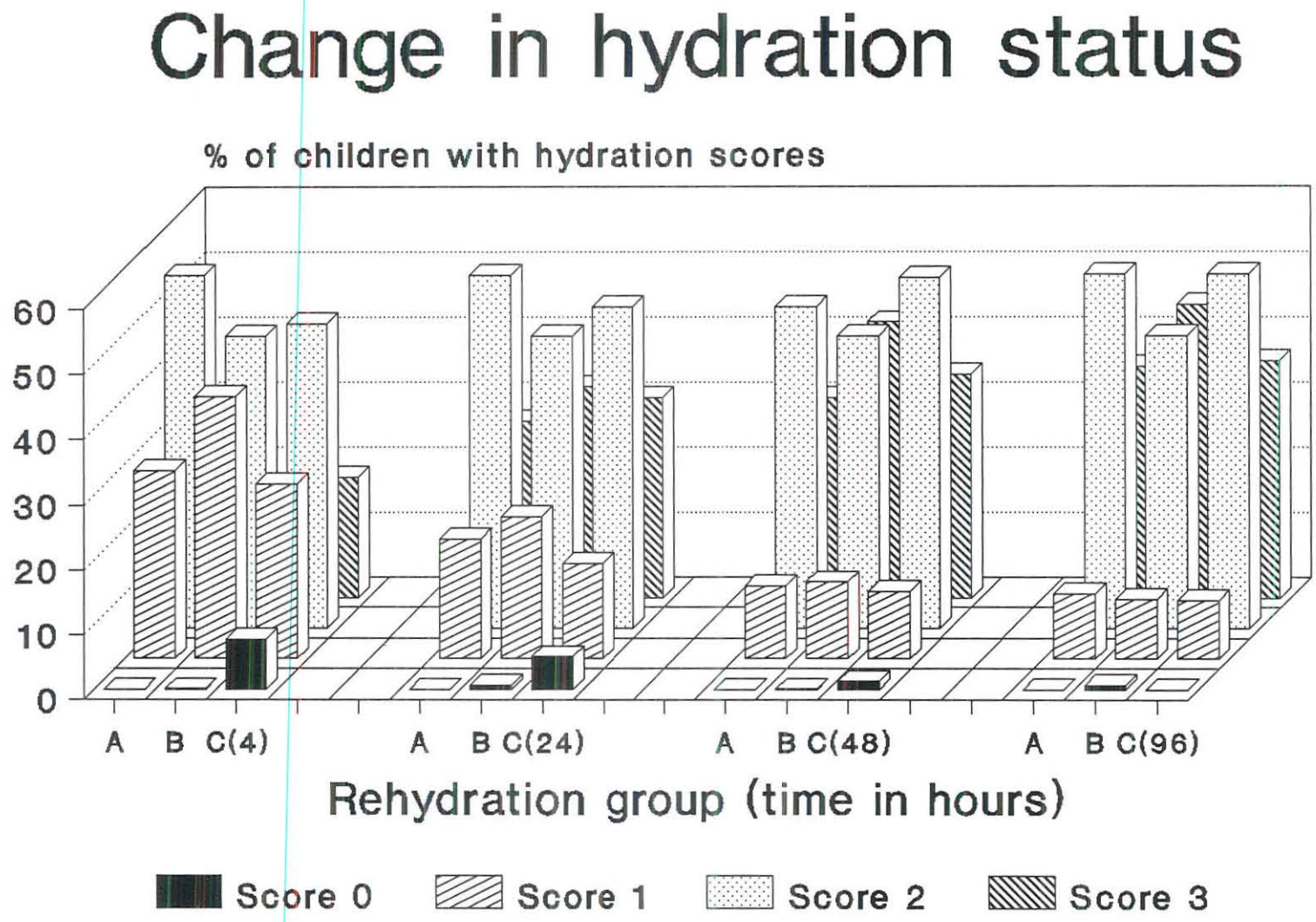

FIGURE 3.CHANGE IN HYDRATION STATUS
OVER TIME BY ORT GROUP.
A= GORS B= CBORS C=CBORT

TABLE 10: MEAN HYDRATION STATUS CATEGORY BY REHYDRATION GROUP.

	REHYDRATION GROUP				
TIME	CBORT	GORS	CBORS	F STATISTICS	P-VALUE
4 HRS.	1.76	1.87	1.72	1.70	NS
24 HRS.	2.06	2.09	2.09	0.10	NS
48 HRS.	2.21	2.23	2.29	0.55	NS
96 HRS.	2.28	2.26	2.34	0.81	NS

TABLE 11. CRUDE RELATIVE RISKS FOR MODERATE TO SEVERE DEHYDRATION BY REHYDRATION GROUP

REHYDRATION GROUP	TIME (HOURS)	OUTCOME MOD. TO SEVERE DEHYD. PRESENT	ABSENT	REL. RISK	95%CI	P-VALUE
I) CBORT	4	54	102			
II) GORS		44	107	0.84	(0.61,1.17)	NS
III) CBORS		62	89	1.19	(0.89,1.58)	NS
I) CBORT	96	14	142			
II) GORS		15	134	1.12	(0.56,2.24)	NS
III) CBORS		15	136	1.11	(0.55,2.21)	NS

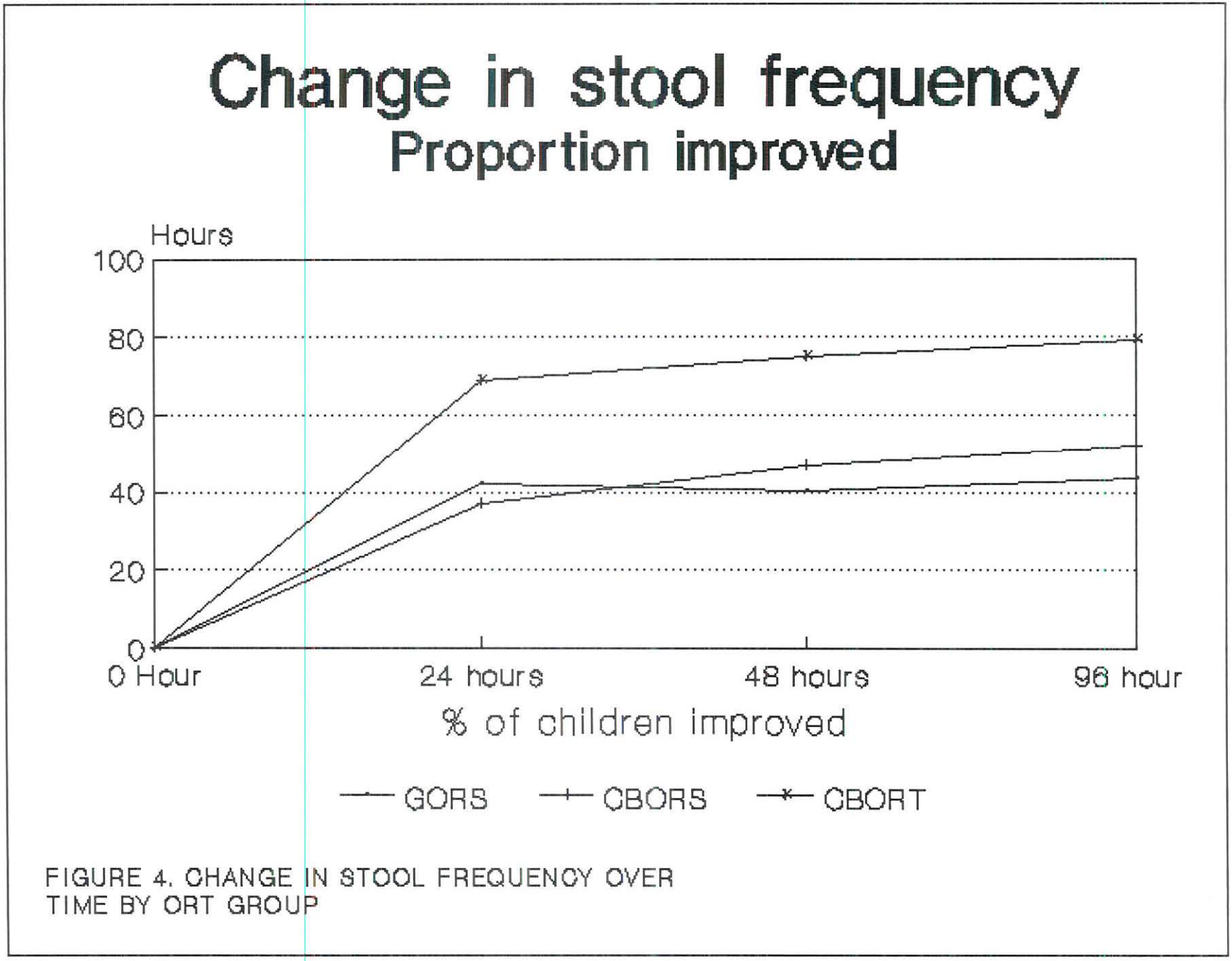

FIGURE 4. CHANGE IN STOOL FREQUENCY OVER TIME BY ORT GROUP

Four mothers assigned CBORS, two CBORT and one GORS did not give additional food at any one time during follow-up despite instructions to the contrary.

v. Child Acceptability. The relative risk of a child rejecting ORT by rehydration group is summarized in table 14. These were not statistically significant. The mean acceptance scores by group over the duration of the study were; 3.714 for CBORT, 3.906 for CBORS, and 3.875 for GORS. The differences are statistically significant ($p < 0.015$), but of uncertain clinical significance.

Initially there were only six children with vomiting more than three times in the CBORS group, 1 case in the CBORT group, and no cases in the GORS group. These numbers were considered insufficient for further inferential statistics.

TABLE 13. MOTHER'S COMPLIANCE IN RELATION TO TREATMENT

REHYDRATION SOLUTION	COMPLIANCE NO	YES	RELATIVE RISK	95%CI	P-VALUE
I) CBORT	1	154			
II) GORS	10	143	10.13	(1.31,78.18)	0.013
III) CBORS	15	137	15.30	(2.05,114.37)	0.001

TABLE 14. CHILD'S REJECTION OF ORT BY REHYDRATION GROUP.

REHYDRATION SOLUTION	CHILD REJECT	CHILD ACCEPT	R.R.	95% CONFIDENCE INTERVAL	P-VALUE *
I) CBORT	22	132			
II) GORS	12	131	0.59	(0.3-1.14)	NS
III) CBORS	9	129	0.46	(0.22-0.96)	NS

* P VALUE- YATES CORRECTED

DISCUSSION

This was a community based randomized field trial done to know the relative efficacy of three modes of oral rehydration therapy in the treatment of acute childhood diarrhoeal disease. The non-packaged CBORT was found to be better than the pre-packaged GORS and CBORS solutions at all follow-up time intervals through 96 hours. In terms of hydration status, CBORT was at least equal to GORS and CBORS. Mothers compliance was best among the CBORT group. Child's acceptance of rehydration fluid was found comparable.

In this trial we used a practical demonstration of the preparation of non packaged CBORT. We did this because of concerns about safety in its preparation. In two earlier studies a verbal explanation was associated with unsafe ORS preparation (composition) while a practical demonstration lead to safe preparation of ORS in the home (34,35).

Weight change. Our finding that CBORS is better than GORS in terms of weight gain is supported by several studies (20,23). The finding that non-packaged CBORT is better than both GORS and CBORS, as far as we know, has not been previously reported. How can the nearly double weight gain among CBORT children be explained? Part of the explanation may be with the documented improved

compliance. Were the CBORT children less ill at baseline, and therefore in a better condition to gain weight? Baseline clinical assessments did not reveal any differences, with the exception of more frequent diarrhoea in the CBORT group, which would tend to diminish weight differences rather than increase them. It may be the case that those mothers not restricted by a set number of ORS sachets will actually give more ORT.

Stool Frequency. The theoretical explanation for reduced stool frequency with cereal vs glucose ORT's is based upon the relative solute loads each solution creates. The carbohydrate in cereals is long chain polymers of glucose. It is speculated that this starch is digested by intra-luminal enzymes , slowly releasing the glucose molecules that stimulate optimum absorbtion of sodium with out imposing an osmotic penalty. The nutritional benefit of cereal over glucose is also well established.

What is the reason the CBORT was found better than both CBORS and GORS in reducing stool frequency? This might need repeated study and observation, but the possible explanations are: more salts like potassium chloride might have no advantage giving in early stage of acute diarrhoeal disease. Another possibility is the simpler the solution the more absorbable, acceptable and adaptable it is in vivo.

Dehydration status. Dehydration status assessment is one of the day to day measurements in acute diarrhoeal disease. However it was not included in many of the studies done to compare oral rehydration solutions. In this investigation there was no clear advantage of one therapy over another in terms of rehydration. This is contrary to some studies which have found improved reabsorption of water with the glucose of both glucose and cereal based solutions (14,15,19).

Mothers' compliance

These are other important factors in the treatment of diarrhoeal disease to observe. This includes mothers' compliance with the preparation and giving of ORT. In this study the best compliance was found among the mothers giving CBORT. This is comparable with an earlier Ethiopian study which found 89% of previously trained women prepared CBORT correctly (21). It may be the pre-packaged ORS (GORS and CBORS) is not acceptable, nor easily adopted by mothers. CBORT may be more acceptable culturally and similar to other home made fluids.

Child acceptability. The relative risks of children rejecting the rehydration fluids were not statistically significant ($p>0.05$). However the mean acceptance score was lowest for the CBORT group, but the difference were quite small and probably not of clinical significance.

The reported outcomes in this study may be effected by inter-observer variation which was created by the specific assignment of rehydration group to specific interviewers. This was minimised by increasing the number of interviewers in each group. Unavailability of exact fluid measuring instruments in most of the houses and use of self reported compliance by mothers are also limitations of this study. However this limitation will affect all rehydration groups in a nondiscriminant fashion.

CONCLUSION AND RECOMMENDATIONS

The non packaged CBORT is found better than the pre-packaged GORS and at least as efficacious as pre-packaged CBORS , in acute diarrhoeal disease management as measured by weight change, stool frequency change, and mothers' compliance. Other outcomes, including hydration status, child acceptability, and giving additional food were not significantly different between groups.

This study was carried out in only one Ethiopian district. The results are considered to be generalizable to rural Ethiopia and are probably applicable to other developing countries.

It is recommended that replication studies on the relative effectiveness of CBORT particularly in comparison with CBORS be conducted, with the view of eventually adding CBORT to CDD recommendations..

A practical demonstration of non-packaged CBORT in the control of diarrhoeal disease is also needed. Initially CBORT requires a thorough discussion with health policy makers and how practically to fit it in the current ORT programs.

It is also recommended that replacement of pre-packaged GORS with pre-packaged CBORS be instituted. In particular the Ethiopian traditional flour beso (toasted and girned barely flour) should be considered in the cereals of both pre-packaged CBORS and non-packaged

CBORT. Beso flour traditionally doesn't require boiling and is simply added to plain water. Starting of CBORS is also beneficiary not only due to its efficacy but also it's similarity with CBORT.

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Appendix A: Oral rehydration solutions

GLUCOSE ORAL REHYDRATION SALT SOLUTION (GORS)

This is pre-packaged WHO/UNICEF ORS. Composition of the solution is Sodium chloride 3.5 grams , Trisodium citrate 2.9 grams, Potassium chloride 1.5 grams and Glucose anhydrous 22 grams.

The molar composition of GORS solution is sodium 90 M.mol/litre, potassium 20 M.mol/litre, chloride 80 M.mol/litre citrate 10 M.mol/litre and glucose 111 M.mol/litre.

CEREAL BASED ORAL REHYDRATION SALT SOLUTION (CBORS)

Cereal in 1.1 litre of water boiled and stirred continuously and a pre-packaged salt with the following composition will be added.

Sodium chloride	3.5 grams
Trisodium citrate	2.9 grams
Potassium chloride	1.5 grams

CEREAL BASED ORAL REHYDRATION THERAPY (CBORT)

50-60 grams cereals of wheat, barely or oat added and one pinch (three finger up to the firs curser) salt (NACL) is added. Then continuously boiled and stirred solution in 1.1 litre of water.

Appendix B: Introduction and Consent Procedure

A greeting and acquaintance by telling the households that they are send from the district health department to be proceeded filling questioner 1.

After you finish questioner 1., tell for care takers that study on diarrhoea treatment is going on in this district of which all are definitely helpful at home.Then ask the care taker consent involving in the study and proceed if the care taker want to be involved.

Appendix C:Assessment of Dehydration in acute diarrhoea

1. Ask about Diarrhoea Vomiting	Less than 4 Liquid st./d less or equal 3	4-10 liquid stool/ day 4 or more	More than 10 liquid st./d greater than 4
Thirst	Normal	Greater than normal	Unable to drink
Urine	Normal	A small amount, dark	No urine for 6 hrs.
2. Look at Condition	Well, alert	Unwell, sleepy or irritable	Very sleepy unconscious, or fits
Tears	Present	Absent	Absent
Eyes	Normal	Sunken	Dry & Sunken
Mouth & Tongue	Wet	Dry	Very Dry
Breathing	Normal	Faster than normal	Very fast & deep
3. Feel Skin	A pinch goes back quickly	A pinch goes back slowly	A pinch goes very slowly
Fontanelle	Normal	sunken	Very sunken
4. Decide	Patient has No or mild signs of dehydration	If the patient has 2 or more of these signs dehydration he has some or moderate dehydration	If the patient has 2 or more of these sign of dehydration he has sever dehydration

Appendix D: Rehydration Plan to Prevent Dehydration for ACD *

Chart 1: Plan A With no or mild sings of Dehydration .

a. Teach mothers how to prepare rehydration solutions show her how much to give:

50-100 ml. (1/4 to 1/2 large cup) of rehydration solution after each stool for a child under 2 years old 100-200 ml. (1/2 to 1 large cup) for older children

b. Give your child food.

Give freshly prepared foods. Recommended foods are mixes of cereal and beans, or cereal an meat or fish. Add a few drops of oil to the food, if possible.
Offer food every 3 or 4 hours (6 times a day) or more often for every young children

Encourage the child to eat as much as he or she wants Cook and mash or grind food well so it will be easier to digest.

After the diarrhoea stops, give one extra meal each day for a week, or until the child has gained normal weight

Tell her if the child vomits, wait 10 minutes. Then continue giving the solution but more slowly - a spoonful every 2-3minutes

Note while a child is getting ORS, he or she should be given breast milk or dilute milk feeds and should be offered food. Food based fluids or salt and sugar solution should not be given in addition to ORS or vice-versa

c. Explain how mother can prevent diarrhoea by:

Give only breast milk for the first 4-6 months and continuing to breast feed for at least the first year
Introducing clean, nutritious weaning foods at 4-6 months
Giving her child freshly prepared and well-cooked food and clean drinking-water.

Having all family members wash their hands with soap after defecating, and before eating or preparing food

Having all family member use latrine

Quickly disposing the stool of a young child by putting it in to a latrine or by burying it

* = Modified from WHO guideline (34)

Chart 2. Rehydration plan B to treat dehydration for acute diarrhoeal disease with some dehydration

a. Amount of Rehydration Solution to Give in the first 4-6 hours

Child's age	1	2	4	6	8	10	12	18	2	3	4	5	6	8	15
	:		months					:			years			:	
Child's Weight in kgm.	:3	4	5	6	7	8	9	10	11	13	15	20	30		
Give this ml. Much Solution for 4-6 Hours	200-400 : 400-600 : 600-800 : 800-1 lt. - 2 lt.														

Use of age is only when one don't know weight. If the child become puffy stop rehydration solutions and give other fluids. If diarrhoea continues, use rehydration salutation when the puffiness gone.

If the child vomits, wait 10 minutes and then continue giving rehydration solution, but more slowly.

b. After 4-6 hours, reassess the child using the assessment chart. Then choose the suitable rehydration plan.

If the child will continue on plan B, tell the mother to offer small amount of food

If the child is under 12 months tell the mother to

- Continue breast feeding or
- If she does not breast-feed, give 100-200 ml. of clean water before continuing rehydration solution

c. Tell her to offer the child small amounts of food every hours

- Tell her to bring the child to the health worker if the child has any of the following
- Passes many stools
- Is very trusty
- Has sunken eyes
- Has a fever
- Doesn't eat or drink normally
- Seems not to be getting better

Appendix E. Questionnaire 1

1. Is there any under 5 years old child in the house? Yes ___
   No ___
2. What type of sickness does the child have ? Diarrhoea ___
   Others ___
3. What is the consistency and frequency ? If the child has 3 or more loose stool or one or more watery stool edit the following.
4. Exclude if diarrhoea is bloody , the child have fever, other illness present, Illness more than 8 days, cases using GORS and cases who are found with sever dehydration of status in assessment of dehydration.
5. Name
6. House number
7. Age ____ months
8. Use table 14 to fill signs of hydration.
9. Decide degree of dehydration after assessment using table 14
   _____ A = None dehydration
   _____ B = Some dehydration
   _____ C = Sever dehydration
11. Weight of the child,____ grams.

DECLARATION

I, the undersigned, declare that this thesis is my original work and has not been presented for a degree in this or any other University and that all sources of materials used for this thesis have been duly acknowledged.

Name Befekadu Teferedegn, M.D.

Signature May 1991

Place Department of community health, Faculty of Mecicine, Addis ababa University

Date of submission May 1991

This thesis has been submitted for examination with our approval as University Advisor.

Dr. Charles P. Larson