DEPARTMENT OF COMMUNITY HEALTH

ADDIS ABABA UNIVERSITY

A RANDOMIZED COMMUNITY TRIAL OF THREE ALTERNATIVE ORAL REHYDRATION THERAPIES IN SULULTA DISTRICT, ADDIS ABABA ADMINISTRATIVE REGION

By

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LIST OF ABBREVIATIONS

ACD	Acute Childhood Diarrhea
CBORS	Cereal Based Oral Rehydration Solutions
CBORT	Cereal Based Oral Rehydration Therapy
CDD	Control of Diarrheal Diseases
Diar	Diarrhea
DHD	District Health Department
Dur	Duration
GORS	Glucose Based Oral Rehydration Solutions
HI	Health Institution
KAP	Knowledge, Attitude and Practice
Mod	Moderate
MUAC	Mid Upper Arm Circumference
NDDCP	National Diarrheal Disease Control Programme
ORS	Oral Rehydration Salt
ORT	Oral Rehydration Therapy
PSC	Peace and Stability Committee
Qs	Questions
St	Stool
UNICEF	United Nations Children's Fund
WHO	World Health Organization

ABSTRACT

This is a randomized community trial which was carried out to compare the relative effectiveness of three modes of ORT in under-5 children with acute diarrhea; to identify the factors associated with compliance and to assess mother's perception of ORTS. The three ORTS were GORS(n=98), prepacked CBORS (n=90), and home made CBORT (n=103). These alternative ORT therapies were compared in terms of mean weight gain and frequency and duration of diarrhea. The CBORT group was equal to or better than the GORS or CBORS in terms of mean weight gain at 24, 48, 72, and 96 hrs following the onset of treatment.

The mean frequency and duration of diarrhea were significantly higher in the GORS group. Increased feeding frequency was associated significantly with higher mean weight gain. Mothers' compliance and child acceptability were higher in CBORT when compared to GORS children and similar to the CBORS children. Mothers' perceptions of ORT as "food and medicine" was found to be an important factor associated positively with caretakers' ORT compliance and child weight gain. This study suggests that beliefs of causation might influence mothers' compliance.

It is concluded that home-made CBORT is as effective as GORS or CBORS and more acceptable in the treatment of ACD. The implementation of well monitored, community based CBORT programs in Ethiopia are recommended.

INTRODUCTION

Diarrheal diseases kill 4 million children under 5 years of age each year. Sixty percent of those deaths are a result of dehydration (1) and this accounts for 25% to 50% of all child mortality in developing countries (2). Death from diarrheal diseases is 20 times more common than in developed countries (3).

In Ethiopia diarrheal disease is one of the leading causes of morbidity and mortality in children under-5 years of age. Several studies undertaken between 1983-1989 in various parts of the country revealed an average of 5 episodes of acute childhood diarrhea (ACD) per child under five/ year (4,5). Current estimates of the period prevalence of ACD (defined as its occurrence over the preceding two weeks) range from 10 to 40 % (5). More than 30% of beds in paediatric wards are occupied by children suffering from diarrheal diseases (4). In children under 5 years of age, annual mortality from diarrhea is 9.2 per thousand (4).

Higher rates of malnutrition and diarrheal diseases consistently co-exist (6,8). In Ethiopia, nearly 20% of the rural population is under 5 years of age and 20% of this population is moderately to severely malnourished (5). Children who are malnourished contribute disproportionately to diarrhoea associated mortality (6). From these facts it is evident that ACD is a major killer and the appropriate design of strategies to reduce morbidity and mortality is a public health concern.

The primary prevention of ACD rests upon improvements in child health and the environment. These include access, use, and maintenance of safe drinking water and sanitation facilities (5). The major interventions advocated by the WHO are improved case management, improved MCH, improved use and maintenance of drinking water and sanitation facilities, improved food hygiene, and detection and control of diarrheal diseases (7).

In light of the socio-economic situation in Ethiopia the provision of safe water to the majority of its rural population may not occur for several more years. Strategies which aim to improve case management and MCH care in health institutions are most applicable to areas with access to a health facility; at this time only 40% of the population. For these and other reasons - the mainstay of treatment and the keystone to the National Diarrheal Disease control program (NDDCP) is the use of oral rehydration therapies (ORT). The NDDCP in Ethiopia primarily emphasizes proper case management as an effective strategy for reducing death due to dehydration from diarrhea (4).

ORT is an inexpensive method of preventing and treating dehydration caused by diarrheal diseases and it has been taught to almost one-third of developing world families over the past decade (1). However, each cultural setting may have different responses to different modes of treatment. Countries, even districts within a nation, have unique cultures and their approach to and acceptance of different forms of treatment will vary.

Will adoption of CBORT improve the levels of appropriate case management by care-givers (mothers) in countries where low coverage and high morbidity and mortality due to diarrheal diseases is high? Or is GORS sufficient to reduce mortality by increasing the access and the coverage under such realities?

Under ideal circumstances the alternative modes of ORT, which include prepackaged and home made preparations, are all known to be efficacious (2-5,9-14,18-24,31-34). However, effectiveness has not been clearly shown for any of the ORT's on a mass scale in Ethiopia. The identification of which mode of ORT is more acceptable, affordable and accessible at the community level is of crucial importance in the control of the consequences of diarrhoeal disease in Ethiopia.

Acceptability of ORT does not merely depend on its effectiveness. An important factor in the acceptability of ORT is the mother's judgement of the treatment which may not be based only on actual observation but on certain cultural influences or perception of the mode of treatment. It is based on these assumptions that the WHO recommends anthropological studies to be carried out simultaneously with clinical or field trials (15).

In Sululta district where ACD ranks first among the ten top diseases in under-5 children, health service coverage is less than one-quarter and less than 5% of the total population (130,000) in the district has access to safe water (16). Therefore, it is not difficult to estimate the impact of ACD on morbidity and mortality of under-5 children in the district where provision of safe water

for most of the population is a remote hope. Hence, it is of paramount importance for the district management to design strategies which will be effective in rural communities with the minimum of reliance on the health facilities.

This requires a policy at the national level. What should be the policy in countries like Ethiopia where the morbidity and the mortality due to ACD is extremely high? Which is more feasible and acceptable? Should there be a shift to CBORT or should it be added to the CDD program as a supplemental approach? Once GORS which is expected to be less superior (9-14, 19-22, 24, 31) has become part of the general medical practice and is used widely, performing an adequate clinical or field trial becomes difficult ethically and logistically (17). Instituting such community trials as early as possible in the evaluation of new therapies is advocated particularly when preliminary evidence of the efficacy of an intervention looks promising enough to warrant the effort and expenses involved. To address these problems, effectiveness studies are required which aid and provide objective guidance in the choice of therapy.

The anticipated utility of the study at the district level is, 1) to identify which mode of treatment is effective in the treatment of ACD in under-five children, 2) to identify which mode of treatment is most culturally acceptable, 3) to identify barriers to compliance with ORT instructions, 4) to further the development of strategies in the control of ACD, and 5) to help in the design of appropriate health education.

LITERATURE REVIEW

The historical appearance of ORT as a treatment for ACD encountered many challenges. As in the progression and development of other medical technologies it has not followed a linear progression. It has passed through a paradoxical path with a step-ladder progression, and a sharp decline in its initial development and later manifested with a remarkable boom since the 1960s. The appearance of ORT and its development are illustrative of the challenges faced by a new- yet simple technology.

HISTORICAL BACKGROUND

It is believed that ancient societies used ORT in the treatment of ACD (9). However,until in 1832 there had been no documented use of ORT. At that time O'Shaighnessy in The Lancet wrote of an oral salt solution that was given to an adult cholera patient. In this instance the solution actually worsened diarrhea (22). Later Lewis and Sellard (1910) suggested and then demonstrated the successful use of oral alkaline solution. However, it was not until 1940 that Harrison used an electrolyte solution with glucose to successfully treat mild diarrhea and dehydration (22). In the early '50s the use of fluids in the treatment of ACD and amino acid uptake in thymic nuclei was demonstrated. Mechanisms of the models were developed by a number of investigators by the early 1960s (22).

The first clear scientific demonstration of the use of oral rehydration therapy was reported by Philip in 1964 (22). He did an absorptive study in which glucose as substrate was added to an

electrolyte solution in adult cholera patients. His results were discouraging.

In the mid '60s a number of studies demonstrated an increase in the transmural water absorption potential when glucose was added to the electrolyte solution bathing the small intestine. The major setback came with a clinical study conducted in the fall of 1967 during a cholera outbreak reported in Malumghat, a small town in Pakistan . The study was carried out in adults and it was a dismal failure. A significant number of patients (over 50%) required IV therapy after ORT was started. Soon after there was an outbreak of cholera in Dhaka, Bangladesh in the late winter and spring of 1967-1968. Clinical studies on the use of ORT in adult cholera patients were conducted after making some modifications to the previous formulation (in particular increasing the potassium concentration). It was demonstrated that in 80% of cases IV rehydration could be avoided in those patients treated with oral therapy after initial dehydration was corrected with IV solution.

Shortly after these clinical studies, research was carried out to test the efficacy of ORT in the field. The Matlab field study was the first to demonstrate the effective use of ORT. In this study there was a 70% reduction in IV fluid use in comparison to a similar group of control patients. Later Mahalanabis and his colleagues demonstrated the dramatic effectiveness of ORT in the treatment of cholera outbreaks among Bangladesh refugees in 1971(22).

In 1977, the WHO adopted a formulation (appendix A) that could be used for most cases of diarrhea regardless of etiology or age of patient, presently known as WHO-ORS (GORS). Its efficacy in rehydration has been reported in many studies (25). But because of its minimal effect in reducing volume and duration of diarrhea, further investigations were performed to find a " Super ORS ".

ORAL REHYDRATION THERAPY

Currently, there are four forms of ORT which are variably utilized worldwide. These are 1) pre-packed glucose-based oral rehydration solutions (GORS), 2) pre-packed cereal-based oral rehydration solutions (CBORS), 3) cereal-based home made oral rehydration therapies (CBORT) and, 4) Sugar-Salt Solutions (SSS). These different forms of treatment have particular advantages and disadvantages. The advantages and disadvantages are presented in Table 1.

The key element in the treatment and prevention of dehydration is replacement of fluid and electrolytes. The physiological basis for ORT efficacy rests upon the enhanced rate of transport of sodium across the mucosal membrane increased in the presence of monosaccharide substrates such as glucose and galactose and nonessential amino acid such as alanine. However, as indicated in table 1 the major concern in the use of the GORS is its failure to stop diarrhea. This is a major barrier in the acceptance of ORT. Continued loose,watery stools might mean to mothers failure of the treatment to cure the child. For greater number of the rural mothers providing fluid when it is clearly coming out in quantity

Table 1. Advantages and Disadvantages of the Different Modes of ORTs.

	GORS	CBORS	CBORT
Advantages			
1. replaces lost fluid and electrolyte and prevent dehydration	+	+	+
2. prolonged stability	+	?	?
3. reduce duration of diarrhea	_	+	+
4. reduces volume of diarrhea	_	+	+
5. cultural acceptability	?	+	+
6. obtained easily at home	_	_	+
Disadvantages			
1. lack of safety	_	_	?
2. fuel cost high	_	+	+
3. inadequate caloric intake	+	_	_
4. logistic problems in relation to manufacturing and distribution	+	+	_
5. osmotic penalty if supplemental sugar is added	+	_	_
6. requires more time for preparation	_	+	+
7. potential for errors during preparation	_	_	+

+ =yes _ = no ?= controversial

makes no sense (22,26). Hence, in the search for other remedies, mothers may end up in using costly, ineffective antibiotics or harmful herbal medicines (22,26). An additional consequence of this is malnutrition or death due to dehydration.

But to the rural mother the most important and crucial element of the treatment is cessation of diarrhea and not replacement of "invisible electrolytes". The concern of the health professionals is to rapidly and appropriately replace lost fluid and electrolytes to prevent or treat dehydration while the concern of mothers is " cessation of diarrhea". In a study in Mexico City on the treatment of diarrheal diseases, drugs that provided symptomatic relief prompted much higher compliance(15). It seems that it is more acceptable when dealing with bodily manifestations for people to view illness as no more and no less than symptoms. Thus what medical personnel see as relatively unimportant signs of diarrhea may, for the users, be a paramount marker of treatment success (15). Improved diarrheal management is primarily a problem of behaviour change, unlike the physiology of the intestine or the action of ORT, behaviour and its cultural bases are different from society to society. Therefore, an ultimate evaluation criterion upon which to judge ORT effectiveness must be its role in stimulating use by mothers and by health workers in the population at large and not only by its clinical effect (22). Another challenge is to ensure access to ORT at the earliest sign of diarrhea. The mother, who is usually the first person to diagnose ACD is also the optimal person to initiate therapy at an early

stage (22). It is estimated that packets provided by the WHO are used only in 19% of episodes of diarrhea worldwide (28). Therefore, to design strategies of early treatment is tremendously important to the rural over-burdened mother who has no access to modern medicine.

Ethiopia adopted the WHO/CDD program and packets of ORS are available in hospitals, health centers, and health stations around the country but the supply to the health institutions is not constant. Moreover, less than one-half of rural families have access to clinical facilities and ORS packets are rarely available in the home for early treatment of diarrheal episodes (18). If the reports that the average child under 5 has about 5 bouts of diarrhea are accurate and 2 packets are necessary for each episode, at least 80 million units would be required in rural Ethiopia every year(18). The availability of this amount, the logistics and distribution requirements would pose major problems. Hence, a search for accessible, acceptable, affordable and safe ORT is an urgent, first order priority in the control of diarrheal diseases in Ethiopia.

Home made solutions of sugar and salt can be used for oral rehydration. However, unavailability of sugar, potentially harmful errors in mixing, lack of the added potassium and base are the major barriers in its utilization (28). The NCDDP of Ethiopia did not recommend its use in Ethiopia (4). It is fascinating, however, to realize that there is an " ancient folk medicine " which is

currently recognized as "scientifically" accurate, affordable and, accessible-the cereal based oral rehydration therapy.

A great deal of work has been carried out in the area of cereal-based oral rehydration solutions. This work was pioneered by Molla and his co-workers (22). A large number of cereals have been studied. Rice was the first and is the most extensively studied. It has been found to be as effective as GORS in replacing fluid losses (9, 12-14, 19-23, 30,36) and in nearly all studies it has resulted in a decreased stool output and shortening of the duration of diarrhea. Other cereals which have been recently studied are maize in Kenya and wheat in Ethiopia, to give some African examples (12,29).

In a study conducted in the Wello region of north central Ethiopia it was found that a wheat-based-ORT was equally effective to GORS in the treatment of mild to moderate dehydration and resulted in superior weight gain over the initial 4 hours of treatment (12). There was no significant weight gain after 4 hours. Recently, in Adama-Boste District, East Shoa, a randomized community-based field trial compared the relative efficacies of CBORT, CBORS and GORS. In this study Befekadu T. reported home-based CBORT to be superior in terms of mean weight gain, stool frequency and mothers' compliance over 96 hours (14).

However, there are several concerns expressed concerning use of cereal-based ORTs. Some suggest that CBORT may be considered as food by mothers, and divert them from supplemental feeding of their children during treatment of diarrhea. Other issues include the

cost of fuel and time of preparation for already overburdened mothers. There is also the potential for error in CBORT preparation of the salt and cereal and lack of prolonged stability (2, 5).

Experience from different countries has demonstrated that the ability of mothers to prepare solutions with a safe sodium concentration appears to vary widely from place to place (37-42, 44-47). Regarding the possible hazards of ORT the potential of hypernatremia in infants receiving high solute loads has received the greatest attention (47). Some reporters indicated side effects due to ORT itself are rare if the solution is prepared correctly (18, 46, 47). The lower osmolarity of cereal compared to glucose solutions should enhance safety; because of this, variation in salt concentration may matter less (2,22).

Studies in north-central Ethiopia showed that the "three - finger pinch " of salt does not lead to the expected fear of hypernatremia (46) and also care-providers were found capable of properly preparing an ORT solution using home salt supplies. Furthermore, this amount is also within the "normal limit" of the WHO recommendation (49). A study conducted in Yifatina Timuga District demonstrated that cereal-based ORT was well accepted and could be properly prepared. 89% were found to prepare CBORT correctly following verbal instruction and practical demonstration (18). The amount of salt added by the countryside women was found to range between 51-103 mg/liter and was thus considered safe (18).

In a recent study the increased cost to the mother of the time, work and fuel needed to prepare CBORT and the complexity of the preparation were considered to reduce its acceptability as compared to the convenience of the more easily and rapidly prepared GORS. Many studies demonstrated that since CBORT is familiar to local people and used traditionally for illness, and is available in virtually every home the comparative cost to the rural mother who is expected to travel hours in search of medical therapy is minimal (2,12,18,46). Moreover, if caretakers are trained in session which combine verbal and practical demonstration a large proportion of mothers could remember specific educational points (67-92%) and 89% could correctly make the solution (2,12,18).

Another problem to be considered is the cost of pre-packed cereal-based solutions. A recent study demonstrated that among the main cost factors was the higher production cost of rice ORS packets (34). Expected early recovery from diarrhea with use of rice ORS was not observed in this study. Furthermore, recently a meta-analysis of thirteen clinical trials revealed in non-cholera acute diarrheal cases that the average reduction in initial rate of stool loss was only 19 % and this is in the opinion of the authors unlikely to justify the major effort and expense required to change over from glucose to pre-cooked rice in the ORS-formulation, especially in the developing countries (50).

With these limitations in mind, WHO recently endorsed (1991) GORS to be the most effective ORT (61). As mentioned earlier there

is strong support for the use of CBORT in several developing countries. Availability, access, safety, cost and effectiveness remain major issues to current health care strategies say the proponents of CBORT. That is, health care strategies must necessarily focus on the local actions which can, wherever possible, be taken at the personal and family level (22). Therefore, the question to be addressed is : Is CBORT as effective as GORS or CBORS accounting for the critical issues explained earlier?

In view of the current concern and based on the recommendation of previous studies it is important to study the relative effectiveness of GORS, CBORS and CBORT.

DETERMINANTS OF HOME MANAGEMENT OF ORT

It has been increasingly recognized that the ultimate control of diarrheal diseases depend upon a comprehensive understanding of local beliefs and practices that relate positively or negatively to its transmission (51). It was 10 years ago that the WHO stated that "there is an urgent need to understand mother's present attitude, perception, and practices regarding diarrhea as well as those of other community workers" (51). Yet too often only little attention is paid to cultural factors, particularly to knowledge, attitude and practice related to treatment of ACD.

In the light of the demonstrated importance of culture in ACD, it seems plausible that individual knowledge, attitude and practices with regard to cause, treatment and behaviour is

relevant. The assumption is that a better description of the relationships between knowledge, attitude and practice will lead to an improved understanding of their relative importance in the management of ACD.

However, lay perception and explanation of diarrhea are often dissonant with the scientific theory and hence proposed treatment often differs accordingly (15,52). The beliefs of mothers are dependent on several factors including information passed on from generation to generation, advice given by the elders and past experiences. However, beliefs vary from place to place due to cross-cultural influences (43, 51-60).

African studies demonstrated that the perceived cause is a significant predictor for utilization of the formal health services: illness ascribed to " physical cause " or to a combination of " physical " and "social " causes were brought to the attention of a representative of the formal health service more often than illness ascribed to "social" or "spiritual" causes only (52). Bertrand revealed that maternal knowledge along with specific knowledge of the causes and treatment of diarrhea may have some protective value against diarrhea in mothers and young children in Columbia (52). Lozoff in South India (52), Escobar in Peru, Erasmus in Ecuador, Green in Swaziland and O.Eisemon in Kenya have studied causes of diarrhea, the beliefs about childhood diarrhea and have demonstrated that various factors -cognitive, attitudinal, and situational- seem to have imposed major constraints on correct use of ORT in the home.

Previous studies offer a basis on which to single out major gaps in our knowledge about determinants of ORTs. In general, the studies revealed that causation of diarrhea may be ascribed to a variety of" etiological" factors, such as evil eye, teething, cold and hot food, etc. There are no simple answers to such complex issues as culture, roles of belief, attitude and individual behaviours. Decisions of source of choice of treatment are influenced by multiple factors which are dependent on the cultural and socio-economic status and their interaction with the range of therapeutic options. This may include belief of causation, the available and accessible mode of treatment and the role of traditional remedies (15, 52).

Major reasons for the poor outcome of diarrhoea episode may be the mothers' treatment of it in her home and the kind of professional treatment she seeks (59). Many studies have reported that mothers restrict the amount of fluid (43,59) and food given to their sick child . Particularly in home-made ORT -the amount given was less than " prescribed dose " (42). Poor treatment by mothers has in turn been attributed to their lack of knowledge about the causes and consequences of diarrhea management of ACD.

Various studies conducted considered the relationship between KAP and occurrence of ACD (43, 51-60). These factors appear to affect the mothers' treatment practices, however, only a few studies have attempted to demonstrate the relationship between knowledge, attitude, practice and the compliance of caretakers and the outcome of the treatment. While providing a strong initial

data base these studies require fuller confirmation by observational studies. The WHO recommends new and innovative types of research that are necessary to better understand the determinants of home management (15). Thus, it is important to delineate various factors- cognitive, attitudinal, and situational- to identify determinants of home management of ORT.

Beliefs and cultures within a given society are not logically consistent, and this supports a certain degree of variations in choice of treatment (51). The anthropological literature suggests there are broad differences across regions and between different ethnic groups. Hence, in treatments which are strongly influenced by beliefs and cultures of societies it is relevant to study the knowledge, attitude, practice and perceptions of caretakers to identify the factors which are associated in reducing compliance of ORT and in the final analysis to help in the design of appropriate strategies in the control of ACD.

OBJECTIVES OF THE STUDY

1. To compare the relative effectiveness of GORS, CBORS, and CBORT in the treatment of ACD in under five year-old children.
2. To identify factors associated with better compliance among caretakers of under five year-old children in the treatment of ACD .
3. To assess mothers' perceptions of ORT and identify its impact on compliance and weight gain.

HYPOTHESIS

There is a statistically significant difference ($p < 0.05$, two-sided) in the effectiveness of CBORT when compared to GORS or CBORS in the treatment of ACD as measured by mean weight gain over the course of seven days.

METHODS

OPERATIONAL DEFINITIONS

1. Acute childhood diarrhoea : occurrence of three or more loose or one or more watery stools over a 24 hours period.

2. Glucose-based ORS (GBORS) : the standard WHO/UNICEF formula for oral rehydration.

3. Cereal-based ORS (CBORS): the standard WHO/UNICEF formula but with glucose substituted by cereal.

4. Cereal-based ORT (CBORT) : the administration of rehydrating fluid composed of a thick but drinkable mixture of cereal mixed with a small amount of salt added to it.

5. Tonic : a therapy which strengthens the child.

6. Case-worker : a female high school student who did the actual intervention and interviewing of caretakers.

STUDY DESIGN

This is a pragmatic, randomized, community trial of the relative effectiveness of GORS, CBORS, and CBORT. The study was carried out in Sululta district, Addis Ababa Administrative Region, from October 1991 to January ,1992.

POPULATION

Desired Sample Size

Based on the findings of the study of the National CDD program the expected 2-week prevalence of ACD was estimated to be .16 in

under-5 children in the district. However, in the pilot phase of this study the estimated prevalence was found to be less. The finding was 8 episodes/2 weeks/ village in under-5 children.

The desired power and confidence limits of the study were set at .90 (1-B) and 95% (.05 alpha) respectively. Based on previous study (14) it was estimated that the standard deviation in mean weight gain at 24 hours would be approximately 100 grams and the minimal detectable difference in mean weight gain between the groups to be 50 grams. The ratio of the study groups was planned to be approximately 1:1:1. Allowing for a 10% dropout and exclusions it was decided to aim for 93 episodes per group.

Calculation of the sample size (62)

$$\frac{N}{group} = \frac{(Z\frac{\alpha}{2} + Z\beta)^2 \sigma^2 (r+1)}{d^2 r}$$

Therefore,

$$N = \frac{(10.5)\quad (100)^2 \quad (2)}{(50)^2} = 84$$

$$(Z \text{ alfa}/2 + Z \text{ beta})^2 = 10.5$$

Sampling Procedure

There are 95 rural villages in Sululta District. Three zones which are geographically isolated areas were selected each representing one treatment area. The purpose of this was to prevent the dangers of spill-over and dilution between adjacent units. Based on the desired sample size and two-week prevalence of under five diarrheal disease in the District 12 villages were judged necessary. These 12 villages were randomly selected from the villages which are within 5 kms. radius of small "zonal" towns (for logistic purposes) by using random numbers from a scientific calculator (SHARP EL-545H). Since there are three modes of treatment four villages were randomly assigned to each zone which is one treatment group (for architecture of trial and sampling frame-work, please see figure 1). Then randomization to treatment groups was performed by using random numbers from the same calculator and the three modes of ORT were assigned to three treatment groups.

Source Population (refer to figure 1 and 2)

Under-5 children in Sululta District rural villages.

i) Inclusion criteria :

1. AGE > 4 months and < 5 years

Ages < 4 months were excluded because of the controversies in this age group with regard to digestion of starch due to lack of amylase (for ethical purpose).

2. ACD less than or equal to 7 days duration

ii) Exclusion criteria:

1. severe dehydration excluded by WHO assessment chart (please see appendix J).

2. bloody or bloody-mucoid diarrhea excluded by history and or physical examination.

3. chronic illness (any illness > 15 days duration) including chronic diarrhea (> 7 days).

4. severe malnutrition excluded by mid-upper arm circumference based on the WHO criteria (63).

5. concomitant treatment with ORT and/or antibiotics as excluded by history.

Study Population (refer to figure 1)

A home to home census was made and the total number of the population in the 12 villages was found to be 11,985. Of these 1163 were under-5 children. A total of 291 cases of under-5 children living in 12 villages who satisfied the criteria were included in the Study.

The basic assumptions and estimates made to determine the desired number of villages were the following :

- Average number of population of village = 1000
- Under - 5 children in a village = 18%
- Hence, excluding < 4 months 170 under-5 children in one village.
- Expected cases/ village = 8
- Three-quarter were expected to attend = 6/village.
- 6/village/two-weeks.
- 24/village / eight - weeks.
- In 4 villages it was calculated to be 96, which allows for a 14 % margin for dropouts and exclusions.
- In 12 villages 288 cases were expected to attend the corners.

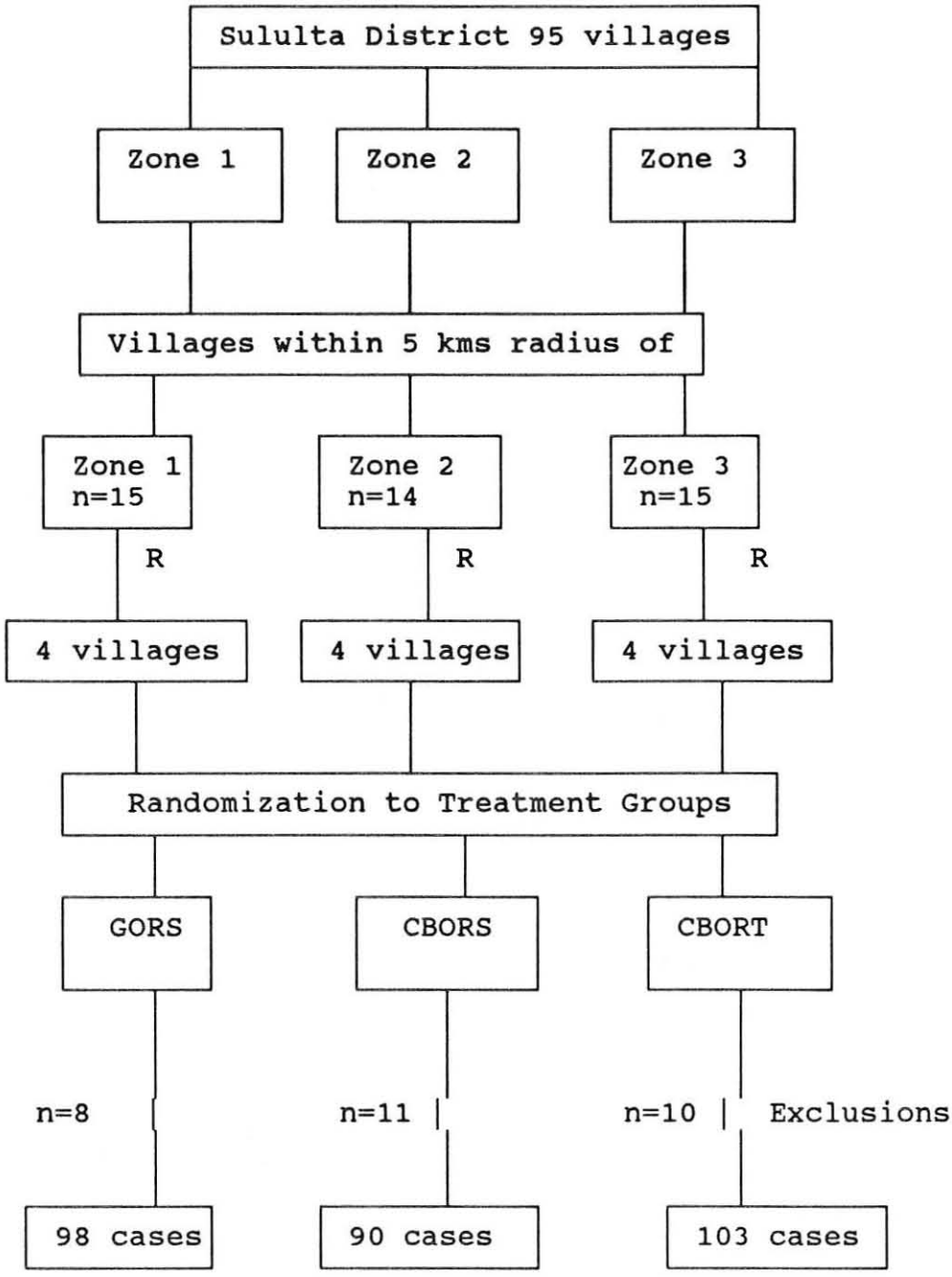


Figure 1. Architecture of Trial and Sampling Frame-work.

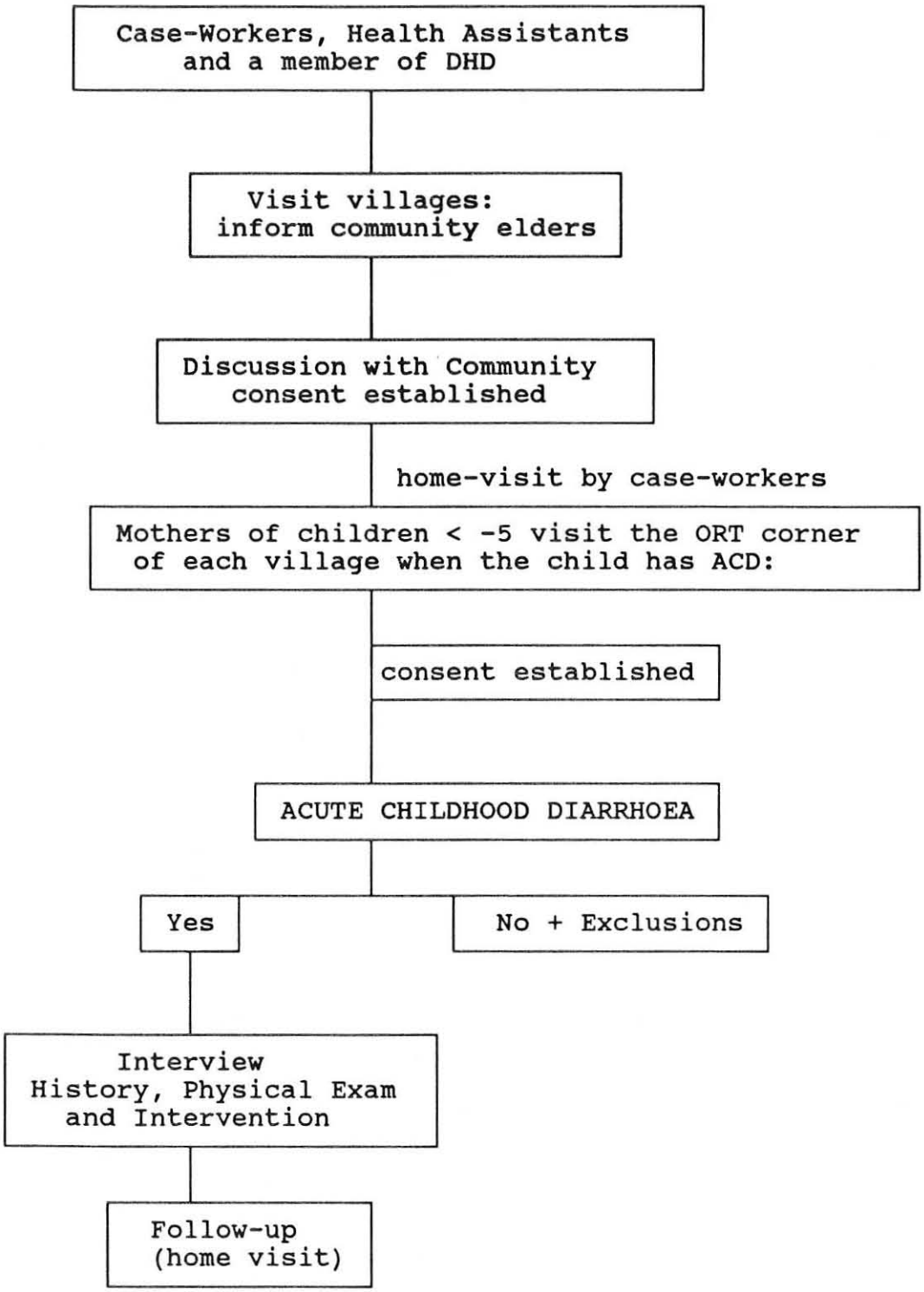


Figure. 2 Enrolment of Villages and ACD cases.

INTERVENTIONS

1. GORS : This is the standard WHO UNICEF formula for Oral Rehydration Therapy (appendix A). For those care-takers who were randomized to GORS explanation about the preparation was given and its preparation was demonstrated by the case-workers. Mothers were then requested to explain and re-demonstrate the preparation. The quantity of ORT given was based on WHO guidelines (appendix B).

2. CBORS : This is the same WHO/UNICEF salt but minus glucose, thus glucose has been substituted by cereals added by the mother. A pre-packed ORS which did not contain glucose was prepared by the Ethiopian Pharmaceutical Corporation factory to be used in this study. The care-takers of children who were randomized to CBORS also passed through the same instruction and demonstration given to the GORS group.

3. CBORT : This is a rehydration therapy composed of a thick, but drinkable mixture of cereal with salt added. It was prepared at home after caretakers received appropriate instruction and follow similar procedures as in the aforementioned groups. In CBORT there is no pre-packaged salt given, however, an appropriate standardized amount of salt (one pinch) was added to the preparation (please see appendix C). At the end of the preparation care-takers were informed that the case-workers would visit their home after 1, 2, 3, 4 and 7 days.

MEASUREMENT

Exposure variable . This included a baseline interview (appendix D) and questionnaires of determinants of compliance (appendices E and F). The major exposure variable was ORT.

Outcome variables . The outcome variables include items which are suggested by The International Child Health Foundation and The Aga Khan foundation for field trials (2).

Weight gain was measured to the nearest 10 grams by using a Salter scale. Each child was weighed naked initially, after 24, 48, 72, 96 hours and on the seventh day. The accuracy of the scale was checked daily by measuring a known weight . ORT solution intake was measured by the numbers of coffee cups the child took and was recorded as reported by the caretaker. Frequency and duration of diarrhoea, frequency of feeding and of vomiting were recorded as reported by the caretaker. ORT acceptability of the child was recorded according to the caretakers' reports and was measured by the amount of ORT taken by the child at each follow up interval. Success of therapy or recovery from an episode was defined as the passage of normal stool for two consecutive days as reported by the mother.

Perception and KAP items were measured by the response of the caretakers to the interview using a structured questionnaire. Mother's compliance was assessed based on the report whether the caretaker prepared the ORT at each follow up interval.

DATA COLLECTION AND MANAGEMENT

Training

Prior to the start of the intervention 12 high school students, all females, were selected and trained for 15 days. Females were selected on the assumption that this might foster more uninhibited communication and exchange of ideas due to gender similarity. All the students who were trained spoke Oromigna.

Theoretical and practical training were given in class and in the field by the principal investigator, project research coordinator(a nurse who was trained for 21 days in the appropriate subjects) and the CDD coordinator of the District Health Team. The training included skills in identifying ACD, inclusion and exclusion criteria, weighing and mid-upper arm circumference measurement (MUAC) techniques, appropriate registration, preparation of ORT and case management. After training a post-test was given and scored high, medium and low. Students from each score group were identified and randomly assigned to form one treatment group. Then they were randomly assigned to the villages within each treatment group. Repeated assessment of filling formats, interviewing, weighing and arm circumference measurements was done.

The case-workers were provided with the WHO format to assess dehydration and plan treatment and an instructional manual which comprises information on how to make measurements of weight and arm circumference, how to prepare ORT, inclusion and exclusion criteria and measures of ORT containers in mls.

Piloting

The structured questionnaires found in appendix D through G were pretested by the trainees in three villages (one for each treatment group). In each village 12 households were randomly selected. The pretest was done to determine how to best phrase questions to maximize the likelihood of response and to assess their acceptability, ease of adminstration, and to determine the time required to carry out the interview. Based on the results of the pre-test appropriate modifications were made.

In the pilot phase conducted in the same villages where the pretest was performed a total of 30 caretakers who brought their children to the ORT corners were involved. This provided valuable information. The following were important findings : a beer bottle was found in 98% of the house holds (three beer bottles of water approximate to one liter) ; a coffee cup was found in 100% of the households visited (one coffee cup of water was measured and it was 100 mls.) ; and the amount of salt - " three finger pinch " was accepted by care-givers. It was found that religion, occupation and ethnicity of the care-givers were similar in all the three village.** Hence these variables were not included in the study.

** This finding was similar with the results of the health profile of the district which displayed that almost 100% of the rural residents are Orthodox Christians, 97% are farmers and nearly 99% are Oromos.

A check list was developed to assess the over-all performance (please see appendix H). Each case-worker was monitored and assessed, based on the check list format. The questionnaire was given to two medical doctors and translation was made from English to Oromigna and back to English and no major difference was noticed, hence was taken as valid (appendix I).

Interview

A structured questionnaire was developed for the purpose of identifying potential determinants of compliance (appendices E and F). It included knowledge, attitudes, practice and perception items. The interview was carried out initially by the case-workers when caretakers brought their child to the ORT corner. Questions on the perception of care-givers, however, were assessed initially with KAP and at the seventh day when the follow-up visit was completed (figure 2).

Conduct of the study

Mothers' and other care-givers were first informed during community meeting and when case-workers did home-to-home visit (which was done twice weekly) to take any diarrheal case to the ORT corner of their village (please see figure 2). In the ORT corner registration, was performed by the case-workers who then took a history and did a physical examination. Children were

assessed according to WHO criteria (appendix J) (63). The appropriate forms prepared for this purpose were completed. Thereafter, instruction was given about home management of diarrhoea, personal hygiene and the importance of continuing feeding (appendix B). Preparation of ORT was demonstrated to the care-givers at the corner. After this care-givers were requested to redemonstrate and if there was misunderstanding it was corrected by the case-worker.

Mothers were informed to count the number of " coffee cups " of ORT fluid that the child took (the small cup of coffee was taken as a standard as it was available in every home during piloting), and to count the number of diarrhoea and vomiting episodes that the child experienced.

The care-givers were expected to provide the ORT to the child in the home if the child was a case of mild dehydration(treatment plan A). Moderate dehydration cases (treatment plan B) were treated at first in the ORT corner according to the WHO recommendations (appendix B).

Follow-up home-visits were made by the case-workers at 1, 2, 3, 4, and 7 day. A structured questionnaire was used during each follow-up (appendix G) and the following information was obtained from care-givers; 1) fluid intake (amount), 2) food (frequency), 3) stooling (frequency), and 4) vomiting (frequency).

During follow-up care-givers were asked to show the bottle used to measure one litre of water and the cup used to provide the ORT. The case-workers were provided with a weight measuring instrument. They carried out the appropriate physical examination and took the history according to the prearranged format (please see appendices B, G and J). Two recall visits were made if the care-taker was absent during the scheduled time of follow- up.

Supervision

Case-workers performances were monitored weekly by the supervisor (the research coordinator). Weekly meetings were conducted with the case-workers to identify problems, monitor activities and appropriate measures taken.

Quality control

The weight measuring apparatus was checked daily by measuring a known weight. Consistency of the data collected was checked weekly by both the project coordinator and the principal investigator.

DATA PROCESSING AND ANALYSIS

In order to facilitate data entry, a coding manual was produced containing both continuous and discrete variables. The data was entered, cleaned, edited and analyzed using the EPI-INFO version+5.0 statistical package. The coding of 10% of the questionnaires from each treatment group were checked for accuracy by the principal investigator.

The general outline of the sequence of analysis is presented as follows:

1. Quality of randomization - baseline description of outcomes and determinant variables.

2. Main group effects

a) weight change : mean weight change was determined by treatment group at each follow up time and statistical tests were tested using ANOVA. If the variance was not homogeneous the nonparametric test of Kruskal Wallis was used. Bivariate analysis of treatment groups was performed among the different rehydration groups to further clarify the results.

b) diarrheal stool frequency : the proportion of diarrheal stool frequency by treatment group was determined at each follow up interval and Chi-square test performed.

c) mean frequency of feeding and the amount of ORT taken were also determined by rehydration group at each follow up time and F-stats were determined accordingly. The proportion of vomiting frequency among the three treatment groups were compared and Chi-square test performed.

d) mother's non-compliance was analyzed among mother's of children with diarrhea in the three treatment groups by determining the proportion of mothers' not preparing the rehydration fluid at any time during 24, 48, 72, and 96 hours.

e) child acceptability : the proportion of children "rejecting" the treatment (those children who did not take ORT at all) following its preparation was compared among the treatment groups at each follow up time.

3. Controlling for confounders : multivariate analysis (multiple linear regression) was performed to identify the major contributing factors and to control for possible confounders of continuous variables.

4. The relation between perception items was compared with the major outcome variable (mean weight gain) and compliance. Caretakers perceptions of ORT, as food, medicine, food and medicine or as tonic were analyzed among the three treatment groups. Mean knowledge score was determined among the three treatment groups and the proportion of caretakers in attitude and practice items were calculated and Chi-square test performed.

Ethical Considerations and Consent

Children with bloody or bloody mucoid diarrhea were referred to the nearby health institutions. In the health institutions an adequate amount of IV solution and anti-dysentery drugs were ensured for the study period. There was no case due to severe dehydration. Severely malnourished children were referred as identified following rehydration in the ORT corner.

Discussion was made with formal and informal leaders of the community concerning the purpose of the study. Mothers' and care-givers were informed about the study and consent established (see appendix K).

RESULTS

Two hundred and ninety one (291) children aged between 5 months and 5 years with acute childhood diarrhoea were found over the 10 weeks duration of the trial. During this period, 98, 90, and 103 episodes of diarrhea were treated among the under-five children in the GORS, CBORS and CBORT zones respectively.

BASELINE DESCRIPTIVE FINDINGS

The baseline socio-demographic characteristics and the results of the history and physical examination are summarised in tables 2, 3, and 4. The baseline characteristics of the three groups are similar. However, there was statistically significant shorter duration of diarrhea in the CBORT children (p= .045). This group also had proportionately more children with moderate as opposed to mild ACD at onset of treatment. Multi-variate analysis revealed that mean duration of diarrhea and mean maternal age were not found to be confounders.

MAIN GROUP EFFECT

Weight Change

The mean weight gain at each follow up interval was greater in the CBORS and CBORT groups than the GORS group (figure 3). These differences, as shown in tables 5 and 6 were significant at day 4 of follow up. There was no statistically significant difference between the CBORS and CBORT in mean weight gain at any point in the study. A significant difference in mean weight gain at all follow up intervals, except the seventh day was found between GORS and CBORS groups (table 7) based on ANOVA or Kruskal Wallis analysis.

Table 2. Age Distribution of Children by Treatment Group

Age(months)*	GORS	CBORS	CBORT
4-6	10	7	11
7-12	35	40	36
13-24	29	23	30
25-63	12	9	14
37-48	7	8	6
49-59	5	3	6
Total	98	90	103

* ns

Table 3. Baseline History and Physical Examination

Measurement	GORS	CBORS	CBORT	p-value
mean weight (grams)	9422	9543	9921	ns
#(%) mod. dehydration	28(28.6)	27(30)	33(32)	ns
#(%) mod.diar. frequency	21(21.4)	19(21.1)	31(30.1)	ns
#(%) watery diar.	46(46.9)	57(63.3)	51(49.5)	ns
mean dur. of diar	3.16	3.12	2.70	<.05
mean child age(months)	19.1	18.1	19.9	ns
median age (months)	14	12	15	ns
child's sex #(%)				
male	53(54.6)	44(48.9)	48(46.6)	
female	45(46.4)	46(51.1	55(53.4)	ns
Breast feeding				
no	32(32.6)	32(35.6)	40(38.8)	
yes	66(67.4)	58(64.4)	63(61.2)	ns
#(%) moderately malnourished	18(18.3)	14(15.5)	20(19.4)	ns

Table 4. Socio-demographic Characteristics by Treatment Group

Measurement	GORS	CBORS	CBORT	p-value
Mean maternal age	29.6	32.5	31.7	.02
% married	91.8	83.3	88.3	ns
% reported able to read and write	23.4	20	24.3	ns
% who visit H/I* when child sick	76.5	72.2	81.5	ns

* Health institution (health centre or health station)

Table 5. Comparison of Mean Weight Gain (grams) Among the Three Treatment Groups Over Time

	Treatment group				
Time (hrs)	GORS	CBORS	CBORT	F-stat	p-value
24	123	171	156	k.w	ns*
48	201	257	242	k.w	<.05*
72	273	333	306	1.71	ns
96	330	413	419	3.39	< .05
168	415	485	482	k.w	ns*

* nonparametric analysis of k.w (Kruskal Waliis)

Table 6. Bivariate Comparison of Mean Weight Gain (grams) Between GORS and CBORT Group Over Time

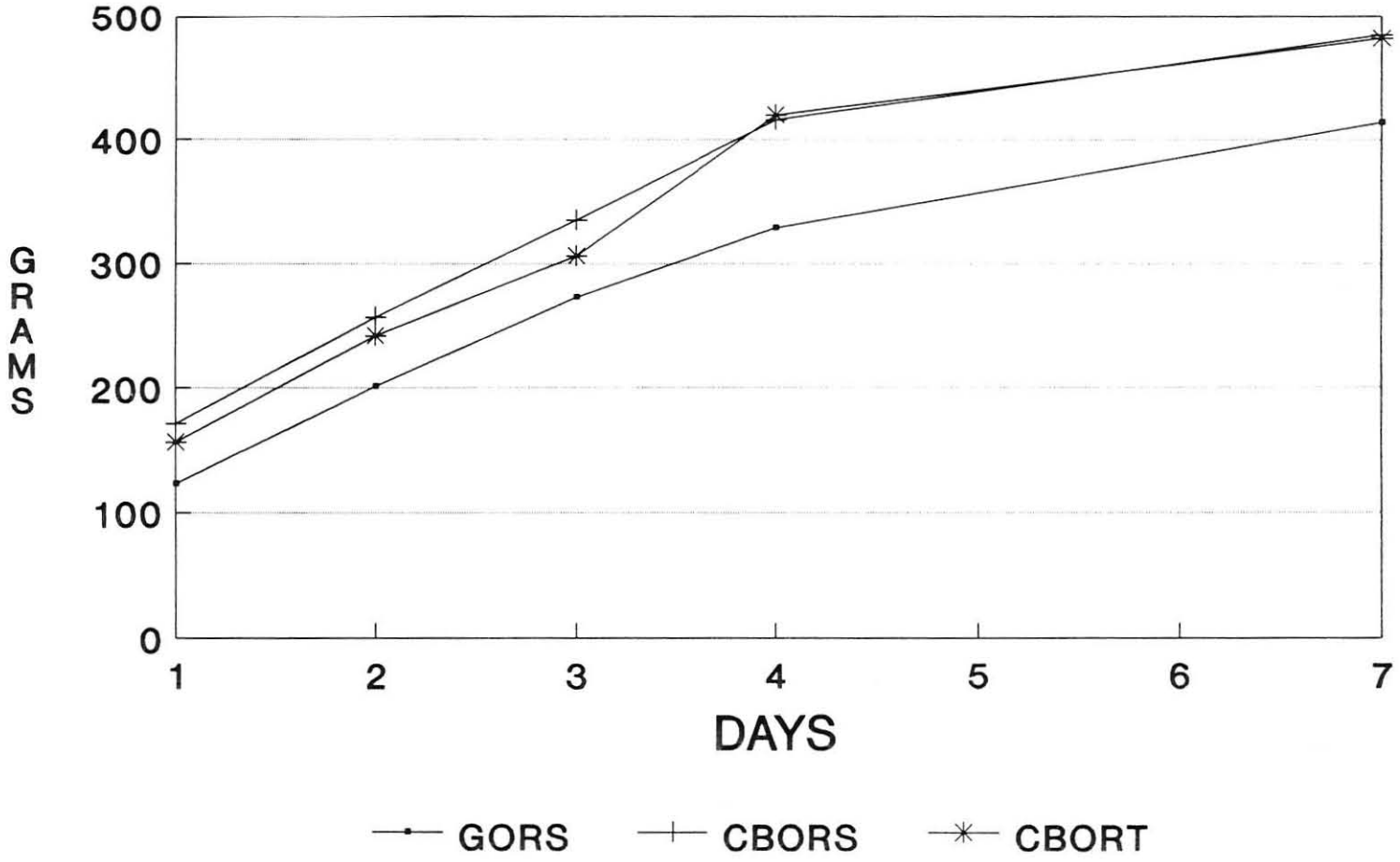
Time (hrs)	Treatment Group			
	GORS	CBORT	F-stat	p-value
24	123	171	2.5	0.1
48	201	242	2.8	0.09
72	273	306	1.2	0.26
96	330	420	6.4	<.05
168	415	482	2.5	0.1

Table 7. Bivariate Comparison of Mean Weight Gain (grams) Between GORS and CBORS Over Time

Time(hrs)	Treatment Group			
	GORS	CBORS	F-stat	p-value
24	123	171	4.5	<.01
48	201	257	k.w	<.05 *
72	273	333	k.w	<.03 *
96	330	413	k.w	<.04 *
168	415	485	2.7	ns

* nonparametric analysis of k.w (Kruscal Wallis)

FIGURE 3. Mean Weight Gain by Treatment Group over Time



Multiple linear regression performed to determine the effect of initial weight revealed no significant contribution to mean weight gain.

Diarrheal stool Frequency

The mean diarrheal stool frequency by treatment group over time is presented in table 8 and figure 4. It is lower in both cereal-based groups at each follow up time. A statistically significant difference in mean diarrheal stool frequency at 24, 48, and 72 hours based upon one-way ANOVA analysis were found.

Vomiting frequency

The mean vomiting frequency of the three groups over time is summarized in table 9 . CBORS and CBORT were found to be better in reducing vomiting frequency and this was statistically significant at all the follow up intervals through 96 hours. The frequency of vomiting in each treatment group was low after 48 hours and the numbers were inadequate for further inferential statistics.

Feeding frequency

There was no significant difference in mean feeding frequency among the three groups in all the follow up intervals. There was a trend of consistent increase of feeding frequency over time in all the three treatment groups (refer to table 10) but no trend in the between group comparison. Multi-variate analysis revealed that feeding had significant contribution in increasing mean weight gain.

Table 8. Comparison of Diarrhea Stool Frequency in the last 24 hours by Treatment Group Over Time

Time (hrs)	Mean diarrheal frequency			
	GORS	CBORS	CBORT	p-value
	n=98	n=90	n=103	
	#(%)	#(%)	#(%)	
24	89(90.8)	74(82.2)	79(76.6)	<.001
48	67(68.3)	35(38.9)	31(31)	<.001
72	23(23.5)	8(8.8)	9(8.7)	<.05
96	4(4)	2(2.2)	4(3.8)	ns
168	2(2)	0(0)	2(1.9)	ns

Figure 4. Mean frequency of diarrhea stools over time

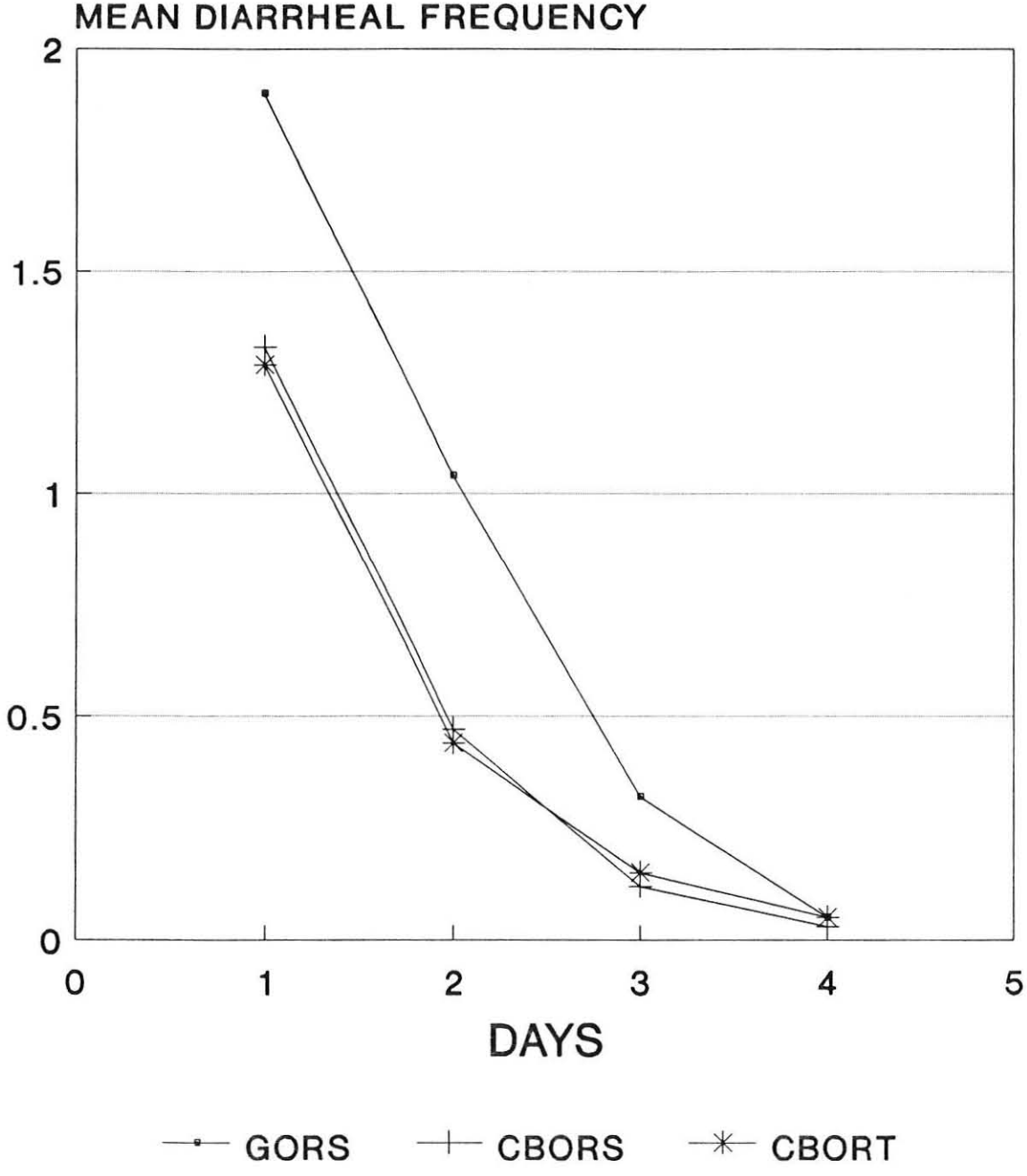


Table 9. Comparison of Vomiting Frequency in the last 24 hours Among the Three Treatment Groups Over Time

Variable	Time (hrs)	Treatment group GORS n=98 # (%)	CBORS n=90 # (%)	CBORT n=103 # (%)
Vomiting	24 *			
no		53 (54.1)	78 (86.7)	90 (87.3)
yes		45 (45.9)	12 (13.3)	13 (12.6)
Vomiting	48 *			
no		80 (81.6)	86 (95.6)	101 (98.1)
yes		18 (18.4)	4 (4.4)	2 (1.9)
Vomiting	72			
no		89 (90.8)	90 (100)	101 (98.1)
yes		9 (9.2)	0 (0)	2 (1.9)
Vomiting	96			
no		93 (94.9)	90 (100)	103 (100)
yes		5 (5.1)	0 (0)	0 (0)
Vomiting	168			
no		98 (100)	90 (100)	103 (100)
yes		0 (0)	0 (0)	(0) (0)

* $p < .001$

Table 10. Comparison of Mean Feeding Frequency in the last 24 hours Among the Three Treatment Groups Over Time

Time (hrs)	Treatment group				
	GORS	CBORS	CBORT	F-stat	P-value
24	2.27	2.18	2.36	k.w	ns*
48	2.73	2.38	2.44	k.w	ns*
72	2.78	2.57	3.04	2.31	ns
96	3.36	2.22	1.54	k.w	ns*
168	3.18	2.73	3.14	K.W	ns*

* Kruskal Wallis, non parametric , no F-stat

Mother's Compliance

The percent of non compliant caretakers by treatment group is as summarized in table 11. There was a higher non compliance in GORS group than in CBORT and CBORS groups in the third day. The non-compliance was compared among mother's of children who had diarrhea.

Child Acceptability

Table 12 shows the proportion of children who rejected ORT among the three treatment groups over time. CBORS and CBORT were least rejected. GORS was the least accepted at all follow up intervals.

ORT Intake

The mean intake of ORT was calculated over time. Based on the one-way ANOVA analysis it was shown that a significantly higher intake was observed in the GORS group in the first 48 hours and in the CBORT group in the third and fourth day of follow up. These results are summarized in table 13 and figure 5.

Perception of ORT

Tables 14 to 15 summarize perceptions of caretakers about ORT at 24 hours and 7 days. There were significant differences among the three groups. GORS was the least to be perceived as food, medicine, food and medicine and tonic at 24 hours and 7 days. The results of CBORS and CBORT were comparable. Each perception item was tested in association with mean weight gain and they were found non significant with the exception of perception of ORT as both " food and medicine " which was significant at 24 hours based upon

Table 11. Percent of non-compliers among the Caretakers of children with diarrhea in the Three Treatment Groups Over Time

Interval (hrs)	Treatment group		
	GORS	CBORS	CBORT
24	4	0	3
48	5	3	3
72	39	13	11

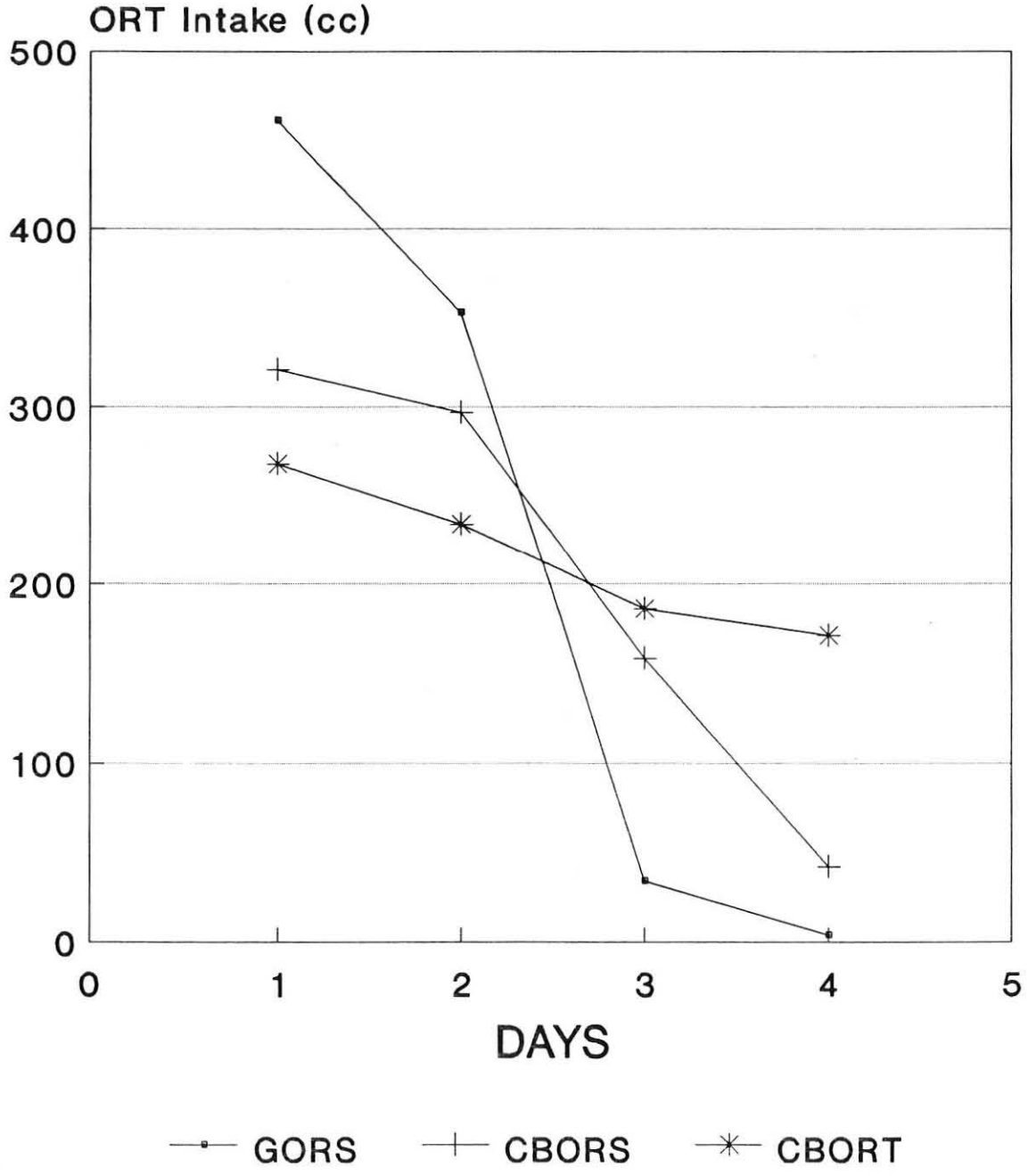
Table 12 . Comparison of the Rejection of ORT in Children Among the Three Treatment Groups

	Treatment group		
	GORS n=98	CBORS n= 90	CBORT n=103
Time (hrs)	#(%)	#(%)	#(%)
24	3(3)	0(0)	2(2)
48	1(1)	3(3)	0(0)
72	12(12)	4(4)	4(4)
96	16(16)	8(9)	13(13)

Table 13. Comparison of the Mean ORT Intake in mls in the Last 24 Hours Among the Three Rehydration Groups Over Time

Time (hrs)	Treatment group				
	GORS	CBORS	CBORT	F-stat	P-value
24	460	320	267	23.59	<.0001
48	353	296	233	8.27	<.001
72	33	158	186	63.7	<.0001
96	4	42	171	54.8	<.0001

Figure 5. Mean ORT intake over time by treatment group



one-way ANOVA analysis. There was low non-compliance(less than a quarter) among the caretakers who perceived ORT as "food and medicine" at 24 hours and the seven day. The majority of the caretakers (77%) who perceived ORT as "food" or "food and medicine" considered it as supplemental food (not substitute). Among the caretakers the greater proportion (84% and 78% at the 24 hours and the seven day respectively) who perceived ORT as "medicine" mentioned that it should stop diarrhea.

KAP items

There were significant differences in knowledge, attitude and practice of the caretakers among the three groups. Tables 16 through 18 reveal the results of knowledge, attitude and practice of caretakers after intervention was started in the villages. Reported use and preference of HI solutions was high in all the groups. The majority of the caretaker's in the three groups blamed the cause of ACD to "mitch" and teething. The mean knowledge score was comparable in the three treatment groups. Only 60.2%, 27.8%, and 53.3% of the caretaker's of GORS, CBORS and CBORT respectively claimed that they knew GORS (20). Further probing revealed that only 16.5% of CBORT, 2% of GORS and none of CBORS group knew GORS as " medicine for diarrhea " ; 41.8% of GORS, 71.1% CBORS and 46.6% of the caretakers of CBORT did not know what GORS was exactly (table 20). Among the non-compliers the majority were those caretakers who blamed cause to "mitch" (57%), and who preferred injection (57%), tablet (73%) and Holy Water (55%). Those mothers who claimed to "practice " and prefer "Buluka" had lower non-compliance (27%).

Table 14. ORT Perceptions at 24 Hours by Treatment Group

Response	Treatment group GORS n=98 # (%)	CBORS n=90 # (%)	CBORT n=103 # (%)	p-value
Food				
NO	78 (79.6)	74 (82.2)	37 (35.9)	
YES	20 (20.4)	16 (17.8)	66 (64.1)	<.0001
Medicine				
NO	30 (30.6)	5 (5.6)	3 (2.9)	
YES	68 (69.4)	85 (94.4)	100 (97.1)	<. 0001
Food and medicine				
NO	93 (94.9)	20 (22.2)	26 (25.2)	
YES	5 (5.1)	70 (77.8)	77 (74.8)	<.0001
Tonic				
NO	25 (25.5)	4 (4.4)	6 (5.8)	
YES	73 (74.5)	86 (95.6)	97 (94.2)	<.0001

Table 15. ORT Perceptions at Seven Days by Treatment Group

Response	Treatment group GORS n=98 # (%)	CBORS n=90 # (%)	CBORT n=103 # (%)	p-value
Food				
NO	83 (84.7)	68 (75.6)	37 (35.9)	
YES	15 (15.3)	22 (24.4)	66 (64.1)	<.00001
Medicine				
NO	29 (29.6)	2 (2.2)	9 (8.7)	
YES	69 (70.4)	88 (97.8)	94 (91.3)	<.00001
Food and medicine				
NO	89 (90.8)	16 (17.8)	18 (17.5)	
YES	9 (9.2)	74 (82.2)	85 (82.5)	<.00001
Tonic				
NO	26 (26.5)	2 (2.2)	4 (3.9)	
YES	72 (73.5)	88 (97.8)	99 (96.1)	<.00001

Table 16. Responses of Caretakers on Knowledge Items about Causes of Diarrhea Among the Three Treatment Groups.

Variable	GORS n=98 # (%)	CBORS n=90 # (%)	CBORT n=103 # (%)	p-value
Mitch**				
no	47 (48)	64 (71.1)	50 (48.5)	
yes	51 (52)	26 (28.9)	53 (51.5)	< .01
Evil eye				
no	90 (91.8)	83 (92.2)	92 (89.3)	
yes	8 (8.2)	7 (7.8)	11 (10.7)	ns
Teething				
no	57 (58.2)	38 (42.2)	70 (68.0)	
yes	41 (41.8)	52 (57.8)	33 (32.0)	< .05
Dirt				
no	61 (62.2)	69 (76.7)	68 (66.0)	
yes	37 (37.8)	21 (23.3)	35 (34.0)	ns
River water				
no	84 (85.7)	81 (90.0)	89 (86.4)	
yes	14 (14.3)	9 (10.0)	14 (13.6)	ns
Fall				
no	82 (83.7)	84 (93.3)	91 (88.3)	
yes	16 (16.3)	6 (6.7)	12 (11.7)	ns
Mean score	58	54.3	59.4	

** Mitch: a cause of disease which is believed to be associated with "spiritual causes", and strong "sun heat".

Note: Score for correct response = 1
Score for incorrect response = 0

Table 17. Responses of Care-takers on Attitude Items Among the Three Treatment Groups

Variable	GORS n=98 # (%)	CBORS n=90 # (%)	CBORT n=103 # (%)	p-value
Herb				
no	57 (58.2)	53 (58.9)	59 (57.3)	
yes	41 (41.8)	37 (41.1)	44 (42.7)	ns
Buluka *				
no	63 (64.3)	77 (85.6)	62 (60.2)	
yes	35 (35.7)	13 (14.4)	41 (39.8)	<.001
Holy water				
no	44 (44.9)	45 (50.0)	29 (28.2)	
yes	54 (55.1)	45 (50.0)	74 (71.8)	< .01
Injection				
no	52 (53.1)	41 (45.6)	23 (22.3)	
yes	46 (46.9)	49 (54.4)	80 (77.7)	< .0001
Syrup				
no	51 (52.0)	47 (52.2)	51 (49.5)	
yes	47 (48.0)	43 (47.8)	52 (50.5)	ns
Tablet				
no	53 (54.1)	49 (54.4)	24 (23.3)	
yes	45 (45.9)	41 (45.6)	79 (76.7)	< .0001
GORS				
no	26 (26.5)	23 (25.6)	36 (35.0)	
yes	72 (73.5)	67 (74.4)	67 (65.0)	ns

Buluka * : locally prepared cereal-based fluid

Table 18. Responses of Caretakers to Practice Items Among the Three Treatment Groups

Variable	Treatment groups GORS n=98 # (%)	CBORS n=90 # (%)	CBORT n=103 # (%)	P-v
Herb				
no	56 (57.1)	49 (54.4)	51 (49.5)	
yes	42 (42.9)	41 (45.6)	52 (50.5)	ns
Buluka				
no	66 (67.3)	75 (83.3)	66 (64.0)	
yes	32 (32.7)	15 (16.7)	37 (36.0)	<.01
Holy water				
no	45 (46.0)	46 (51.1)	29 (28.2)	
yes	53 (54.0)	44 (48.9)	74 (71.8)	< .01
Prayer				
no	22 (22.4)	19 (21.1)	29 (28.2)	
yes	76 (77.6)	71 (78.9)	81 (78.6)	ns
Abdominal manipulation				
no	53 (54.0)	61 (67.8)	54 (52.4)	
yes	45 (46.0)	29 (32.2)	49 (47.6)	ns
Gum manipulation				
no	52 (53.1)	44 (48.9)	63 (61.2)	
yes	46 (46.9)	46 (51.1)	40 (38.8)	ns
ORS				
no	20 (20.4)	17 (18.9)	25 (24.3)	
yes	78 (79.6)	73 (81.1)	78 (75.7)	ns

Table 19. Responses on Knowledge of GORS by Treatment Group

Variable	Treatment group GORS	CBORS	CBORT	p-value
	n=98	n=90	n=103	
	# (%)	# (%)	# (%)	
Knowledge of ORS				
no	39 (39.8)	65 (72.2)	46 (44.7)	
yes	59 (60.2)	25 (27.8)	57 (55.3)	<.0001

Table 20. Specific Responses to the Question "What is GORS?" Among the Caretakers of the Three Treatment Groups

	Treatment group			
	GORS # (%)	CBORS # (%)	CBORT # (%)	Total
I don't know	41 (41.8)	64 (71.1)	48 (46.6)	153 (52.6)
Epsom Salt	45 (45.9)	11 (12.2)	34 (33.0)	90 (30.9)
Salt and sugar	9 (9.2)	0 (0)	0 (0)	9 (3.1)
Medicine for diarrhea	2 (2.0)	0 (0)	17 (16.5)	19 (6.5)
Others	1 (1.0)	15 (16.7	4 (3.9)	20 (6.8)
Total	98 (100)	90 (100)	103 (100)	291 (100)

Table 21. Expectations of Caretakers Towards ORT by Treatment Group

	TREATMENT GROUP			
	GORS	CBORS	CBORT	p-value
	n=98	n=97	n=103	
	#(%)	#(%)	#(%)	
Stops diarrhea				
NO	9(10)	21(23)	35(34)	
YES	88(90)	69(77)	68(66)	<.001
Cures diarrhea				
NO	75(77)	73(81)	60(58)	
YES	22(23)	17(19)	43(42)	<.001

DISCUSSION

This study was designed for three purposes. First to compare the relative effectiveness of GORS, pre-packed cereal-based ORS and home made cereal-based ORT. Thus it was carried out to identify which mode of treatment is effective in the treatment of ACD in under-five children in the Ethiopian context using cereals available in Ethiopia and to identify which is most culturally acceptable. Effectiveness was measured in terms of weight gain as the major outcome and secondarily, in terms of reduction of diarrheal stool and vomiting frequency. The influence feeding frequencies have on mean weight gain was also measured. The second purpose of the study was to identify factors associated with better compliance, while the third purpose was to assess the perception of mothers in relation to caretaker's compliance and weight gain.

In this study the prevalence of ACD was lower and the duration of follow-up was longer than expected. This might be due to seasonal variation. It is known that the prevalence of ACD is higher during the rainy season while the study was done in the dry season.

The baseline characteristics of the subjects and caretakers were comparable among the three groups, however, caretakers in the GORS group were younger. This difference was not thought to be practically important in the field setting in which the study was conducted. The initial clinical manifestations of the three groups were also comparable except for the duration of diarrhea which was significantly less in CBORT group. This may indicate that this

group of children were entered into the trial at an earlier point in their illness due to the familiarity of "buluka" which enhances its acceptability.

In this study the two cereal based ORT's were found to result in better weight gain than the glucose based ORT. The home made formulation was found to be equal to or better than CBORS or GORS at all follow up intervals. There was no statistically significant difference in weight gain among the three treatment groups at 72, 96 and 168 hours (seventh day). Other studies have also reported similar findings (23, 33, 34). There was a trend for relative increased weight gain in both the cereal-based preparations. The trend of increase in weight gain in both cereal-based oral rehydration solutions is considered to be practically important, particularly in rural villages where access to GORS is denied.

Although in the CBORT group ORT intake was reportedly less over the first 48 hours, the mean weight gain was equivalent or higher than the GORS group. These results suggest that cereal based solutions were very efficient in promoting electrolyte and fluid absorption.

The diarrheal stool frequency was lower and the duration shorter in children receiving either CBORS or CBORT as compared to the GORS. Several studies have demonstrated that cereal-based oral rehydration therapies result in shorter duration of diarrhea and reduced frequency of diarrhea and vomiting (9-14, 19-22, 24, 31, 32). This is known as the " anti-diarrheal " effect of "SUPER ORS". Thus, the study demonstrated that CBORT is equal to or better than

the GORS and CBORS at all follow up intervals in terms of the major outcome weight gain and the secondary outcomes of reduction in frequency and duration of diarrhea and frequency of vomiting (from mother's view point this may be the most important factor).

Why is it that the cereal-based preparations outshine GORS? Possible explanations are the higher degree of acceptability, improved functional access to treatment, and the higher compliance rates.

This is the second study to support home made CBORT in Ethiopia. The two studies were done in different regions and districts of Ethiopia. The previous, an efficacy study and the present, an effectiveness study, both have demonstrated an increased mean weight gain which is remarkably similar in the two studies. CBORT is familiar to people locally and the ingredients can be found in virtually every home (functional access to treatment) hence this can substantially enhance the ability of families to manage diarrhea at home (26).

CBORS, although effective when available, may not be applicable locally due to the higher cost of packets of CBORS compared with the cost of home made CBORT and even GORS (26). Thus this may decrease the potential for self reliance. Hence, consideration should be given to promoting low-cost, locally available ORT which can be found at home.

Feeding frequency was found to have a significant effect in mean weight gain. Its contribution to an increase in weight gain as shown by the multivariate analysis was higher at all follow up

intervals except the seventh day. The importance of feeding in the treatment of ACD has been demonstrated in several studies. Recently it has been recognized that food produces substrate for the absorption of sodium and water, but also helps absorption of the fluid secreted into the gut during diarrhea (22,33). Increased intestinal villous turnover is known to occur in the presence of food and this phenomenon may be responsible for increase weight gain. In addition the nutritional advantage may break the diarrhea-malnutrition cycle (22,33).

The fact that ORT was less rejected in CBORT and CBORS groups reflects its higher "acceptability" in children. This finding was also observed in the Adama-boste study of East Shoa (14), although in that study it was not statistically significant..

The finding in this study that there was a relatively higher non-compliance rate in the GORS group at 72 hours may be because of its failure to stop diarrhea. Hence, mothers may gave up preparing the solution with the assumption that "it is failure of the treatment to cure the child" . As shown in the result the major expectation of caretakers in the treatment of ACD was cessation of diarrhea.

The purpose of the research was not to study safety which had been studied elsewhere (46). The higher compliance of mothers to instructions in the preparation of ORT in the CBORT group may be due its "cultural acceptability". The familiarity of CBORT or " buluka" (locally prepared cereal based fluids) has a remarkable influence in its acceptability, particularly in pluralistic health

care system where use of ineffective antibiotics or herbal medicine might be an alternative approaches to treatment of ACD. The point here is that attempts should be made at promoting ORT in terms that make sense to users to support greater utilization or compliance. This was seen in Pakistan (15). Therefore, the introduction of " ORT " in a " modified " form to rural communities may represent a true revolution in the treatment of ACD and brings the " case management " issue into almost every home. In this study reported use of "buluka" was shown less in comparison to other " traditional therapies" such as herbal medicine, prayer and Holy Water. This might be because of the external locus of control which is predominant in traditional societies. But preference and "practice" of "buluka" was associated with higher compliance. Thus, in relation to acceptance of new medical technology which may take 5-10 years introduction of " buluka " may take less time (18). If modern knowledge and practice of CBORT could be combined with the trust and familiarity of " buluka " there may be further strengthening of child care in rural Ethiopia (18). The higher compliance in the CBORT group reflects that " traditionally accepted therapies " although previously not well used could be easily introduced. That is, previous experience facilitates acceptability.

Some researchers were suggesting that CBORT may be perceived as food and hence, caretaker's might not provide the child with other foods. The consequence of this is malnutrition. Contrary to this, the finding of our study shows feeding frequency has

increased with each follow-up time. This may be due to the instruction given initially " to continue feeding " and the perception of the caretakers about ORT (as food and medicine). The fact that cereal-based preparations were more perceived as food and medicine than GORS could enhance acceptability and compliance. There was a trend in increased weight gain in those who perceive ORT as both" food and medicine". This indicates that not only mother's perception of diarrhea, as suggested by some authors (15,52) perception of ORT might have a role in compliance. As discussed earlier CBORT although traditional may be considered as "medicine" if certain modifications are made in its preparation. Moreover, the majority of the caretaker's responded affirmatively and perceived the treatment as a " tonic ", a therapy which could strengthen children (there was no specific word in Oromigna- a phrase was used to describe it). This is encouraging and it may be helpful in the design of health education messages. However, these findings require further study to provide substantial conclusion.

In this study the majority of the caretaker's responded that "mitch" and teething are the major causes of ACD but their response to the attitude and practice items revealed that they preferred GORS and used it when their child has diarrhea- than other forms of treatment. This may be due to desirability bias, that is considering the case-workers as health professionals. Injections and Holy Water were highly preferred. This might reflect the role of external locus of control which often seeks

remedy from other sources. Although the proportions of caretakers using and preferring " buluka" were lowest in CBORS group, the study revealed that there was higher degree of child acceptability and lower non-compliance rate in the same group. The non-compliance was higher in those who blamed the cause of ACD on "mitch" and who preferred injections, tablets and Holy Water. These findings reflect in traditional societies which are characterized by pluralistic health system treatment choices might be influenced by the belief of causation, the available and accessible mode of treatment and the role of traditional remedies available in particular area. This reflects that the tendency to use ineffective antibiotics and harmful traditional "remedies" is remarkable. In addition, treatment choice may be compromised in either direction.

This study revealed that 46% of the caretakers of GORS and 33% of CBORT considered GORS as Epsom salt (a laxative which increases diarrhea). Contrary to this the majority of the caretakers expectation in the treatment of ACD was shown to be cessation of diarrhea. Therefore, this might be one of the major concerns which reduced its compliance (apart from its failure to stop diarrhea). The significant difference in some of the knowledge, attitude, practice and perception items might be due to the reasons discussed above, ie the accessible mode of treatment and its acceptability and the role of locally available traditional remedies. The higher proportion of expectation of cessation of diarrhea and the lower proportion of expectation of cure of the child in the treatment of

ACD indicate that there might be an influence of beliefs of causation in determining curative therapy for a particular treatment. Hence, ACD ascribed to "spiritual causes" such as "mitch" and evil eye may not be expected to be cured by providing ORT. Since the majority of the caretakers blamed the causes of ACD on "mitch" and teething the expected treatment might be a locally available traditional treatment for the specific "etiologic agents". Thus knowledge, attitude and beliefs of caretakers probably are important determinants of home management of ACD.

With regard to the validity of the study the high quality of randomization was demonstrated by the comparable results in baseline characteristics among the three treatment groups. There was no placebo effect since the different treatment groups had been given an ORT. Systematic bias is not expected because different individuals did the physical examination and follow up visits in each village. Interobserver variation might be the limitation in this study . Nevertheless, case-workers were assigned randomly to low-score, medium-score, and high-score groups and then were randomized to the different treatment groups (after a post-test) to reduce the interobserver variation in the group. The sample size was sufficient, based on the desired level of significance (95%) and the power of the study which is 90 %. The possibility of under estimation of the number of ACD cases might be another limitation. Although efforts were made to include all cases of ACD by informing the care-takers at the outset and by doing home-to-home visits twice weekly in each village it is difficult to

boldly say that every case of ACD was included in the study since care-takers may not observe some of the cases. However, the number of missed children would be very low (even mothers brought their children who did not fulfil the operational definition - for example a child with a frequency of two loose stools-indicating that many of the cases might have appeared in the ORT corner). Even if there were significant number of cases who did not attend to the "ORT Corners", there are no reasons why the children in one community would be different from the others. The baseline finding illustrated that they were comparable.

In summary, this study found that GORS was less "accepted" by the children, less perceived as medicine, more considered as laxative and had resulted in higher non-compliance rate. On the other hand, the CBORT was found to have greater local acceptance, compliance was high, and the weight gain achieved equal to the alternative therapies.

CONCLUSIONS AND RECOMMENDATIONS

The home-made ORT was found to be as effective as or more effective than GORS in terms of mean weight gain. With regard to reduction of diarrheal duration and frequency CBORS and CBORT were superior. The primary concern of caretaker's as revealed from the study is cessation of diarrhea. Hence, considering the cultural acceptability, availability, and accessability of treatment options, the most feasible mode of treatment for the management of ACD in under-five children will be the home-made CBORT. We suggest that in developing countries like Ethiopia, where access to pre-packaged solutions is a problem, CBORT should be the recommended solution because of its cost, availability and accessability.

An operational research which emphasizes the implementation of CBORT programs and an anthropological study to determine the role of perception of ORT in compliance are recommended to further clarify the finding of this study. The implementation of a well monitored community-based CBORT program is also recommended in Ethiopia. Priority should be given to discuss the major findings of this study with the NDDCP to help in the design of appropriate strategies in the control of ACD and which will have a higher impact in the reduction of childhood mortality.

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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 solution is added to 1 liter of water (after boiling).

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]

60- 70 grams of cereals of wheat, barley, oat or teff in 1.1 litre of water boiled and stirred continuously and a pre-packaged salt with the following composition will be added (for preparation of CBORS OR CBORT please see appendix C):

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

CEREAL BASED ORAL REHYDRATION THERAPY [CBORT]

60-70 grams cereals of wheat, barely, oat or teff added and one pinch (three finger up to the first cursor) salt [NaCl]is added. Then continuously boiled and stirred solution in 1.1 litre of water.

* The first formulation was sodium bicarbonate, 2.5 grams

APPENDIX B

REHYDRATION PLAN TO PREVENT OR TREAT DEHYDRATION FOR ACD*

Chart 1: plan A with no or mild signs of dehydration.

a. Teach mothers how to prepare rehydration solutions show her how much to give:
50-100 ml. [1/2 to 1 cup] of rehydration solution after each stool or vomiting for a child under 2 years old.
100-200 ml.[1 to 2 cups] for older children.

b. Give your child food.

- Give freshly prepared foods.
- Offer food frequently for every young child.
- Encourage the child to eat as much as he or she wants. Cook and mash 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 2-3 minutes

Note while a child is getting ORT, he or she should be given breast milk or dilute milk feeds.

* = Modified from WHO guideline [63]

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 weights in kg.	: 3 4 5 6 7 8 9 10 11 12 13 15 20 30
Give this ml. much solution for 4-6 hours	200-400 : 400-600 : 600-800 : 800-1lt. -2 lt.

If the child become puffy stop rehydration solutions and give other fluids. If diarrhoea continues, use rehydration solution when the puffiness is gone.

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 frequently.
- Tell her to bring the child to the health worker if the

  - child passes many stools;
  - is thirsty;
  - has sunken eyes;
  - has a fever;
  - does not eat or drink normally;
  - seems not to be getting better.

APPENDIX C

Preparation of CBORT or CBORS.

The preparation follows these steps:

1. Put 3 beer bottles [about 1000 cc] of water into a cooking pot.

2. Take a clean stick (10-20 cm) and hold it vertical/in the pot above the water.

3. Lower the stick just above fluid level (don't put stick in water).

4. Make a mark on the stick at the spot where it touches the rim of the cooking pot.

5. Add another 1 coffee cup of water because there will be evaporation during boiling (100 cc)

6. Put a scoop of flour (sorghum, teff, wheat, barley, oats, corn) in to the cooking pot (50-70 gms).

7. Put one 3-fingered pinch of salt into the pot (pinch goes only to first finger crease). Fingers are held vertically up and down to avoid lumps or chunks of salt.

8. Put the pot on the fire to cook for some time (15-20 minutes).

9. Use the marked stick to see if it has boiled enough, so that the mark is at the rim of the pot. But don't let stick touch the fluid.

10. Take pot off the fire. Let it cool before giving to the sick child.

APPENDIX D

Questionnaire format I for ORT study ,Sululta

Date _____ Village _____ ID # _____

House # Name of the caseworker

I. Background Information Response

1. Mother's age years
2. Marital status
   1. married 3. divorced
   2. single 4. widowed
3. Educational status
   Grade completed _____
4. Neither read nor write = 0
   Read = 1
   Read and write = 2

II. Clinical

A) 1.Sickness of the child
   1. Diarrhoea 2. Others
   3. child not sick

If the child has disease other than diarrhea advice the mother to visit the nearby health institution. Express your good will and leave.

2.If diarrhoea

a) Consistency
   1) watery 2) loose 3) others
b) Frequency -_____- in numbers
c) Duration of diarrhoea before visiting the ORT corner -_____- days

If three or more loose stool or one or more watery stool include the subject to the study, after excluding the signs and symptoms of the exclusion criteria. If the child's age is less than 5 months or greater than 59 months exclude from the study.

B) If included in the study,please fill the following:

1. Age of the child in months ——————
2. sex of the child 1. male 2. sex ——————
3. Weight of the child ——————grams
   - to the nearest 10 grams
4. Arm circumference of the child (MUAC technique)
   1. green 2. yellow 3. red

5. Use the WHO format to fill signs of dehydration

   - fill the ID # in the format

6. Use the WHO format to decide the degree of dehydration and treatment plan
   1. A 2. B 3. C ——————

7. Mode of treatment
   1. GORS 2. CBORS 3. CBORT ——————

Exclude if the child is on treatment with other ORT or antibiotics)

8. Did you visit a health station when your child is sick
   1.yes 2. no ——————

APPENDIX E

KAP QUESTIONS

1. What do you do to your child when sick with diarrhea ?

	Yes	No
a) herbal medicine		
b) "Buluka"		
c) Holy Water		
d) Prayer		
e) Abdominal massage		
f) Gum manipulation		
g) Solution from H/I		

2. What do you expect from the treatment ?

	Yes	No
a) to stop the diarrhea		
b) to reduce the frequency of the diarrhea		
c) to make the child strong		
d) to cure the child		
e) disappearance of dehydration		
f) no expectation		

3. What do you prefer to give when your child has diarrhea?

	Yes	No
a) herbal medicine		
b) "buluka"		
c) Holy water		
d) injection		
e) syrup		
f) tablet		
g) solution from the H/I (ORS)		
h) others (specify)		

4. Why did you prefer ?

	Yes	No
a) it is easily available		
b) it is a good treatment		
c) it does not take too much		
d) others (specify)		

5. What is the cause of diarrhea ?

	Yes	No
a)" mitch"		
b) evil eye		
c) teething		
d) dirt		
e) fly		
f)accidental fall		
g) others		

6. Show the GORS sachet, and ask if she knew it
   1. yes, I know it 2. no, I don't

7. If, yes what is it ?

   a) Epsom salt
   b) salt and sugar
   c) medicine for diarrhea
   d) I do not know
   9) others (specify)

APPENDIX F

PERCEPTION QUESTIONS

1. Opinion of the mother about ORT

	Yes	No
a) food		
b) medicine		
c) food and medicine		
d) tonic *		

20. If it is food	Yes	No
a) it substitutes other foods		
b) it is supplementary to other foods		
c) others (specify)		

21. If it is medicine
    a) it is a purgative
    b) stops diarrhea
    c) stops vomiting
    d) others(specify)

22. If tonic
    a) reduces weakness
    b) restores appetite
    c) strengthens the child
    d) others (specify)

* There was no specific word in Oromigna. A phrase was used to describe it.

APPENDIX G

Questionnaire format II for ORT study, Sululta.

Date_____ Village _____ Name of case-worker _____

House # _____ Age _____ Sex _____ of the child

ID # _____

Follow-up Questions

Time interval (hrs)

24 48 72 96 168

1. Diarrhea stopped
   1.yes 2. no

2. Frequency of stool

3. Vomiting stopped
   1.yes 2.no

4. Frequency of vomiting

5. Food supplement

   If yes,specify
   - type
   - frequency

6. ORT intake
   -yes
   - no
   If yes
   - amount(cups)

7. Left-over packets (#)

   (if GORS,CBORS)

8. Mothers opinion about child's condition

   1.worsened
   2.improved
   3.no change
   4.others(specify)

9. ORT preparation
   1. completely correct
   2. partially correct
   3. incorrect

10. weight of the child

11. breast feeding

    1. yes 2. no

12. If yes, did he fed today

    1.yes 2.no

APPENDIX H

CHECK LIST (weekly,monthly)

Date_____ Group_____

1. # of cases seen
2. Referral
   Cause of referral

+(poor) ++(good) +++(v.good)

3. Weighing skill
4. Arm circumf. measurement
5. Preparation of ORT
6. Formats filled
   Format 1
   Format 2
   Format 3
   Perception Qs.
      first
      last
7. Support from local PSC
8. ORT corner
   1. good room
   2. no available room
      (working outside)
9. Amount of flour
   average grams
10. Amount of salt
   1. acceptable to mothers
   2. not acceptable
11. If not acceptable, it is
   1. too high
   2. too low
12. Salt used
   1. powdered
   2. not powdered

Comment

APPENDIX J

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 and 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 K

CONSENT PROCEDURE

1.In each village discussion was made with formal and informal community leaders about the purpose of the study.

2. Then discussion was made in the villages with the community and they were informed about the purpose of the study,its importance in the control of acute childhood diarrhea and consent as obtained to conduct the study in the villages. The agreement included establishment of an" ORT corner in the village.

3. When mothers came to the ORT corner the case-worker greeted the mother and after acquaintance she informed the mother about the study. Then she asked the mothers consent to be involved in the study and would proceed if consent was established.

APPENDIX I

የተቅማጥ በሽታ ?ቋ? ቅጽ1

መንደር ___________________ ቀን ______________

መለያ ቁጥር ________________ የቤት ቁጥር ______

ጥያቄውን የመለሰው ______________

ስጋን ሐዳ ዓ.ም ______________ ዳሊሚኒ ስጋ ዓ.ም ______

ከአምስት አመት በላይ ከሆነ በጥያቄ አይገባም:

ወገፋዳፊጤሬማ 1/ ከንዬሬምቴ

2/ ከንአንዬሬሚኒ

3/ ከንዬበቴ

4/ ካንባሬ

አነበቡ ደንደና

1/ ሌዩኒ 2/ ለቤ

ፀፋ ሊንደንዴቴኒ

1/ ሌዩኒ 2/ ለኪ

አነበቡና ፀፋ አደንዴትን በፍሊ ዓ.ም ________

መበረተ ትምህርት ________ በፍሊ __________

ዲቤንዳሊማ ማሊሊኒ

1/ አሰበቴ 2/ ካንባሬ 3/ ሄንቶኩበሰኒ

ሌላ ዘሆነ ወደ ሀኪም ቤት አንደሄደ ኮር ሰጥተው አመበግ ነው ይሰናበቱ::

ሰዐበቴ የተሌ ቢሬበ

ሀ/ ቢሸን ከንፌከተ ሀ/

ለ/ ዩለ የተሌ ለ/

ሐ/ ካንባሬ ሐ/

2/ ቀኒቴ ጊዜ ዓ.ም __________

3/ የም ጀመሬ ____________

1/ ዳሊሚኒ ስጋ ዓ.ም ________ ጀሉ ________

2/ ዲሬፍ ዲበሬ ተማ

1/ ዲሬ 2/ ኦበሬ

3/ ዳሊሚኒ አማት ኡሰፋታ _________

4/ የከንቶ ዘሬ ያ ቢለከ ________ ./ሚ ______ ነው 1/ አረንጊዴ

2/ ቤጩ 3/ ቀዩ

5/ በተበሚ ቢበ ?

1/ ሌዩኒ 2/ ለኪ

ሊዩኒ ሆጀተኒ ካርዴ ነቴ አጀርቢበ

1/ ጀሬ 2/ ኡንጀሬ

6/ ዳሊሚኒ የ ቶኩቢ መነ ሐኪሚ ሄንጊቼቴኒ

1/ ሌዩኒ 2/ ለኪ

ቁጥር _____

ናሙና ታኅሣሥ ቀጽር

መንደር _____
ሩቅ ሰው ናሥሪው _____
የቤት ቁጥር _____

የሰው ሥም _____
የአያት ሥም _____
የአባት ሥም _____

1. ዕድሜን ግበ ቴፌ

1. ጡት ኒ / ለቢ

2. ቀኒቲ ጊዜ ሜታ ሰፊበባ?

3. ሆሞኒቶ ግበ ቴፌ

1. ሊናኒ 2, ለቢ

4/ በለቻ ፲መሪ ጊዜ ሜታ ሆሞሚሜ?

5/ ሰደ ኑቢሬ ለንሥጉን ሠነናታ ፍደቲ ?

ሀ. ሊናኒ ሆፒቲኒ

ሚሰናኛቲ?

ጊዜ ሜታ?

6/ ፈና ተገሥ ዘንቢናሚቲ ፍደ ቱፒራ?

ኑፋደቲ

ጳሉን ማሊኒ

ቢኔ ሜታ / ሊተር /

ቂኒን ሑጀተኒ ቦፅበ ሜቀተ ሀፅ?

7. ኣ_ሚን ለበሚ

1. ሊቲፒቦሴራ

2. ሊቲፋሬ

3. በ ኑሚ

4. በንገሬራ

8/ ንሰፀ ጉገሙ በና ለበሚቲለበ ቀጲስ ተን ኑቲ

1, ሠሉሉ ለመሥሉ ትክክሉ 2. ቦሰፊሰ ተ ን/ ሰቢ ቱተ

9.

ኃኣቢሚኒ ለሚሃሃ ኑሥፋታ?

1. ሀርሚ ሂናሚ

1. ሂንሆሃ 2. ሀርሚ ሂንሆጵ

ሂንሆሃ ሃራ ሆኒ ፲ራ

1. ሊናኒ 2: ለቢ

24ሰዓት	48ሰዓት	72ሰዓት	96ሰዓት	7ቀንሳምንት

[illegible] ቋፀ 3/ ... [illegible]

ፍርሙን የምላሹ ...

1/ ኣሊሚኒ ዘጣኒ ስጋ ይብን ኣለባቲ ቀቢ ዓሰንተኒፍ ?

ሀ/ ባለ 1/ ሊፍኒ 2/ ለኪ

ለ/ ቡሉቃ 1/ ሊየኒ 2/ ለኪ

ሐ/ ቢሻኒ 1/ ሊፍኒ 2/ ለኪ

መ/ ዌቃ ከለተኒፍ 1/ ሊፍኒ 2/ ለኪ

ሠ/ ገሬ ሊሊፎዴኒ 1/ ሊፍኒ 2/ ለኪ

ረ/ ሊለካን ባሲስተኒ 1/ ሊየኒ 2/ ለኪ

ሰ/ ቁርጃ ካንዱገሙ መነ ሐኪሚቲ ካን ስርገሚ ሊንኪኒተኒፊ

1. ሊፍኒ 2. ለኪ

2/ ማነ ሐኪሚቲተ ገርገርሳ ጎደመረማሊ ስርገሚሊ ሊገዳኒ

ሀ/ ስለቢቲን ስከዳበተ

ለ/ ለበፍስ ስለባቲ ስካ ፒናተፍ

ሐ/ ዳሊሚኒ ጀባታ ስካ ተሎፍ

መ/ ዳሊሚኒ ስካ ሊቲፈረፊ

ሠ/ ሟሸሹን ደገና ዳሊማ ስካበቶፍ

[illegible] ረ/ ከንቢራ ሆጂሬቲ

3/ ዳሊሚኒ ቤሰን ዴቤ ስለባቲን ሆቀበሚ ለለኪ ኮፋ ጃለታን ?

ሀ/ ባለ 1/ ሊፍኒ 2/ ለኪ

ለ/ ቡሉቃ 2/ ሊፍኒ 2/ ለኪ

ሐ/ ቢሻኒ 1/ ሊፍኒ 2/ ለኪ

መ/ ሌሞ 1/ ሊፍኒ 2/ ለኪ

ሠ/ ሸርጊ 1/ ሊፍኒ 2/ ለኪ

ረ/ ከሊኒ 1/ ሊፍኒ 2/ ለኪ

ሰ/ ቁርጃ ዳቡ ዱገሙ ስሸገሚ መ... ጊሚቲ 1. ሊፍኒ 2. ለኪ

መ/ ከንቢራ ሆጂሬቲ

4. ማሊፍ ቁሬጋ ከነ በርበዬ ኒ?

ሀ/ ደፊ ሰለ ስርገማፍ

ለ/ ቁርጋ ሸጋ ሰለተሊ

ሐ/ ቁጸጋፍ ጊዜ በፍ ፍን ሸገጹሙ ...

መ/ ከንቢራ

5/ ...ጋን ስለባቲ ኬኒ ዓሊራን ሆንዱፊ ሊቢቲ ፊካታ ?

ሀ/ ዶጊ ለ/ ሊጃሆማ ሐ/ ሆሊ ባን መገርሱ መ/ ቀሻሸራን

ሠ/ ቱቢባራኒ ረ/ ከንቢራ ሆጂሬ

6/ ቁርጃ ዳቡ መነሆኪሚቲ ስቢኒ ዜነሚካ ... ሬ ሊጌሰኒ ቢዘተኒ ?

1/ ሊየኒ 2/ ለኪ

[illegible] የስነ መሰረተ ቡዴን በገሮ ...

— [illegible]?

[illegible]

ቀን ______________________

ጎንደር ______________________ የሰው ዕድሜ ______________________

ፍርውን የጥሳሮ ______________ የሰው ፆታ ______________________

የቤት ቁጥር ________________ የመለያ ቁጥር ____________________

መጀመሪያና መጨረሻ ቀን የሚጠየቅ ፡

1. ቀሪያ ጉገጦ ከንአሰን ከነሜሬ አሰበወሰት ቀበጻ ፡

   1. ወነኛታቲ   1/ ኢየና   2/ ለኪ
   2. ቀርቻ   1/ ዱየኒ   2/ ለኪ ፡
   3/ ወነኛታውፍ ቀርቻ 1/ ኢየኒ   2/ ለኪ ፡
   4. ጀበኛ ወነነመኬኑፍ ወነጉገጦ   1/ ኡየኒ 2/ ለኪ
   5. ካንቢራ

2/ ዋኒ ኡገመኣ ናታ የዱቲሩ ......

   1/ ጻኢሚን ናታ ካንቢራ ኡንበርባቹ
   2/ ዋኒኡገሙ ናታኢቲጻባለታቲ
   3/ ካንቢራ

   3/ ዋኒ ኡጋሙ ቀርቻ የጀታን

      1/ ቀርቻ ግጸቴቹሱጻ
      2/ አሰባቲ ተን ኢጀቹሱጻ
      3/ ሀቀፉ ተንእቹሱጻ
      4/ ካንቢራ

3/ ወኒ ጉገመሰን ኬነሜፍ ኩኒከንጀቤን ነመፍኢኑ

   የዱቱኒ

   ሀ. ጻኢማ ሂኒ ጀቤሣለ/ቧርባጻ ሜና ኒ ሃንጋቡ ፉሣ
   ለ. ደዶበ ና ኒኒ ጥ ኔሣ
   ሐ. ካንቢራ ዱጀረቲ

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 Mesfin Kassaye

Signature

Place Addis Ababa

Date of submission March 31, 1992

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

Dr. Chales P. Larson

Advisor