Outcome evaluation study of the Targeted Supplementary Food (TSF) program in Ethiopia

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ABBREVIATIONS

DMFSS	Disaster Management and Food Security Sector
DPPA	Disaster Preparedness and Prevention Agency
EOS	Enhanced Outreach Strategy
HEP	Health Extension Program
MUAC	Mid-upper arm circumference
NGO	Non-governmental organization
NNP	National Nutrition Program
PRRO	Protracted Relief and Recovery Operation
TSF	Targeted supplementary food
WFP	World Food Programme
UNICEF	United Nations Children's Fund
WHZ	Weight-for-height z-score

EXECUTIVE SUMMARY

Background

The Targeted Supplementary Food (TSF) program is a large supplementary feeding program targeted to children less than 5 years of age and pregnant or lactating women who screen positive for acute malnutrition during 6-monthly interventions in selected areas of Ethiopia. The TSF program distributes food twice, at 3 month intervals, to enrolled children. There is no monitoring of nutritional response and therefore no discharge criteria. Children may be re-admitted to the program at a subsequent screening if they again screen positive for acute malnutrition.

A recent large evaluation recommended that outcomes be measured to demonstrate its program effectiveness. This study was implemented to determine if there are differences in nutritional outcomes between children who receive TSF food and those who do not. Both program effectiveness and efficacy were measured.

Materials

Eight districts were identified in which to recruit children for this prospective cohort study: the four intervention districts had a history of prompt delivery of TSF food after screening, and the four control districts had a history of substantial delay in delivery of TSF food, sometimes as much as 3 months after screening. Children were enrolled if their screening mid-upper arm circumference (MUAC) was less than 12.0 cm, they were 6-59 months of age, and a care giver gave consent. They were then revisited 1, 2, 3, and 6 months after enrollment.

The major outcomes measured were change in weight-for-height z-score from enrollment, change in weight from enrollment, and change in MUAC from enrollment. Other variables were measured in order to estimate the role of confounding and effect modification in biasing the study results. The target sample size was 750 children in each group. Because food was delivered in the four control districts much earlier than expected, the intervention and control groups were redefined: the intervention group consisted of children who had received TSF food by the first follow-up visit, and the control group consisted of children had not yet received TSF food by the first follow-up visit.

Efficacy was measured by defining a new group of children who had received the best TSF intervention. These children had TSF food in the house at the time of a study visit and shared the TSF food with no other household members or only another children less than 5 years of age in the household. The comparison group was children who had not yet received TSF food at the time of the follow-up visit.

Results

Data were collected on 1614 eligible children at enrollment. At the end of 6 months of follow-up, 1411 remained in the study. At enrollment, 36.4% of children had acute malnutrition defined by a weight-for-height z-score < -2.0 using the World Health Organization (WHO) Child Growth Standard, and 53.6% had acute malnutrition defined by a MUAC less than 12.0 cm as measured by the study teams. At the time of the first follow-up visit, 973 children had received TSF food and were defined as intervention children; 588 children had not received TSF food and were defined as control children.

Intervention and control children differed at baseline by age, the proportion of children receiving deworming at the prior EOS screening, the prevalence of having a safe water source, and nutritional status defined by weight-for-height z-score. These groups differed at the first follow-up visit by the period prevalence rates of diarrhea, cough with difficulty breathing, and fever; the proportion having another household member enrolled in TSF; and the prevalence of household enrollment in other programs providing nutrition or cash. These variables were analyzed for their potential influence in biasing the difference in nutrition outcome between intervention and control groups.

Overall at all four follow-up visits, intervention children had greater change in weight-for-height z-score from baseline than control children ($p \leq 0.001$ at each visit). Weight gain differed much less between the two study groups and was not statistically significant, with the exception of the fourth follow-up visit ($p<0.001$). Change in MUAC also did not differ greatly between the intervention and control groups; however, at the first follow-up visit, the difference was marginally statistically signficiant ($p=0.05$).

By the end of follow-up at 6 months, 49.2% of children with a low MUAC at baseline measured by the study teams had a MUAC greater than or equal to 12.0 cm and were considered "recovered", 47.6% had a MUAC less than 12.0 cm and were considered "not recovered", 2.9% had died, and 0.3% did not pick up either the first or second food distribution and were considered "defaulted." The risk of death during follow-up was higher for younger children and those with more severe malnutrition at baseline.

Of those variables listed above which differed between the intervention and control group, only two were effect modifiers: nutritional status at baseline and type of household water supply. Children with more severe malnutrition had a much greater change in weight-for-height z-score during the follow-up period than did children with less severe malnutrition. Among children with safe water sources, there was less difference between the intervention and control groups in change in weight-for-height z-score than among children with unsafe water sources.

Compliance with TSF program recommendations was generally poor. The majority of children a) lived in households where the food was consumed faster than expected, b) ate less than one-half of the TSF food, or c) shared the food to some extent with other persons in the household. At the first two follow-up visits, there was a much greater difference between the study groups in the change in weight-for-height z-score among children in households with less food sharing than among children with more food sharing.

The analysis of efficacy early in the follow-up was hampered by the relative lack of "high compliance" children and later in the follow-up period by the small number of children who had not yet received TSF food. Although "high compliance" children seemed to have greater change in weight-for-height z-score and change in weight during the first 3 months of follow-up than children without TSF food, the differences were not statistically significant. The difference between groups in change in MUAC was less clear.

Discussion

These results indicate that the TSF program has a beneficial effect on enrolled children; however, the effect seen was smaller than expected. One reason for this may be that a very large proportion of children enrolled in the TSF program are not acutely malnourished. In this and other studies, children with less severe acute malnutrition show less improvement during participation in supplementary feeding programs than children with more severe acute malnutrition. Comparison of MUAC measurements taken during the EOS screening to MUAC measurements taken a few days later by study personnel demonstrates that EOS measurements have both an systematic error due to bias toward lower meaurements and a potentially large random error.

A second reason for the low apparent effect of the TSF program may be due to poor compliance. Although the TSF food is theoretically targeted to a specific malnourished child, sharing with other household members was common. As a result, the targeted child ate less than ½ of TSF food in many households, and in almost no households did the food last the entire 3 months before the next food distribution. Children living in households with increased food sharing tended to have less improvement in nutritional status than children in households with more food sharing.

Other factors which may have resulted in a lower apparent effect of the TSF program may be increased food insecurity during the follow-up period. Households may have increased sharing of TSF food in order to compensate for this increased food insecurity. In addition, child care practices may have changed, even for control children, because the child was diagnosed during EOS screening as malnourished. Once mothers knew their child had malnutrition, she may have given the child extra food from the normal household supply, even in the absence of TSF distribution. And finally, there may have been other differences between the intervention and control groups in this study due to the non-random allocation of study children to study groups.

Because household compliance with TSF recommendations was so poor, the study's definition of "high compliance" was quite loose. As a result, the estimate of efficacy was not truly a measurement of the effect of the TSF program if it were ideally implemented. For very few children was the TSF program delivered as planned.

Although the target group for the TSF program is children with moderate acute malnutrition, many children with severe acute malnutrition are also enrolled. The study results demonstrates that such children derive some nutrition benefit from TSF program enrollment, although is cannot be concluded that the TSF program is sufficient treatment for such children.

Future planned revisions include integration of the TSF program into the National Nutrition Program and Health Extension Program, which will lead to the use of full-time government employees for Extended Outreach Strategy (EOS) screening instead of using volunteers engaged ad hoc for only one round of screening. This should greatly increase the accuracy and precision of EOS MUAC measurements and decrease the proportion of enrolled children who are not acutely malnourished.

Conclusions and recommendations

To strengthen TSF program effectiveness, several recommendations can be given:

1. The targeting of the program should be improved to exclude more children who do not have acute malnutrition. Possible methods include:
    a. The EOS screening teams who act as ‘gate-keepers’ to the TSF program should be better trained in measuring MUAC to increase the accuracy and precision of their measurements.
    b. Supervisory checks should be done of a portion of EOS screening MUAC measurements and action taken if accuracy falls below a specific threshold
    c. EOS screening teams should use permanently hired screening personnel to carry out EOS screening MUAC measurements.
    d. Two-stage screening could be used to verify the TSF eligibility of children initially identified as malnourished by EOS screening.
2. Intra-household food sharing should be minimized.
    a. There should be further investigation of the reasons for intra-household food sharing.
    b. Better education could be provided to mothers at the time of TSF food distribution. The TSF food could be described as a medicine to cure the child’s nutritional disease.
    c. The TSF food ration could be increased to increase the amount of food consumption by the child enrolled in TSF as well as other vulnerable persons in household .

3. The TSF program should be linked more closely to health centers to improve the referral of severely malnourished children for more appropriate therapeutic care.
   a. Access to therapeutic feeding programs in rural areas should be improved. This may require broader implementation of community-based therapeutic care.

BACKGROUND

The Enhanced Outreach Strategy (EOS) program delivers specific preventive health interventions to children less than 5 years of age throughout Ethiopia during campaigns carried out every 6 months. (Federal Ministry of Health - Ethiopia and UNICEF, 2004) In selected woredas defined as chronically food insecure by the Disaster Preparedness and Prevention Agency (DPPA), EOS team members measure mid-upper arm circumference (MUAC) and examine for oedema every child 6-59 months of age. Children with a MUAC measurement less than 12.0 cm or with bilateral pitting oedema are enrolled in the Targeted Supplementary Food (TSF) program which delivers to the mothers of each enrolled child a 6-month supply of supplementary food in two food distributions 3 months apart.

At each food distribution, the child receives 25 kg of fortified blended food (Corn soya blend (CSB)) and three liters of vegetable oil. If consumed solely by the beneficiary child, the TSF food should add to the child's daily diet the following nutrients:

Table 1. Nutrient content of TSF ration

Nutrient	Grams per day	Energy (kcal)	Protein (grams)	Fat (grams)	Iron (mg)	Vit A (mcg RE)
CSB (Famix)	274.0	1,101	40.3	19.2	21.9	-
Oil	31. 3	277	0	31.3	0	281.7
TOTAL		1,378	40.3	50.5	21.9	281.7

In 2008 the TSF program reached approximately 720,000 children 6-59 months of age and 420,000 pregnant or lactating women. In that year, the program cost about US$ 42 million, making it one of the largest supplementary feeding programs in the world. Moreover, operational procedures of the TSF program differ substantially from those of other, more traditional supplementary feeding programs. Other supplementary feeding programs are often smaller in scale because they require substantially more personnel and resources. Wet feeding programs requires personnel to cook food, and mothers and children must come to the feeding centre daily to eat the food. Even dry supplementary programs are expensive because they require frequent distribution of food and frequent measurement of enrolled children's nutritional status. In contrast, the TSF program distributes a larger quantity of food every 3 months to the mothers of enrolled children. Moreover, there are no re-measurements of nutritional status of after enrolment and, therefore, no discharge criteria. Ideally, because the EOS program measures MUAC on all children 6-59 months of age, children requiring additional nutritional support after completion of one cycle of 6 months will screen positive during the next EOS screening and be re-enrolled in the TSF program.

Because the TSF program is so different from other supplementary feeding programs, what little evidence which exists for the efficacy and effectiveness of supplementary feeding programs in general is largely inapplicable to the TSF program (Navarro-Colorado 2004, Duffield 2004).

Because of the size and expense of the TSF program, all parties participating in the program, including the government of Ethiopia, WFP, the United Nations Children's' Fund (UNICEF), non-governmental organizations (NGOs) working in nutrition and health, and donors, are interested in seeing evidence of the effectiveness of the program. In addition, recently conducted evaluations of the TSF and EOS programs have stressed the need for measuring the outcomes of the TSF program (WFP Office of Evaluation, 2007; Hall and Khara, 2006).

GOALS AND OBJECTIVES

Although the TSF program has been operated by WFP since 2004, there is no documentation of nutrition outcomes or impacts. Therefore, the findings of this study will be used to make decisions about continued operation and funding of the TSF program and potential revisions to program activities to enhance its effectiveness. In addition, if the TSF program should prove highly effective, it could serve as a model for supplementary feeding in other populations subjected to high rates of child mortality and malnutrition, especially in those populations with a large number of potential beneficiaries and limited programmatic resources.

The specific objectives of this study are:

1. To measure the program effectiveness of the TSF program in Ethiopia, as currently implemented, in reducing the severity of acute malnutrition in children 6-59 months of age who are identified as moderately acutely malnourished by EOS screening.
2. To measure the efficacy of providing supplementary food according to the Activity Implementation Manual (DPPB and WFP, 2007) of the TSF program in Ethiopia in reducing the level of acute malnutrition in children 6-59 months of age who are identified as moderately acutely malnourished by EOS screening.
3. To measure the effect of the TSF program, apart from the preventive health interventions delivered by the EOS program, on the severity of acute malnutrition in children 6-59 months of age who are identified as moderately acutely malnourished by EOS screening.

The accuracy of the MUAC measurements taken during the EOS nutrition screening has been frequently questioned. Poor measurements will result in poor targeting of the nutrition intervention, that is, inclusion of children in the TSF program who may not need nutrition support and/or exclusion of children who do need nutrition support. Moreover, some systematic errors, for example, consistently underestimating MUAC, as well as random errors in MUAC measurements will potentially increase the number of children enrolled in TSF who would not otherwise be classified as acutely malnourished. A quick review of MUAC measurements taken by one screening team on 12 November 2007 in Arsi Zone in Oromiya Region demonstrated the following results:

1. Sixty-four (46%) of the 138 measurements were equal to exactly 11.9 cm
2. Of the remaining 74 measurements, virtually all had a decimal equal to 0 or 5.

This demonstrates the strong tendency toward systematic error: the tape was pulled tighter on children who may have had a MUAC measurement equal to or just above the qualification cut-off of 12.0 cm in order to enrol them in the TSF program. This resulted in many measurements of 11.9 cm. In addition, there is substantial random error because many measurements were rounded up or down to either .0 or .5.

HYPOTHESES

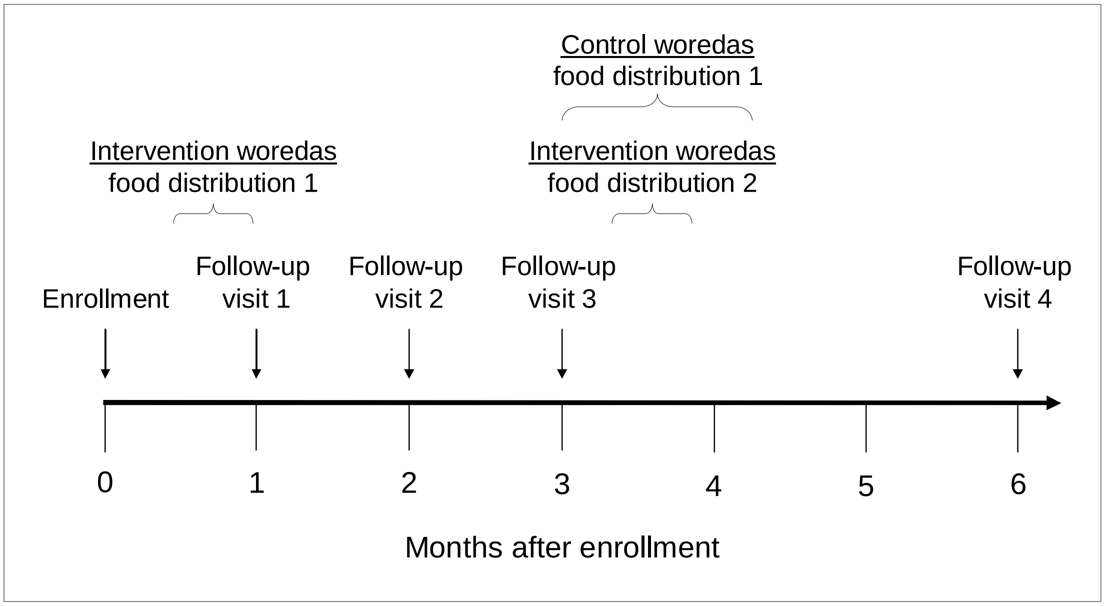
The researchers hypothesized that receiving TSF food early in the program cycle would result in a greater change in weight-for-height z-score and weight gain of enrolled children than receiving TSF food late or not receiving TSF food at all.

METHODS

Study design

The present study is a prospective cohort study with an intervention and a control group. It was conducted in eight rural districts of four regions in Ethiopia during the period 25 May 2008 to 28 March 2009. Children in selected areas were enrolled as soon as possible after EOS screening identified them as eligible to receive TSF food. Children were followed for 6 months with repeated measurements of specific nutrition outcomes as well as additional variables which could be considered potential confounders or effect modifiers of the association between participation in the TSF program and the measured outcomes. Follow-up visits were monthly for the first 3 months, followed by a final visit 6 months after enrollment, as shown in Figure 1. At enrollment and at all follow-up visits, anthropometric measurements were taken and information was collected on different variables that may have affected the child's nutritional status since enrollment or the last follow-up visit.

Figure 1. Schedule of study enrollment, TSF food distribution, and data collection rounds

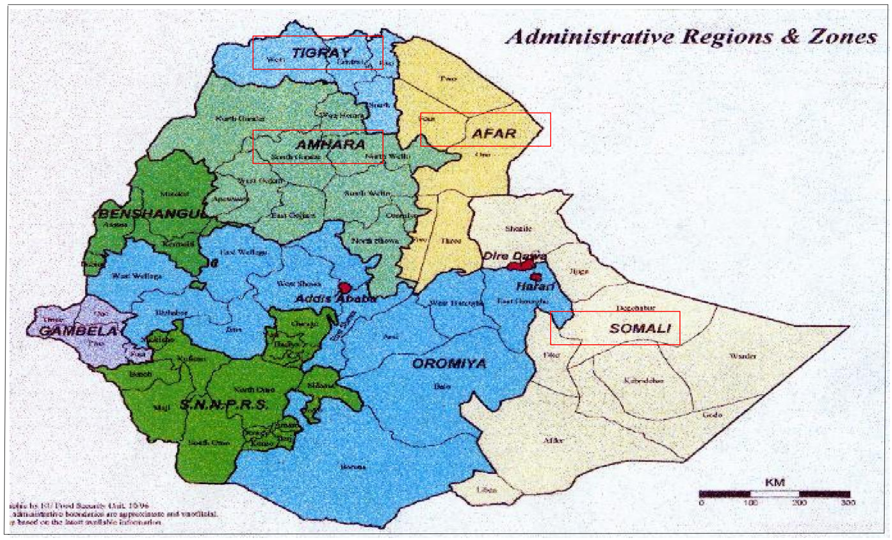


The original design defined intervention children and control children by the woreda in which they lived. As described below, study managers attempted to select woredas in which the TSF food would arrive early and those where the TSF food would arrive late.

Study sites

The study was conducted in Afar, Amhara, Tigray, and Somali Regions. The locations of these four regions are presented in Figure 2.

Figure 2. Map of Ethiopia showing selected Regions



In each region one woreda was selected as the intervention woreda (predicted to receive TSF food promptly after the EOS screening) and another woreda was selected as the control woreda (predicted to receive TSF food more than 3 months after EOS screening and study enrollment). However, because food was unexpectedly delivered more promptly than expected, this definition of intervention and control children had to be abandoned and the intervention and control groups redefined (see section "Data analysis, Redefinition of intervention and control groups" below). See Annex 1 for more detail on the original selection of intervention and control woredas.

Selection of children

In each of the eight selected woredas, one or more kebeles were selected from which children were recruited. The kebele selection was dependent on:

- Where the EOS-screening was started – Study recruitment in the woreda began as soon as EOS screening started
- The kebele's accessibility – Study teams had to be able to travel to the kebele
- The population size of the kebele – Study teams could more efficiently recruit and re-visit children if travel during data collection was minimized

As a result of this purposive selection, enrolled children were not randomly selected nor randomly assigned to either the intervention or the control group.

The children who were eligible for participation in the study:

- Were identified as acutely malnourished by the EOS screening team. The EOS definition of acute malnutrition was a MUAC less than 12.0 cm or the presence of bilateral pitting edema in the feet or lower legs.
- Were 6-59 months of age at the time of enrollment in the TSF program.
- Had a mother or primary caretaker who consented to all follow-up visits and study activities.
- Were not critically ill requiring immediate referrals to an in-patient health facility.
- Were not enrolled in the prior TSF program cycle regardless of whether or not they received TSF food (in practice virtually all enrolled children receive TSF food). Because of unavoidable and extensive program delays, such children may not have received TSF food until six months after the screening in November or December 2007. As a result, some children would still be defined as malnourished during the current EOS-screening. In addition, children assigned to the control group, even if the prior TSF food delivery were not so late, may have had access to TSF food just before the current EOS screening, thus diluting the difference in exposure to TSF food between the study intervention and control groups.

Field procedures

Study enrollment started on the second day of the EOS-screening in the intervention woredas. It was estimated that the data collection team needed 26 days to collect data for each region's 400 children during each round of data collection. Table 2 shows on which date each data collection round started.

Table 2. The start date of the five data collection rounds in each woreda

Region	Woreda	EOS screening	Baseline	1st Follow up	2nd Follow up	3rd Follow up	4rd Follow up
Tigray	Hawsien	14-06-2008	15-06-2008	23-07-2008	15-09-2008	29-10-2008	17-12-2008
	N/Aidet	14-06-2008	02-07-2008	14-08-2008	08-10-2008	22-11-2008	06-01-2009
Afar	Dubti	17-07-2008	17-07-2008	23-08-2008	02-10-2008	01-11-2008	30-01-2009
	Aba Ala	17-07-2008	06-08-2008	15-09-2008	15-10-2008	16-11-2008	14-02-2009
Amhara	Sekota	23-05-2008	25-05-2008	08-07-2008	09-08-2008	13-09-2008	01-01-2009
	Lasta	23-05-2008	19-06-2008	25-07-2008	21-08-2009	29-09-2008	17-12-2008
Somali	Gursum	31-08-2008	01-09-2008	11-10-2008	23-11-2008	10-01-2009	27-02-2009
	Dolo Ado	05-09-2008	23-09-2008	04-11-2008	14-12-2008	06-02-2009	24-03-2009

The team leader was responsible for obtaining the EOS screening logbooks from the Health Bureau of the woreda. These books contained information about the children enrolled in the TSF program. The team leader then copied the names of 230 consecutive children who met the inclusion criteria to the study registration form[1]. Study teams usually followed EOS screening teams when they began screening in a study woreda. Local guides at the study sites were hired to help data collection teams find children's homes. At enrollment, study team interviewers explained the study and sought consent for participation from the primary caretaker. In order to compensate for inconvenience, each caretaker of an enrolled child received a bar of soap at the second and fourth data collection round. If all five data collection rounds were completed, the caretaker received a certificate of study completion.

Outcome indicators

Four principal outcome indicators were used to measure the TSF program's effect on nutritional status:

1. Change in weight-for-height z-scores - Change in weight-for-height z-score is probably the most precise and accurate measure of changes in the degree of acute malnutrition; therefore, this outcome is the most important in assessing the efficacy and effectiveness of the TSF program. Weight-for-height z-scores were calculated using the new World Health Organization Child Growth Standard (de Onis, 2004).

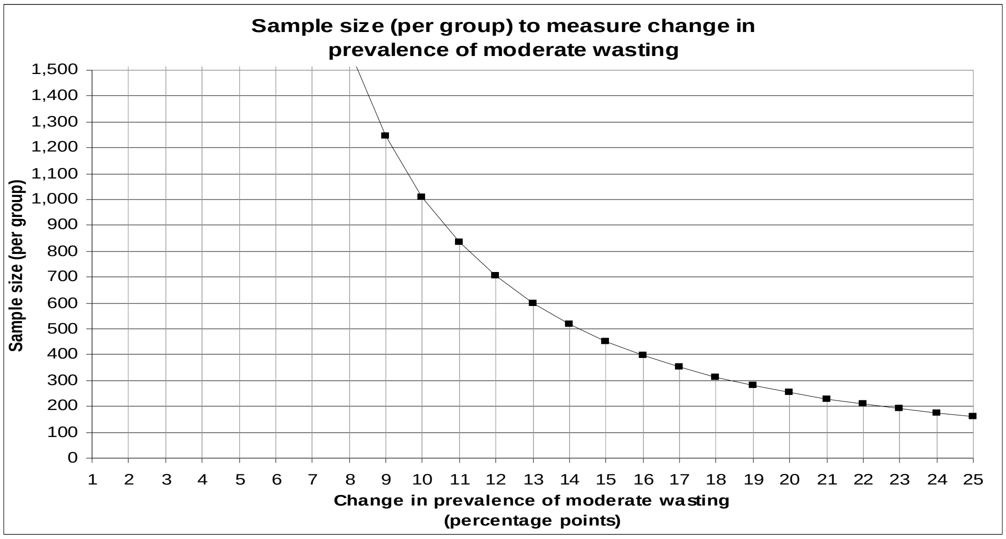
[1] The registration form is a list of the children who are enrolled in the study. The team leader keeps track of which round of data collection each child has completed and notes any reason for loss to follow-up.

2. Weight gain - Weight gain is expressed as the number of grams change in weight from baseline. Weight gain is the most common indicator used to measure an individual child's progress after enrolment in traditional supplementary feeding programs for moderately malnourished children.
3. Change in MUAC - The baseline and follow-up MUAC measurements were taken by the study teams. The MUAC measured by the EOS screening teams was NOT used to calculate change in MUAC during follow-up.
4. Recovery and defaulting - Recovery is the proportion of enrolled children who are no longer defined as acutely malnourished at the third follow-up visit. Defaulting is the proportion of children who do not receive either the first or second TSF food distribution after EOS screening during the 6-month follow-up. The Sphere Project (Sphere Project, 2004) standards for supplementary feeding programs stipulate that in successful programs, more than 75% of enrolled children recover and fewer than 15% of enrolled children default. These definitions of recovery and defaulting are not the same as the standard definitions used to monitor traditional supplementary feeding programs. Therefore, the Sphere standards, as well as other standards meant for traditional supplementary feeding programs, cannot be directly applied to the TSF program.

Sample size

The minimum sample size for the study was calculated based on change in the prevalence of moderate acute malnutrition. Figure 3 below shows the sample size needed to achieve statistical significance. The x-axis is the difference between the intervention and control groups or between the baseline and final data collections. This graph assumes that 1) 58% of the children identified with moderate acute malnutrition by EOS screening actually have moderate acute malnutrition, as found by a prior study (WFP, 2008), 2) the design effect for weight-for-height z-score will be 1.5, and 3) all children identified with moderate acute malnutrition by EOS screening will be included in the study, including those without true moderate acute malnutrition and those with severe acute malnutrition as defined by weight-for-height z-score.

Figure 3. Sample size relative to minimum statistically significant change in the prevalence of moderate acute malnutrition



This study used a sample size of 750 children in each group, for a total sample size of 1500, with the expectation of finding at least a decrease of 12 percentage points in the prevalence of moderate acute malnutrition between enrollment and the final follow-up visit in the intervention population and/or a 12 percentage point difference in the prevalence of moderate acute malnutrition between the intervention and control populations. These 1500 children were apportioned equally to each selected woreda. As a result, in each of the eight woredas selected as study sites, about 188 children were enrolled. To account for non-response and drop-out, 200 children were enrolled per woreda giving a total sample size of 1623. The sample size calculation assumed a precision of 0.05 and power of 0.8.

Variables

The entire list of variables for which data were collected can be seen in the data collection form, as shown in annex 1. Items in blue font were included only in the first data collection at enrollment.

For data analysis, water source was categorized as "safe" if it consisted of piped water system, a tube well or borehole, or a protected well or spring. "Unsafe" sources included an unprotected well or spring, rainwater or community rainwater storage reservoir, a tanker truck or other water seller, or surface water. The household source of drinking water was assessed at each follow-up visit in the study because, unlike other household and demographic variables, water source often changes over time in rural Ethiopia. Therefore, the variable is re-classified at each follow-up visit. Because none of the study households adequately treated their water in the house, this variable was not taken into account when defining safe and unsafe water sources.

Training of enumerators

The four data collection teams consisted of nine enumerators and four team leaders selected from the study areas for to ensure local acceptability and language skills. An effort was made to identify enumerators who already had experience with anthropometric measurement and especially experience with nutrition surveys. Furthermore, the enumerators needed to speak and read English to undergo training and supervision in English.

The enumerators received three days of training which included class lectures about the objectives of the study, the data collection forms, interview techniques, anthropometric measurements and field procedures. The training was conducted by members of the evaluation study team in English and Amharic (national language of Ethiopia). In addition to the training, a study manual was developed in English.

A standardization test of the enumerators was carried out in order to assess the accuracy and precision of their height, weight and MUAC measurements. The standardization test involved each team repeating two independent measurements (height, weight, MUAC and check for edema) on 10 different children, with a time interval between measurements on the same child. For each team, the difference between the two measurements was calculated to assess the precision and a mean of the two measurements was compared to an expert measurement to assess accuracy, as per international recommendations (SMART, 2006). The same equipment used during the standardization test was to be used during study data collection. During the field test, each data collection team also carried out two pilot interviews with two caretakers. This was partly done for interview training, but also to field-test the developed questionnaire. During the field test the data collection teams were closely supervised by the study team.

Data analysis

Redefinition of intervention and control groups

The original plan of having intervention and control groups geographically segregated and having intervention and control woredas matched within Regions did not work out. As shown in Table 3, many kebeles (or subdistricts) in control woredas received food before the first follow-up visit, and some kebeles in intervention woredas received food after the first follow-up visit.

Table 3. Timing of TSF distribution and first follow-up visit, by study woreda

Woreda	Region	Average number of days with food at first follow-up visit*	Range of number of days with food at first follow-up visit*
Intervention			
Sekota	Amhara	22	27 to 14
Dubti	Afar	12	18 to 7
Hawsien	Tigrey	23	33 to 14
Gursum	Somali	-3	17 to -21
Control			
Lasta	Amhara	-12	20 to -18
Aba Ala	Afar	13	18 to 8
N/Aidet	Tigrey	3	21 to -37
Dolo Ado	Somali	-17	-14 to -23

* The days with food was calculated for each kebele with enrolled children using the formula: (the date of first follow-up visit in a kebele) - (the date of TSF food delivery in that kebele). As a result, a positive number means that the household received food BEFORE the first follow-up visit. A negative number means that the household received food AFTER the first follow-up visit.

The average number of days for a woreda is the unweighted arithmetic mean of the kebeles in that woreda. As a result, a positive number indicates TSF food delivery before the first follow-up visit; a negative number indicates TSF food delivery after the first follow-up visit.

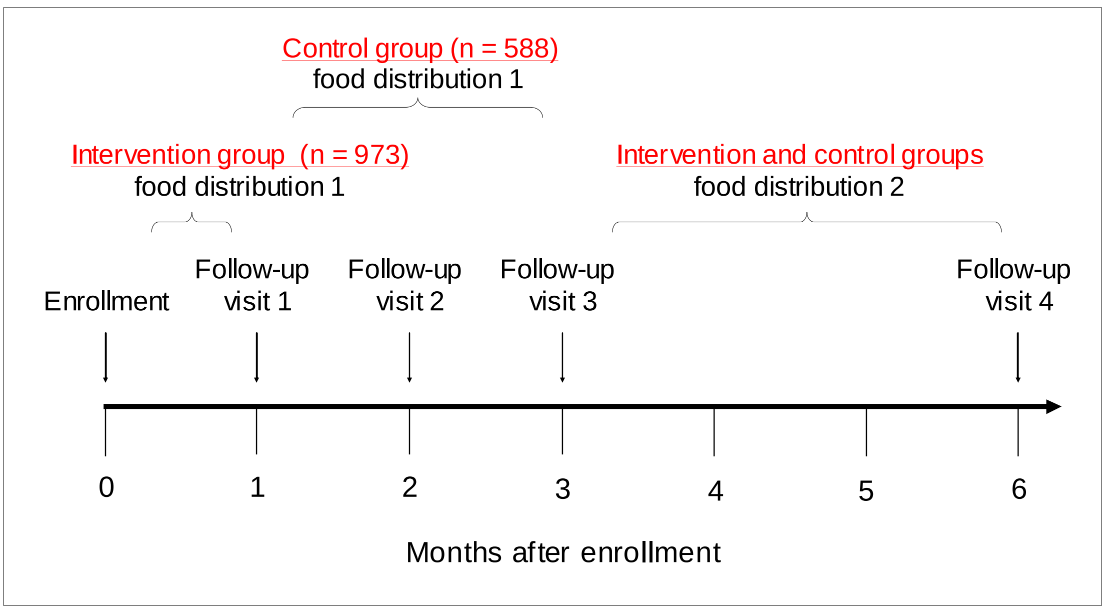
As a result of this blurring of the difference in time of food delivery between intervention and control woredas, study children were reassigned to intervention and control groups using the following criterion:

1. Intervention group: a child living in a household in which the interview respondent reported at the first follow-up visit having already received TSF food.
2. Control group: a child living in a household in which the interview respondent reported at the first follow-up visit NOT having received TSF.

All analyses presented in this report use these definitions of intervention and control groups, NOT the originally planned study groups defined by woreda of residence. Wherever the terms "intervention group" and "control group" are used, they apply to the redefined study groups.

Even after this redefinition of intervention and control groups, the intervention and control groups did not differ as much as might be desired in the duration of their eating TSF food, as shown in Figure 4 below.

Figure 4. Timeline of actual food distributions during study follow-up



Effectiveness and efficacy

Program effectiveness is defined as "…a measure of the extent to which a specific intervention, procedure, regimen, or service, when deployed in the field in routine circumstances, does what is intended to do for a specified population." (Cochrane, 1972) In contrast, efficacy is defined as "…the extent to which a specific intervention, procedure, regimen, or service produces a beneficial result under ideal conditions…". (Last, 2001) No public health program delivers its intervention to all recipients according to the ideal protocol. Program shortcomings and other factors can result in a program effectiveness which is substantially below the theoretical efficacy of an intervention as demonstrated in high-quality controlled trials. This leads to a difference between efficacy and program effectiveness. In nutrition programs, poor coverage, poor quality of distributed food, food sharing beyond the targeted individual, improper food utilization by recipients, and many other factors may result in a relative lack of efficacy. Program effectiveness in this study was measured by comparing all children in the intervention group to all children in the control group, regardless of reported lapses in program recommendations.

Measuring the efficacy of the TSF program would require observation of children who receive the optimal feeding intervention according to TSF protocols. This would include prompt delivery of food after screening, preparation of food according to directions given at the time of food distribution, consumption of food only by the target child, and consumption of the 3-month ration over 3 months, not more rapidly or more slowly. Recommendations for use of TSF food are taught to mothers when the first food distribution is picked up. To measure deviations from these recommendations, study interviews included questions on several compliance variables, including the availability of the TSF CSB and oil in the household at the time of study visits, the number and identity of other household members eating the TSF food, and the proportion of TSF food eaten by the enrolled child. Because these questions asked specifically about TSF food prepared the day before the interview, compliance data were collected only from households in which TSF food had been prepared the day before.

To assess the efficacy of the TSF program, a subgroup of children who were moderately malnourished at baseline according to weight-for-height z-score ($-3.0 \geq$ WHZ < -2.0) were selected from the study data who, at the first follow-up visit, were reported as sharing TSF food with no other household members or with only one other child less than 5 years of age. These children were then compared to children who had not yet received TSF food. Thus, the study subjects receiving the best intervention were compared to those receiving no intervention at all. Efficacy is only analyzed at the three first follow-up visits.

Confounding and effect modification

In a prospective follow-up study such as this, confounding and effect modification could potentially produce serious bias resulting in erroneous conclusions and recommendations. Confounding is the influence of differences between the intervention and control groups which may have an effect on the difference between the study groups in change in outcome. An effect modifier is a variable which changes the association between the intervention and the outcome, or in this study, between the consumption of TSF food and the nutritional outcome. As a result, if the intervention and control group differ according to an effect modifying variable, this will influence the difference between the study groups in the measured outcome. For example, if younger children respond to the TSF program better than older children, and the control group has a higher proportion of younger children than the intervention group, the apparent difference between the study groups in change in weight-for-height z-score after some period of follow-up will be less than if the age distribution of the study groups were the same. In this case, age is an effect modifier; the assocation between study group and change in weight-for-height group is different depending on the age of the child. Such confounding is much more likely when study subjects have not been randomly allocated into treatment groups. Because this study chose intervention and control areas, rather than individually assigning children randomly into either the intervention or control group, and because this study chose these areas intentionally and not randomly, the danger of confounding, and the resultant bias, is higher. Therefore, the study collected extensive data on potential confounding variables in order to detect and, if necessary, correct for any confounding present.

To produce confounding, a variable must differ between the intervention and control groups. For example, in the example above, analysis of the age distribution of children in the intervention and control groups at enrollment would show that the study group did not have the same proportion of younger and older children. Therefore, as an initial screen for confounding variables, the intervention and control groups were compared by several variables. If the distribution of a specific variable did not differ between the two study groups, that variable could not produce confounding.

If the distribution of a specific variable differed between the study groups, a stratified analysis was done for that variable. In these stratified analyses, study group was the independent variable, the outcome change in weight-for-height z-score was the dependent variable, and the specific variable was the stratification variable. Such analyses measured the association between study group and change in weight-for-height z-score independently of the potential confounding variable. It also showed the association between the potential confounding variable and change in weight-for-height z-score.

Compliance

Data were gathered at each follow-up visit on whether or not each child's household had TSF food present. If TSF food was present, interviewers asked if the TSF food prepared the day before the interview was eaten by other members of the household, and if so, by whom? Interviewers also asked what proportion of TSF food prepared the day before the interview was eaten by the study child.

Because only intervention children had received TSF food before the first follow-up visit, compliance variables were measured only in the intervention group at the first follow-up visit. For analyses of outcomes by compliance variables at the second and third follow-up visits, measures of compliance at those follow-up visits were used for households in which TSF food was present. These analyses were carried out only at the three first follow-up visits. Because TSF food was consumed much more rapidly than recommended, the number of households in which compliance variables were measured at these follow-up visits, especially the third, was relatively small.

Data entry, editing and management

Data were doubly entered by two data clerks into the EPIdata computer program using logical and legal value definitions to reduce clerical errors. The calculation of weight-for-height z-score was done in Nutrition Assessment Program for SMART (ENA) using the WHO Child Growth Standard. The data were then exported to and analyzed using SPSS for windows version 15.0.

Data were cleaned by producing frequency distributions for all variables. Outlying values were checked against the paper data collection forms and corrected if necessary. Values, even if clearly written on the data collection forms, which were obviously wrong, for example, values incapable with life, were coded as missing values. If necessary, study teams were sent back to subject's households to remeasure values. Missing values were excluded from analyses.

After completion of these steps, all preliminary copies of the dataset were securely archived. The computer database field names were added to an electronic copy of the data collection form to indicate precisely the origin of the data in each field of the database. This reference document was stored both electronically with the computer dataset and in hardcopy along with the paper data collection forms.

Ethical considerations

In many countries, formal ethical review of data collections is mandated only for research studies. One widely-used definition of "research" is any data collection which is meant to produce results which can be generalized outside the population from which the data were collected and which, therefore, contribute to the larger scientific body of knowledge. This evaluation planned for the TSF program is meant only to evaluate the TSF program and not to produce generalizable knowledge; it therefore does not meet this definition of research. Nonetheless, the protocol for this study was submitted to and approved by the Jimma University Ethical Review Board.

Notifying participants of study findings

Because there are few study results which might be of use to study participants, study participants were not given any specific data collected at the time of data collection. Although subsequent data analysis calculated anthropometric z-scores, the children participating in the study were already enrolled in the major, and in most areas the only, nutrition program available to them, the TSF program. Children who appear severely ill were not eligible for study participation; these children were referred to the nearest health facility. Children who were severely malnourished were, however, eligible for participation in the study, but at the same time, they were referred to the nearest therapeutic feeding centre for more intensive nutritional rehabilitation, if such a center was available. Unfortunately, therapeutic feeding services are available for only about 15% of those children needing them, so most children identified as severely malnourished by EOS screening and enrolled in this study received only TSF program food.

RESULTS

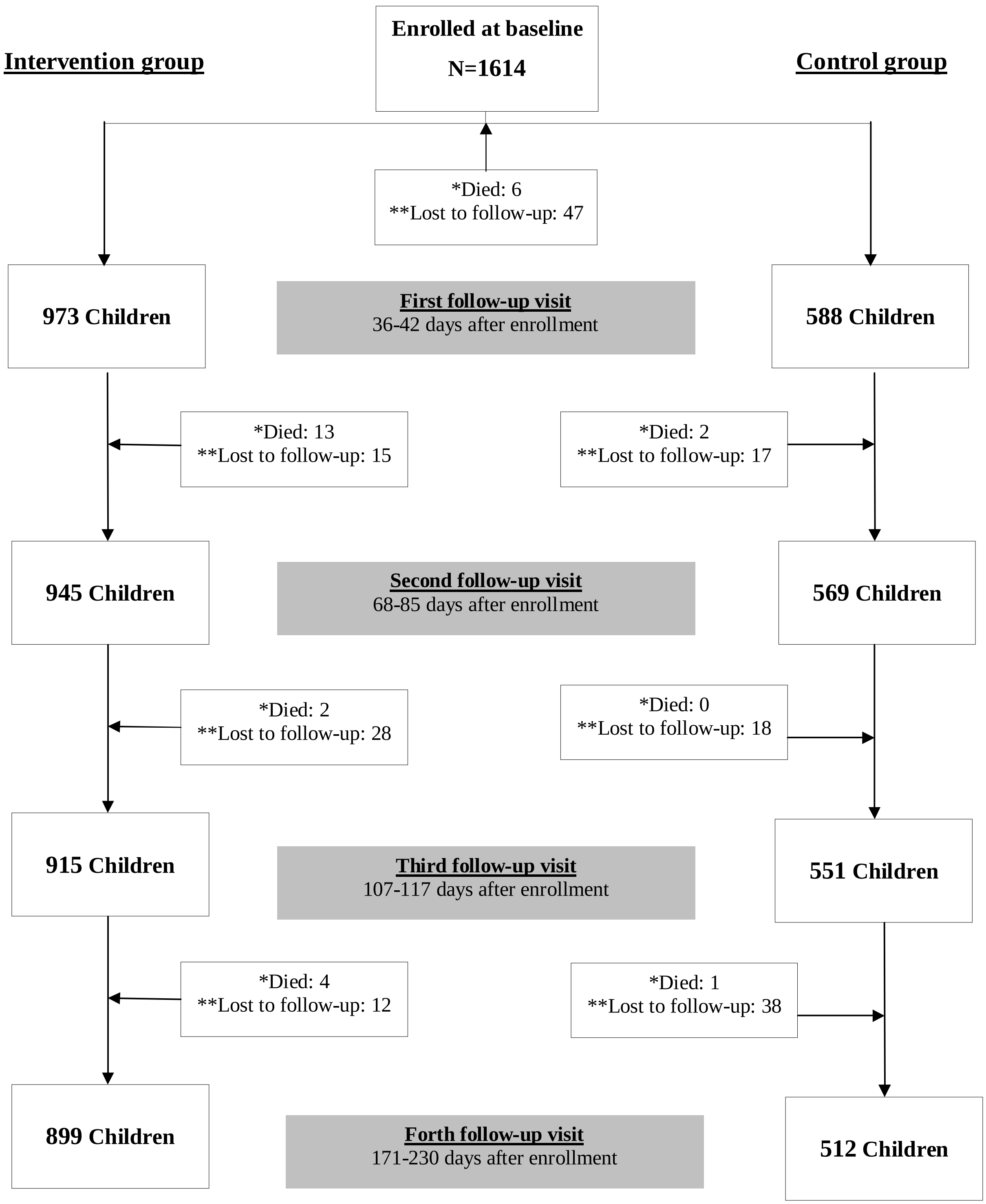
Enrollment and follow-up

The flow-chart presented in Figure 5 gives an overview of the study population during the follow-up period. Initially, 1623 study children were recruited. Nine children were excluded from any analysis: five had an EOS MUAC above 12.0 cm and thus should not have been eligible for inclusion in the study, and four had no information recorded at baseline. Hence, the total study population comprised 1614 children of which 762 (47.2%) were boys and 852 (52.8%) were girls.

The mean average age at baseline was 19.9 months, and 70.3% were less than 24 months old. The mean baseline weight-for-height z-score was -1.70 (range: -5.65 to 2.47) and the prevalence of malnutrition defined by enrollment weight-for-height z-score was 36.4%. The mean baseline study MUAC was 11.9 cm (range: 7.0 cm to 15.5 cm) and the prevalence of malnutrition defined by enrollment MUAC measured by the study teams was 53.6%. Five (0.3%) children had edema at baseline.

Children in the control group who received TSF food during the first three months of follow-up received it an average of 21.6 days (range 6 – 99 days) after the first follow-up visit. By the third follow-up visit, 37 (2.3%) children had never received TSF food and 23 (1.4%) of the 1614 children died. By the fourth follow-up visit 28 (1.7 %) of the 1614 children died and 175 (10.8 %) children had been lost to follow-up.

Figure 5. Follow-up of enrolled children, by follow-up visit



* Causes of death: diarrhea: 10; hunger related diseases: 4; malaria: 2; bee sting: 1; measles: 1; unknown: 1

** All losses to follow-up were due to the household moving or the enumerators being unable to find the household.

Description of intervention and control groups

The distributions of various demographic, health, and nutritional characteristics at baseline in the intervention and control groups are presented in Table 4, Table 5, and Figure 6. The study groups did not differ substantially regarding 1) the proportion of girls and boys, 2) the identity of the interview respondent, 3) the proportion of children who received vitamin A supplementation at the prior EOS round, 4) the mean household size, 5) the mean number of children less 5 years in the household, 6) type of sanitation facilities, and 7) breastfeeding history. However, intervention group children were somewhat younger, more likely to live in households in which the primary source of income was salary or other payment for work, more likely to receive deworming, and more likely to have a safe water source. Nutritional status, as defined by weight-for-height z-score, also differed, albeit with marginal statistical significance, between the intervention group and control groups. In contrast, according to the MUAC measurement made by the study teams, the difference in nutritional status between the two groups was highly statistically significant. The distribution of weight-for-height z-scores did not differ substantially between the two study groups (see Figure 6). At enrollment only 4 (0.2%) of the 1614 children enrolled in the study had bilateral pedal edema. One of these children died before the first follow-up visit. All were in the intervention group.

Table 4. Distribution of various demographic, health, and nutritional characteristics at baseline

Characteristic	**Number (%) or mean in inter-vention group** N=973	**Number (%) or mean in control group** N=588	P-value*
Sex			
Boys	463 (47.6)	277 (47.1)	0.9
Girls	510 (52.4)	311 (52.9)	
Age at baseline			
<24 months	744 (76.5)	355 (60.4)	
24-41 months	154 (15.8)	168 (28.6)	**< 0.001**
42-59+ months	75 (7.7)	65 (11.1)	
The interviewed person			
The biological mother	929 (95.5)	559 (95.4)	0.9
Other	44 (4.5)	27 (4.6)	

Characteristic	Number (%) or mean in intervention group N=973	Number (%) or mean in control group N=588	P-value*
Person with primary child care responsibility			
Interviewed person	968 (99.5)	583 (99.1)	0.6
Other	5 (0.5)	5 (0.9)	
Primary source of household income			
Farming and/or raising livestock	631 (66.6)	366 (63.0)	
Relief and/or remittances	68 (7.2)	191 (32.9)	**<0.001**
Salary or other payment for work	249 (26.3)	24 (4.1)	
EOS intervention received			
Vitamin A supplementation	955 (98.2)	583 (99.1)	0.3
De-worming (only children > 24 months of age)	252 (33.9)	99 (27.9)	**0.05**
Mean household size at baseline	6.2	6.3	0.3
Mean number of children less than 5 years of age in the household at baseline	1.8	1.8	0.2
Safe water source**			
Yes	555 (57.2)	290 (49.4)	**0.003**
No	416 (42.8)	297 (50.6)	
Sanitation facilities			
Flush toilet or pit latrine	343 (35.3)	207 (35.4)	0.9
Bush, field or compound	629 (64.7)	378 (64.6)	
Breastfeeding			
Ever breastfed	717 (96.4%)	340 (95.8)	0.4
Breastfed last 24 hours (children< 24 months)	620 (83.3)	304 (85.6)	
Nutrition status at baseline:			
*By weight-for-height z-score***			
Severe acute malnutrition	116 (12.0)	48 (8.3)	
Moderate acute malnutrition	248 (25.7)	147 (25.3)	**0.053**
Not acute malnutrition	600 (62.2)	386 (66.4)	
*By MUAC***			
Severe acute malnutrition	134 (13.8)	42 (7.2)	
Moderate acute malnutrition	425 (43.7)	299 (39.1)	**<0.001**
No acute malnutrition	413 (42.5)	315 (53.8)	

* P-value for the difference between the study groups. P-values were calculated using Student t-test for continuous variables and chi-square test for categorical variables.

** See text for definitions

Figure 6. Distribution of weight-for-height z-scores at baseline, by study group

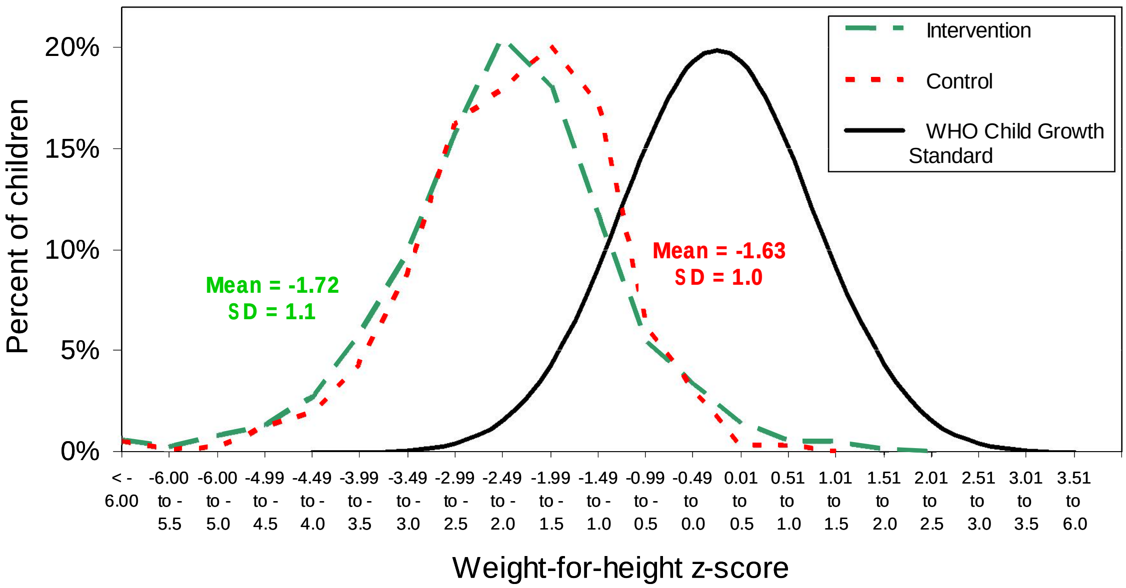


Table 6 presents the distribution of various characteristics measuring health and participation in other programs for children in the intervention and control groups at the time of the first follow-up visit. The period prevalence rates of diarrhea and cough with difficulty breathing were statistically significantly greater in the control group. Furthermore, the control group had a higher period prevalence of fever than the intervention group; however, this difference lacked statistical significance. The proportion of households in which another household member was enrolled in the TSF program was greater in the control group than in the intervention group. In contrast, the proportion of households which were enrolled in other programs providing food or cash was greater in the intervention group than in the control group.

Table 5. Distribution of various characteristics measuring health and current participation in other programs at the time of the first follow-up visit

Variable	Number (%) in intervention group N=973	Number (%) in control group N=588	P-value*
Had diarrhea in past 2 weeks **	398 (42.3)	280 (48.4)	**0.02**
Had cough with difficulty breathing in past 2 weeks	202 (20.8)	184 (31.3)	**<0.001**
Had fever in past 2 weeks	440 (45.2)	291 (49.5)	**0.07**
Current participation of a household member in the TSF program **			
Yes	131 (13.5)	122 (20.7)	**0.01**
No	839 (86.2)	464 (78.9)	
Current participation of household in another program providing food or cash**			
Yes	542 (57.7)	162 (28.0)	**<0.001**
No	397 (42.2)	416 (72.0)	

* p-value for the difference between the study groups and was calculated using chi-square test.
** See text for definition

As a result of the analysis of these characteristics, the variables included in further analyses because they were considered as potential confounders were: age group at baseline, the proportion of children receiving deworming at the prior EOS screening, the prevalence of having a safe water source, nutritional status at baseline defined by weight-for-height z-score, the period prevalence rates of the three forms of morbidity, the proportion having another household member enrolled in TSF at the first follow-up visit, and the prevalence of household enrollment in other programs providing nutrition or cash at the first follow-up visit.

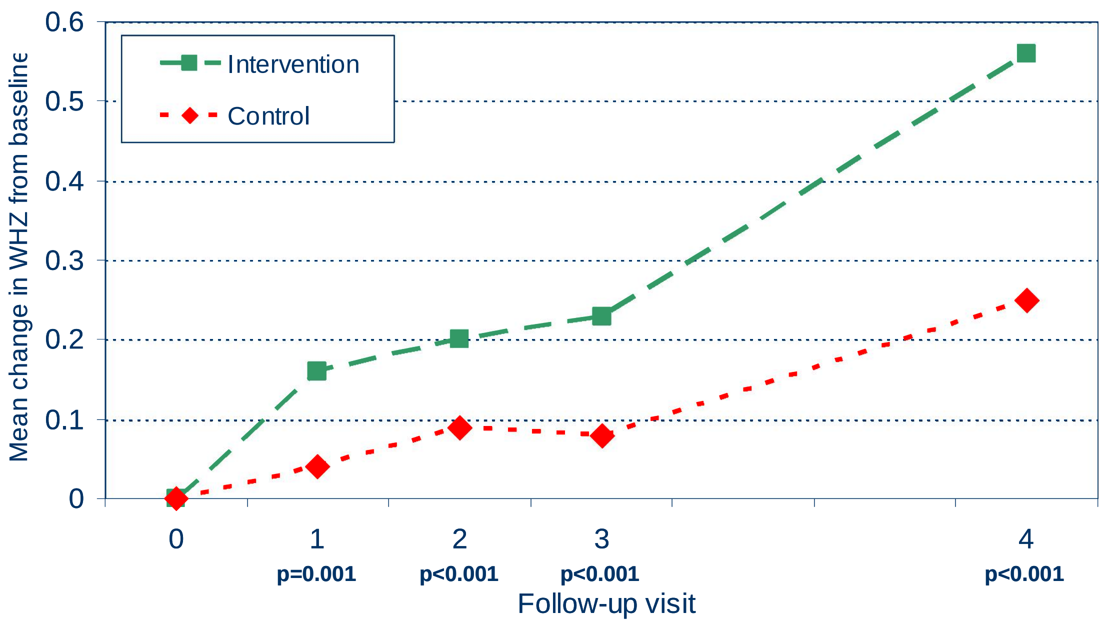
Program effectiveness

The effectiveness of the TSF program was evaluated by comparing between the intervention and control groups the mean change in indicators of nutritional status, including mean change in weight for height z-score, mean weight gain, and mean change in MUAC, from baseline to each of the three monthly follow-up visits.

Mean change in weight-for-height z-score

Figure 7 shows the mean change in weight-for-height z-score from baseline to each of the four follow-up visits without adjustment for other variables. The mean change at every follow-up visit was statistically significantly greater in the intervention children than in the control children. The greatest increase in both the intervention and control group occurred between the baseline visit and the fourth follow-up visit after 6 months of follow-up. Over the entire follow-up period of 6 months, the intervention group had a mean change in weight-for-height z-score of 0.56 z-score, and the control group had a mean change of 0.25 z-score.

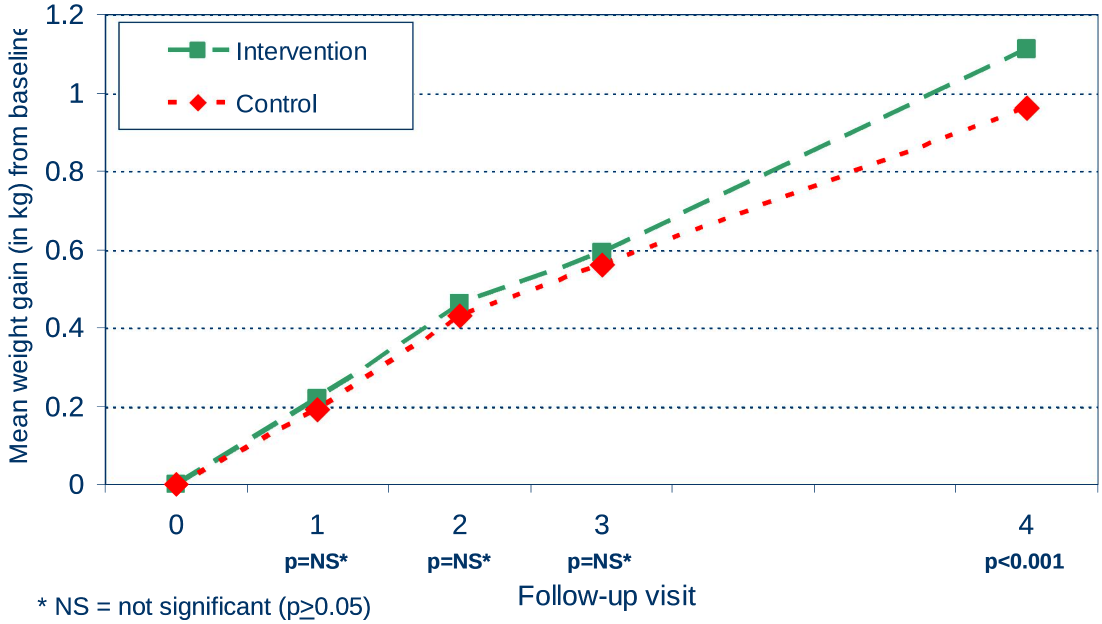
Figure 7. Change in weight-for-height z-score during the follow-up period, by study group



Weight gain

Figure 8 presents the mean weight gain from baseline to each follow-up visit for the intervention and control children. The intervention children and the control children did not differ substantially at the three first follow-up visits, but did at the fourth visit. From baseline to the fourth follow-up visit, intervention children had an mean weight gain of 1.11 kg and the control children had a mean weight gain of 0.96 kg.

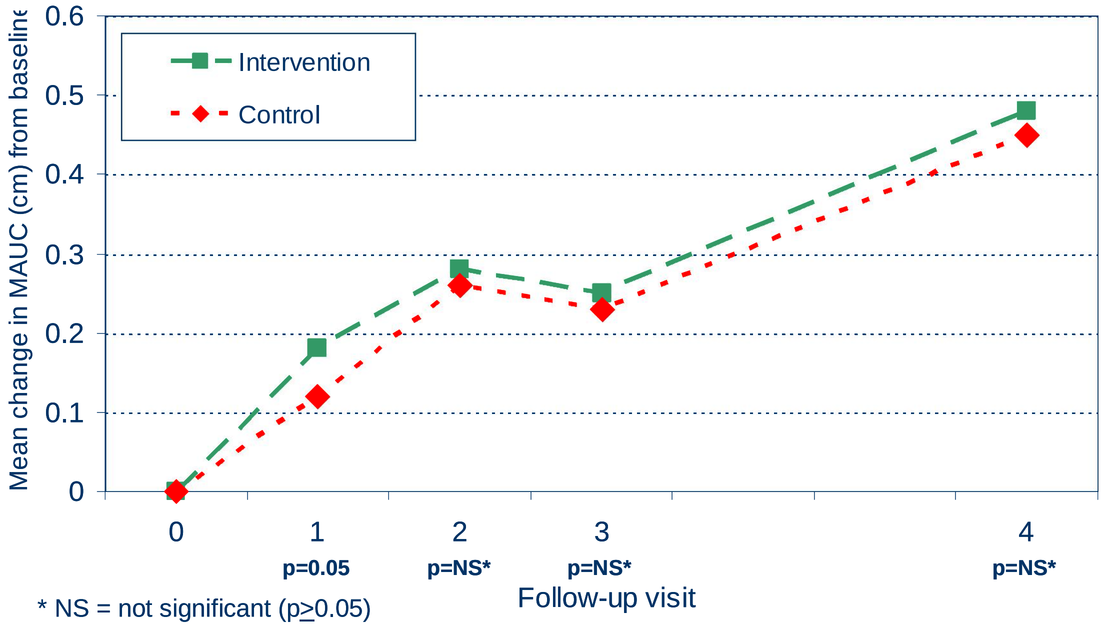
Figure 8. Weight gain during the follow-up period, by study group



Change in MUAC

Figure 9 shows the mean change in MUAC from baseline to each follow-up visit. The difference between the intervention and control groups in change in MUAC from baseline was greatest at the first follow-up visit, before the control children had received TSF food. At the second through fourth follow-up visits, the difference between the groups was much smaller and not statistically significant. Over the entire 6-month follow-up, the mean change in MUAC for the intervention children was 0.48 cm and for the control children 0.45 cm.

Figure 9. Change in MUAC during the follow-up period, by study group



Death, recovery and default rates

As depicted in Table 6, about half of all study children who were malnourished at enrollment, as measured by the study MUAC (not the EOS MUAC) recovered during the 6-month follow-up, and about half did not recover. A substantial proportion of children died during the follow-up. Defaulting, as defined above in the Methods section, was not very common. Table 6 presents a pooled analysis of all children together.

Table 6. Number (%) of all study children (intervention and control groups combined) with enrollment MUAC less than 12.0 cm who recovered (based on study MUAC measurements), who died, and who defaulted

Outcomes	Number (%)	
Children who **recovered*** during 6-month follow-up	384	(49.2)
Children who **did not recover**** by third month follow-up visit	371	(47.6)
Children who **died** during 6-month follow-up	23	(2.9)
Children who **defaulted**‡ out of the TSF program	2	(0.3)
Total	**780**	**(100)**

* Recovered = Study MUAC $\geq$ 12.0 cm at three-month follow-up visit
** Did not recover = Study MUAC < 12.0 cm at three-month follow-up visit
‡ Defaulted = Failed to appear at first and second food distribution after TSF enrollment

Table 7 compares the risk of death during the 6-month follow-up period by various characteristics. Boys and girls had about the same risk of death. In contrast, a greater proportion of children <24 months of age died than did older children. As expected, a much higher proportion of severely malnourished children died than did children who were moderately malnourished or not malnourished at all. Mortality rates in the intervention and control groups were not compared because: 1) the study was not powered to detect with statistical significance a difference in mortality between the study groups and 2) the study groups differ substantially on variables which are strong determinants of mortality, especially age and baseline nutritional status. As a result of these differences, a true comparison of mortality would require a more complex analysis than can be presented in this report.

Table 7. Number and percent of children who died during the 6-month follow-up, by various characteristics

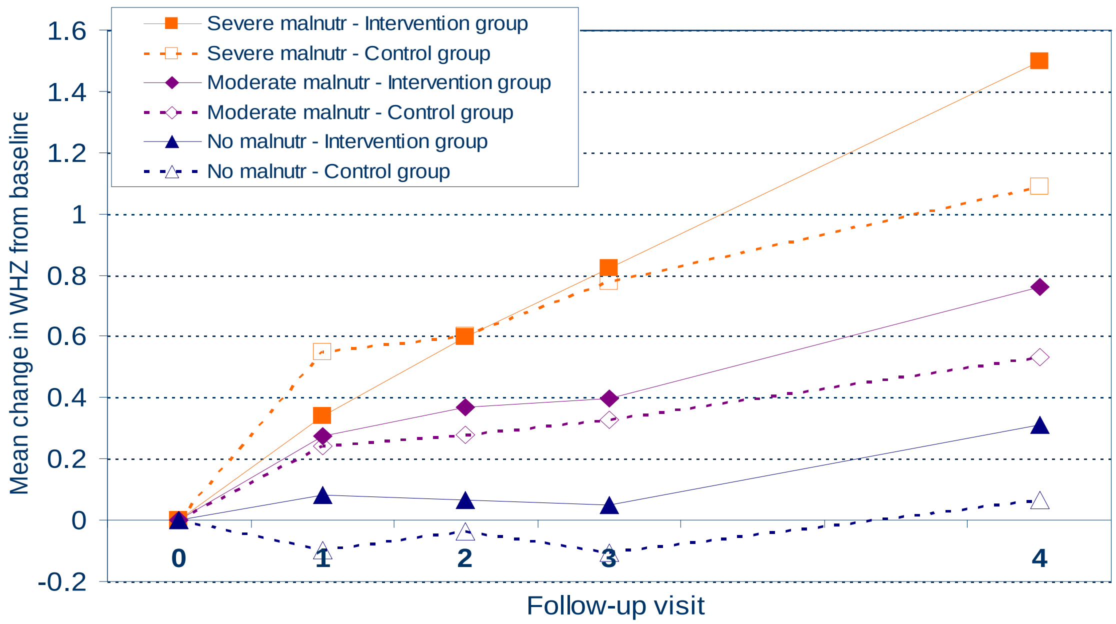
Characteristic	Number children who died	Total number children	Percent children who died
TOTAL	28	1614	1.7
Sex			
Boys	12	762	1.5
Girls	16	852	1.8
Age			
<24 months	25	1135	2.2
24-41 months	2	334	0.6
42-59 months	1	145	0.7
Nutritional status at baseline (by WHZ)			
Severely malnourished	15	174	8.6
Moderately malnourished	4	407	1.0
Not malnourished	9	1011	0.9

Potential confounding and effect modification

Partly because of the non-random selection of intervention and control areas, the intervention and control groups differed on several important variables (as shown above in Table 5 and Table 6). As described in the Methods section, these variables were included in stratified analysis. Annex 2 shows the tables for all stratified analyses of potential effect modifiers. In these tables, the statistical significance of possible effect modification was judged by calculating the t-test for the difference in change in weight-for-height z-score between different levels of the potentially effect modifying variable, as shown in the last column on the right in each table.

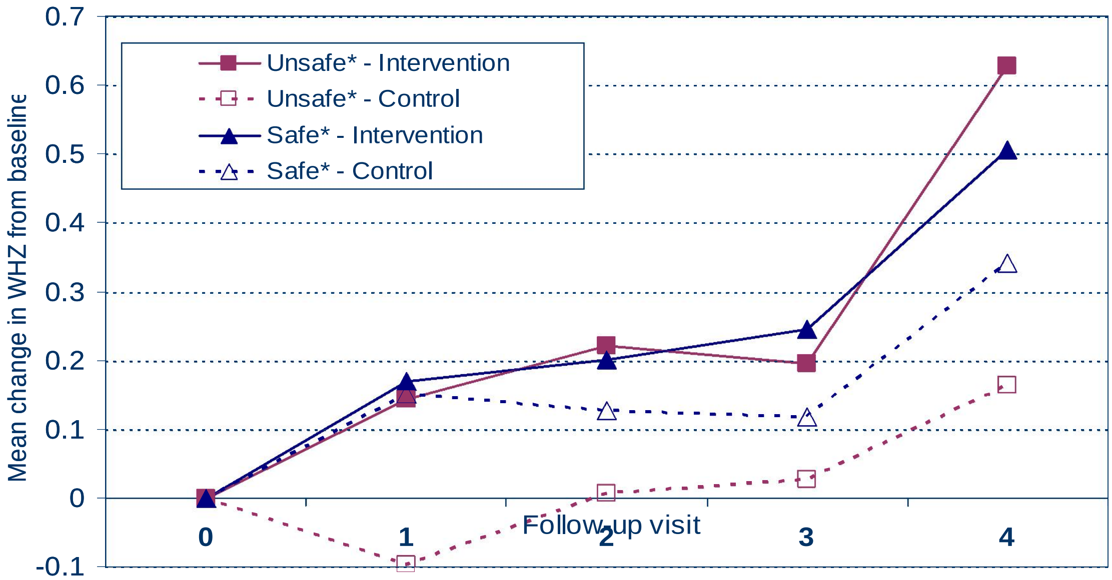
Only two variables were clearly acting as effect modifiers: nutrition status at baseline as measured by weight-for-height z-score, and safe water source. Figure 10 presents the analysis of baseline nutritional status as a potential effect modifier. It shows the mean change in weight-for-height z-score at all follow-up visits for the intervention and control groups separately, by nutritional status at baseline. Throughout the follow-up period in both the intervention and control groups, more severely malnourished children had substantially and statistically significantly greater increases in weight-for-height z-score than did less severely malnourished children in the same study group. In general, nutritional status at baseline had a much greater influence on change in weight-for-height z-score during the 6-months of follow-up than did study group. Within each study group, the changes in weight-for-height z-score were statistically significantly different among children with severe malnutrition, moderate malnutrition, and no malnutrition ($p<0.001$ for all categories and follow-up visits).

Figure 10. Change in weight-for-height z-score from baseline in intervention group and control groups separately, by nutritional status at baseline



As shown in Figure 11, the comparable analysis of water source also demonstrates effect modification. Among children with an unsafe water source, the mean change in weight-for-height z-score is statistically significantly different between the intervention and control groups ($p < 0.001$ at all follow-up visits). Among children with a safe water supply, there is much less difference between intervention and control groups in change in weight-for-height z-score, and these smaller differences were only marginally statistically significant at the fourth follow-up visit ($p=0.03$).

Figure 11. Change in weight-for-height z-score from baseline in intervention group and control groups separately, by type of water source



* Unsafe source = unprotected well or spring, rainwater or community rainwater storage reservoir, tanker truck or other water seller, or surface water.
Safe water source = piped water system, tube well or borehole, or protected well or spring.

Compliance

How long TSF food lasted

Of the households in the intervention group, all of which by definition had received TSF food before the first follow-up visit, study teams confirmed the presence of TSF food in 97.4% of households at the first follow-up visit, 50.6% of the households at the second follow-up visit, and 13.1% of households at the third follow-up visit. Analyses of compliance were not done at the fourth follow-up visit. This implies that, in the majority of households, TSF food, which was meant to last 3 months, was consumed much faster than recommended.

Food sharing

Table 8 presents the distribution of households in which the TSF food was eaten by various other household members. In those households which cooked and ate TSF food the day before the interview, the vast majority of enrolled children consumed at least some of the TSF food. Furthermore, in about two-thirds of households the TSF food was shared with another child less than five years. In more than one-third of households the TSF food was also eaten by a child older than five years or the mother in the household. Overall at the first follow-up visit, 34.1% of children lived in households in which the TSF food was shared with no one else in the household or only another child <5 years of age. Conversely, 65.9% of children lived in households in which the TSF food was shared with an older child or adult or more than one person.

Table 8. Number (%) of children for whom TSF food was reported as eaten by various other household members, at the first follow-up visit*

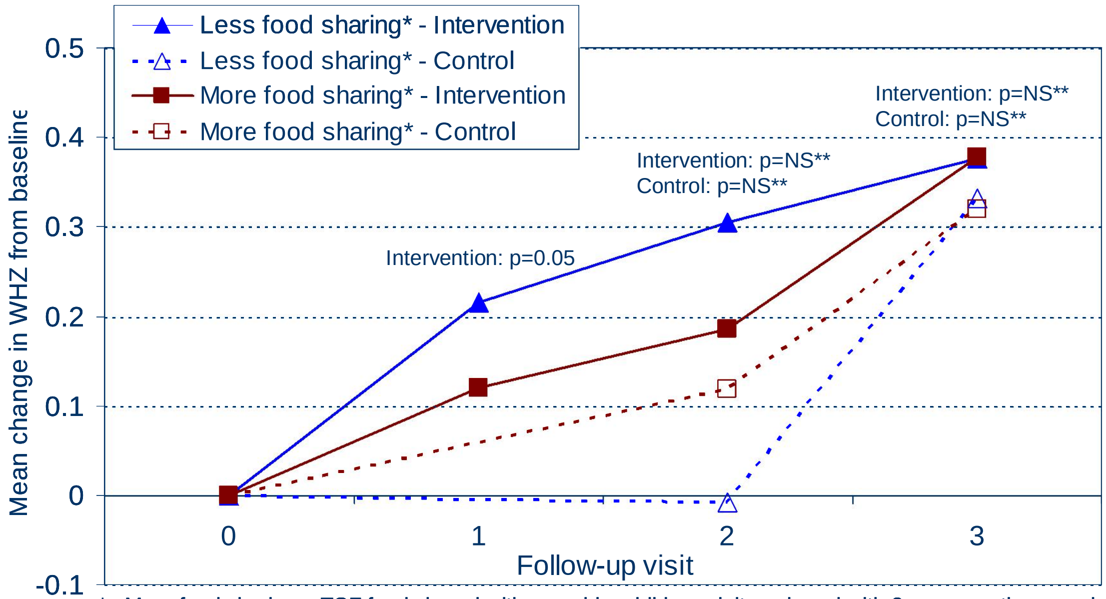
Person with whom TSF food shared	Number (%) of children
Enrolled child	725 (98.1)**
Another child <5 years old	478 (64.7)
Another child 5+ years old	286 (38.7)
Mother	283 (38.3)
Father	92 (12.4)
Elderly person	6 (0.8)
Other household members	13 (1.8)

* The table only includes children whose households had received TSF food and in which TSF food was prepared the day before the first follow-up visit

** For 14 (1.9%) of the 739 children, the study child did not get any of the TSF food prepared.

As shown in Figure 12, in both the intervention and control groups, children with less food sharing (TSF food shared with no one or only one other children <5 years of age) had greater change in weight-for-height z-score during the first two follow-up visits than children with more food sharing (TSF food shared with an older child or adult or with more than one other person). Although this was true in both the intervention and control groups, the effect of food sharing was much greater in the intervention group. Regardless, the overall increase in weight-for-height z-score at the third follow-up visit was similar for children in both the intervention and control groups who had both less and more food sharing.

Figure 12. Mean change in weight-for-height z-score from baseline in intervention group and control groups separately, by extent of food sharing*



* More food sharing = TSF food shared with one older child or adult or shared with 2 or more other people
Less food sharing = TSF food shared with no one else or only one child <5 years of age
** NS = not significant (p≥0.05)
Note: Compliance variables could not be measured in control households at first follow-up visit because, by definition, they had no TSF food

Food proportion

Table 9 shows how much of the TSF food prepared the day before was eaten by the study child at the first follow-up visit. Among study children who lived in households in which TSF food was prepared and eaten the day before the first follow-up visit, 53.5% ate less than one-half of the prepared food while 46.4% ate one-half or more of the TSF food. In only a small minority of households the enrolled child ate all of the TSF food.

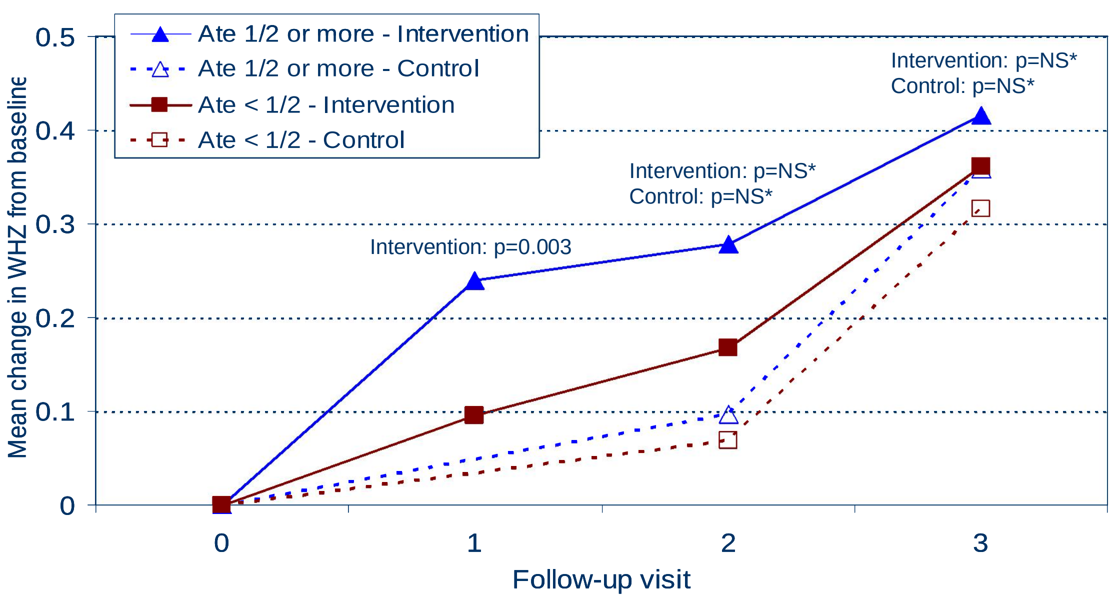
Table 9. Number (%) of study children who at various proportions of the TSF food prepared the day before, at the first follow-up visit*

Proportion TSF food prepared yesterday eaten by the study child	Number (%) of study children
None	14 (1.9)
Less than ½	380 (51.6)
About half	188 (25.5)
Most	92 (12.5)
All	62 (8.4)

* The table only includes the study children from households which had received TSF food and prepared the TSF food the day before the first follow-up visit

Figure 13 shows the mean change in weight-for-height z-score at each follow-up visit by proportion of TSF food eaten by the study child. At each follow-up visit, intervention children who ate more of the TSF food had greater increase in weight-for-height z-score than intervention children who ate less of the TSF food. The comparable difference in the control group was minimal.

Figure 13. Mean change in weight-for-height z-score from baseline in intervention and control groups separately, by proportion of TSF food eaten by the study child

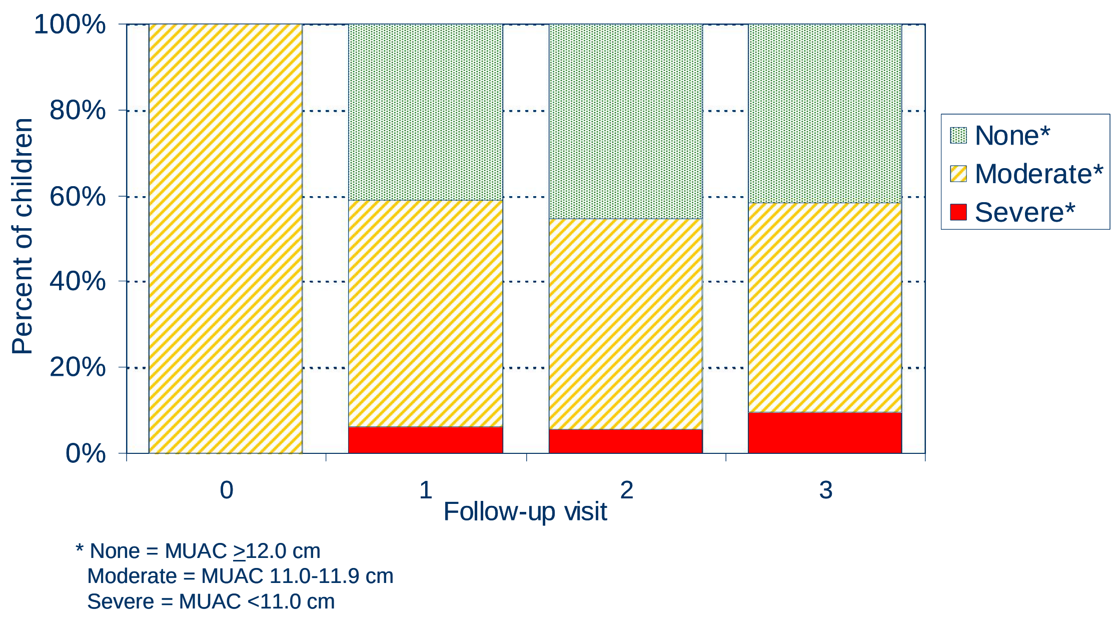


* NS = not significant (p≥0.05)
Note: Compliance variables could not be measured in control households at first follow-up visit because, by definition, they had no TSF food

Efficacy

As seen above in the section on compliance, the TSF food program was not commonly used according to recommendations. In addition to poor household compliance, another important reason for differences between efficacy and program effectiveness is poor targeting of an intervention by program personnel. If persons are enrolled in a program who should not be, they may not respond as well to the intervention. This would decrease the apparent effectiveness of the intervention. The target group for the TSF program is moderately malnourished children 6-59 months of age. Of the 1,610 children enrolled, 863 (53.6%) had moderate malnutrition as defined by a study MUAC measurement of 11.0 – 11.9 cm. Figure 14 shows the nutritional status at each follow-up visit for these children. By the first follow-up visit, almost half of these children had recovered, as defined by a MUAC >12.0 cm. This proportion did not increase substantially at the second and third follow-up visits. Because only two children had not received any TSF food at both the first and the second distribution, the comparison group at the fourth follow-up visit was too small to carry out an efficacy analysis.

Figure 14. Degree of malnutrition at each follow-up visit in the 863 children who, at the time of enrollment, had a study MUAC 11.0 – 11.9 cm



Because of the poor targeting and compliance, no group of study children can be defined as having received the optimum TSF program intervention. However, in order to measure efficacy, a group of children who received the best possible intervention must be compared to children receiving no intervention. Therefore, at each follow-up visit, children who fulfilled the following conditions were defined as “high compliance:”

1. The child was moderately malnourished at baseline as indicated by weight-for-height z-score at study enrollment.
2. The study team confirmed that the household in which the child lived had TSF food present.
3. The child shared the TSF food prepared the day before the interview with no one else in the household or with only another child <5 years of age

The nutrition outcomes in these “high compliance” children were compared to the outcomes in children who lived in households in which TSF food had never been obtained, as confirmed by the study teams at each follow-up visit. This comparison is independent of the prior classification of children into intervention and control groups.

Unfortunately, the analysis of efficacy contains relatively few children for several reasons: 1) most study households had obtained TSF food by the second follow-up visit which decreased the size of the comparison group after the first follow-up visit; 2) good compliance was rare, and 3) the TSF food was consumed relatively quickly after obtaining it. At the first follow-up visit, there were 72 “high compliance” children and 144 comparison children; at the second follow-up visit, there were 42 “high compliance” children and 21 comparison children, and at the final follow-up visit, there were 28 “high compliance” children and 10 comparison children. Figure 15,

Figure 16, and Figure 17 show the results of the analysis of efficacy. “High compliance” children had consistently higher mean change in weight-for-height z-score and mean weight gain at each follow-up visit than did children who had not yet received TSF food. For mean change in MUAC this was true only at the first follow-up visit. However, with the exception of the difference in change in MUAC at the first follow-up visit, none of the differences were statistically significant.

Figure 15. Efficacy as measured by change in weight-for-height z-score from baseline, “high compliance” children vs. children without TSF food

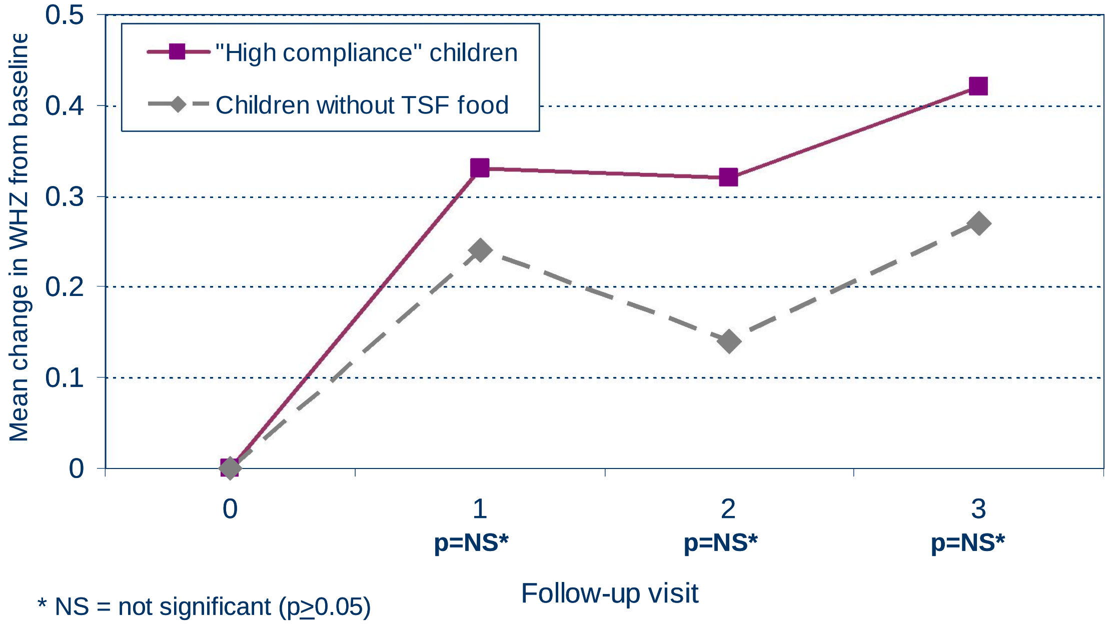


Figure 16. Efficacy as measured by weight gain from baseline, “high compliance” children vs. children without TSF food

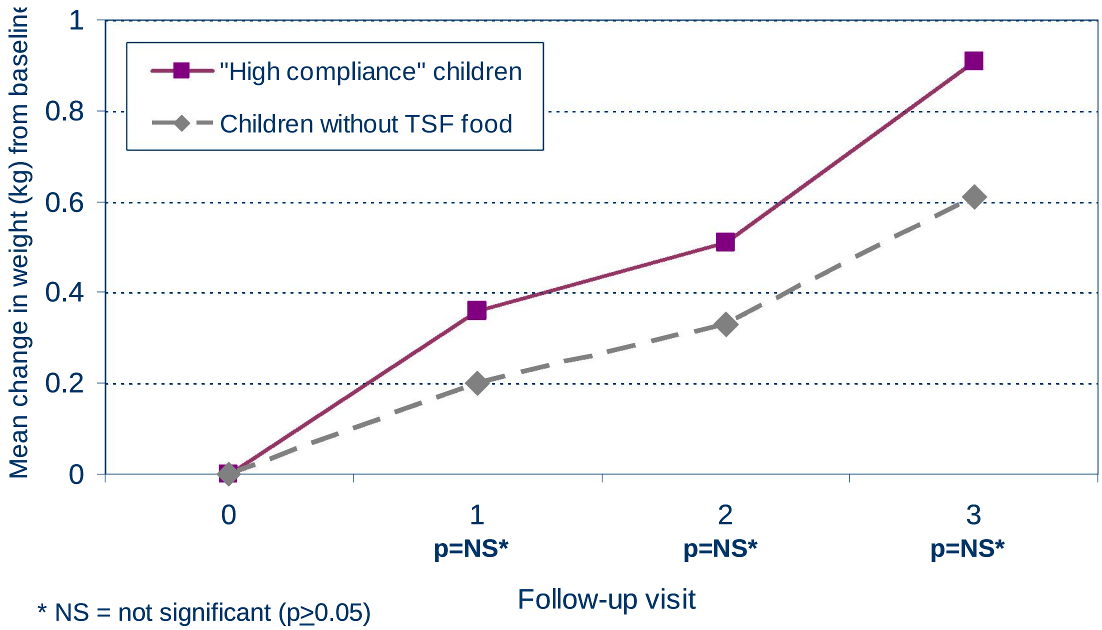
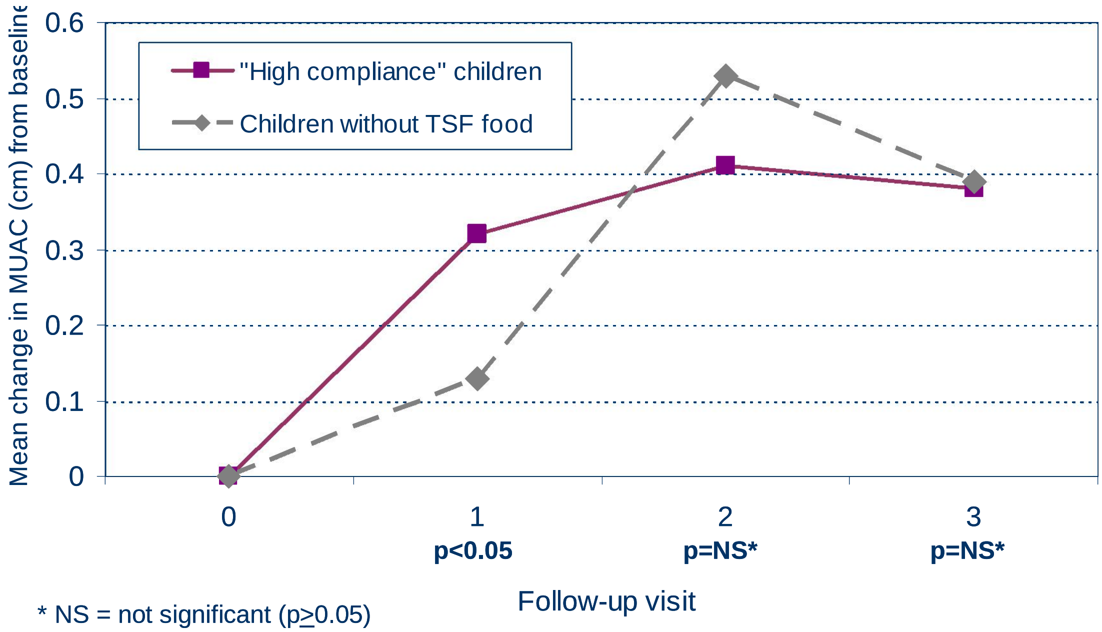


Figure 17. Efficacy as measured by change in MUAC from baseline, "high compliance" children vs. children without TSF food



DISCUSSION

Effectiveness of TSF program

Overall, the results of this study indicate that the TSF program has some beneficial nutritional effect on children who were identified as acutely malnourished by the EOS screening and enrolled in the program. Study children who received TSF food before the first follow-up visit had a significantly greater increase in weight-for-height z-score from baseline to each of the monthly follow-up visits than did children who had not received TSF food by the first follow-up visit.

However, at least a small portion of this difference may have resulted from a higher prevalence of severely malnourished children in the intervention group; such children had a substantially greater increase in weight-for-height z-score than children with less severe malnutrition, especially at the first follow-up visit. This would tend to increase the difference in change in nutritional status between the intervention and control groups. In addition, the differential distribution of safe water source between the intervention and control groups could also influence the overall difference in change in weight-for-height z-score between the two study groups. However, separate weighted analyses of each of these variables using group-specific estimates of the change in weight-for-height z-score (analyses not shown) demonstrates little difference between the crude analysis and the weighted analysis.

As a result, after accounting for potential confounding, the TSF program produced an apparent improvement in nutritional status. Nonetheless, one may justifiably raise the question "Why didn't this study show a much greater effect?"

Why didn't the study show greater effect?

There are several possible explanations of why this study, and by implication the TSF program as a whole, showed less effect on nutritional status than was expected, especially in the first three months of follow-up.

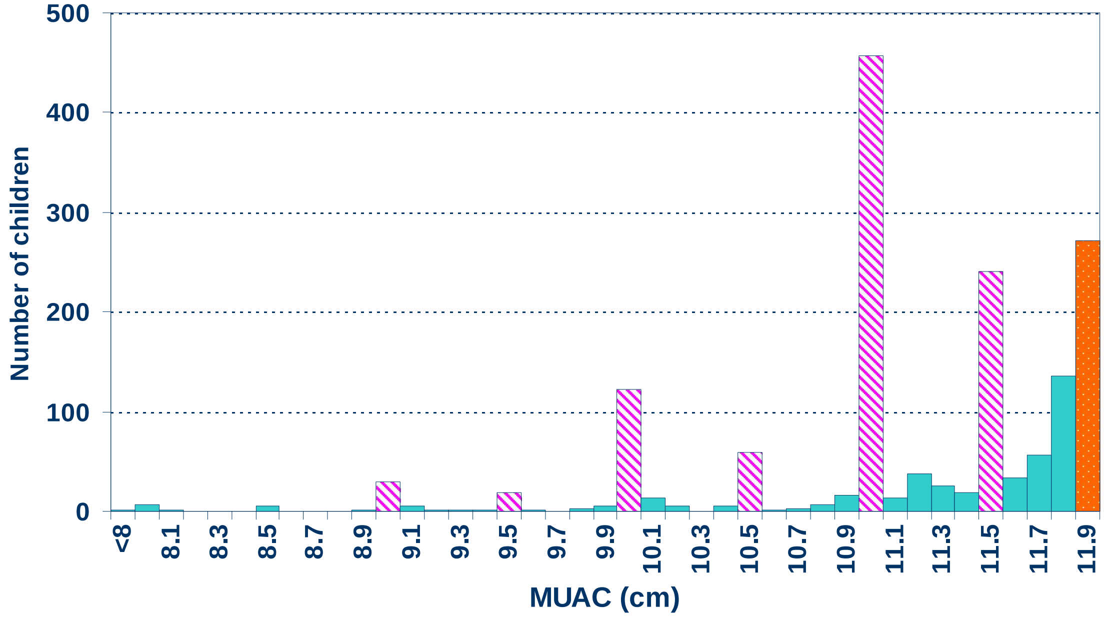
Nutritional status at baseline

One reason for the small apparent effect is that relatively few children enrolled in the TSF program truly had acute malnutrition, as defined by either weight-for-height z-score or MUAC. In this study, children without acute malnutrition demonstrated little nutritional improvement as a result of participation in the TSF program. This lack of response among non-malnourished children has been seen in other studies. A review on the efficacy and effectiveness of community-based treatment of severe malnutrition by Ann Ashworth (Ashworth 2006) concluded that one of the reasons for the ineffectiveness of some community-based programs may be due to the enrollment of children without wasting in the programs. As in our study, non-malnourished children grow more slowly than wasted children when given extra food. A review by Beaton and Ghassemi refers to a similar association (Beaton and Ghassemi, 1982). The authors describe a study from Columbia done in 1974 which demonstrated that children who were initially classified as acutely malnourished upon admission to the feeding program had significantly better growth after discharge from the program than children who were not acutely malnourished at admission. The reason for this relative lack of growth in non-malnourished children is largely unknown. Non-malnourished children may be more physically active, and therefore expend more calories, than malnourished children. Thus, non-malnourished children may use a greater proportion of any additional food for energy production and devote a smaller proportion to anabolic tissue regeneration and re-accumulation of energy stores than malnourished children.

If the intervention group in this study had a larger proportion of children without malnutrition than the control group, the diminished nutritional response in the intervention group would lead to an apparent decrease in the difference between the intervention and control groups, thus decreasing the apparent program effectiveness of the TSF program. However, in this study the intervention group actually had a slightly higher prevalence of severe malnutrition than the control group. Nonetheless, the potential bias from this difference was overwhelmed by the high prevalence of normally nourished children in both groups. Such a high prevalence would mean that, for a majority of children in both groups, little improvement in nutritional status would result from TSF program enrollment. This relative lack of response in both study groups would, in and of itself, lead to a narrowing of the difference between the intervention and control groups.

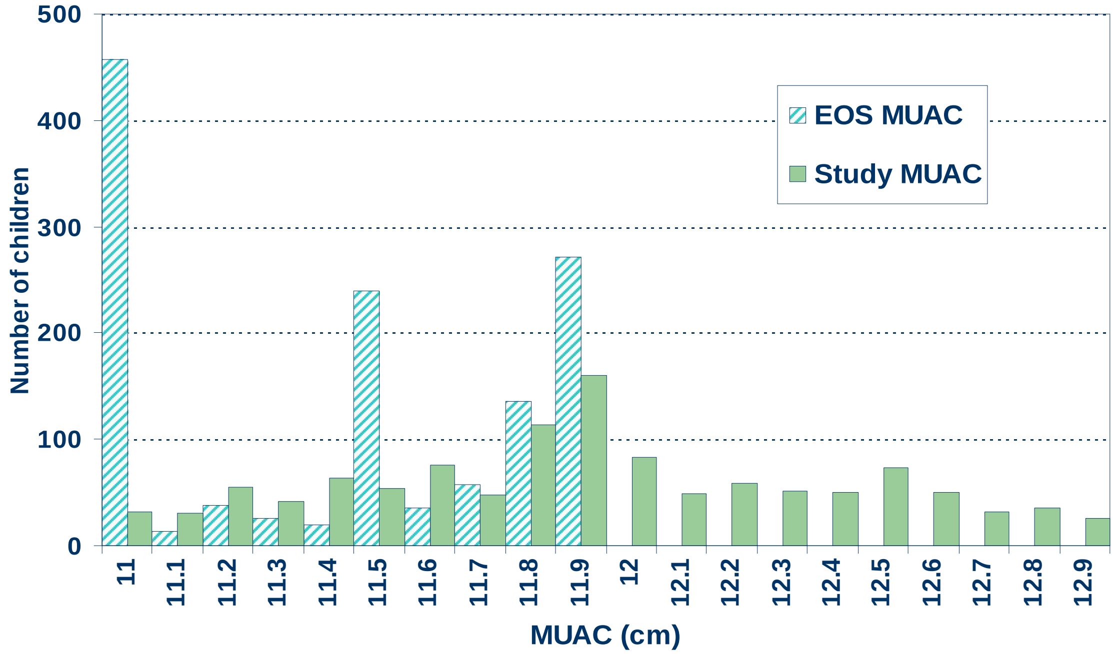
Of course, the next question is “Why are so many non-malnourished children enrolled in the TSF program?” One major cause is poor MUAC measurements by the EOS-screening teams. The EOS screening uses MUAC to identify children with acute malnutrition to determine eligibility for enrollment in the TSF program. During supervision of the data collection teams in the field, one of the authors visited EOS screening sites and observed the training of the EOS workers. Her impression was that the MUAC measurements were not of high quality. In addition, other evaluations have found that the EOS MUAC measurements lack specificity. (Addis Continental Institute of Public Health, 2008; Hall and Khara, 2006; WFP, 2008). Although it was not a major objective of this study to assess the quality of EOS measurements, when children were recruited based on the EOS lists of TSF-eligible children, study workers copied the EOS MUAC measurements for each enrolled child. As shown in Figure 18 below, EOS MUAC measurements showed a marked preference for the decimals 0 and 5, implying that MUAC measurements were rounded to the nearest ½ centimeter. This is contrary to usual practice. In fact, according to the EOS Implementation Manual, EOS screening teams are instructed to measure MUAC to the nearest millimeter (DPPB and WFP, 2007). Such rounding, if carried out according to normal rounding rules or if done randomly, would increase the dispersion of the MUAC measurements which could increase the proportion of MUAC measurements which fall below a certain cut-off point; however, this effect is very unlikely to produce the large inclusion errors seen in this study and other evaluations of EOS screening .

Figure 18. Distribution of the decimal of EOS MUAC measurements for all study children



The EOS MUAC was also compared directly to the MUAC measurement taken upon enrollment of children into this evaluation study. Because in most cases the study MUAC measurement was taken within a few days of the EOS measurement, no change over time in MUAC should be expected. Figure 19 shows a strong bias towards MUAC measurements less than 12.0 cm. In fact, there are a disproportionate number of measurements of exactly 11.9 cm, even though most measurements are rounded to a decimal of 0 or 5, as described above. This may be due to a tendency of EOS screening workers, when measuring children with marginal nutritional status, to pull the MUAC just tight enough to enroll that child in the TSF program.

Figure 19. Distribution of the EOS and study MUAC measurements for all study children



The inclusion of non-malnourished children in the TSF program may provide a benefit to individual children, but it decreases the overall nutritional effect of the TSF program. Not only does it diminish the program's apparent effect in studies such as this one, but it also expends valuable program resources on those children who derive the least nutritional benefit from participation in the TSF program.

Compliance

A second factor which could lead to a lower apparent effect of the TSF program than expected is lack of compliance with program recommendations at the household level. One major type of such non-compliance is intrahousehold food sharing, with the attendant decrease in the portion of the TSF food prepared in the household which is eaten by the enrolled child. This study demonstrates that intrahousehold food sharing occurs in the majority of households of TSF enrolled children. Among children with less food sharing, the difference between intervention and control groups in change in weight-for-height z-score was much greater than among children with more food sharing. Moreover, children in households where food sharing occurs generally have poorer nutritional response to the TSF program than children in households with less food sharing. The high degree of food sharing in TSF recipient households has also been demonstrated by other studies of the TSF program.

The 2007 TSF performance study (WFP, 2008) indicated that in 56.4% of households TSF food was shared with household members other than the specific beneficiary. In addition, sharing an individual ration from other food aid programs is common in Ethiopia (Yamano, 2005; Quisumbing, 2003). In fact, it has been considered by researchers that some households keep one child under-fed to have access for the entire household to food distribution programs (Vazquez-Garcia, 1999); however, this may be an example of extreme food sharing in extreme circumstances.

Food sharing has also been widely reported in other studies of other targeted supplementary feeding programs (Beaton and Ghassemi, 1982, Schilling, 1990, Varquez-Garcia, 1999). The review by Beaton and Ghassemi estimated that food leakage accounted for 30 to 60% of the food distributed by the programs included in their review. However, the authors argue that food sharing or food leakage does not necessary lead to inefficient programs. The authors considered that food leakage may also benefit a larger population group which could contribute to the home environment and thereby have an indirectly beneficial impact on the growth and development of young children. The authors have been unable to find published evidence to verify this assertion. In contrast, our findings indicate that intra-household food sharing reduces the nutritional benefit to individual malnourished beneficiaries. It is beyond the scope of the present study, but further investigation of the effect of food sharing and its causes would be very useful in improving the efficiency of the TSF program.

The TSF ration of 1,378 kcal per person per day is much larger than the ration used by many other supplementary feeding programs. It was originally calculated recognizing that substantial intra-household food sharing would occur. Nonetheless, this study's evidence indicates that the degree of sharing has overcome this compensatory calculation.

Food sharing among study children may have been exacerbated by the high level of food insecurity at the study sites during the follow-up period. In addition, the study was carried out in the annual hunger season, just before the harvest. As a result, TSF food might have represented a large proportion of food available in the households of enrolled children. A combination of the high level of food sharing and a lower change in weight-for-height z-score in children residing in households with food sharing may have decreased the apparent change in weight-for-height z-score in children in the intervention group, thus minimizing the apparent difference between the intervention and control groups.

Other factors

Other factors may have exacerbated the factors listed above or directly led to a diminished difference between the intervention and control children and the consequent decreased estimate of the TSF's program effectiveness.

1. Recent evidence implies that the foods used in the TSF program, CSB and oil, are not optimal for treating young children with moderate malnutrition (WFP and DSM, 2008). CSB contains inadequate quantities of some miconutrients; has low nutrient density, especially when made into porridge; and contains high levels of anti-nutrients, especially phytates which inhibit the absorption of many micronutrients, including iron and zinc. Better supplementary food may demonstrate greater effect on nutritional status.
2. EOS screening and TSF enrollment, even without receiving the TSF food, may have influenced caring practices for children in the control group. The results for the control group, especially at the first follow-up visit, indicate that even though control children had not yet received TSF food, there was still a positive change in weight-for-height z-score, especially among the most malnourished children. Notifying the mother that her child is malnourished at the time of EOS screening may lead to changes in caring practices, such as giving the child a greater proportion of existing household food, resulting in improvement in nutritional status. In addition, at some EOS screening sites, there is health education of caretakers; however, this is not consistently practiced at all sites. Such improved caring, leading to better nutritional status in control children, could narrow the difference between intervention and control children, thus leading to a smaller measured effect of consumption of the TSF food. Nonetheless, this study collected no data which could be used to support or refute this hypothesis.
3. There may be other differences between intervention and control children which were not measured by this study. Although delivery of TSF food to the study woredas did not follow the predicted pattern, intervention children tended to live in those woredas originally selected as intervention woredas, and control children tended to live in those woredas originally selected as control woredas. These woredas were selected because of past difference in the timing of TSF food delivery, which is almost certainly associated with other differences between the woredas which may influence response to the TSF program.

Summary

This study provides evidence for two major causes for the relatively low measured effectiveness of the TSF program on the nutritional status of enrolled children: poor targeting and lack of compliance. The influence of both these influences can be decreased with program revisions. Targeting should be strengthened by improving the performance of the EOS screening. Currently ongoing changes in the EOS program will at least partially accomplish this. Screening personnel will, in the future, be employees of the government health services. This will facilitate better training, supervision, and accountability. Screeners should be trained to measure MUAC to the nearest millimeter. In addition, a second screen could be added for children whose MUAC is just below 12.0 cm to be sure that the screeners are not pulling to tape too tight to enroll children in TSF who are not truly eligible.

In addition, this study shows evidence that some factors outside of the TSF program play a role in improving the nutritional status of children who are enrolled in the TSF program. The authors hypothesize that mothers change their care practices after being informed that their children are malnourished, but there is little evidence for this hypothesis, which should be further studies.

Efficacy

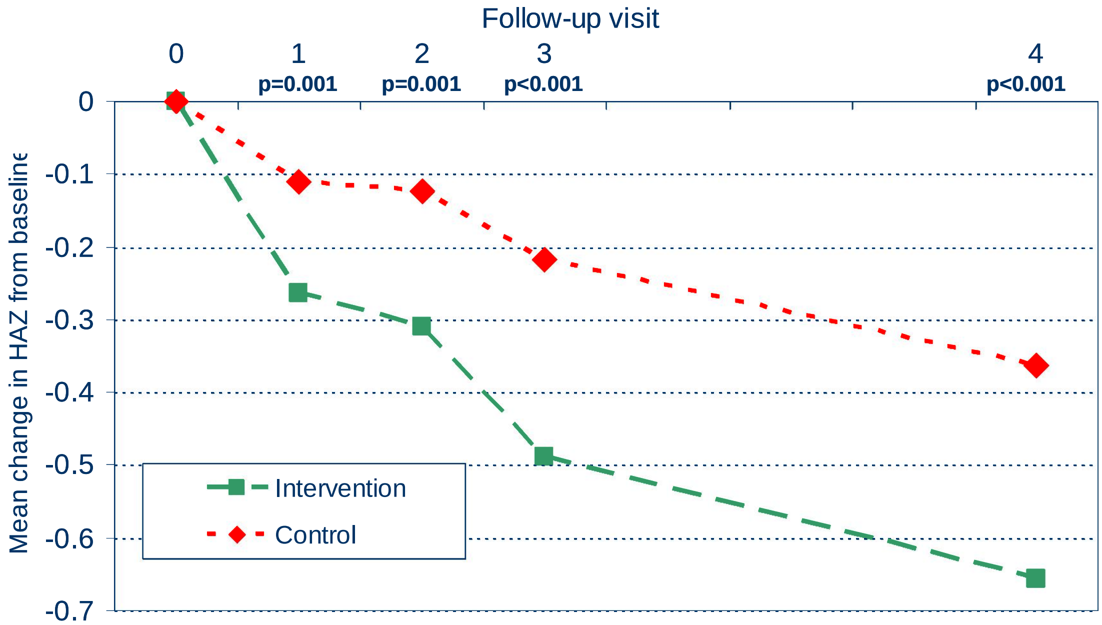
The factors leading to a lower-than-expected program effectiveness are discussed above; however, the analysis of efficacy presented above attempts to remove at least some of these factors to obtain a purer measure of the effect of TSF feeding if it were ideally done. Unfortunately, because compliance within the households of enrolled children was so poor, it was impossible to obtain a pure measure of the effect of the TSF program if it were delivered as intended. Nonetheless, the best possible measure of efficacy showed consistently better nutritional outcome in children who ate the TSF food using better practices when compared to children who had never eaten TSF food. On the other hand, because the efficacy was also not as high as expected and because there were a relatively small number of “high compliance” children, especially at later follow-up visits, the differences seen were not statistically significant.

Although additional studies may be needed to measure with maximum accuracy and precision the true efficacy of the TSF program and other supplementary feeding programs, certain overriding ethical considerations may preclude the use of the most epidemiologically stringent methods. The strongest evidence for the efficacy of any intervention is a randomized controlled trial, preferably with masking so that neither the investigator nor the subject knows what treatment is received. Obviously such studies are not practical with feeding programs. Masking is virtually impossible because it is impossible to mask whether or not the subject is eating supplementary food. In addition, the importance of a comparison group is highlighted by this study's results showing a marked improvement in nutritional status in control children even before TSF food became available. However, assigning children to a comparison group would require identifying malnourished children, then intentionally denying them supplementary food. This has been deemed by most investigators and organizations as entirely unethical, in spite of the lack of empirical evidence of the efficacy of supplementary feeding programs. These limitations leave researchers with only one option – the "natural" experiment. This was attempted in this study, but did not result in as much separation as planned between intervention and control children.

Change in weight-for-height z-score and change in weight

Although intervention children increased their average weight-for-height z-score more than control children, the two study groups did not differ substantially in weight gain during the 6-month follow-up period. Because weight is a function of both girth and height, intervention children therefore must have not have gained height as rapidly as control children during the follow-up period. **Figure 20** below shows change in height-for-age z-score for all study visits in the intervention and control groups separately. Change in height-for-age z-score was used instead of change in height because the age distribution of the two study groups differed, and linear growth velocity differs by age. As a result, any difference between the study groups in the change in height may be due to the difference in age distribution. The change in height-for-age z-score adjusts for this difference in age between the study groups.

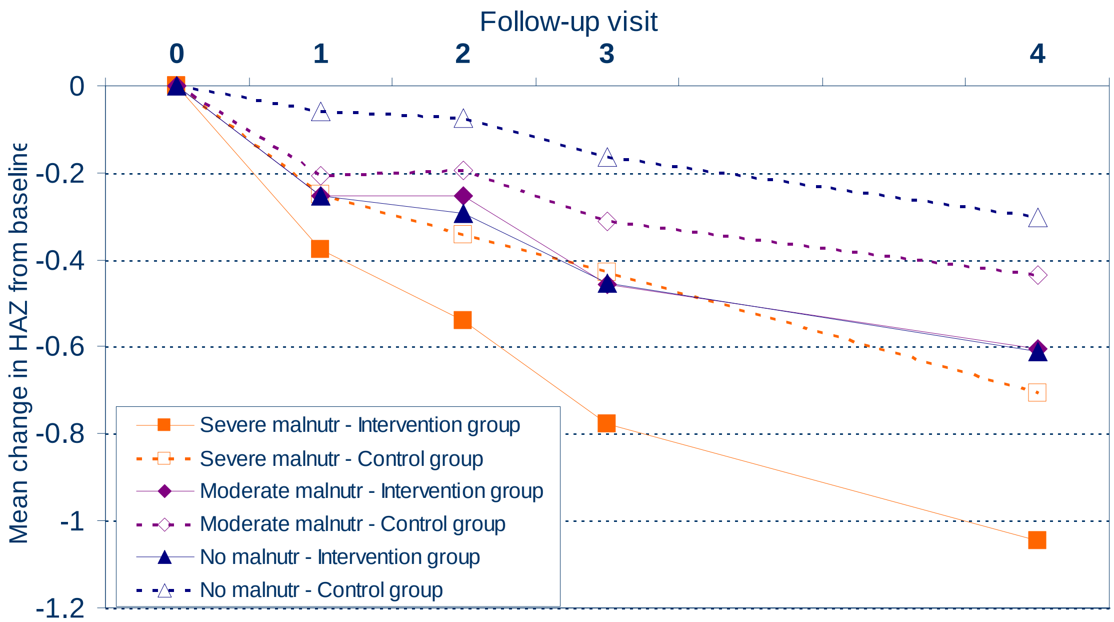
Figure 20. Change in height-for-age z-score during the follow-up period, by study group



In both study groups, the mean height-for-age z-score declined steadily during the follow-up period implying that study children did not grow as fast as children in the WHO Child Growth Standard. Moreover, the rate of growth in intervention children was lower than in the control children, which would account for the lack of difference between the two study groups in the change in weight. Intervention and control children gained weight at the same rate during follow-up, but intervention children added more girth while control children added more height.

In addition, similar to the change in weight-for-height z-score, the change in height-for-age z-score was dependent on nutritional status at baseline, as shown below in Figure 21. In both the intervention and control children, those with more severe acute protein-energy malnutrition had greater loss of height-for-age z-score than children with less severe malnutrition. Because the intervention group had a higher prevalence of severe acute malnutrition than the control group, this may account for some of the difference in change in height-for-age z-score between the study groups. However, for all categories of malnutrition, children in the intervention group had a greater lost of height-for-age z-score than children in the control group.

Figure 21. Change in height-for-age z-score from baseline in intervention group and control groups separately, by nutritional status at baseline



The reason behind this phenomenon is completely unknown. Beaton's review describes several studies of supplementary feeding programs in which the intervention group had significantly greater linear growth than the control group. On the other hand, it also mentions studies in which there was little or no difference in linear growth rate. A pooled analysis of studies in another large review demonstrated that in food insufficient populations, young children receiving supplementary food had a statistically significantly greater increase in height-for-age z-score than children who did not receive supplementary food. (Bhutta, 2008) Some studies of micronutrient supplementation have demonstrated a decline in height-for-age z-score during supplementation. (Giovannini, 2006 and Zlotkin, 2003) Unfortunately, neither change in height-for-age z-score nor the prevalence of stunting are commonly measured outcomes in supplementary feeding programs. Given our study's findings and the lack of consistent evidence on the effect of supplemental feeding on stunting in emergency situations, we are unable to conclude that there is no deleterious effect of supplemental feeding on linear growth rate. This possible effect certainly warrants further investigation, and such studies may require the use of a better control group in order to more sensitively measure the effects of supplementary feeding programs.

Regardless, because the goal of the TSF program is the alleviation of acute protein-energy malnutrition and because acute protein-energy malnutrition probably poses greater risk of morbidity and mortality in emergency-affected populations, the gain in weight-for-height z-score may be more important than the loss in height-for-age z-score in emergency situations.

Severely malnourished children

Although the target group for the TSF program is children with moderate acute malnutrition, the program also enrolls many children with severe malnutrition. Ideally, severely malnourished children should be enrolled in a therapeutic feeding program, which includes much more intensive nutritional rehabilitation, intensive medical care, and more frequent monitoring. Such therapeutic feeding programs are usually implemented in hospitals or health centers (UNHCR and WFP, 1999). However, in most of rural areas of Ethiopia, there is very limited access to therapeutic feeding. As a result, the TSF program is often the only available feeding program for such children.

In spite of not being powered to analyze mortality rates nor outcomes specifically in severely malnourished children, this study provides some evidence that severely malnourished children obtained some nutritional benefit from enrollment and participation in the TSF program. However, only 37 (20.6%) of the 180 children identified as severely malnourished at enrollment were no longer severely malnourished at the third follow-up visit. This recovery rate is much lower than the 75% recommended by the SPHERE project guidelines (Sphere Project, 2004); however, the Sphere guidelines do not recommend specific discharge criteria, and the TSF program has no discharge criteria. Much more evidence is required before any claim can be made that supplementary feeding provides a benefit to severely malnourished children, and supplementary feeding should never be considered sufficient treatment for severely malnourished children if therapeutic feeding is available.

TSF in the future

TSF will, in the near future, be included in the National Nutrition Program (NNP) of Ethiopia. The NNP will attempt to link complementary interventions that address household food insecurity, nutrition, and health (Federal Ministry of Health - Ethiopia, 2008). With the

NNP, Ethiopia has already taken steps to integrate the TSF program with other interventions addressing underlying causes of malnutrition.

The TSF program will, in the long term, be included in the Health Extension Program (HEP) that is currently being rolled out by the Ministry of Health. As a result, the TSF program will be part of the community-based nutrition program, one activity of which will be nutrition screening of children 6-59 months of age conducted every three months by trained health extension workers deployed and supervised by the Ministry of Health.

The NNP also includes an extension plan for access to therapeutic feeding programs. The target is that therapeutic feeding programs be available at 50% of health centers and hospitals in Ethiopia. Part of the plan includes proper referral of children from EOS screening to a therapeutic feeding program, if necessary, and referral for children who discharged from a therapeutic feeding program to the TSF.

As a result of these changes in the EOS program and its personnel, the quality of EOS screening may improve so that fewer non-malnourished children receive TSF food. In addition, fewer severely malnourished children will be enrolled in the TSF program.

Limitations of the study

The reassignment of the study groups resulted in changes in study design which may have affected both the estimate of TSF's program effectiveness and the precision around this estimate. First, the delivery of TSF food to children in the original control woredas was not as delayed as expected. As a result, the distribution of TSF food to children in the original intervention and control groups occurred at more similar times than anticipated. Although the new definition of intervention and control children was based on the distribution of TSF food before the first follow-up visit, many children in the new intervention group may had received TSF food only a few days before this visit. Conversely, children in the new control group may have received TSF food only a few days after the first follow-up visit. As a result, the actual difference between the intervention and control groups in the time of exposure to TSF food at each follow-up visit, even at the first visit, may have been quite small. However, in spite of this minimal difference in exposure, the study still demonstrated a difference in the outcome between intervention and control children. Second, the original study design planned intervention and control groups of approximately equal size, but after the reassignment the control group was much smaller than the intervention group because so many enrolled children had received TSF food before the first follow-up visit. As a result, the data analysis lost precision. Furthermore, the number of children in some categories of some variables, such as low food sharing, was very small, which led to poor precision around some estimates of the association between that variable and a nutritional outcome.

Because the present study has only measured the short term effect of the TSF program (the TSF program cycle is 6 months), the findings cannot predict the longer term effects of the program. Authors of other studies of supplementary feeding programs have argued that even though such programs have only short-term objectives, they remain a priority in humanitarian complex emergencies because they save lives in situations of short-term urgency (Taylor, 1983; Vautier, 1999; Nielsen, 2004). For this study, data will be collected after six months of enrollment in the TSF program allowing for measurement of slightly longer term effects. Because little difference from the 3-month follow-up findings is expected, the results 6-month results are not expected to change the overall study's overall conclusions.

When caretakers pick up TSF food at distribution sites, they receive education on how to prepare the food and to whom it must be served. Therefore, it is expected that the caretakers know that sharing the TSF food with other household members is not compliant with the TSF program recommendations. However, the study data on compliance variables is self-reported. Therefore, caretakers may underestimate food sharing when answering the interview questions. This misclassification of food sharing may be why the study results did not show a larger difference in nutritional outcome between children from households with less food sharing and children from households with more food sharing.

One way to look at the quality of the weight and height measurement is to measure the dispersion of the z-scores calculated from these measurements. The standard deviation was calculated for weight-for-height z-scores after applying the range exclusion criteria described in the Methods section. By definition, the standard deviation of z-scores in the WHO Child Growth Standard is 1.0. Therefore, population-based data collection should, if weight and height measurements are precise, produce a similar standard deviation for weight-for-height z-scores. WHO recommends that in nutrition surveys the standard deviation of the survey sample weight-for-height z-scores should be from 0.85 to 1.1 (WHO Expert Committee on Physical Status, 1995). The standard deviation of the baseline weight-for-height z-scores in the present study was 1.1, providing evidence that the weight and height measurements were of reasonable quality.

The time gap between the third and the fourth follow-up visit is also a limitation to the study, which especially impedes the ability to analyze data from the fourth follow-up pertaining to potential confounding and effect modification. Anecdotal reports indicated that the second food distribution, which should have occurred 3 months after the first distribution, was delayed in some areas. As a result, intervention children may have had a prolonged period without TSF food; however, because there was no monthly follow-up during the second 3-month follow-up period, there are no data on how late enrolled children received the second food distribution nor how long was the gap in TSF food availability for individual children. Regardless, the 6-month follow-up visit generally shows a greater difference in outcome between intervention and control children.

There may have been other factors which could have biased the estimate of the program effectiveness of the TSF program. As discussed earlier, data collection was carried out during a period of high food insecurity in some of the study areas. As a result, other programs, such as the Relief and Safety Net program, which provided food and/or cash to families vulnerable to food insecurity, were highly active during the data collection period. This combination of circumstances could have resulted in an underestimate of TSF program effectiveness by two mechanisms. First, households enrolled in these other programs may show less difference in nutrition outcome between intervention children and control children. The higher the proportion of the study population enrolled in additional programs, the greater the risk of underestimation of the effectiveness of the TSF program exists. In fact, almost 50% of study households were enrolled in other programs at the first follow-up visit. The second mechanism is that increased food insecurity may result in greater intra-household food sharing because all household members become relatively malnourished, and TSF food may be the only food source. As demonstrated in the analysis of the compliance variable, food sharing is associated with less change in weight-for-height z-score. As a result, the difference between the intervention and control groups would be reduced.

In addition, in any study which uses non-random allocation of subjects to intervention and control groups, there may be unmeasured difference between study groups which lead to a biased estimation of the effectiveness of the intervention. As discussed above in the Methods section, in order to bias the conclusions of this study, a variable must be an effect modifier, that is, the apparent effect of the intervention (participation in the TSF program) must vary depending on the value of the effect modifying variable. This is easily understood for a variable like nutritional status at baseline, where enhanced absorption and more efficient utilization of nutrients in malnourished children may lead to a greater response to consumption of additional food; however, the potential for effect modification by other variables is less readily apparent. Nonetheless, such a possiblity exists. Unfortunately, the best way to minimize the potential for such bias is to randomly allocated malnourished children to either intervention or control group. This is probably not possible because it is widely considered unethical.

The calculation of sample size was based on clustered enrollment of children at selected EOS screening sites. Ideally, data analyses should therefore have accounted for the increased variance resulting from the geographic clustering of the study children. The analysis of study data did not account for this clustering. As a result, the measures of precision, such as p-values and confidence intervals, may reflect more precision than the data actually have. That is, in this report, the p-values may be smaller and the confidence intervals narrower than they actually should be if the data analysis accounted for the clustered enrollment of children.

The results of this assessment of program effectiveness of the TSF program should not be generalized to other supplementary feeding programs because the TSF program is markedly different from traditional supplementary feeding programs. Nonetheless, because the TSF program is standardized throughout Ethiopia, this study's results can be generalized to other rural areas where the TSF program is implemented. Therefore, it is possible to make overall recommendations regarding the TSF program.

Finally, this study suffers from many of the usual limitations of cross-sectional surveys relying on standardized interviews. Although this study has demonstrated the importance of various factors in impeding the effectiveness of the TSF program, it has not provided the additional information and explanation necessary to address these factors in a programmatic context. Such information is better collected by other methods, including qualitative methods. An ongoing survey and qualitative study of knowledge, attitudes, and practices regarding the TSF program and household use of TSF food may provide this essential information.

CONCLUSIONS AND RECOMMENDATIONS

On average, the TSF program had a beneficial nutritional effect on children who were identified by EOS screening as acutely malnourished and enrolled in the program. However, to strengthen program effectiveness in combating the severity of acute malnutrition in Ethiopia several recommendations can be given:

1. The targeting of the program should be improved to exclude more children who do not have acute malnutrition. Possible methods include:
    b. The EOS screening teams who act as 'gate-keepers' to the TSF program should be better trained in measuring MUAC to increase the accuracy and precision of their measurements.
    c. Supervisory checks should be done of a portion of EOS screening MUAC measurements and action taken if accuracy falls below a specific threshold
    d. EOS screening teams should use permanently hired screening personnel to carry out EOS screening MUAC measurements.
    e. Two-stage screening could be used to verify the TSF eligibility of children initially identified as malnourished by EOS screening.
2. Intra-household food sharing should be minimized.
    f. There should be further investigation of the reasons for intra-household food sharing.
    g. Better education could be provided to mothers at the time of TSF food distribution. The TSF food could be described as a medicine to cure the child's nutritional disease.
    h. The TSF food ration could be increased to increase the amount of food consumption by the child enrolled in TSF as well as other vulnerable persons in household .
3. The TSF program should be linked more closely to health centers to improve the referral of severely malnourished children for more appropriate therapeutic care.
    i. Access to therapeutic feeding programs in rural areas should be improved. This may require broader implementation of community-based therapeutic care.

As described above, the stakeholders of the EOS and TSF programs have already taken some of these recommendations into consideration in the design of the National Nutrition Program.

Therefore the findings of the present study suggest that the WFP, in collaboration with the Government of Ethiopia and other stakeholders of the TSF program, is heading in the right direction to improve the program effectiveness of the TSF program.

REFERENCES

Addis Continental Institute of Public Health (2008): Post Campaign evaluation survey Enhanced Outreach Strategy in Ethiopia- Final Report. UNICEF - Addis Ababa Ethiopia

Ashworth A (2006): Efficacy and effectiveness of community-based treatment of severe malnutrition, Food and Nutrition Bulletin; 27 (3): 524-546

Beaton GH; Ghassemi H (1982): Supplementary feeding programs for young children in developing countries, American Journal of Clinical Nutrition; 3: 846-913

Bhutta ZA, Ahmed T, Black RE, et al (2008): What works? Interventions for maternal and child undernutrition and survival, Lancet; 371: 417–40

Cochrane AL (1972): Effectiveness and Efficiency: Random Reflections on Health Services. London: Nuffield Provincial Hospitals Trust.

de Onis M, Garza C, Victora CG, Bhan MK, Norum KR, eds. (2004): The WHO Multicentre Growth Reference Study (MGRS): Rationale, planning, and implementation. Food and Nutrition Bulletin; vol. 25, no. 1 (supplement 1): S1-S45.

DPPB and WFP (2007): Targeted Supplementary Food (TSF) in support of the Enhanced Outreach Strategy (EOS) for Child Survival Interventions: Activity Implementation Manual. Regional Disaster Preparedness and Prevention Bureau and World Food Programme, Addis Ababa Ethiopia

Duffield A, Reid G, Walker D, Shoham J (2004). Review of the published literature for the impact and cost-effectiveness of six nutrition related emergency interventions: Report prepared by the ENN. London, December 2004.

Federal Ministry of Health - Ethiopia and UNICEF (2004): Guidelines for Enhanced Outreach Strategy (EOS) for child survival intervention. Federal Ministry of Health, Ethiopia and UNICEF Addis Ababa Ethiopia

Federal Ministry of Health, Ethiopia (2008): Program Implementation Manual of the National Nutrition Program (NNP) – July 2008 - June 2013. Federal Ministry of Health, Addis Ababa Ethiopia

Giovannini M, Sala D, Usuelli M, et al (2006): Double-Blind, Placebo-Controlled Trial Comparing Effects of Supplementation with Two Different Combinations of Micronutrients Delivered as Sprinkles on Growth, Anemia, and Iron Deficiency in Cambodian Infants. Journal of Pediatric Gastroenterology and Nutrition; 42:306-312.

Hall A and Khara T (2006): Mission Report: Enhanced Outreach Strategy / Targeted Supplementary Food For Child Survival Interventions. UNICEF and WFP, Addis Ababa

Last (2001): A Dictionary of Epidemiology. 4th Edition, Oxford University Press

Navarro-Colorado C (2004). A Retrospective Study of Emergency Supplementary Feeding Programs. Emergency Nutrition Network and Save the Children-U.K. London, June 2004.

Nielsen J, Valentiner-Branth P, Martins C, Cabral F, Aaby P (2004): Malnourished children and supplementary feeding during the war emergency in Guinea-Bissau in1998-1999, American Journal of Clinical Nutrition; 80: 1036-1042.

Quisumbing AR (2003): Food aid and child nutrition in rural Ethiopia, World Development; 31(7): 1309-1323

Schilling PR (1990): Supplementary feeding programme: a critical analysis, Revista de Saúde Pública; 24: 412-419

SMART (2006): Measuring Mortality, Nutritional Status, and Food Security in Crisis Situations: SMART Methodology.

Sphere Project (2004): Humanitarian Charter and Minimum Standards in Disaster Response. The Sphere Project, Geneva, Switzerland.

Taylor WR (1983): An evaluation of supplementary feeding in Somali refugee camps, International Journal of Epidemiology; 12(4): 433-436

UNHCR and WFP (1999): UNHCR/WFP Guidelines for Selective Feeding Programmes in Emergency Situations. UNHCR and WFP, Geneva and Rome.

Sphere Project (2004): The Sphere Project - Humanitarian Charter and Minimum Standards in Disaster Response. The Sphere Project, 2004 edition

Vautier F, Hildebrand K, Dedeurwaeder M, Baquet S, Herp van M (1999): Dry supplementary feeding programmes: an effective short-term strategy in food crisis, Tropical Medicine and International Health; 4(12): 875-879

Vazquez-Garcia L (1999): Supplementary feeding in Madera: the right intervention? Field Exchange, no 6: 26-27

WFP (2008): 2007 Performance Study Report of the Targeted Supplementary Food program (TSF), WFP Addis Ababa Ethiopia

WFP and DSM (2008): Improving corn soy blend and other fortified blended foods, why and how. Sight and Life; (1) 4.

WFP Office of Evaluation (2007): Full Report of the Mid-Term Evaluation of PRRO 10362.0: Enabling Livelihood Protection and Promotion (First Draft, 12 March 2007), WFP Rome

WHO Expert Committee on Physical Status (1995): Physical Status: The Use and Interpretation of Anthropometry. WHO Technical Report Series no. 854, WHO Geneva Switzerland

Yamano T, Alderman H, Christianesen L: Child growth, shocks, and food aid in rural Ethiopia, American Journal of Agricultural Economics; 87(2): 273-288

Zlotkin S, Arthur P, Schauer C, et al (2003). Home-fortification with iron and zinc sprinkles or iron sprinkles alone successfully treats anemia in infants and young children. Journal of Nutrition; 133: 1075–1080.

ANNEX 1. ORIGINAL SELECTION OF INTERVENTION AND CONTROL WOREDAS

The selection of study woredas was based on historical program data; some woredas received food quite late for various reasons, including delays in arranging shipment of food from central warehouses to the woreda depots from which food is distributed to individual community food distribution centers. This definition of intervention and control groups took advantage of naturally occuring differences between woredas and was necessitated by the general opinion among all study collaborators that intentional allocation of malnourished children to a control group receiving no supplemental feeding was entirely unethical. In spite of the lack of strong evidence of the efficacy of supplemental food in alleviating acute malnutrition, supplemental feeding has become the normal and expected response to moderate acute malnutrition. Children identified as malnourished cannot be denied supplemental food if a program is available to them.

Woreda selection attempted to match the intervention and control woredas in the same region on as many variables as possible, except for past delivery of TSF food, in order to minimize differences between the two woredas. The following variables were used to pair intervention and control woredas:

- Climate
- Socio-economic level
- Food security in the household
- Household livelihoods
- Disease pattern
- Geographical location of the woreda regarding the food distribution
- Security in the woreda[2]

Information about these variables was collected through:

- The Disaster Management and Food Security Sector early warning system containing agricultural and market information.

[2] Parts of the selected regions are estimated as UN security phase III: Relocation. This means that UN staff are not allowed to have their dependants live with them, and strict security procedures are in place (UN Department of Safety and Security, 2009).

- The Ministry of Health early warning database providing health surveillance information.
- The WFP's internal databases, including
    - a data-set used to produce the chronic vulnerability index
    - the livelihood zoning baseline, available for Tigray, Amhara, Afar and Somali Regions, which is based on the household economy approach; and
    - the 2004 atlas from the Central Statistics Authority of the government of Ethiopia.

Based on the mapping exercise and further discussions with researchers in the study team and staff from WFP, the specific woredas selected are listed below:

Region	Intervention	Control
Tigray	Hawsien	N/Aidet
Afar	Dubti	Aba Ala
Amhara	Sekota	Lasta
Somali	Dembel / Gursum*	Dolo Ado

*As the result of the mapping exercise, Dembel woreda in the Somali region was selected. However, one of the investigators visited Dembel woreda and the authorities of the woreda said that the EOS-screening was postponed additional six days. Furthermore, accessibility to Dembel was found to be very difficult which could have had a critical influence on the study. Therefore, Gursum was chosen as an acceptable substitute for Dembel.

ANNEX 2. DATA COLLECTION FORM

Region: ______________________ **Woreda**: ___________________ **Kebele** ________________

Interviewer: _____________________

Date of data collection _____ / _____ / _____ **Number of data collection: 1 / 2 / 3 / 4 / 5**
(Ethiopian calendar: Day Month Year)

EOS MUAC ☐☐ • ☐ **EOS oedema Yes=1 / No=2**

EOS screening date ______ / _______ / ________

HELLO, MY NAME IS ___________ AND I AM COLLECTING DATA FOR WFP AS PART OF AN OUTCOME EVALUATION ON THE TARGETED SUPPLEMENTARY FOOD PROGRAMME. I WOULD LIKE TO ASK YOU SOME QUESTIONS ABOUT YOUR HOUSEHOLD AND TAKE SOME MEASUREMENTS ON YOUR CHILD WHO IS ENTERED IN THE TSF. THE INTERVIEW SHOULD TAKE ABOUT 30 MINUTES. AT EACH STUDY VISIT, YOU WILL RECEIVE A BAR OF SOAP. AT THE END OF THE STUDY, YOU WILL RECEIVE A CERTIFICATE OF PARTICIPATION. YOUR PARTICIPATION IN THE STUDY IS COMPLETELY VOLUNTARY, AND YOUR TSF BENEFITS WILL NOT CHANGE AS A RESULT OF YOUR PARTICIPATION (OR REFUSAL TO PARTICIPATE) IN THE STUDY. THE ANSWERS YOU PROVIDE ARE CONFIDENTIAL AND YOUR NAME WILL NOT BE USED IN THE FINAL REPORT. DO YOU AGREE TO PARTICIPATE IN THE STUDY?

If the eligible primary care- taker is not present, schedule another visit to the household

Verbal consent obtained from primary caretaker .... Yes ☐ No ☐

FIRST, I WOULD LIKE TO ASK QUESTIONS ABOUT THE CHILD ENROLLED IN TSF AND IN THIS STUDY.

3.	**CHILD´S NAME:** ______________________ **FATHER'S NAME:** ______________________ **MOTHER'S NAME:** ______________________ **GRANDFATHER'S NAME:** ______________________	
4.	**CARETAKER´S NAME:** ______________________ **HEAD OF HOUSEHOLD NAME:** ______________________	
5.	**WHAT IS YOUR RELATIONSHIP TO *(name)*?** *Circle ONLY ONE answer*	Biological mother .... 1 Grandmother .... 2 Sister .... 3 Stepmother........ 4 Aunt .... 5 Other female relative .... 6 Brother .... 10 Father .... 11 Answer refused .... 7 Don't know .... 8 Other (specify) .... 9 ______________________
6.	**HAVE YOU HAD PRIMARY RESPONSIBILITY FOR TAKING CARE OF (name) FOR AT LEAST THE LAST TWO WEEKS?** *Circle ONLY ONE answer*	Yes .... 1 No .... 2 Answer refused .... 7 Don't know 8

7. **WHERE IS (name) TODAY?** *Circle ONLY ONE answer* *If **died**, continue.* *If **other answer**, jump to question 8.*	Home .... 1 Away from the house .... 2 Died .... 3 Answer refused .... 7 Don't know .... 8 Other (specify) .... 9 ________________
8. **WHAT DID *(name)* DIE OF?**	________________
9. **WHO DETERMINED THE CAUSE OF DEATH?** ***END INTERVIEW** and remove child from register of study participants.*	Diagnosis by health care worker .... 1 Own judgement or opinion .... 2 Family member's opinion .... 3 Answer refused .... 7 Don't know .... 8 Other (specify) .... 9 ________________
10. **IS *(name)* A BOY OR GIRL?** *Circle ONLY ONE answer*	Boy .... 1 Girl 2
11. **WHAT IS *(name)*´S DATE OF BIRTH?** *Even if the mother knows the exact date of birth, ask if she has an immunization card or other document and check that the date is correct. **Use Ethiopian calendar to record date of birth***	Day _ _ Month _ _ Year _ _ _ _
12. SOURCE OF DATE OF BIRTH INFORMATION *Circle ONLY ONE answer* *If a **date of birth is available**, jump to question 12.*	Immunization or vaccination card .... 1 Birth certificate .... 2 Caretaker's recall .... 3 Other (specify) .... 9 ________________
13. **HOW OLD IS *(name)*?**	Age in months .... _ _

The recent EOS screening

I WILL NOW ASK YOU SOME QUESTIONS RELATED TO THE RECENT EOS SCREENING *(NAME)* PARTICIPATED IN.

14. **AT THE TIME OF THE RECENT SCREENING, DID *(name)* RECEIVE VITAMIN A CAPSULE LIKE THIS?** *Circle ONLY ONE answer* *Show the vitamin A capsule to the respondent*	Yes .... 1 No .... 2 Answer refused .... 7 Don't know 8
15. **AT THE TIME OF THE RECENT SCREENING, DID *(name)* RECEIVE A DE-WORMING TABLET LIKE THIS?** *Circle ONLY ONE answer* *Show the deworming tablet to the respondent*	Yes .... 1 No .... 2 Answer refused .... 7 Don't know 8

Child morbidity

I WILL NOW ASK YOU SOME QUESTIONS ABOUT ANY ILLNESSES (NAME) HAS HAD DURING RECENT PAST.

16. **TRY TO REMEMBER THE LAST TWO WEEKS. DURING THIS PERIOD, HAS *(name)* HAD DIARRHEA? DIARRHEA IS DEFINED AS HAVING THREE OR MORE LOOSE STOOLS DURING A 24-HOUR PERIOD** *Circle ONLY ONE answer*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know 8
17. **TRY TO REMEMBER THE LAST TWO WEEKS AGAIN. HAS *(name)* HAD A COUGH AND DIFFICULTY BREATHING?** *Circle ONLY ONE answer*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know 8
18. **TRY TO REMEMBER THE LAST TWO WEEKS AGAIN, HAS *(name)* HAD A FEVER?** *Circle ONLY ONE answer*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know 8
19. **HAS *(name)* HAD MEASLES IN THE PAST 3 MONTHS?** *Circle ONLY ONE answer*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know 8

Care practice *(ask questions 18-20 ONLY for children less than 24 months of age)*

I WILL NOW ASK YOU SOME QUESTIONS ABOUT HOW YOU TAKE CARE OF *(NAME)*, FOR EXAMPLE, HOW LONG YOU HAVE BEEN BREAST FEEDING YOUR CHILD AND WHEN DID YOU START TO GIVE *(NAME)* COMPLEMENTARY FOOD.

20. **HAS *(name)* EVER BEEN BREASTFED?** *Circle ONLY ONE answer* *If **no**, jump to question 21.* *If **other answer**, continue.*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know 8
21. **SINCE THIS TIME YESTERDAY, HAS *(name)* BEEN BREASTFED?** *Circle ONLY ONE answer*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know 8
22. **AT WHAT AGE DID *(name)* START EATING COMPLEMENTARY FOOD? COMPLEMENTARY FOOD IS ANY FOOD WHICH IS NOT BREASTMILK EXCEPT MEDICATIONS.**	Number of months .... ☐☐

(for all children, ask the following questions; read each item below)

23.	**SINCE THIS TIME YESTERDAY HAS *(NAME)* RECEIVED ANY OF THE FOLLOWING?**	1=yes	2= no
A	VITAMINS, MINERAL SUPPLEMENTS, MEDICINES, ORS	1	2
B	PLAIN WATER	1	2
C	SWEETENED OR FLAVOURED WATER, TEA OR INFUSION, OR OTHER LIQUIDS (INCLUDE SOUPS AND BROTH)	1	2
D	FRUIT JUICE	1	2
E	INFANT FORMULA	1	2
F	TINNED, POWDERED OR FRESH MILK (NOT BREASTMILK)	1	2
G	ANY FOOD MADE FROM CEREALS SUCH AS TEFF, SORGHUM, WHEAT, MAIZE BARLEY	1	2
H	ANY FOOD MADE FROM CARROTS, RED SWEET POTATOES, GREEN LEAFY VEGETABLES	1	2
I	ANY FOOD MADE FROM TUBERS OR ROOTS, SUCH AS WHITE POTATOES, LOCAL ROOTS/TUBERS, ONIONS	1	2

J	ANY FOOD MADE FROM LEGUMES (LENTILS, BEANS, SOYBEANS, PULSES, PEAS, VETCH, LINSEED, NIGER SEED, SESAME)	1	2
K	ANY OTHER FRUITS/VEGETABLES SUCH AS ORANGE, LEMON, BANANA, PAPAYA	1	2
L	MEAT, EGGS, POULTRY, CHEESE OR YOGHURT	1	2
M	ANY FOOD MADE WITH OIL OR BUTTER OR GHEE	1	2
N	WILD FOODS, SUCH AS BERRIES, SAMA, OR BELES	1	2
O	OTHER (SPECIFY) ________________________________	1	2

Demographic and socio-economic variables

I WILL NOW ASK YOU ABOUT THE PEOPLE WHO LIVE HERE AND OTHER THINGS ABOUT YOUR HOUSEHOLD.

24. **WHAT IS THE HIGHEST LEVEL OF SCHOOLING YOU** *(the caretaker)* **HAVE COMPLETED?** *Write in NUMBER OF YEARS of school.*	Number of years of school .... [ ][ ] Informal schooling .... 66 Answer refused .... 77 Don't know 88
25. **WHAT IS THE HIGHEST LEVEL OF SCHOOLING** *(say the name of the head of household, see question 2)* **HAS COMPLETED?** *Write in NUMBER OF YEARS of school*	Number of years of school .... [ ][ ] Informal schooling .... 66 Answer refused .... 77 Don't know 88
26. **HOW MANY PEOPLE ATE AT THIS HOUSE YESTERDAY?** *Include children under 5 years old*	Number of people: .... [ ][ ]
27. **HOW MANY PEOPLE USUALLY LIVE IN THIS HOUSEHOLD, THAT IS, HOW MANY PEOPLE USUALLY COOK AND EAT FROM THE SAME POT?**	Number of people: .... [ ][ ]
28. **HOW MANY CHILDREN UNDER 5 YEARS OF AGE USUALLY LIVE IN THIS HOUSEHOLD?**	Number children under 5 years [ ][ ]
29. **WHAT IS <u>NOW</u> THE MAIN SOURCE OF DRINKING WATER FOR MEMBERS OF YOUR HOUSEHOLD?** *Circle ONLY ONE answer*	Piped water .... 1 Tube well or borehold .... 2 Protected well .... 3 Unprotected well .... 4 Water from protected spring .... 5 Water from unprotected spring .... 6 Rainwater/Birka .... 10 Tanker truck or water seller .... 11 Surface source (stream, river, pond, lake, canal) .... 12 Answer refused .... 7 Don't know .... 8 Other (specify) .... 9 ________________________________

30. **DO YOU TREAT YOUR WATER IN ANY WAY TO MAKE IT SAFER TO DRINK?** *Circle ONLY ONE answer* *If **yes**, continue.* *If **other answer**, jump to question 30.*	Yes .... 1 No .... 2 Answer refused .... 7 Don't know 8
31. **WHAT DO YOU DO NOW TO THE WATER TO MAKE IT SAFER TO DRINK?** *Circle ALL applicable answers*	Boil .... 1 Add bleach, chlorine or Agar .... 2 Mix with leaves .... 3 Strain it through a cloth .... 4 Use a water filter .... 5 Let it stand and settle .... 6 Answer refused .... 7 Don't know .... 8 Other (specify) .... 9 ____________
32. **WHERE DO MEMBERS OF YOUR HOUSEHOLD USUALLY GO TO RELIEVE THEMSELVES?** *Circle ONLY ONE answer*	Flush toilet .... 1 Pit latrine .... 2 Composting toilet .... 3 Bush or field .... 4 On ground within compound .... 5 Answer refused .... 7 Don't know .... 8 Other (specify) .... 9 ____________
33. **WHAT IS NOW THE PRIMARY SOURCE OF INCOME FOR THIS HOUSEHOLD?** *Circle ONLY ONE answer*	Farming, including cash crops .... 1 Livestock .... 2 Employment/salary .... 3 Petty trading (including sale of fire-wood, charcoal, grass, local brewery) . 4 Daily labor .... 5 Relief food//Safety net .... 6 Handicrafts/artisan .... 10 Remittances .... 11 Answer refused .... 7 Don't know .... 8 Other (specify) .... 9 ____________
34. **I WILL NOW MENTION SOME ANIMALS, AND I WOULD LIKE YOU TO TELL ME HOW MANY ANIMALS OF EACH TYPE YOU HAVE.** *Fill in NUMBER of each type of animal*	CAMELS: .... [ ][ ][ ] PLOW OXEN: .... [ ][ ][ ] COWS: .... [ ][ ][ ] HEPHERS: .... [ ][ ][ ] CALVES: .... [ ][ ][ ] BULLS: .... [ ][ ][ ] SHEEP AND GOATS: .... [ ][ ][ ] HORSES, DONKEYS, MULES: [ ][ ][ ] CHICKENS: .... [ ][ ][ ]

35. **HOW MUCH LAND DOES YOUR HOUSEHOLD OWN?** *Write in number of local units and the name of the local unit*	Number of local units: .... ☐☐☐ Name of local unit: Timad .... 1 Kodi..................... 2 Hectare .... 3 Other .... 7 Specify: ______________________ Don't know how much land 999
36. **DOES YOUR HOUSEHOLD HAVE:** *Circle 1 or 2 for each item*	Yes No **ELECTRICITY/GENERATOR:** .... 1 2 **A SEWING MACHINE:** .... 1 2 **A TRIDLE PUMP:** .... 1 2 **A RADIO:** .... 1 2 **A TELEVISION:** .... 1 2 **A MOBILE TELEPHONE:** .... 1 2 **A NON-MOBILE TELEPHONE:** .... 1 2 **A REFRIGERATOR:** .... 1 2 **A TABLE:** .... 1 2 **A CHAIR:** .... 1 2 **A BED:** .... 1 2 **AN ELECTRIC MITAD:** .... 1 2 **A KEROSENE OR PRESSURE LAMP:** 1 2 **A KEROSENE STOVE:** 1 2
37. **HAS ANYONE DIED IN THIS HOUSEHOLD IN THE PAST YEAR / SINCE OUR LAST VISIT?** *If **yes**, continue.* *If **other answer**, go to question 38.*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know 8
38. **WHO IN THE HOUSEHOLD DIED?** *Circle ALL applicable answers*	Biological mother .... 1 Other primary caretaker .... 2 Primary income earner........................... 3 Head of household .... 4 Answer refused .... 7 Don't know .... 8 Other (specify) .... 9 ______________________

39. **WHAT IS THE AGE AND SEX OF PEOPLE/PERSON WHO DIED?** *Record age in completed years.* *For less than one year enter 0*	Age / Sex
Person 1	[ ][ ] Male (1) / Female (2)
Person 2	[ ][ ] Male (1) / Female (2)
Person 3	[ ][ ] Male (1) / Female (2)
Person 4	[ ][ ] Male (1) / Female (2)

Compliance

I WILL NOW ASK YOU SOME QUESTIONS ABOUT THE UTILIZATION OF THE SUPPLEMENTARY FOOD (CSB AND OIL) IN THE HOUSEHOLD.

40. **SINCE *(name)* HAS BEEN ENROLLED IN THE TSF PROGRAM, HAS SOMEONE IN YOUR HOUSEHOLD COLLECTED FOOD FROM THE TSF PROGRAM?** *Circle ONLY ONE answer* *If **no**, continue.* *If **yes or other answer**, jump to question 40.*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know 8
41. **WHY NOT?** *Circle ONLY ONE answer* *After completing this question, jump to question 49.*	Food has not yet been distributed .... 1 No time to collect food .... 2 Distance to collect food too far .... 3 Was not informed about the distribution .... 4 Answer refused .... 7 Don't know .... 8 Other (specify) .... 9 ____________________
42. **WHEN COLLECTING THE FOOD, DID THE PERSON WHO PICKED UP THE FOOD RECEIVE INFORMATION ON HOW TO PREPARE FOOD FROM THE CSB?** *Circle ONLY ONE answer*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know 8
43. **CAN YOU PLEASE SHOW ME SOME OF THE FOOD YOU HAVE RECEIVED FROM THE TSF PROGRAM.** *Confirm presence of CSB and oil.* If **no TSF food present**, continue If **TSF food present**, jump to question 43.	CSB present .... 1 Oil present .... 2 Both CSB and oil present .... 3 Neither CSB nor oil present .... 4 Answer refused 7

44. **WHY IS THERE NO TSF FOOD PRESENT?** *Circle ONLY ONE answer* *After answering this question, jump to question 49.*	Already eaten all the food .... 1 Sold the food .... 2 Gave it to others outside the household.......... 3 Answer refused .... 7 Don´t know .... 8 Other (specify) .... 9 ____________________________________
45. **YESTERDAY, DID YOU PREPARE AND SERVE ANY OF THE CSB YOU GOT FROM THE TSF PROGRAM?** *Circle ONLY ONE answer* *If **no**, jump to question 49.* *If **yes**, continue.*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know 8
46. **YESTERDAY, HOW MANY "CUPS" OF CSB DID YOU PREPARE AND SERVE IN TOTAL?** *Circle ONLY ONE answer*	Less than 1 cup... 0 1 cup .... 1 2 cup .... 2 3 cups .... 3 4 cups .... 4 5 cups .... 5 More than 5 cups .... 6 Answer refused .... 7 Don't know 8
47. **YESTERDAY, DID YOU MIX TSF OIL WITH THE CSB DURING PREPARATION?** *Circle ONLY ONE answer*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know 8
48. **YESTERDAY, HOW MANY SINE OF OIL DID YOU MIX WITH THE CSB IN TOTAL?** *Circle ONLY ONE answer*	None .... 0 ½ sine .... 1 1 sine .... 2 1 ½ sine .... 3 2 sine .... 4 More than 2 sine .... 5 Answer refused .... 7 Don't know 9
49. **YESTERDAY, WHO IN THE HOUSEHOLD ATE THE CSB YOU PREPARED?** *Circle ALL applicable answers*	(name) .... 1 Another child in the HH under 5 years of age.. 2 Another child in the HH 5 years or older .... 3 Father .... 4 Mother .... 5 Pregnant/lactating woman in the household ... 6 Elderly member .... 10 Other member of household .... 11 Answer refused .... 7 Don't know .... 8 Other (specify) .... 9 ____________________________________

50. **YESTERDAY, WHAT PROPORTION OF THE CSB YOU PREPARED WAS EATEN BY *(name)*?** *Circle ONLY ONE answer*	None .... 0 Less than 1/2 .... 1 About half .... 2 Most .... 3 All .... 4 Answer refused .... 7 Don't know 8
51. **IN YOUR VIEW, WHAT IS THE MAIN PURPOSE OF FEEDING *(name)* THE CSB AND OIL YOU GOT FROM THE TSF PROGRAM?** *Circle ONLY ONE answer*	Recover from malnutrition .... 1 Have enough food in the household .... 2 For normal growth .... 3 Answer refused .... 7 Don't know .... 8 Other (specify purpose) .... 9 ____________________

Participation in other food distribution or nutrition programs

I WILL NOW ASK YOU SOME QUESTIONS ABOUT YOUR HOUSEHOLD'S PARTICIPATION IN PROGRAMS WHICH DISTRIBUTE FOOD OR CASH, FOR EXAMPLE, THE SAFETY NET PROGRAM. YOUR ANSWERS WILL NOT CHANGE YOUR ELIGIBLITY FOR ANY PROGRAM.

52. **IS THERE ANYONE IN THE HOUSEHOLD OTHER THAN (name) WHO IS CURRENTLY ENROLLED IN THE TARGET SUPPLEMENTARY FOOD PROGRAM?** *Circle ONLY ONE answer* *If **yes**, continue* *If **other answer**, jump to question 52.*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know .... 8 Other (specify) .... 9 ____________________
53. **WHO ELSE IS CURRENTLY ENROLLED IN THE TARGETED SUPPLEMENTARY FOOD PROGRAM?** *Circle ALL applicable answers*	Other child(ren) under 5 years old .... 1 Pregnant mother .... 2 Lactating mother .... 3 Answer refused .... 7 Don't know .... 8 Other (specify) .... 9 ____________________
54. **IS THERE ANYONE IN THE HOUSEHOLD WHO IS CURRENTLY ENROLLED IN ANOTHER PROGRAM, OTHER THAN TSF, WHICH PROVIDES YOUR HOUSEHOLD WITH FOOD OR CASH TO PURCHASE FOOD?** *Circle ONLY ONE answer* *If **yes**, continue.* *If **other answer**, jump to question 54.*	Yes .... 1 No .... 2 Answer refused .... 7 Don´t know 8
55. **WHAT IS THE NAME OF THIS PROGRAM?** *Circle ALL applicable answers*	NGO supplementary feeding program .... 1 CTC / OTP .... 2 Safety net (PSNP) .... 3 Relief food .... 4 Answer refused .... 7 Don´t know .... 8 Other (specify) .... 9 ____________________

56. **HAS (name) BEEN ENROLLED IN ANOTHER FEEDING PROGRAM, SUCH AS THERAPEUTIC FEEDING, SINCE OUR LAST VISIT?** *Circle ONLY ONE answer* *If **yes**, continue.* *If **no**, jump to anthropometry section.*	Yes ....1 No ....2 Answer refused ....7 Don´t know 8
57. **WHAT IS THE NAME OF THIS PROGRAM?** *Circle ALL applicable answers*	NGO supplementary feeding program ....1 CTC / OTP....................2 Inpatient therapeutic feeding....................3 Answer refused ....7 Don´t know ....8 Other (specify) ....9 ____________________

Anthropometric measurements

58. WEIGHT	Weight (kg) .... [ ][ ] • [ ]
59. HEIGHT or LENGTH	Height (cm) .... [ ][ ][ ] • [ ] Measured height? Yes.................... 1 No .... 2 Reason cannot measure: ____________________
60. MUAC	MUAC (cm) .... [ ][ ] • [ ]
61. PRESENCE OF BILATERAL PITTING OEDEMA	Yes .... 1 No .... 2 Could not examine .... 9 (specify why)____________________

THANK YOU VERY MUCH FOR TAKING YOUR TIME FOR THIS INTERVIEW.

Signature of team leader:

____

ANNEX 3 – STRATIFIED ANALYSIS

Stratified analyses of variables which differ between intervention and control groups, as demonstrated in Table 4 and Table 5 above. (In all tables, NS = not significant [p<0.05])

Table 1: Age at Baseline

1.Follow-up	<24 months	24-41 months	42-59+ months	**p-value**
Intervention	0.156	0.195	0.137	**NS**
Control	0.096	-0.034	-0.133	**0.02**
Difference	0.061	0.229	0.27	**0.08**
p-value	**NS**	**0.003**	**0.01**	
2.Follow-up				
Intervention	0.208	0.248	0.132	**NS**
Control	0.103	0.129	-0.119	**0.08**
Difference	0.105	0.119	0.251	**NS**
p-value	**0.05**	**NS**	**0.03**	
3.Follow-up				
Intervention	0.231	0.256	0.231	**NS**
Control	0.023	0.141	0.145	**NS**
Difference	0.208	0.115	0.086	**NS**
p-value	**0.001**	**NS**	**NS**	
4.Follow-up				
Intervention	0.571	0.612	0.279	**NS**
Control	0.309	0.188	0.073	**NS**
Difference	0.262	0.424	0.206	**NS**
p-value	**<0.001**	**<0.001**	**NS**	

Table 2: Primary source of household income

1.Follow-up	Farming and livestock	Relief and remittances	Salary and other payment for work	**p-value**
Intervention	0.160	0.014	0.217	**0.07**
Control	0.156	-0.187	0.132	**<0.001**
Difference	0.004	0.201	0.085	**NS**
p-value	**NS**	**NS**	**NS**	
2.Follow-up				
Intervention	0.183	0.092	0.295	**0.08**
Control	0.141	0.004	0.06	**NS**
Difference	0.042	0.088	0.235	**NS**
p-value	**NS**	**NS**	**NS**	
3.Follow-up				
Intervention	0.145	0.185	0.439	**<0.001**
Control	0.081	0.004	0.228	**NS**
Difference	0.064	0.181	0.211	**NS**
p-value	**NS**	**NS**	**NS**	
4.Follow-up				
Intervention	0.43	0.245	0.904	**<0.001**
Control	0.349	0.024	0.39	**0.002**
Difference	0.081	0.221	0.514	**NS**
p-value	**NS**	**NS**	**0.07**	

Table 3: EOS intervention: Deworming (Only children > 24 months)

1.Follow-up	Yes	No	**p-value**
Intervention	0.197	-0.107	**0.03**
Control	-0.044	-0.207	**NS**
Difference	0.241	0.1	**NS**
p-value	**<0.001**	**NS**	
2.Follow-up			
Intervention	0.209	0.2362	**NS**
Control	0.064	0.0900	**NS**
Difference	0.145	0.146	**NS**
p-value	**0.03**	**NS**	
3.Follow-up			
Intervention	0.233	0.425	**NS**
Control	0.154	0.001	**NS**
Difference	0.079	0.424	**NS**
p-value	**NS**	**NS**	
4.Follow-up			
Intervention	0.521	0.523	**NS**
Control	0.160	0.137	**NS**
Difference	0.361	0.386	**NS**
p-value	**<0.001**	**NS**	

Table 4: Safe water source

1.Follow-up	Yes	No	**p-value**
Intervention	0.141	0.19	**NS**
Control	0.153	-0.075	**<0.001**
Difference	-0.012	0.115	**<0.001**
p-value	**NS**	**<0.001**	
2.Follow-up			
Intervention	0.173	0.258	**NS**
Control	0.142	0.039	**0.09**
Difference	0.031	0.0219	**0.02**
p-value	**NS**	**<0.001**	
3.Follow-up			
Intervention	0.168	0.326	**0.005**
Control	0.112	0.03	**NS**
Difference	0.056	0.296	**0.01**
p-value	**NS**	**<0.001**	
4.Follow-up			
Intervention	0.506	0.628	**0.08**
Control	0.341	0.164	**0.04**
Difference	0.165	0.464	**0.01**
p-value	**0.03**	**<.001**	

Table 5: Nutrition status at baseline WHZ

1.Follow-up	Severe malnutrition	Moderate malnutrition	No malnutrition	**p-value**
Intervention	0.338	0.273	0.082	**<0.001**
Control	0.547	0.242	-0.0997	**<0.001**
Difference	-0.209	0.031	0.182	**0.004**
p-value	**NS**	**NS**	**<0.001**	
2.Follow-up				
Intervention	0.597	0.338	0.064	**<0.001**
Control	0.606	0.279	-0.037	**<0.001**
Difference	-0.009	0.088	0.101	**NS**
p-value	**NS**	**NS**	**0.02**	
3.Follow-up				
Intervention	0.824	0.399	0.057	**<0.001**
Control	0.779	0.329	-0.104	**<0.001**
Difference	0.045	0.07	0.161	**NS**
p-value	**NS**	**NS**	**0.002**	
4.Follow-up				
Intervention	1.5	0.762	0.313	**<0.001**
Control	1.09	0.533	0.064	**<0.001**
Difference	0.41	0.229	0.249	**NS**
p-value	**NS**	**0.03**	**<0.001**	

Table 6: Morbidity - diarrhea

1.Follow-up	Yes	No	**p-value**
Intervention	0.067	0.229	**<0.001**
Control	-0.049	0.114	**0.01**
Difference	0.117	0.115	**NS**
p-value	**0.05**	**0.01**	
2.Follow-up			
Intervention	0.067	0.282	**<0.001**
Control	0.102	0.081	**NS**
Difference	-0.035	0.201	**0.01**
p-value	**NS**	**<0.001**	
3.Follow-up			
Intervention	0.077	0.313	**<0.001**
Control	-0.02	0.123	**0.08**
Difference	0.097	0.19	**NS**
p-value	**NS**	**<0.001**	
4.Follow-up			
Intervention	0.425	0.6	**0.03**
Control	0.211	0.276	**NS**
Difference	0.214	0.324	**NS**
p-value	**0.03**	**<0.001**	

Table 7: Morbidity - cough and difficulties of breathing

1.Follow-up	Yes	No	**p-value**
Intervention	0.128	0.17	**NS**
Control	-0.12	0.107	**0.002**
Difference	0.248	0.063	**0.02**
p-value	**0.002**	**NS**	
2.Follow-up			
Intervention	0.121	0.242	**0.03**
Control	0.025	0.115	**NS**
Difference	0.096	0.127	**NS**
p-value	**NS**	**0.01**	
3.Follow-up			
Intervention	0.135	0.2772	**0.02**
Control	0.039	0.0818	**NS**
Difference	0.096	0.195	**NS**
p-value	**NS**	**<0.001**	
4.Follow-up			
Intervention	0.445	0.585	**NS**
Control	0.082	0.318	**0.01**
Difference	0.363	0.267	**NS**
p-value	**0.002**	**<0.001**	

Table 8: Morbidity - fever

1.Follow-up	Yes	No	**p-value**
Intervention	0.114	0.201	**0.05**
Control	0.004	0.068	**NS**
Difference	0.109	0.133	**NS**
p-value	**0.05**	**0.003**	
2.Follow-up			
Intervention	0.131	0.27	**0.07**
Control	0.047	0.128	**NS**
Difference	0.084	0.142	**NS**
p-value	**NS**	**0.01**	
3.Follow-up			
Intervention	0.13	0.315	**0.001**
Control	-0.008	0.15	**0.04**
Difference	0.138	0.165	**NS**
p-value	**0.05**	**0.01**	
4.Follow-up			
Intervention	0.361	0.634	**0.001**
Control	0.069	0.357	**0.001**
Difference	0.292	0.277	**0.02**
p-value	**0.004**	**<0.001**	

Table 9: Another household member enrolled in TSF

1.Follow-up	Yes	No	**p-value**
Intervention	0.1082	0.1691	**NS**
Control	-0.0725	0.0644	**NS**
Difference	0.018	0.105	**NS**
p-value	**0.09**	**0.01**	
2.Follow-up			
Intervention	0.18	0.215	**NS**
Control	0.105	0.085	**NS**
Difference	0.075	0.13	**NS**
p-value	**NS**	**0.004**	
3.Follow-up			
Intervention	0.236	0.237	**NS**
Control	0.199	0.031	**NS**
Difference	0.037	0.206	**NS**
p-value	**NS**	**<0.001**	
4.Follow-up			
Intervention	0.842	0.519	**0.001**
Control	0.208	0.267	**NS**
Difference	0.634	0.252	**0.01**
p-value	**<0.001**	**<0.001**	

Table 10: Household enrolled in another program providing nutrition or cash

1.Follow-up	Yes	No	**p-value**
Intervention	0.202	0.102	**0.02**
Control	0.229	-0.038	**<0.001**
Difference	-0.027	0.14	**0.04**
p-value	**NS**	**0.01**	
2.Follow-up			
Intervention	0.187	0.237	**NS**
Control	0.069	0.098	**NS**
Difference	0.118	0.139	**NS**
p-value	**0.05**	**0.02**	
3.Follow-up			
Intervention	0.199	0.284	**NS**
Control	-0.093	0.138	**0.003**
Difference	0.292	0.146	**NS**
p-value	**<0.001**	**0.03**	
4.Follow-up			
Intervention	0.504	0.630	**0.07**
Control	0.235	0.259	**NS**
Difference	0.269	0.371	**NS**
p-value	**0.002**	**<0.001**	