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EFFECTS OF NUTRITIONAL SUPPORT ON GROWTH AND DEVELOPMENT OF CHILDREN RECEIVING ANTI-RETROVIRAL THERAPY (ART) IN SELECTED SLUMS OF NAIROBI, KENYA
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EFFECTS OF NUTRITIONAL SUPPORT ON GROWTH AND DEVELOPMENT OF CHILDREN RECEIVING ANTI-RETROVIRAL THERAPY (ART) IN SELECTED SLUMS OF NAIROBI, KENYA

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ABSTRACT

Background: **Anti-retroviral therapy (ART) in infants and children has been proven effective. For optimal outcomes of ART, other factors such as the nutrition status of the patient, dietary patterns, treatment adherence, economic status and incidence of opportunistic infections are essential for effective therapeutic outcomes.**
Objective: **To determine the effect of nutritional support on growth and development patterns of HIV-infected children aged 6-59 months, receiving ART in urban resource-poor setting of Nairobi, Kenya.**
Study Design: **Quasi experimental study design.**
Study Setting: **Eight slum areas of Nairobi namely Kibera, Kawangware, Kangemi, Dagoretti, Mukuru, Dandora, Kariobangi and Mwiki**
Study Subjects: **Two hundred and sixty (260) HIV-infected children (aged 6-59 months) on ART were randomly selected from eight comprehensive care centres (CCCs) and followed for a period of up to six months.**
Results: **Nutritional support had significant effect on HAZ (P<0.05) and was protective against stuntedness of children (P=0.044; 95% CI, 0.20-0.98). However, the association between nutritional support and weight-for-age (WAZ) (P=0.477) or weight-for-height (WHZ) (P=0.924) were not significant. The WAZ improved for both the experimental and control groups by the end of the study. Additionally, the study showed that nutritional support was not significantly protective of children in experimental study arm from becoming underweight compared to controls (P=0.521; 95% CI, 0.51-3.70). Similarly, food support was not protective of children in experimental group from being wasted compared to controls (P=0.586; 95% CI, 0.54-2.94). The association between nutritional support and motor development was not significant (P=0.091). The**

CD4 cell counts between the study groups was not statistically different (P=0.087) and neither was disease incidence (P=0.166).

Conclusion: **Despite results indicating non-significant differences of four of the five parameters measured, the results show that growth and development parameters of children in the experimental group had improved. Given the food insecurity status in the experimental group, growth and development parameters of children improved and may have been worse had support not been provided. In light of this, the study recomends that interventions on nutritional support for HIV-infected children in limited resource settings should be implemented to cater for the short term acute shortages. Additionally, the appropiateness of support provided with regard to the formulation and content of food for the 6-59 months age group should always be considered for better outcomes.**

INTRODUCTION

Globally, the most efficient and cost-effective way to tackle paediatric HIV is to reduce mother-to-child transmission (MTCT) (1). However, every day there are nearly 1500 new infections in children under five years of age where more than 90% of them occur in developing world, majority being associated with MTCT (2).

In Kenya, there are about 11,000 new child infections annually according to the National HIV estimates (3). HIV-infected infants frequently present with clinical symptoms in the first year of life (4, 5). This consequently affects their overall growth and development, including their physical and motor skills. Growth and development of HIV-infected children are furthermore complicated by lack of nutritious food necessary to boost normal growth and development, especially in limited resource settings (6).

HIV progression is dependent upon treatment and nutrition. The provision of specific nutritional support has been noted to augment therapeutic interventions especially in resource-limited settings. Good nutrition is associated with increased tolerance to infection and disease in addition to improved energy and productivity (7). Although ART is a key intervention, nutritional support is also needed to fully benefit from improved CD4+ counts. ART protocols consistently identify “good nutrition” as an integral part of a comprehensive care package. Diarrhoea, a major clinical manifestation among HIV-infected persons has been known to reduce significantly with appropriate nutritional support and ART regime (8, 9). Although data is often taken in the course of a child’s treatment, there has been no systematic analysis to show possible effect of nutrition on infants and children on ART. In part, this study worked to fill the systematic gap of linking growth and development of HIV-infected children to ART and nutrition. Studies examining the benefits of macronutrient interventions for adults exist. However, notably absent are substantial data on infants and children regarding effects of food-based supplementation in HIV care and treatment programmes in the developing world. Limited published information, abstracts and unpublished work are emerging regarding HIV-related outcomes such as viral load, CD4 counts (10,11), clinical symptoms, coinfections, and hospitalizations (12,13), even among the available adult studies. These studies indicate a correlation between nutrition and HIV. In children such data is limited. The gaps in information on the effects of nutrition support for children infected by HIV indicate a need for detailed systematic review of effect of food support that focus mainly on macronutrients and locally available foods on growth and development and its effect on infections and immune system. This study in part provides some critical data that will alleviate the aforementioned shortcomings regarding effects of nutritional support, especially for young children.

MATERIALS AND METHODS

***Study Design*:** The study employed a quasi-experimental design with two parallel groups. One group comprised HIV-infected children receiving food support, and the other group consisted of HIV-infected children not receiving food support.

***Study Setting*:** The study was carried out in eight comprehensive care centres (CCCs) managed by the Nyumbani Children's Home, Lea Toto Programme. These are located in eight informal settlements of Nairobi County namely Kibera, Kawangware, Kangemi, Dagoretti, Mukuru, Dandora, Kariobangi and Mwiki (Figure 1).

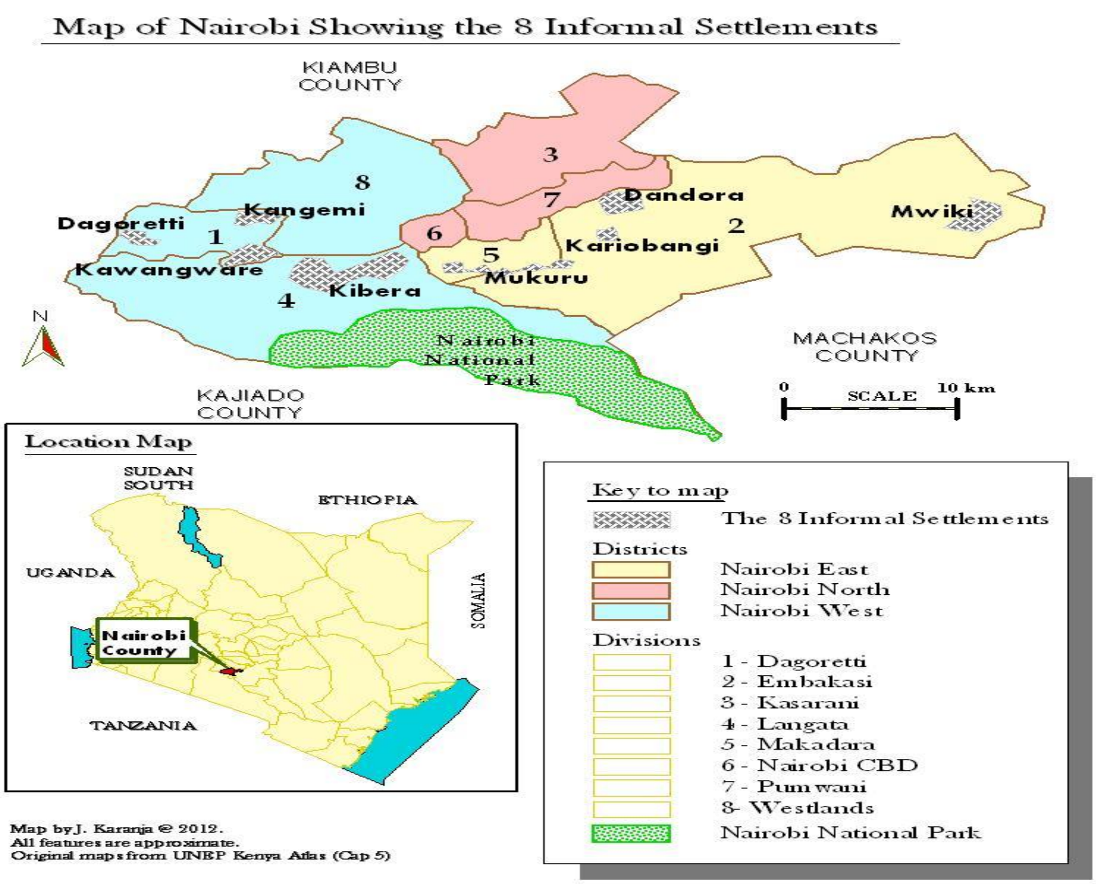

Figure 1: Map of the study sites where the eight comprehensive care clinics are located

Source: UNEP Kenya Atlas (Cap 5)

***Study Population*:** A total of 260 study participants aged 6-59 months were enrolled into the study together with their mothers or guardians. The subjects comprised consenting mothers or guardians of two categories of HIV-positive children aged 6-59 months. The first category was mothers/guardians of children receiving food support as experimental group. The second category consisted of mothers/guardians of children not receiving food support from the CCCs as the control group of the study.

Inclusion criteria:

(i). Consenting mothers/guardians of HIV-positive children aged between 6-59 months. To qualify as a guardian, key requirements were proof of living in the same household as the sampled child, responsibility for daily upkeep of the child and accountability for the child's medical care.

(ii). Children (6-59 months) who were HIV-positive and were receiving ART from the selected CCCs.

(iii). Residents of sampled informal settlement and expected to remain in the area for a period of at least six months.

(iv). HIV-positive children with CD4 count above 200.

(v). Children and infants who were not malnourished or TB-infected at the start of study. Determination of the above factors was done by the programme during routine treatment.

Exclusion criteria:

(i). Non-consenting mothers/guardians of HIV-positive children aged between 6-59 months.

(ii). Mothers/guardians of HIV-positive children whose age bracket fell outside of 6-59 months.

(iii). Children aged 6-59 months who were not on ART.

(iv). HIV-infected children and infants aged 6-59 months and were malnourished or TB-infected at start of study.

(v). Resident of sampled informal settlement who were not to remain in the area for a period of at least six months.

(iv). HIV-positive children with CD4 count below 200.

***Sample size determination*:** Since no study has been done to estimate the proportion of underweight, stunting and wasting among children living with HIV in the study sites, the study proposed to use 50% assumed proportion of wasting among HIV-infected children enrolled in a HIV programme receiving nutritional counselling alone and 30% among HIV infected children enrolled in a HIV programme receiving food support. The minimum sample required to detect a 20% effect as significant was then calculated using the formulae developed by Casagrande *et al*., 1978 as follows:

$$n = \frac{\{Z_{1-\alpha/2}\sqrt{[2P(1-P)]} + Z_{1-\beta}\sqrt{[P_1(1-P_1)+P_2(1-P_2)]}\}^2}{(P_1-P_2)^2}$$

Where:

n= Minimum sample size required

α = Type I error (0.05)

β = Type II error (0.10)

At 95% confidence, $Z_{1-\alpha/2}$ = 1.96

At 90% power, $Z_{1-\beta}$ = 1.28

P_1= Assumed proportion of wasting among HIV positive children enrolled in a HIV programme receiving nutritional counselling and food support (30%)

P_2= Estimated proportion of wasting among HIV positive children enrolled in a HIV programme receiving nutritional counselling alone (50%)

$$P = \frac{P_1 + P_2}{2}$$

n=124

Therefore

n =

$$\frac{\{Z_{1-\alpha/2}\sqrt{[2P(1-P)]} + Z_{1-\beta}\sqrt{[P_1(1-P_1) + P_2(1-P_2)]}\}^2}{(P_1 - P_2)^2}$$

= 124

The minimum sample size required for each group was 124. Allowing for 20% attrition due to the nature of study site and participants, the sample size was adjusted upwards to 149 for each study group. Therefore, the total sample size for the two groups was determined at 298 HIV-infected children. However, as the study progressed, there were losses to follow up. Analysis was carried out for a total of 260 participants, 151 and 109 for the experimental and control groups respectively. Analysis was conducted on participants who completed the designated six months duration of the study. The power analysis for the 151 participants in the experimental group yielded 86% power, this sample is deemed sufficient for the study.

Sampling Procedure: The children were enrolled from eight CCCs managed by the Lea Toto Programme. The eight clinics handle approximately three thousand (3000) children aged from 0-15 years. A comprehensive list of the programme beneficiaries was obtained from the programme head office in Kangemi. The list was used to identify eligible target children (6-59 months) to be included in the study. 832 children qualified to be included in the study. Of the 832 eligible children, 130 children received food support, qualifying them to be in the experimental group. However, seven (7) of these declined to participate in the study, leaving 123 in the experimental group. The 123 were then matched with the remaining 702 children who did not qualify for food support (control group). From the control group, a similar number of 123 children, matched for age and sex were selected. Both arms experienced attrition and replacements were done based on continuous household assessments and enrolment of children into the food support programme. Enrolment of children into the study was done until the desired number of children in each arm was attained. Figure 3.3 outlines the sampling procedure employed during the study.

All the recruited study children were required to attend the CCCs once a month to undergo routine assessment by the CCC staff. Those in the food support group were given supplies to last them until the next visit. For purposes of the study, assessment of the parameters of interest (nutritional assessment, assessment of motor skills developmental milestones through observation and monitoring of morbidities) was conducted at mid and end point, namely the third and sixth month after enrolment.

Study Variables: The study's dependent variables are:

i) Growth and development which was assessed using physical parameters defined using nutritional indicators namely height for age (stunting), weight for age (underweight) and weight for height (wasting).
ii) Motor skills which were assessed using gross and fine motor skills namely sitting, standing, crawling, walking, standing and visual skills.

The independent variables were:

i) Dietary practices of the study children. This involved assessment of consumption of various food types and the frequency of consumption of these food types by the study child.
ii) Socio-demographic and socio-economic characteristics among the study children's households.

Parameters assessed included the mothers' or guardians' age, level of education, marital status, income, and the study child's household size and composition.

The study's intermediate variables were:

i) Episodes of common childhood diseases among the study children. This focused on diarrhoea, febrile illnesses and respiratory infections.
ii) The immunological status (CD4 cells count) of the study children. The measurement parameters were the CD4 cell count.

***Data Collection Procedures*:** Data collection tools were developed to gather primary data through interviews and Focus Group Discussions (FGDs) with mothers/guardians of the study children and health workers. Data sheets were also developed to collect data on anthropometric measurements, motor skills, dietary patterns and CD4 count. The tools were then pretested to check their reliability and validity for data collection. The validity of the tools was examined in a pilot study in four CCCs with 48 mothers/guardians, children and healthcare workers not participating in the study. Issues identified during pre-test exercise such as sequencing, clarity and appropriateness of questions, and length of the tools were noted and corrected.

***Data Management*:** To ensure quality data was collected, a team of research assistants was recruited and trained on data entry and analysis. This comprised a team of qualified nutritionists working with the programme. The data analysts entered data into computer entry files and cross-checked for errors and omissions. Information from questionnaires was entered into excel or Epi-info data sheets and cross-checked by the principal investigator. Frequency distribution by variables was conducted for completeness and appropriate coding including for missing physical values. Those with missing information and errors were re-checked and corrected. Corrected and completed questionnaires were filed and kept in safe custody by the principal investigator.

Ethical Considerations:

Ethical Approval and scientific clearance were sought from the KEMRI Scientific Steering Committee (SSC) and the National Ethical Research Committee (ERC).

RESULTS

A total of 260 participants were studied. They comprised 151 (58.1%) and 109 (41.9%) participants in the experimental and control group respectively. The ages of the study children at baseline ranged from 6 to 59 months with a mean age of 35.7 months (SD=17.2). The males were 126 (48.5%) and the females were 134 (51.5%). There was no statistical difference in the demographic characteristics of the children by study group ($P>0.05$). The study children's demographic characteristics are shown in Table 1.

Table 1

Distribution of study children's demographic characteristics at baseline

	Study pop. (n=260)	ART only (n=109)	ART + Food (n=151)	χ^2 value	p value
	n (%)	n (%)	n (%)		
Age of child in months					
6 -11	31 (11.9)	15 (13.8)	16 (10.6)	8.573	0.380
12-17	23 (8.8	10 (9.2)	13 (8.6)		
18- 23	20 (7.7)	10 (9.2)	10 (6.6)		
24-29	20 (7.7)	7 (6.4)	13 (8.6)		
30-35	18 (6.9)	11(10.1)	7 (4.6)		
36-41	28 (10.8)	11 (10.1)	17 (11.3)		
42-47	23 (8.8)	10 (9.2)	13 (8.6)		
48-53	44 (16.9)	20 (18.3)	24 (15.9)		
54-59	53 (20.4)	15 (13.8)	38 (25.2)		
Sex of child					
Male	126 (48.5)	53 (48.6)	73 (48.3)	0.002	0.965
Female	134 (51.5)	56 (51.4)	78 (51.7)		

Socio-demographic characteristics of study children's caregivers: The caregivers' ages at baseline ranged from 16 to 45 years. The majority of the care givers, 254 (97.7%), were female. One hundred and seventy-nine (68.8%) had primary education and 175 (67.3%) were married. Christianity was the dominant region comprising 95.8% of respondents. One hundred and thirty-three (59.9%) of the caregivers had lived in the study areas for a period ranging between 4 to 6 years with only 14 (6.4%) having resided in the study areas for a period exceeding 10 years.

With the exception of the duration of residence in the study area ($\chi2$=8.290, df=3, P=0.040), there were no significant differences ($P<0.05$) in the socio-demographic characteristics of respondents between the two study groups. A higher proportion of respondents in the experimental group had lived in the study area for longer durations of time compared to those in the control group. Results of the socio-demographic characteristics of the guardians are shown in Table 2.

Table 2
Distribution of respondents by socio-demographic characteristics

	Study Pop. (n=260) n (%)	ART only (n=109) n (%)	ART + Food (n=151) n (%)	χ^2 value	p value
Age in years					
16-25	54 (20.8)	25 (22.9)	29 (19.2)	1.274	0.529
26-35	158 (60.8)	67 (61.5)	91 (60.3		
36-45	48 (18.5)	17 (15.6)	31 (20.5)		
Sex					
Male	6 (2.3)	3 (2.8)	3 (2.0)	0.165	0.685
Female	254 (97.7)	106 (97.2)	148 (98.0)		
Education attainment					
No formal education	19 (7.3)	12 (11.0)	7 (4.6)	4.575	0.102
Primary	179 (68.8)	75 (68.8)	104 (68.9)		
Secondary	62 (23.8)	22 (20.2)	40 (26.5)		
Marital status					
Single	35 (13.5)	15(13.8)	20 (13.2)	1.799	0.407
Married	175 (67.3)	69 (63.3)	106 (70.2)		
Separated/ Divorced	50 (19.2)	25 (22.9)	25 (16.6		
Religious affiliation					
Christian	249 (95.8)	105 (96.3)	144 (95.4)	0.146	0.703
Other	11 (4.2)	4 (3.7)	7 (4.6)		
Duration of stay in study area					
1-3 years	72 (31.1)	35 (28.1)	77 (26.2)	8.290	0.040
4-6 years	133 (59.9)	53 (45.6)	80 (61.8)		
7-9 years	41 (18.6)	23 (22.8)	18 (15.1)		
>10 years	14 (6.4)	10 (9.9)	4 (3.4)		

Respondents' household characteristics: The average household size was 4 members, with a majority of households (65.4%), consisting of 4 to 6 members. Results of household composition shows that 88.8% of the households had between 1and 3 adult members, 80.8% of the households had children aged 6-17 years and only 1.5% of households had more than 3 children below the age of 5. There were no significant differences in the household size and composition between the study groups ($P<0.05$). Most of the caregivers (82.7%) engaged in casual labour to earn an income in the month preceding the survey. The experimental group had significantly lower incomes (χ^2=17.011, df=2, $P<0.001$) than the control group.

Table 3

Socio-economic characteristics of respondents' household

	Study pop. (n=260)		ART only (n=109)		ART + Food (n=151)		χ^2 value	df	p value
	n	%	n	%	n	%			
Household size									
1-3	44	16.9	20	18.3	24	15.9	1.261	2	0.532
4-6	170	65.4	73	67.0	97	64.2			
7-9	46	17.7	16	4.7	30	19.9			
Number of adults in the household									
1-3	231	88.8	94	86.2	137	90.7	1.288	1	0.256
4 or more	29	11.2	15	13.8	14	9.3			
Number of children 6-17 years									
1-3	210	80.8	88	80.7	122	80.8	<0.001	1	0.99
4 or more	50	19.2	21	19.3	29	19.2			
Number of children below 5 years									
1-3	256	98.5	109	100.0	147	97.4	2.933	1	0.087
4 or more	4	1.5	0		4	2.6			
Source of income in the last month									
None	13	5.0	5	4.6	8	5.3	0.227	3	0.973
Small scale business	26	10.0	11	10.1	15	9.9			
Casual labour	215	82.7	90	82.6	125	82.8			
Regular employment	6	2.3	3	2.8	3	2.0			
Average monthly income									
<1000	59	22.7	11	10.1	48	31.8	17.011	2	**<0.001**
1001-3000	157	60.4	77	70.6	80	53.0			
3001-5000	44	16.9	21	19.3	23	15.2			

Respondents' household food availability: Nearly all (97.7%) respondents purchased their food with no significant difference (P=>0.05) in the proportion of those who purchase food between study groups. However, a significantly higher proportion of respondents (P=<0.001) in the experimental group received food from well-wishers compared to those in the control group. Most of the respondents' (66.2%) daily expenditure on food was less than one hundred shillings with no significant difference between the study groups. Over half of the respondents (56.9%) indicated that the study child consumed three main meals in a day with no significant differences in number of meals consumed by the study children between the study groups. A majority (70.0%) of the respondents' household members consumed similar number of meals as the study child. Results of respondents'' household food availability are summarized in Table 4.

Table 4

Distribution of food availability among respondents

	Study pop. (n=260)		ART only (n=109)		ART + Food (n=151)		χ value	df	p value
	n	%	N	%	n	%			
Source of food for the household									
Purchase	254	97.7	106	97.2	148	98.0	0.165	1	0.685
Well-wishers	64	24.6	13	11.9	51	33.8	16.284	1	<0.001
Daily expenditure on food									
<100	172	66.2	70	64.2	102	67.5	0.853	2	0.653
101-300	77	29.6	33	30.3	44	29.1			
>300	11	4.2	6	5.5	5	3.3			
Meals study child consumes per day									
More than three	89	34.2	32	29.4	57	37.7	2.537	2	0.281
Breakfast, lunch and supper	148	56.9	65	59.6	83	55.0			
Two	23	8.8	12	11.0	11	7.3			
Do other household members eat similar number of meals as study child?									
Yes	182	70.0	82	75.2	100	66.2	2.444	1	0.118
No	78	30.0	27	24.8	51	33.8			

Assessment of dietary pattern among study children: Table 5 details weekly consumption of various food types by children in the two study groups during the three study phases. At baseline, the proportions of children consuming different food groups in ART only group compared favourably to food consumed by children in the ART + food group. Different food types including cereals (87.2% vs. 88.7%; P=0.697), root tubers (91.7% vs. 92.1%; P=0.928), meat (95.4% vs. 94.0%; P=0.628), vegetables (88.1% vs. 94.7%; P=0.053), were consumed in almost equal proportions between the study groups at baseline survey except for vegetables (88.1%vs.94.7% P=0.053).

At midpoint evaluation, there were no significant differences in consumption of the different food types between the study arms (P<0.05). Cereals were used inn almost equal proportions between the two groups (92.7% vs. 91.4%; P=0.711). Results of consumption of other food groups show that root tubers (90.8% vs. 93.4%; P=0.446), meat (94.5% vs. 95.4%; P=0.751), vegetables (91.7% vs. 96.0%; P=0.144), pulses (76.1% vs. 78.1%; P=0.704, and fruits (98.2% vs. 98.0%; P=0.930) were consumed in almost equal proportions between the two study groups.

At end point, proportion of children consuming different food groups in ART only compared to ART + food arm was not significantly different: cereals (95.4% vs. 95.4%; P=0.985), root tubers (86.2% vs. 92.1%; P=0.129), animal products (91.7% vs. 90.7%; P=0.776), vegetables (94.5% vs. 98.0%;

P=0.126), pulses (78.9% vs. 80.1%; P=0.808, and fruits (99.1% vs. 97.4%; P=0.316). The dietary diversity patterns were comparable between the study arms during the three study phases (P=0.331 at baseline; P=0.643 midpoint and P=0.260 end point, respectively).

Table 5

Weekly consumption of food groups among study children by study group

	Baseline			Midpoint			Endpoint		
	ART only (n=109)	ART + Food (n=151)	p value	ART only (n=109)	ART + Food (n=151)	p value	ART only (n=109)	ART + Food (n=151)	p value
	n (%)	n (%)		n (%)	n (%)		n (%)	n (%)	
Cereals	95 (87.2)	134 (88.7)	0.697	101 (92.7)	138 (91.4)	0.711	104 (95.4)	144 (95.4)	0.985
Roots/tubers	100 (91.7)	139 (92.1)	0.928	99 (90.8)	141 (93.4)	0.446	94 (86.2)	139 (92.1)	0.129
Meat	104 (95.4)	142 (94.0)	0.628	103 (94.5)	144 (95.4)	0.751	100 (91.7)	137 (90.7)	0.776
Vegetables	96 (88.1)	143 (94.7)	0.053	100 (91.7)	145 (96.0)	0.144	103 (94.5)	148 (98.0)	0.126
Pulses	85 (78.0)	115 (76.2)	0.731	83 (76.1)	118 (78.1)	0.704	86 (78.9)	121 (80.1)	0.808
Fruits	107 (98.2)	145 (96.0)	0.324	107 (98.2)	148 (98.0)	0.930	108 (99.1)	147 (97.4)	0.316
Dietary diversity score									
Low (1-3)	12 (11.0)	12 (7.9)	0.331	7 (6.4)	6 (4.0)	0.643	5 (4.6)	2 (1.3)	0.260
Moderate (4-5)	21(19.3)	40 (26.5)		32 (29.4)	43 (28.5)		35 (32.1)	47 (31.1)	
High (>5)	76 (69.7)	99 (65.6)		70 (64.2)	102 (67.5)		69 (63.3)	102 (67.5)	

24-hour recall on consumption of three main meals among study children: Results of 24-hour recall on consumption of three main meals and an analysis of whether the food consumed was balanced is as shown in Table 6. At baseline, consumption of the three main meals (breakfast, lunch, and supper) was not significantly different between the ART only and ART + food study arms (88.1% vs. 90.7%; P=0.489). However, a significantly lower proportion of children in the ART + Food arm consumed a balanced diet on the three main meals compared to the ART only arm; breakfast (8.3% vs. 2.0%; P=0.017), lunch (14.7% vs. 4.0%; P=0.002), supper (16.5% vs. 4.0%; P=0.001) at baseline.

Like at baseline survey, there were no significant differences in the proportion of children consuming three main meals (breakfast, lunch, and supper) between the ART only and ART + Food group (82.6% vs. 85.4%; P=0.532). Likewise, there were no significant differences in the proportion of children consuming a balanced diet on the three main meals in the ART only compared to ART + Food (breakfast 3.7% vs. 0.7%; P=0.081, Lunch 5.5% vs. 2.6%; P=0.237 and supper (6.4% vs. 3.3%; P=0.238) during midpoint evaluation.

Consumption of three main meals among children by study groups at end point evaluation was not significantly different between ART only and ART + Food group (81.7% vs. 85.4%; P=0.414). However, the proportion of children consuming a balanced diet on two of the three main meals - breakfast (5.5% vs. 0.7%; P=0.017) and supper (8.3% vs. 2.0%; P=0.017) - was significantly different between the two study groups. A higher proportion of children in the ART only group ate balanced meal for breakfast and supper compared to those in the ART + Food group.

Table 6

24-hour recall and consumption of balanced diet by study group

	Baseline			Midpoint			End point		
	ART only (n=109)	ART + Food (n=151)	p value	ART only (n=109)	ART + Food (n=151)	p value	ART only (n=109)	ART + Food (n=151)	p value
	n (%)	n (%)		n (%)	n (%)		n (%)	n (%)	
Child ate all the three main meals									
	96 (88.1)	137 (90.7)	0.489	90 (82.6)	129 (85.4)	0.532	89 (81.7)	129 (85.4)	0.414
Child ate a balanced diet for breakfast									
	9 (8.3)	3 (2.0)	0.017	4 (3.7)	1 (0.7)	0.081	6 (5.5)	1 (0.7)	0.017
Child ate a balanced diet for lunch									
	16 (14.7)	6 (4.0)	0.002	6 (5.5)	4 (2.6)	0.237	4 (3.7)	3 (2.0)	0.408
The child ate a balanced diet for supper									
	18 (16.5)	6 (4.0)	0.001	7 (6.4)	5 (3.3)	0.238	9 (8.3)	3 (2.0)	0.017

Effect of food support on nutritional status of children: Factors assessed for nutritional status of the study children were grouped into three aspects; stunting, underweight and wasting. The children's anthropometrical measurements were used as the basis for measuring their nutritional status. An analysis of the children's anthropometrical measurements shows that there was no significant difference in mean age between study arms at baseline (P=0.102), midline (P=0.204), and end point (P=0.791). Similarly, there was no significant difference in mean weight between study arms at baseline (P=0.173), midline (P=0.393), and end point (P=0.196). Likewise, analysis of mean height was not significantly different between study arms at baseline (P=0.180), midline (P=0.419), and end point (P=0.606). Table 7 summarizes the anthropometrical parameters of the study children by study group.

Table 7
Mean anthropometrical measurement of study children by study groups

Anthropometric variable	ART only (n=109)		ART+ Food (n=151)		t value	df	p value
	Mean	**SD**	**Mean**	**SD**			
Age in months: Baseline	33.94	16.96	37.5	17.49	-1.641	258	0.102
Age in months: Midline	36.21	15.89	38.88	17.24	-1.273	258	0.204
Age in months: End point	39.82	16.3	40.39	17.9	-0.265	258	0.791
Weight in kgs: Baseline	12.14	4.21	12.87	4.44	-1.367	258	0.173
Weight in kgs: Midline	13.07	4.23	13.51	4.44	-0.856	258	0.393
Weight in kgs: End point	13.97	4.29	14.26	4.47	-1.297	258	0.196
Height in cms: Baseline	87.48	14.92	90.13	15.78	-1.343	258	0.18
Height in cms: Midline	90.36	14.49	91.96	15.12	-0.809	258	0.419
Height in cms: End point	92.47	14.77	94.84	14.36	-0.517	258	0.606

Effect of the food support on stunting among children: Table 8 shows the mean scores of HAZ among children between and within study arms. Mean HAZ scores in the ART only group was -1.33 while that of the ART + Food arm was -1.31 at baseline. The difference was not statistically significant (P=0.956). At midpoint three months later, the HAZ scores between the two arms were not significantly different (-1.08 vs. -1.07; P=0.978). However, the mean HAZ scores in the ART only arm was significantly different from the ART + food arm at end point (-1.17 vs. -0.56; P=0.046).

Table 8

Mean comparison of HAZ scores among children between and within study groups

Indicator	ART only (n=109)		ART+Food (n=151)		t value	df	p value
	Mean	**SD**	**Mean**	**SD**			
HAZ: Baseline	-1.33	2.65	-1.31	2.46	-0.055	258	0.956
HAZ: Midpoint	-1.08	2.5	-1.07	2.33	-0.027	258	0.978
t value	-1.269		-2.254				
p value	0.207		0.026				
HAZ: End point	-1.17	2.44	-0.56	2.35	-2.005	258	0.046
t value	-0.802		-3.983				
p value	0.424		<0.001				

There was no statistically significant difference in HAZ scores at baseline and midpoint (-1.33 vs. -1.08; P=0.207) and at baseline and end point (-1.33 vs. -1.17; P=0.424) within the ART only arm. Analysis of mean HAZ scores in the ART + food arm showed a significant difference between baseline and midpoint (-1.31 vs. -1.07; P=0.026). Similarly, for this experimental group, there was a significant difference between baseline and end point (-1.31 vs. -0.56; P<0.001). The mean HAZ scores at baseline, midpoint, and end point are shown in Figure 1

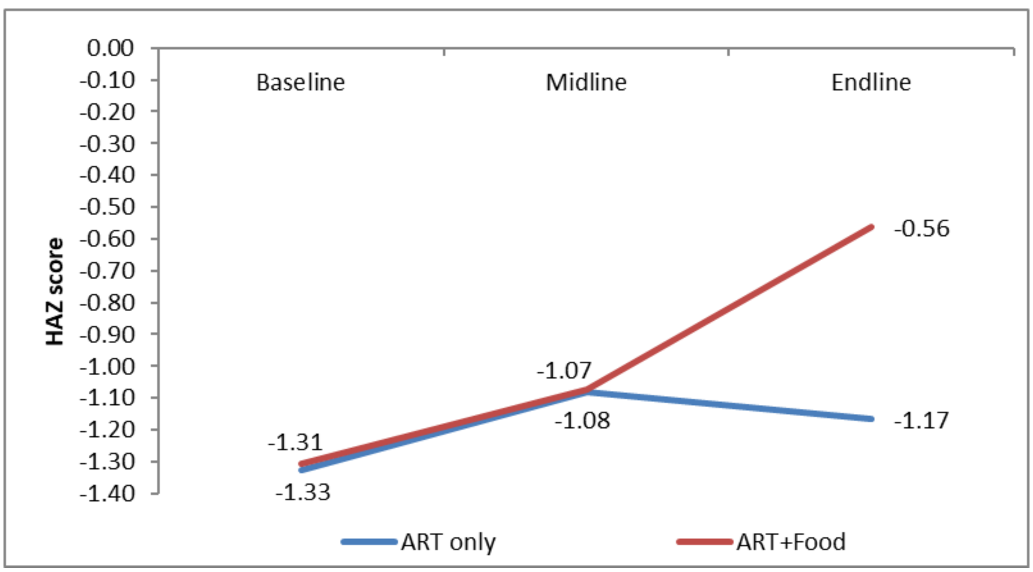

Figure 1: Mean HAZ score among children between and within study groups

Figure 2 shows the cumulative distribution of children by HAZ score between study arms. At baseline and midpoint, the cumulative curves for children on ART only and ART + Food arms overlap. There is no clear difference between the ART only and ART + Food arms. However, at end point, the cumulative curve for children on ART + Food arm shift forward compared to those on ART only.

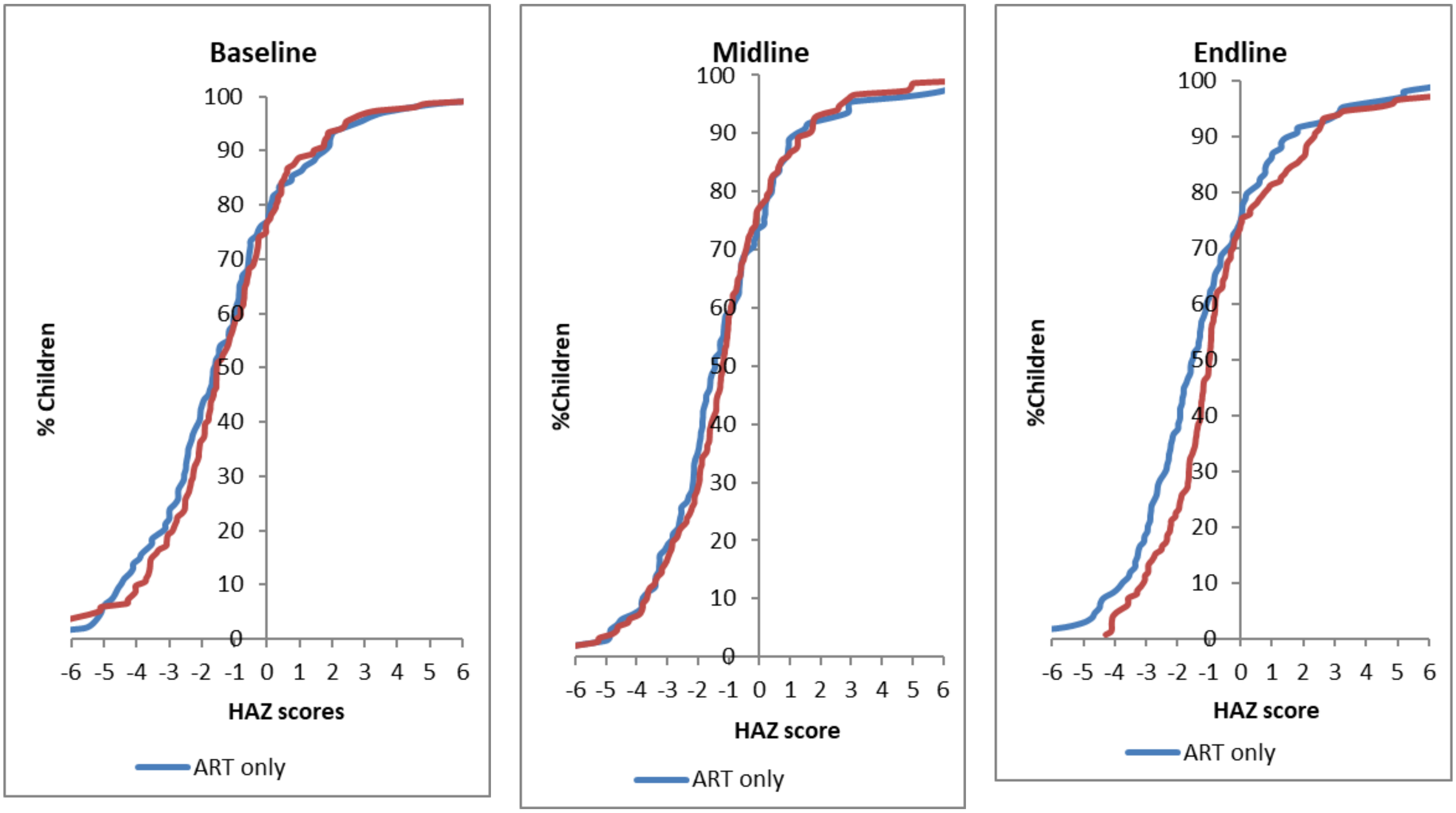

Figure 2: Mean HAZ score of children between study groups

Figure 3 presents cumulative distribution of children by HAZ score within study arms. Considering children on ART only, there is no clear shift of the cumulative curve between baseline and end point. However, there is a clear forward shift of the cumulative curve between baseline and endpoint for children on ART + Food arm.

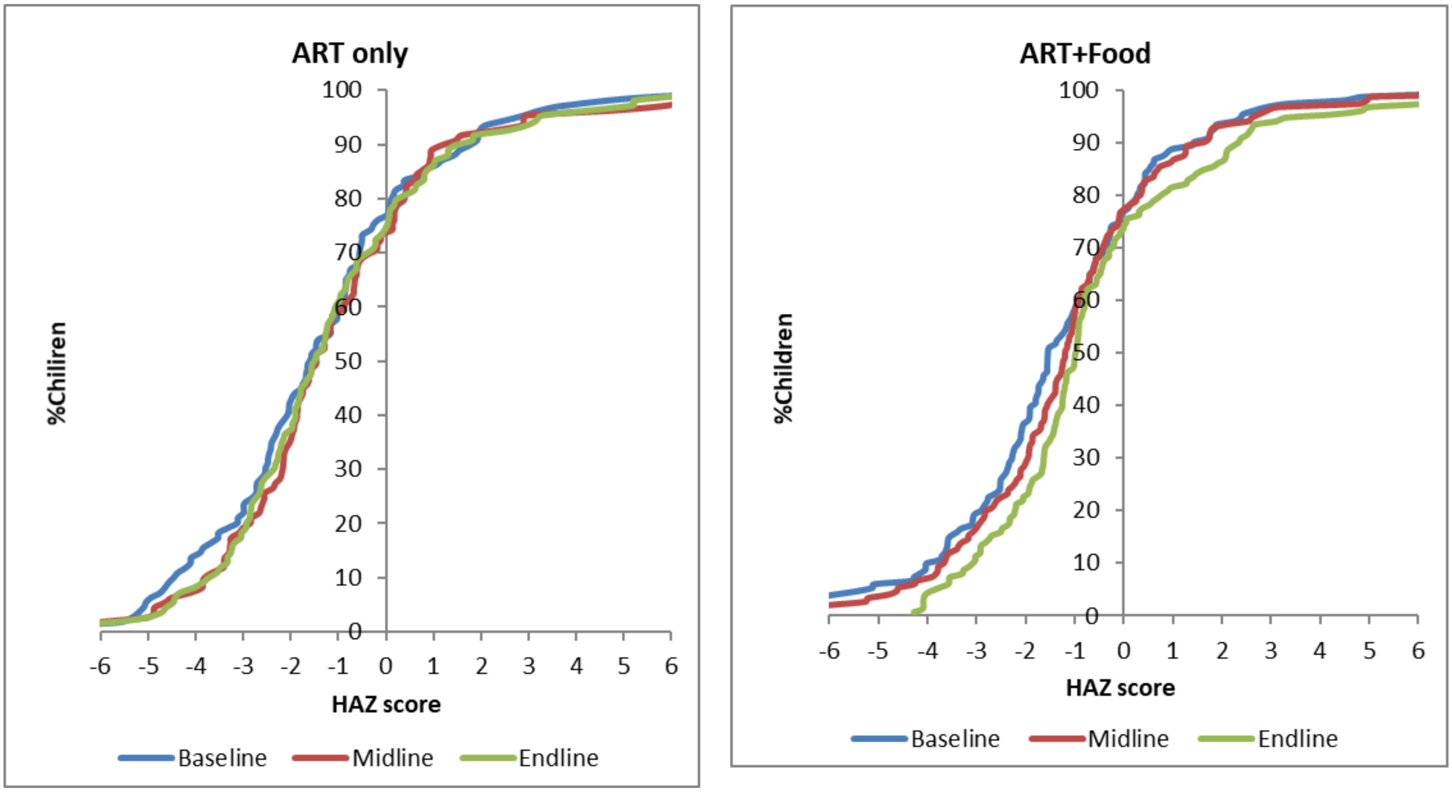

Figure 3: Cumulative distribution of children by HAZ score within study arms

Results of proportion of children with stunting between and within study arms are as shown in Table 9. At baseline, the proportion of stunted children in the ART only arm (42.2%) was not significantly different from that in the ART + Food arm (36.4%), (P=0.346). Analysis after six months of intervention, showed statistical significance in the proportion of stunted children in ART only arm (36.7%), compared to the ART + Food arm (22.5%), (P=0.012).

Table 9

Distribution of stunting among children between and within study arms

Variable	ART only (n=109)		ART + Food (n=151)		χ^2 value	df	p value
	n	%	n	%			
Height for age: Baseline							
Stunted	46	42.2	55	36.4	0.89	1	0.346
Height for age: Midline							
Stunted	38	34.9	44	29.1	0.96	1	0.327
% change: Midline - Baseline		7.3		7.3			
χ^2 value		1.24		1.818			
p value		0.266		0.178			
Height for age: End point							
Stunted	40	36.7	34	22.5	6.252	1	0.012
% change: End point - Baseline		5.5		13.9			
χ^2 value		0.691		7.026			
p value		0.406		0.008			

Within group comparisons demonstrated high performance in ART + Food arm compared to ART only. Within the ART only, the proportion of stunted children decreased insignificantly from 42.2% at baseline to 34.9% (7.3% change) at midline, (P=0.266). Within ART + Food arm for the same duration, the drop from 36.4 % at baseline to 29.1% at midline (7.3% change) was insignificant, (P=0.178). After six months of intervention, the proportion of stunted children decreased insignificantly from 42.2% at baseline to 36.7% (5.5% change) at end point (P=0.406). Within ART + Food arm for the same duration, the drop from 36.4 % at baseline to 22.5% at end point (13.9% change) was significant, (P=0.008).

Table 10 shows the effect of food support on stunting among children at endpoint adjusting for baseline stunting, midpoint stunting, and consumption of balanced diet for the three main meals (breakfast, lunch, and supper). The results showed that food support was significantly protective to children from becoming stunted (AOR=0.44; 95% CI: 0.20-0.98; P=0.044). Adjusting for other factors, a child receiving ART + Food was 56% less likely to become stunted compared to one receiving ART only.

Table 10

Effect of food support on stunting among children at endpoint adjusting for baseline and midpoint stunting, and consumption of balanced diet for the three main meals

	AOR	95% CI Lower	Upper	p value
Study arm				
ART only	1.00			
ART + Food	0.44	0.20	0.98	0.044
Stunting: Baseline				
Stunted	4.81	2.02	11.48	<0.001
Not stunted	1.00			
Stunting: Midpoint				
Stunted	14.93	6.20	35.94	<0.001
Not stunted	1.00			
The child ate a balanced diet for breakfast in the last 24 hours				
Yes	3.10	0.42	22.85	0.266
No	1.00			
The child ate a balanced diet for lunch in the last 24 hours				
Yes	7.15	0.90	56.74	0.063
No	1.00			
The child ate a balanced diet for supper in the last 24 hours				
Yes	0.43	0.06	3.08	0.404
No	1.00			

Effect of food support on underweight among children: Mean comparison for WAZ score among children between and within study arms is presented in Table 4.11. Mean comparison of ART only and ART+ food arm revealed no significant difference between the two study arms at baseline (-1.12 vs. -1.06; P=0.773), midpoint (-0.80 vs. -0.82; P=0.935) and end point (-0.61 vs. -0.46; P=0.477).

Table 11

Mean comparison for WAZ score among children between and within study arms

	ART only (n=109)				ART+food (n=151)						
			95% CI of Mean				95% CI of Mean				
	Mean	SD	Lower	Upper	Mean	SD	Lower	Upper	t value	df	p value
WAZ: Baseline	-1.12	1.82	-1.47	-0.77	-1.06	1.65	-1.32	-0.79	-0.289	258	0.773
WAZ: Midpoint	-0.80	1.82	-1.15	-0.46	-0.82	1.53	-1.07	-0.57	0.082	258	0.935
t value	-2.255				-3.497						
p value	0.026				0.001						
WAZ: End point	-0.61	1.68	-0.93	-0.29	-0.46	1.69	-0.73	-0.19	-0.712	258	0.477
t value	-2.755				-4.852						
p value	0.007				<0.001						

Comparison of WAZ scores between evaluation points within study arms showed significant differences (Table 11). In ART only arm, there was significant difference between baseline and midpoint (-1.12 vs. -0.80; P=0.026). Similarly, there was significant difference between baseline and endpoint (-1.12 vs. -0.61; P=0.007). In the ART+ food arm, significant results were recorded at baseline and midpoint evaluation (-1.06 vs. -0.82; P=0.001), and between baseline and end point (-1.06 vs. -0.46; P<0.001) evaluations. A graphical presentation of mean WAZ scores at baseline, midpoint, and end point are presented in Figure 4.4.

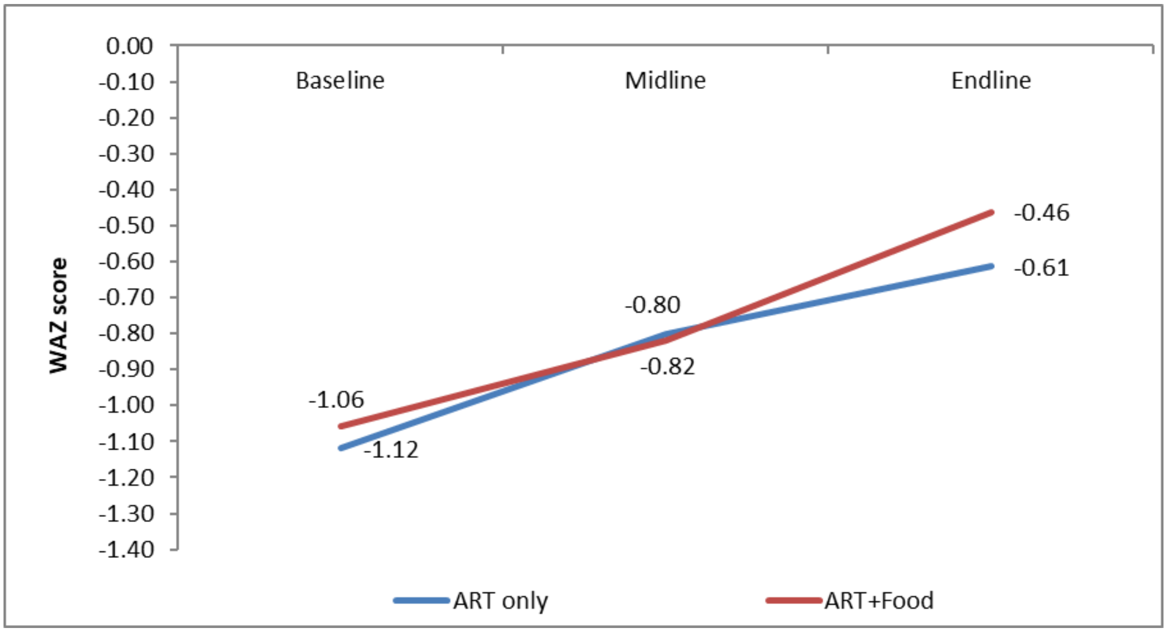

Figure 4: Mean WAZ score among children between and within study arms

Cumulative distribution of children by WAZ score between study arms overlap at baseline, midpoint and endpoint evaluation, with no clear difference between the ART only and ART + food arms (Figure 4.5). However, cumulative distribution of children by WAZ score within study arms show clear forward shift for both study arms between baseline and endpoint evaluation (Figure 6).

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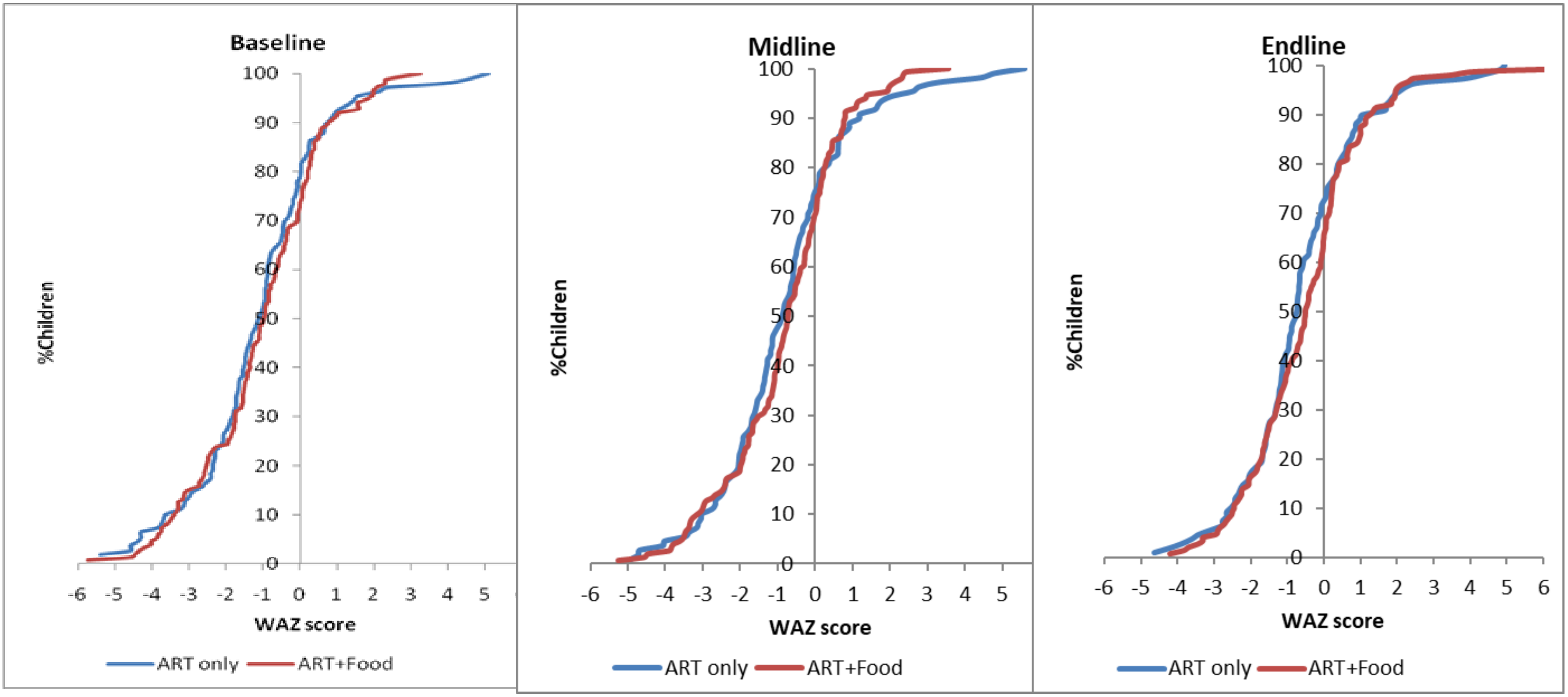

Figure 5: Cumulative distribution of children by WAZ score between study arms

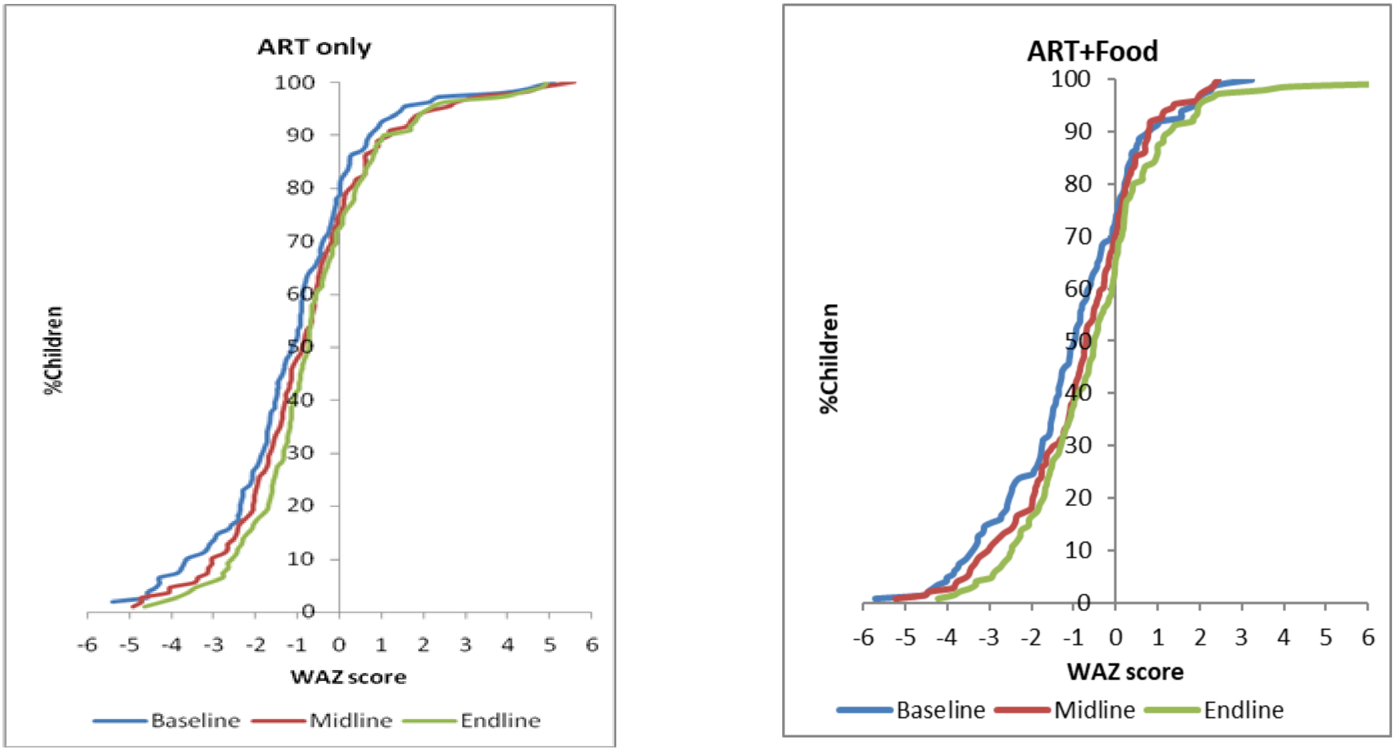

Figure 6: Cumulative distribution of children by WAZ score within study arms

There were no significant differences in the proportion of underweight children between the two study arms at all evaluation points (Table 4.12). At baseline, the proportion of underweight children in ART only arm (26.6%) was not significantly different from the one in ART + food arm (23.8%), (P=0.611). At midpoint evaluation, the proportion of underweight children in ART only arm (22.0%) was not significantly different from the one in ART + Food arm (18.5%), (P=0.489). Similarly, after six months of intervention, the proportion of underweight children in ART only arm (16.5%) was not significantly different from the one on ART + Food arm (15.9%), (P=0.893).

Table 12

Underweight among children between and within study arms

	ART only (n=109)	**ART+Food (n=151)**	**χ^2 value**	**df**	**p value**
	n, %	**n, %**			
Underweight: Baseline	29, 26.6	36, 23.8	0.258	1	0.611
Underweight: Midpoint	24, 22	28, 18.5	0.478	1	0.489
% change: Midpoint - Baseline	4.6	5.3			
χ^2 value	0.623	1.269			
p value	0.43	0.26			
Underweight End point	18, 16.5	24, 15.9	0.018	1	0.893
% change: End point - Baseline	10.1	7.9			
χ^2 value	3.28	2.995			
p value	0.07	0.084			

There was a reduction in the proportion of underweight children in both study arms at all study evaluation points (Table 4.12). However, these proportions were not statistically significant (P>0.05). Within the ART only arm, the proportion of underweight children decreased insignificantly from 26.6% at baseline to 22.0% (4.6% change) at midpoint, (*P=0.430*). Within ART + Food arm for the same duration, the drop from 23.8 % at baseline to 18.5% at midpoint (5.3% change) was insignificant, (P=0.260). After six months of intervention, the proportion of underweight children in the ART only arm, decreased insignificantly from 26.6% at baseline to 16.5% (10.1% change) at end point, (P=0.070). Within ART + Food arm for the same duration, the drop from 23.8% at baseline to 15.9% at end point (7.9% change) was not significant, (P=0.084).

Table 13 shows the effect of food support on underweight among children at end point adjusting for baseline underweight, midpoint underweight, and consumption of balanced diet for the three main meals (breakfast, lunch, and supper). The analysis shows that ART + Food support was not significantly protective to children from becoming underweight compared to ART only (AOR=1.39; 95% CI: 0.51-3.70; P=0.521).

Table 13

Effect of food support on WAZ among children at end point adjusting for baseline and midpoint underweight, and consumption of balanced diet for the three main meals

	AOR	95% CI Lower	Upper	p value
Study arm				
ART only	1.00			
ART + Food	1.39	0.51	3.70	0.521
Underweight: Baseline				
Underweight	3.46	1.12	10.69	**0.031**
Not underweight	1.00			
Underweight: Midpoint				
Underweight	30.77	9.42	100.48	**<0.001**
Not underweight	1.00			
The child ate a balanced diet for breakfast in the last 24 hours				
Yes	0.39	0.02	7.22	0.530
No	1.00			
The child ate a balanced diet for lunch in the last 24 hours				
Yes	2.34	0.04	135.07	0.681
No	1.00			
The child ate a balanced diet for supper in the last 24 hours				
Yes	1.55	0.03	91.76	0.832
No	1.00			

Effect of food support on wasting among children: Analysis of mean comparison between ART only and ART + Food arm revealed no significant difference at baseline (-0.44 vs. -0.37; P=0.695), midpoint (-0.23 vs. -0.23; P=0.981) and endpoint (-0.20 vs. -0.18; P=0.924) (Table 4.18).

Table 14

Mean comparison for WHZ score among children between and within study arms

	ART only (n=109)				**ART+Food (n=151)**						
			95% CI of Mean				**95% CI of Mean**				
	Mean	**SD**	**Lower**	**Upper**	**Mean**	**SD**	**Lower**	**Upper**	**t value**	**df**	**p value**
WHZ: Baseline	-0.44	1.66	-0.76	-0.13	-0.37	1.40	-0.59	-0.14	-0.393	258	0.695
WHZ: Midpoint	-0.23	1.43	-0.50	0.04	-0.23	1.69	-0.50	0.04	0.024	258	0.981
t value	-1.708				-.155						
p value	0.091				0.250						
WHZ: End point	-0.20	1.67	-0.52	0.12	-0.18	1.58	-0.43	0.07	-0.096	258	0.924
t value	-1.433				-1.515						
p value	0.155				0.132						

Intra-study arm analysis showed no statistically significant differences in WHZ for both study arms at all study points (Table 4.14). In the ART only arm, there was no significant difference in WHZ between baseline and midpoint (-0.44 vs. -0.23, P=0.091), and neither between baseline and end point evaluation (-0.44 vs. -0.20; P=0.155). Similarly, analysis within the ART + Food arm showed no significant difference in WHZ between baseline and midpoint evaluation (-0.37 vs. -0.23; P=0.250) and between baseline and end point evaluation (-0.37vs. -0.18; P=0.132). A Mean WHZ scores at baseline, midpoint, and end point are presented in Figure 4.7.

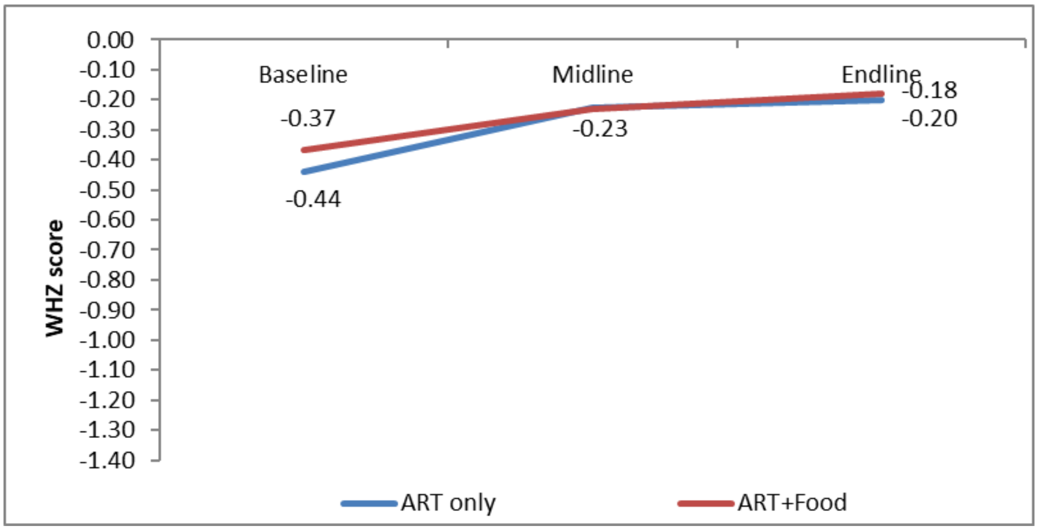

Figure 7: Mean WHZ score among children between and within study arms

Figures 4.8 and 4.9 show the cumulative distribution of children by WHZ score between and within study arms respectively. Cumulative curves for children on ART only and those on ART + Food arms overlap at baseline, midpoint, and end point with no clear difference between the ART only and ART + Food arms (Figure 4.8). Similarly, there is no clear forward shift of the cumulative curve between baseline and end point for children on ART + Food arm.

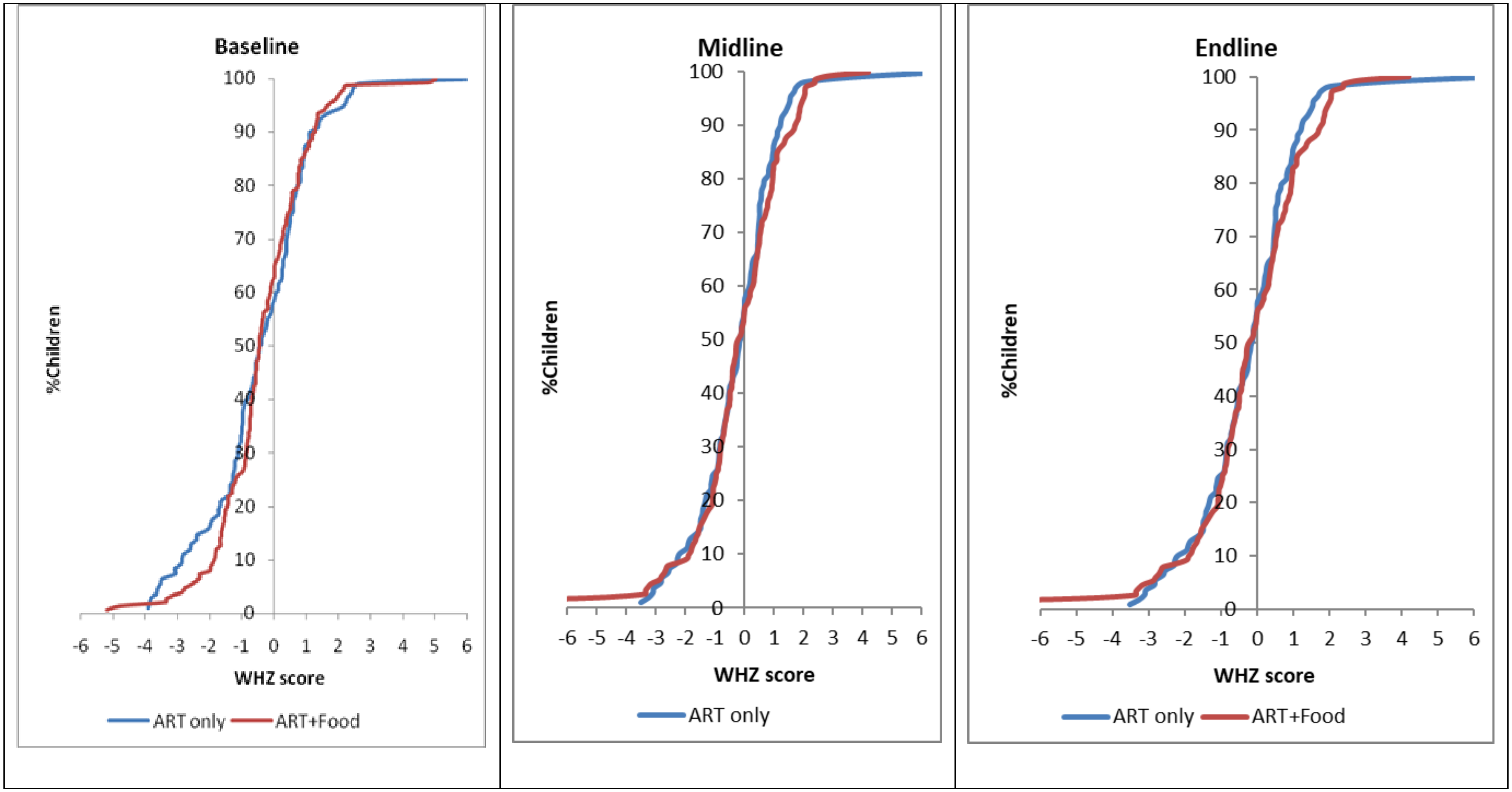

Figure 8. Cumulative distribution of children by WHZ score between study arms

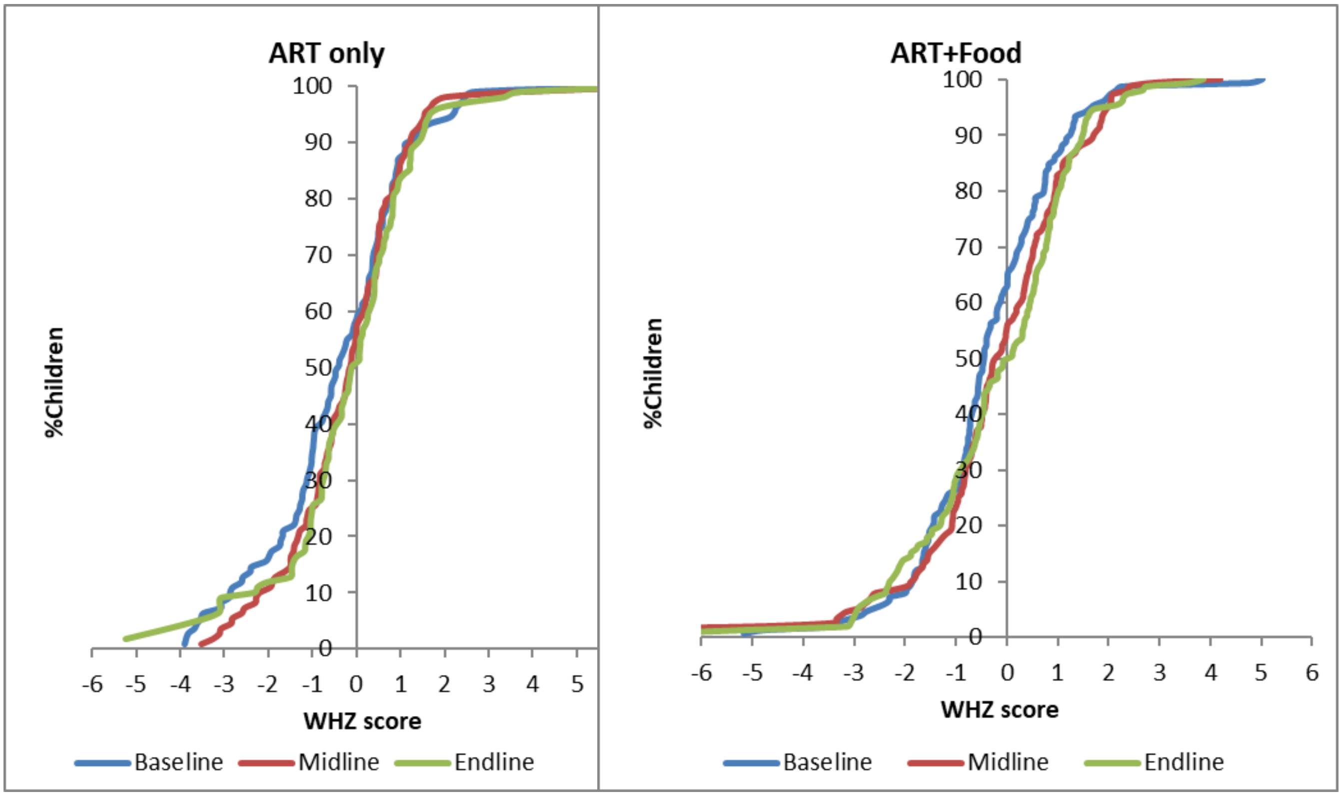

Figure 9: Cumulative distribution of children by WHZ scores within study arms

Results of the analysis on the proportions of wasting among children between and within study arms are as shown in Table 4.15. Between groups comparisons showed no significant differences (P>0.05). At baseline, the proportion of wasted children in ART only arm (15.6%) was not significantly different from the one in ART + Food arm (7.9%), (P=0.053). At midpoint, the proportion of wasted children in ART only arm (10.1%) was not significantly different from the one in ART + Food arm (8.6%), (P=0.684). Similarly, after six months of intervention, the proportion of wasted children in ART only arm (11.9%) was not significantly different from the one on ART + Food arm (13.9%), (P=0.640).

Table 15

Proportion of wasting among children between and within study arms

Variable	ART only (n=109)		ART + Food (n=151)		χ^2 value	df	p value
	n	%	n	%			
WHZ Baseline : Wasted	17	15.6	12	7.9	3.738	1	0.053
WHZ Wasted: Midpoint	11	10.1	13	8.6	0.166	1	0.684
% change: Midpoint - Baseline		5.5		-0.7			
χ^2 value		1.475		0.044			
p value		0.225		0.835			
WHZ Wasted: End point	13	11.9	21	13.9	0.218	1	0.64
% change: End point - Baseline		3.7		-6			
χ^2 value		0.618		2.756			
p value		0.432		0.097			

Intra-study group comparisons showed comparable performance within study arms between evaluation points. The proportion of wasted children in the ART only arm decreased insignificantly (P=0.225) from 15.6% at baseline to 10.1% at midpoint, and to 11.9% at end point, (P=0.432). Within ART + Food arm, the proportion of wasted children at baseline (7.9 %) was not significantly different (P=0.835) with the proportion at midpoint (8.6%). Similarly, the endpoint proportion (13.9%) of wasted children within the ART and Food arm was not statistically different (P=0.097) from the baseline proportion.

Table 16 shows the effect of food support on wasting among children at endpoint adjusting for baseline and midpoint wasting, and consumption of balanced diet for the three main meals (breakfast, lunch, and supper). The analysis showed that food support was not significantly protective of children from becoming wasted (AOR=1.27; 95% CI: 0.54-2.94; P=0.586).

Table 16

Effect of food support on wasting among children at end point adjusting for baseline wasting, midpoint wasting, and consumption of balanced diet for the three main meals

		95% CI		
	AOR	**Lower**	**Upper**	**p value**
Study arm				
ART only	1.00			
ART + Food	1.27	0.54	2.94	0.586
Wasting: Baseline				
Wasted	1.00	0.29	3.44	1.000
Not wasted	1.00			
Wasting: Midpoint				
Wasted	16.69	5.88	47.34	**<0.001**
Not wasted	1.00			
The child ate a balanced diet for breakfast in the last 24 hours				
Yes	UD	UD	UD	0.999
No	1.00			
The child ate a balanced diet for lunch in the last 24 hours				
Yes	0.19	0.01	3.54	0.264
No	1.00			
The child ate a balanced diet for supper in the last 24 hours				
Yes	6.00	0.55	65.46	0.142
No	1.00			

Effect of food support on motor skills among children: Table 17 presents data on noted delays in attainment of the observed motor skills between and within study arms. Between groups comparisons revealed no significant differences in motor skills development. At baseline, the proportion of children with delayed milestones in ART only arm (30.3%) was not significantly different from the one in ART + food arm (26.5%), (P=0.503). At midpoint, the proportion of children with delayed motor milestones in ART only arm (9.2%) was not significantly different from the one in ART + food arm (16.6%), (P=0.085). Similarly, after six months intervention, the proportion of children with delayed milestones in ART only arm (8.3%) was not significantly different from the one on ART + food arm (15.2%), (P=0.091).

Table17

Distribution of recorded delays in child attainment of the concerned milestone between and within study arms

	Total (n=260)		ART only (n=109)		ART+ Food (n=151)		χ² value	df	p value
	n	%	n	%	n	%			
Noted delays in the child attainment of the concerned milestone: Baseline									
Yes	73	28.1	33	30.3	40	26.5	0.449	1	0.503
No	187	71.9	76	69.7	111	73.5			
Noted delays in the child attainment of the concerned milestone: Midpoint									
Yes	35	13.5	10	9.2	25	16.6	2.961	1	0.085
No	225	86.5	99	90.8	126	83.4			
Change: Midpoint - Baseline		14.6		21.1		9.9			
χ² value				15.325		4.411			
p value				**<0.001**		**0.036**			
Noted delays in the child attainment of the concerned milestone: End point									
Yes	32	12.3	9	8.3	23	15.2	2.853	1	0.091
No	228	87.7	100	91.7	128	84.8			
Change: End point - Baseline		15.8		22.0		11.3			
χ² value				16.987		5.797			
p value				**<0.001**		**0.016**			

Within group comparisons demonstrated comparable performance in for both study groups. Within the ART only, the proportion of children with delayed milestones decreased significantly from 30.3% at baseline to 9.2% (21.1% change) at midpoint, (P<0.001). Within ART + food arm for the same duration, the change from 26.5 % at baseline to 16.6% at midpoint (9.9% change) was significant, (P=0.036). Similarly, after six months intervention, there were significant changes in both arms. Within the ART only arm, the proportion of children with delayed milestones decreased significantly from 30.3% at baseline to 8.3% (22.0% change) at end point, (P<0.001). Within ART + food arm for the same duration, the change from 26.5% at baseline to 15.2% at end point (11.3% change) was significant, (P=0.016).

Table 4.18 shows the effect of food support on attainment of motor skills among children at end point adjusting for baseline delay, midpoint delay, and consumption of balanced diet for the three main meals (breakfast, lunch, and supper). The analysis showed that ART + food support was not significantly protective to children from getting delay in attaining motor skills compared to ART only (AOR=1.69; 95% CI: 0.70-4.17; P=0.238).

Table 18

Effect of food support on delay in attaining motor skills among children at end point adjusting for baseline delay, midpoint delay, and consumption of balanced diet for the three main meals

	AOR	95% CI Lower	Upper	p value
Study arm				
ART only	1.00			
ART + Food	1.69	0.70	4.17	0.238
Noted delays in the child attainment of the concerned milestone: Baseline				
Yes	3.18	1.37	7.40	**0.007**
No	1.00			
Noted delays in the child attainment of the concerned milestone: Midpoint				
Yes	4.58	1.84	11.40	**0.001**
No	1.00			
The child ate a balanced diet for breakfast in the last 24 hours				
Yes	2.99	0.08	105.93	0.547
No	1.00			
The child ate a balanced diet for lunch in the last 24 hours				
Yes	0.53	0.02	11.60	0.685
No	1.00			
The child ate a balanced diet for supper in the last 24 hours				
Yes	0.47	0.02	10.97	0.642
No	1.00			

Assessment of disease occurrence among children: Results of occurrence of common childhood diseases was not statistically different between the two study arms during the different evaluation points (Table 4.19). Occurrence of common childhood diseases at baseline was not significantly different between children on ART only and those on ART + food: diarrhea (6.4% vs. 3.3%; P=0.238), cough, common cold and fever (27.5% vs. 21.9%; P=0.293) and vomiting and loss of appetite (33%vs 25.2; P=0.166). Diarrhea was determined by presence of soft and/or watery stool lasting from a few days up to a week.

Similarly, occurrence of disease at midpoint was not significantly different between children on ART only compared to those on ART + food; diarrhea (1.8% vs. 0.7%; P=0.382), cough and fever (13.8% vs. 18.5%; P=0.306) and vomiting and loss of appetite (15.6% vs. 18.5%; P=0.535). Analysis of disease occurrence at end point was not significantly different between children on ART only and those on ART + food; diarrhea (1.8% vs. 0.7%; P=0.382), cough and fever (10.1% vs. 14.6%; P=0.285and vomiting and loss of appetite (11.0% vs. 15.2%; P=0.325).

Table 19

Disease occurrence among children by study arms

	ART only (n=109)		ART+ Food (n=151)		χ^2 value	df	p value
	n	%	n	%			
Baseline							
Diarrhea	7	6.4	5	3.3	1.391	1	0.238
Cough/common cold/fever	30	27.5	33	21.9	1.108	1	0.293
Vomiting/loss of appetite	36	33	38	25.2	1.922	1	0.166
Midpoint							
Diarrhea	2	1.8	1	0.7	0.763	1	0.382
Cough/common cold/fever	15	13.8	28	18.5	1.049	1	0.306
Vomiting/loss of appetite	17	15.6	28	18	0.384	1	0.535
End point							
Diarrhea	2	1.8	1	0.7	0.763	1	0.382
Cough/common cold/fever	11	10.1	22	14.6	1.145	1	0.285
Vomiting/loss of appetite	12	11	23	15.2	0.969	1	0.325

Assessment of CD4 count among children: Mean comparison between ART only and ART + food arm showed significant difference in CD4 counts at baseline (1581 vs. 1378; P=0.060), and end point (1650 vs. 1463; P=0.087) as shown in Table 4.20.

Table 20

Mean CD4 count comparison among children between and within study arms

	ART only (n=109)				ART+Food (n=151)						
			95% CI of Mean				95% CI of Mean				
Indicator	**Mean**	**SD**	**Lower**	**Upper**	**Mean**	**SD**	**Lower**	**Upper**	**t value**	**df**	**p value**
CD4 count: Baseline	1581	730	1421	1742	1378	663	1234	1521	1.891	165	**0.060**
CD4 count: End point	1650	733	1489	1811	1463	671	1318	1607	1.723	165	**0.087**
t value	-0.979				-1.364						
p value	0.330				0.176						

Considering the ART only arm, there was no significant difference between baseline and end point CD4 count among the children (1581 vs. 1650; P=0.330). Analysis of mean comparison within the ART + Food arm showed similar results. There was no significant difference between baseline and end point (1378 vs. 1463; P=0.176).

DISCUSSION

The objective of this study was to assess the effect of a six-month nutrition support intervention on growth and development of HIV-infected children, aged 6-59 months, on ART in limited resource settings. The growth and development indicators measured were nutritional status and motor skills. We also analysed the dietary and morbidity patterns of the study children in recognition that these may have a direct influence on the children's overall growth and development.

Analysis of the 24-hour dietary recall showed no significant differences in consumption of the three main meals for both the experimental and control group at baseline (P=0.489 and end point (P=0.414), but a significant difference at midpoint (P=0.532). Differences were observed in the quality of meals, with a higher proportion of children in the experimental group having lower quality of meals than those in the control group at both baseline and end point. The results of this study showed efficacy of food support only at mid-point. The experimental group registered improvements by having a comparable proportion of children consuming a balanced diet. These finding compare with that of Cheshire *et al.*, (14) who found that the proportion of experimental children who consumed a balanced diet improved significantly during midpoint. The end point findings of this study however also contrast with Chesire's findings that showed significant improvement of food quality at end point. A possible explanation for the difference in sustaining improved quality of meals in this study compared to the Chesire *et al.*, is that the study intentionally focused on nutrition education for their experimental group, whereas the current study had all study groups being provided with nutrition education by virtue of being enrolled in an ART programme. The sudden rise in improvement of food quality at midpoint in this study could have been boosted by the additional element of food rations, which were originally missing in the food insecure households. However, the situation changed again at end point with less proportion of the experimental group compared to the control group consuming a balanced diet on two of the three main {breakfast (5.5% vs. 0.7%; P=0.017), supper (8.3% vs. 2.0%; P=0.017). This finding implies a need for re-assessing the food rations support intervention - mainly conducting follow ups to ensure children receive food supplied, and that other extraneous factors, such as illness, did not interfere with the intended purpose of the rations provided.

Based on outcomes of other studies and programs assessing the effect of food support or HIV-infected in limited resource settings, a number of assumptions can be made to explain the results of this study. First, given that the experimental group was more constrained in their food security situation (hence the food support), the food provided, and which was meant for the infected children was more likely to be shared by other household members, than would be the case with the control group. This assumption is made given evidence from other programs and studies that have shown often programs are targeted to individuals on ART but the food or other nutrition support provided is normally shared within the family (15-17). It is therefore important that reasons for sharing of food support be understood because it is critical to improve targeting of 'therapeutic' foods versus foods intended for general household consumption (15, 18).

Secondly, evidence has shown that providing ready-to-use-therapeutic foods (RUTFs) (a nutrient dense supplement) for HIV-infected individuals and food aid rations to affected family members to serve as buffer for other family members from consumption inadequacy, can potentially result in nutritional gains across the household (19-21). In the case of the current study, food support (food rations as opposed to RUTF) was only targeted at the infected children, thus possibilities of the food not entirely being utilized by the intended child only cannot be ruled out. Thirdly, based on the results of the study, provision of RUTF to HIV-infected individuals can more likely yield higher quantity and quality of calories in terms of the nutrient components than the food basket rations (22).

The overall nutritonal status of childen in both study groups were not statistically different at baseline. The anthropometric measurements of children in the two study arms did not change significantly at midpoint and endpoint. The mean age between study groups (control vs. experimental) was 34 and 38 months (P=0.102) at baseline, 36 and 39 months (P=0.204) at midpoint, and 40 and 40 months (P=0.791) at end point. Similarly, mean weight and height at all measurement points showed insignificant differences. These findings reinforce the homogeneity of the study sample and provided a good basis to compare outcomes of food support. All the study children were not malnourished (not less than -2 Z scores) at baseline. This is due to the study design that excluded malnourished children to enable comparison and effective analysis of the effect of food support. Besides, the malnourished children were provided with a different type of support by the programme such as RUTF, and as such were not included in the sampling frame. Given several findings of nutrition status of children of a similar age and within similar contexts that show compromised nutrition status (23-29) it is evident that the sampled children's nutrition status was way above the normal threshold of resource poor settings. One of the key explanations for this state is the fact that the study children had been enrolled into a comprehensive care HIV programme immediately after birth. By virtue of being in HIV comprehensive care, they were closely monitored and treated thus providing both nutritional and health advantages compared to the aforementioned studies.

Mean WAZ comparison between control and experimental arms revealed no significant difference at baseline (-1.12 vs. -1.06; P=0.773) and end point (-0.61 vs. -0.46; P=0.477). These findings are similar to those in a study conducted in Peru (an area with low HIV prevalence), that found no improvement in WAZ (and HAZ) in children who were given multi-micronutrients (30). In contrast, Mda *et al.,*(23) found that WAZ (and WHZ) over a six month period of multi-micronutrient supplementation among HIV-infected under fives was significantly greater among children who were given supplements in South Africa. It is however worth noting that the two aforementioned studies provided micro-nutrients supplementation whereas the current study offer food support, mainly meant to provide macronutrients.

Mean comparison of WAZ within study arm revealed significant differences between baseline and end point in the control and experimental arms (-1.12 vs. -0.61; P=0.007) and (-1.06 vs. -0.82; P=0.001), respectively. These findings show that there is a greater positive change in WAZ for the experimental arm. It can be concluded that although there were no significant differences between groups, the food support has an effect on the WAZ scores of the experimental arm given the level of significant positive change within this arm compared to the control arm.

Analysis of proportions and significance levels of underweight between the control and experimental group show no significant differences from baseline to end point (*P=0.893*). There was however reduction in the proportion of underweight children in the two groups at end point. In the control group, the proportion of underweight children dropped to 16.5% at end point from a baseline proportion of 26.6%. The proportion of underweight children in the experimental group fell to 15.9% from a baseline of 23.8%. As can be argued for HAZ/stunting, it is apparent that being enrolled in an ART program has positive effect of the nutritional status (growth and development) of HIV-infected children (even when not on food support) as has been shown by Rose *et al.* (31) who found that treatment with HAART is associated with sustained improvement in growth. The finding on WAZ contrast Weigel *et al*.,(32) and Musoke, *et al.*,(33) studies among, HIV-infected children from Malawi and Uganda respectively who found significant improvements in weight-for-age Z-scores within one to two years of HAART initiation.

CONCLUSION

In conclusion, findings of this study show improvement in growth and development parameters of HIV-infected children receiving nutritional support. The significant improvement in growth performance and insignificant differences in morbidities between the groups as observed in this study suggests that nutrition care and support are useful not only as adjunct therapy in HIV-infected children but also on growth and development parameters.

RECOMMENDATIONS

We recommend an integrated approach in antiretroviral programmes not only through the provision of staple foods, but also regular monitoring of actual utilization and effectiveness of the food provided on a regular basis and also by including foods that are age-appropriate for especially under-fives.

REFERENCES

1. World Health Organization. (2012). The strategic use of antiretroviral to help end the HIV epidemic. Geneva: WHO Press.
2. World Health Organization. (2014). Optimizing treatment options and improving access to priority products for children living with HIV. Geneva, World Health Organization.
3. National AIDS Control Council (NACC) & National AIDS & STI Control Programme (NASCOP). (2014). Kenya AIDS Response Progress Report 2014 Progress towards Zero. Nairobi. Government Press.
4. Kellerman, S.E., Ahmed, S., Feeley-Summerl, T., Jay, J., Kim, M. and Phelps, B.R. (2013). Beyond prevention of mother-to-child transmission: keeping HIV-exposed and HIV-positive children healthy and alive. *AIDS*. 27 (2):225-233
5. Brahmbhatt, H., Godfrey, K., Fred, W.M., David. S., Tom, L., Fred, N., Nelson, S., Kiduggavu, Mohamed, K., Maria, W., and Ronald, G. (2006). Mortality in HIV-Infected and Uninfected Children of HIV-Infected and Uninfected Mothers in Rural Uganda. *Journal of Acquired Immune Deficiency Syndromes*: 41(4):504-508
6. Magadi, A. (2011). Household and community HIV/AIDS status and child malnutrition in sub-Saharan Africa: Evidence from the demographic and health surveys. *Social Science and Medicine*, 73(3): 436–446. doi: 10.1016/j.socscimed.2011.05.042
7. World Health Organization. (2013). Guideline: Updates on the management of severe acute malnutrition in infants and children. Geneva, World Health Organization.
8. Prasitsuebsai, W., Kariminia, A., Puthanakit, T., Lumbiganon, P., Siew, M. F. and Annette, H. (2014). Impact of Antiretroviral Therapy on Opportunistic Infections of HIV-infected Children in the Therapeutic Research, Education and AIDS Training Asia Pediatric HIV Observational Database. *Pediatric Infectious Disease Journal.* 33 (7): 747–752
9. Egge, K. and Strasser, S. (2006). Measuring the Impact of Targeted Food Assistance on

HIV/AIDS-Related Beneficiary Groups: Monitoring and Evaluation Indicators. *In AIDS, poverty, and hunger*. Gilespie, Stuart (Ed.). Chapter 16. Pp. 305-324. Washington, D.C.: International Food Policy Research Institute (IFPRI). http://ebrary.ifpri.org/cdm/ref/collection/p15738coll2/id/129582

10. Mahlungulu, S., Grobler, L.A., Visser, M.E. and Volmink, J. (2007). Nutritional Interventions for Reducing Morbidity and Mortality in People with HIV. Cochrane Database System Review. 2007;CD004536
11. Kadiyala, S and Rawat, R. (2014). Food access and diet quality independently predict nutritional status among people living with HIV in Uganda. *Public Health Nutr*: 1–7.
12. Hughes, S.M., Amadi, B., Mwiya, M., Nkamba, H., Mulundu, G., Tomkins, A. & Goldblatt, D. (2013). CD4 counts decline despite nutritional recovery in HIV-infected Zambian children with severe malnutrition. *Pediatrics*, 123:e347–51.
13. Manary, M.J., Ndkeha, M.J., Ashorn, P., Maleta, K. and Briend A. (2007). Home based therapy for severe malnutrition with ready-to-use food. *Archives of Disease in Childhood – British Medical Journals*, 89(6):557-61.
14. Chesire, E.J. (2011). The Effect of an Integrated Nutrition Care Intervention on the Nutritional Status of Children Orphaned and made Vulnerable by HIV/AIDS in Kilifi District, Kenya. Unpublished thesis.
15. The President's Emergency Plan for AIDS Relief (PEPFAR). (2006). Report on food and nutrition for people living with HIV/AIDS. Washington, D.C.
16. Ivers, L.C., Cullen, K.A., Freedberg, K.A., Block, S. and Coates, J. (2009). HIV/AIDS, under-nutrition, and food insecurity. Journal of *Clinical Infectious Disease,* 49: 1096–1102. doi: 10.1086/605573
17. Mamlin, J., Kimaiyo, S.K., Lewis, S.T., Tadayo, H., Jerop, F.K., Gichunge, C., Petersen, T., Yih, Y. and Braitstein, P. (2009). Integrating nutrition support for food-insecure patients and their dependents into an HIV care and treatment program in Western Kenya. *American Journal of Public Health,* 6 (99):215-21.
18. Samuels, F. and Rutenberg, N. (2008). HIV, food and drugs: Livelihoods, nutrition and Anti-retroviral Therapy (ART) in Kenya and Zambia. London: Overseas Development Institute.
19. Sunguya, B.F., Poudel, K.C., Otsuka, K., Yasuoka, J. and Mlunde, L.B. (2012). Ready to Use Therapeutic Foods (RUTF) improves undernutrition among ART-treated, HIV-positive children in Dar es Salaam, Tanzania. *Nutrition Journal,* 2(11):60.
20. FANTA (Food and Nutrition Technical Assistance) Project (2007). Food Assistance Programming in the Context of HIV. Washington, D.C.: Academy for Educational Development
21. LoPriore, C., Guidoum, Y., Briend, A. and Branca, F. (2004). Spread fortified with vitamins and minerals induces catch-up growth and eradicates severe anemia in stunted refugee children aged 3-6 years. *American Journal of Clinical Nutrition*, 80(4):973–81.
22. Oldewage-Theron, W., Dicks, E. and Napier, C. (2009). Poverty, household food insecurity and nutrition: coping strategies in an informal settlement in the Vaal Triangle, South Africa. *Public Health*. 120:795–804.
23. Mda, S., van Raaij, J.M., de Villiers, F.P. and Kok, F.J. (2013). Impact of multi-micronutrient supplementation on growth and morbidity of HIV-infected South African children. *Nutrients,* 5: (30) 4070-4092.
24. Kimani-Murage, E. W., Penny A., Fotso, H.J., Ezeh, A.C., Madise, N.J., Kahurani, E.N., and. Zulu, E.M. (2012). Food security and nutritional outcomes among urban poor orphans in Nairobi. *Journal of Urban Health: Bulletin of the New York Academy of Medicine,* 88, (Suppl. 2): 1054-76.
25. Sunguya, B.F., Poudel, K.C., Otsuka, K., Yasuoka, J. and Mlunde, L.B. (2011). Undernutrition among HIV-positive children in Dar es Salaam, Tanzania: Antiretroviral therapy alone is not enough. *BMC Public Health*, 2011, 11: 869.

26. Olack, B., Burke, H., Cosmas, L., Bamrah, S., Dooling, K. and Feikin DR. (2011). Nutritional status of under-five children living in an informal urban settlement in Nairobi, Kenya. J Health Popul Nutr 29: 357–363.
27. Ndirangu, M., Wariero, J.O., Sachs, S.E., Masibo, F. and Deckelbaum, R.J. (2011). Nutrition Status of under-five Children in HIV-affected Households in Western Kenya. *Food and nutrition Bulletin.* 32 (2): 159-67
28. Nalwoga, A., Maher, D., Todd, J., Karabarinde, A., Biraro, S. and Grosskurth, H. (2010). Nutritional status of children living in a community with high HIV prevalence in rural Uganda: a cross-sectional population-based survey. *Tropical Medicine and International Health*, 15(4):414–422.
29. Matee, M.I, Msengi, A.E., Simon, E., Lyamuya, E.F., Mwinula, J.H., Mbena, E.C., Mbena, E.C., Samaranayake, L.P. and Scheutz, F. (1997). Nutritional status of under fives attending maternal and child health clinics in Dar es Salaam, Tanzania. *East African Medical Journal*.74(6):368-71.
30. Penny, M.E., Marin, R.M., Duran, A., Peerson, J.M., Lanata, C.F., Lönnerdal, B., Black, R.E. and Brown, K.H. (2005). Randomized controlled trial of the effect of daily supplementation with zinc or multiple micronutrients on the morbidity, growth, and micronutrient status of young Peruvian children. *American Journal of Clinical Nutrition,* 79:457–465
31. Rose, A.M., Hall, C.S. and Martinez-Allier, N. (2014) Aetiology and management of malnutrition in HIV-positive children. *Archives of Disease in Childhood,* 99:546-551.
32. Weigel, R., Phiri, S., Chiputula, F., Gumulira, J. and Brinkhof, M. (2010). Growth response to antiretroviral treatment in HIV-infected children: A cohort study from Lilongwe, Malawi. *Tropical Medicine and International Health*, 2010, (15): 934-944.
33. Musoke, P.M., Mudiope, P., Barlow-Mosha, L.N., Ajuna, P. and Bagenda, D. (2010). Growth, immune and viral load responses in HIV-infected African children receiving highly active antiretroviral therapy: A prospective cohort study. *BMC Pediatrics,* 2010, 10: 56.