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The Effect of Community-Based Nutritional Interventions on Children of Women Living With Human Immunodeficiency Virus in Rural India: A 2 × 2 Factorial Intervention Trial

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Background. Malnutrition is a common clinical concern among children in low-income communities affected by human immunodeficiency virus (HIV). We examined the effect of a community-based nutritional intervention on anthropometric and clinical outcomes of children of women living with HIV in rural India.

Methods. We assigned women living with HIV and their child (oldest 3–8 years) to 1 of 4 programs: (1) community-based HIV care program, (2) program 1 + nutrition education, (3) program 1 + food supplement, and (4) all elements of programs 1–3. Study data were collected at baseline and months 6, 12, and 18. We applied mixed-effects modeling with restricted maximum likelihood estimation to examine changes in weight (all children) and CD4⁺ T-cell counts (children with HIV only).

Results. Overall, 600 mother–child pairs were enrolled (150/group) with 100% retention at follow-up visits. Approximately 20% of children were living with HIV. Children in program 4 had higher weight gain than those in programs 1, 2, and 3 at all time points (adjusted $P < .001$). We found a higher increase in CD4⁺ T cells across all time points among participants in programs 3 and 4 compared with program 1 (adjusted $P < .001$). Factorial analysis suggested a synergistic effect of combining nutrition education and food supplements for weight gain but not for increase in CD4⁺ T cells.

Conclusions. A combination of nutrition education and food supplements provided to women living with HIV significantly increased weight and CD4⁺ T cells, and such interventions can be integrated into HIV-care programs in low-income settings.

Keywords. malnutrition; body weight; community intervention; longitudinal follow-up.

The health and development of children of women living with human immunodeficiency virus (HIV) may be impaired by food insecurity, poverty, disability, stigma, and marginalization, as well as limited access to healthcare [1]. These problems are amplified when the children are also living with HIV [2]. Malnutrition is a common condition among people living with HIV and their children in resource-poor settings [3]. Deficiency in nutrients may accelerate the progression of HIV disease [4]. Human immunodeficiency virus infection can also weaken nutritional status through acute or chronic malabsorption, increased energy consumption, and secondary infections [4]. Children living with HIV require

additional caloric and nutrient intake to promote growth and development [5, 6].

We previously developed an HIV treatment-support program delivered by community health workers (referred to as Asha [Accredited Social Health Activist]) under the supervision of nurses [7–9]. This program sought to reduce the effects of stigma, improve social support, and increase HIV/acquired immunodeficiency syndrome (AIDS) knowledge among women living with HIV and their children. We previously showed that adding food supplements and nutrition education to this program significantly improved body mass index (BMI) and CD4⁺ T-cell counts among women living with HIV [8]. Importantly, these improvements were sustained over 18 months after program initiation [7].

Most studies of food supplements among children living with HIV were conducted prior to the widespread use of antiretroviral therapy (ART). To our knowledge, no study has evaluated the effect of providing nutrition education and food supplements to women living with HIV on children's outcomes. The aim of the present study was to examine the effect of a

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community-based nutritional intervention on weight and CD4⁺ T-cell counts in children who are receiving care from women living with HIV in Andhra Pradesh, India.

METHODS

Study Design and Participants

Detailed description of the Asha Nutrition study design and methods can be found in previous publications [8, 9]. The study recruited participants from primary healthcare centers (PHCs) in 2 districts in Andhra Pradesh between April 2014 and November 2016. Women aged 18 to 50 years who had a verified HIV diagnosis, received ART for at least 3 months, and were living with at least 1 child aged 3–8 years were eligible for inclusion in the study. We excluded women who had a CD4⁺ T-cell count less than 100 cells/mm³ and those who participated in our previous Asha interventions. Study participants received approximately US\$172–\$182 during the 18-month study period as compensation for transportation, time, and childcare. All children living with HIV were receiving ART through the India's National AIDS Control Organization pediatric ART program during the study period [10].

The study received approval by the human subjects protection or ethics committees at the University of California Los Angeles, University of California Irvine, All India Institute of Medical Science, and the Ministry of Health in India. All study participants provided written informed consent and assent for their children.

Intervention

All participants received the Asha support intervention, which included 6 group sessions, life-skills classes, and treatment support provided by Asha. Asha are lay women health workers who resided in neighboring villages of study participants and were trained to reinforce health education and medication adherence support to study participants. Participants assigned to program 1 received weekly one-on-one support from an Asha health worker who accompanied them to clinic visits, emphasized the importance of ART adherence, and provided assistance in navigating the health system. Group and individual sessions emphasized caregiving skills, including the following: (1) breastfeeding and sterilizing infant formula, (2) caregiving for family while caring for self, and (3) engaging with children and identifying their needs.

We used a 2 × 2 factorial design to assign participants in 1:1:1:1 ratio to receive 1 of the following 4 programs: (1) Asha support only, (2) Asha support plus nutrition education, (3) Asha support plus nutritional supplement, and (4) Asha support plus nutrition education and nutritional supplement (all elements of programs 1–3). Participants assigned to program 2 were provided with additional educational sessions

guided by nutrition experts about inexpensive food rich in nutrients within the cultural preferences. Healthy recipes were also shared among participants. In lieu of education sessions, participants assigned to program 3 were provided with monthly food supplements for the entire household [8]. Food supplements consisted of high-protein legumes and high-polyunsaturated vegetable oils, with the amount of food based on household size [8]. We aimed to provide sufficient food for an additional 500 kcal (bowl-sized serving) per day for each adult and an additional 250 kcal (half-bowl) per day for each child in the household. The average cost of food supplements was \$12 per month per family over 6 months. Participants assigned to program 4 received all components of programs 1, 2, and 3.

Randomization was done by grouping 16 PHCs into 4 regional clusters of villages that are located close to each other. Each cluster was then randomly assigned to 1 of the 4 intervention programs. It was not feasible to mask the participants and the field staff to intervention cluster assignment.

Procedures

Data were collected during study visits at baseline (pre-intervention) and at months 6, 12, and 18. During each visit, trained research interviewers administered a standardized questionnaire via face-to-face interview using a computer tablet. The questionnaire included sociodemographic questions, clinical history, and psychosocial instruments. We also drew blood samples to measure CD4⁺ T-cell counts for mothers and children living with HIV. Additionally, anthropometric measurements for both mother and child, such as height and weight, were collected by the research staff. All children identified as being underweight were referred to existing government food-ration programs regardless of their intervention group allocation.

Measures

The primary outcomes were changes in weight (all children) and CD4⁺ T-cell counts (among children living with HIV only) at months 6, 12, and 18. CD4⁺ T-cell testing was performed at the Nellore District Hospital using the Act Diff Coulter Analyzer (Beckman Coulter). Household food insecurity was ascertained using the Household Food Insecurity Access Scale, a 9-item scale that assessed the history of food-related experiences during the previous 4 weeks [11]. This scale had an internal consistency coefficient (Cronbach's α) of 0.82 in our study. We ascertained depressive symptomatology using the Center for Epidemiological Studies–Depression Scale (CES-D), short version. This 10-item scale has been used extensively for measuring depression symptomatology in general populations, including in India, with acceptable reliability and validity [12, 13].

Statistical Analysis

We conducted power analysis by drawing assumptions from our pilot study [14, 15]. We assumed an intraclass correlation of 0.05, a moderate effect size (Cohen's $d = 0.48$), and a 90% attrition over 18 months. Cronbach's α was set at 0.01 to account for multiple outcomes tested. We estimated that 150 per group would be needed to achieve 80% power for detecting differences in each intervention group compared with the standard Asha support only (program 1). We did not power the study specifically for HIV-related outcomes among children living with HIV.

For our primary analysis, we used mixed effects modeling with restricted maximum likelihood (REML) estimation [16]. We modeled "Subject ID" as a random intercept variable to account for correlation within individuals. All other variables were specified as fixed effects. Separate models were fitted for each of the primary outcomes: weight and CD4⁺ T-cell count. Two approaches were used to model the effect of the intervention. First, we specified each group category as a dummy variable, with program 1 defined as the reference category to compare the outcomes between each intervention group with program 1 in a single model. Second, we performed factorial analysis by specifying nutrition education and supplements as main-effects variables along with a nutrition education \times supplements interaction term. The interaction term in the multiplicative scale estimates the synergistic effect of the 2 interventions on the outcome [17, 18]. In these models, the estimated coefficient of the interaction term represents the excess effect on the outcome among participants receiving both nutrition education and food supplements than would be expected by the cumulative individual effect of each nutritional intervention. The final model excluded the interaction term if the statistical test for difference of the coefficient from 0 resulted in $P > .10$. For both approaches, the time \times group/intervention interaction term was fitted in each model to estimate the between-group differences in changes in outcome over time.

Covariates were selected based on differences in distribution at baseline, as variables that are differentially distributed in the intervention groups could introduce confounding if they are also associated with the outcome. Age and sex of children were included in the final model regardless of baseline distribution. We included the following baseline variables as covariates for the weight outcome: mother's age, mother's education (none, 1–9 years, and ≥ 10 years), mother's depression symptomatology score, monthly household income, household food insecurity, household size, age of child, and child's HIV status. The model for the CD4⁺ T-cell outcome was fitted for children living with HIV ($n = 120$). This model included the same covariates as above except that child's HIV status was replaced with child's weight. We assessed differences in weight gain by HIV status by fitting the interaction term, HIV \times group \times time. For each model, we calculated unadjusted

and adjusted P values for multiple testing using the Bonferroni method [19]. R version 3.4.4 was used for all analyses [20].

RESULTS

Baseline Characteristics

Overall, 600 (74.8%) of 802 eligible mother–child pairs were enrolled in the study (150 per group). All participants completed follow-up visits at months 6, 12, and 18. Table 1 shows baseline characteristics of all participants by intervention group. Most mothers had received less than 5 years of formal education, and the average monthly household income was less than 2200 rupees (approximately US\$32). Differences in baseline distribution between programs were found for mother's age, household food insecurity, mother's education, and child's sex. Children's baseline mean weight ranged from 19.4 kg in program 4 to 21.8 kg in program 1. Human immunodeficiency virus status was known for all children at baseline. Twenty percent of children were living with HIV, with no differences observed between groups. Among children living with HIV, baseline mean CD4⁺ T-cell counts ranged from 701 cells/mm³ in program 3 to 861 cells/mm³ in program 4.

Effect of Intervention in Children's Weight

Table 2 shows the mean change in children's weight over time in each program adjusted for child's HIV status, sex, and age; mother's age and education; and baseline household food insecurity. For all programs, the greatest weight gain occurred during the first 6 months (intervention period). At 6 months, participants in programs 3 and 4 had higher weight gain from baseline (mean increase, 0.85 and 1.17 kg, respectively; adjusted $P < .001$ for both comparisons) compared with participants in program 1. The mean increase in weight at 6 months was similar between participants in programs 1 and 2 (mean = 0.17 kg; adjusted $P = .648$). Differences in weight between the 4 groups were maintained at 12 and 18 months (postintervention follow-up visits). At 12 and 18 months, differences in weight gain from baseline were higher among participants in programs 2, 3, and 4 compared with participants in program 1 (adjusted $P < .001$ for all comparisons). Participants in program 4 experienced higher weight gain compared with participants in programs 2 and 3 at all time points (adjusted $P < .001$ for all comparisons).

Overall, we found weak evidence of a synergistic effect of nutrition education and supplements on children's weight gain. At months 12 and 18, the estimated coefficients for the interaction terms were 0.20 (95% confidence interval [CI], $-0.03, 0.43$) and 0.27 (95% CI, $0.04-0.50$), respectively. After adjusting for multiplicity, the P values for these terms were 1.000 and .360, respectively.

Children living with HIV had similar weight at baseline compared with those without HIV (21.5 and 20.9 kg, respectively).

Table 1. Characteristics of the Study Participants at Baseline

	Program 1: Asha	Program 2: Asha + Nutrition Education	Program 3: Asha + Nutritional Supplement	Program 4: ASHA + Nutrition Education + Supplement
Mothers' characteristics				
Age, years	36.0 ± 7.0	34.6 ± 6.9	33.6 ± 6.4	32.9 ± 7.2
Education				
No education	85 (56.7)	74 (49.3)	71 (47.3)	62 (41.3)
<5 years	25 (16.7)	29 (19.3)	25 (16.7)	19 (12.7)
5–9 years	24 (16.0)	31 (20.7)	33 (22.0)	35 (23.3)
≥10 years	16 (10.7)	16 (10.7)	21 (14.0)	34 (22.7)
Marital status				
Married	51 (34.0)	67 (44.7)	53 (35.3)	67 (44.7)
Divorced/separated	12 (8.0)	15 (10.0)	12 (8.0)	15 (10.0)
Widowed	87 (58.0)	68 (45.3)	85 (56.7)	68 (45.3)
Household monthly income (rupees)	2110 ± 758.9	2158.7 ± 612.0	2137.3 ± 627.0	2048.0 ± 707.9
Years since HIV diagnosis	3.8 ± 3.2	3.3 ± 2.4	3.6 ± 2.8	3.5 ± 2.9
Food insecurity	20.3 ± 4.3	21.6 ± 2.6	20.8 ± 3.5	21.9 ± 3.0
BMI, kg/m ²	19.7 ± 3.8	20.2 ± 4.0	20.6 ± 4.7	19.9 ± 4.2
CD4 ⁺ T cells, cells/mm ³	442.6 ± 272.7	459.6 ± 284.5	426.2 ± 275.3	461.3 ± 262.8
Children's characteristics				
Age, years	6.9 ± 1.5	7.2 ± 1.4	6.9 ± 1.7	6.6 ± 1.8
Gender				
Male	66 (44.0)	68 (45.3)	74 (49.3)	86 (57.3)
Female	84 (56.0)	82 (54.7)	76 (50.7)	64 (42.7)
Living with HIV	29 (19.3)	31 (20.7)	29 (19.3)	31 (20.7)
Height, cm	119 ± 17	120 ± 14	118 ± 17	114 ± 17
Weight, kg	21.8 ± 7.0	21.1 ± 5.4	21.7 ± 7.0	19.4 ± 6.6
BMI, kg/m ²	15.0 ± 2.4	14.4 ± 1.8	15.4 ± 2.5	14.8 ± 2.5
CD4 ⁺ T cells, ^a cells/mm ³	712.8 ± 257.3	768.4 ± 260.2	700.7 ± 242.3	861.1 ± 310.0

Data are presented as n (%) or mean ± SD. N = 600.

Abbreviations: Asha, Accredited Social Health Activist; BMI, body mass index; HIV, human immunodeficiency virus; SD, standard deviation.

^aAmong children living with HIV with CD4⁺ T-cell counts available at baseline (n = 109).

Similar increases in weight were observed between children living with and without HIV in programs 1, 3, and 4 (Figure 1). In program 2, children living with HIV achieved greater increase in weight than those without HIV at 12 months (0.55 kg; $P = .007$) and 18 months (interaction term = 0.53 kg; $P = .010$).

Effect of Intervention in Children's CD4⁺ T-cell Counts

Table 3 shows the changes in CD4⁺ T-cell counts among children living with HIV by program adjusted for baseline characteristics as described above. The mean increase in CD4⁺ T-cell counts was highest at 6 months for all programs. Mean CD4⁺ T-cell counts continued to increase in all groups at 12 and 18 months, although at lower rates of increase compared with 6 months. We found a higher increase in CD4⁺ T-cell counts from baseline to all time points among participants in programs 3 and 4 compared with those in program 1 (adjusted $P < .001$ for all comparisons). The increase in CD4⁺ T-cell counts among program 2 participants was similar to that for program 1 participants at month 6 (difference = 19 cells/mm³; adjusted $P = 1.000$), and slightly higher at month

12 (difference = 76 cells/mm³; adjusted $P = .090$) and month 18 (difference = 73 cells/mm³; adjusted $P = .120$). Participants in programs 3 and 4 experienced higher gains in CD4⁺ T-cell counts compared with participants in program 2 at all time points (adjusted $P < .001$ for all comparisons). We found minimal differences in increased CD4 counts between programs 3 and 4 at all time points (adjusted $P > .162$ for all).

Factorial models for the CD4⁺ T-cell outcome showed that the unadjusted P values were greater than .10 for all interaction terms tested and were excluded from the final models. Adding nutrition education did not lead to changes in increased CD4⁺ T-cell counts at 6 months compared with Asha support only. However, nutrition education led to greater gains in CD4⁺ T-cell counts at 12 and 18 months compared with baseline (adjusted $P = .015$ and $<.001$, respectively). Adding nutritional supplements to Asha support led to a higher increase in CD4⁺ T-cell counts from baseline at all time points (adjusted $P < .001$ for all comparisons). Six months of nutritional supplements resulted in an increase in CD4⁺ T-cell counts of 197 cells/mm³ (95% CI, 160–234 cell/mm³) at 18 months.

Table 2. Effect of Intervention on Children's Weight Over Time Based on Mixed-Effects Models

	Change From Baseline Mean \pm SD, kg	β (95% CI)	<i>P</i>	Adjusted <i>P</i> ^a
Six months after enrollment				
Individual program comparison				
1. Asha only	1.9 \pm 0.7	Reference		
2. Asha + nutrition education	2.1 \pm 0.9	0.17 (.01, .33)	.036	.648
3. Asha + nutritional supplements	2.8 \pm 0.7	0.85 (.69, 1.01)	<.001	<.001
4. Asha + nutrition education + supplements	3.1 \pm 1.2	1.17 (1.01, 1.33)	<.001	<.001
Factorial analysis				
Nutrition education				
No	2.4 \pm 0.8	Reference		
Yes	2.6 \pm 1.2	0.17 (.01, .33)	.036	.648
Nutritional supplements				
No	2.0 \pm 0.8	Reference		
Yes	3.0 \pm 1.0	0.85 (.69, 1.01)	<.001	<.001
Interaction coefficient	...	0.15 (-.08, .38)	.204	1.000
12 months after enrollment				
Individual program comparison				
1. Asha only	3.0 \pm 0.7	Reference		
2. Asha + nutrition education	3.4 \pm 1.1	0.38 (.22, .54)	<.001	<.001
3. Asha + nutritional supplements	3.9 \pm 0.8	0.86 (.70, 1.02)	<.001	<.001
4. Asha + nutrition education + supplements	4.4 \pm 1.2	1.44 (1.28, 1.60)	<.001	<.001
Factorial analysis				
Nutrition education				
No	3.4 \pm 0.9	Reference		
Yes	3.9 \pm 1.2	0.38 (.22, .54)	<.001	<.001
Nutritional supplements				
No	3.2 \pm 0.9	Reference		
Yes	4.1 \pm 1.0	0.86 (.70, 1.02)	<.001	<.001
Interaction coefficient	...	0.20 (-.03, .43)	.089	1.000
18 months after enrollment				
Individual program comparison				
1. Asha only	3.9 \pm 0.7	Reference		
2. Asha + nutrition education	4.3 \pm 1.0	0.43 (.27, .59)	<.001	<.001
3. Asha + nutritional supplements	4.8 \pm 0.7	0.92 (.76, 1.08)	<.001	<.001
4. Asha + nutrition education + supplements	5.5 \pm 1.2	1.63 (1.46, 1.79)	<.001	<.001
Factorial analysis				
Nutrition education				
No	4.4 \pm 0.9	Reference		
Yes	4.9 \pm 1.3	0.43 (.27, .59)	<.001	<.001
Nutritional supplements				
No	4.1 \pm 0.9	Reference		
Yes	5.2 \pm 1.0	0.92 (.76, 1.08)	<.001	<.001
Interaction coefficient	...	0.27 (.04, .50)	.020	.360

N = 600. Note: All models were adjusted for the following baseline variables—child HIV status, child's sex, age of child, mother's age, household food insecurity, household size, and mother's education.

Abbreviations: Asha, Accredited Social Health Activist; β , coefficient estimate; CI, confidence interval; HIV, human immunodeficiency virus; SD, standard deviation.

^aAdjusted for multiple testing using the Bonferroni method.

DISCUSSION

In the present study, we extended our prior study findings among women living with HIV by examining outcomes among their children enrolled in our study. We found significant improvements in weight gain and CD4⁺ T-cell counts among children whose mothers participated in the nutritional intervention programs. Moreover, differences between programs were maintained across 18 months (12 months after the 6-month intervention period). The combination of food supplements and

nutrition education led to greater improvements in weight gain compared with the combined individual effects of both interventions. In contrast, the combination of nutritional interventions had a similar effect on CD4⁺ T-cell counts compared with food supplements only.

Our findings are consistent with intervention trials of food supplements conducted among malnourished children living with HIV [21–24]. Of those, 1 study among children living with HIV who were not taking ART found that food supplements

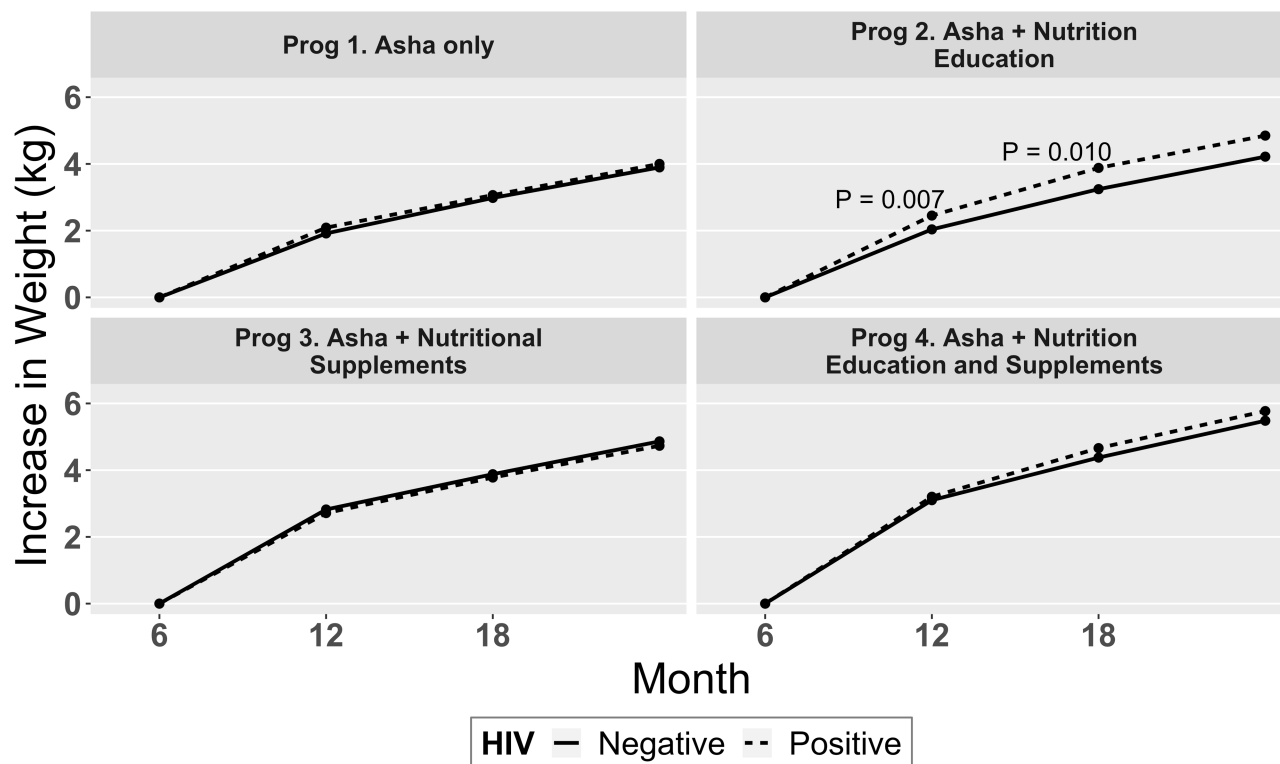


Figure 1. Change in weight over time by HIV status and program among children of mothers living with HIV infection in rural India based on a mixed-effects model (N = 600). Weight was specified as the dependent variable, and HIV × group × time interaction terms were evaluated. Baseline variables included as covariates were child's weight, child's sex, age of child, mother's age, household food insecurity, household size, and mother's education. *P* values < .05 for the difference in weight gain by HIV status are presented in blue. Abbreviations: Asha, Accredited Social Health Activist; HIV, human immunodeficiency virus; Prog., program.

led to significant gains in weight and CD4⁺ T-cell counts [21]. Another study of protein-rich spirulina therapy found that children living with HIV, none of whom were receiving ART, were less likely to gain full nutritional recovery compared with children who were not living with HIV [24]. Our findings add new knowledge by demonstrating that nutritional interventions improve weight and CD4⁺ T-cell outcomes among children receiving ART. Moreover, we observed similar improvements in weight gain between children living with HIV receiving ART and children without HIV in most of the intervention programs. Our findings suggest that food supplements have similar potential for achieving weight gain among children regardless of HIV status in the era of ART.

Interestingly, nutrition education alone was more effective in improving weight gain among children living with HIV compared with children who are not living with HIV. Children living with HIV are at increased risk of wasting from the combination of insufficient nutritional intake and HIV disease [4, 25, 26]. Therefore, mothers of children living with HIV might have had stronger motivation for improving feeding behavior due to heightened concerns about their children's health.

Our findings have significant clinical and public health implications. We show that a combination of nutrition education and

food supplements provided to women living with HIV can achieve significant improvements in children's outcomes in a low-income setting. Moreover, such nutrition-focused interventions can be integrated into community-based ART-adherence programs [7, 8]. Strengths of our study include the use of culturally acceptable, locally available food supplements to address nutritional needs of children of women living with HIV. Thus, our intervention has a high likelihood of sustainability and cultural acceptability.

We note several limitations of our findings. Our study design involved enrolling 1 child per mother, and outcomes of other children are not known. Among children who were not living with HIV, we did not have information on history of perinatal exposure to HIV. Future studies should determine whether the effectiveness of nutritional interventions differ between children with and without HIV exposure. Only 20% of our child participants were living with HIV, which reduced our statistical power for detecting an interaction between the 2 interventions on the CD4⁺ T-cell count outcome. For the weight-outcome models, we were not able to adjust for baseline differences in CD4⁺ T-cell counts, as they were not available for child participants not living with HIV. However, we performed additional analysis among children living with HIV while controlling for CD4⁺ T-cell counts and found no changes in our results (data

Table 3. Effect of Intervention on Children's CD4+ T-cell Count Over Time Based on Mixed-Effects Models

	Change From Baseline, Mean ± SD, cells/mm ³	β (95% CI)	P	Adjusted P ^a
Six months after enrollment				
Individual program comparison				
1. Asha only	304 ± 85	Reference		
2. Asha + nutrition education	328 ± 89	19 (–34, 73)	.484	1.000
3. Asha + nutritional supplements	473 ± 112	162 (109, 216)	<.001	<.001
4. Asha + nutrition education + supplements	497 ± 127	181 (128, 235)	<.001	<.001
Factorial analysis				
Nutrition education				
No	392 ± 131	Reference		
Yes	417 ± 139	19 (–18, 56)	.309	1.000
Nutritional supplements				
No	316 ± 87	Reference		<.001
Yes	485 ± 120	163 (126, 200)	<.001	<.001
12 months after enrollment				
Individual program comparison				
1. Asha only	383 ± 124	Reference		
2. Asha + nutrition education	461 ± 109	76 (22, 129)	.006	.090
3. Asha + nutritional supplements	594 ± 140	209 (155, 262)	<.001	<.001
4. Asha + nutrition education + supplements	652 ± 156	257 (203, 310)	<.001	<.001
Factorial analysis				
Nutrition education				
No	492 ± 169	Reference		
Yes	561 ± 166	62 (24, 99)	.001	.015
Nutritional supplements				
No	423 ± 122	Reference		
Yes	624 ± 150	195 (157, 232)	<.001	<.001
18 months after enrollment				
Individual program comparison				
1. Asha only	493 ± 124	Reference		
2. Asha + nutrition education	578 ± 109	73 (19, 127)	.008	.120
3. Asha + nutritional supplements	705 ± 156	202 (149, 256)	<.001	<.001
4. Asha + nutrition education + supplements	773 ± 172	264 (211, 318)	<.001	<.001
Factorial analysis ^b				
Nutrition education				
No	603 ± 176	Reference		
Yes	680 ± 175	68 (30, 105)	<.001	<.001
Nutritional supplements				
No	537 ± 123	Reference		
Yes	740 ± 167	197 (160, 234)	<.001	<.001

N = 120. Note: All models were adjusted for the following baseline variables: child's weight, child's sex, age of child, mother's age, household food insecurity, household size, and mother's education.

Abbreviations: Asha, Accredited Social Health Activist; β, coefficient estimate; CI, confidence interval; SD, standard deviation.

^aAdjusted for multiple testing using the Bonferroni method.

^bInteraction terms were excluded from the final model as unadjusted $P > .10$ for all interaction terms.

not shown). Last, we did not collect extensive data on cost, and cost-effectiveness was not assessed. However, given the low cost of the food supplements, integrating this intervention into routine HIV programs may be feasible at relatively low cost.

In conclusion, we report promising results from a community-based nutritional intervention trial for children of women living with HIV. We recommend the integration of food supplements and nutrition education into community-based HIV care programs. Future implementation studies, including cost-effectiveness studies, could provide valuable

information for integration of nutritional interventions in HIV programs.

Notes

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Potential conflicts of interest. S. S. S. has received payment for providing statistical consultation to Beckman Coulter, Inc, and Hycor Biomedical. All other authors report no potential conflicts. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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