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A pilot study of food supplementation to improve adherence to antiretroviral therapy among food insecure adults in Lusaka, Zambia

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Abstract

Background: The provision of food supplementation to food insecure patients initiating antiretroviral therapy may improve adherence to medications.

Methods: A home-based adherence support program at 8 government clinics assessed patients for food insecurity. 4 clinics provided food supplementation and 4 acted as controls. The analysis compared adherence (assessed by medication possession ratio [MPR]), CD4, and weight gain outcomes among food insecure patients enrolled at the food clinics to those of controls.

Results: Between May 1, 2004 and March 31, 2005, 636 food insecure adults were enrolled. Food supplementation was associated with better adherence to therapy. 258 of 366 (70%) of patients in the food group achieved an MPR of 95% or greater versus 79 of 166 (48%) among controls (relative risk, RR=1.5; 95%CI:1.2-1.8). This finding was unchanged after adjustment for sex, age, baseline CD4 count, baseline WHO stage, and baseline hemoglobin. We did not observe a significant effect of food supplementation on weight gain or CD4 cell response.

Conclusions: This analysis suggests that providing food to food insecure patients initiating ART is feasible and may improve adherence to medication. A large randomized study of the clinical benefits of food supplementation to ART patients is urgently needed to inform international policy.

Keywords

HIV; adherence; food supplementation; food insecurity; Zambia

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INTRODUCTION

HIV disease causes progressive disability and in its more advanced stages can interfere with an individual's ability to obtain food.[1;2] In Zambia, one-third of the population is "food insecure" – a condition where people lack consistent access to enough food of sufficient variety to meet dietary needs[3] – and nearly one-fifth is infected with HIV.[4] Malnutrition and HIV may interact in a vicious cycle, where malnutrition accelerates immunosuppression and HIV infection worsens malnutrition.[5] Since energy demands are increased by 10% to 30% in HIV-infected adults,[6-9] meeting these caloric needs can be especially challenging in the face of poverty. Poor nutrition may also affect a patient's adherence to antiretroviral therapy (ART) by depriving him or her of the energy to travel to the pharmacy to collect antiretroviral drugs[10] or by potentiating drug toxicity.[11;12] Evidence has shown that micronutrient supplementation can delay HIV disease progression among adults not yet requiring HIV treatment.[13;14]

Observations from developing countries link malnutrition characterized by low body mass index and severe anemia to an increased risk of mortality among patients initiating ART.[15-17] The benefits of providing food supplementation to food insecure individuals on ART, however, have only been speculated[10;18;19] but not tested. The goal of this pilot project was to evaluate the effect of food supplementation on adherence to antiretroviral therapy among food insecure adults initiating ART in Lusaka, Zambia.

METHODS

In May 2004, the Zambian Ministry of Health implemented HIV care and treatment services in Lusaka.[15] Alongside ART service expansion, a number of supporting services were provided, including a home-based adherence support initiative. Linked to the home-based adherence support program, some ART sites received a food donation from the United Nations World Food Programme (WFP). The food supplementation pilot program was launched at 4 sites in September 2004 and later expanded to 4 additional sites 14 months later. The staggered rollout of this activity offered an opportunity to compare adherence and clinical response among food insecure patients starting ART with and without food supplementation available.

HIV-infected patients enroll into care at primary centers in Lusaka as part of the Zambian Ministry of Health's national program for HIV care and treatment. The protocol for clinical care in this program has been described elsewhere.[15;20] In brief, all patients with a confirmed HIV diagnosis undergo physical examination including weight measurement, World Health Organization (WHO) staging, CD4+ T-lymphocyte (CD4) counting with a Beckman Coulter Epics XL and FlowCARE PLG CD4 reagents (Fullerton, CA), and hemoglobin measurement at their initial visit. ART eligibility is determined according to WHO guidelines.[2122] Those starting ART return to the clinic pharmacy each month to collect their drugs. Each pharmacy dispensation includes a 3-day buffer of extra tablets. Clinical visits are performed at weeks 2, 4, 8, and 12, then 3 monthly. A weight measurement, CD4 cell count and WHO staging are performed every 6 months, more frequently if clinically indicated. Clinical and laboratory data are entered into an electronic patient tracking system, which also tracks scheduled and attended clinical and pharmacy appointments.[23]

Patients initiating ART are offered home-based adherence support. This program employs community health workers (CHWs) who visit patients in their homes to monitor and encourage ART adherence. The CHWs begin with daily visits and gradually reduce to monthly visits over a 15 week period. If patients are deemed by the CHW to be having

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difficulty adhering to their prescribed regimen, they are visited more frequently and may be referred to their respective clinics for further assessment and counseling. At the initial home visit, the CHW also performs a household food security assessment, using a standardized instrument that gathers information on income, household size, and food consumption patterns (Table 1).

Food insecure patients receive monthly rations provided by WFP. The initial commitment is for 6 months of food supplementation, with the option to receive an additional 6 months if the household still meets criteria upon reassessment. At the beginning of the pilot program, patients who were not the primary income earners in their households received an individual ration of micronutrient-fortified corn-soya blend and vegetable oil while primary income earners received the same individual ration along with an additional household ration of micronutrient-fortified corn-soya blend, oil, maize meal, and beans sufficient for 6 household members (Table 1). In July 2005, a programmatic change was made to base the ration size solely upon the number of people living in the household, instead of on primary income earner status. Households with fewer than three people received an individual ration while households with three or more people received a ration sufficient for 6 adults.

This analysis takes advantage of a staggered rollout of the pilot food supplementation program to make its comparisons. We classified patients in the 4 clinics assigned to begin ration distribution in September 2004 as the “food” group and patients in the 4 clinics assigned to begin ration distribution at a later time as the “control” group. (NB: eligible patients in the control group were offered food at a later time, once the pilot program became available at their respective clinics, but that intervention occurred after the outcomes we describe in this report had been measured.)

We limited the data to adult (> 15 years) patients on antiretroviral therapy who were food insecure and enrolled in the voluntary home-based adherence support program. Adherence to ART was measured during the first 12 months of therapy by timeliness of pharmacy visits using a variation of the medication possession ratio (MPR).[24;25] We divided the number of days late for pharmacy refills by total days on therapy in the first year, and then subtracted that percentage from 100% to calculate the MPR. We did not count a person as late until after 3 days to account for the extra pills they received. The end product estimates the amount of time that a given patient has medication on hand during the first 12 months of therapy,[26;27] an adherence measure that has correlated with good ART outcomes in both North American and African settings.[28] For purposes of analysis, we dichotomized the outcome into “adherent” (≥ 95% MPR) and “non- adherent” (< 95% MPR).[29]

Since patients accessed food supplementation based upon the clinic they attended, we adjusted for potential correlation of patient characteristics within clinics using hierarchical logistic regression models (SAS GLIMMIX Procedure) for categorical variables[30] and hierarchical linear regression models (SAS MIXED Procedure) for continuous variables,[31] with random intercepts for clinic. To calculate relative risk (RR) estimates, we converted the odds ratio (OR) estimates from hierarchical logistic regression.[32] Analysis of variance was used to calculate adjusted mean changes in weight and CD4 count. All analyses were performed with SAS version 9.1.3 (SAS Institute, Cary, North Carolina). This study was approved by the institutional review boards of the University of Zambia (Lusaka, Zambia) and the University of Alabama at Birmingham (Birmingham, Alabama, USA).

RESULTS

Between May 1, 2004 and March 31, 2005, 8 participating clinics enrolled 1,335 adults into the home-based adherence support program, of whom 636 (48%) met criteria for household

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food insecurity. These included 442 of 881 (50%) at the 4 participating food clinics and 194 of 454 (43%) at the 4 control clinics. At 12 months post ART initiation, 532 patients (84%) remained alive and in the program. The distribution of alive, dead, and withdrawn or lost at 12 months was not significantly different across groups. In the food group, 366 (83%) were alive, 28 (6%) were dead, and 48 (11%) had withdrawn or were lost compared to 166 (85%), 15 (8%), and 13 (7%), respectively, in the control group (p=0.23).

Baseline Characteristics

The 636 food insecure adults were a median of 35 years of age (interquartile range [IQR]: 31, 42) and 414 (65%) were female. The mean (standard deviation [SD]) weight of 411 female patients and 218 male patients with a baseline measure was 52.9 kg (9.9 kg) and 56.1 kg (7.9 kg), respectively. The mean CD4 cell count (SD) among 614 patients with a baseline measure was 131 cells/mm^3 (107 cells/mm^3), with 134 (22%) having fewer than 50 CD4 cells/mm^3. Of 605 patients with baseline hemoglobin measured, the mean (SD) concentration was 10.7 g/dL (2.1 g/dL), with 59 (10%) having a concentration < 8.0 g/dL.

Patients in the food group received a median of 9 monthly rations (IQR: 7, 10). Compared to controls, patients in the food group were somewhat more likely to be severely immunosuppressed but less likely to be WHO stage III or IV. Otherwise, the two groups did not differ according to other measured baseline characteristics: age, sex, hemoglobin concentration, weight, or presence of active tuberculosis (Table 2).

Adherence to Antiretroviral Therapy

Adherence to ART was higher among patients in the food group compared to controls. 258 of 366 (70%) of patients in the food group achieved an MPR of 95% or greater versus 79 of 166 (48%) among controls (RR=1.5; 95% CI: 1.2, 1.7). This finding remained consistent after adjustment for sex, age, baseline CD4 cell count, baseline WHO stage, and baseline hemoglobin concentration (adjusted RR=1.5; 95% CI: 1.2, 1.7; Figure and Table 3).

Clinical Response

We did not observe a significant difference in weight gain or CD4 cell response between individuals in each group. The mean increase in weight adjusted for age, sex, baseline CD4 count, WHO stage, and hemoglobin among the 329 patients in the food group with data available was 5.4 kg (95% CI, 4.7-6.1) at 6 months versus 5.1 kg (95% CI, 4.0-6.2) among 131 patients in the control group (p=0.68). At 12 months, the mean increase in weight adjusted for the same factors among the 302 patients in the food group with data available was 6.3 kg (95% CI, 5.5-7.2) versus 5.4 kg (95% CI, 4.0-6.8) among 113 patients in the control group (p=0.34). This pattern persisted when stratifying by sex, with men trending toward more adjusted weight gain at 12 months, 5.5 kg (95% CI, 4.3-6.7) among 105 men in the food group with data available versus 3.2 kg (95% CI, 1.1-5.3) among 35 men in the control group, (p=0.12) (Table 4).

The mean increase in CD4 cell count adjusted for age, sex, baseline CD4 count, WHO stage, and hemoglobin among the 279 patients in the food group with data available was 154 cells/mm^3 (95% CI, 136-172) at 6 months versus 171 cells/mm^3 (95% CI, 144-198) among 125 patients in the control group (p=0.50). At 12 months, the mean adjusted increase in CD4 cell count among the 241 patients in the food group with data available was 182 cells/mm^3 (95% CI, 160-204) versus 180 cells/mm^3 (95% CI, 147-214) among 105 patients in the control group (p=0.96).

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DISCUSSION

This analysis suggests that providing food supplements to food-insecure patients initiating ART improves adherence. Patients in the food group received a median of 9 monthly rations and were 50% more likely than controls to be adherent, defined here as possessing their medication on at least 95% of days during the first year of therapy. While we did not observe a statistically significant effect of food supplementation on the clinical outcomes of weight and CD4 cell response, there is a trend toward modest benefit, particularly among men.

This pilot study demonstrated the feasibility of food supplementation in the context of a home-based adherence support program and assessed the prevalence of food insecurity among patients starting ART. That 48% of participants met criteria for food insecurity is concerning and, if unaddressed could pose a serious threat to the long-term success of ART programs in impoverished settings such as ours. We have previously reported from the Lusaka cohort that low body mass index among adults[15] and low weight-for-age *Z* scores among children[20] are associated with poor ART survival. This information, coupled with the known relationship between adherence and good long-term ART outcomes, argues strongly for nutrition as an essential component of integrated HIV care and treatment.

A weakness of this study is its small patient numbers and limited follow-up time. This is especially evident in the observed clinical effects. Our available sample size and clustered design has only 19% power to detect a 1 kg increase in weight between groups, and the smallest weight gain we would have 80% power to detect would be 2.9 kg (assuming alpha = 0.05 and intraclass correlation coefficient = 0.01).[33;34] Additionally, the provision of ART without food supplementation is known in this same population to increase weight and CD4 cell count,[12] so isolating the incremental effect attributable to food is difficult in this small non-randomized analysis. Unmeasured confounding is another limitation as we did not record information on access to and consumption of other sources of food. Finally, it is possible that we lack enough follow-up time to observe the full effect of the food intervention, particularly regarding adherence to therapy, where there is known to be considerable delay between poor adherence and failure of the antiretroviral regimens. A definitive study would need to be much larger, have longer patient follow-up, and include virologic suppression as a primary outcome.

These results indicate to us that food insecurity is an important reality for many of our ART patients, and that it extends not only to the individual, but into their entire household. Over the first ten months of the pilot program (approximately half the study period), we provided an individual ration to participants who were not the primary income earners in their household, and a larger, household ration to participants who were. As the study proceeded it became evident to the team that this distinction was not particularly helpful, and that there was considerable sharing of allocated rations among all people living with the primary beneficiary. For this reason, a modification was made to provide a more substantial ration to all (although in neither case was more than 68% recommended daily energy allowance provided; Table 1).

The issue of food sharing, we believe, can explain some of our study findings. Since food is such a valuable commodity, our participants were highly motivated to come to the clinic on time to collect their ration and their medicine (thus, the higher observed adherence). However, if sharing was as common as we believe, it is possible that each patient did not get enough protein-energy to produce additional weight gain relative to those who did not get food. It should be noted that these results were achieved with a locally-available, fortified corn-soya blend. The use of a more calorically dense product, such as Ready to Use

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Therapeutic Food (RUTF, or "Plumpy Nut,") might have produced different results. Although more expensive than corn-soya blend, RUTF can be packaged in small containers, labeled with the patient's name, and even dispensed by the clinic pharmacy. Such "food by prescription" might mitigate to some extend the degree of household sharing and ensure the ART patient receives an adequate supplement.

While this study does not definitely demonstrate a direct clinical benefit of food supplementation on ART outcomes, it does suggest that providing it will substantially improve adherence. It also shows that food supplementation with commodities that are cheap and easily available locally is feasible as part of a comprehensive adherence support program and can be evaluated in a rigorous way. We believe that food insecure people should have food, irrespective of whether it improves measurable ART outcomes. However, there has historically been reluctance among donors to allow funding earmarked for HIV/AIDS treatment to go toward procurement of food. A well designed, randomized study that demonstrated a clear clinical benefit of food supplementation would provide a powerful evidence base from which to advocate for food assistance to become allowable within the context of large medical aid programs, such as those funded by the U.S President's Emergency Plan for AIDS Relief or the Global Fund for AIDS, Tuberculosis, and Malaria. Such a study seems an urgent international priority.

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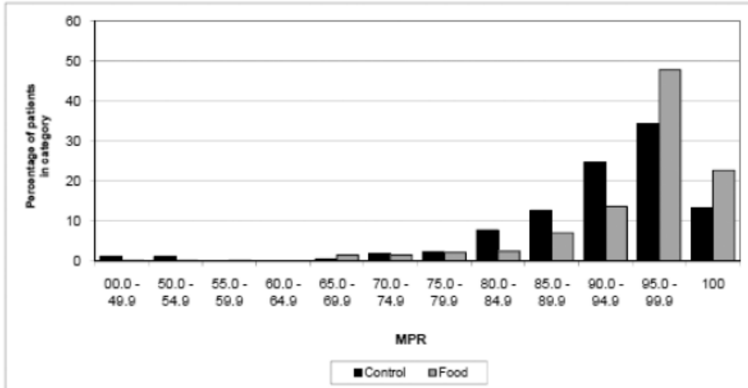

Figure.
Distribution of adherence at 12 months of food insecure patients on antiretroviral therapy by food supplementation category

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TABLE 1

Description of food supplementation pilot program

Selection criteria used to determine food insecurity and eligibility to participate in the food supplementation program

1. Monthly household income less than 50,000 Zambian Kwacha per month (equivalent to ~$10 USD).
2. Patient was the household's primary income earner AND the household's monthly income was less than or equal to K200,000.
3. The household purchased 25 kg of maize meal or less per month AND household size was more than five people.
4. The household purchased 50 kg of maize meal or less per month AND household size was more than 10 people.
5. The respondent reports that during the past month, members of the household cut the size of meals or skipped meals because there was not enough food, daily or every other day.
6. The respondent reports that the food eaten yesterday in the household came exclusively from borrowing, bartering, and and/or gathering in the wild AND at least one of the above criteria was also met.

Ration sizes and nutritional composition

	Individual Ration	Household Ration
High Energy Protein		
Supplement (per month)	6.2 kg	37.2 kg
Oil (per month)	620 ml	1.9 L
Maize (per month)	---	37.2 kg
Beans (per month)	---	3.7 kg
Adult Daily Requirements (WHO)		
Energy (2310 Kcal)	42%	68%
Protein (53 g)	53%	98%
Fat (40 g)	59%	105%

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TABLE 2

Characteristics of food insecure patients on antiretroviral therapy by food supplementation category

	Food Group		Control Group		
Baseline Variables	N	Value	N	Value	p*
Age, mean years (SD)	442	36.5 (8.4)	194	36.4 (8.7)	0.91
≤ 35 years	217	49.1%	101	52.1%	0.10
> 35 years	225	50.9%	93	47.9%	
Sex					
Female	282	63.8%	132	68.0%	0.27
Male	160	36.2%	62	32.0%	
CD4 count, mean cells/mm^3 (SD)	427	132 (115)	187	129 (87)	0.96
≥ 50 cells/mm^3	325	76.1%	155	82.9%	0.02
< 50 cells/mm^3	102	23.9%	32	17.1%	
WHO Stage					
I or II	92	21.0%	30	15.5%	0.02
III or IV	347	79.0%	164	84.5%	
Hemoglobin, mean g/dL (SD)	429	10.9 (2.1)	176	10.3 (1.9)	0.06
≥ 8.0 g/dL	389	90.7%	157	89.2%	0.99
< 8.0 g/dL	40	9.3%	19	10.8%	
Weight, mean kg (SD)					
Female	279	53.1 (10.5)	132	52.5 (8.6)	0.57
Male	158	56.2 (8.5)	60	55.9 (6.0)	0.80
BMI, mean kg/m^2 (SD)					
Female	171	21.0 (4.2)	101	20.8 (3.3)	0.78
Male	101	19.6 (2.6)	48	19.7 (2.2)	0.95
Anti-tuberculosis Therapy					
No	353	79.9%	164	84.5%	0.31
Yes	89	20.1%	30	15.5%	

* p-values are calculated to account for the effect of clustering inherent in the study design [see methods]

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TABLE 3

Relative risk of being adherent* at 12 months among food insecure patients on antiretroviral therapy**

Variables	Crude Relative Risk (95% CI) n=532	Adjusted Model Relative Risk¶ (95% CI) n=487
Food Supplementation Category		
Control Group	1.0	1.0
Food Group	1.5 (1.2-1.8)	1.5 (1.2-1.8)

*defined at 12 months of therapy as MPR ≥ 95% [see methods]

**using PROC GLIMMIX to produce ORs and then converting to RRs[30]

¶adjusted for age, sex, baseline CD4 count, WHO stage, and hemoglobin.

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TABLE 4

Clinical responses at 6 and 12 months among food insecure patients on antiretroviral therapy*

	Food Group		Control Group		
	N	Value	N	Value	p**
Weight gain, mean kg (95% CI)					
Total					
6 Month	329	5.4 (4.7-6.1)	131	5.1 (4.0-6.2)	0.68
12 Month	302	6.3 (5.5-7.2)	113	5.4 (4.0-6.8)	0.34
Men					
6 Month	114	4.8 (3.7-5.8)	39	4.9 (3.1-6.8)	0.90
12 Month	105	5.5 (4.3-6.7)	35	3.2 (1.1-5.3)	0.12
Women					
6 Month	215	5.7 (4.8-6.6)	92	5.1 (3.7-6.5)	0.50
12 Month	197	6.8 (5.7-7.9)	78	6.4 (4.6-8.2)	0.71
CD4 count increase, mean cells/mm^3 (95% CI)					
6 Month	279	154 (136-172)	125	171 (144-198)	0.50
12 Month	241	182 (160-204)	105	180 (147-214)	0.96

*overall models are adjusted for age, sex, baseline CD4 count, WHO stage, and hemoglobin while sex specific models are adjusted for age, baseline CD4 count, WHO stage, and hemoglobin

**p-values are calculated to account for the effect of clustering inherent in the study design [see methods]