The impact of a food assistance program on nutritional status, disease progression and food security among people living with HIV in Uganda

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Note to readers

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ABSTRACT

Background

Although the last decade has seen significant increases in access to anti-retroviral therapy (ART) across the developing world, widespread food insecurity and undernutrition where the HIV epidemic is most severe compromises an effective response to the epidemic. Although the relationship between food insecurity, undernutrition, and HIV has been well established, limited data exist on the potential benefit of food security and nutrition interventions to people living with HIV (PLHIV).

While policy makers have long acknowledged the potential for food security interventions to mitigate the effect of the HIV/AIDS epidemic, after more than 10 years of experience in integrating food assistance into HIV care and treatment programs, there remains a dearth of evidence on the impacts of food assistance to people living with HIV (PLHIVs), particularly from sub-Saharan Africa where there is a large geographic overlap between food insecurity and HIV. Consequently, recent reviews have highlighted the need for additional research.

There are currently no randomized controlled trials of the impact of food assistance in an HIV program context. This is likely due to the challenges of randomizing individuals or groups of individuals to a control group while at the same time adhering to programming and funding guidelines that target food assistance to eligible individuals, typically within the catchment area of an HIV clinic. When randomization is not feasible, we must therefore turn to quasi-experimental approaches that try to establish a valid counterfactual.

Methods

We capitalize on an established arrangement of a food-based intervention to HIV infected individuals, between The AIDS Support Organization (TASO) in Uganda, an HIV care and treatment program, and the World Food Programme (WFP), to design and conduct a prospective quasi-experimental study evaluating the impact of a monthly household food basket, provided to food insecure ART naive HIV-infected individuals for 12 months.

Our design and analytical techniques are more rigorous than previous published studies. We recruit matched intervention and comparison subjects, based on a set of program eligibility criteria and use difference-in-difference propensity score matching methods to estimate the impact of food assistance. This matching method attempts to control for all observable differences between groups, except the presence or absence of food assistance. Furthermore, we carry out impact estimates for a comprehensive range of outcomes that include nutritional status, disease progression, and food security outcomes.

Results

The primary outcomes of interest were nutritional status (Body mass index (BMI); mid-upper arm circumference (MUAC), and hemoglobin status (Hb)), disease severity (CD4 count), and two measures of food security - diet quality (Individual Dietary Diversity Score (IDDS)) and food access (Household Food Insecurity Access Scale (HFIAS)). We utilize difference-in-difference propensity score matching to examine the impact of food assistance. We find significant positive impacts on nutritional status; food assistance significantly increased BMI by 0.6 kg/m^2 ($p< 0.01$), and MUAC by 6.7 mm ($p<0.05$). We

found no impact of food assistance on CD4 count, Hb concentrations, or IDDS. However, when restricting the analysis to individuals with CD4 counts >0 cells/uL, food assistance resulted in large significant impacts on Hb concentrations (improvements of approximately 1 g/L; $p<0.05$). At the household level, food assistance improved food security, reducing HFIAS by 2.1 points ($p<0.01$).

Conclusions

This study contributes needed evidence of the impact of food assistance targeted to PLHIV on their nutritional status and food security outcomes. It is among only a handful of rigorously designed studies that examine this, and is the first in sub-Saharan Africa, where the overlap of HIV and food insecurity is greatest, to demonstrate impacts on both nutritional status and food security. While policies and programs of food assistance within the context of high HIV and food insecurity are widespread, they are justified on only scant evidence regarding the impacts of such integrated models.

By carrying out the study in a routine program context, and in coordination with one of the largest providers of food assistance in the region, the results are valuable to programmers and have a degree of external validity they would not have had if the evaluation had altered program design. By restricting initial enrollment to individuals ineligible for ART, based on CD4 counts, and excluding individuals who subsequently went on ART, this study examined the potential beneficial role of a food and nutrition security intervention during a critical disease stage where CD4 counts were low, but not yet low enough to meet the eligibility criteria for ART.

While the past few years have seen a dramatic expansion of ART access across sub-Saharan Africa, significant challenges to universal access remain. Food insecurity remains a critical barrier to both access and adherence to ART. This study demonstrates the benefit of food assistance in the absence of ART, and highlights the potential for food assistance programming to be part of the standard of care for PLHIV in areas of widespread food insecurity.

Key words: HIV infection, nutrition, food assistance, food security, Uganda

INTRODUCTION

Though the last decade has seen significant increases in access to anti-retroviral therapy (ART) across the developing world [1, 2], widespread food insecurity and undernutrition in eastern and southern Africa, where the HIV epidemic is most severe, continue to complicate an effective response. The evidence on the interconnectedness between HIV/AIDS, food insecurity, and undernutrition is substantial [3-6]. Lack of food security and poor nutritional status may hasten progression to AIDS-related illnesses and undermine adherence and response to antiretroviral therapy. HIV infection itself undermines food security and nutrition by reducing work capacity and jeopardizing household livelihoods.

With mounting evidence that HIV prevention, care, and treatment is being compromised by food insecurity and undernutrition, national governments and international agencies now recognize the importance of integrating food and nutrition security interventions into their response to the HIV/AIDS epidemic [13-15, 17]. For example, the United States government's President's Emergency Plan for AIDS Relief (PEPFAR) recently developed the nutrition assessment, counseling, and support (NACS) approach, which aims to improve the nutritional status of individuals and populations affected by HIV (FANTA 2012). The NACS framework includes strengthening the capacity of facility- and community-based health care providers to deliver nutrition-specific services while linking clients to nutrition-sensitive interventions provided by the health, agriculture, food security, social protection, education, and rural development sectors. This framework, and others [18, 19], can guide programs and policies toward a more comprehensive and therefore more effective response to the HIV/AIDS epidemic.

Presently, several HIV/AIDS service providers in sub-Saharan Africa already incorporate food and nutrition security interventions into their programming. While policy makers and program implementers acknowledge the potential for food security interventions to mitigate the effects of the HIV/AIDS epidemic, even after more than 10 years of programmatic experience, there is little evidence on the impacts of food assistance on PLHIV. Recent reviews identified only a small number of food-based supplementation studies in HIV/AIDS care and treatment programs in developing county settings and highlighted the need for additional research [20-22]. For example, to our knowledge, currently there are no randomized controlled trials (RCTs) of the impact of food assistance in an HIV program context. While such RCTs remain the gold standard for evidence generation, implementing them in routine program settings brings substantial challenges associated with randomizing individuals to a control group while at the same time adhering to ethical, programming, and funding guidelines that may have limited flexibility, for example, with respect to altering eligibility criteria.

When randomization is not feasible, we must turn to other approaches to establish a valid counterfactual. With careful planning, it is possible for researchers to work within routine program operations to conduct an evaluation that incorporates a strong design and applies rigorous statistical methods to estimate the causal impact of such interventions. Such evaluations, of program effectiveness rather than efficacy, reflect the real-world operating environment of many implementing organizations. Consequently, this type of evidence is especially valuable in guiding programs and policies as they integrate food-based interventions into the expansion of programs tackling the HIV/AIDS epidemic.

Policies on HIV, food security and nutrition

Addressing food security and nutrition in all settings is vital to achieving the goal of universal access to HIV prevention, treatment, care and support, to which all Member States of the United Nations have committed themselves. In 2002, the World Food Program (WFP) deployed a four-country mission to rethink food aid in the context of the AIDS epidemic in eastern and southern Africa. Then, in 2005, the World Health Organization (WHO), in partnership with National Institutes of Health (NIH), held a consultation in Durban, South Africa. Following this consultation RENEWAL/IFPRI also convened a conference in Durban, South Africa in 2005. These consultations resulted in a number of recommendations on integrating food security and nutrition as a critical component of a comprehensive global AIDS response. They culminated in a resolution approved by the World Health Assembly in May, 2006. The e-forum in 2006 leading up to the second partnership forum of the Global Fund to Fight AIDS, Tuberculosis and Malaria urged the Global Fund to consider nutrition a critical "complementary health product." This growing emphasis was sustained in the 2011 United National General Assembly declaration that recognized the need for ART to be complemented with food and nutrition support.

In line with this shift in the policy dialogue acknowledging the importance of food and nutrition security, several policies and frameworks have been advanced to aid the integration of such programs into a comprehensive responsive against the AIDS epidemic. While each of these takes a slightly different approach, a similar line of thought flows through all; improvement in food and nutrition security of people infected with the virus and affected by the AIDS epidemic can address prevention as it may decrease risky behaviors, it can be seen as part of a care and treatment package as it may improve drug adherence and decrease morbidity, and it can mitigate

socioeconomic impacts as it decreases stress on household human, economic and physical and social capital. In short, food and nutrition security are necessary aspects of sustainably and holistically addressing the epidemic.

Along these lines, in 2008 UNIADS published a policy brief outlining their understanding of and approach to HIV, food security and nutrition. It discussed the implications for food and nutrition security on prevention, treatment and care, support and impact mitigation. Furthermore, it recommended that international partners support the incorporation effective food and nutrition interventions—such as school feeding, cash transfers, and livelihood interventions—into multisectoral HIV programming.

Similarly, WFP's 2010 policy on HIV and AIDS envisions "a world in which nutritional support is integrated into treatment programmes so that food-insecure people on anti-retroviral therapy (ART) in low-income countries receive adequate nutritional support". Their HIV and AIDS policy framework addresses two main objectives. The first is ensuring nutritional recovery and treatment success through nutrition and food support. Program activities to meet this objective include nutrition assessment, education and counseling, as well as the provision of nutrition supplementation for undernourished people living with HIV during the first six months of antiretroviral treatment. The second is mitigation of the effects of AIDS through safety nets wherein the WFP provides food assistance, usually in the form of a household food basket, to help mitigate the socio-economic effects of the disease on individuals and families.

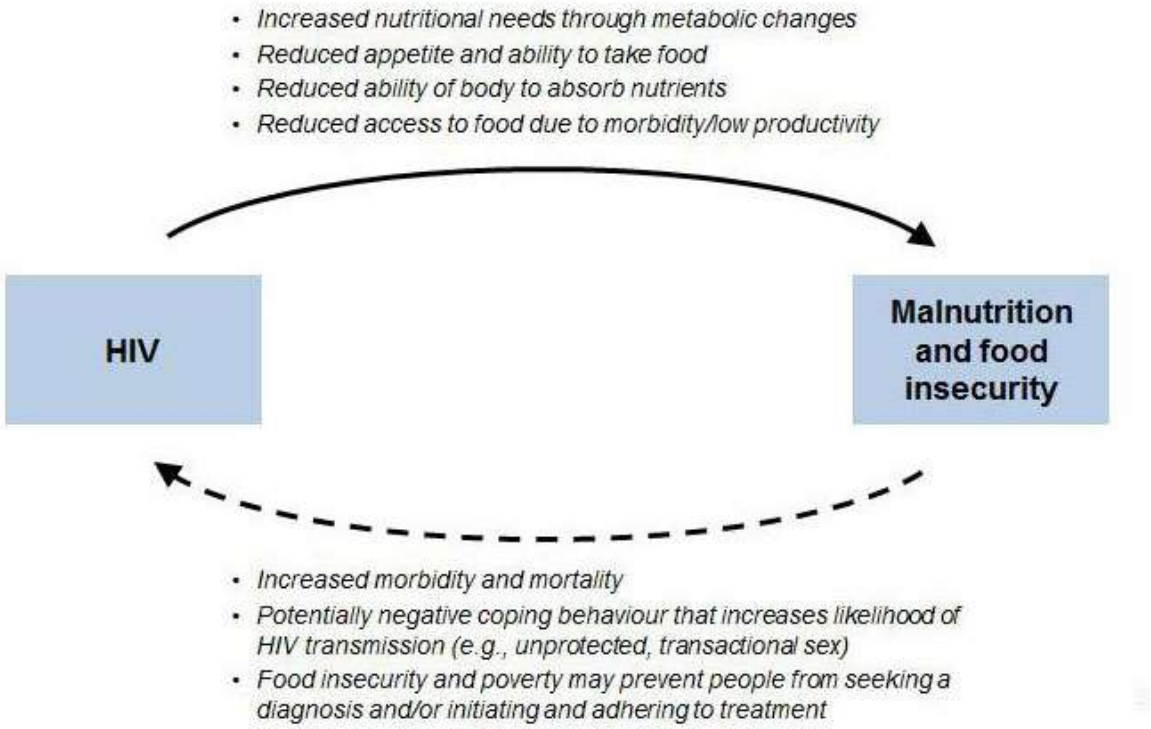
Another example is the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) nutrition assessment, counseling, and support (NACS) approach. The NACS approach specifies four components: nutrition assessment, nutrition counseling, nutrition support and referral. Referral refers to nutrition-sensitive interventions that can help improve food security and nutritional status, thereby improving health outcomes. The framework emphasizes the strengthening of links between nutrition-specific services and those provided by the health, agriculture, food security, social protection, education, and rural development sectors for more comprehensive care.

Together these policies and frameworks show a clear indication that in the last decade global recognition of the importance of food and nutrition in addressing the AIDS epidemic has grown.

Program Theory of Food Transfer Programs within the Context of HIV/AIDS

In addition to the well-documented negative impacts of HIV/AIDS on food security and other socioeconomic outcomes [1,2,7], there is growing recognition that food insecurity and undernutrition contribute to poor health outcomes among people living with HIV (PLHIV) (Figure 1) . For PLHIV, wasting and undernutrition are strong risk factors for mortality [8, 9], even among people receiving ART [10-12]. Recent evidence from Uganda indicates that food security and diet quality are associated with undernutrition and quality of life among PLHIV [13, 14], and that diet quality is inversely associated with disease severity and mortality [15]. Food insecurity is also a significant barrier to prevention [16], access to care and treatment services [8, 9], and adherence to ART [10-12].

Figure 1: HIV and Nutrition



Source: WFP HIV and AIDS policy, WFP (http://www.wfp.org/hiv-aids/hiv-and-nutrition)

Adults with HIV have 10–30% higher energy requirements than a healthy adult without HIV, and children with HIV 50–100% higher than normal requirements. Food availability and good nutrition are thus essential for keeping people with HIV healthy and able to resist opportunistic infections.

Therefore, International organizations such as the WHO, Joint United Nations Programme on HIV/AIDS (UNAIDS), WFP, Food and Agriculture Organization (FAO), and PEPFAR have recommended integration of food assistance into AIDS care and treatment programs. Likewise, organizations involved in HIV care and treatment are increasingly utilizing targeted food assistance. The AIDS Support Organization (TASO), the largest indigenous non-governmental organization providing comprehensive HIV prevention and AIDS care and support services in Uganda. With 11 centers across the country, it reaches 100,000 PLHIV annually.

There are two prevalent types of food supplementation programs. The first type is nutrition supplementation programs, which typically involve the provision of specialized foods given to undernourished people living with HIV (usually BMI<18.5 Kg/m^2) or those experiencing rapid weight loss specifically aimed at undoing the nutritional damage due to the HIV infection for about six to eight months. These programs aim to treat undernutrition, reduce early mortality, as well as act as an enabler for people living with HIV to access and adhere to treatment, and thereby to improve health outcomes.

The second type—food assistance programs—are targeted to food insecure people living with HIV and their households (and/or people affected by the epidemic, such as the orphans and vulnerable children). The duration of the food assistance is variable, usually ranging between 6 -12 months. The hypothesized benefits to PLHIV from such programs include: 1) improved nutritional status 2) slowed disease progression 3) improved food security 4) improved health status and quality of life, and 5) improved ART adherence and retention in care and 6) mitigate immediate socioeconomic impact of HIV. ***This program model is the focus on our study.***

TASO Intervention Being Evaluated

Recognizing the interconnectedness between HIV prevention, care, and treatment and food and nutrition insecurity, TASO began partnering with organizations such as WFP to provide food supplementation to food insecure HIV-infected clients in the early 2000s. WFP distributed monthly household food rations for 12 months to registered HIV-positive TASO clients, eligible for food assistance based on WFP's poverty assessment criteria. The criteria used to determine eligibility cover the following domains:

household composition, ownership of valuable assets, employment status and income, housing characteristics, and past experience of food insecurity. The **primary objectives** of the intervention are to: 1) improve the nutritional status of the TASO client, and to 2) improve household food security.

Continued food assistance eligibility is conditional on remaining a TASO client and maintaining routine contact with a TASO social support officer. The WFP standard food basket (consisting of 200g of maize meal, 40g of pulses, 10g of vitamin A fortified vegetable oil, 5g salt, and 50g corn-soy blend per person per day for up to 7 adult HH members) provides approximately 1100 kcal/day for up to 7 adult household members.

Evaluation Objectives

We capitalized on an existing food-based intervention for ART naïve PLHIV in Uganda, coordinated by The AIDS Support Organization (TASO)—a large HIV care and treatment organization—and the World Food Program (WFP), to design and conduct a quasi-experimental longitudinal study evaluating the impact of food assistance in the form of a monthly household food basket on **three key outcomes**. These included the stated program objectives of: 1) improved nutritional status of targeted PLHIVs, and 2) improved food security using two dimensions of food security: diet quality and food access; as well as the theoretical considerations of intervention benefit which includes 3) decreased disease progression that we measure using CD4 counts.

METHODS

Study Design

To evaluate the impact of the food assistance in the form of this monthly household food basket , we conducted a 12-month, quasi-experimental, longitudinal study nested within the routine programmatic context of both TASO and WFP in two districts in northern Uganda. The study districts, Gulu and Soroti, are both highly food insecure, with a history of conflict and displacement. TASO operated under standard procedures in both districts. At the time the study was initiated, however, WFP operated only in Gulu and not in Soroti. Thus, Gulu served as the intervention district and Soroti the non-randomized comparison district. Study participants from Soroti were recruited based on meeting the program eligibility criteria for food assistance that was in place for Gulu district.

We estimated that a sample size of 180 HIV-positive individuals in each of the two study arms was sufficient to detect a minimum increase in 1) BMI of 0.5 kg/m^2, assuming a standard deviation of 1.9 kg/m^2, 2) CD4 count of 30 cells/μL, assuming a standard deviation of 100 cells/μL, and 3) Hb of 0.5

g/dL, assuming a standard deviation of 1.5 g/dL. The calculation was made for a one-sided test (assuming that nutritional supplementation would not be detrimental to these outcomes) and based on specificity (1-α) of 95% and power (1-β) of 80%. This sample was increased to 405 to accommodate a design effect of 2.25. Allowing for a 10% loss to follow-up, we recruited 450 individuals per study arm. This sample size also allowed us to detect changes in two additional outcomes: individual dietary diversity [23] and household food access [24].

We recruited HIV-positive non-pregnant adults (over 18 years of age), during their visits to the TASO clinics in Gulu and Soroti, using the following criteria: 1) initial eligibility for food assistance based on WFP's poverty assessment criteria 2) non-receipt of food assistance in the previous 12 months 3) CD4 count between 200 and 450 cells/μL and 4) ART naïve. Names and contact information of study participants in Gulu were given to WFP after baseline interviews were completed. Food distribution, conducted at a location away from the TASO clinic, began 7–30 days after recruitment and lasted 12 months. On average, the value of the food basket to beneficiaries was approximately 1/3 of pre-program monthly household food expenditures.

Surveys

Multipurpose individual and household level surveys were administered to study participants, at baseline recruitment and at 12 months follow-up. Upon recruitment, an individual questionnaire was administered to the study participants in a private room at the TASO clinic. Additionally, the study team took anthropometric measurements and a TASO laboratory technician drew blood for CD4 count and hemoglobin assessments. Then, within approximately 7 days, a study team member visited the home of the participant to administer the household questionnaire. The study team was trained to maintain strict confidentiality and did not refer to TASO or the HIV status of the study participant in the household interview.

The protocol was the same for the 12-month follow-up interview. We were unable, however, to re-interview all study participants (a full) 12 months after recruitment. Two developments outside our control necessitated either earlier than 12-month follow-up interviews, or exclusion, for some participants: 1) individuals beginning ART in either district, which may have been accelerated by the 2010 increase in the WHO recommended CD4 count criteria from 200 to 350 for ART initiation; and 2) another organization offering food assistance to select individuals in the comparison district after study initiation. We re-interviewed as many of the affected individuals as possible prior to receipt of ART or receipt of food assistance. Consequently, for a small percentage of those re-interviewed (8%), fewer than 9 months had elapsed since baseline. If a follow-up interview prior to receipt of food assistance in the

comparison group or ART was not feasible, the individual was considered as lost-to-follow up and not re-interviewed. Baseline interviews were conducted between August 2008 and October 2009, and follow-up interviews between August 2009 and October 2010.

Statistical Analysis

The principal outcome variables include changes in BMI (kg/m^2), MUAC (mm), and hemoglobin concentration (g/dL) as measures of nutritional status, CD4 count (cells/μL) as a measure of disease progression, and diet quality using the Individual Dietary Diversity Score (IDDS)([23] and food access using the Household Food Insecurity Access Scale (HFIAS) [24], as measures of food security.

To estimate the impact of the food assistance intervention on the outcomes of interest, we employed non-experimental matching techniques combined with difference-in-difference estimators [25]. We compared the change over time in outcomes for individuals in the intervention district with the change over time for matched individuals in the comparison district. This approach is increasingly used to estimate impacts of food assistance and other anti-poverty programs when randomization is infeasible or unethical [26-30] The approach also has been used in analyses assessing the impact of prime age adult mortality and HIV/AIDS on households [31, 32].

First, guided by theoretical considerations and exploiting the rich individual and household survey data, we determined a set of "balance" variables on which the matches would be based (**Table 1**), including baseline values of the key outcome measures. The variables were chosen to have predictive power for the outcomes under study and for whether individuals were receiving food assistance (i.e., whether living in Gulu district [33-36].

Second, we constructed a propensity score for each individual. The propensity score model was the logit of living in the intervention district as explained by all of these variables. In cases of missing values for CD4 or hemoglobin, we imputed the baseline values using sample medians for this model. We transformed some of the underlying variables and then calculated the logit so that the distributions of the variables for each quantile of the propensity score were statistically the same across intervention and comparison individuals, a procedure referred to as balancing [37, 38].

We then used the propensity score, as well as a subset of the balance variables (logarithmic per capita expenditures, the food share, and the time between surveys), to match each individual in the intervention district to the most similar individual, or "nearest neighbor," of the same gender in the comparison district [25]. The estimated average treatment effect on the treated, then, is the difference-in-difference in mean outcomes over 12 months for the intervention group compared to the matched comparison group. We

allowed matching with replacement, therefore a single comparison individual could be matched to more than one treatment individual and thus the matched comparison group includes repeated observations of some individuals. To calculate the standard errors, we implemented a heteroskedasticity robust variance estimator developed for this nearest neighbor matching technique [25].

One concern is that despite all of these controls there still may have been different unobservable trends in the two districts influencing nutritional status or disease progression, but not captured by our matching variables. We therefore replicated the above analyses on a subsample for which in addition to baseline CD4 count we had available a prior CD4 measurement (from TASO records). Using this earlier measurement, we calculated the average monthly change in CD4 count prior to the baseline and included it as an additional matching variable (second row for select outcomes in **Table 3**). In this analysis, then, we control for prior trends in disease progression for each individual. We do this only for the outcomes most likely to be influenced by such trends—the individual level nutritional outcomes.

We also undertook several analyses to assess the sensitivity of the results to the choice of methodology and matching variables used because estimates may be sensitive to these factors [38]. These included the following: 1) Alternative matching methods such as nearest neighbor matching with between 1 and 5 neighbors. In general, there is a tradeoff between bias and statistical precision in nearest neighbor matching; single neighbor matching is the least biased but greater precision is gained when there are more matches (that is, when matching a single intervention individual to his or her 2 or more nearest neighbors in the comparison group). Results reported in **Table 3** are from nearest neighbor matching with the 1 and, separately, 3 nearest neighbors. 2) Alternative sets of matching variables, for example including all of the balancing variables directly in the matching procedure (as opposed to including only the propensity score and a subset of the variables), while always matching exactly on gender. 3) Alternative subsamples, in particular limiting to the sample for which estimated propensity scores were between 0.1 and 0.9 only. And, (4) an alternative estimation procedure using Gaussian kernel matching based only on the estimated propensity scores and with bootstrapped standard errors using 1000 replications [38, 39]

All analyses were carried out using Stata version 12 [40]. We set statistical significance at a two-tailed $P<0.05$.

Ethics statement

The ethics review boards of TASO, the Uganda National Council on Science and Technology (UNCST), and the International Food Policy Research Institute (IFPRI) approved the study protocol. Interviewers read consent forms to study participants, who gave signed informed consent.

RESULTS

Between August 2008 and October 2009, we recruited a total of 904 study participants from the intervention and comparison districts, and followed up 640 participants between August 2009 and October 2010 (**Figure 1**). We did not re-interview individuals who, during the study period, began ART (190 individuals, 21.0%), lived in the comparison district and had been provided food assistance from another program (25 individuals, 2.8%), could not be tracked (20 individuals, 2.2%), or died (29 individuals, 3.2%).

Baseline characteristics are presented for the intervention group (Column A), the full comparison group (Column B), and the weighted matched comparison group (Column C) (**Table 2**). Average baseline characteristics for the intervention and weighted matched comparison groups are very similar for most indicators, providing evidence of the credibility of the matching exercise. There are two significant differences between the treatment and matched comparison (age and HFIAS), but both are relatively small (less than 0.2 standard deviations). For the intervention district, the average time between surveys was 11.8 months. Over three quarters of the study participants were female. The mean highest grade completed was less than 5 years and just over 40% of the study participants reported being married at the time of the study. Mean BMI and hemoglobin concentration at baseline were 20.9 kg/m^2 and 12.6 g/dL, and the mean baseline CD4 count was 356 cells/μL. The mean IDDS was 3.7 food groups and the mean HFIAS score was 16.3.

We generated a propensity score of the probability of receiving food assistance, and used it to match individuals in the intervention group to the most similar individual, or "nearest neighbor" of the same gender in the comparison group and then calculated difference-in-difference matching estimates of the average impact of food assistance on the outcomes of interest (**Table 3**). For each outcome, we present impact estimates for the complete sample. In addition, for the nutritional status outcomes, which are likely to have been influenced by prior CD4 levels, we present estimates that control for prior CD4 trend on the sub-sample for whom that prior trend data is available.

At follow-up, we find that food assistance had significant positive impacts on nutritional status. Food assistance increased BMI by 0.6 kg/m^2 and MUAC by 6.7 mm. These results were larger in magnitude, though less significant, when controlling for CD4 trend (estimates based on half of the total sample). They were also similar, and more highly significant, when matching to the 3 nearest neighbors. We find no statistically significant impact of food assistance on hemoglobin or CD4 count. However, there were large and significant impacts on hemoglobin concentration (increases of approximately 1 g/dL; results not presented) when restricting the analysis to individuals with CD4 counts >350 cells/μL.

Turning to food security, there was no statistically significant effect on individual dietary diversity, based on previous day consumption of the 9 different food groups measured in the IDDS. Consumption of the food group categories containing two of the components of the food basket (beans and cooking oil), however, showed statistically significant improvements. At the household level, we find large significant decreases in food insecurity as a result of the intervention; the mean HFIAS score decreased by 2.1 points, equivalent to an approximately 50 percentage point reduction in the probability of being designated as severely food insecure.

DISCUSSION

While many have theorized about the potential benefits of integrating food assistance into HIV care and treatment programs operating in food insecure areas, and such combined program models have been widely implemented, there is little evidence documenting their impacts. Notably absent are rigorous impact studies of food based interventions nested within otherwise routine HIV care and treatment program settings. We investigated the impact of a WFP food assistance program within an HIV programmatic context, on nutritional, clinical, and food security outcomes among PLHIV not yet receiving ART. We demonstrated that food assistance, provided to ART naïve PLHIV in northern Uganda, significantly improved BMI, MUAC, and household food security, compared to a matched comparison group receiving otherwise similar HIV care and treatment. We found no impact of food assistance on CD4 count, Hb concentrations, or IDDS. Restricting the analysis to individuals with CD4 counts >350 cells/uL, however, food assistance resulted in large significant impacts on Hb concentrations.

Our study contributes to the literature in three important ways. *First*, it is one of only a handful of studies investigating the impact of food assistance to adult PLHIV in a developing country context [30, 41-43]; and the first to focus exclusively on ART-naïve adult PLHIV. *Second*, our design and analytical techniques are more rigorous than previous published studies. We recruit matched intervention and comparison subjects, based on a set of program eligibility criteria and use difference-in-difference propensity score matching methods to estimate the impact of food assistance. In addition to avoiding any selection bias or confounders associated with several explicit eligibility criteria (including HIV status, receipt of TASO services, and eligibility for WFP food assistance), using rich survey data, we attempt to control for all other observable differences between groups, except the presence or absence of food assistance. *Third*, it is comprehensive in its examination of a broad range of outcomes of interest in HIV and food security programming that include nutritional status indicators (BMI, MUAC, and Hb), a disease progression outcome (CD4 count), and food security outcomes (IDDS and HFIAS).

To our knowledge, there are only a handful published studies examining the impact of food assistance on nutrition outcomes among PLHIV in developing country contexts, and the findings across studies are not consistent. In a prospective observational cohort study in Haiti, a monthly WFP family food transfer to adult PLHIV was associated with improved BMI at 6 and 12 months, compared to individuals who did not receive food assistance [42]. In this study, however, the food assistance and the control group differed substantially at recruitment (multivariate models controlled for a small number of baseline characteristics). By design, individuals who did not meet the eligibility criteria for food assistance were enrolled in the study as the comparison group. In another observational study in Zambia, a monthly WFP individual or household food ration was not associated with weight gain or BMI increases (after adjusting for a small set of baseline characteristics) at 6 and 12 months among PLHIV on ART, compared to the control group [41]. A third observational cohort study in India found a small daily WFP individual supplement provided to adult PLHIV on ART was not associated with improvements in weight, BMI, MUAC or hemoglobin concentrations at 6 months, compared to those in two comparison clinics after adjusting for baseline CD4 count, age, and sex [43]. Lastly, in a retrospective observational cohort study from Uganda using a large program administrative database, individuals receiving food assistance for a period of 12 months had a higher mean weight gain compared to their matched control, and had statistically significant, but biologically insignificant slower disease progression ([30]). This final study is most similar to ours in terms of methodology, though it matches on a much more limited set of controls available in an administrative data set not originally designed for evaluation purposes.

There appears to be consistency in the published literature on the lack of impact of food assistance on immunological outcomes. Similar to our study, results from Zambia [41] and India [43] show no impacts of food assistance on changes in CD4 counts. Of note, ours is the only study to examine impacts on CD4 count of exclusively ART naïve individuals. There is also consistency in the published literature on the impacts of food assistance on ART adherence and retention into care and treatment programs. Because our study was among ART naïve PLHIV, adherence was not a measurable outcome, and we were unable to examine the impacts of food assistance on retention into TASO clinic services. By design, receipt of food assistance was conditional on monthly visits with TASO case officers.

The lack of any impact on hemoglobin concentrations was unexpected, and we propose three possible explanations for it. First, the prevalence of anemia in this population was low (15%) and therefore the potential to benefit at the population level was minimal, and we lacked sufficient power to detect minor improvements. Second, we are unable to determine whether the anemia that is present is due to iron deficiency or HIV infection itself. In the absence of interventions that treat the infection, if the attributable fraction of anemia due to iron deficiency is low, it is unlikely that reductions in anemia will be observed.

This is supported by the positive impacts of food assistance on hemoglobin concentrations, of approximately 1g/dL, among those individuals with a lower degree of immunosuppression (CD4 count > 350 cells/μL), and not among those with lower CD4 counts. It is plausible that in these individuals the relatively lower level of immunosuppression may provide greater potential to benefit from nutritional interventions, compared to those with more severe immunosuppression in whom hemoglobin concentrations may be more strongly influenced by disease severity. Third, although the food assistance basket contained micronutrient fortified commodities (corn-soy blend (CSB) and vitamin A fortified vegetable oil), the composition of the basket may be inadequate to meet the micronutrient requirements of PLHIVs, as they are for infants [44], and therefore might not be expected to have an impact on anemia.

We also conducted several sensitivity analyses which increase confidence in the findings. First, there is internal consistency between the impacts on individual nutritional status (BMI and MUAC) and household food security, suggesting that improved household food security is a likely mechanism underlying the observed improvements in nutritional status. Second, we used an extensive set of balance variables in the matching procedure, capturing nutritional, health, economic, and behavioral conditions prior to the intervention. We derived our impact estimates based on difference-in-difference techniques incorporating baseline measures of the examined outcomes prior to the intervention. Moreover, in addition to the matching methods presented here, we considered alternative matching techniques (see **statistical methods**), all of which yielded similar results. Third, we applied the same methodology to individual self-reports of the existence and severity of 16 physical symptoms associated with HIV, such as skin rash, body pains, and dizziness, among others. We examined the number of symptoms mentioned as well as an index of their overall severity. The index was constructed as the sum over all symptoms of an indicator which was 0 for those who did not report the symptom, 1 for those reporting the symptom had exhibited but had not been a problem, 2 if it had been a small problem, 3 if it had been a larger problem, and 4 if it had been a very serious problem. There were highly significant reductions in reported symptoms (1.5 fewer symptoms, $P<0.01$) and in the severity index, consistent with improved health, and possibly associated with higher clinic attendance. Estimation of reports of the individual symptom of losing weight was also significantly negative, consistent with the results for measured BMI and MUAC.

In addition to the sensitivity analyses detailed above, the results of a qualitative study conducted in in 4 districts (Jinja, Tororo, Gulu and Soroti) provides further evidence on the impacts of food assistance. In 2008-2009, the study team conducted an in-depth qualitative study to understand how food security interventions, including food assistance, are operationalized into HIV/AIDS programs. The study team interviewed 71 TASO clients who have received food security interventions. Each of the study participants was interviewed on average three times using semi-structured qualitative study guides that

were pre-tested and revised to reflect the local contexts. All of the interviews were conducted in the language the interviewee was most comfortable with (either English or a local language) and were digitally audio-recorded. The recordings were transcribed and, where necessary, translated into English by the field researchers who carried out the interviews. Code lists were developed to reflect key themes of interest to the research. All data were coded and analysed using NVivo 8.0 qualitative data analysis software. Coding was carried out by a sub-group of the research team, selected for their analytical skills and subsequently trained in a deductive coding approach. Below we report the most widely elicited responses on perceived impacts of food assistance. The quotes are indicative of the broader patterns observed.

Food assistance program was well-received by beneficiaries, who identified a number of key areas of their lives where they felt that the programme had particularly beneficial effects. The most widely-reported benefits among FA recipients concerned improvements in *household food security*.

"The problem of hunger has reduced in my family; in fact hunger was another disease which would have killed me for instance before enrolling on food [assistance]. At times I would go the whole day without tasting anything, not because I had no appetite but the problem was there was nothing to cook and consume. But these days I feel relieved because at any time I feel like eating I just prepare the porridge and take even these days I do not worry much on what I will eat."

The beneficiaries valued corn soy blend included in the food basket and reported improvements in their *weight, resistance, appetite, and energy* are widely reported in interviews:

"At times you lose appetite and you do not feel like eating other solid food so the corn soya blend is usually prepared and gives you the energy and you feel better….This Corn Soya blend is so nutritive because you take it and it gives you the energy instantly I may not describe how nutritive it is but when I take it I it gives me a lot of energy... My experience is that when am ill I lose appetite and am always comfortable with corn soya blend so I take it which gives energy for faster recovery "

Although not included in the quantitative analysis in this paper, the beneficiaries also noted that the food basket served as a *cushion or buffer* which allowed them to maintain some food surplus (which could be sold) in the home:

"We just used to grow food in those days when that food assistance was not there. Then if the harvest was not very good, we had to buy. Here comes a situation whereby the food assistance came in and it created a gap where by instead of eating the grown or purchased, there was a gap filled up there in such that even if you had grown maize just for home consumption, you find that you would remain with some surplus for sale hoping that there was something to eat because the food kept coming routinely though as I told you they would miss some times but one would be assured that in this period, I will be getting / eating it for survival because I was assured would drink / eat my porridge, the cooking oil is available, so it changed the circumstances". (Beneficiary from JinJa)

Informants also note that *adhering to treatment* was easier when they are not hungry.

> "It helped me a lot to adhere because they tell us to first eat before we take the drugs, so whenever I would drink my porridge, I would take my drugs when I am feeling well and it also helped me in a way that drugs would not weaken me since I would be strong" (Beneficiary, Jinja)

There are several limitations to our study. First, because the comparisons were drawn from a different geographical area, it is possible that unobserved geographical level factors explain part of the observed differences between groups. Gulu district, for example, may have suffered more intensively from civil conflict in the past [45], though it is difficult to assess whether and how this would alter the impact of food assistance on PLHIV. We attempted to mitigate this potential bias by differencing the outcomes (so that time invariant factors are controlled for) and by including a large number of matching variables (including prior CD4 trends in some specifications), many of which reflect conditions specific to the geographic areas as well as trends in those areas. Second, we are unable to document actual food consumption by the target PLHIV who received the household food transfer. Receipt of the household food transfer was monitored by the program, but beyond the food collection point, no detailed assessment of intake was made. The majority of individuals in our study were women, and it may be possible that some intra-household food allocation bias towards women prevented target PLHIV women from consuming the food. Lastly, a relatively large proportion of individuals (21%) became eligible for, and received, ART, during the study period, and were therefore excluded from the impact analysis. Hemoglobin concentrations were unavailable for an additional 15% of individuals included in our impact estimates on hemoglobin, due to logistical issues around delivery of routine program services. We examined baseline characteristics of individuals who were put on ART and for whom follow-up hemoglobin concentrations were unavailable, and found no significant differences by study group.

CONCLUSIONS

This study contributes needed evidence of the impact of food assistance targeted to PLHIV on their nutritional status and food security outcomes. It is among only a handful of rigorously designed studies that examine this, and is the first in sub-Saharan Africa, where the overlap of HIV and food insecurity is

greatest, to demonstrate impacts on both nutritional status and food security. While policies and programs of food assistance within the context of high HIV and food insecurity are widespread, they are justified on only scant evidence regarding the impacts of such integrated models. By carrying out the study in a routine program context, and in coordination with one of the largest providers of food assistance in the region, the results are valuable to programmers and have a degree of external validity they would not have had if the evaluation had altered program design. By restricting initial enrollment to individuals ineligible for ART, based on CD4 counts, and excluding individuals who subsequently went on ART, this study examined the potential beneficial role of a food and nutrition security intervention during a critical disease stage where CD4 counts were low, but not yet low enough to meet the eligibility criteria for ART. While the past few years have seen a dramatic expansion of ART access across sub-Saharan Africa, significant challenges to universal access remain [46, 47]. Food insecurity remains a critical barrier to both access [48-50] and adherence [51-53] to ART. This study demonstrates the benefit of food assistance in the absence of ART, and highlights the potential for food assistance programming to be part of the standard of care for PLHIV in areas of widespread food insecurity.

FUTURE DIRECTIONS

While this study has made a significant contribution to our understanding of the impact of one typology of food assistance programming within the context of HIV/AIDS, there is a clear need for addition work. Over the last decade, rapid advances have been made in science, in characterizing and quantifying the impacts, in organizational approaches, and in funding to fight the causes and consequences of the epidemic. At the same time, the evidence base around the importance of food and nutrition security in HIV prevention, treatment, and mitigation, is strengthening, albeit lagging in comparison to our understanding of the basic science of the disease. Nonetheless, there is now widespread recognition of the need to strengthen and mainstream food and nutrition programming into the HIV response.

In recognition of the need to foster closer collaborations between stakeholders active in the nexus of HIV and food and nutrition, to improve their ability to integrate Nutrition Assessment, Counseling and Support (NCAS) systematically into the HIV response, an Inter-Agency Task Team (IATT) was formed in 2012 with representatives from UN organizations, academia and civil society. This IATT lays out to key broad objectives which are to: 1) promote the integration of NACS into the HIV response to improve continued access and adherence to HIV treatment and care and to enhance nutritional recovery and (ultimately) treatment success; and 2) foster collaboration and partnership in areas where clear synergies exist. Three

distinct areas of foci have been identified related to 1) programming, 2) funding and advocacy, and 3) research. We further elaborate on these three priority areas.

Programming

While integration of NACS into HIV treatment, care and support services is an intended program objective, gaps remain in our understanding of *how* to achieve this integration. As part of a broader health system strengthening, specific attention needs to be prioritized for the food and nutrition components within the HIV response. Currently, retention of clients within HIV services remains a major impediment towards progress in combating HIV; large proportions of clients are lost between diagnosis and treatment initiation, and similarly during the first few months after ART imitation. The evidence suggests that food and nutrition interventions may improve client retention. Therefore, strategies by service providers to ensure retention to services are needed which will require concerted efforts to improve linkages between health facility-based nutrition services and community-based nutrition and food security services.

Funding and Advocacy

Recent critical funding shortages for the AIDS response threaten to undermine effective programming across eastern and southern Africa. Recent research from Malawi, Swaziland and Zimbabwe has highlighted the negative impact of the cancellation of Round 11 funding on the HIV and TB response in the region. Funded by the Open Society Initiative for Southern Africa (OSISA) and the Open Society Foundations (OSF), the report details how the funding crisis has severely undermined efforts to tackle HIV and AIDS in southern Africa. The Report calls on the Board of the Global Fund to issue a new call for applications as soon as possible and to emphasize the importance of investing in 'critical enablers' to increase the effectiveness of core program activities. A clear focus of stakeholders should be to ensure coordinated efforts to obtain funding for NACS interventions.

The funding crunch is important because although significant resources will still flow towards treatment and care, holistic approaches, of which food and nutrition security is key, may be neglected. Policy frameworks incorporating food become meaningless if they are not financed – and external sources have been the main drivers of these. In the aftermath of these changes, countries have often had to choose between biomedical interventions and the activities that support them (53). Further, funding to program implementers and research will also likely dwindle which has implications for developing innovative ways of supporting food and nutrition security interventions.

Parallel to coordinated fundraising activities, a joint advocacy strategy is needed to raise the profile of access and retention in care issues, and how food and nutrition interventions can help overcome barriers to access and retention in care in particular, as well as benefit individuals and families across the HIV timeline, from prevention to mitigation of the consequences of HIV.

Research

Given the important relationship between diet quality and nutrition and clinical outcomes, further research is needed in the composition of food transfers to meet both macro and micronutrient needs among both immunosuppressed and non-immunosuppressed people living with HIV in resource-limited settings. More research is needed to understand which assistance modalities improve clinical and economic outcomes, and under what conditions. In Ecuador, for example, a recent impact evaluation of three different modalities of WFP transfers – food, cash, and vouchers – given to Colombian refugees found that voucher transfers led to the greatest increases in household dietary diversity. However, no equivalent data exists on the comparative effectiveness of different transfer types among HIV infected populations.

When and how to transition from food transfers to livelihood support programs requires further investigation. A study of livelihood program and HIV care and treatment program implementers conducted under the TASO-RENEWAL/IFPRI collaboration offers no firm consensus about when clients should be expected to transition fully to livelihood activities. In part, this lack of consensus reflected a dearth of evidence to support any particular timeline. Some informants argued that livelihood activities should begin only after clients had started benefitting from the food and medicine. They believed that that initiating too many different educational components at once would be difficult for participants. Others suggested that livelihood activities should be started earlier to emphasize the temporary nature of food supplementation.

The findings of the research studies on the perceived impacts of livelihood programs integrated to HIV care and treatment are encouraging. However, well-thought through, implemented, and evaluated HIV-responsive livelihood programs continue to be scant. The findings from the studies on operational process show several opportunities to strengthen the impact of these livelihood interventions.

Finally, we conclude with a call for action: Research cannot be conducted in a vacuum: program interventions are an opportunity to generate evidence for refinement of future interventions. Serious investments should be made to strengthen monitoring systems, integrate operations research and impact evaluations into the program design and implementation strategy to fully

understand the range of impacts of these programs and to dynamically inform intervention development.

Figure 1: Recruitment and Follow-up of study participants

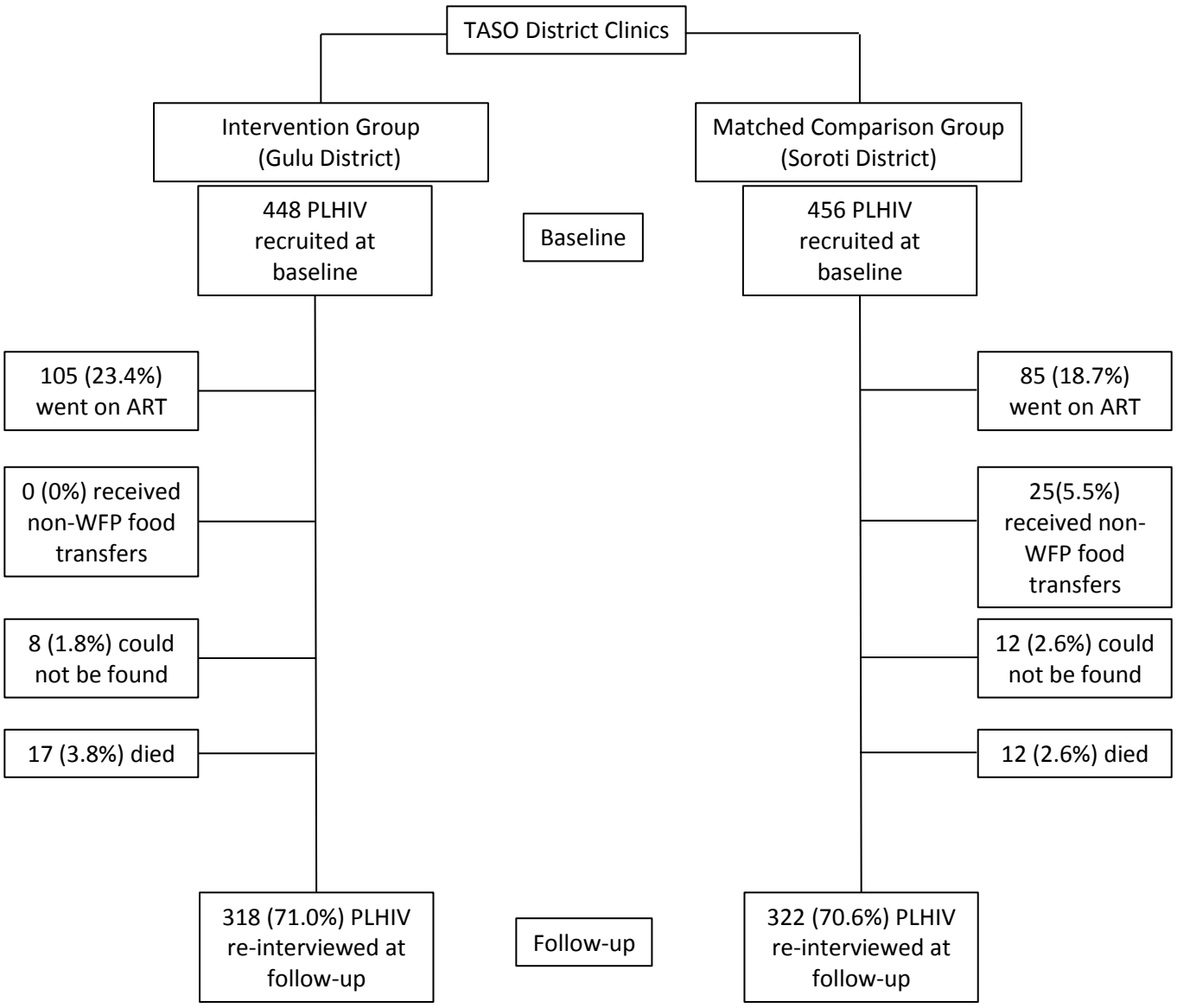


Table 1. Baseline control variables used in matching

Individual background	
	Male
	Age
	Highest grade attained
	Widow
	Marital or other partner
Individual measured health status	
	Height
	Weight
	BMI
	MUAC
	CD4
	Hemoglobin
Individual reported health status	
	Little or no pain in previous month
	Weight loss significant problem in previous month
	Too sick to work in previous month
Household background	
	Household size
	Number of children < 10 years old in household
	Dependency ratio
	Per capita expenditures
	Per capita food expenditures
	Food share
	Value of assets
	Own land
	Household member works in agriculture
	Benefits from a social program
	Negative economic shock in previous 5 years
Community distance from household to:	
	TASO clinic
	Nearest government health clinic
	Nearest market
	Nearest primary school
Survey characteristics	
	Time between baseline and follow up surveys
	Calendar quarter of follow-up survey

Table 2. Comparison of Baseline Characteristics

Baseline Characteristics	Intervention (A) (N=318)	Comparison All (B) N=322	Comparison Matched Weighted (C) (N=318)	P-Values (A vs. B)	P-Values (B vs. C)
Individual					
Male, n (%)	76 (23.90%)	106 (32.92%)	76 (23.90%)	0.011	1.000
Age, mean (sd)	38.05 (9.26)	40.74 (10.00)	36.32 (9.47)	0.001	0.019
Education in years, mean (sd)	4.57 (4.22)	4.42 (4.47)	4.81 (4.72)	0.656	0.495
Widow/er, n (%)	122 (38.36%)	94 (29.19%)	143 (44.97%)	0.014	0.092
Married, n (%)	139 (43.71%)	175 (54.35%)	133 (41.82%)	0.007	0.631
Time Between Surveys, mean (sd)	11.76 (1.42)	10.73 (2.29)	11.60 (1.35)	<0.001	0.149
Household					
Household size, mean (sd)	6.41 (2.59)	6.35 (3.00)	6.27 (2.65)	0.783	0.506
Per capita expenditures (Shillings), mean (sd)	40,743 (32,966)	55,752 (33,872)	40,850 (23,603)	<0.001	0.963
Distance in km, mean (sd):					
TASO clinic	7.77 (9.49)	10.11 (8.28)	7.15 (6.87)	0.001	0.344
Nearest Market	1.14 (1.50)	2.24 (1.94)	1.17 (1.07)	<0.001	0.775
Outcome variables , mean (sd)					
Body mass index (kg/m2)	20.86 (2.52)	20.31 (2.70)	21.20 (3.73)	0.008	0.185
Mid upper arm circumference (mm)	270.54 (30.85)	265.95 (26.68)	270.30 (34.31)	0.044	0.924
CD4 count (cells/µL)	355.73 (57.27)	351.81 (57.85)	350.58 (53.30)	0.405	0.251
Hemoglobin (g/dL)	12.55 (1.52)	12.64 (1.70)	12.81 (1.79)	0.507	0.063
Individual Dietary Diversity Score (IDDS) (9 food groups)	3.70 (1.24)	4.45 (1.22)	3.91 (1.22)	<0.001	0.034
Household Food Insecurity Access Scale (HFIAS) (0-27)	16.27 (4.38)	14.27 (5.12)	15.46 (4.84)	<0.001	0.026
Propensity Score, mean (sd)	0.72 (0.25)	0.29 (0.27)	0.72 (0.25)	<0.001	0.975

Table 3. Difference-in-Difference Average Treatment Effect on the Treated (ATT)

OUTCOME	N	Matching Results: Single nearest neighbor	Matching Results: Three nearest neighbors
I. INDIVIDUAL NUTRITIONAL STATUS			
BMI (kg/m^2)	640	0.59** (0.21)	0.45** (0.17)
Estimate controlling for CD4 trend	317	0.87* (0.38)	0.50* (0.24)
MUAC (mm)	640	6.73* (2.79)	7.90** (2.79)
Estimate controlling for CD4 trend	317	9.83 (6.27)	7.63* (3.48)
Hemoglobin (g/dL)	532	0.43 (0.31)	0.20 (0.31)
Estimate controlling for CD4 trend	281	0.57 (0.39)	0.25 (0.28)
(INDIVIDUALS WITH CD4 COUNT > 350 CELLS/MM3 AT BASELINE)			
Hemoglobin (g/dL)	286	0.47 (0.44)	0.53 (0.33)
Estimate controlling for CD4 trend	153	1.10* (0.49)	0.94** (0.36)
II. INDIVIDUAL LEVEL DISEASE PROGRESSION			
CD4 (cells/µl)	599	-16.53 (13.95)	-18.46 (11.60)
III. FOOD SECURITY			
IDDS	640	0.06 (0.27)	-0.06 (0.24)
HFIAS	640	-2.08** (0.63)	-2.32** (0.67)

** P<0.01; * P<0.05;

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