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***Shamba Maisha*: Randomized controlled trial of an agricultural and finance intervention to improve HIV health outcomes in Kenya**

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Abstract

Objectives—Food insecurity and HIV/AIDS outcomes are inextricably linked in sub-Saharan Africa. We report on health and nutritional outcomes of a multisectoral agricultural intervention trial among HIV-infected adults in rural Kenya.

Design—Pilot cluster randomized controlled trial

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AUTHOR CONTRIBUTIONS

Conceived and designed the experiments: SDW, EAB, SLD, KP, SS, KS, CRC. Study implementation: SDW, EAB, RLS, EW, KP, LMB, CRC. Analyzed the data: SDW, RLS, EAF, CRC. Wrote the paper: SDW, RLS, CRC. Contributed to the writing of the manuscript: SDW, EAB, RLS, EAF, EW, SLD, KP, SS, KS, LMB, CRC.

COMPETING INTERESTS

The authors declare that they have no competing interests.

Trial Registration: This trial is registered at ClinicalTrials.gov, NCT01548599 <http://clinicaltrials.gov/ct2/show/NCT01548599?term=shamba&rank=1>

Methods—The intervention included a human-powered water pump, a microfinance loan to purchase farm commodities, and education in sustainable farming practices and financial management. Two health facilities in Nyanza Region, Kenya were randomly assigned as intervention or control. HIV-infected adults 18 to 49 years old who were on antiretroviral therapy and had access to surface water and land were enrolled beginning in April 2012 and followed quarterly for one year. Data were collected on nutritional parameters, CD4 T lymphocyte counts, and HIV RNA. Difference in difference fixed-effects regression models were used to test whether patterns in health outcomes differed over time from baseline between the intervention and control arms.

Results—We enrolled 72 and 68 participants in the intervention and control groups, respectively. At 12 months follow-up, we found a statistically significant increase in CD4 cell counts (165 cells/mm³, $p < 0.001$) and proportion virologically suppressed in the intervention arm compared to the control arm (comparative improvement in proportion of 0.33 suppressed, OR 7.6, 95% CI: 2.2–26.8). Intervention participants experienced significant improvements in food security (3.6 scale points higher, $p < 0.001$) and frequency of food consumption (9.4 times per week greater frequency, $p = 0.013$) compared to controls.

Conclusion—Livelihood interventions may be a promising approach to tackle the intersecting problems of food insecurity, poverty and HIV/AIDS morbidity.

Keywords

HIV; food insecurity; microfinance; agriculture; livelihoods; intervention

INTRODUCTION

HIV/AIDS and food insecurity are two leading causes of morbidity and mortality in sub-Saharan Africa (SSA), linked in a vicious cycle with each enhancing vulnerability to and worsening the severity of the other [1]. In SSA, 240 million persons are food insecure [2]. Food insecurity increases risk of HIV acquisition [3, 4], and food-insecure HIV-infected individuals have worse adherence to antiretroviral therapy (ART) and clinic visits [5], worse mental health [6, 7], and worse nutritional status [1], all contributing to poor HIV treatment outcomes and increased morbidity and mortality [8–11]. HIV/AIDS in turn worsens food insecurity by eroding economic productivity [12, 13], causing loss of social support due to HIV-related stigma [14] and increasing medical expenses.

There has been increasing international recognition that improving food security and reducing poverty are essential for a successful global response to the HIV epidemic [15, 16]. Yet, there is little evidence of the impacts of food-security or poverty-reduction interventions on nutrition and HIV outcomes, particularly from randomized controlled trials (RCTs). The few studies to date have used clinic-based food support, showing improved ART adherence and nutritional status with this strategy [17, 18]. International experts call for sustainable approaches addressing drivers and consequences of food insecurity such as agricultural and other livelihood approaches. In this study, we conducted a pilot cluster RCT to assess the effects of a multisectoral agricultural and finance intervention we initially

developed and evaluated in a small feasibility study [19], on health outcomes among people living with HIV/AIDS [PLHIV] in rural Kenya.

METHODS

The study was conducted in Rongo and Migori districts in the Nyanza Region in Kenya which has an HIV prevalence of 15.1%, more than twice the national average [20]. As described elsewhere, we selected two health facilities supported by Family AIDS Care & Education Services (FACES) and randomly selected one as intervention and the other as control [21]. Control participants were eligible for the intervention at the end of the one-year follow-up period.

The *Shamba Maisha* intervention has three components [21]: 1) Loan program: Microfinance loans were provided and managed by *Adok Timo*, a Kenyan microfinance organization, with support from UCSF and KEMRI. Intervention participants were required to save 500 Kenyan shillings (~\$6.00 USD) prior to receiving the loan (~\$150 USD), which was used to purchase farming implements and a MoneyMaker water pump. Participants were expected to repay the loan in full by the end of two harvest seasons (about one year) and were not asked to forfeit personal belongings, except for the water pump, to cover loan payments. 2) The MoneyMaker pumps enable farmers to irrigate crops year-round, avoiding dependence on seasonal rainfall thus capitalizing on higher crop prices in the marketplace [22]. 3) Agricultural and financial training: Intervention participants received eight training sessions on agriculture and financial management. Agricultural trainings included didactic sessions and practical demonstrations on sustainable farming techniques, use of the MoneyMaker pump, seed selection, plant spacing, soil and water conservation, integrated pest and disease management, pre- & post-harvest handling and marketing. Financial training focused on record keeping, savings, investments, and group dynamics.

Participants, recruitment and data collection

Inclusion criteria were: HIV-infected individual on ART, ages of 18–49 years, access to farm land and surface water, evidence of moderate to severe food insecurity at enrollment or malnutrition during the year preceding the study, and willingness to save the down payment for the loan. Participants were recruited through clinic announcements, followed by individual screening for eligibility, including questionnaires, record review, and home visits to verify access to farm land and surface water. A total of 140 HIV-positive individuals were enrolled from April – July 2012 and followed quarterly for one year; an additional two (1.4%) eligible screened participants declined to participate in the study. All participants gave written informed consent prior to enrollment.

We conducted quarterly home visits with structured interviews on food security, food frequency, household wealth, and agricultural indicators. We collected biannual data at the health facility including anthropometry, phlebotomy for HIV RNA and CD4 cell count, and structured interviews for clinical and sensitive behavioral data. Data were collected using a handheld computer tablet (Morotola™ Xoom Android Tablets operating Open Data Kit Collect). Participants were reimbursed up to 800 Ksh per clinic-based interviews (~\$9.4 USD) and 400 Ksh for home-based interviews (~\$4.70). The study was approved by the

Committee on Human Research at the University of California San Francisco (UCSF) and the Ethical Review Committee at the Kenya Medical Research Institute (KEMRI). This clinical trial was registered at ClinicalTrials.gov (NCT01548599).

Primary outcomes—Food insecurity was measured using the Household Food Insecurity Access Scale (HFAS) [23, 24]. Diet quality was measured using a 56-item scale adapted from the World Food Programme Food Consumption Score to capture the number of different food groups and the frequency consumed [25]. A modification of the World Bank Living Standards Measurement Study questionnaire [26] was used to measure household wealth including expenditures, household income, and inter-household commodity and cash transfers. Nutritional status was assessed through body mass index (BMI) and mid-upper arm circumference (MUAC) [27]. HIV RNA testing was performed on venous blood using the COBAS TaqMan HIV viral load (HIV VL) platform (Roche Molecular Diagnostics, Pleasanton, CA) with a lower limit of detection of <40 copies/mL. Absolute CD4 T lymphocyte cell count testing was performed on whole blood using the BD FACSCount (BD Bioscience, San Jose, CA).

Analysis

Intent-to-treat, repeated-measures analyses were done using the xtreg or xtlogit procedure in Stata v13 (StataCorp LP, College Station, TX) [28]. For continuous outcomes, fixed-effects linear models were used to remove all individual-to-individual variability, thereby controlling for any baseline differences between groups and accounting for all potential confounding from measured or unmeasured time-invariant variables. For viral load suppression, a random-effect logistic model was used. The interaction of group (intervention vs. control) and month was used to test differences between groups in the changes from month 0 to each follow-up month.

RESULTS

Screening and Enrollment

We screened 142 and 154 adults, respectively at intervention and control sites. Supplemental Figure 1 describes study screening and enrollment numbers, and reasons for participant ineligibility. We enrolled 72 and 68 participants at the intervention and control sites, respectively, allowing for more withdrawals from the intervention group in case they were unable to save the down payment for the loan. Four intervention participants withdrew from the study, three participants died (two intervention, one control), and one control participant migrated away. We analyzed data for 66 participants from each site.

Baseline Characteristics of Participants

At baseline, intervention and control participants were similar in age, gender, education, number of people in household, food security status, CD4 cell counts, and marital status (Table 1). Intervention participants had a greater proportion with low BMI (<18.5), lower proportion with HIV VL suppressed below 40 copies/mL, and lower monthly expenditures and frequency of food consumption. In both groups, 91% were on efavirenz-based or nevirapine-based regimens and the mean time on ART was 2.8 years.

Intervention impacts

Food insecurity, nutritional, and economic indicators: Intervention participants reduced their food insecurity progressively throughout follow-up (Supplemental Figure 2). Control participants also reduced food insecurity to a lesser extent. At month 12, the difference in reduction in food insecurity from baseline between intervention and control was 3.6 scale points ($p<0.001$, Table 2), an effect size of 1.2 standard deviation units.

Frequency of food consumption improved for intervention compared to control participants throughout follow-up. At month 12, the difference in additional frequency of food consumption from baseline between intervention and control was 9.4 times per week ($p=0.013$, Table 2). BMI tended to improve for the intervention compared to the control group during the follow-up period, with differences of more than a third of a BMI unit at both 6 and 12 months ($p<0.12$), with no significant differences for MUAC (Table 2). There were no significant differences between intervention and control participants in change in food or non-food expenditures (Table 2). There were marginally significant differences ($p<0.10$), however, for expenditures on dairy, beverages, and cooking fat (data not shown).

HIV clinical outcomes: For intervention participants, mean CD4 cell counts increased by 75.6 cells/mm³, while for control participants, mean CD4 cell counts decreased by 89.3 at endline. The difference in these changes between intervention and control at 12 months was 164.9 cells/mm³, $p<0.001$. Over follow-up, the percentage virologically suppressed in the intervention increased from 51% to 79% and the percentage suppressed in the control decreased from 72% to 67%. The comparative improvement in the proportion virologically suppressed was 33% (odds ratio 7.60, 95% CI 2.2–26.8, $p=0.002$, Supplemental Figure 3).

DISCUSSION

In this pilot cluster RCT, we found that an agricultural and finance intervention was feasible, acceptable and had high retention, consistent with the high retention seen in FACES-supported clinics broadly. Several previous studies from resource-limited settings found that macronutrient supplementation delivered as part of HIV care can improve food security, BMI, treatment adherence and clinic attendance [15, 17, 18, 29–31]. Our findings extend this literature by demonstrating that a potentially sustainable agricultural and financial intervention improved immunologic and virologic outcomes, food security, and diet quality for HIV-infected individuals. This supports previous research attesting to the critical role of poverty and food insecurity alleviation to improve health outcomes [1].

These findings have important implications for policy and practice. At least 70% of HIV-infected individuals in East Africa are food insecure [32, 33] suggesting relevance of such interventions for a large segment of the population. Food insecurity in the region stems from combined effects of extreme poverty, environmental change, insufficient agricultural output, and rising food prices [34, 35], all factors that may be improved by this intervention. Given that HIV-infected individuals often relinquish food to obtain medical care and stay on treatment [36], adherence to ART in SSA may not be sustainable without incorporating strategies to reduce food insecurity into ART treatment programs. Therefore, locally available and potentially sustainable models for improving food security are needed to

improve HIV clinical outcomes. Since food insecurity negatively impacts health for many conditions beyond HIV including other infectious diseases, mental health, reproductive health outcomes, pediatric health outcomes, and diabetes and risk for cardiovascular disease [1, 37–39], similar sustainable food security interventions may be beneficial in prevention and treatment of other illnesses. In line with the obligation of States to implement general health and well-being interventions, our study supports the growing international interest to integrate agriculture, nutrition, and health programs to improve outcomes in these sectors simultaneously.

With only two communities randomized, we could not definitively separate intervention effects from cluster-level variables, highlighting the need for a larger cluster-RCT. There were significant baseline differences between intervention and control participants including several outcomes of interest. The 12-month follow-up could not detect the full range and sustainability of intervention effects. Only participants who had access to farming land and available surface water were eligible to participate in the study, limiting the generalizability to other populations. Yet, these criteria are likely to be met by many HIV-infected individuals in Kenya where the agriculture sector accounts for >75% of the total workforce, and 51% of the gross domestic product [40].

In summary, this multisectoral agricultural and finance intervention improved HIV control, food security, and diet quality among HIV-infected individuals in Kenya. Livelihood interventions may be a promising approach to tackle the intersecting problems of food insecurity, poverty, and HIV/AIDS morbidity. If proven effective and cost-effective in larger trials, such interventions should be incorporated into HIV treatment efforts in Kenya and similar resource-limited settings.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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ABBREVIATIONS

ART	Antiretroviral therapy
BMI	Body mass index

FACES	Family AIDS Care & Education Services
HFAIS	Household Food Insecurity Access Scale
HIV VL	HIV viral load
KEMRI	Kenyan Medical Research Institute
MUAC	Mid upper arm circumference measurements
NGO	Non-governmental organization
PLHIV	People living with HIV/AIDS
RCT	Randomized control trial
UCSF	University of California, San Francisco

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Table 1

Comparison of baseline characteristics of participants enrolled in Shamba Maisha at the intervention and control sites.

	Intervention N=72	Control N=68	P-value
	n (%) or mean (SE)	n (%) or mean (SE)	
Mean age in years (SE)	37 (0.80)	38 (0.80)	0.16
Female gender	37 (51)	35 (51)	0.92
Education secondary school	14 (19)	12 (18)	0.82
Current married	54 (75)	54 (79)	0.25
Number of people in household	6 (0.2)	7 (0.3)	0.12
Severely food insecure (vs. moderately)	57 (80)	53 (78)	0.86
Body mass index (BMI) <18.5	13 (18)	5 (7)	0.054
Food expenditures (Ksh)	1694 (117)	2176 (127)	0.006
Non-food expenditures (Ksh)	5931 (1559)	14788 (1941)	<0.001
Frequency of food consumption (times/week)	69.6 (3.1)	93.9 (3.2)	<0.001
CD4 (cells/mm ³)	497 (32.7)	536 (37.7)	0.428
Viral load < 40 copies/mL	35 (51)	49 (72)	0.010

1 US dollar = 90.00 Kenyan Shillings (Ksh)

Differences between intervention and control groups in the changes from month 0 to follow-up months in food insecurity, frequency of foods consumed, body mass index, CD4, and viral load suppression.*

Table 2

Outcome	3		6		9		12	
	Differ.	p-value	Differ.	p-value	Differ.	p-value	Differ.	p-value
Food insecurity (scale points)	-1.063	0.142	-2.308	0.002	-2.572	<0.001	-3.685	<0.001
Frequency food consumption (times/w)	3.611	0.333	1.205	0.748	11.854	0.002	9.437	0.013
Body mass index (kg/m ²)			0.386	0.082			0.355	0.114
Mid-upper arm circumference (cm)			0.294	0.308			0.214	0.311
Food expenditures (Ksh)			223.7	0.387	191.7	0.458	273.3	0.293
Non-food expenditures (Ksh)			2074.5	0.709	6411.6	0.249	465.3	0.934
CD4 (cells/mm ³)			59.129	0.175			169.99	<0.001
Viral load suppression (log-odds)			1.845	0.003			2.028	0.002
Viral load suppression (odds ratio)			6.33	0.003			7.60	0.002

* Each difference shown is a difference-in-differences obtained from a fixed-effects (or random-effects for viral load suppression) model accounting for among-individual variation calculated as: (intervention at follow-up month - intervention at 0 months) - (control at follow-up month - control at 0 months).

1 US dollar = 90.00 Kenyan Shillings (Ksh)