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Characteristics and Clinical Outcomes of People
Living with HIV/AIDS Participating in a Home-
Delivered Meal Program in New Haven, CT.



Isy Tavarez

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ABSTRACT

Background: Food insecurity is an issue of great concern among people living with HIV/AIDS (PLWHA). Food insecurity can lead to anxiety, and depression which is in turn associated with poor medication adherence. Food insecurity is a threat to the nutritional status of PLWHA. PLWHA already have a higher energy demand due to the presence of the virus. The lack of food intake can further compromise the immune system and encourage wasting. Because Food insecurity is such a concern among PLWHA, Caring Cuisine which is a program run by Aids Project New Haven in CT, delivers meals for clients who are homebound or unable to access food on their own. In this study we wanted to determine if Caring Cuisine clients had better clinical outcomes than non-participants after adjusting for confounding factors.

Methods: This was a five year retrospective study looking at clinical outcomes (Viral load and CD4) and intake form data (risk behavior, mental health, medication adherence, co-morbidities, HIV disease progression symptoms). It was designed as a matched case-control study where two controls (case-management clients of APNH, n=68) were matched to each case (n=34). Controls were matched to cases based on gender, HIV diagnosis date, age, and race.

Results: No difference was found in viral load suppression between Caring Cuisine and controls at t1. We found that there was a statistically different change in CD4 counts between females (n=48) and males (n=54) in the population ($p=0.002$). Males in Caring Cuisine had a much greater drop in CD4 counts between t0 and t1 than controls ($p=0.071$)

Conclusion: Further research needs to be done to determine how home-delivery meal programs affect clinical outcomes of PLWHA.

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INTRODUCTION

As of 2011, there are 34 million people living with the HIV virus worldwide (1). In the same year 1.7 million died of AIDS related illnesses (1). There is no doubt that HIV/AIDS presents a great global burden, but ARTs are becoming more accessible worldwide and their effectiveness has been proven with studies reporting viral load suppression in up to 86% of patients receiving treatment (2). Additionally ARTs have shown to increase CD4 cell counts by up to 123 cells/ul if the patient is adherent to medication (3) and drop AIDS mortality rates by up to 40% per year (4); however, the effectiveness of the treatment is highly dependent on adherence to the medication; otherwise, the patient can develop drug resistant strains that will no longer respond to treatment (5).

While ARTs are highly effective, having access to this medication doesn't guarantee reduced rates or HIV morbidity and mortality because there are other factors that contribute to HIV outcomes. HIV is often linked to poverty in a bi-directional relationship. Poverty can lead to HIV through three pathways (6):

1. Structural poverty (lack of access to services, gender imbalances etc.)
2. Developmental poverty (socio-economic changes, rural-urban migration etc.)
3. Poverty created by war or civil unrest (refugee crisis, rape etc.)

While in the United States people are not currently faced with issues of war or civil unrest, both structural poverty, and developmental poverty do exist. People living in poverty even in the US are more likely to use drugs, exchange sex to meet survival needs, have limited access to health

services, and have other existing STDs (7). These are all risk factors for acquiring HIV. In turn, people living with HIV/AIDS (PLWHA) are also likely to perpetuate their poverty status due to poor health (7). One of the greatest effects of poverty is hunger and food insecurity. This is an issue both in developed and developing countries. A study in 2005 looked at food insecurity among 1213 people receiving ARTs in British Columbia; they found that over 50% of the population was food insecure and this was five times higher than in the general population (8). In another study involving 250 participants from an existing cohort of HIV positive homeless people in San Francisco, it was found that 54% of the study population was food insecure. (9). There are many problems associated with food insecurity among PLWHA. Not having sufficient food has been connected to poor drug adherence among PLWHA (10, 11), 77% lower odds of viral load suppression (10), and greater mortality (12). Food insecurity has been found to affect HIV morbidity and mortality through three pathways that will be explored here: mental health, behavioral health, and nutrition (13).

Food Insecurity and Mental Health

Food security has been correlated to symptoms of depression and anxiety (14). A cross-sectional study in 20 large US cities involving 2870 mothers participating in the Fragile Families and Child Wellbeing Birth Cohort found that 9% more mothers suffered of anxiety and depression among those who were food insecure even after adjusting for drug use, domestic violence, and socioeconomic status (15). However, for a long time it was not clear if food insecurity led to depression or vice versa. A longitudinal study published in 2008 involving 413 low-income women living in the United States, found that the relationship between food

insecurity and depression is bidirectional (16). This study used the Core Food Security module to measure food insecurity ($\alpha=0.81$). They found that depression leads to food insecurity ($p=0.034$) and food insecurity leads to depression ($p=0.003$). The study conducted using the cohort of homeless, HIV positive people in San Francisco, also found that those who suffered of depression also had two times the odds of being food insecure (9). People who are food insecure are likely to be depressed due to feelings of stress and hopelessness; while, people who are depressed might be at higher risk of food insecurity due to disability.

Depression in PLWHA is of great concern because it has been found to hasten the progression from HIV to AIDS (17). In a study conducted using 1809 homosexual male participants from the Multicenter Cohort AIDS Study, it was found that average CD4 counts were lower among men who had depression (18). Studies looking at the association of between depression and HIV/AIDS find that the main connection between the two is that depression has been associated with discontinuation of ART treatment especially in African American and Hispanic populations (19, 20, 21). It has also been associated with greater substance abuse among PLWHA (22). This is troubling since some studies have found that up to 39% of PLWHA have had a mood/anxiety disorder, 79% of which is depression (23).

Food Insecurity and Behavioral Health

Food insecurity also changes people's spending behavior. A study involving 1000 low-income elderly people living in the United States found that participants who were are food insecure were 2.9 times more likely to not adhere to medications due to cost (24). Another cross-sectional study with 188 women and men with poor health literacy found that one in four

participants had to choose between having food or medicine (20). In some cases food insecurity can also lead to risky sexual behaviors and greater drug usage, increasing the likelihood of both spreading and contracting HIV (25).

Food Insecurity and Nutrition

Food insecurity might have its greatest impact in the nutritional status of PLWHA since difficulties with access to food leads to undernutrition. The relationship between malnutrition and HIV is complex. The presence of the virus, as well as the use of ARTs are contributing factors to malnutrition in PLWHA. PLWHA have greater REE due to the mere presence of the virus thus increasing the body's need for protein and energy rich food (26). Additionally ARTs increase resting energy by causing lipodystrophy or uneven fat distribution which can further lead to malnutrition (26, 27). Also, frequent diarrhea due to poor immunity, can lead to malnutrition (27). The relationship is bidirectional where malnutrition acts as a catalyst to HIV disease progression, and HIV worsens the severity of the malnutrition. Additionally, malnutrition increases the toxicity of ARTs due to poor absorption which can have an effect on drug adherence (28).

Normally, when a person is in starvation mode, the body will slow down its metabolic processes in order to decrease energy usage and conserve fat and protein storage (27). However, in a PLWHA, the opposite happens. When they become symptomatic, their body will increase metabolic processes using up both protein and fat storages leading to wasting; this loss in protein can further compromise the immune system of an HIV infected individual (29). Wasting is associated with lower a CD4 count which is an independent predictor of mortality (26).

Additionally, increases in fat storage occur at a much quicker rate than protein storage leading to a decrease in lean body mass (30). The CDC reports wasting as the third most common AIDS-indicator condition and it is most prevalent in people of low SES (31). Because of the important role that nutrition plays in HIV/AIDS, there have been many interventions in the past which have addressed this issue.

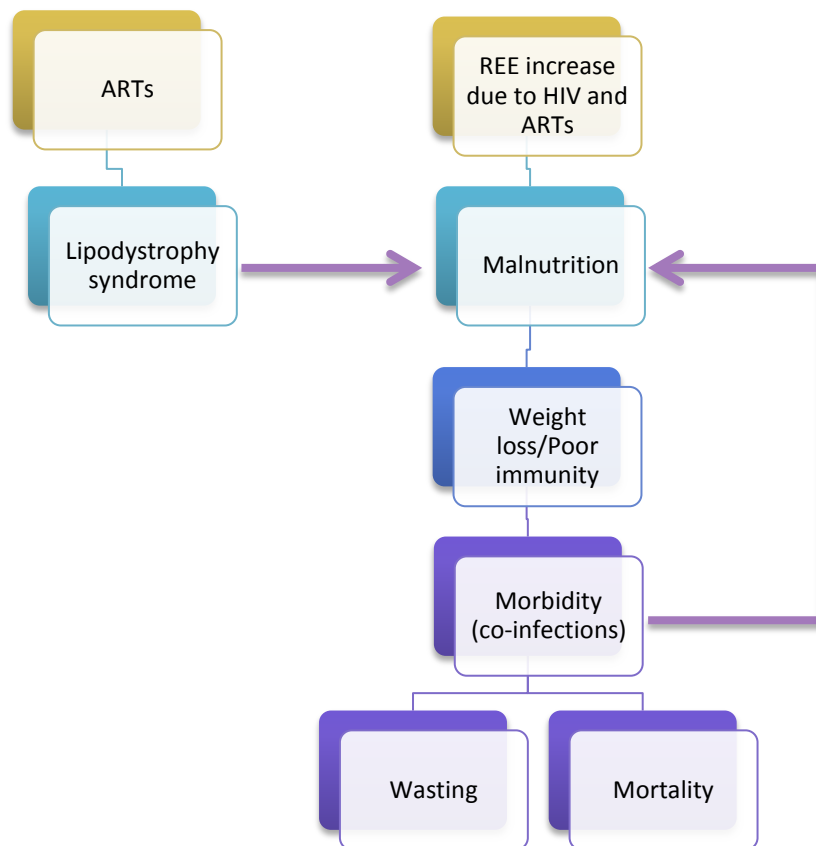


FIGURE 1: The Role of Malnutrition in People living with HIV/AIDS

Two studies provided both macronutrient and micronutrient supplementation as well as nutritional counseling to a group of HIV-infected individuals. One study included 15 HIV positive individuals with a body mass below 21 kg m^{-2} and CD4 counts below 500 (32). They were randomized into either treatment or non-treatment group. The second study was a randomized

control trial of 118 HIV positive men who had less than 90% of the usual weight for height or had lost more than 10% body weight (33). Both studies found an increase in lean body mass (32, 33). The first study also found that compared to the control group, the treatment group showed decreased protein catabolism, and decreased fat mass. Another randomized control study with 70 participants both males and females showed a significant increase in weight after 3 months of supplementation with a nutritional formula (34). There have also been studies looking at the effect of micronutrient supplementation by itself. In a 12 week long randomized control trial involving 40 HIV positive participants who were on a stable HAART regimen, it was that there was a greater increase in CD4 count in the treatment group than in the control group ($p=0.029$) after twelve weeks of supplementation (35). Another randomized control study carried out in Bangkok with 481 men and women living with HIV/AIDS showed that multiple micronutrient supplementations decreased mortality rates among PLWHA, but had no effect on viral load and CD4 counts (36). In smaller randomized study ($n=49$), providing vitamin E and C supplementation for three months lead to a trend in viral load reduction although the result were not statistically significant (37).

By addressing food insecurity among PLWHA, there is the potential to improve mental health, reduce risk behavior, and increase nutritional outcomes. In doing so, this could lead to greater drug adherence, decreased morbidity and mortality, as well as an overall improvement in the quality of life of PLWHA.

For these reasons, several programs throughout the USA have evolved to provide home-delivered meals to this population (38). Although there have not been any studies conducted to test the effectiveness of home-delivered meal programs for PLWHA, there have been studies

that have shown the effectiveness of a similar program, such as Meals on Wheels, among the elderly. One evaluation study concluded that daily meals significantly increased the participants' weight after six months (39), and in another study they found improvement in nutrient intake (40). Of course the nutritional needs of PLWHA and the elderly are not the same, but much like Meals on Wheels helps to fight food insecurity among the elderly, in the same way, home-delivered meals could also do the same for PLWHA.

One program that provides home-delivered meals to PLWHA is AIDS Project New Haven (APNH). In New Haven there are close to 1500 people living with AIDS (41). APNH serves this community as well as the greater New Haven community. They offer case management, substance abuse recovery, support groups, nutritional counseling, and education among other services (42). Caring Cuisine is a program that is run by APNH and delivers meals to clients who are homebound or unable to access food, three times a week to provide for a seven day period (42).

The purpose of this study is to look at viral load suppression among clients of APNH who either participate in the Caring Cuisine program or are just a part of their Case Management program. A previous study looking at viral load and food security among Caring Cuisine and case management clients showed significant viral load suppression among those who participated in the Caring Cuisine program; however, that study was cross-sectional and did not control for co-morbidities, drug adherence and baseline conditions. This study was designed to account for some of the differences between these two populations.

This study seeks to answer the following question:

1. Do Caring Cuisine program participants have greater viral load suppression and CD4+ counts than non-participants after controlling for co-morbidities, drug adherence and baseline status?
2. Are Caring Cuisine participants less likely to suffer from mental health problems, and show a reduced probability of sexual risk behavior and drug use?

Since food security plays such an important role in reducing morbidity and the progression from HIV to AIDS among PLWHA, we want to test whether there will be different rates of viral load suppression and CD4+ changes among Caring Cuisine and non-Caring Cuisine participants. Additionally, as previous studies have shown that food insecurity increases sexual risk behavior and drug use among people living with AIDS, we want to see if similar results are found in the APNH population.

METHODS

This study is a retrospective, longitudinal study looking at matched cases-controls. For cases, Time zero was defined as the date when they entered the Caring Cuisine program, and time one was defined as one year after the Caring Cuisine program start date. For the controls, t0 and t1 were selected as close as possible to the t0 and t1 of the case to which it was matched to.

Study Population

We used APNH client data from July 1st 2006 to June 30th 2012. To obtain the total population of clients we used the APNH CAREWARE which contains background information on the client as well as any tests and clinical outcomes since 2007. From this data we were able to pick out Caring Cuisine clients who had been in the program for six months or more. From these clients

we selected the ones who had viral load measurements within a six month period of starting Caring Cuisine and another viral load as close as possible to a year later. We then selected two controls per case and matched them according to age, time since diagnosis, gender, and race. This gave us 34 matched pairs which make up study population one. Only 16 matched pairs had intake forms within six months at starting at Caring Cuisine and these make up study population two.

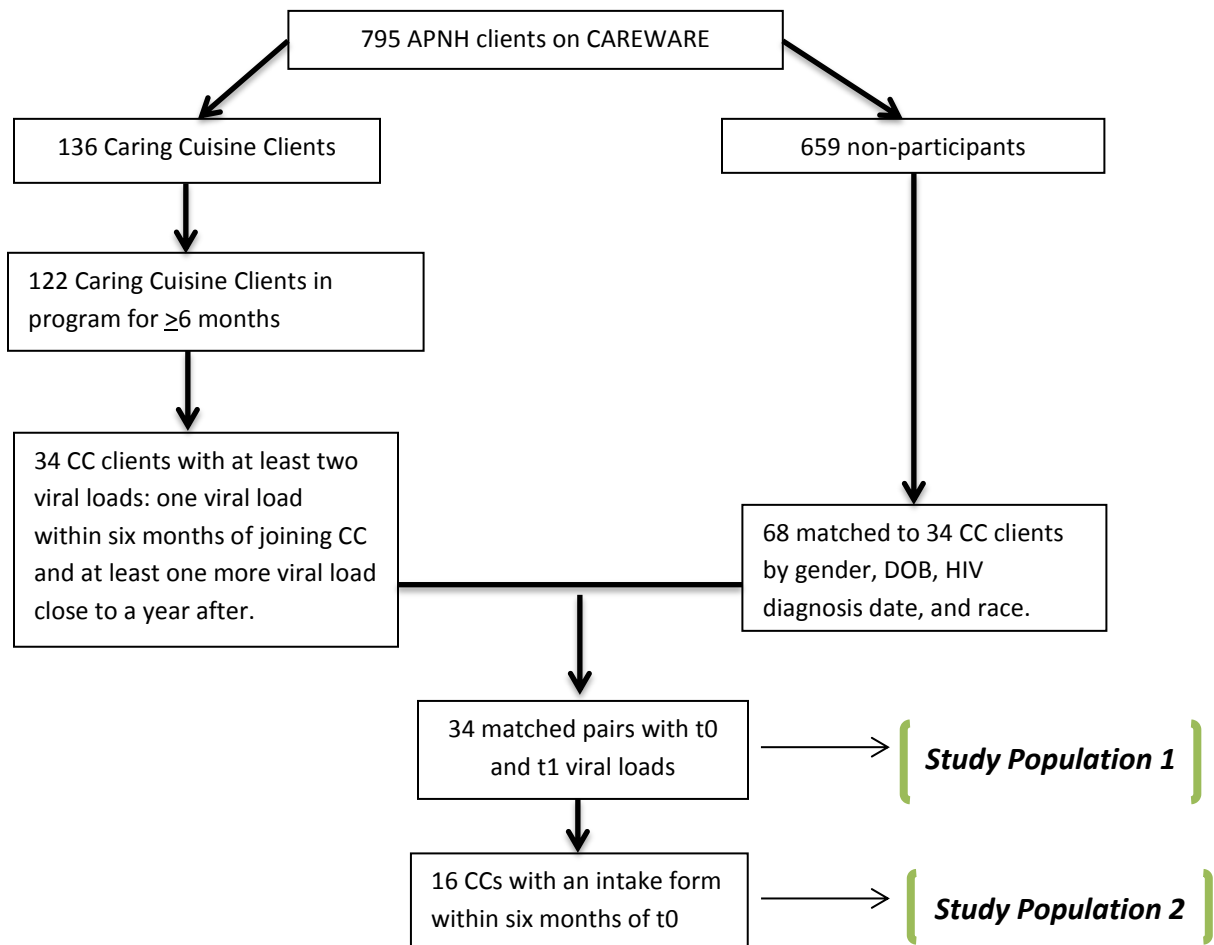


Figure 2: Selection of Study Populations

Procedures

Demographic Information: Information on age, race, gender, household size, household income, and Caring Cuisine start date were obtained on CAREWARE. This information was available for both study populations.

Clinical Data: Viral loads, CD4+, STD tests, and STD diagnosis between 2007 to 2012 were obtained on CAREWARE. Prior to 2007, the information was obtained from the chart reviews. Information on STDs was only available for study population 2.

Intake Forms: Intake forms were obtained from the charts. We collected information on medical symptoms such as weight change, vomiting and diarrhea. We also collected information on risk behaviors such as drug use. Intake forms also contained information on TB and HEPC diagnosis, drug adherence, mental health, and problems with transportation or food.

Chart Review: Other than the intake forms, we also obtained other information from the chart review such as medication lists and additional viral loads not in CAREWARE.

Medication lists were used to determine use of antidepressants and other medications used to treat mood disorders and anxiety.

Data Analysis:

Demographic data and comparative analysis between cases and controls was done using a chi-square test and Fisher's exact test. Income data, CD4 count data, and viral load suppression were analyzed using a two sampled t-test. Due to large numbers of missing intake data at t0, we were not able to adjust for drug adherence, co-morbidities, and risk factors.

RESULTS

Table 1: Demographics for study population 1 and 2.

Study Population 1 (N=102)			
Characteristic	Caring Cuisine \bar{x} (SD)	Case Management \bar{x} (SD)	p-Value
Age ^a	54.6 (7)	51.7 (6)	0.068
Household Income ^a	7941.3 (7377)	11108.4 (9056)	0.249
	Caring Cuisine % (N)	Case Management % (N)	p-Value
Household Size			0.400
1	58.8 (20)	61.8 (42)	
2+	11.8 (4)	19.1 (13)	
Housing			0.886
Stable	67.7 (23)	67.7 (46)	
Unstable	14.7 (5)	17.7 (12)	
Risk			0.377
None	26.5 (9)	36.8 (25)	
MSM	17.7 (6)	20.6 (14)	
IDU	17.7 (6)	22.1 (15)	
Other ^b	5.9 (2)	1.5 (1)	
Study Population 2 (N=32)			
Characteristic	Caring Cuisine \bar{x} (SD)	Case Management \bar{x} (SD)	p-Value
Age ^a	52.0 (9)	51.2 (7)	0.787
Household Income ^a	9015.6 (7449)	12563.9 (9010)	0.235
	Caring Cuisine % (N)	Case Management % (N)	p-Value
Household Size			0.335
1	68.8 (11)	75.0 (12)	
2+	18.8 (3)	2.0 (4)	
Housing			1.000
Stable	87.5 (14)	81.3 (13)	
Unstable	12.5 (2)	18.8 (3)	
Risk			0.561
None	31.3 (5)	43.8 (7)	
MSM	18.8 (3)	31.3 (5)	
IDU	18.8 (3)	6.3 (1)	
Other ^b	12.5 (2)	0	

a: mean (SD)

b: hemophiliac, perinatal

**Number may not add up due to missing values

Demographic Data: Table 1

Study population 1: 34 matched pairs, 53% males. 32% of the population was white, 62% black, 6% Hispanic. No differences were statistically significant, but the following trends were observed. Average household income among Caring Cuisine clients was lower than for controls. Caring Cuisine clients were also found to have larger household size. We found that there were higher percentages of injection drug users and MSM among the controls.

Study population 2: 16 matched pairs, 43.8% males. 31% of the population was white, 56% black, and 12.5% Hispanic. No differences were statistically significant, but the following trends were observed. Household income was lower for Caring Cuisine clients. Household size was similar in both populations. This population had a higher percentage of injection drug users in the Caring Cuisine clients.

Clinical Outcome Data: Table 2

Study population 1: There was no significant difference in change in viral load suppression among cases and controls. Graph 1 shows the percentage of the population that has a suppressed viral load at t0 and t1. 73% of Caring Cuisine clients have suppressed viral loads at t0 and 59% of the controls. At t1 this percentage remains the same for Caring Cuisine and rises to 60% for controls. CD4 counts at time 0 and time 1 were also similar in both groups. The average change in CD4 counts from time 0 to time 1 was -40 for Caring Cuisine clients and 39 for case management clients ($p=0.142$). The average change in CD4 counts among males and females was statistically significant showing that females had an increase of 88.5 while males decreased 46.9 ($p=0.002$).

When stratifying change in CD4 count by gender for cases and control. We found that Caring Cuisine males had a much larger drop in CD4 count than controls (-40 vs. 39 p=0.071).

Graph 1. Percentage of Population with Viral Load Suppression at t0 and t1

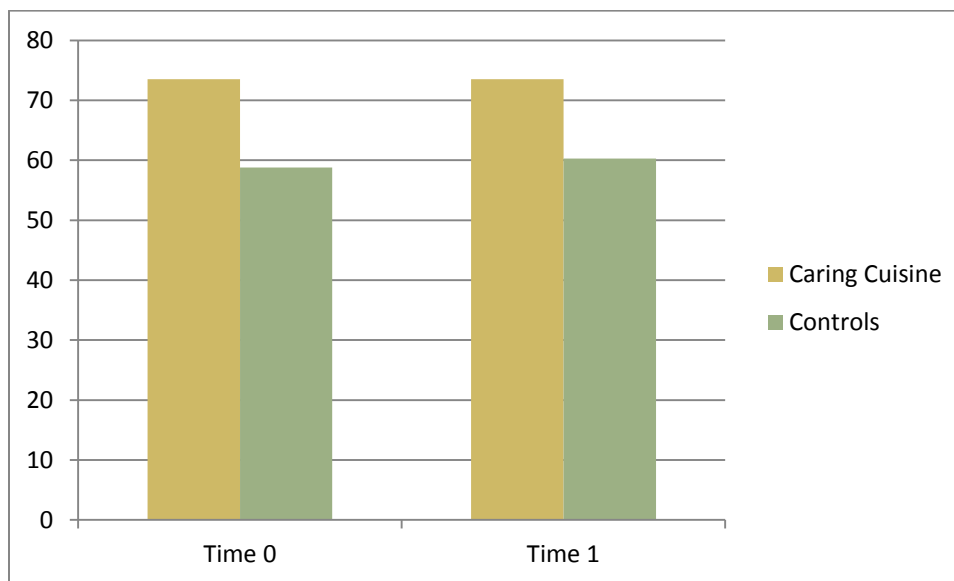


Table 2: Clinical Outcomes at Time 0 and Time 1

Study Population 1			
	Caring Cuisine	Case Management	p-value
Viral Load Suppression (time 0 to time 1)			0.886
No Change	76.5 (26)	72.1 (49)	
Non-suppressed to suppressed	11.8 (4)	13.2 (9)	
Suppressed to non-suppressed	11.8 (4)	14.7 (10)	
CD4 at time 0 ^a	550.0 (393.5)	516.8 (355.0)	0.680
CD4 at time 1 ^a	532.4 (349.4)	539.6 (372.4)	0.923
Change in CD4 count (time 0 to time 1)			0.142
Females	81.6 (235.4)	102.2 (208.5)	0.779
Males	-136.0 (288.6)	-2.54 (141.5)	0.071

Intake form comparison: Table3

Intake form data was only obtainable for time zero and it showed few significant differences in physical symptoms, mental health, medications or co-morbidities. A greater percentage of controls were found to drink alcohol ($p=0.035$). Twice as many Caring Cuisine clients were found to be current smokers, but this was not statistically significant due to missing data.

Table 3: Intake Form Comparisons

Study Population 2			
Characteristic	Caring Cuisine % (N)	Case Management % (N)	p-Value
Problems with:			
Food	37.5 (6)	12.5 (2)	0.225
Shopping	12.5 (2)	18.8 (3)	0.550
Walking	37.5 (6)	18.8 (3)	0.359
Physical Symptoms			
Nausea/vomiting	50.0 (8)	37.5 (6)	0.722
Weight Change	37.5 (6)	31.3 (5)	1.000
Difficulty Eating	18.8 (3)	31.3 (5)	0.685
Diarrhea	25.0 (4)	25.0 (4)	1.000
Uneven Fat	6.25 (1)	6.25 (1)	1.000
Mental Health			
Anxious/Nervous	43.8 (7)	56.3 (9)	0.643
Depressed	56.3 (9)	43.8 (7)	0.643
Medication for mental illness	68.8 (11)	56.3 (9)	0.716
Medications			
HIV medication	93.8 (15)	75.0 (12)	0.333
Drug Adherence	68.8 (11)	43.8 (7)	0.430
Drugs			
Smoking	62.5 (10)	31.3 (5)	0.110
Alcohol	12.5 (2)	25.0 (4)	0.035
Co-morbidities			
STD Diagnosis	43.8 (7)	31.3 (5)	0.716
HEP C	43.8 (7)	43.8 (7)	1.000
TB	0	0	1.000

DISCUSSION

Although the population was too small to make any conclusions, it is still of interest to look at the patterns of the data. The most significant result was the great drop in CD4 counts experienced for males in both groups compared to females who generally increased count

between time 0 and time 1. This result may have been due to healthier behaviors and greater drug adherence among females as previous studies have suggested (43, 44). Looking at the clinical outcomes we find that CD4 counts among Caring Cuisine clients as well as case management clients at time zero is very similar; however when we look at change in CD4 counts, we see that Caring Cuisine Males have a greater drop in CD4 counts than control matches. We could not account for the large difference and further research needs to be done. In addition, we see that prevalence of mood disorders, drug adherence, Hep C and physical symptoms are also similar at time zero. This might be indicative that the two populations are not as different as one might think; however, we see that Caring Cuisine clients do start off with more viral load suppression than controls although not statistically significant ($p=0.140$). We find that 37.5% of Caring Cuisine clients versus 12.5% of case management clients had problems with accessing food at time 0; this is to be expected since Caring Cuisine clients were assigned to the program due to poor food access. We did not see a greater prevalence of depression, poorer drug adherence and greater use of alcohol and other drugs at time for Caring Cuisine clients as might have been expected due to previous studies that show food insecurity can lead to these factors; however, the data sample was too small to draw conclusions on these issues.

Research on the effectiveness of community-based home-delivered meal programs among people living with AIDS is a challenge. Finding an appropriate control population is difficult because those who are similar to the program participants cannot ethically be denied participation in the program for the purpose of research.

This study has several limitations. Identifying controls that were as similar to the Caring Cuisine participants as possible was difficult. By using the intake form data, we hoped to be able to control for other factors like co-morbidities, drug adherence, and mental illness; however, in this study that was not possible. It was assumed at the initiation of the study, that after finding eligible Caring Cuisine clients with viral loads, they could then be matched to controls by age, gender, date of diagnosis, and race, and that the selected controls would have intake forms. Unfortunately, we discovered that many clients had missing intake forms and this greatly diminished our study population. Because we were working under a time restraint, it was not possible to go back and find additional controls who had viral loads and intake forms. Among the clients who had intake forms, there were many with missing information. Since the information in the forms was not collected for the purpose of research, the data was often incomplete or illegible. It was also difficult to find clients with sufficient viral load results because the NGO does not always receive the client's clinical information and does not have the capacity to do these tests themselves. Additionally, the fact that some clients are homebound helps to explain why there were many missing intake forms since it is difficult for these clients to attend all appointments at the APNH office.

RECOMMENDATIONS

Research on home-delivered meal programs for PLWHA is currently lacking because of the difficulty of obtaining data from community based programs, and the challenges in accounting for the numerous confounders between clinical outcomes and nutrition. This study was reflective of many of these challenges. In the future, figuring out ways to improve the quality of the data would be beneficial. This could be done by training case managers, who normally fill

out intake forms and maintain client folders, the importance of research data to back up with statistics the effect they are having in the community. This information could be useful to potential donors to the meal programs. Case Managers could be encouraged to answer all questions on the intake forms. Additionally, small incentives can be provided for clients who come to their appointments.

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