#### 1 ABSTRACT

#### 2 Objective

3 Food insecurity, or self-reports of inadequate food access due to limited financial resources, remains

4 prevalent among people living with HIV (PLHIV). We examined the impact of food insecurity on

- 5 combination antiretroviral therapy (cART) adherence within an integrated care facility that provides
- 6 services to PLHIV, including two meals per day.

#### 7 Design

- 8 Adjusted odds ratios (aOR) were estimated by generalized estimating equations, quantifying the
- 9 relationship between food insecurity (exposure) and cART adherence (outcome) with multivariable
- 10 logistic regression.

#### 11 Setting

- 12 We drew on survey data collected between February 2014-March 2016 from the Dr. Peter Centre Study
- 13 based in Vancouver, Canada.

### 14 **Participants**

- 15 This study included 116 PLHIV at baseline, with 99 participants completing a 12-month follow-up
- 16 interview. The median age was 46 years (IQR: 39-52) at baseline, and 82% (n=95) were biologically 17 male at birth.

### 18 **Results**

- 19 At baseline, 74% (n=86) of participants were food insecure ( $\geq 2$  affirmative responses on Health
- 20 Canada's Household Food Security Survey Module) and 67% (n=78) were adherent to cART > 95% of
- 21 the time. In the adjusted regression analysis, food insecurity was associated with suboptimal cART
- 22 adherence (aOR=0.47, 95% confidence interval = 0.24-0.93).

### 23 Conclusions

- 24 While food provision may reduce some health-related harms, there remains a relationship between this
- 25 prevalent experience and suboptimal cART adherence in this integrated care facility. Future studies that 26 elucidate strategies to mitigate food insecurity and its affects on cART adherence among PLHIV in this 27 setting and in other similar environments are necessary.
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### **36 INTRODUCTION**

Advances in combination antiretroviral therapy (cART) have improved morbidity and mortality
for people living with HIV (PLHIV) <sup>(1-3)</sup>. However, social and structural barriers, such as food
insecurity (FI), homelessness, and poverty continue to prevent marginalized PLHIV from fully
benefiting from cART <sup>(4-6)</sup>. Notably, FI, or self-reports of uncertain or inadequate food access due to
limited financial resources, is associated with adverse HIV-related clinical outcomes <sup>(7-9)</sup>; FI has a
known association with incomplete HIV viral load suppression <sup>(10,11)</sup>, lower CD4 cell counts <sup>(12)</sup>, and a
heightened risk for mortality <sup>(4,13)</sup>.

Research has suggested that the impact of FI on adverse HIV-related outcomes is due, in part, to
its negative association with adherence to cART <sup>(9,14,15)</sup>. A study based in San Francisco revealed that
PLHIV who were food insecure were almost half as likely to be adherent to cART than their food
secure counterparts <sup>(11)</sup>. Additional research has illustrated mechanisms through which FI may impact
cART adherence <sup>(16–19)</sup>. For example, individuals may skip doses or discontinue treatment to mitigate
the actual or anticipated side effects of taking cART without food (e.g. nausea, stomach pain) <sup>(9,16)</sup>.

50 While past studies have established a link between FI and suboptimal cART adherence <sup>(16,18,20)</sup>. 51 this relationship has yet to be explored within the context of integrated care programs that aim to attenuate 52 the consequences of socio-structural inequities among PLHIV. For example, the Dr. Peter Centre (DPC) 53 is an integrated care program serving PLHIV in Vancouver, British Columbia (BC), Canada. PLHIV are 54 eligible to access DPC programming if they are at risk of health deterioration and demonstrate a need 55 (eg., limited financial or social supports) for assistance to maintain independence<sup>(21)</sup>. The DPC aims to 56 reduce barriers to access and retention in HIV care by offering a wide array of harm reduction services<sup>(21)</sup>. 57 These services include counselling, therapies (eg., art, music, recreational), nursing (eg., wound care, 58 foot clinic, cART support), and amenity access (eg., nap room, showers)<sup>(21)</sup>. DPC clients can also access 59 two nutrient-rich meals per day, including balanced portions of meat/alternatives, dairy products, fruits and vegetables, and whole grains<sup>(22)</sup>. While we acknowledge that food provision does not directly reduce 60 the root causes of FI in resource-rich settings, which is inadequate financial resources<sup>(23,24)</sup>, we 61 62 hypothesize that this service, along with other supports that are offered in this setting, may help mitigate 63 the relationship between FI and cART adherence. Therefore, we undertook a study to examine this 64 relationship among clients of the DPC. Further understanding this relationship within an integrated care 65 setting may have implications for optimizing HIV care among structurally vulnerable PLHIV.

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### 67 **METHODS**

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This study used data from a community-based observational study exploring the impact of the

DPC's services on health outcomes and HIV-related care for marginalized PLHIV. The quantitative study, described in detail elsewhere <sup>(21,25)</sup>, is comprised of a longitudinal cohort of DPC clients who participated in baseline (n=121) and follow-up (n=102) socio-behavioral surveys. Participant recruitment was conducted by peer research associates (PRAs) – individuals with common experiences to DPC clients – and DPC staff. Study invitations were placed at the DPC reception desk and included the study coordinator's number, whom participants could call if interested in participating.

Individuals were eligible for this analysis if they had been enrolled as a DPC client after
February 27, 2011, had completed a baseline survey, and were on cART at baseline. Baseline surveys
that collected socio-demographic, behavioural, and FI-related data were administered by the PRAs to
the DPC clients between February 2014 and March 2016. Follow-up surveys were conducted
approximately 12 months after the baseline surveys. Participants received \$30 Canadian dollars

80 honoraria as compensation for their involvement.

81 Survey data was supplemented with comprehensive clinical data from the HIV Drug Treatment 82 Program (DTP) held at the BC Centre for Excellence in HIV/AIDS. The DTP provides cART free-of-83 charge to all PLHIV in the province of BC <sup>(26)</sup>. As described in detail elsewhere, individuals are 84 enrolled in the DTP when they are first prescribed cART by any physician in BC, and all subsequent 85 measures of HIV-related clinical variables (eg., CD4 count, HIV viral load, cART refill compliance) 86 are stored in the DTP database <sup>(26)</sup>. Because our analysis required that DPC clients be on cART at 87 baseline, all the participants in this study were enrolled in the DTP.

## 88 Measures

The primary explanatory variable of interest was FI in the past 12 months, which was measured using the ten-item adult scale of Health Canada's Household Food Security Survey Module (HFSSM) (<sup>27,28)</sup>. This tool classifies FI status based on the number of affirmative responses to the ten items. In accordance with Health Canada's guidelines, zero or one affirmative response on the HFSSM indicates food security, while two or more affirmative responses denotes FI <sup>(28)</sup>.

94 The outcome variable of interest for this analysis was cART adherence, based on refill 95 compliance, which is a previously validated method of estimating adherence when direct observation of 96 medication consumption is not feasible <sup>(29)</sup>. Refill compliance is calculated as the number of days that 97 cART was dispensed divided by the number of days of follow-up during the 12 months prior to the interview date <sup>(30,31)</sup>. This measure was expressed as a percent and dichotomized as optimal (adhering 98 99 to  $\geq$ 95% of prescribed cART) or sub-optimal (adhering to <95% of prescribed cART) adherence; this cut-off has been validated as having clinical relevance for HIV viral load suppression <sup>(31,32)</sup>. Potential 100 101 confounding variables for inclusion in the statistical models were selected a priori based on their

102 hypothesized relationship with FI (exposure) and cART adherence (outcome).

# 103 Data Analyses

104 Descriptive p-values were calculated using Pearson Chi-square tests and Wilcoxon rank-sum 105 tests for binary/categorical variables and continuous variables, respectively. Adjusted odds ratios (aOR) 106 were estimated by generalized estimating equations (GEE), quantifying the relationship between binary 107 FI (food secure vs. moderate/severely food insecure) and binary cART adherence (adhering to < 95% 108 of prescribed cART vs. adhering to >95% of prescribed cART) with logistic regression  $^{(33,34)}$ . GEE 109 were used to account for the longitudinal nature of the baseline and follow-up measures taken from 110 individual participants using an exchangeable correlation structure with robust standard errors <sup>(35,36)</sup>. To 111 select the variables for the multivariable model, a change-in-estimate approach to confounder selection 112 was used <sup>(37,38)</sup>. Specifically, if the coefficient for FI changed by less than 5% after the omission of a given confounder, the variable was not adjusted for in the final model <sup>(37,39)</sup>. All data were analyzed 113 114 using SAS software version 9.4 (SAS Institute, Cary, North Carolina, Version 9).

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### 116 **RESULTS**

117 Among the 121 DPC clients in the total cohort, 116 individuals and 215 total visits 118 (observations) were included in this analysis after excluding those who were not on cART at baseline 119 or who were missing data on the FI or cART adherence measures. Table 1 reveals no significant 120 differences in the proportions of responses to the HFSSM questions or overall FI status between 121 baseline and follow-up. As shown in Table 2, 74% (n=86) of participants reported experiencing FI in 122 the past 12 months, at baseline, and 67% (n=78) of participants were adherent to cART in the past six 123 months. The median age of participants at baseline was 46 years (Q1, Q3: 39, 52), and 82% (n=95) of 124 participants were biologically male at birth. Notably, 35% (n=41) identified as Indigenous, 70% (n=81) 125 had been diagnosed with hepatitis C, and 53% (n=62) had used illicit drugs (excluding marijuana) in 126 the past six months.

In the unadjusted analysis (Table 3), experiences of FI were associated with suboptimal cART
adherence (unadjusted odds ratio [OR] = 0.44, 95% confidence interval [CI] = 0.24 - 0.82).

129 Furthermore, after adjustment for potential confounding factors, FI remained associated with

suboptimal adherence (aOR=0.47, 95% CI = 0.24 - 0.93). In other words, those who experienced FI

131 were approximately half as likely to be adherent to cART (<95%) compared to those who were food

- 132 secure.
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### 134 **DISCUSSION**

135 This study examined the relationship between FI and cART adherence among a cohort of PLHIV who are clients of the DPC in Vancouver, Canada. Nearly three-quarters of DPC participants in 136 137 this study reported experiencing FI in the past 12 months. The high prevalence of FI among DPC clients was similar to that documented in other Canadian studies of PLHIV<sup>(7,8,40,41)</sup>. Two studies 138 139 conducted in BC (2011 and 2016) found the percentage of food insecure PLHIV to be almost identical to the 74% of participants identified in this study <sup>(8,40)</sup>. Also in line with other studies, individuals who 140 141 were food insecure were approximately half as likely to be adherent to cART after adjusting for potential clinical, social, and demographic confounders of the FI-cART adherence relationship <sup>(9,42)</sup>. 142

143 The results of this study must be interpreted in the context of previous literature detailing how 144 interventions that focus on food provision (e.g., food banks, community gardens) do not necessarily 145 alleviate FI over an extended period of time, particularly in resource-rich settings <sup>(23,43–45)</sup>. While food 146 provision can provide other benefits (e.g., the mitigation of acute nutritional needs or hunger<sup>(24)</sup> [a physical sensation experienced by those with severe  $F\Pi^{(46)}$ , entry points to healthcare services<sup>(25)</sup>, 147 promotion of social interactions  $^{(41,47)}$ , and support for development of daily routines  $^{(25,45)}$ ), the root 148 driver of FI in resource-rich settings is inadequate financial resources <sup>(43,48–50)</sup>. Our study further 149 150 demonstrates this as FI remains prevalent among DPC clients despite the provision of food. In addition, 151 there remains a relationship between this prevalent experience and sub-optimal cART adherence in this 152 integrated care facility.

153 While our study cannot evaluate any of the potential mechanisms by which FI leads to 154 suboptimal cART adherence, our work provides impetus for additional research to better understand 155 how to attenuate the relationship between these two factors in this setting and in other similar environments. For example, FI has a known association with depression <sup>(51,52)</sup> and dependence on 156 157 drugs and alcohol<sup>(53)</sup>, all of which are linked with suboptimal cART adherence <sup>(39,54–56)</sup>. FI, along with 158 other needs (e.g. housing, transportation) that stem from limited financial resources, may also impact 159 cART adherence when meeting these needs interferes with medication access or medical appointments <sup>(19,57,58)</sup>. Analyses that explicate how these pathways may be leveraged to attenuate the impact of FI on 160 161 cART adherence among structurally vulnerable PLHIV are necessary.

162 The findings of this study also point to a need to consider the broader implications of food 163 provision within integrated care models, beyond the scope of mitigating FI. In particular, the food 164 program at the DPC can be conceptualized within the organization's broader harm reduction mandate, 165 which aims to improve health and reduce health- and drug-related harms <sup>(21,41,45)</sup>. For example, the 166 food program at the DPC has been shown to be an integral element of the Centre and a primary access 167 point for individuals interacting with the space <sup>(25,45)</sup>. Overall, the benefits of integrated care models that include food provision must consider how programming may positively impact clients through aharm reduction approach, even if experiences, such as FI, remain prevalent.

The DPC offers a unique environment in which to study FI and adherence to cART. However, it also warrants consideration of some potential limitations. Participants of this study were not randomly selected and are thus not representative of the general population of PLHIV in BC. In fact, because the admission requirements for the DPC necessitate a deteriorating health status <sup>(21)</sup>, the sample in this study may overrepresent individuals with complex health needs. In addition, while the HFSSM is a validated measurement tool for FI, fluctuations in FI within a 12-month period is an inherent limitation to the use of the HFSSM <sup>(46)</sup>. Another limitation of this study is that we are unable to stratify our analysis or adjust our regression models by whether a participant in fact received meals at the DPC. Therefore, we cannot directly attribute the impact of this particular service on the relationship between FI and adherence. However, previous work conducted among 30 DPC clients who use illicit drugs showed that 100% (n=30) of clients surveyed accessed the DPC food program for some of their meals, with 80% (n=24) using the program daily and the other 20% (n=6) using the program weekly (Miewald C, unpublished results). Our findings are contextualized based on this understanding, as well as other published literature including DPC clients (25,45). 

In conclusion, this study documented a high prevalence of FI among DPC clients in Vancouver,
Canada. As such, while food provision may have benefits related to harm reduction, there remains a
relationship between this prevalent experience and cART adherence in this integrated care facility.
Future studies that elucidate strategies to mitigate FI among PLHIV in this setting and in other similar
environments are necessary.

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 Table 1: Baseline and follow-up responses to the 10-Item Adult Scale of the Household Food Security Survey Module of Dr. Peter Center clients in Vancouver, Canada (February 2014-March 2016)

HFSSM Item	Response Options	Baseline Response (n=116) n (%)	Follow-Up Response (n=99) n (%)	p-value
1. You and other household members worried that	Often true*	38 (34.23)	35 (35.71)	
food would run out before you got money to buy more.	Sometimes true	37 (33.33)	32 (32.65)	
Was that often true, sometimes true, or never true in the past 12 months?	Never true	36 (32.43)	31 (31.63)	0.975
2. The food that you and other household members	Often true*	45 (40.54)	32 (32.99)	
bought just didn't last, and there wasn't any money to	Sometimes true	35 (31.53)	33 (34.02)	
get more. Was that often true, sometimes true, or never true in the past 12 months?	Never true	31 (27.93)	32 (32.99)	0.513
3. You and other household members couldn't afford to	Often true*	43 (38.39)	26 (26.80)	
eat balanced meals. In the past 12 months was that	Sometimes true	40 (35.71)	39 (40.21)	
often true, sometimes true, or never true?	Never true	29 (25.89)	32 (32.99)	0.193
4. In the past 12 months, did you or other adults in	Yes*	64 (78.05)	54 (72.97)	
your household ever cut the size of your meals or skip meals because there wasn't enough money for food?	No	18 (21.95)	20 (27.03)	0.461
5. How often did this happen? (Referring to Item-4)	Almost every month*	39 (48.75)	30 (40.54)	
	Some months but not every month	19 (23.75)	23 (31.08)	
	Only 1 or 2 months	4 (5)	1 (1.35)	
	Not applicable ('No' to Item- 4)	18 (22.5)	20 (27.03)	0.378
6. In the past 12 months, did you ever eat less than you	Yes*	68 (79.07)	48 (65.75)	
felt you should because there wasn't enough money to buy food?	No	18 (20.93)	25 (34.25)	0.060
7. In the past 12 months, were you ever hungry but	Yes*	69 (80.23)	52 (69.33)	
didn't eat because you couldn't afford enough food?	No	17 (19.77)	23 (30.67)	0.110
8. In the past 12 months, did you lose weight because	Yes*	60 (71.43)	42 (56.76)	
you didn't have enough money for food?	No	24 (28.57)	32 (43.24)	0.054
9. In the past 12 months, did you or other adults in	Yes*	49 (60.49)	37 (59.68)	
your household ever not eat for a whole day because there wasn't enough money for food?	No	32 (39.51)	25 (40.32)	0.921
10. How often did this happen? (Referring to Item-9)	Almost every month*	22 (27.85)	16 (25.81)	
	Some months but not every month	19 (24.05)	17 (27.42)	
	Only 1 or 2 months Not applicable ('No' to Item- 9)	6 (7.59) 32 (40.51)	4 (6.45) 25 (40.32)	0.965
Food Security Status	Food Insecure	86 (74.14)	69 (69.7)	
	Food Secure	30 (25.86)	30 (30.3)	0.469

\*Indicates an affirmative response on the HFSSM

(February 2014-March 2016)	Total n=116	
Variables	<u>n</u>	%
cART* adherence in the past 12 months (Outcome)		
Less than 95%	38	32.76
95% or more	78	67.24
_ Food security (Exposure)	20	25.06
Food secure	30	25.86
Food insecure Potential confounders (Categorical variables)	80	/4.14
Often have a drink containing alcohol		
Never	46	39.66
Sometimes	70	60.34
Illicit drug use in the past 6 months (excluding marijuana)		
No	54	46.55
Yes	62	53.45
Biological sex at birth	101	97.07
Male Famela	101	87.07
Homeless in the past 12 months	15	12.93
No	89	76.72
Yes	27	23.28
Self-reported anxiety and/or depression		
Not anxious or depressed	29	25.00
Anxious or depressed	87	75.00
Prison or jail ever		10.1.1
No Vec	57	49.14
108 Ever diagnosed with Henetitic C	39	30.80
No	35	30.17
Yes	81	69.83
Food assistance for most recent regimen		
Taken without food/with or without food	26	22.41
Taken with food	81	69.83
With DPC less than a year at baseline		
No	50	41.10
Yes Commently working for new	66	56.90
No	107	92.24
Yes	9	7.76
Current smoking status	<i>.</i>	
No	35	30.17
Yes	81	69.83
Currently living with someone		
Alone	100	86.21
With others	16	13.79
Indigenous ancestry	75	61.66
NO Yes	41	35 34
Highest level of education	11	55.51
Some post-secondary and above	46	39.66
High school and below	70	60.34
Issues with performing usual activities due to health state		
No issues	67	57.76
Some issues/unable	49	42.24
3 antiretrovirals in current regimen	109	02 10
res	108	93.10
NU Potential confounders (Continuous variables)	0 Madian	0.90
Age at interview date	46	39-52
Household monthly income before taxes (CAD)	1100	1064.5-1151
Cumulative months on cART at visit	47	21-97
*Combination antiretroviral therapy		

Table 2: Baseline descriptive characteristics of 116 Dr. Peter Centre clients in Vancouver, Canada

# Table 3: Univariable and multivariable analyses of the relationship between food insecurity and 95% combination antiretroviral therapy (cART) adherence among clients of the Dr. Peter Centre in Vancouver, Canada (February 2014-March 2016)

( / /			Unadjusted logistic	Adjusted logistic
			regression models	regression models
			(Estimated by gener	alized estimating
	Tota	al n=116	equations)	
	<95% cART	> 95% cART	Outcome: >95% vs <9	5% cART adherent
	adherent	adherent	(Total observa	ations=215)
	(n=77)	(n=138)	(	
		· · /	Unadjusted odds	Adjusted odds
Variables	n (%)	n (%)	radio (95% CI)	ratio (95% CI)
Food security (Exposure)				
Food secure	13 (16.88)	47 (34.06)	Ref.	Ref.
Food insecure	64 (83.12)	91 (65.94)	0.44 (0.24-0.82)	0.47 (0.24-0.93)
Confounders (categorical variables)	_			
Often have a drink containing alcohol			Ref.	
Never	32 (41.56)	56 (40.48)		
Sometimes	45 (58.44)	82 (59.42)	0.99 (0.53-1.85)	Not selected*
Illicit drug use in the past 6 months (excluding				
marijuana)	20 (20 00)	01 (50 50)		D (
No	30 (38.96)	81 (58.70)	Ref.	Ref.
Yes Dialagian and high	47 (61.04)	57 (41.30)	0.51 (0.28-0.92)	0.59 (0.32-1.09)
Biological sex at Dirth	69 (99 21)	119 (95 51)	Pof	
Formala	00(00.31)	20(14.40)	1 21 (0 47 2 62)	Not colocted
Homoloss in the past 12 months	9 (11.09)	20 (14.49)	1.51 (0.47-5.05)	Not selected
No	61 (79 22)	114 (82 61)	Ref	
Ves	16(20.78)	24(17.39)	0.88(0.43-1.80)	Not selected
Self-reported anxiety and/or depression		(17.57)	0.00 (0.10 1.00)	1.01.000000
Not anxious or depressed	18 (23.38)	44(31.88)	Ref.	Ref.
Anxious or depressed	59 (76.62)	94 (68.12)	0.64 (0.32-1.29)	0.77 (0.35-1.70)
Prison or jail ever				
No	35 (45.45)	70 (50.72)	Ref.	
Yes	42 (54.55)	68 (49.28)	0.84 (0.45-1.59)	Not selected
Ever diagnosed with Hepatitis C				
No	18 (23.38)	46 (33.33)	Ref.	Ref.
Yes	59 (76.62)	92 (66.67)	0.63 (0.30-1.33)	0.56 (0.25-1.26)
Food assistance for most recent regimen				
Taken without food/with or without food	13 (16.88)	37 (26.81)	Ref.	
Taken with food	64 (83.12)	101 (73.19)	0.63 (0.32-1.21)	Not selected
With DPC less than a year at baseline	24 (44 16)	(2 (11 02)		
NO X	34 (44.16)	62 (44.93)	Ker.	Not colored
1 cs Currently working for new	45 (55.64)	70 (33.07)	0.97 (0.32-1.84)	Not selected
No	71 (02 21)	124 (80.86)	Pof	
NO Ves	6(7.79)	124(69.60) 14(10.14)	0.91 (0.33-2.49)	Not selected
Current smoking status	0(1.1))	14 (10.14)	0.91 (0.33-2.49)	Not selected
No	19 (24.68)	49 (35,51)	Ref	
Yes	58 (75.32)	89 (64.49)	0.68 (0.35-1.34)	Not selected
Currently living with someone	,		,	
Alone	71 (92.21)	114 (82.61)	Ref.	Ref.
With others	6 (7.79)	24 (17.39)	2.55 (1.09-5.94)	3.32 (1.47-7.50)
Indigenous ancestry				
No	46 (59.74)	93 (67.39)	Ref.	
Yes	31 (40.26)	45 (32.61)	0.75 (0.40-1.42)	Not selected
Highest level of education				
Some post-secondary and above	30 (38.96)	56 (40.58)	Ref.	
High school and below	47 (61.04)	82 (59.42)	0.98 (0.54-1.78)	Not selected
Issues with performing usual activities due to				
health state	45 (50 44)	01 (50 70)	D (	
No issues	45 (58.44)	81 (58.70) 57 (41.20)	Ref. 0.87 (0.40, 1.56)	Not colocted
3 antiretrovirals in current regimen	52 (41.50)	57 (41.50)	0.07 (0.49-1.30)	not selected
Ves	74 (96 10)	125 (90 58)	Ref	
No	3 (3 90)	13 (9.42)	2 14 (0.61.757)	Not selected
Confounders (continuous variables)	Median (01-03)	Median (01-03)	2.17 (0.01-7.37)	1 tot belocitu
Age at interview date	45 (37-51)	49 (42-54)	1.41 (1.03-1.93)	1.16 (0.82-1.63)
The at little view date		12 (12 5 1)	per 10-year increase	
Household monthly income before taxes (CAD)	1100 (1071-1111)	1100 (1091-1245)	1.05 (0.98-1.13)	Not selected
Cumulative months on cART at visit	38 (19-70)	70.5 (35-121)	1.15 (1.07-1.24) per 12-month increase	1.14 (1.05-1.23)

\*Not selected after change-in-estimate approach: if the coefficient for food insecurity changed by less than 5% after the omission of a given confounder, the variable was not adjusted for in the final model