From Eligibility to Enrollment Without a Clinic Visit: The Eat Well Produce Prescription Trial for Patients with Diabetes at Risk of Food Insecurity

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Background

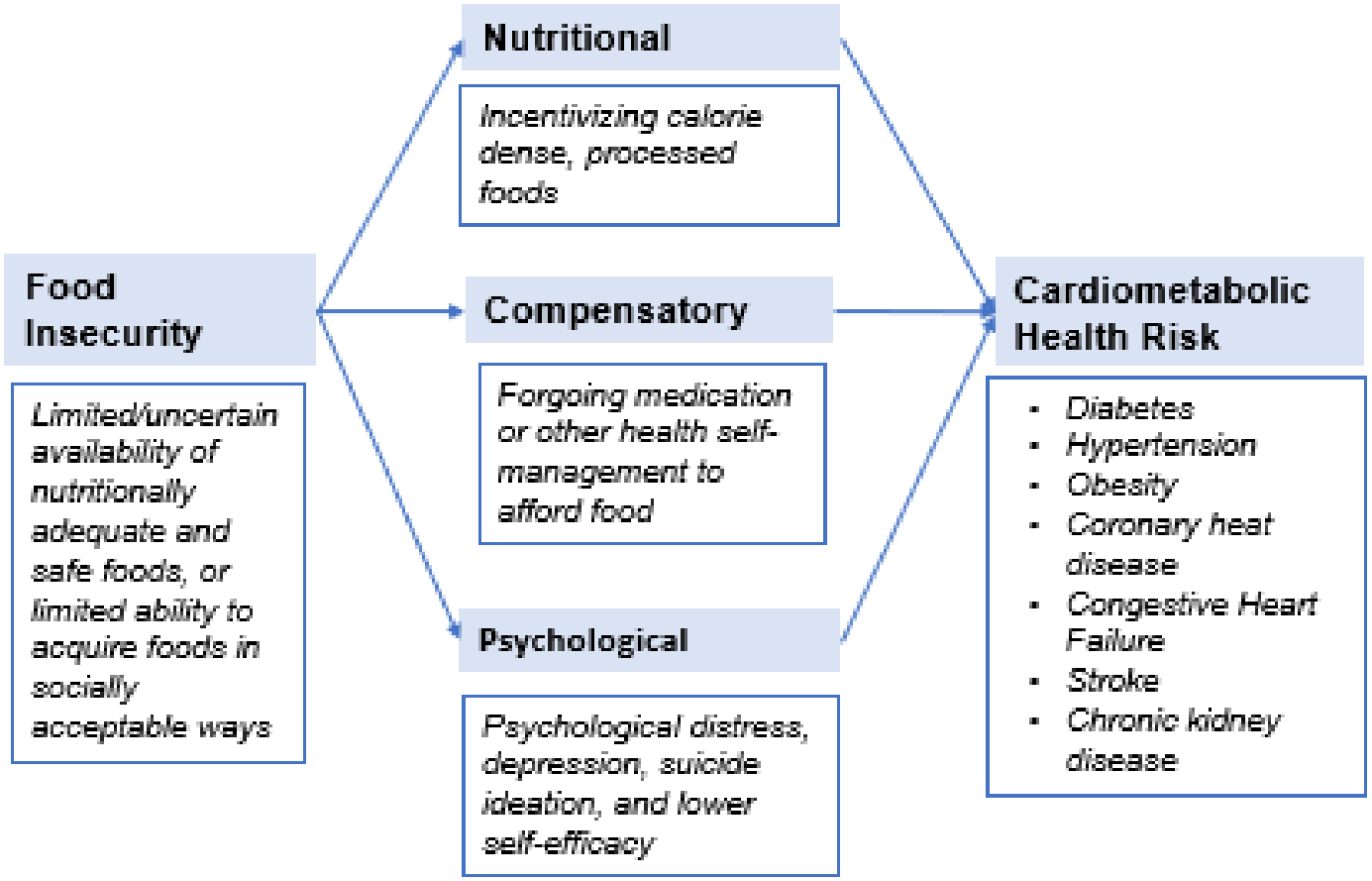
Food insecurity

- Food insecurity (FI), is defined as ‘a lack of consistent access to safe, nutritious, or enough food for every person in a household to live an active, healthy life’
- In 2022, an estimated 12.8% of US households experienced FI
- Screening for FI as a patient reported unmet social need is increasingly common in routine clinical encounters

Food and Agriculture Organization of the United Nations, International Fund for Agricultural Development, World Food Programme. The state of food insecurity in the world. Published 2015. Accessed January 10, 2025. https://www.fao.org/3/i4646e/i4646e.pdf

Background

Relationship between food insecurity and cardiometabolic health



Hill-Briggs, Felicia, Nancy E. Adler, Seth A. Berkowitz, Marshall H. Chin, Tiffany L. Gary-Webb, Ana Navas-Acien, Pamela L. Thornton, and Debra Haire-Joshu. "Social determinants of health and diabetes: a scientific review." *Diabetes care* 44, no. 1 (2020): 258.

Evidence Gaps

- Interventions to improve food security show promise for improving cardiometabolic health but evaluations have high risk of bias due to methodological limitations, including the lack of pragmatic or experimental designs, limiting conclusions on effectiveness

- Implementation evidence gaps exist on how to best promote uptake and use of food security and FIM interventions

O'Connor, Elizabeth A., et al. "Preventive services for food insecurity: evidence report and systematic review for the US Preventive Services Task Force." *JAMA* (2025).
Volpp, K.G., et al. "Food is medicine: a presidential advisory from the American Heart Association". *Circulation* (2023).

Study Objective

Overall Study Objective:

This study sought to test a produce prescription (PRx), within a pragmatic randomized controlled to better understand its real-world effectiveness for improving cardiometabolic health related outcomes and utilization patterns. *Co-primary outcomes were HbA1c and emergency department visits.*

Secondary Objective:

Implement the PRx using a low-cost, automated, and affirmative outreach strategy and evaluate patient engagement. *Outcomes of interest were enrollment and adherence.*

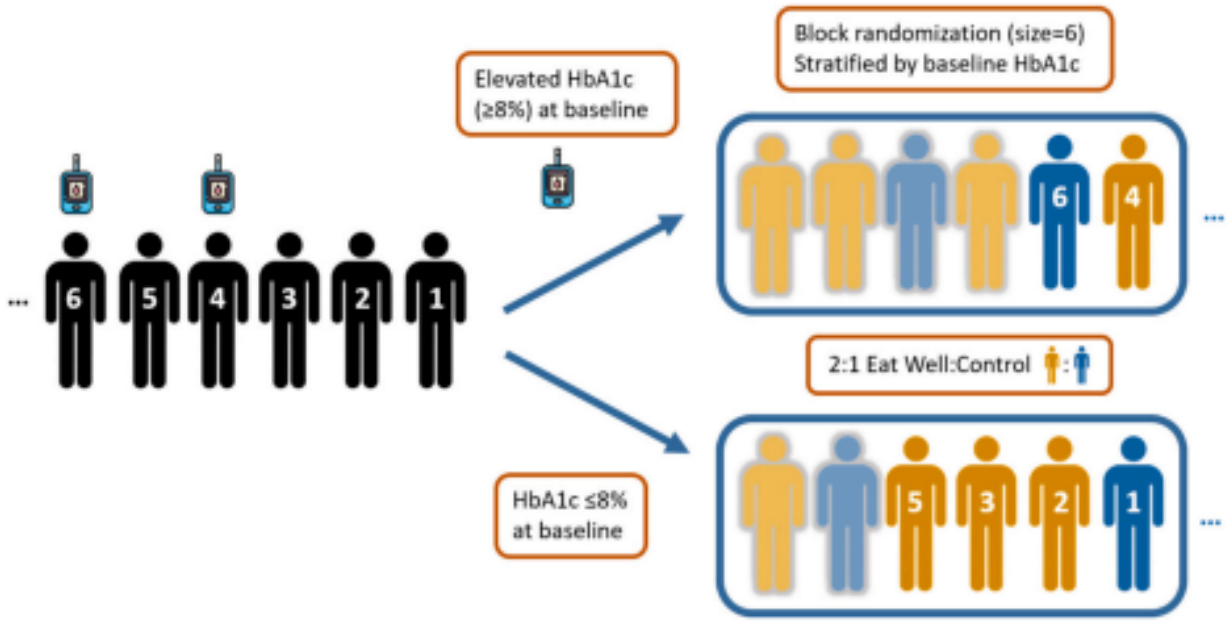
Study Design

Study Design:
Participants were randomized (2:1) to one of two arms stratified based on elevated HbA1c (>8%):

Arm 1 : Eat Well PRx

Arm 2 : Usual care

All participants were sent educational materials related to nutrition and cooking and other diabetes self-management topics.



Study Design

Inclusion Criteria:
Age 18+, in Diabetes Registry, had at least one outpatient A1c measurement in the previous year, and at-risk for FI:

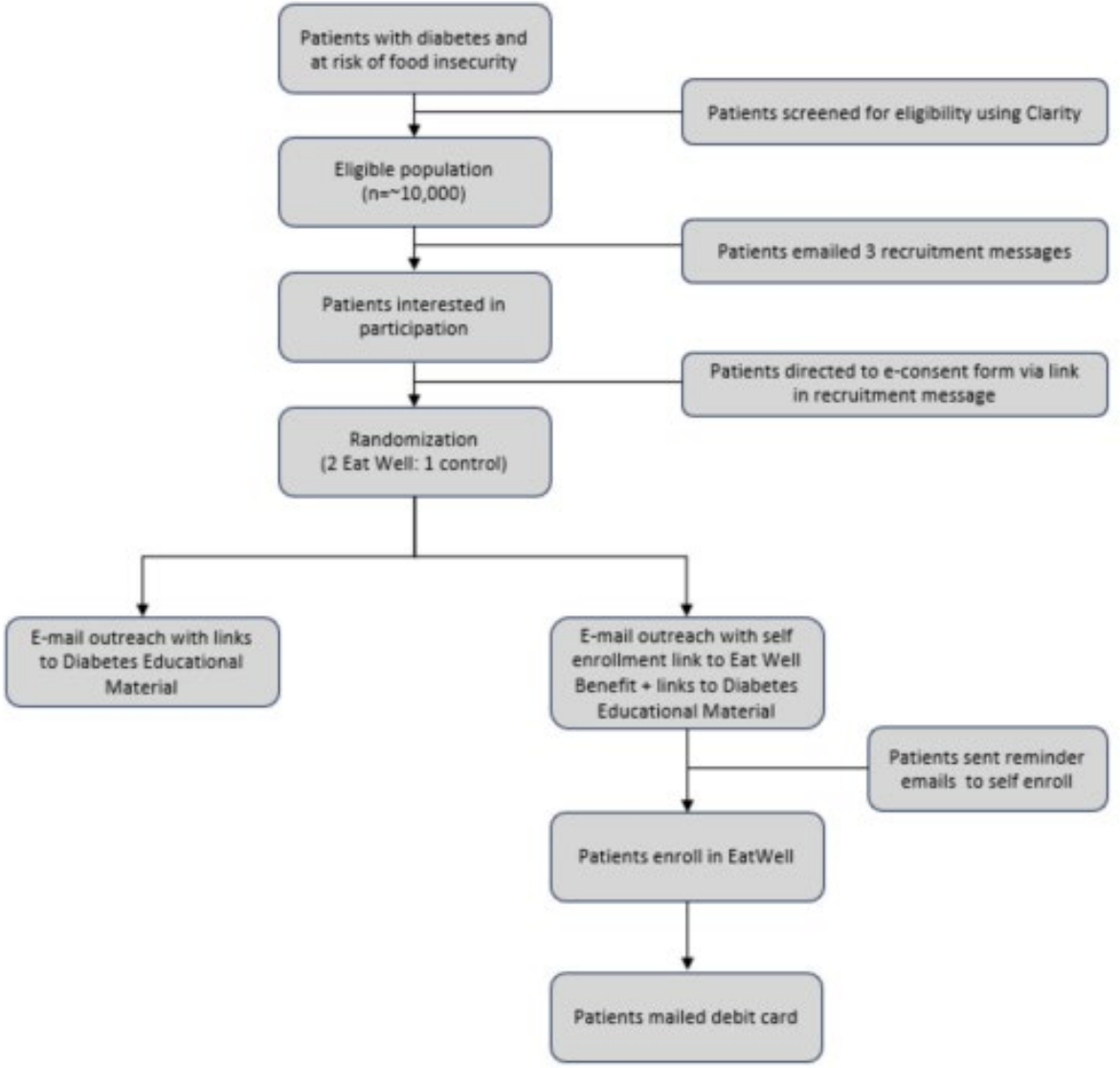
- Answered positive on FI questions as part of social history <12 months OR
- Answered positive on financial stress question as part of social history <12 months OR
- has Medicaid as insurance payer OR
- lives in ADI zip code of 7th decile or higher

‘Eat Well’ – A Produce Prescription Program

- ‘Eat Well’ provides subsidies ($80/month for a year) to buy fresh, frozen, and canned fruits and vegetables via a reloadable debit card
- Enrollment is online and a brief process (<5 minutes)
- Funds are electronically loaded onto a debit card
- Participants choose which WIC approved fruits and vegetables to buy with their Eat Well funds
- The price of the fruits and vegetables come off the bill are charged separately to the ‘Eat Well’ debit card

Implementation as a Population Health Management Strategy

- Mass affirmative outreach approach proposed based on feedback from community partner
- Patients from historically marginalized neighborhoods were prioritized for outreach

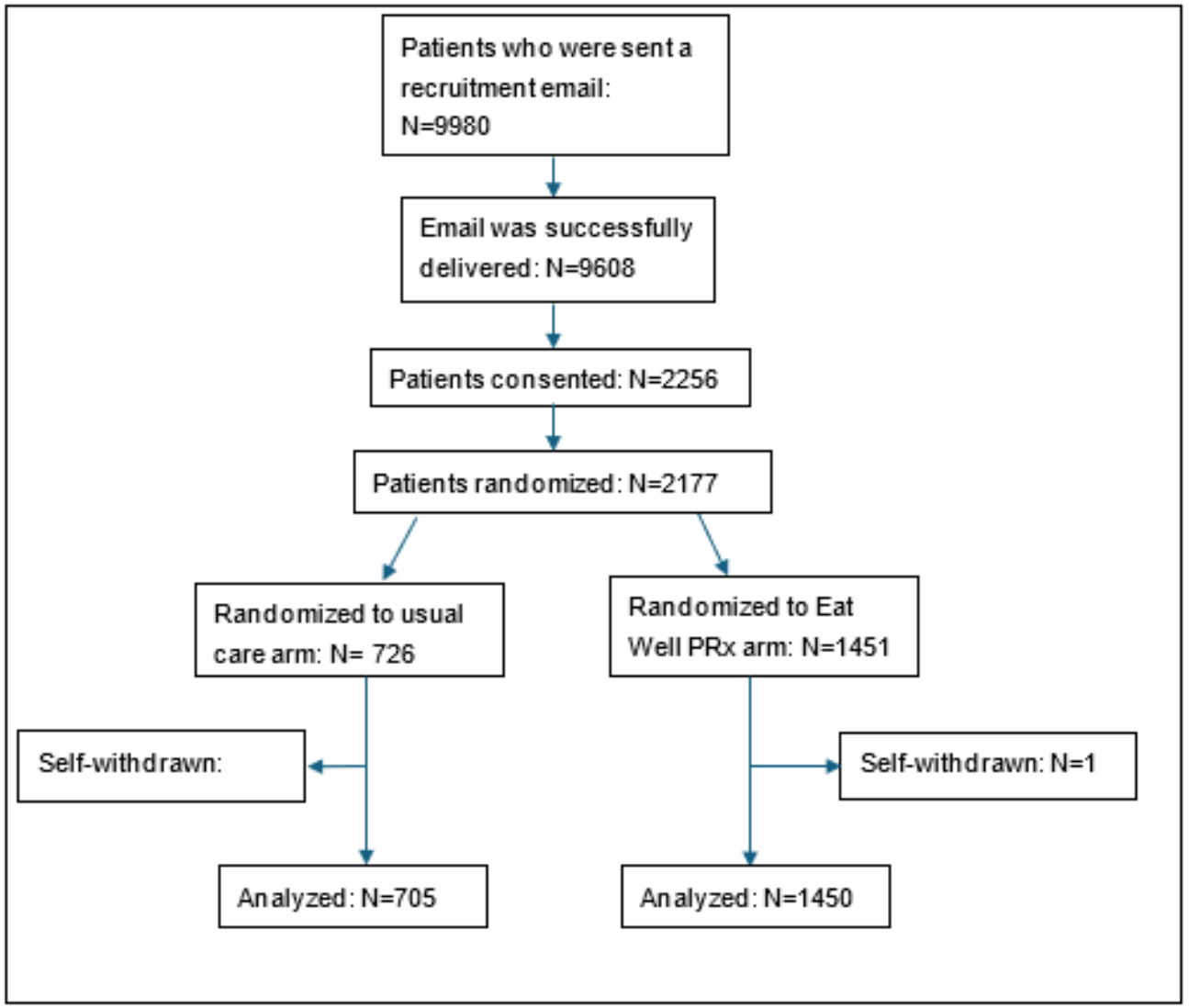


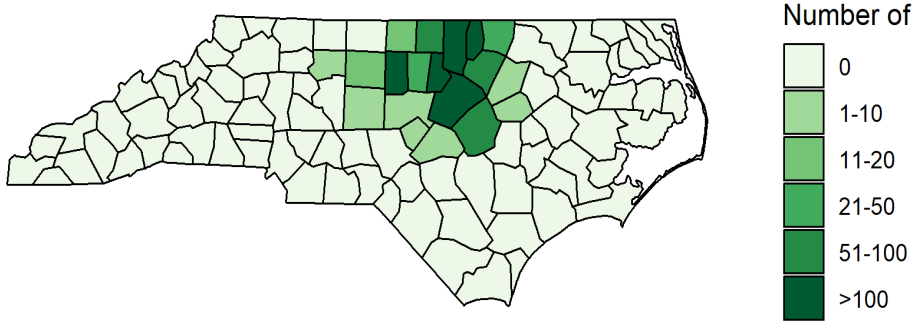
Cohort Description

Characteristic	Overall N = 2,155	Usual Care N = 705	Eat Well PRx N = 1,450
Sociodemographics			
Age (years; mean [SD])	56 (14)	56 (14)	56 (14)
Sex, female (n [%])	1,524 (71%)	491 (70%)	1,033 (71%)
Race-ethnicity (among n=2099 nonmissing)			
Non-Hispanic Black	1,272 (61%)	408 (60%)	864 (61%)
Non-Hispanic White	663 (32%)	223 (33%)	440 (31%)
Hispanic	112 (5.3%)	39 (5.7%)	73 (5.2%)
Other	52 (2.5%)	15 (2.2%)	37 (2.6%)
State ADI decile >=7 (among n=2139 nonmissing)	1,092 (51%)	363 (52%)	729 (51%)
Insurance (among n=2054 nonmissing)			
Dual eligible	38 (1.8%)	13 (1.8%)	25 (1.7%)
Medicaid	426 (20%)	134 (19%)	292 (20%)
Medicare	309 (14%)	102 (14%)	207 (14%)
Medicare Advantage	571 (27%)	195 (28%)	376 (26%)
Commercial	586 (27%)	191 (27%)	395 (27%)
Self-Pay	211 (9.8%)	65 (9.2%)	146 (10%)
Other	13 (0.6%)	5 (0.7%)	8 (0.6%)
Comorbidities			
Diabetic renal disease	716 (33%)	238 (34%)	478 (33%)
Ischemic heart disease	353 (16%)	108 (15%)	245 (17%)
Neuropathy	965 (45%)	304 (43%)	661 (46%)
History of stroke/TIA	273 (13%)	90 (13%)	183 (13%)
Retinopathy	326 (15%)	98 (14%)	228 (16%)
Medications*			
SGLT2-inhibitor	356 (17%)	119 (17%)	237 (16%)
GLP-1 agonist	875 (41%)	288 (41%)	587 (40%)
Metformin	831 (39%)	279 (40%)	552 (38%)

Results

Recruitment:
Utilized an e-mail-based mass outreach recruitment strategy to complete recruitment of 2,155 participants in approximately 5 weeks.





County	Number of participants	Cumulative % of total study sample	Individual % of total study sample	Rural-Urban Continuum Code*
Durham	709	33%	33%	2
Wake	429	53%	20%	1
Alamance	315	67%	15%	3
Vance	157	75%	7%	6
Granville	153	82%	7%	6
Person	96	86%	4%	2
Franklin	91	90%	4%	1
Johnston	52	93%	2%	1
Orange	46	95%	2%	2
Warren	45	97%	2%	8
Caswell	17	98%	1%	8
Guilford	13	99%	1%	2

*Rural-Urban Continuum Codes (RUCC) is a county-based classification scheme used to delineate rural areas. The codes range from 1 (most urban) to 9 (most rural). RUCC distinguishes metropolitan (metro) counties by the population size of their metro area, and nonmetropolitan (nonmetro) counties by degree of urbanization and adjacency to a metro area or areas

Numbers of patients meeting each eligibility criterion

Characteristic	Overall, N = 2,155	Control, N = 705	Treatment, N = 1,450
Met Medicaid eligibility criterion	770 (36%)	249 (35%)	521 (36%)
Met ADI decile >=7 criterion	1,266 (59%)	425 (60%)	841 (58%)
Met SDOH eligibility criterion	538 (25%)	176 (25%)	362 (25%)
Met food insecurity SDOH criterion	497 (23%)	161 (23%)	336 (23%)
Met financial insecurity SDOH criterion	250 (12%)	81 (11%)	169 (12%)

Enrollment and Adherence

Definitions

Enrollment:

- Patients who enrolled in the study, regardless of their assigned treatment group

Adherence: *Measured by monthly spending (max: $80/month)*

1) Any spending (all treatment group patients)

- Outcome: Non-zero spending
- *Note: of those with zero spending, 99% never activated their card*

2) High adherence (card activators only)

- Outcome: Spending >$53 (median)

3) Highest adherence (card activators only)

- Outcome: Spending >$70 (around Q3)

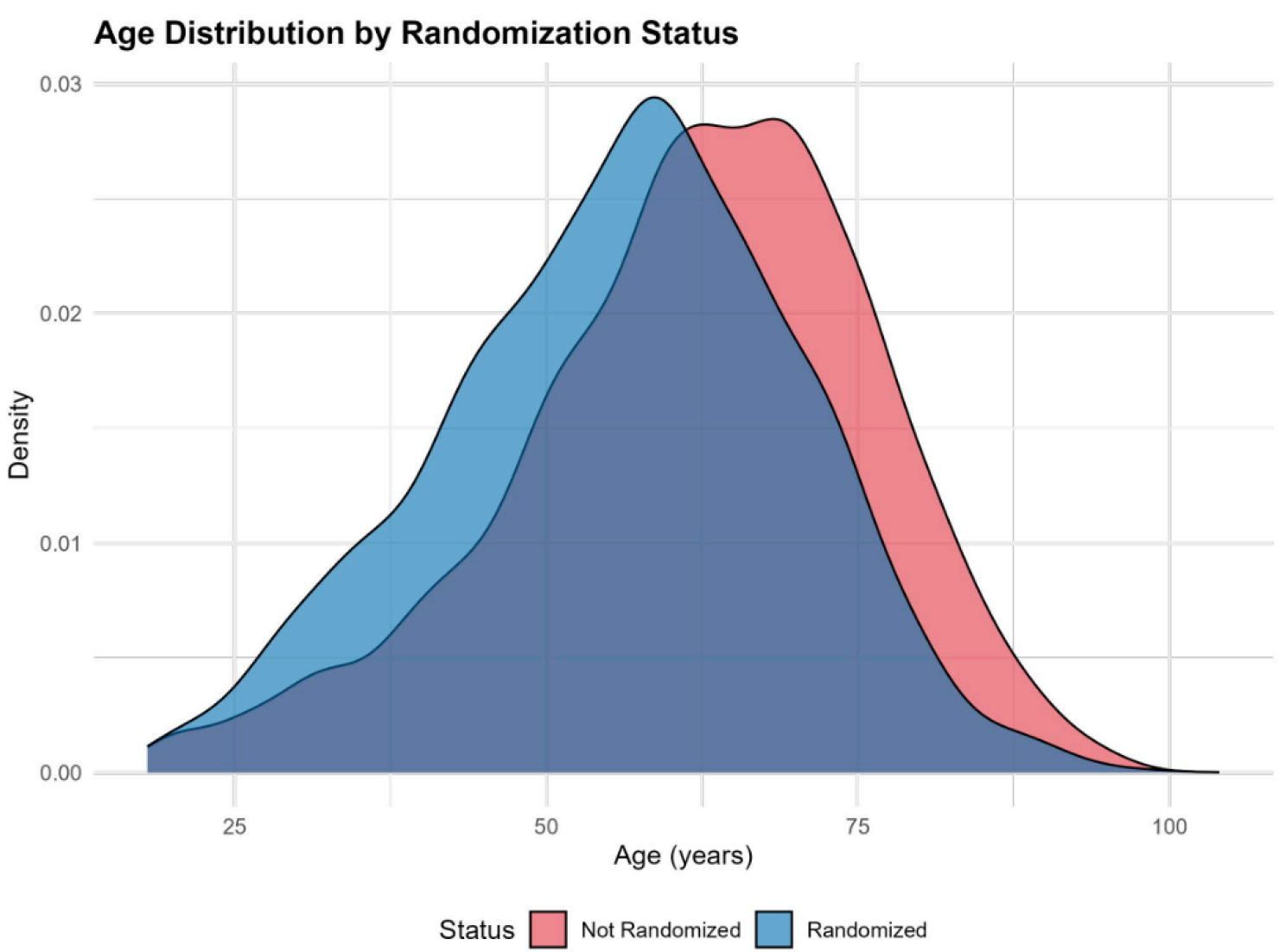
Program Enrollment

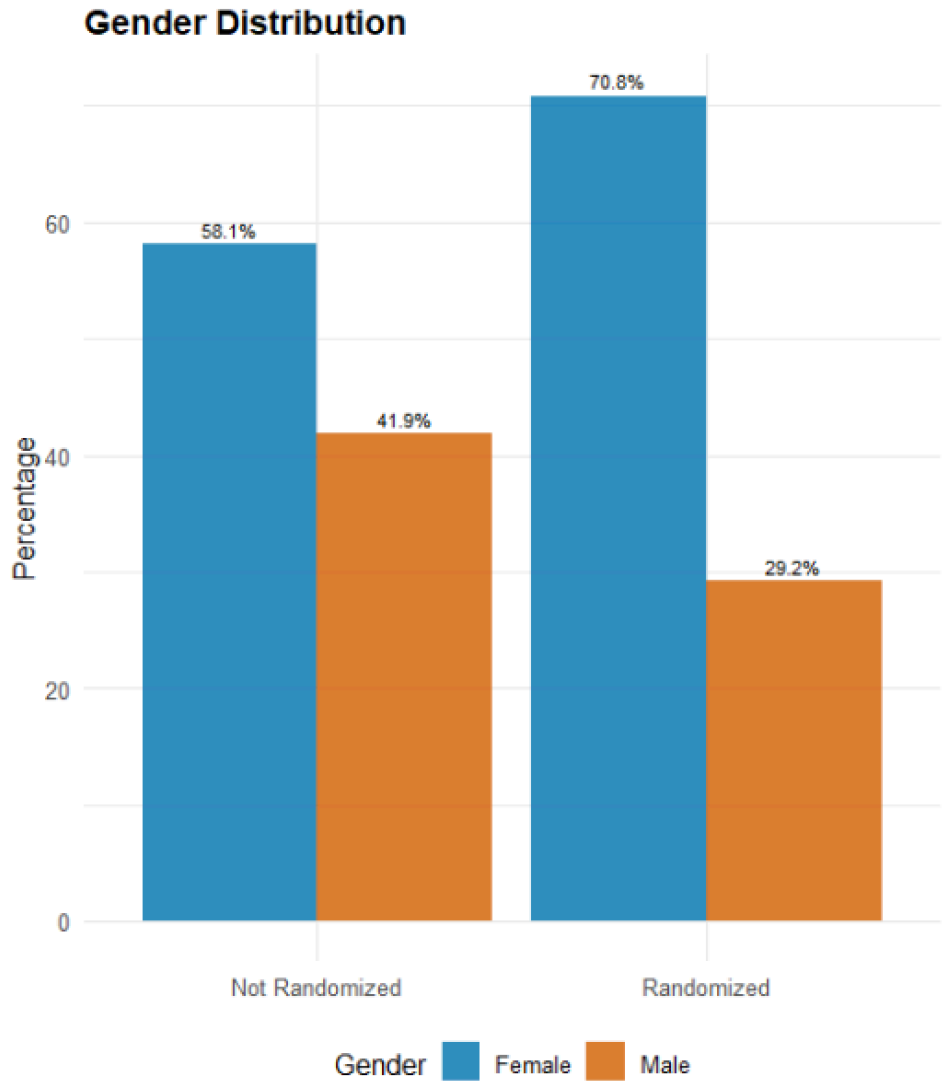
Program enrollment

Characteristic	Total (N=9644)	Not Enrolled (N=7467)	Enrolled (N=2177)	SMD
Age, Mean (SD)	60.56 (14.62)	61.94 (14.48)	55.82 (14.10)	0.43
Gender Male (%)	3761 (39.0)	3126 (41.9)	635 (29.2)	0.27
Race/Ethnicity (%)				0.18
Hispanic	494 (5.1)	382 (5.1)	112 (5.1)	
NH Black	5106 (52.9)	3809 (51.0)	1297 (59.6)	
NH White	3578 (37.1)	2891 (38.7)	687 (31.6)	
Other	466 (4.8)	385 (5.2)	81 (3.7)	
Marital Status (%)				0.24
Married	3937 (37.3)	3129 (42.4)	808 (37.3)	
Single	5620 (62.7)	4260 (57.6)	1360 (62.7)	
ADI ≥ 7 (%)	6189 (64.2)	4908 (65.7)	1281 (58.8)	0.14
On Medicaid (%)	3574 (37.1)	2798 (37.5)	776 (35.6)	0.04
HbA1c ≥ 8% (%)	6938 (71.9)	5414 (72.5)	1524 (70.0)	0.06
Hypertension (%)	7870 (81.6)	6171 (82.6)	1699 (78.0)	0.12
Elix-Conditions,* Mean (SD)	6.21 (3.66)	6.29 (3.73)	5.93 (3.41)	0.10

Around **23%** of all patients contacted enrolled in the study

Program Enrollment

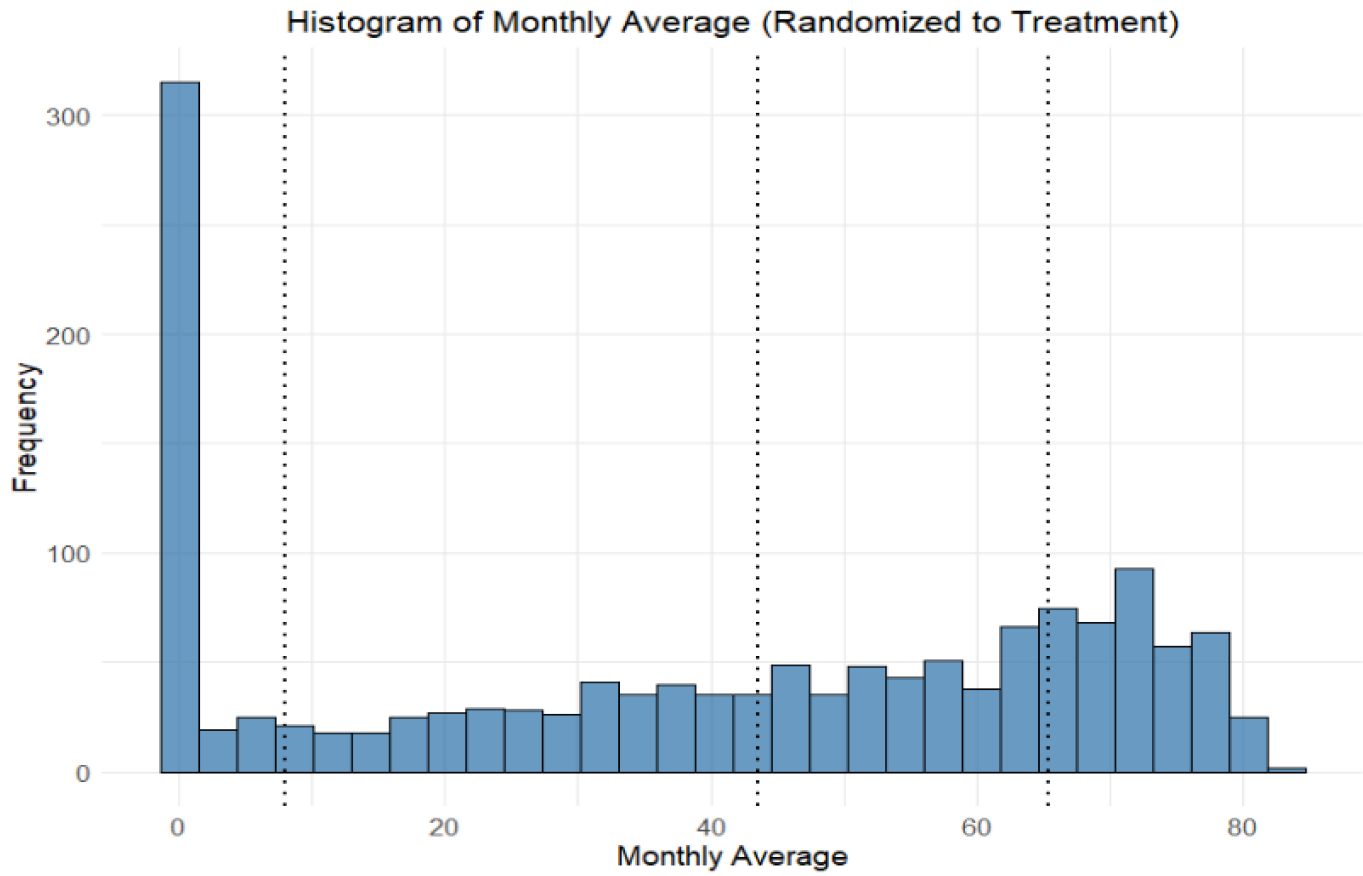




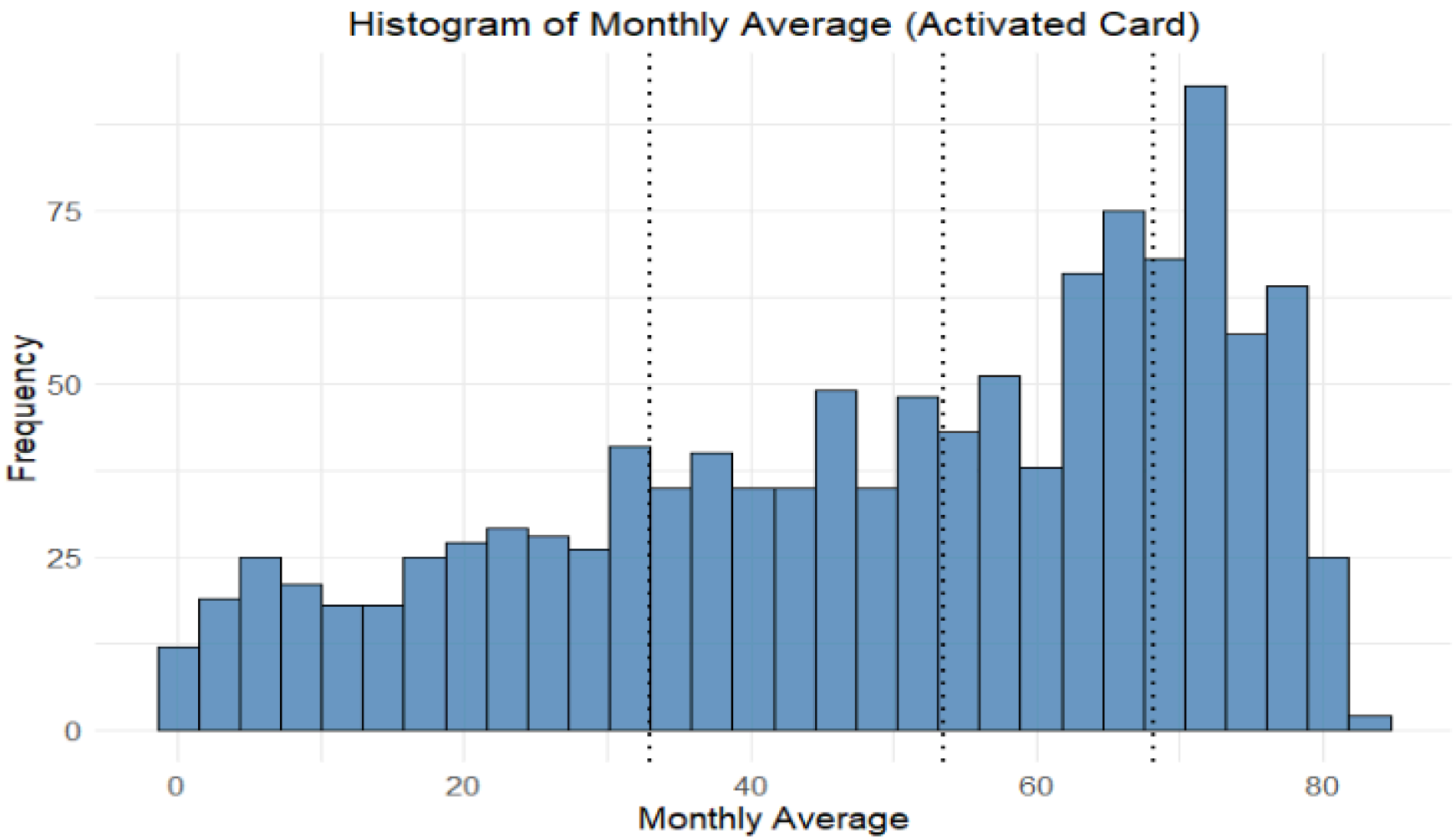
Program Adherence

Program adherence

- 79% of participants assigned to Eat Well used their PRx debit card
- 32.4% used it at a high level (75%+ average monthly spending)
- 20.6% in the 50-74% average monthly spending range
- 10.1% had low engagement (<25% average monthly spending)



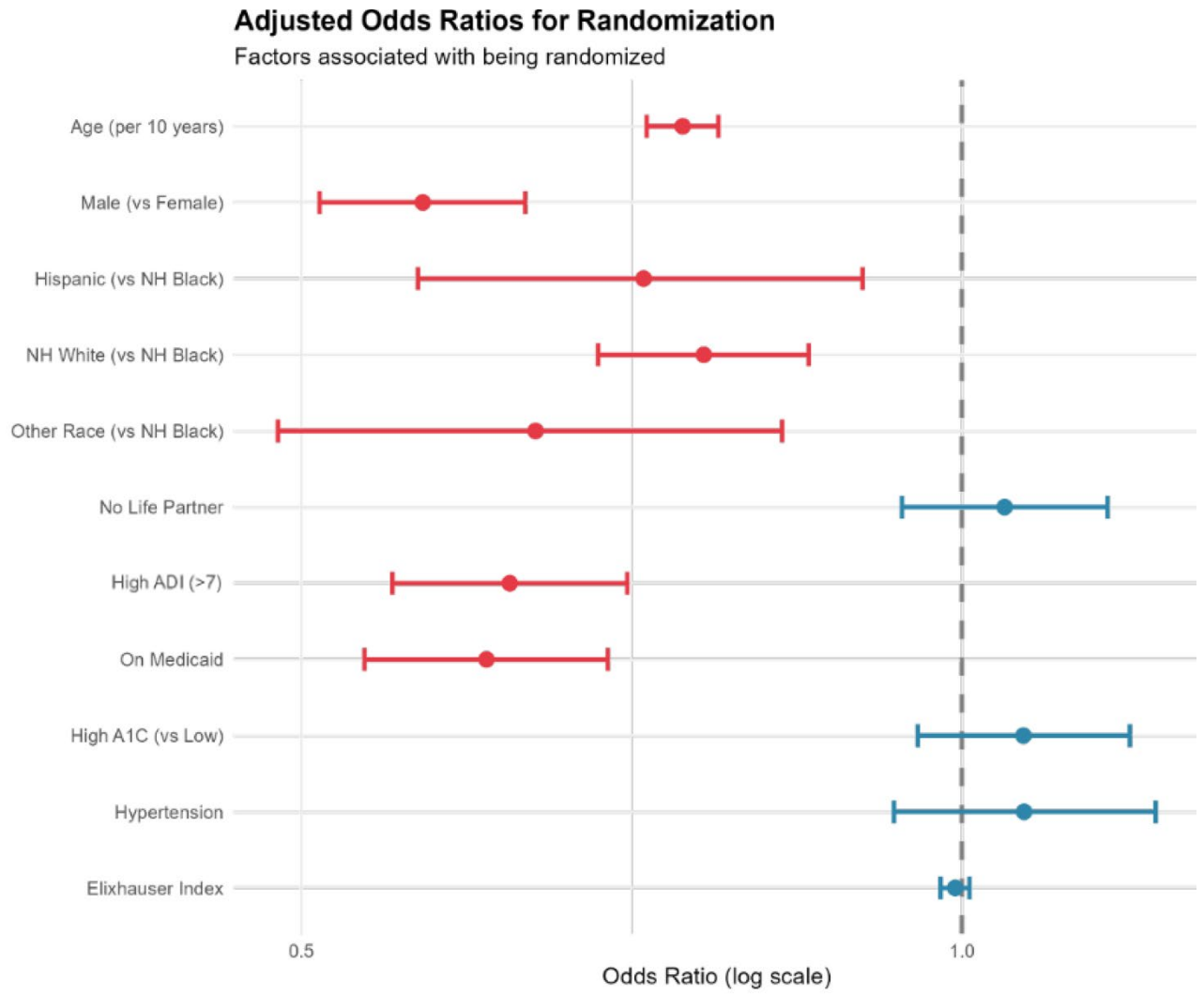
Program Adherence

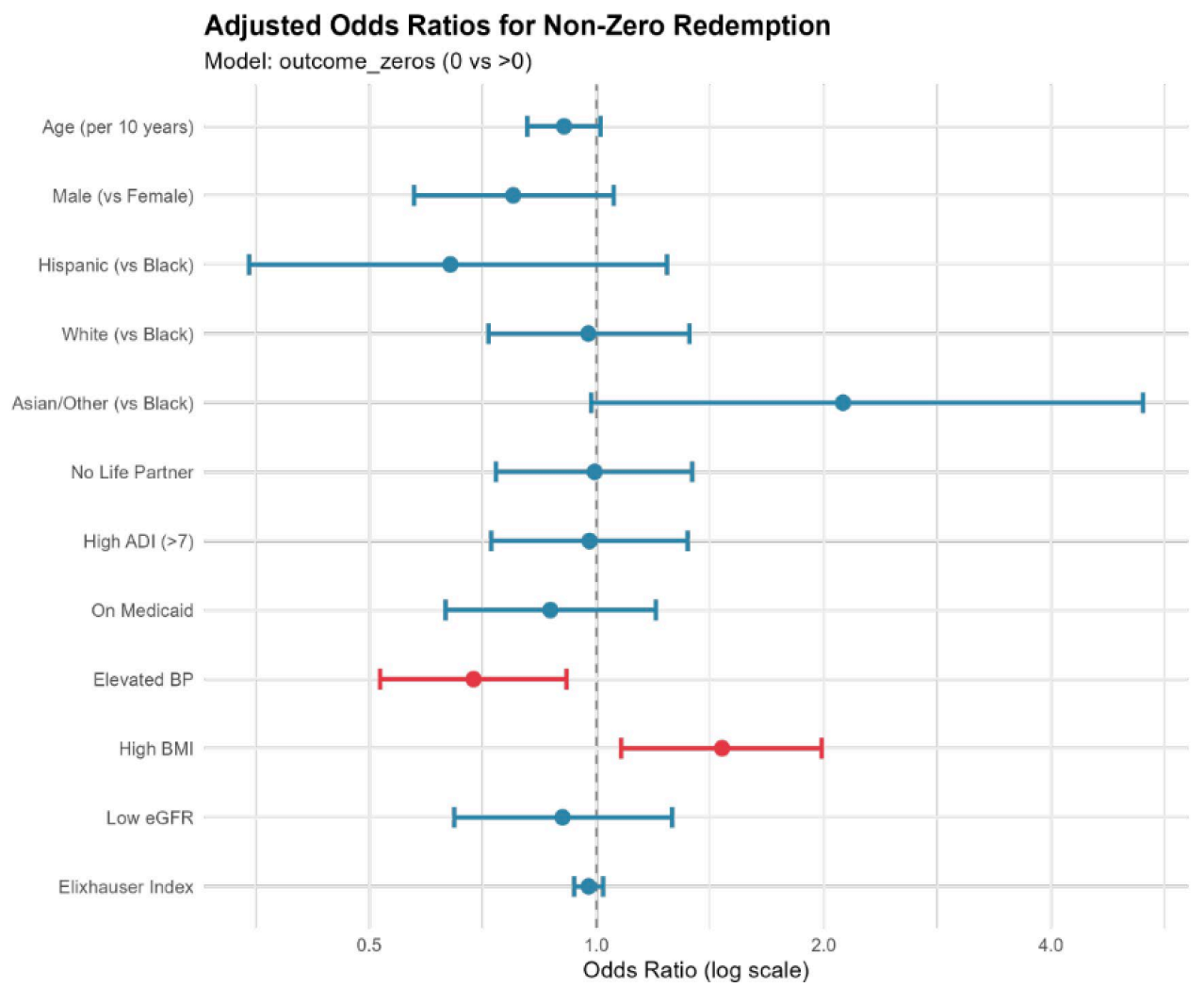


Median: 53.5

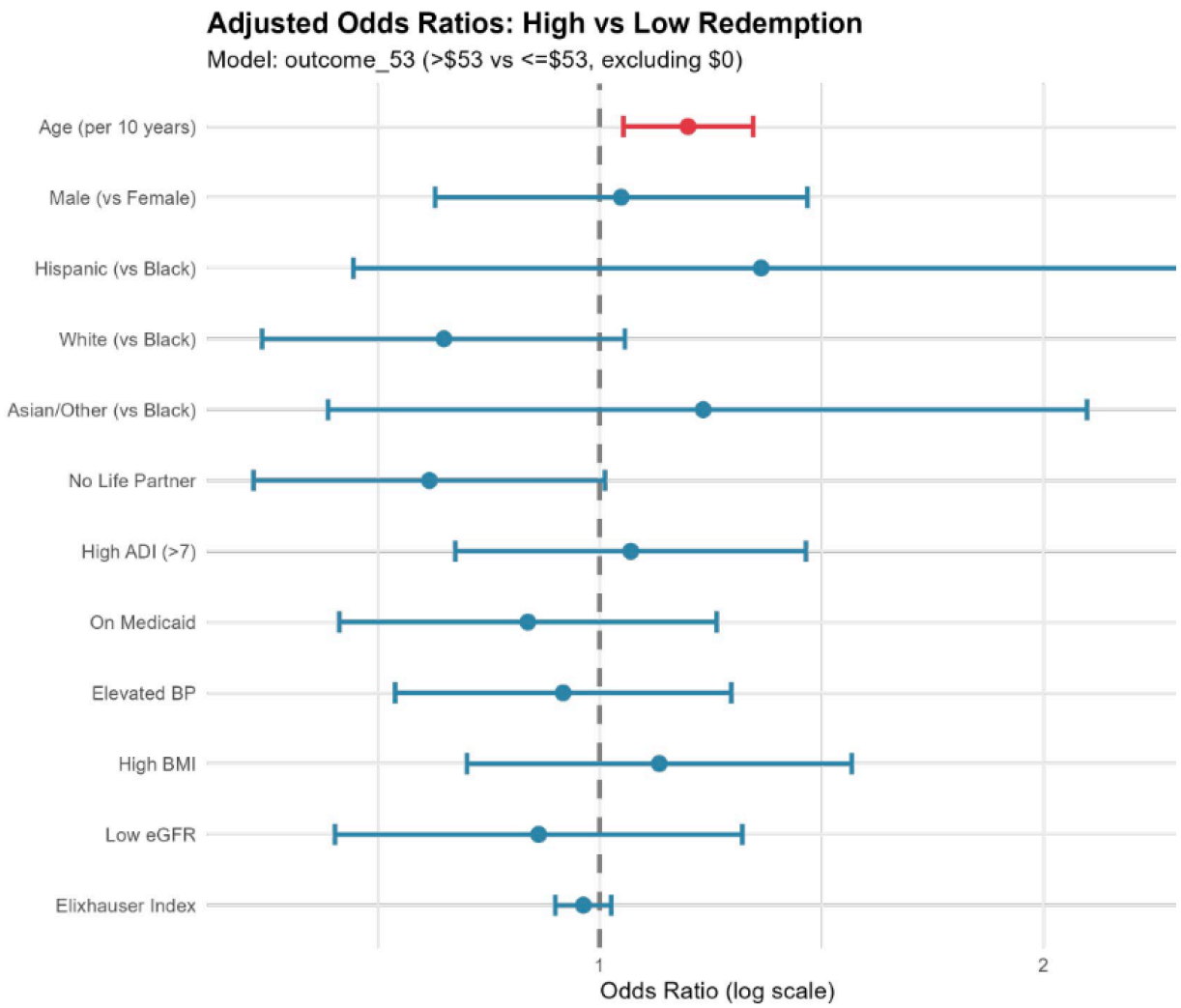
Q1, Q3: 32.9, 68.2

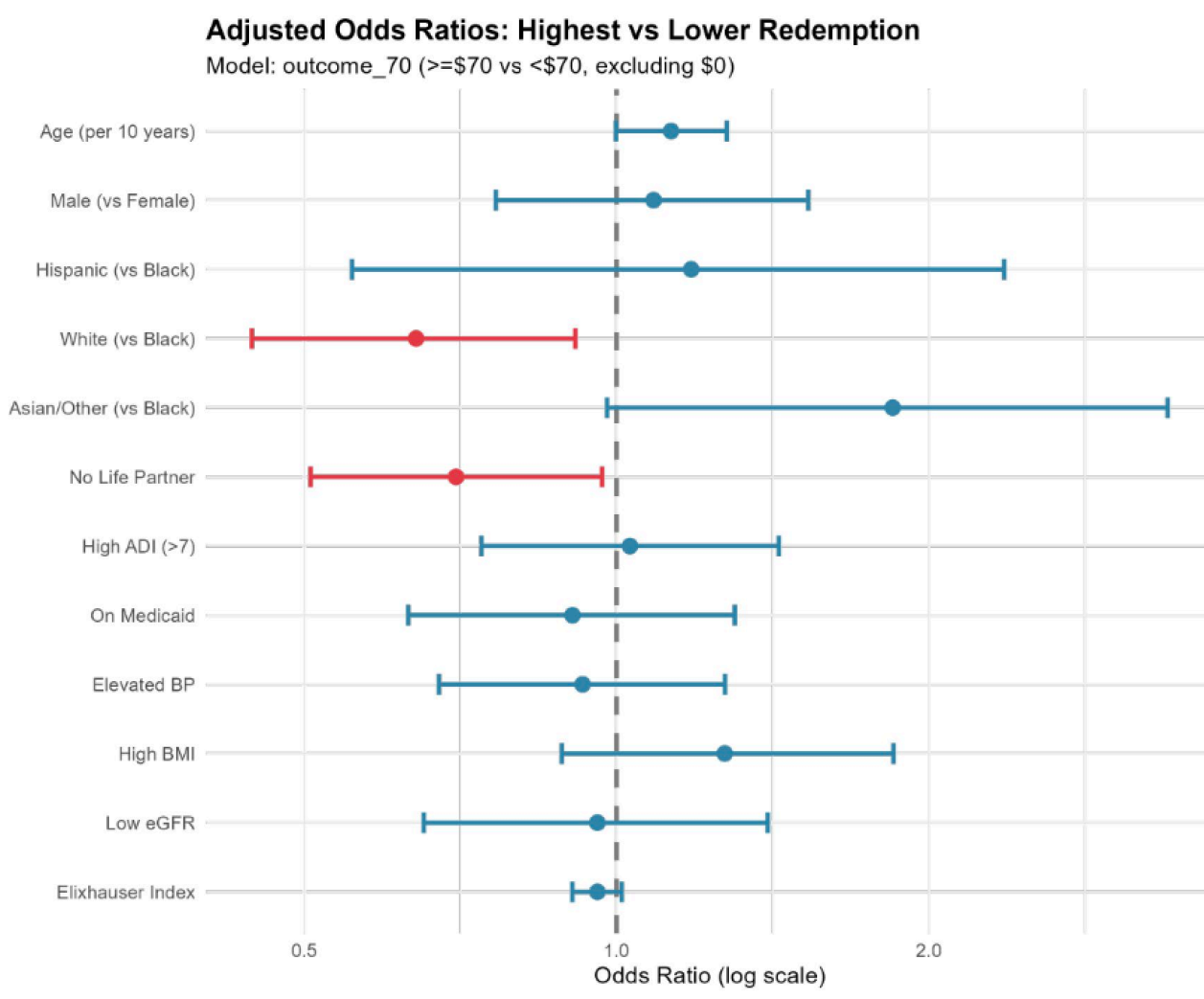
Results


Adjusted Odds Ratios for Randomization
Factors associated with being randomized
Age (per 10 years)
Male (vs Female)
Hispanic (vs NH Black)
NH White (vs NH Black)
Other Race (vs NH Black)
No Life Partner
High ADI (>7)
On Medicaid
High A1C (vs Low)
Hypertension
Elixhauser Index
0.5
1.0
Odds Ratio (log scale)


Adjusted Odds Ratios for Non-Zero Redemption
Model: outcome_zeros (0 vs >0)
Age (per 10 years)
Male (vs Female)
Hispanic (vs Black)
White (vs Black)
Asian/Other (vs Black)
No Life Partner
High ADI (>7)
On Medicaid
Elevated BP
High BMI
Low eGFR
Elixhauser Index
0.5
1.0
2.0
4.0
Odds Ratio (log scale)

Results


Adjusted Odds Ratios: High vs Low Redemption
Model: outcome_53 (>$53 vs <=$53, excluding $0)
Age (per 10 years)
Male (vs Female)
Hispanic (vs Black)
White (vs Black)
Asian/Other (vs Black)
No Life Partner
High ADI (>7)
On Medicaid
Elevated BP
High BMI
Low eGFR
Elixhauser Index
1
2
Odds Ratio (log scale)


Adjusted Odds Ratios: Highest vs Lower Redemption
Model: outcome_70 (>=$70 vs <$70, excluding $0)
Age (per 10 years)
Male (vs Female)
Hispanic (vs Black)
White (vs Black)
Asian/Other (vs Black)
No Life Partner
High ADI (>7)
On Medicaid
Elevated BP
High BMI
Low eGFR
Elixhauser Index
0.5
1.0
2.0
Odds Ratio (log scale)

Health Outcomes and Utilization

Summary Statistics for Outcomes Overall and by Study Arm			
Characteristic	**Overall** N = 2,155	**Usual Care** N = 705	**Eat Well PRx** N = 1,450
***HbA1c* (%)**			
Baseline HbA1c, Mean (SD)	7.48 (1.77)	7.52 (1.85)	7.46 (1.73)
Body Mass Index (kg/m2)			
Baseline BMI, Mean (SD)	35.96 (9.16)	35.90 (9.37)	35.99 (9.06)
Blood Pressure (mmHg)			
Baseline systolic blood pressure, Mean (SD)	129 (13)	129 (13)	130 (14)
Baseline diastolic blood pressure, Mean (SD)	77 (9)	77 (8)	77 (9)

Summary Statistics for Outcomes Overall and by Study Arm: Among HbA1c >=8 % Subgroup			
Characteristic	**Overall** N = 2,155	**Usual Care** N = 705	**Eat Well PRx** N = 1,450
***HbA1c* (%)**			
Baseline HbA1c, Mean (SD)	9.25 (1.92)	9.33 (2.01)	9.22 (1.88)
Body Mass Index (kg/m2)			
Baseline BMI, Mean (SD)	35.95 (9.01)	35.64 (9.47)	36.10 (8.78)
Blood Pressure (mmHg)			
Baseline systolic blood pressure, Mean (SD)	130 (14)	130 (15)	130 (14)
Baseline diastolic blood pressure, Mean (SD)	78 (9)	78 (9)	78 (9)

HbA1c Results

Outcome/Comparison	Model estimates	p-value
	Mean difference* (95% CI)	
HbA1c (%)		
Between-arm differences (PRx vs usual care)	0.20 (0.05, 0.35)	0.008
Change from baseline within usual care arm	-0.17 (-0.29, -0.05)	
Change from baseline within PRx arm	0.03 (-0.06, 0.12)	

BMI & Blood Pressure Results

Outcome/Comparison	Model estimates Mean difference* (95% CI)	p-value
BMI (kg/m²)		
Between-arm differences (PRx vs usual care)	0.02 (-0.32, 0.36)	0.914
Change from baseline within usual care arm	-0.70 (-0.98, -0.42)	
Change from baseline within PRx arm	-0.68 (-0.86, -0.50)	
Systolic Blood Pressure (mmHg)		
Between-arm differences (PRx vs usual care)	-0.94 (-2.12, 0.24)	0.118
Change from baseline within usual care arm	-0.11 (-1.14, 0.91)	
Change from baseline within PRx arm	-1.05 (-1.72, -0.39)	
Diastolic Blood Pressure (mmHg)		
Between-arm differences (PRx vs usual care)	0.56 (-0.20, 1.31)	0.147
Change from baseline within usual care arm	-0.92 (-1.58, -0.27)	
Change from baseline within PRx arm	-0.37 (-0.79, 0.05)	

HbA1c, BMI & Blood Pressure Results Among A1c> 8% Subgroup

	Model estimates	p-value
	Mean difference* (95% CI)	
***HbA1c** (%)*		
Between-arm differences (PRx vs usual care)	0.39 (0.03, 0.75)	0.035
Change from baseline within usual care arm	-0.76 (-1.05, -0.46)	
Change from baseline within PRx arm	-0.37 (-0.59, -0.14)	
***BMI** (kg/m^2)*		
Between-arm differences (PRx vs usual care)	-0.26 (-0.88, 0.35)	0.396
Change from baseline within usual care arm	-0.51 (-0.99, -0.03)	
Change from baseline within PRx arm	-0.77 (-1.13, -0.42)	
***Systolic Blood Pressure** (mmHg)*		
Between-arm differences (PRx vs usual care)	-1.82 (-3.93, 0.3)	0.092
Change from baseline within usual care arm	0.67 (-1.18, 2.51)	
Change from baseline within PRx arm	-1.15 (-2.33, 0.03)	
***Diastolic Blood Pressure** (mmHg)*		
Between-arm differences (PRx vs usual care)	-0.07 (-1.32, 1.17)	0.907
Change from baseline within usual care arm	-0.66 (-1.75, 0.42)	
Change from baseline within PRx arm	-0.74 (-1.45, -0.03)	

Conclusion & Discussion

Conclusions

- A produce prescription subsidy did not improve outcomes among patients with diabetes at risk for food insecurity

- An affirmative outreach approach supported rapid scaling of the program. Preliminary findings suggest that characteristics such as age and gender may influence enrollment following email recruitment.

- PRx may require greater duration, dose, intensity, and attention to household and implementation factors, including a focus on different at-risk groups, to improve health outcomes

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Limitations

- FI was not measured directly for assessing eligibility, instead we used proxies derived from existing EHR data, which may have been suboptimal

- We did not collect patient reported outcomes, including FI, psychological status (e.g. depression burden), dietary intake, financial security, or quality of life

- Hispanic participants represented only 5% of the sample, which limits generalizability and likely contributed to the wide confidence intervals from the adherence analysis

Implications

- There may be opportunity to improve uptake and adherence. Qualitative analysis is underway to understand drivers of program adherence and identify opportunities for intervention refinement and improved implementation.

- Reducing cost barriers to purchasing fruits and vegetables alone may not be sufficient to improve food security enough to improve cardiometabolic health outcomes.

- Diabetes management requires coordination of many factors: food, exercise, medications, education, behavioral health support, and monitoring.

- Future research should identify opportunities to improve implementation, test interventions in higher risk populations, and collect additional detail on patient reported outcomes.

- Social policy levers may be more efficient and optimal for promoting food security at a population level.

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