

Effect of an Intensive Food-as-Medicine Program on Health and Health Care Use: A Randomized Clinical Trial

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NIH Pragmatic Trials Collaboratory: Grand Rounds

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Introduction

Background

Intervention

Data

Randomized design

Results



Background

Diabetes is common and costly (ADA, 2018; CDC 2018)

9% of the US (and expected to increase)

300,000 premature deaths / year

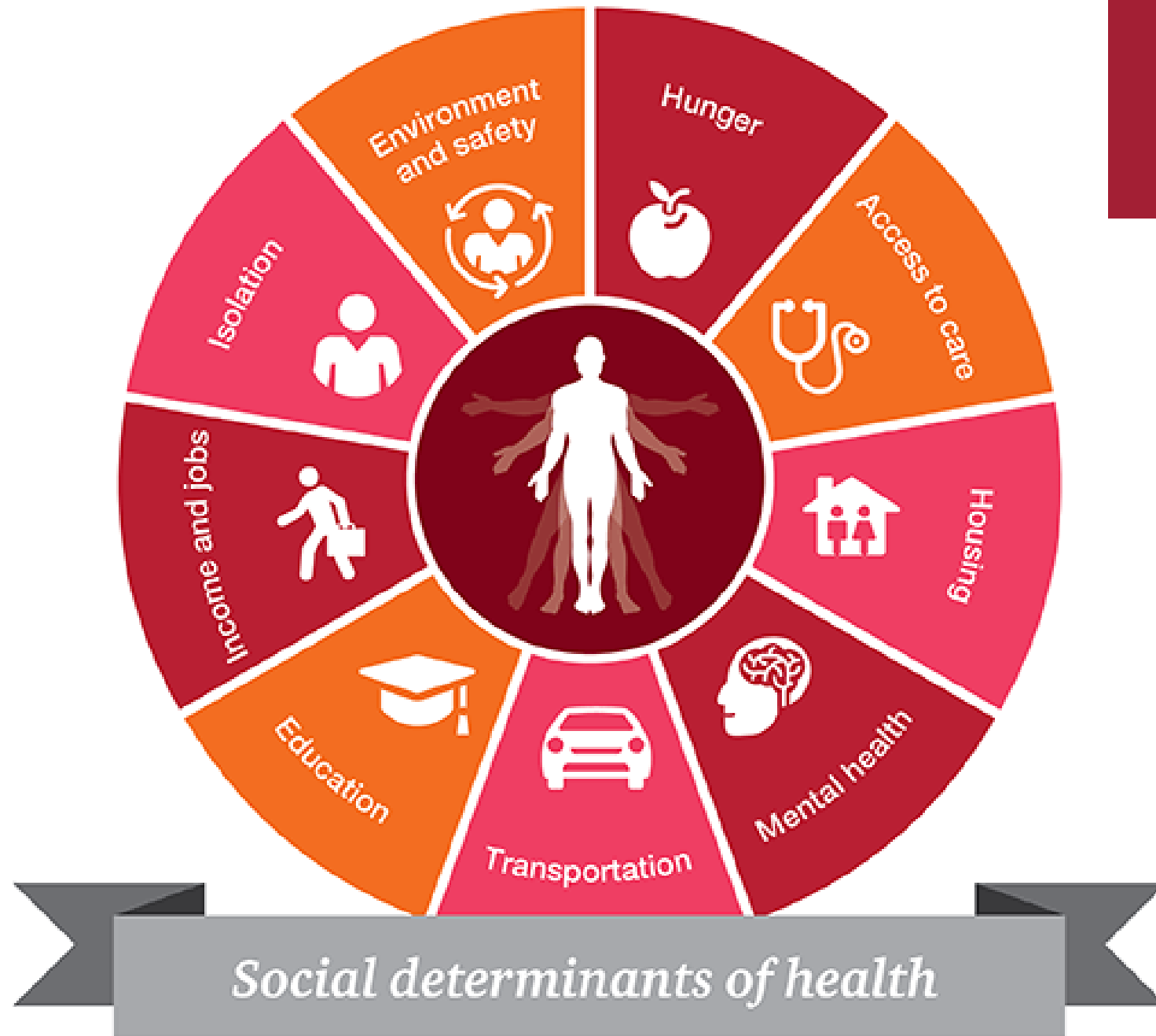
\$330bn in annual healthcare spending

Sustained reduction in HbA1c from poor to fair → \$3-5K/year in cost savings
(Juarez et al., 2013; Wagner et al., 2001)

Food insecurity is associated with Diabetes
(Seligman et al., 2014; Berkowitz et al., 2014)



Social risk factors



Food as Medicine

White House Conference; Congressional Hearings; Rockefeller Foundation

Medicare Advantage

Medicaid demonstrations



Brief Literature Review

Large literature on diets and health outcomes (Sacks et al., 2001; Sargrad et al., 2005; review by Micha et al., 2017; Estruch et al., *NEJM* 2013 PREDIMED Trial & “Mediterranean Diet”)

Food Insecurity & Poor Health

Food-as-Medicine Observational Studies

Berkowitz et al. (2018, 2019a)

Gurvey et al. 2013; Palar et al., 2017; Feinberg et al. 2018

Large correlation w/ improved health (~30% reduction in hospitalization)



Previous evidence: Food-as-Medicine RCTs

Seligman et al., 2018: RCT of food-bank intervention (N=409)

Improvement in food insecurity but no effect on HbA1c

Medically-tailored meals:

Go et al. 2022: null effect on re-hospitalization

Rock et al., 2016: short-run reduction in weight

Ferrer et al. 2019 pilot RCT of produce delivery: improvement in HbA1c



The Intervention

Brick-and-Mortar Clinics



The Intervention

Prescribe healthy meals to food-insecure patients w/ diabetes

“Fill” the prescription each week at the program’s clinic

10+ meals/week for participants and their families

Staffing: dietitian, nurse, community health worker

Education

About nutrition: dietitian and nurses; recipes

About diabetes: Diabetes Self Management Program (optional)

Screen for complications and close care gaps

Intensive

Average duration: 1 year

Average cost: \$2000 per participant



The Intervention

Diet based on American Diabetes Association plate method



Starch

White Potatoes
Sweet Potatoes
Peas
Corn

Beans

Bag of Small Red beans
Bag of Pinto beans
Blackeyed Peas
Northern Beans

Fish

Pollock
Tuna (canned)

Salad Dressing

Surprise Me

Entrée Options

Recipe Kit:

Three Bean Salad

CHICKEN BREASTS

Turkey ground

Fruits & Vegetables

Fresh:

Mushrooms
Brussel Sprouts
Cucumber
Carrots
Broccoli
Romaine hearts (lettuce)
Eggplant

Kiwi

Apple Slices

Bananas

Canned

Apple sauce

Peaches

Mandarin oranges

Green Beans

Diced Tomatoes

Frozen

Blueberries

The Intervention

Diet based on American Diabetes Association plate method

Recent menu included:

Recipe kit for 3 bean salad

Fish: pollock and tuna (canned)

Poultry: chicken breasts and ground turkey

Fresh Fruits & Vegetables: mushrooms, Brussels sprouts, carrots, broccoli, romaine hearts, cucumber, eggplant, beans, peas, bananas, kiwi

Canned / bottled: applesauce, peaches, mandarin oranges, green beans, diced tomatoes, various beans, salad dressing

Frozen: blueberries



Potential Mechanisms for Improved Health

1. Lowers the cost of eating healthy meals

Relative price

Learn how to prepare healthy meals (diet education)

2. Education about diabetes and self care

3. Income effect

4. Lowers stigma associated with food bank take-up → Lowers food insecurity

5. Improves self-efficacy / control → Improved adherence to healthy behaviors

6. Improves engagement with healthcare



Background: The intervention

More intensive than most: more food; 1 year +

- Food is curated by the dietitians

- Clinic-based approach may facilitate education take-up

Annual variable costs are ~\$2000 per patient per year (food largely donated)

Small pilot study pre-post comparison:

- 1-2 point drop in HbA1c

- 80% drop in healthcare costs over 18 months

- Influential: similar facilities opening around the country



The Trial

Recruitment and Randomization

Eligibility:

Age ≥ 18 ; HbA1c ≥ 8.0

Food insecure (2-question instrument)

Residential ZIP ≤ 25 miles from a clinic

Recruitment

Phone calls and physician referrals

Consent over the phone

Randomization

Stratified by: HbA1c > 9.5 and Site

Treatment: Start Now

Control: Start in 6 months + mailed a brochure that lists addresses of area food banks



Data Sources

1. Lab results (HbA1c, cholesterol, triglycerides, blood pressure, weight) at 0, 6 and 12 months into the program
2. Surveys at 0, 6, and 12 months into the program
 - Questions about diet, exercise, and smoking
 - Questions about diabetes self-management behaviors, best practices, knowledge
 - Questions about preventive healthcare
 - Self-efficacy questionnaire (perseverance)
 - Self-assessed physical and mental health

\$50 gift card for completion of #1 and #2



Data Sources

3. Electronic Health Records
4. Health Plan paid claims (40% are plan participants)
5. Program participation data (including food visits, education)



Estimation

Intent to Treat $Y_i = \beta_0 + \beta_1 1(\text{Treatment})_i + \beta_2 X_i + \varepsilon_i$

Primary outcome: HbA1c after 6 months into the study

Secondary outcomes:

- HbA1c after 12 months into the study (12 vs 6 months of the program)

- Other biometrics

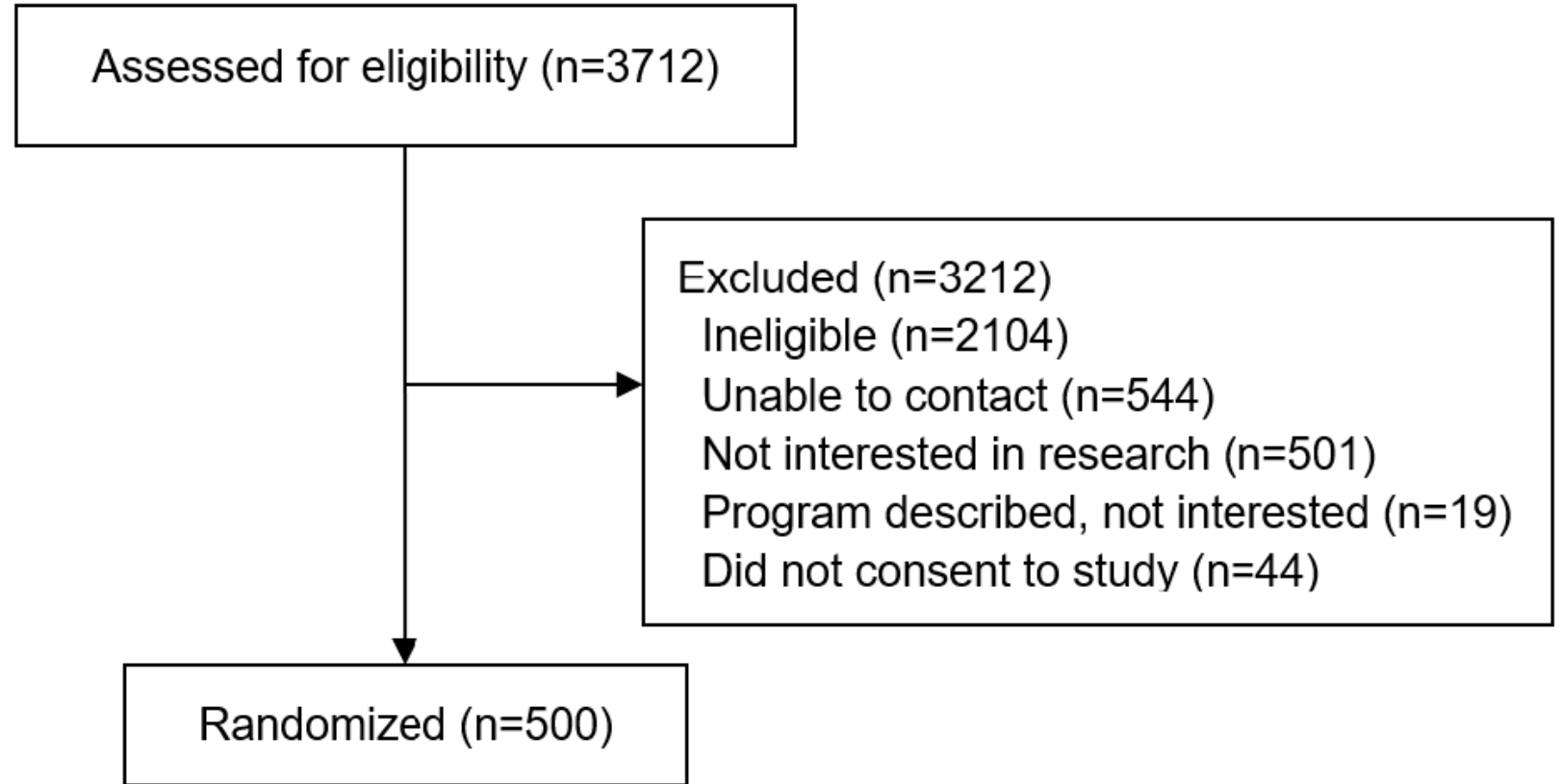
- Utilization

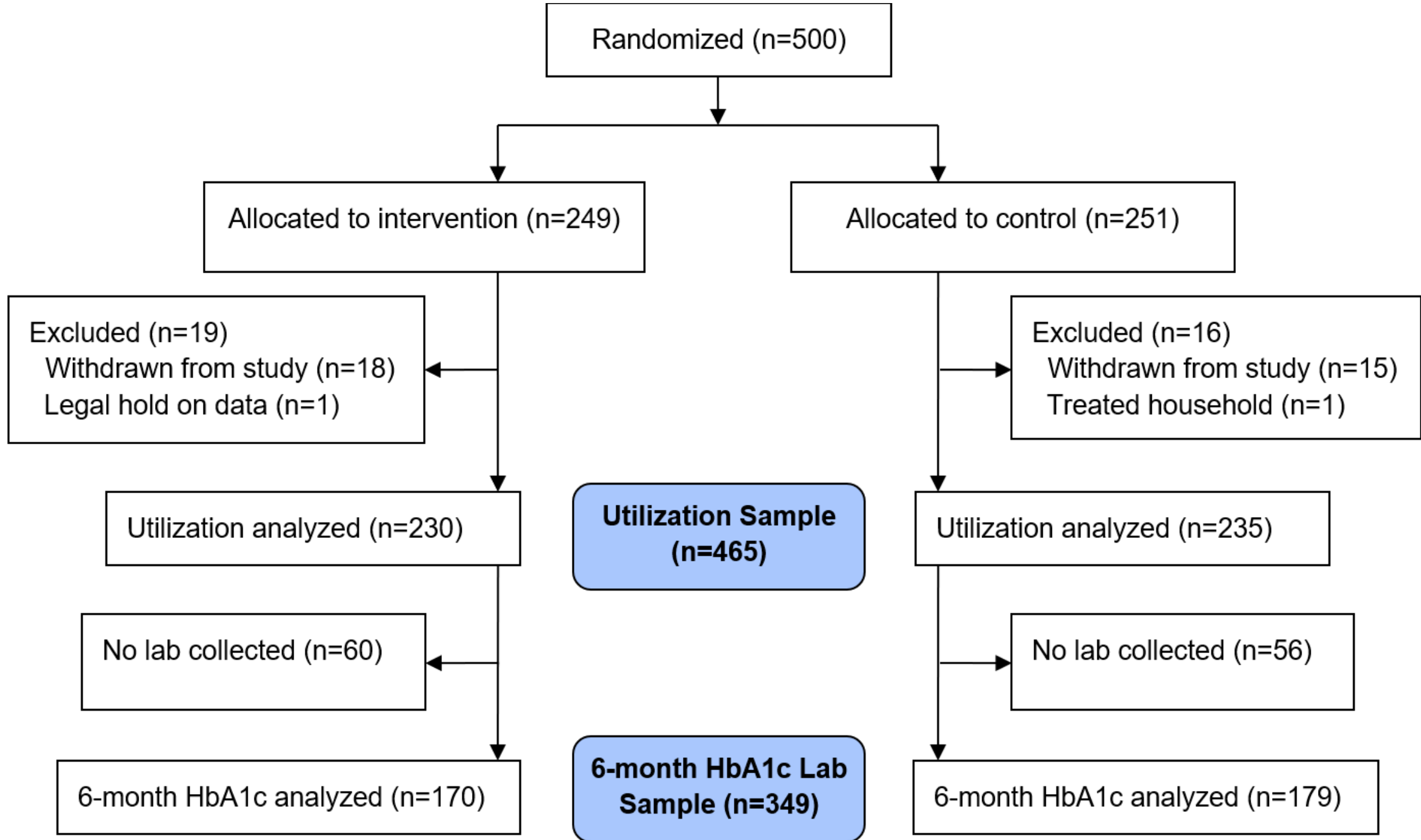
- Survey answers

Controls include lag of dependent variable, age, race, sex, and days between baseline (used for study enrollment) and follow-up test results



Figure 1: Screening, Randomization, and Analysis





Characteristics of the Patients at Baseline

Characteristic	Overall (N=465)	Control (N=235)	Treatment (N=230)
Baseline outcome			
HbA1c	10.29	10.29	10.30
Demographics			
Age	54.6	54.4	54.8
Non-Hispanic Black (%)	8.82	7.66	10.0
Hispanic (%)	8.39	9.79	6.96
Male (%)	45.2	46.8	43.5
Location			
Rural (%)	28.2	28.5	27.8
Urban (%)	71.8	71.5	72.2
Prior-year Utilization			
Any inpatient admission (%)	23.0	20.4	25.7
Any ED visit (%)	41.1	40.0	42.2
Metformin prescription (%)	49.7	49.4	50.0
Any diabetes prescription	87.1	87.7	86.5

Engagement & Self-Reported Behavior Changes

Timeframe:	6 months		12 months		Obs.
	Control	Treatment	Control	Treatment	

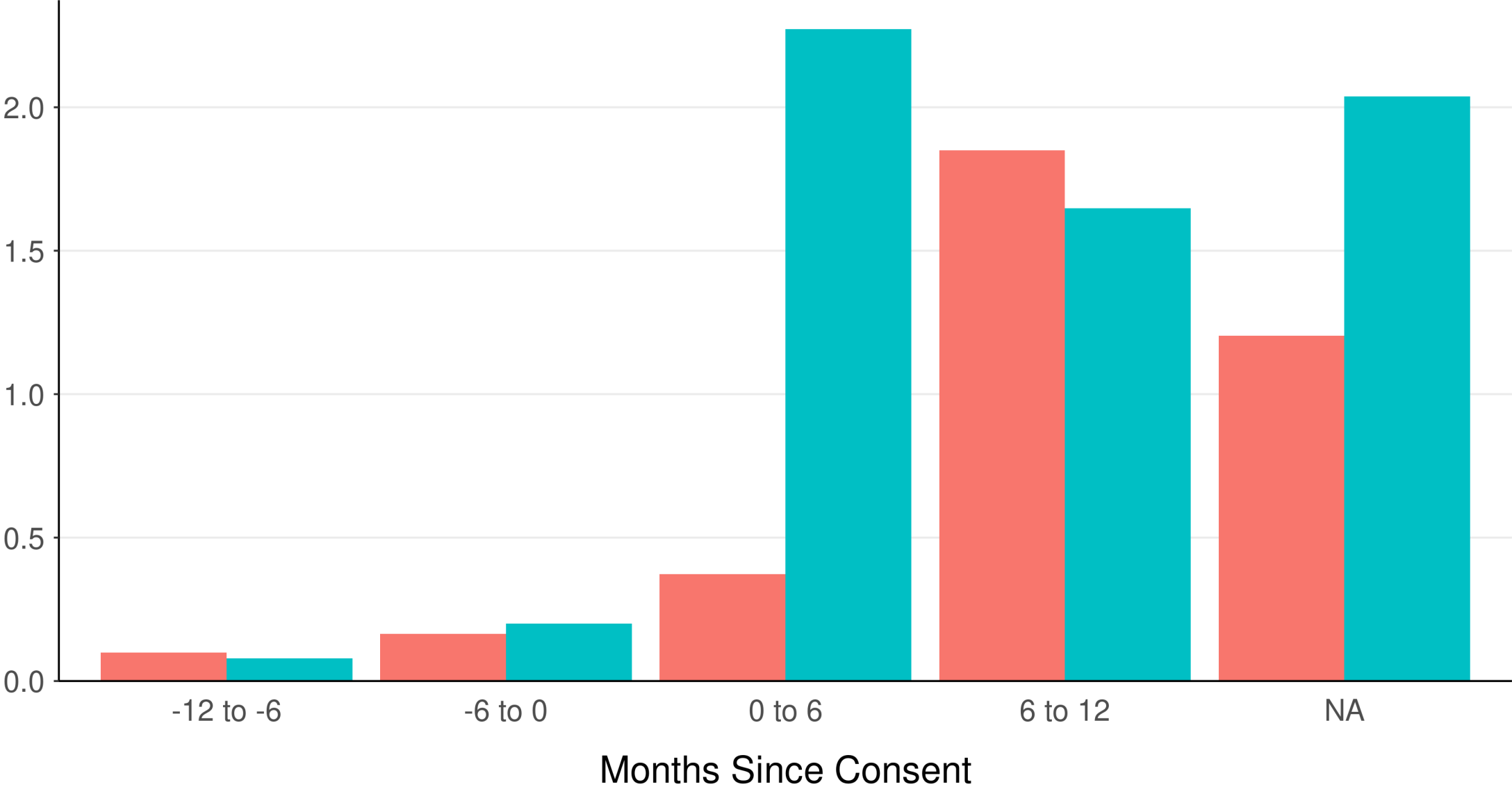
Program tracking measures

Number of months with at least one visit	0.36	4.91	4.58	9.26	349
Mean number of visits	0.72	13.0	10.64	23.4	349

Median days in the program: 342

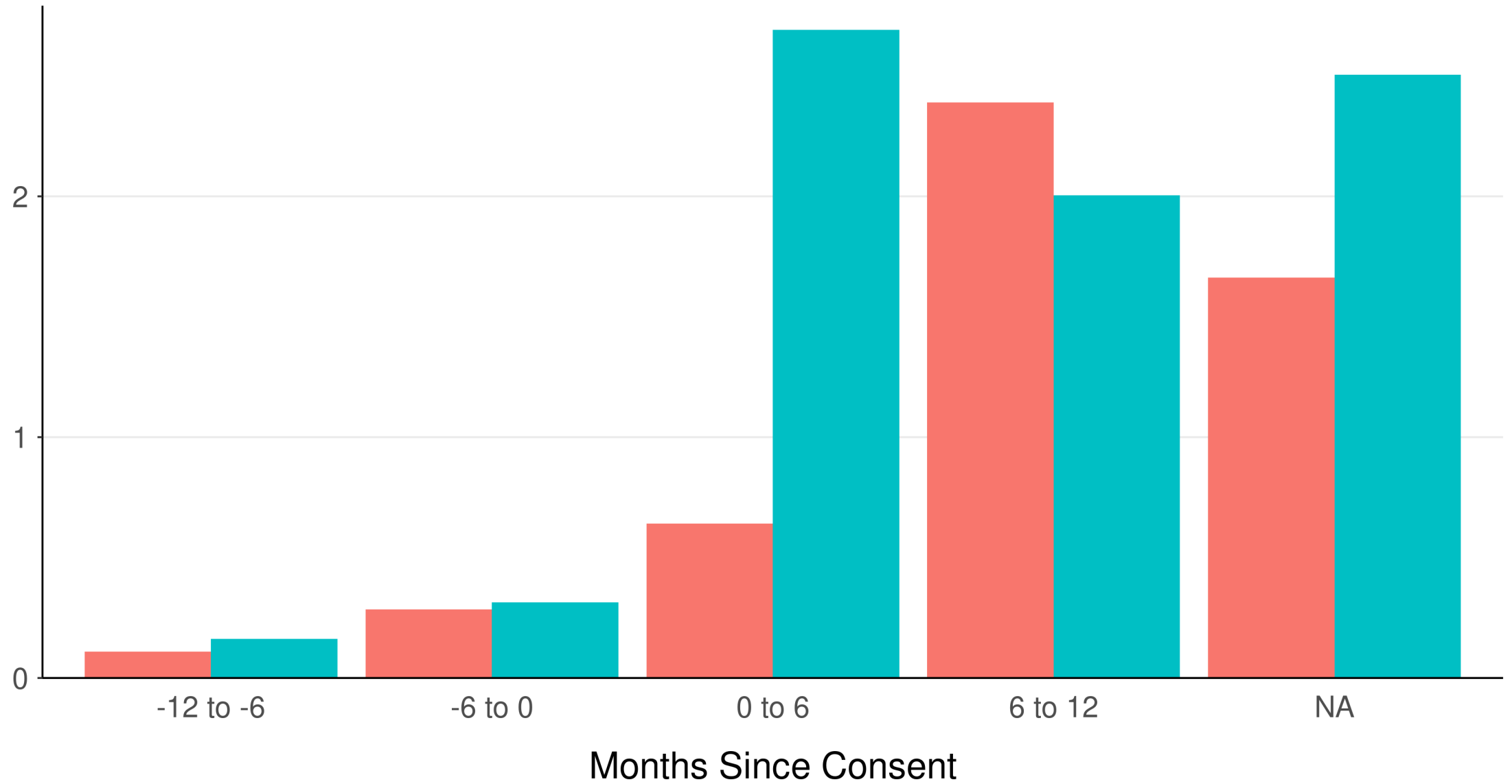
Diabetes Self-
Management Trainings

Control Treatment



Dietitian Visits

Control Treatment



Self-Reported Behavior Changes

Timeframe:	6 months				
	Control	Treatment	Adjusted Difference (95% CI)		Obs.
Primary outcomes					
Met a dietitian in the past year	0.538	0.901	0.343	(0.253,0.432)	333
Taken a diabetes class in the past year	0.053	0.208	0.153	(0.080,0.225)	335
Secondary outcomes					
Received a diabetic foot exam in the past year	0.596	0.707	0.108	(0.008,0.208)	335
Engagement/preventive care index	0	0.402	0.364	(0.166,0.561)	335

6-Month Survey Results

	Control mean	SD	Adjusted Difference for Full Controls (95% CI)		Obs
Positive Diet Index					
Number of times ate fruit past wk	5.241	3.398	0.306	(-0.434,1.047)	333
Number of times ate dark green vgs past wk	4.012	2.901	2.182	(-0.827,5.192)	333
No. times drank sweetened beverages past wk	3.407	4.495	-0.528	(-1.393,0.337)	329
Never eats fast food/takeout/restaurant	0.363	0.482	0.058	(-0.048,0.163)	335
Diet improved from one year ago	0.772	0.421	0.172	(0.095,0.249)	335
Positive diet index	0.000	1.000	0.382	(0.188,0.576)	335

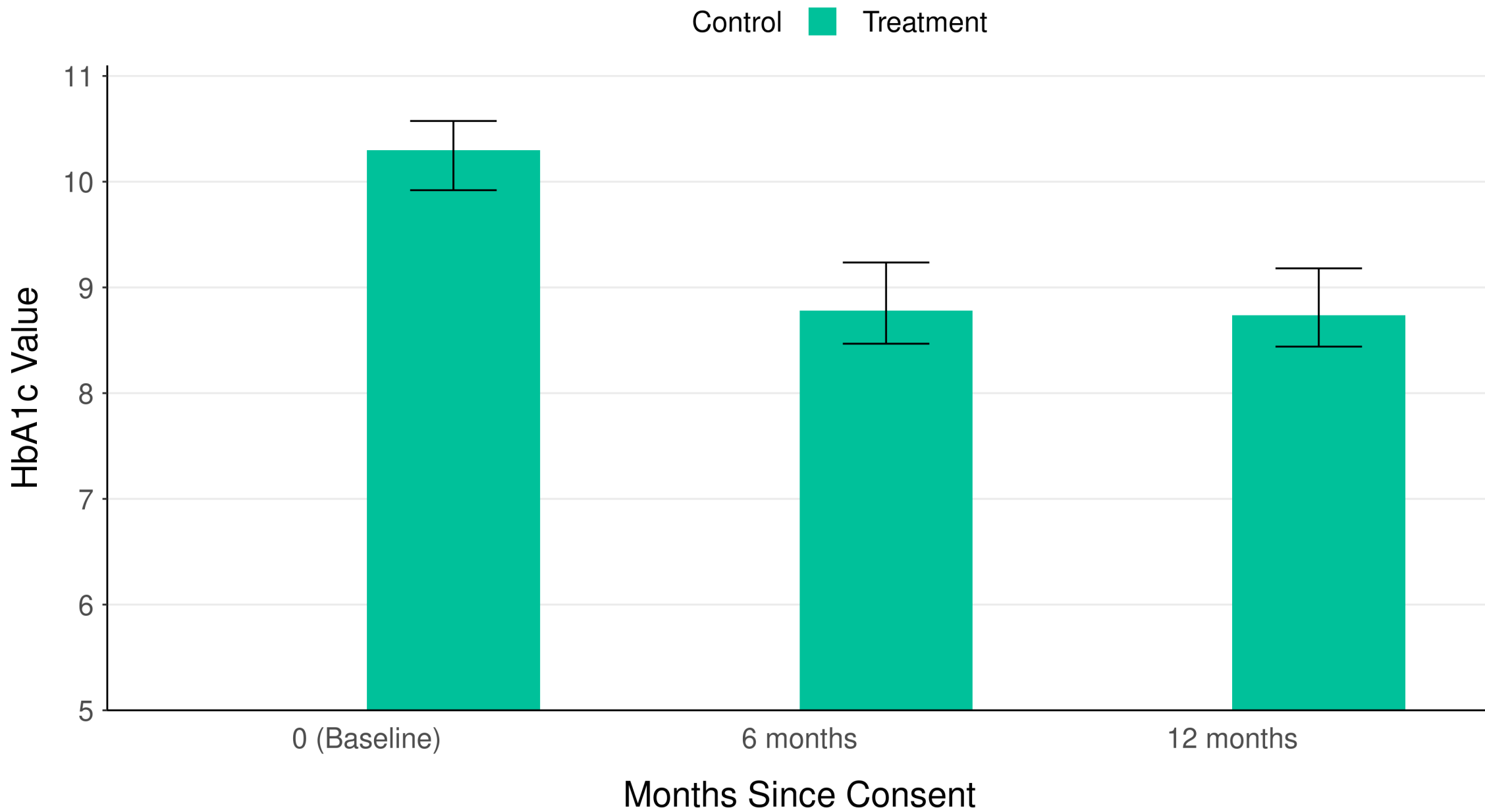
6-Month Survey Index Results

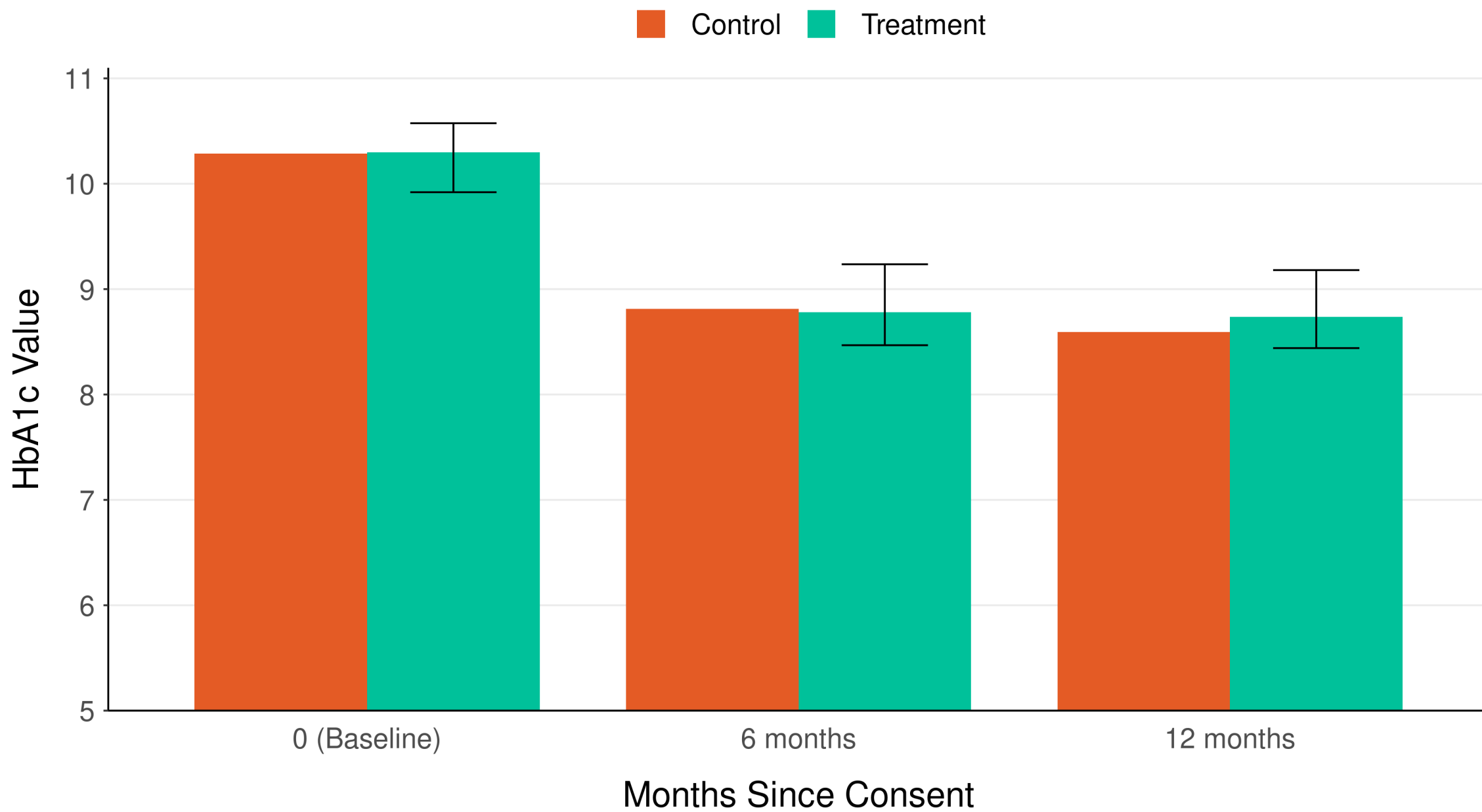
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6-Month Survey Index Results

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Engagement/preventive care index	0.000	1.000	0.364	(0.166,0.561)	335
Positive diet index	0.000	1.000	0.382	(0.188,0.576)	335
Patient diabetes knowledge score	0.776	0.147	0.045	(0.012,0.078)	330
Exercise and smoking index	0.000	1.000	0.063	(-0.164,0.290)	335
Lowering barriers to healthy eating index	0.000	1.000	0.082	(-0.109,0.274)	335
Positive healthy attitudes index	0.000	1.000	0.137	(-0.062,0.335)	334
Positive self efficacy index	0.000	1.000	-0.058	(-0.277,0.160)	335
Positive health & wellbeing index	0.000	1.000	0.201	(-0.021,0.424)	335

Outcomes: Lab Results





Effects on Biometric Outcomes at 6 months

	Control mean	SD	Adjusted Difference for Full Controls (95% CI)		Obs.
HbA1c	8.82	1.98	-0.018	(-0.375,0.339)	349

Effects on Biometric Outcomes at 6 months

	Control mean	SD	Adjusted Difference for Full Controls (95% CI)		Obs.
HbA1c	8.82	1.98	-0.018	(-0.375,0.339)	349
LDL Cholesterol	85.5	36.8	6.80	(-1.21,14.81)	85.5
HDL Cholesterol	41.9	12.1	-0.649	(-2.98,1.68)	41.9
Total Cholesterol	161	48.2	4.31	(-6.10,14.73)	161
Triglycerides	202	158	11.5	(-19.24,42.17)	202
Fasting Glucose	198	100	-13.5	(-35.36,8.42)	198

Effects on Biometric Outcomes at 6 months

	Control mean	SD	Adjusted Difference for Full Controls (95% CI)		Obs.
HbA1c	8.82	1.98	-0.018	(-0.375,0.339)	349
LDL Cholesterol	85.5	36.8	6.80	(-1.21,14.81)	307
HDL Cholesterol	41.9	12.1	-0.649	(-2.98,1.68)	308
Total Cholesterol	161	48.2	4.31	(-6.10,14.73)	308
Triglycerides	202	158	11.5	(-19.24,42.17)	309
Fasting Glucose	198	100	-13.5	(-35.36,8.42)	264
Weight kg	108	30.1	1.62	(0.04,3.19)	400
BMI	38.0	10.4	0.057	(-0.49,0.61)	340
Systolic BP	129	19.8	-0.75	(-4.35,2.85)	378
Diastolic BP	75	10.8	0.92	(-1.20,3.03)	378

Effects on Biometric Outcomes at 12 Months

	Control mean	SD	Adjusted Difference for Full Controls (95% CI)		Obs.
HbA1c	8.60	2.04	0.114	(-0.285,0.513)	325

Effects on Biometric Outcomes at 12 Months

	Control mean	SD	Adjusted Difference for Full Controls (95% CI)		Obs.
HbA1c	8.60	2.04	0.114	(-0.285,0.513)	325
Triglycerides	225	270	0.615	(-37.08,38.31)	275
Fasting Glucose	172	68.2	10.6	(-9.44,30.63)	208
LDL Cholesterol	85.2	36.4	3.24	(-4.92,11.40)	271
HDL Cholesterol	43.7	17.1	-1.78	(-5.48,1.92)	278
Total Cholesterol	165	57.0	-0.85	(-12.26,10.57)	278
Weight (kg)	108	28.8	0.62	(-0.85,2.10)	368
Systolic BP	130	18.4	-2.53	(-6.15,1.09)	350
Diastolic BP	74.1	10.6	1.12	(-0.95,3.19)	350

Outcome: Utilization

Effects on 6-month Utilization Measures

	Control Mean	SD	Adjusted Difference (95% CI)		Obs.
Number of inpatient or ED admissions	0.791	1.68	-0.051	(-0.287,0.185)	465
Number of outpatient visits	7.136	6.59	1.686	(0.646,2.725)	465

Effects on 12-month Utilization Measures

	Control Mean	SD	Adjusted Difference (95% CI)		Obs.
Number of inpatient or ED admissions	1.498	3.35	-0.154	(-0.582,0.273)	465
Number of outpatient visits	16.02	13.56	0.166	(-1.671,2.003)	465

Effects on Prescription Drug Usage at 6 Months

	Control Mean	SD	Adjusted Difference for Full Controls (95% CI)		Obs.
Active Prescription: Insulin	0.515	0.501	0.026	(-0.040,0.093)	465
Active Prescription: Metformin	0.506	0.501	0.068	(0.004,0.133)	465
Active Prescription: Sulfonylureas	0.174	0.38	-0.009	(-0.051,0.033)	465
Active Prescription: GLP-1 & related	0.4	0.491	0.102	(0.026,0.178)	465
Active Prescription: Any Diabetes Medication	0.928	0.26	0.025	(-0.014,0.063)	465

Effects on Prescription Drug Usage at 12 Months

	Control Mean	SD	Adjusted Difference for Full Controls (95% CI)		Obs.
Active Prescription: Insulin	0.515	0.501	0.027	(-0.047,0.102)	465
Active Prescription: Metformin	0.468	0.5	0.086	(0.016,0.157)	465
Active Prescription: Sulfonylureas	0.17	0.377	-0.014	(-0.066,0.037)	465
Active Prescription: GLP-1 & related	0.409	0.493	0.037	(-0.046,0.119)	465
Active Prescription: Any Diabetes Medication	0.923	0.267	0.032	(-0.008,0.072)	465

Effects on 6-month Claims

	Control Mean	SD	Adjusted Difference (95% CI)		Obs.
Inpatient claims (\$)	\$1,408	\$4,007	-\$218	(-1473,1037)	201
ED claims (\$)	\$753	\$2,150	-\$113	(-572,347)	201
Inpatient or ED claims (\$)	\$2,162	\$5,285	-\$320	(-1803,1162)	201
Outpatient claims (\$)	\$2,023	\$3,493	\$1,439	(-245,3123)	201
Total claims (\$)	\$5,368	\$7,993	\$739	(-2004,3482)	201

Effects on 12-month Claims

	Control Mean	SD	Adjusted Difference (95% CI)		Obs.
Inpatient claims (\$)	\$3,040	\$7,270	-\$1,131	(-3144,883)	183
ED claims (\$)	\$1,505	\$4,663	-\$572	(-1473,330)	183
Inpatient or ED claims (\$)	\$4,545	\$9,951	-\$1,678	(-4125,769)	183
Outpatient claims (\$)	\$4,118	\$5,206	\$1,380	(-743,3504)	183
Total claims (\$)	\$11,082	\$14,797	-\$774	(-4896,3349)	183

Heterogeneity

We lack statistical power to differentiate subgroups but can look for suggestive differences.

Qualitatively similar across a number of subgroups:

- Strata (baseline A1c, and Site)
- Men/Women
- Single-households vs. Multi-person households
- High/low utilization prior to joining the study
- Payer

Pre-COVID & Post-COVID

Study results

We find a null effect on HbA1c

We do find substantial effects on diet and healthcare engagement

Preventive care

- » Program healthcare: Dietitian appointments, foot exams
- » Increase in outpatient visits and claims
- » Increase in metformin and modern glucose-lowering-drug prescriptions

Diabetes Knowledge

We find null effects on:

Diabetes self-efficacy; other healthy behaviors (exercise; smoking);

We find statistically-insignificant improvement in self-assessed health
& reduction in inpatient/ed utilization

Interpretation

Study demonstrates the value of a control group

Programs targeted to elevated biomarkers → mean reversion

Context: patients connected to a health system

Food as Medicine: many parameters

Mode (home delivery vs. produce prescription)

Duration; Amount of food; Coupled with Education



Thank you



MEDICAL REPORT JANUARY 24, 2011 ISSUE

THE HOT SPOTTERS

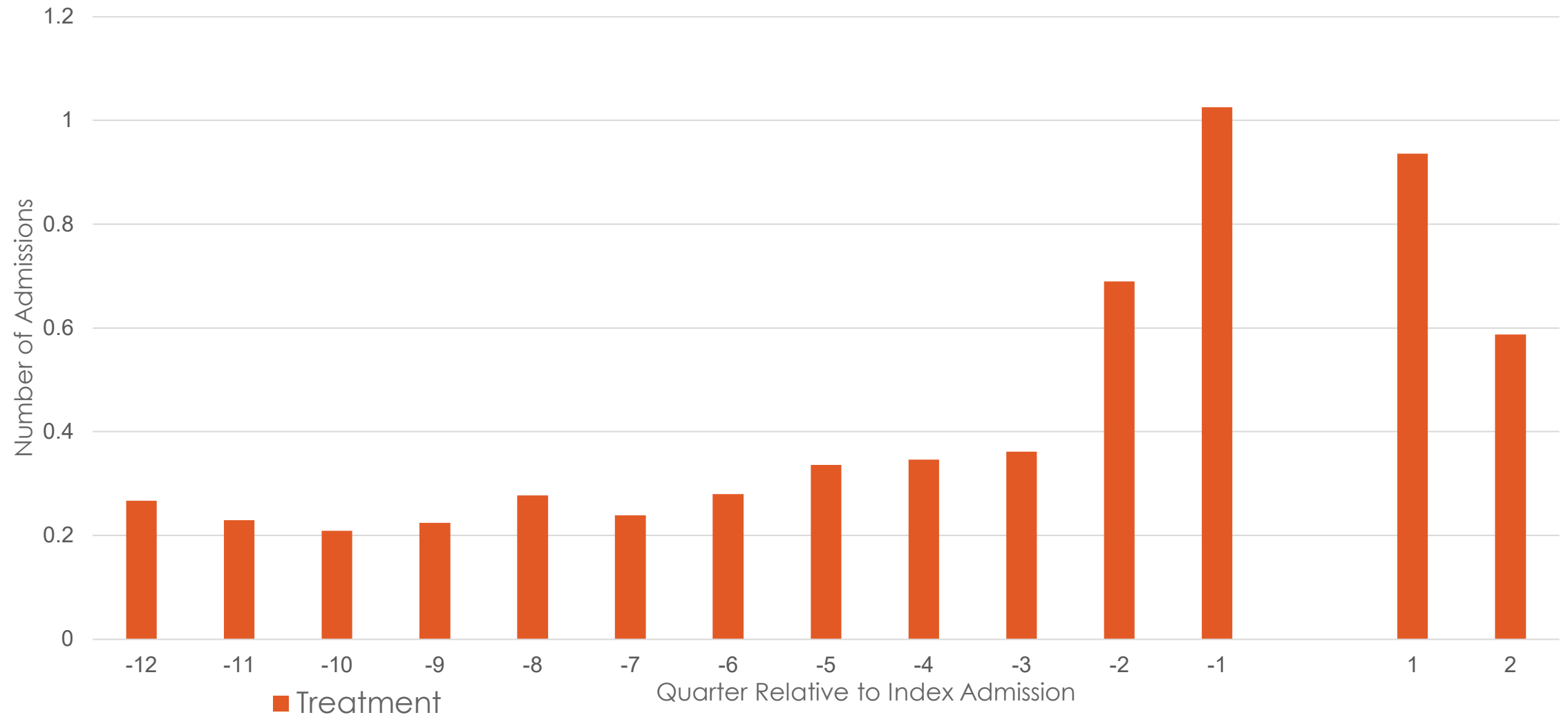
Can we lower medical costs by giving the neediest patients better care?



By Atul Gawande

January 17, 2011

Program participants visited the hospital about 40% less in the six months post-intervention



Clinical trial findings:
Control group mirrors treatment group
→ No effect on re-hospitalization

