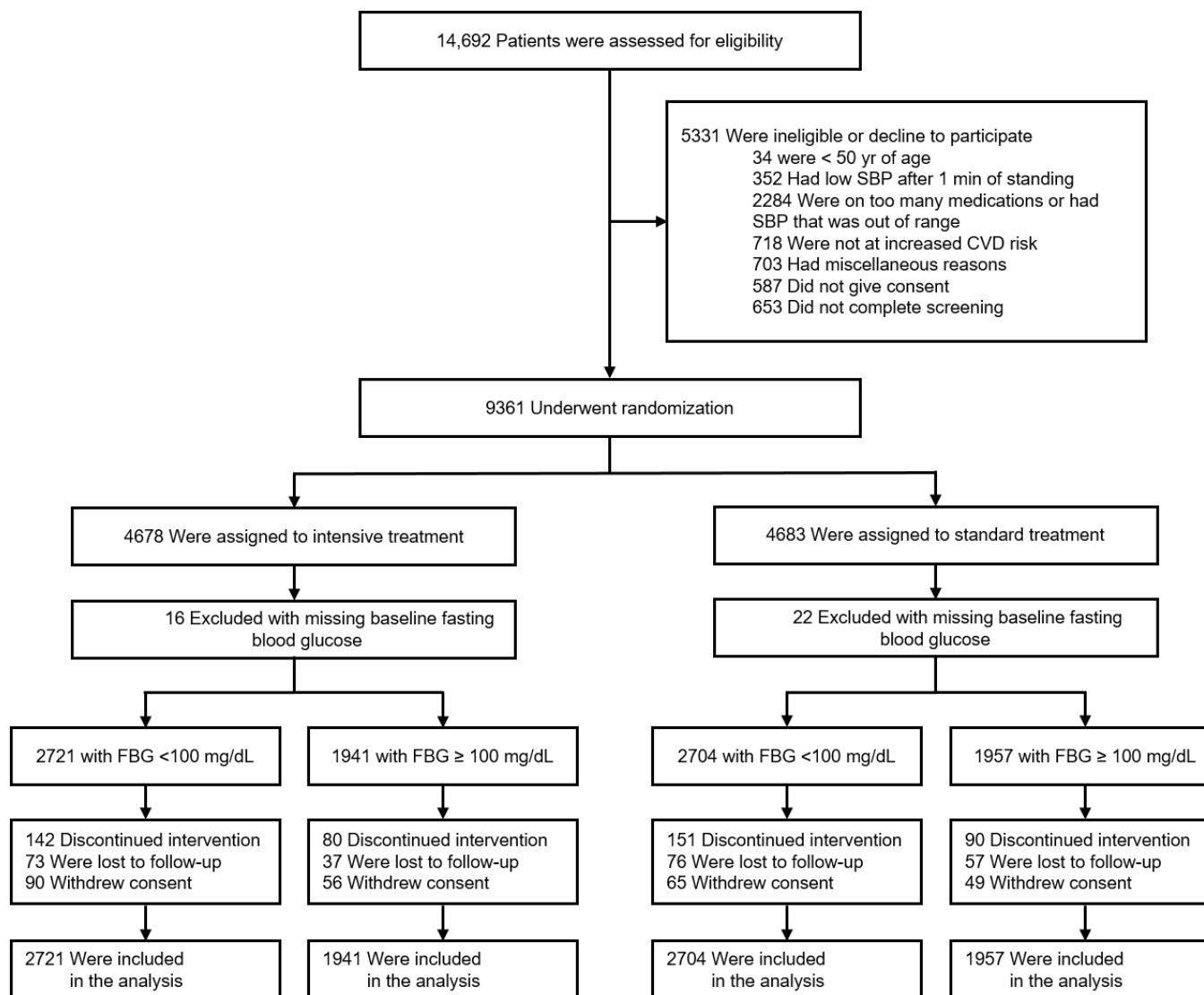


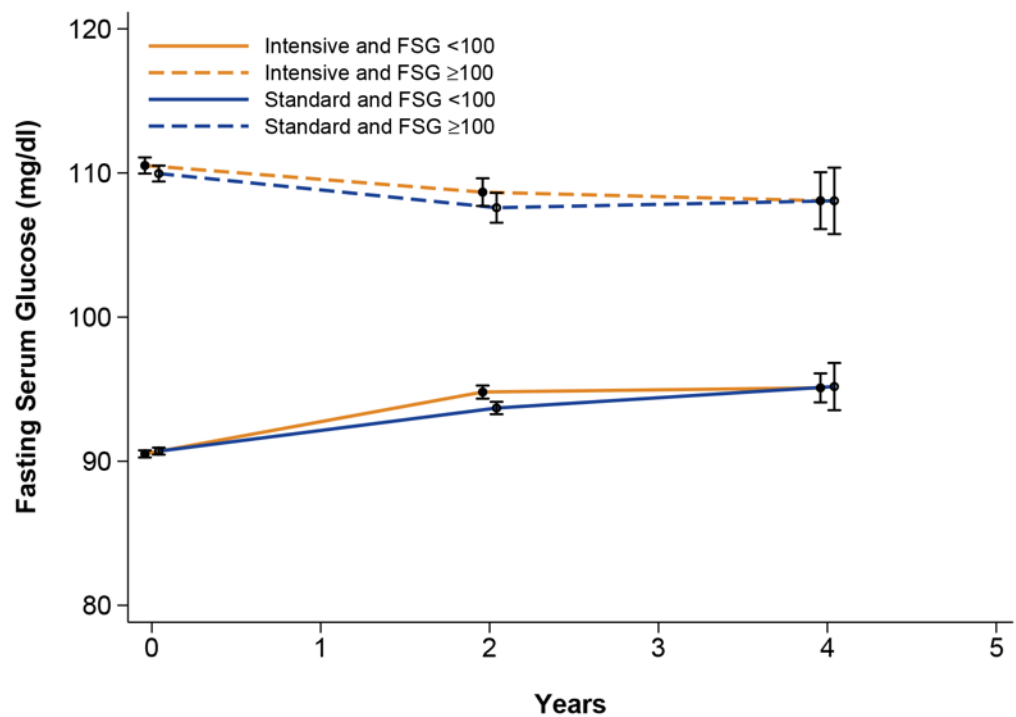
SUPPLEMENTARY DATA

Supplementary Figure 1. Eligibility, randomization, and follow-up of SPRINT participants among those with prediabetes and normoglycemia at baseline



SUPPLEMENTARY DATA

Supplementary Figure 2. Fasting serum glucose in the two treatment arms over the course of the trial among those with prediabetes and normoglycemia.



SUPPLEMENTARY DATA

Supplementary Figure 3. Systolic blood pressure in the intensive and standard treatment arms over the course of the trial among those with normoglycemia (Panel A) and with prediabetes (Panel B) at baseline.

The mean number of medications is the number of antihypertensive medications administered at study each visit. I bars represent 95% confidence intervals.



Mean No. of Medications

Standard treatment	1.9	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.7	1.9
Intensive treatment	2.2	2.6	2.7	2.7	2.7	2.7	2.7	2.7	2.8	3.0

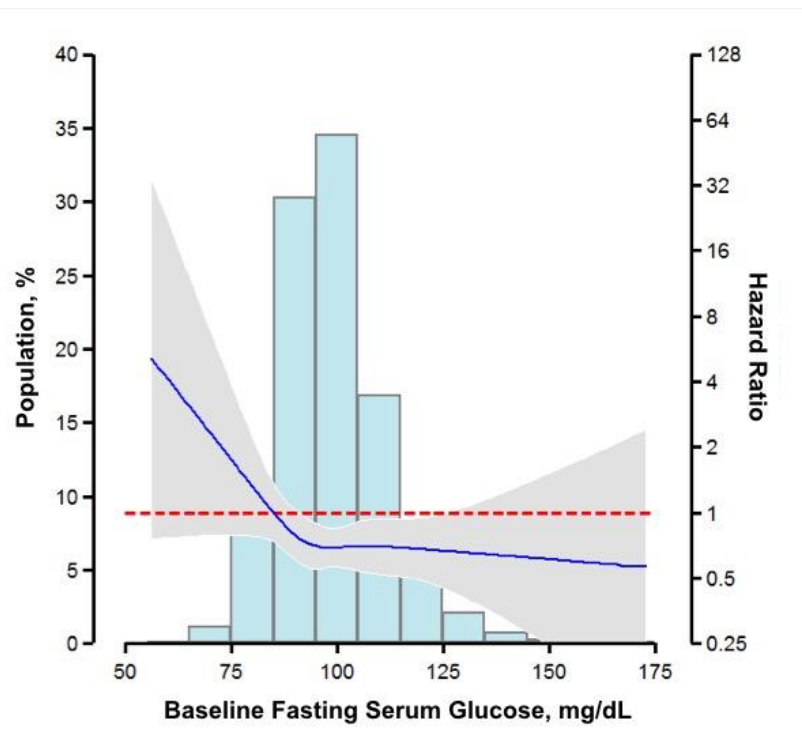
Mean No. of Medications

Standard treatment	2.0	1.9	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9
Intensive treatment	2.3	2.8	2.9	2.9	2.9	2.9	2.9	3.0	2.9	2.9

SUPPLEMENTARY DATA

Supplementary Figure 4. Hazard ratios for the primary outcome with intensive vs. standard treatment across a range of baseline fasting serum glucose as a continuous variable using restricted cubic splines.

The solid blue line represents the hazard ratio, and the grey shaded area represents the 95% CI. The histogram represents the distribution of baseline fasting serum glucose in SPRINT.



SUPPLEMENTARY DATA

Supplementary Table 1. Baseline fasting serum glucose cross classified with year 2 follow-up visit fasting serum glucose.

Baseline Serum Glucose, mg/dL	Year 2 Fasting Serum Glucose, mg/dL				Total
	Missing	< 100	100 – 125	> 125	
< 100	752	3485	1134	54	5425
100-125	419	1015	1925	244	3603
> 125	43	29	126	97	295
Total	1214	4529	3185	395	9323

Supplementary Table 2. Fasting serum glucose values at baseline, 24 months and 48 months post-randomization by treatment arm among those above and below a baseline fasting serum glucose of 100 mg/dL

Baseline Serum glucose Group	Randomized Group Assignment	Time Point	N	Mean, mg/dL	95% CI lower bound, mg/dL	95% CI upper bound, mg/dL
< 100 mg/dL	Standard	Baseline	2704	90.70	90.46	90.94
		24 months	2325	93.69	93.26	94.12
		48 months	545	95.18	93.54	96.82
	Intensive	Baseline	2721	90.51	90.26	90.75
		24 months	2348	94.80	94.34	95.25
		48 months	603	95.09	94.08	96.09
≥ 100 mg/dL	Standard	Baseline	1957	109.96	109.41	110.51
		24 months	1707	107.59	106.55	108.62
		48 months	455	108.07	105.76	110.37
	Intensive	Baseline	1941	110.52	109.96	111.08
		24 months	1729	108.67	107.71	109.63
		48 months	435	108.08	106.11	110.05

SUPPLEMENTARY DATA

Supplementary Table 3. Interaction analysis between treatment arm and baseline fasting serum glucose status for the primary outcome

Baseline fasting serum glucose	Randomized Treatment Arm				HR (95% CI) for treatment arm within strata of baseline fasting serum glucose
	Standard		Intensive		
	N event/no event	Hazard Ratio (95% CI)	N event/no event	Hazard Ratio (95% CI)	
< 100 mg/dL	174/2530 6.3%	1.0 (reference)	142/2579 5.0%	0.82 (0.65 – 1.02) p=0.077	0.83 (0.66 – 1.03) p=0.095
≥ 100 mg/dL	144/1813 6.9%	1.17 (0.93 - 1.46) p=0.178	101/1840 4.7%	0.80 (0.62 - 1.02) p=0.073	0.69 (0.53 - 0.89) p=0.005

Measure of interaction on additive scale: Relative excess risk due to interaction (RERI) (95% CI): -0.19 (-0.52 to 0.15), p=0.27

Measure of interaction on multiplicative scale: ratio of hazard ratios (95% CI) = 0.83 (0.59 to 1.17), p=0.30

The primary outcome was the first occurrence of myocardial infarction, acute coronary syndrome, stroke, heart failure, or death from cardiovascular causes. CI=confidence interval, HR=Hazard Ratio

SUPPLEMENTARY DATA

Supplementary Table 4. Incidence and hazard ratios for serious adverse events by treatment arm among those with normoglycemia and prediabetes at baseline

Outcome	Baseline fasting serum glucose						P-value for Interaction
	Normoglycemia <100 mg/dL			Prediabetes ≥ 100 mg/dL			
	Intensive Treatment (n=2,721)	Standard Treatment (n=2,704)	Hazard Ratio (95% CI)	Intensive Treatment (n=1,941)	Standard Treatment (n=1,957)	Hazard Ratio (95% CI)	
All serious adverse events	1052 (38.7)	1000 (37.0)	1.06 (0.97 - 1.15)	737 (38)	733 (37.5)	1.03 (0.93 - 1.14)	0.67
Conditions of interest							
Serious adverse event only							
Hypotension	61 (2.2)	44 (1.6)	1.33 (0.90 - 1.97)	49 (2.5)	22 (1.1)	2.38 (1.43 - 3.95)	0.08
Syncope	66 (2.4)	46 (1.7)	1.42 (0.97 - 2.07)	40 (2.1)	34 (1.7)	1.20 (0.75 - 1.91)	0.58
Bradycardia	51 (1.9)	41 (1.5)	1.20 (0.79 - 1.81)	36 (1.9)	32 (1.6)	1.10 (0.67 - 1.78)	0.79
Electrolyte abnormality	88 (3.2)	60 (2.2)	1.45 (1.04 - 2.02)	56 (2.9)	47 (2.4)	1.17 (0.79 - 1.74)	0.41
Injurious fall	70 (2.6)	69 (2.6)	1.00 (0.72 - 1.40)	35 (1.8)	41 (2.1)	0.91 (0.58 - 1.44)	0.75
AKI or ARF	111 (4.1)	69 (2.6)	1.59 (1.18 - 2.16)	82 (4.2)	48 (2.5)	1.69 (1.18 - 2.42)	0.81
ED visit or serious adverse event							
Hypotension	92 (3.4)	59 (2.2)	1.49 (1.08 - 2.07)	66 (3.4)	34 (1.7)	2.06 (1.36 - 3.13)	0.24
Syncope	95 (3.5)	68 (2.5)	1.40 (1.03 - 1.92)	67 (3.5)	45 (2.3)	1.50 (1.020 - 2.2)	0.79
Bradycardia	59 (2.2)	48 (1.8)	1.19 (0.81 - 1.75)	45 (2.3)	35 (1.8)	1.33 (0.85 - 2.08)	0.72
Electrolyte abnormality	102 (3.7)	70 (2.6)	1.45 (1.07 - 1.97)	75 (3.9)	59 (3.0)	1.29 (0.91 - 1.82)	0.62
Injurious fall	206 (7.6)	207 (7.7)	0.97 (0.80 - 1.18)	128 (6.6)	125 (6.4)	1.05 (0.82 - 1.35)	0.64
AKI or ARF	117 (4.3)	71 (2.6)	1.64 (1.22 - 2.20)	87 (4.5)	49 (2.5)	1.74 (1.22 - 2.48)	0.79
Monitored Clinical Events							
Adverse laboratory measures							
Serum sodium <130 mmol/liter	116 (4.3)	60 (2.2)	1.81 (1.32 - 2.5)	64 (3.3)	40 (2)	1.64 (1.08 - 2.48)	0.70
Serum sodium >150 mmol/liter	3 (0.1)	0 (0)	-	3 (0.2)	0 (0)	-	-
Serum potassium <3.0 mmol/liter	57 (2.1)	43 (1.6)	1.16 (0.77 - 1.74)	57 (2.9)	31 (1.6)	1.84 (1.16 - 2.92)	0.14
Serum potassium >5.5 mmol/liter	104 (3.8)	111 (4.1)	0.89 (0.68 - 1.18)	72 (3.7)	60 (3.1)	1.37 (0.95 - 1.98)	0.07
Orthostatic hypotension							
Alone	448 (16.5)	513 (19)	0.82 (0.72 - 0.94)	328 (16.9)	340 (17.4)	0.94 (0.8 - 1.1)	0.22
With dizziness	43 (1.6)	41 (1.5)	0.91 (0.59 - 1.43)	19 (1)	30 (1.5)	0.52 (0.29 - 0.96)	0.15

A serious adverse event was defined as an event that was fatal or life-threatening, that resulted in clinically significant or persistent disability, that required or prolonged a hospitalization, or that was judged by the investigator to represent a clinically significant hazard or harm to the participant that might require medical or surgical intervention to prevent one of the other events listed above. An injurious fall was defined as a fall that resulted in evaluation in an emergency department or that resulted in hospitalization. Acute kidney injury or acute renal failure were coded if the diagnosis was listed in the hospital discharge summary and was believed by the safety officer to be one of the top three reasons for admission or continued hospitalization. A few cases of acute kidney injury were noted in an emergency department if the participant presented for one of the other conditions of interest. Adverse laboratory measures were detected on routine or unscheduled tests; routine laboratory tests were performed at 1 month, then quarterly during the first year, then every 6 months. Orthostatic hypertension was defined as a drop in systolic blood pressure of at least 20 mm Hg or in diastolic blood pressure of at least 10 mm Hg at 1 minute after the participant stood up, as compared with the value obtained when the participant was seated. Standing blood pressures were measured at screening, baseline, 1 month, 6 months, 12 months, and yearly thereafter. Participants were asked if they felt dizzy at the time the orthostatic measure was taken.

SUPPLEMENTARY DATA

Supplementary Table 5. Sensitivity analysis excluding those with baseline fasting serum glucose ≥ 100 and year 2 fasting serum glucose of < 100 mg/dL (n=1044 excluded)

Outcome	Baseline fasting serum glucose						P Value for Interaction
	Normoglycemia < 100 mg/dL			Prediabetes ≥ 100 mg/dL			
	Intensive Treatment (n=2,721)	Standard Treatment (n=2,704)	Hazard Ratio (95% CI)	Intensive Treatment (n=1,452)	Standard Treatment (n=1,402)	Hazard Ratio (95% CI)	
Primary outcome	142 (1.7)	174 (2.1)	0.83 (0.66,1.03)	77 (1.7)	110 (2.5)	0.66 (0.49,0.89)	0.25
Secondary outcomes							
Myocardial infarction	57 (0.7)	72 (0.8)	0.80 (0.56,1.14)	31 (0.7)	32 (0.7)	0.98 (0.59,1.61)	0.62
Acute coronary syndrome	23 (0.3)	17 (0.2)	1.32 (0.71,2.51)	14 (0.3)	15 (0.3)	0.95 (0.45,2.02)	0.54
Stroke	36 (0.4)	32 (0.4)	1.19 (0.73,1.92)	20 (0.4)	33 (0.7)	0.62 (0.35,1.09)	0.08
Heart failure	37 (0.4)	52 (0.6)	0.72 (0.47,1.1)	17 (0.4)	36 (0.8)	0.4 (0.22,0.71)	0.13
Death from CVD causes	21 (0.2)	37 (0.4)	0.62 (0.35,1.05)	14 (0.3)	23 (0.5)	0.58 (0.29,1.13)	0.80
Death from any cause	89 (1)	125 (1.4)	0.71 (0.54,0.94)	58 (1.2)	68 (1.5)	0.81 (0.56,1.15)	0.63
Primary outcome or death	197 (2.3)	240 (2.9)	0.82 (0.68,0.99)	107 (2.3)	142 (3.3)	0.71 (0.55,0.92)	0.37

Numbers are counts and annual rates. The primary outcome was the first occurrence of myocardial infarction, acute coronary syndrome, stroke, heart failure, or death from cardiovascular causes. CVD=cardiovascular disease, CI= Confidence interval.

SUPPLEMENTARY DATA

Supplementary Table 6. Sensitivity analysis excluding those blood sample was recorded as not fasting at the time of the blood draw by study staff (n=580 excluded).

Outcome	Baseline fasting serum glucose						P Value for Interaction
	Normoglycemia < 100 mg/dL			Prediabetes ≥ 100 mg/dL			
	Intensive Treatment (n=2,547)	Standard Treatment (n=2,539)	Hazard Ratio (95% CI)	Intensive Treatment (n=1,834)	Standard Treatment (n=1,1823)	Hazard Ratio (95% CI)	
Primary outcome	126 (1.6)	161 (2.0)	0.80 (0.63,1.01)	96 (1.7)	129 (2.3)	0.73 (0.56,0.95)	0.62
Secondary outcomes							
Myocardial infarction	49 (0.6)	66 (0.8)	0.75 (0.51,1.08)	38 (0.6)	37 (0.6)	1.04 (0.66,1.65)	0.31
Acute coronary syndrome	22 (0.3)	16 (0.2)	1.37 (0.72,2.66)	16 (0.3)	23 (0.4)	0.70 (0.36,1.33)	0.17
Stroke	29 (0.4)	31 (0.4)	0.99 (0.59,1.65)	25 (0.4)	30 (0.5)	0.87 (0.51,1.48)	0.70
Heart failure	32 (0.4)	50 (0.6)	0.65 (0.41,1.01)	24 (0.4)	42 (0.7)	0.51 (0.3,0.84)	0.49
Death from CVD causes	21 (0.3)	33 (0.4)	0.70 (0.39,1.20)	14 (0.2)	25 (0.4)	0.52 (0.26,0.99)	0.49
Death from any cause	82 (1.0)	116 (1.4)	0.71 (0.53,0.95)	59 (1.0)	77 (1.3)	0.76 (0.54,1.07)	0.79
Primary outcome or death	177 (2.2)	223 (2.8)	0.80 (0.65,0.97)	125 (2.2)	164 (2.9)	0.75 (0.59,0.95)	0.68

Numbers are counts and annual rates. The primary outcome was the first occurrence of myocardial infarction, acute coronary syndrome, stroke, heart failure, or death from cardiovascular causes. CVD=cardiovascular disease, CI= Confidence interval.

SUPPLEMENTARY DATA

Supplementary Table 7. Sensitivity analysis excluding those with baseline serum fasting glucose ≥ 126 (n=295).

Outcome	Baseline fasting serum glucose						P Value for Interaction
	Normoglycemia < 100 mg/dL			Prediabetes ≥ 100 mg/dL			
	Intensive Treatment (n=2,721)	Standard Treatment (n=2,704)	Hazard Ratio (95% CI)	Intensive Treatment (n=1,791)	Standard Treatment (n=1,812)	Hazard Ratio (95% CI)	
Primary outcome	142 (1.7)	174 (2.1)	0.83 (0.66 - 1.03)	92 (1.6)	134 (2.4)	0.68 (0.52 - 0.88)	0.26
Secondary outcomes							
Myocardial infarction	57 (0.7)	72 (0.8)	0.80 (0.57 - 1.14)	34 (0.6)	40 (0.7)	0.88 (0.56 - 1.4)	0.75
Acute coronary syndrome	23 (0.3)	17 (0.2)	1.32 (0.70 - 2.47)	17 (0.3)	22 (0.4)	0.79 (0.41 - 1.5)	0.26
Stroke	36 (0.4)	32 (0.4)	1.19 (0.73 - 1.91)	25 (0.4)	34 (0.6)	0.77 (0.46 - 1.3)	0.24
Heart failure	37 (0.4)	52 (0.6)	0.72 (0.47 - 1.1)	23 (0.4)	46 (0.8)	0.45 (0.27 - 0.75)	0.17
Death from CVD causes	21 (0.2)	37 (0.4)	0.62 (0.36 - 1.06)	13 (0.2)	25 (0.4)	0.49 (0.25 - 0.96)	0.60
Death from any cause	89 (1.0)	125 (1.4)	0.71 (0.54 - 0.94)	56 (1.0)	78 (1.3)	0.72 (0.51 - 1.02)	0.96
Primary outcome or death	197 (2.3)	240 (2.9)	0.82 (0.68 - 0.99)	122 (2.1)	169 (3.0)	0.72 (0.57 - 0.91)	0.39

Numbers are counts and annual rates. The primary outcome was the first occurrence of myocardial infarction, acute coronary syndrome, stroke, heart failure, or death from cardiovascular causes. CVD=cardiovascular disease, CI= Confidence interval.

SUPPLEMENTARY DATA

Supplementary Table 8. Primary and secondary outcomes stratified by quartile of baseline fasting serum glucose and by treatment arm

Outcome	Fasting Serum Glucose Quartile, mg/dL	Intensive Arm			Standard Arm			Intensive vs. Standard			Interaction P-value
		N	Events	% per Year	N	Events	% per Year	HR	Lower 95% CL	Upper 95% CL	
Primary Outcome	Q1	1357	71	1.7	1280	69	1.7	0.98	0.7	1.37	0.29
	Q2	1050	49	1.5	1099	84	2.5	0.62	0.43	0.89	
	Q3	1108	62	1.8	1187	84	2.3	0.8	0.58	1.12	
	Q4	1147	61	1.7	1095	81	2.4	0.69	0.49	0.97	
Myocardial Infarction	Q1	1357	33	0.8	1280	33	0.8	0.94	0.57	1.53	0.43
	Q2	1050	18	0.5	1099	31	0.9	0.63	0.35	1.15	
	Q3	1108	25	0.7	1187	24	0.6	1.21	0.69	2.13	
	Q4	1147	21	0.6	1095	28	0.8	0.74	0.42	1.32	
Acute Coronary Syndrome	Q1	1357	14	0.3	1280	4	0.1	2.9	0.95	8.88	0.10
	Q2	1050	7	0.2	1099	9	0.3	0.71	0.26	1.94	
	Q3	1108	11	0.3	1187	12	0.3	0.98	0.43	2.24	
	Q4	1147	8	0.2	1095	15	0.4	0.49	0.2	1.21	
Stroke	Q1	1357	17	0.4	1280	10	0.2	1.55	0.7	3.41	0.46
	Q2	1050	12	0.4	1099	19	0.5	0.68	0.32	1.42	
	Q3	1108	16	0.5	1187	22	0.6	0.77	0.4	1.49	
	Q4	1147	17	0.5	1095	19	0.5	0.84	0.43	1.64	
Heart Failure	Q1	1357	16	0.4	1280	20	0.5	0.81	0.41	1.58	0.34
	Q2	1050	12	0.4	1099	25	0.7	0.51	0.25	1.03	
	Q3	1108	20	0.6	1187	26	0.7	0.83	0.46	1.51	
	Q4	1147	14	0.4	1095	29	0.8	0.41	0.21	0.79	
Death from CVD causes	Q1	1357	10	0.2	1280	15	0.4	0.73	0.33	1.64	0.87
	Q2	1050	8	0.2	1099	21	0.6	0.45	0.19	1.05	
	Q3	1108	7	0.2	1187	13	0.3	0.64	0.25	1.62	
	Q4	1147	12	0.3	1095	15	0.4	0.66	0.3	1.45	
Death from any cause	Q1	1357	44	1	1280	57	1.4	0.74	0.5	1.1	0.78
	Q2	1050	36	1	1099	60	1.7	0.64	0.42	0.98	
	Q3	1108	29	0.8	1187	35	0.9	0.89	0.54	1.48	
	Q4	1147	45	1.2	1095	57	1.6	0.68	0.45	1.02	
Primary outcome or death	Q1	1357	98	2.3	1280	105	2.6	0.88	0.67	1.17	0.60
	Q2	1050	73	2.2	1099	110	3.2	0.7	0.51	0.94	
	Q3	1108	74	2.1	1187	98	2.6	0.81	0.6	1.11	
	Q4	1147	86	2.4	1095	109	3.2	0.7	0.52	0.94	

Numbers are counts and annual rates. The primary outcome was the first occurrence of myocardial infarction, acute coronary syndrome, stroke, heart failure, or death from cardiovascular causes. CVD=cardiovascular disease, CL= Confidence limit.

Quartile 1 (Q1) = ≤91 mg/dL, Quartile 2 (Q2) =92-97 mg/dL, Quartile 3 (Q3) = 98-105 mg/dL, Quartile 4 (Q4) ≥106mg/dL

SUPPLEMENTARY DATA

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