An Update of the Systolic Blood Pressure Intervention Trial

SPRINT

Horner Lecture

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Presenter Disclosure Information
Karen C. Johnson, MD, MPH

FINANCIAL DISCLOSURE: Nothing to disclose

The content does not necessarily represent the official views of the SPRINT Steering Committees, the NIH, or the US government.

A QUICK WORD FROM OUR SPONSORS

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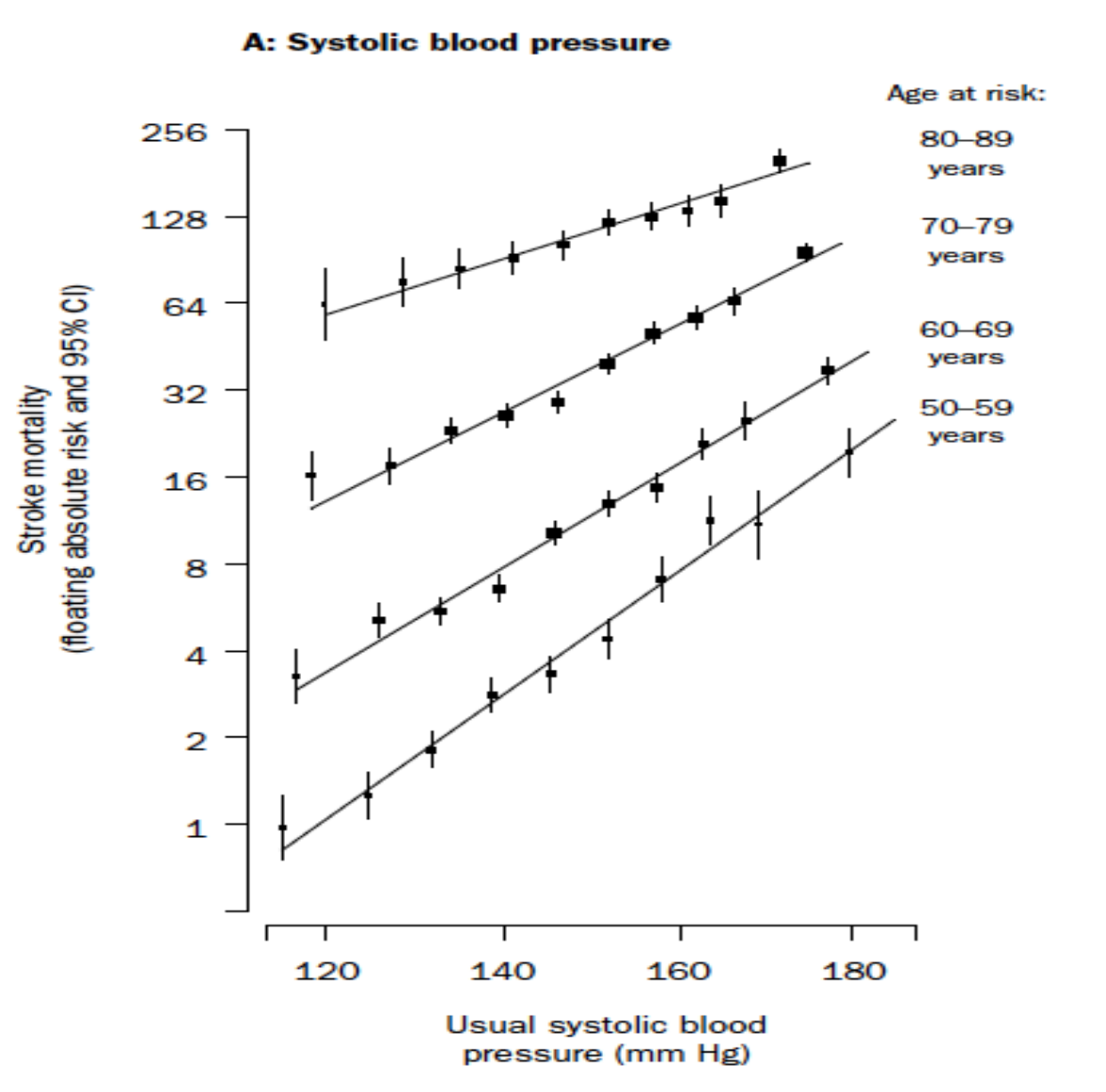
- Support from a number of CTSAs funded by NCATS
- Contribution of study medications (azilsartan and azilsartan/ chlorthalidone) from Takeda Pharmaceuticals International, Inc.

SBP vs Stroke Mortality Risk Relationship



- At all ages there is no apparent SBP threshold
- Stroke mortality risk doubles for every 20/10 mm Hg increase above 115/75
- 20 mm Hg increase in systolic BP associated with a 10-fold larger annual absolute stroke risk in age 80s vs. age 50s.

Lewington et al. *Lancet.* 2002;360:1903-1913.

SPRINT Research Question

Will CVD composite event rate be lower in intensive compared to standard SBP treatment (N = 9,361)?

Randomized Controlled Trial
Target Systolic BP

Intensive Treatment
Goal SBP < 120 mm Hg

FU Time 3.33 years

Standard Treatment
Goal SBP < 140 mm Hg

SPRINT design details available at:

- ClinicalTrials.gov (NCT01206062)
- Ambrosius WT et al. Clin. Trials. 2014;11:532-546.

Primary Outcome and Primary Hypothesis

- ***Primary outcome***
  - *CVD composite: first occurrence of*
    - *Myocardial infarction (MI)*
    - *Acute coronary syndrome (non-MI ACS)*
    - *Stroke*
    - *Acute decompensated heart failure (HF)*
    - *Cardiovascular disease death*
- ***Primary hypothesis****
  - *CVD composite event rate lower in intensive compared to standard treatment*

**Estimated power of 88.7% to detect a 20% difference - based on recruitment of 9,250 participants, 4-6 years of follow-up and loss to follow-up of 2%/year.*

Additional Outcomes

- All-cause mortality
- Primary outcome + all-cause mortality
- Dementia /Mild Cognitive Impairment
- Brain MRI for small vessel ischemic disease
- Renal:
  - Main secondary outcome
    - Participants with CKD at baseline: ≥50% decline in eGFR or ESRD
- Health-related quality of life assessments
- Outcomes in subgroups

Pre-specified Subgroups of Special Interest

- Age (<75 vs. ≥75 years)
- Gender (Men vs. Women)
- Race/ethnicity (African-American vs. Non African-American)
- CKD (eGFR <60 vs. ≥60 mL/min/1.73m^2)
- CVD (CVD vs. no prior CVD)
- Level of BP (Baseline SBP tertiles: ≤132, 133 to 144, ≥145 mm Hg)

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BP Intervention

- BP monitored monthly for 3 months and every 3 months thereafter (additional visits could be scheduled)
- Antihypertensive medication titration decisions based on seated visit BP, using a structured stepped-care approach
- Agents from all major antihypertensive drug classes available free of charge
  - Classes with best CVD outcomes in trials given priority
    - Chlorthalidone encouraged as thiazide-type diuretic
    - Amlodipine encouraged as CCB
- Periodic assessment for orthostatic hypotension and related symptoms and measured serum electrolytes and renal function

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Blood Pressure Measurement in SPRINT

- Similar to what has been used in virtually all HTN outcome trials.
- Similar to what has been recommended for clinical practice by virtually all HTN guidelines
- SPRINT Blood Pressure Measurement Procedures
  - SPRINT BP was the average of 3 BP measurements obtained using an automated measurement device (Omron 907XL) after a **5 minute** rest period.
  - Appropriate cuff size was determined by measuring arm circumference.
  - Participant was seated with back supported and arm bared and supported at heart level.
  - Omron Device was set to delay 5 minutes and then take/average 3 BP measurements, during which time participants refrained from talking or texting.

SPRINT Systolic Blood Pressure Intervention Trial

Cushman, et al. Hypertension. 2016;67:263-5

SPRINT Intensive Intervention

- Initiate therapy with at least 2 drugs – senior participants on 0-1 drugs could be started on 1 drug
- BP medications were added and/or titrated at monthly visits to achieve SBP <120 mm Hg
- Intervention goal was to create a minimum mean difference between randomized groups of at least 10 mm Hg

SPRINT Inclusion/Exclusion Criteria

- Age: ≥50 years old
- BP: systolic blood pressure : 130–180 mm Hg (treated or untreated)
- Additional cardiovascular disease (CVD) risk
  - Clinical or subclinical CVD (excluding stroke)
  - Chronic kidney disease (CKD), defined as eGFR 20–59 ml/min/1.73m^2
  - Framingham Risk Score for 10-year CVD risk ≥ 15%
  - Age ≥75 years
- Exclude for:
  - Stroke, diabetes mellitus, polycystic kidney disease, heart failure
  - Proteinuria >1g/d
  - CKD with eGFR <20 mL/min/1.73m^2 (MDRD)
  - Adherence concerns
  - Residing in nursing home or dementia Dx

Clin. Trials. 2014;11:532-546

N Engl J Med. 2015;373:2103-16

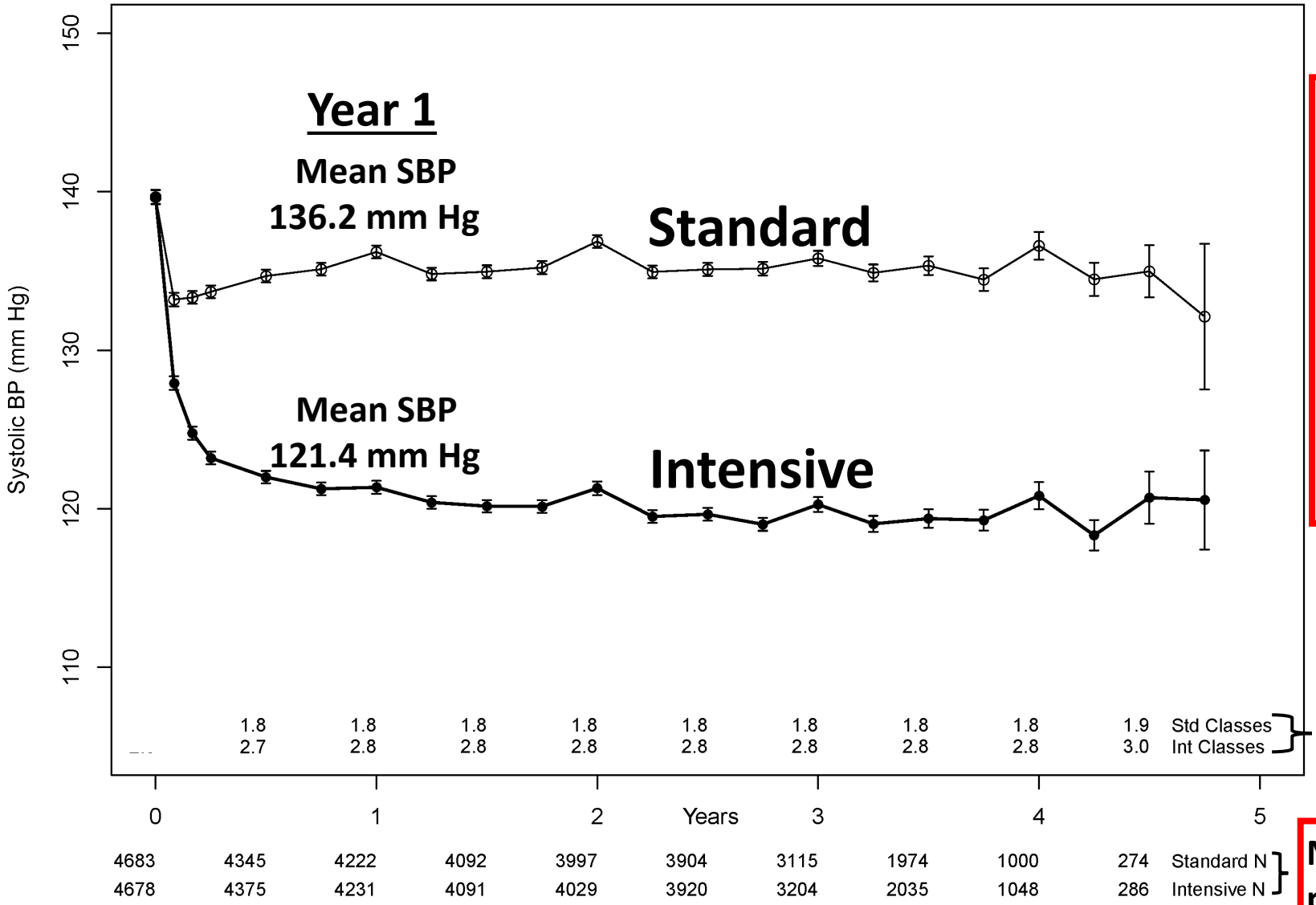
SPRINT: Selected Baseline Characteristics

	Total N=9361
Mean age	68 years
≥75 years	28%
Female	36%
White	58%
African-American	30%
Hispanic	11%
Prior CVD	20%
Prior CKD	28%
Mean 10-year Framingham CVD risk	24%
Taking antihypertensive meds	91%
Mean number of antihypertensive meds	1.8
Mean Baseline BP, mm Hg	140/78

Clin. Trials. 2014;11:532-546

N Engl J Med. 2015;373:2103-16

Systolic BP During Follow-up



Average SBP
(During Follow-up)

Standard: 134.6 mm Hg

Delta: 13.5 mm Hg

Intensive: 121.5 mm Hg

Average number of antihypertensive medications

Number of participants

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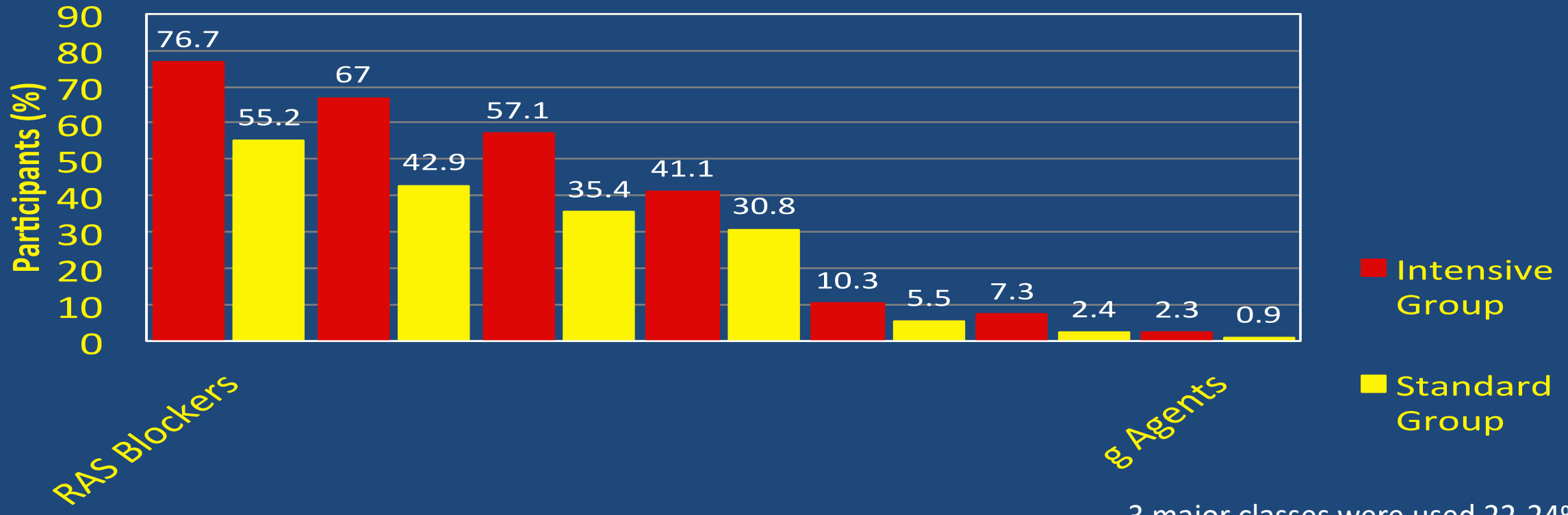
Medication Classes by Treatment Group

Last Visit Per Participant Prior to 8/20/2015



3 major classes were used 22-24% more often in Intensive than Standard Group, but pattern of drug class usage was similar.

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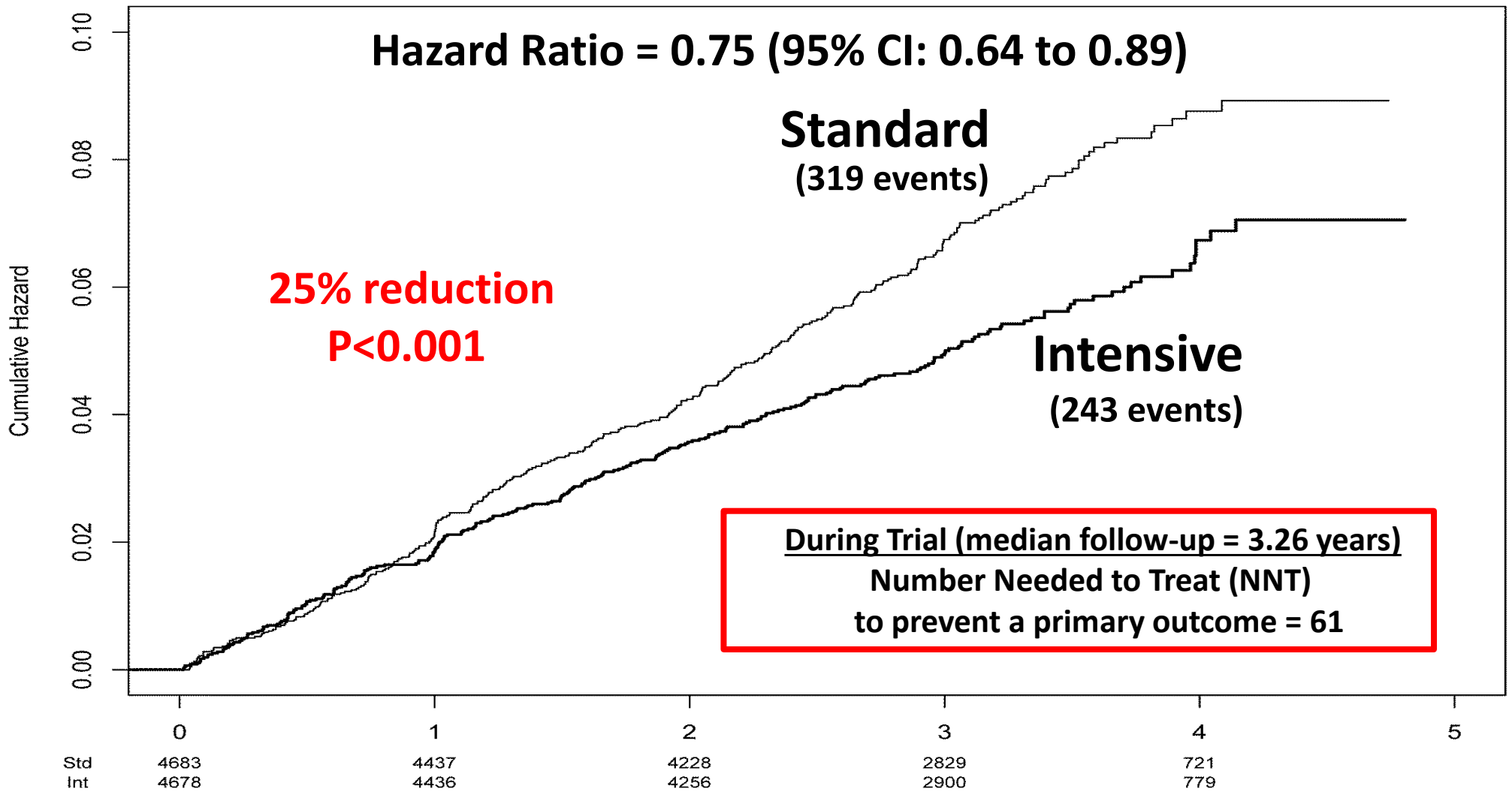
National Heart Lung and Blood Institute | NIDDK National Institute of Diabetes and Digestive and Kidney Diseases | National Institute on Aging

Decision to Stop BP Intervention

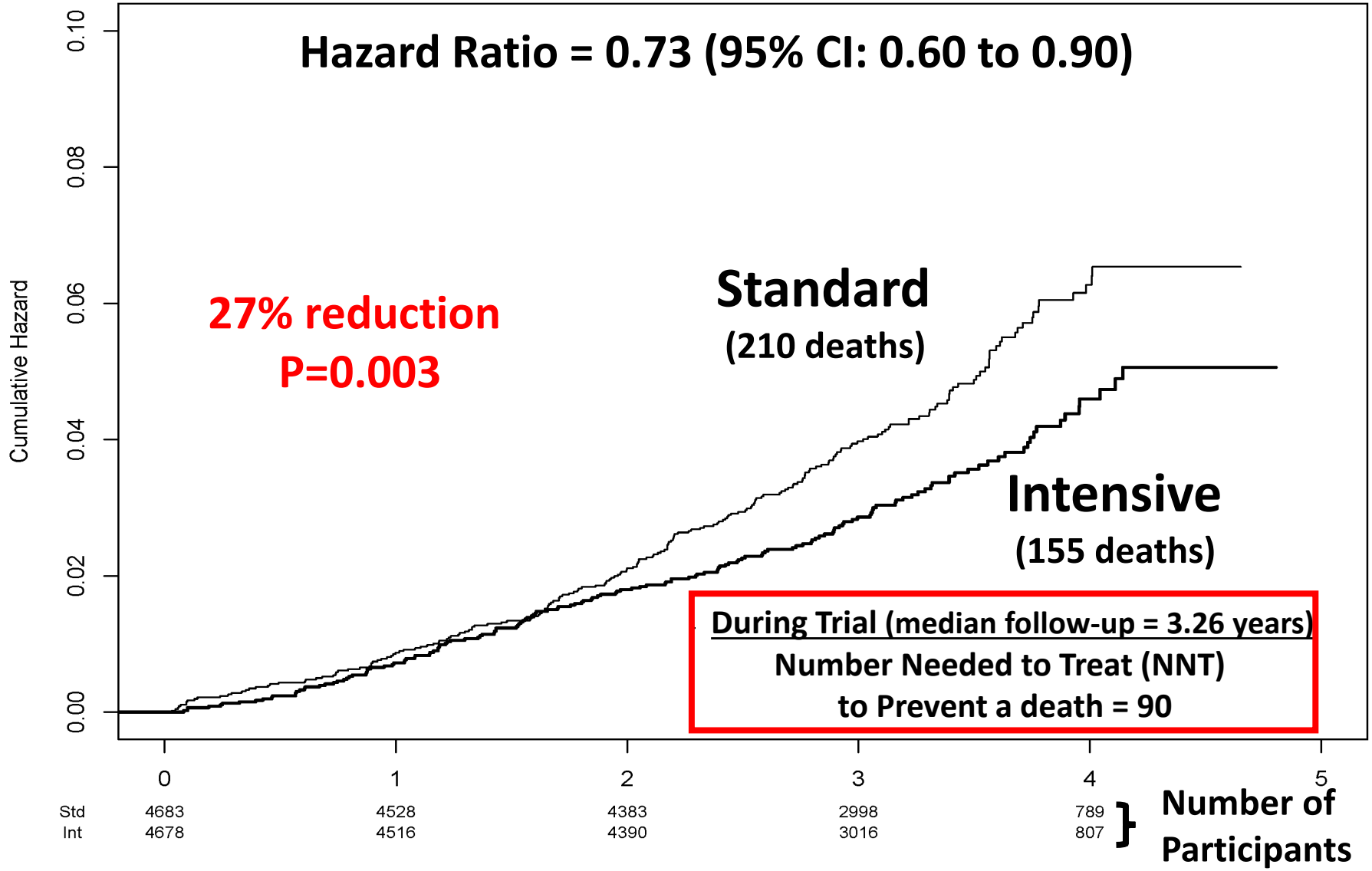
- On August 20, 2015, NHLBI Director (Dr. Gary Gibbons) accepted the DSMB recommendation to inform SPRINT investigators and participants of CVD results
- Concurrently, decision made to stop BP intervention and return BP care to PCP
- Blinded data for secondary non-CVD outcomes (e.g., dementia and cognitive impairment) continued to be collected

SPRINT Primary Outcome (CVD)
Cumulative Hazard



The SPRINT Research Group. N Engl J Med. 2015;373:2103-16

All-cause Mortality
Cumulative Hazard



The SPRINT Research Group. N Engl J Med. 2015;373:2103-16

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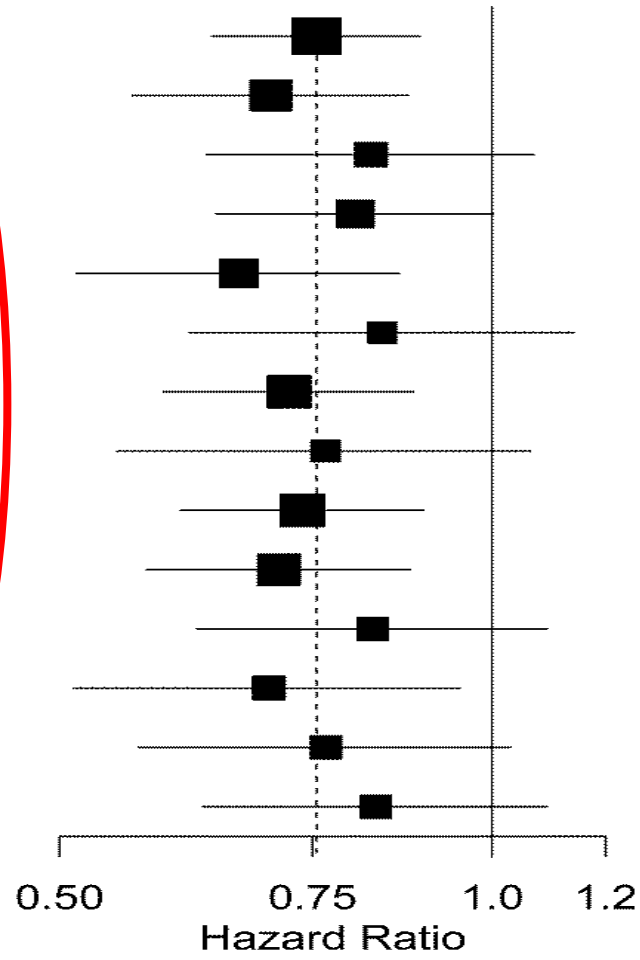
Experience in the Six Pre-specified Subgroup Populations of Interest

Primary Outcome (CVD Composite) Treatment by subgroup interaction

Subgroup	HR	P*
Overall	0.75 (0.64,0.89)	
No Prior CKD	0.70 (0.56,0.87)	0.36
Prior CKD	0.82 (0.63,1.07)	
Age < 75	0.80 (0.64,1.00)	0.32
Age ≥ 75	0.67 (0.51,0.86)	
Female	0.84 (0.62,1.14)	0.45
Male	0.72 (0.59,0.88)	
African−American	0.77 (0.55,1.06)	0.83
Non African−American	0.74 (0.61,0.90)	
No Prior CVD	0.71 (0.57,0.88)	0.39
Prior CVD	0.83 (0.62,1.09)	
SBP ≤ 132	0.70 (0.51,0.95)	0.77
132 < SBP < 145	0.77 (0.57,1.03)	
SBP ≥ 145	0.83 (0.63,1.09)	

*Unadjusted for multiplicity



The SPRINT Research Group. N Engl J Med. 2015;373:2103-2116

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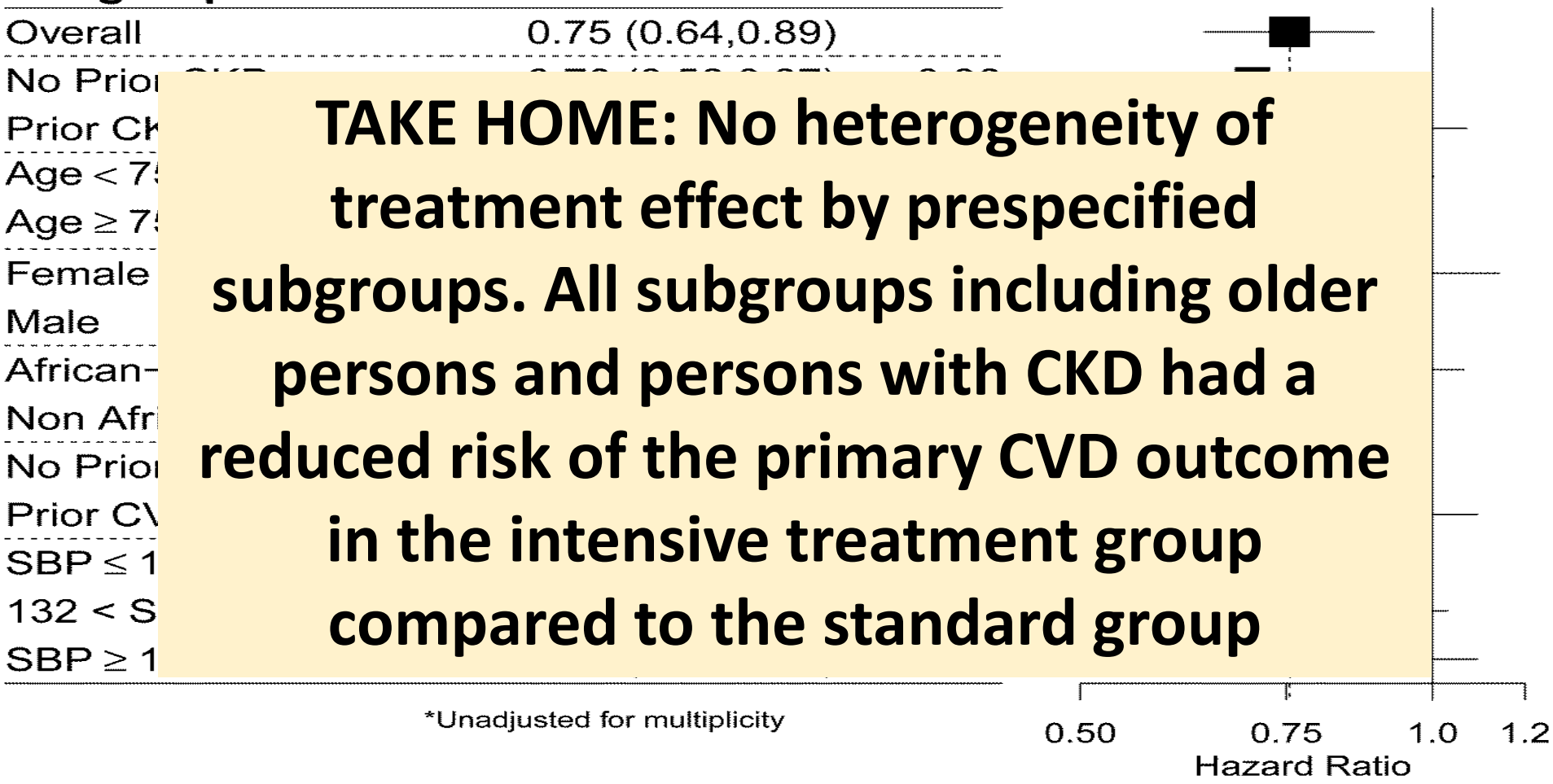

TAKE HOME: No heterogeneity of treatment effect by prespecified subgroups. All subgroups including older persons and persons with CKD had a reduced risk of the primary CVD outcome in the intensive treatment group compared to the standard group

The SPRINT Research Group. N Engl J Med. 2015;373:2103-2116

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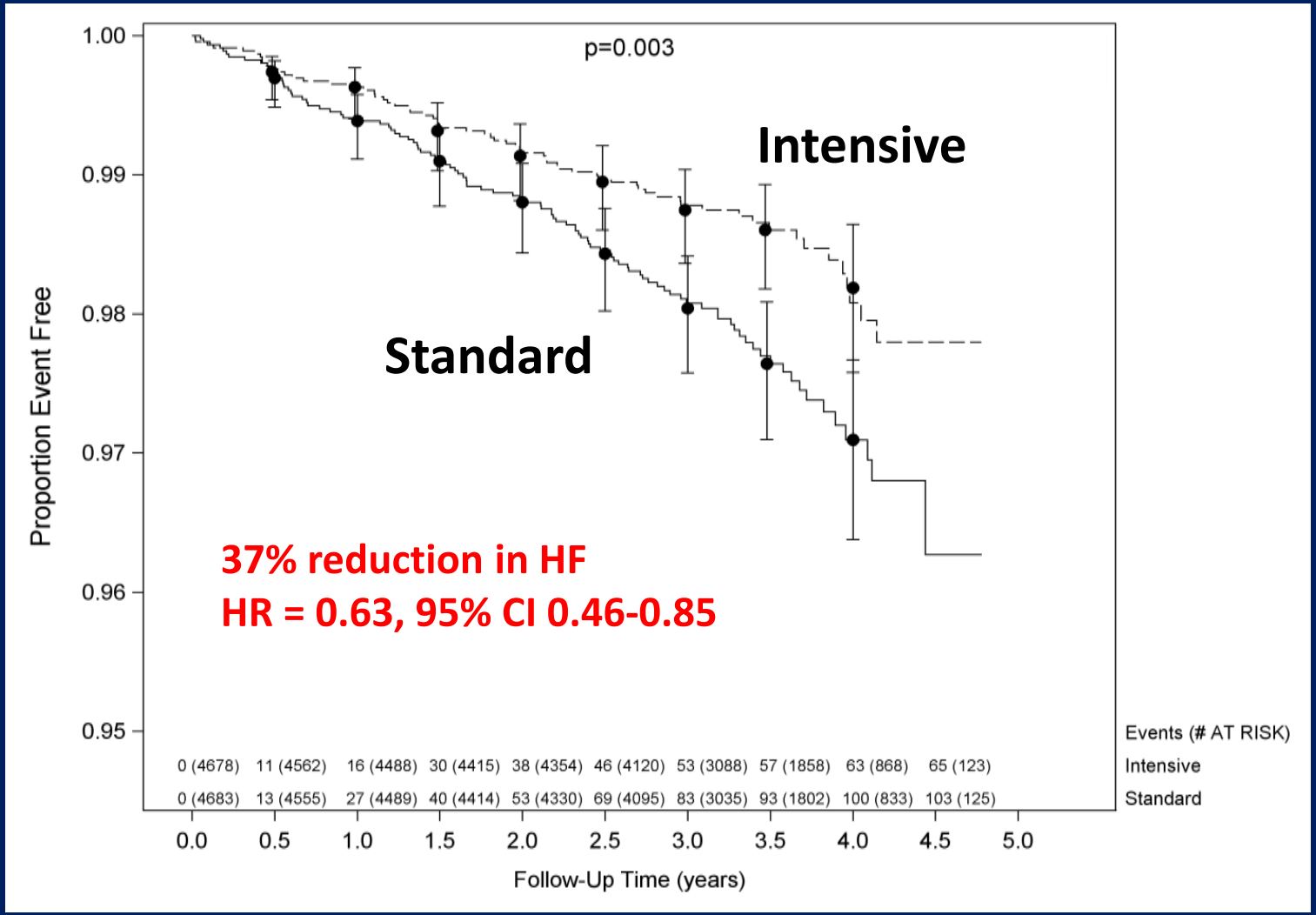
Kaplan-Meyer curves for the SPRINT Acute Decompensated Heart Failure Outcome by Treatment Group



- Intensive treatment group had a 37% reduced risk of ADHF
- NNT to prevent ADHF = 130
- Participants who developed ADHF had markedly increased risk of subsequent cardiovascular outcomes

Upadhya B, et al. Circ Heart Fail. 2017 Apr;10(4).

Subsequent Clinical Outcomes Based on Initial ADHF Occurrence

Outcome	No ADHF (n=9193) N (%)	ADHF (n=168) N (%)	Hazard Ratio (95% CI)	*P* Value
Death from any cause, n (%)	323 (3.5)	44 (26.2)	**9.5 (6.7-13.1)**	<0.001
Death from cardiovascular causes, n (%)	79 (0.9)	26 (15.5)	**26.8 (16.2-43.0)**	<0.001
Myocardial infarction, n (%)	180 (2.0)	38 (22.6)	**15.7 (9.9-24.0)**	<0.001
Non-MI acute coronary syndrome, n (%)	75 (0.8)	7 (4.2)	**9.9 (3.7-21.6)**	<0.001
Stroke, n (%)	122 (1.3)	16 (9.5)	**4.0 (1.4-8.8)**	0.003

Data are adjusted for treatment arm, sex, baseline age (in years), baseline chronic kidney disease, and baseline cardiovascular disease. ADHF was a time-dependent covariate in these models. ADHF indicates acute decompensated heart failure; and CI, confidence interval.

Upadhya B, et al. Circ Heart Fail. 2017 Apr;10(4).

1^0 and 2^0 Outcomes: First Occurrence During Trial Intervention Period

All Participants	Intensive (N=4678) % per year	Standard (N=4683) % per year	HR (95% CI)
Primary outcome	1.77	2.40	0.73 (0.63-0.86)
Primary (w/out HF)	1.48	1.97	0.75 (0.63-0.89)
Secondary Outcomes			
MI	0.68	0.93	0.72 (0.56-0.93)
ACS	0.28	0.27	1.02 (0.66-1.57)
Stroke	0.45	0.52	0.89 (0.64-1.23)
Heart failure	0.45	0.70	0.63 (0.46-0.86)
CVD Death	0.27	0.47	0.58 (0.39-0.84)
Death – any cause	1.06	1.41	0.75 (0.61-0.92)

SPRINT Systolic Blood Pressure Intervention Trial

Lewis CE. NEJM 2021;384:1921-30

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TAKE HOME: Intensive Beat Standard for 1^0 Composite CVD Outcome, Including and Excluding Heart Failure

SPRINT Systolic Blood Pressure Intervention Trial

Lewis CE. NEJM 2021;384:1921-30

Number (%) of Participants with a Monitored Clinical Measure During Follow-up

	Number (%) of Participants		
	Intensive	Standard	HR (P Value)
Laboratory Measures[1]			
Sodium <130 mmol/L	180 (3.9)	100 (2.2)	1.76 (<0.001)
Potassium <3.0 mmol/L	114 (2.5)	74 (1.6)	1.50 (0.006)
Potassium >5.5 mmol/l	176 (3.8)	171 (3.7)	1.00 (0.97)
Signs and Symptoms			
Orthostatic hypotension[2]	777 (16.6)	857 (18.3)	0.88 (0.013)
Orthostatic hypotension+dizziness	62 (1.3)	71 (1.5)	0.85 (0.35)

1. Detected on routine or PRN labs; routine labs drawn quarterly for first year, then q 6 months
2. Drop in SBP ≥20 mm Hg or DBP ≥10 mm Hg 1 minute after standing (measured at 1, 6, and 12 months and yearly thereafter) in the SPRINT clinic

Primary CVD Outcomes, Mortality, and Kidney Outcomes in Persons with CKD at Baseline

With CKD at Baseline	Intensive (N = 1330) # Events (% per year)	Standard (N = 1316) # Events (% per year)	HR (95% CI)
50% Decline eGFR, dialysis, or kidney transplantation	10 (0.25)	12 (0.31)	0.79 (0.34-1.83)
Incident albuminuria	63 (3.93)	85 (5.61)	0.71 (0.50-1.00)
1^0 CVD Outcome or All-Cause Death	152 (3.62)	179 (4.35)	0.82 (0.66-1.02)
1^0 CVD Outcome	112 (2.68)	131 (3.19)	0.81 (0.63-1.05)
Death Any Cause	70 (1.61)	95 (2.21)	0.72 (0.53-0.99)

No significant between group difference in the Renal Composite outcome in persons with CKD but there were very few events

SPRINT Systolic Blood Pressure Intervention Trial

Cheung AK. J Am Soc Neph 2017; 28:2812-23

Primary CVD Outcomes, Mortality and Kidney Outcomes in Persons without CKD at Baseline

Without CKD at Baseline	Intensive (N=3326) # Events (Events per 100 P-Y)	Standard (N=3335) # Events (Events per 100 P–Y)	HR (95% CI) per 100 P-Y
Incident CKD	140 (1.33)	40 (0.37)	3.54 (2.50-5.02)
1^0 CVD Outcome or All-Cause Death	189 (1.78)	264 (2.51)	0.71 (0.59-0.86)
1^0 CVD Outcome	136 (1.28)	202 (1.92)	0.67 (0.54-0.84)
All-Cause Death	83 (0.77)	114 (1.05)	0.74 (0.55-0.98)

Asymptomatic Incident CKD (30% reduction in eGFR to less than 60) was more common in the intensive treatment group than the standard group but neither group had to have long-term dialysis or received a kidney transplant

SPRINT Systolic Blood Pressure Intervention Trial

Beddhu S. Ann Int Med 2017;167:375-83

Primary Outcomes, Mortality and Kidney Outcomes in Persons without CKD

Without CKD	Intensive (N=3326)	Standard (N=3335)	HR (95% CI)	Absolute Risk

TAKE HOME: Persons with and without CKD had a reduced risk of the 1^0 CVD Composite Outcome and reduced risk of Death in the intensive group compared to the standard group

Intensive SBP lowering did have an increased risk for asymptomatic incident CKD events, but this is outweighed by CVD and Death benefits

SPRINT Systolic Blood Pressure Intervention Trial

Beddhu S. Ann Int Med 2017;167:375-83

Serious Adverse Events* (SAE) During Follow-up

	Number (%) of Participants		HR (P Value)
	Intensive	Standard	
All SAE reports (no different in age ≥75 yrs)	1793 (38.3)	1736 (37.1)	1.04 (0.25)
SAEs associated with Specific Conditions of Interest			
Hypotension	110 (2.4)	66 (1.4)	1.67 (0.001)
Syncope	107 (2.3)	80 (1.7)	1.33 (0.05)
Injurious fall (no different in age ≥75 yrs)	105 (2.2)	110 (2.3)	0.95 (0.71)
Bradycardia	87 (1.9)	73 (1.6)	1.19 (0.28)
Electrolyte abnormality	144 (3.1)	107 (2.3)	1.35 (0.020)
Acute kidney injury or acute renal failure	193 (4.1)	117 (2.5)	1.66 (<0.001)

Acute Kidney Serious Adverse Events in SPRINT

- AKI (ER or hospitalization) was collected as part of SAE reporting in SPRINT.
- Post hoc, all cases of AKI were adjudicated by Nephrologists.
- For participants with sufficient data, complete or partial resolution of AKI was seen more frequently observed in the intensive group than the standard group.
- More intensive BP lowering resulted in more frequent episodes of AKI SAEs - most cases were mild, most cases appeared to be related dehydration, and most participants had complete recovery of kidney function.

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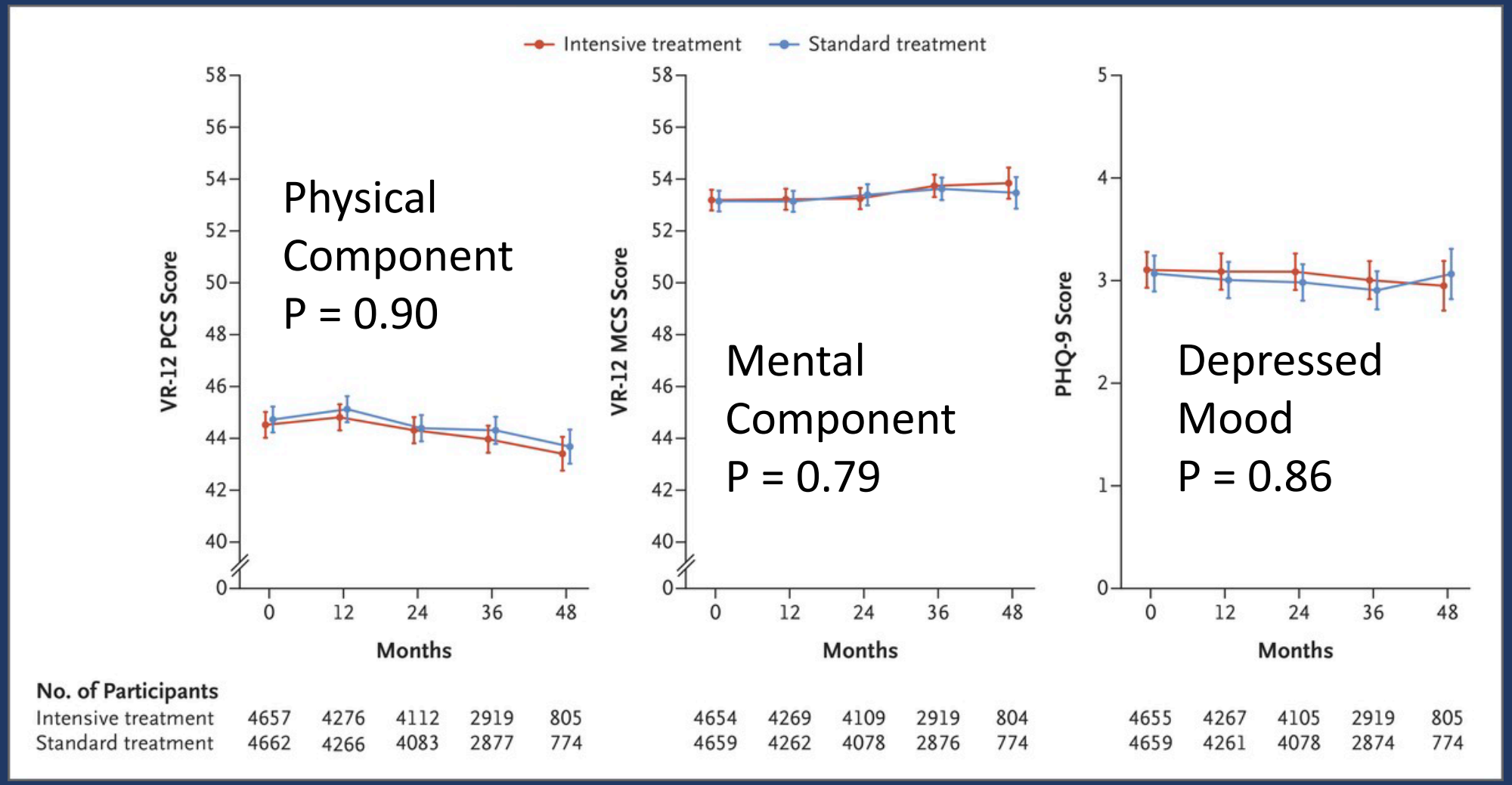
Rocco MV, et al. AKJD 2018

Health Related Quality of Life and Depressed Mood Outcomes



No difference in physical function, mental function and depressed mood between the intensive and standard groups

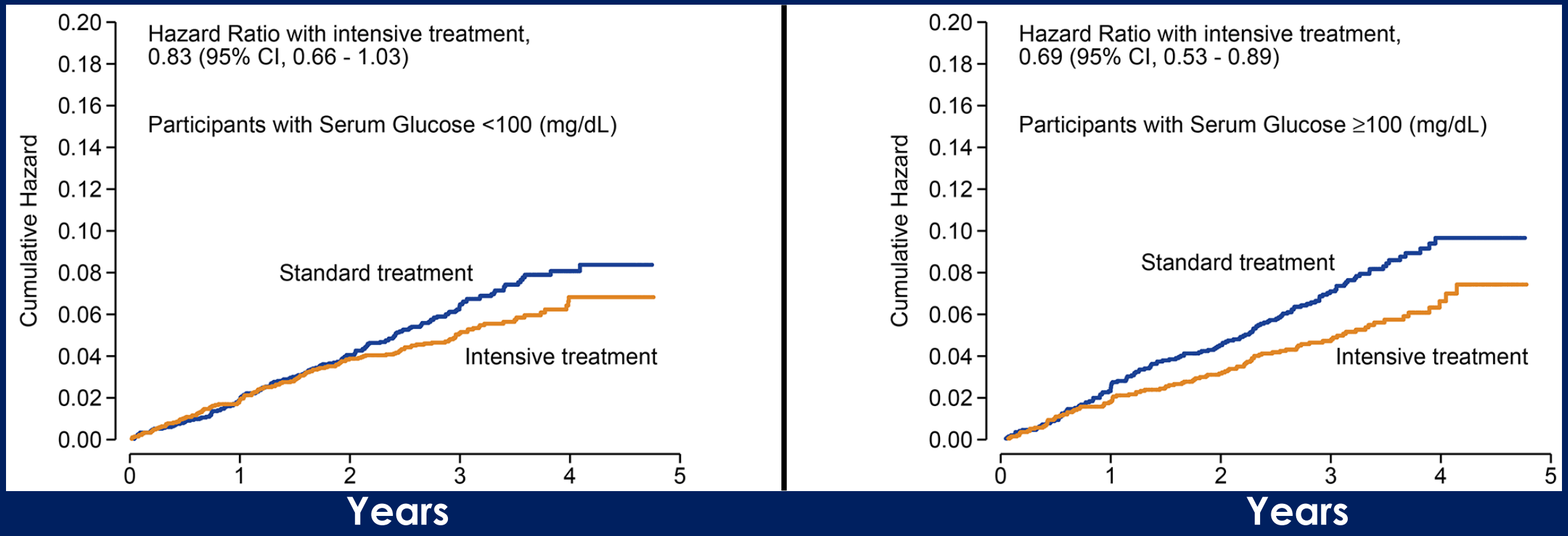
Berlowitz DR. NEJM 2017;377:733-44

Primary CVD Outcome Benefits of Intensive Treatment Are Similar in Prediabetes and Normoglycemia

Normoglycemia (n=5,425, 58%)
(Serum glucose <100 mg/dL)

Interaction
P= 0.30

Prediabetes (n=3,898, 42%)
(Serum glucose ≥100 mg/dL)



Bress AP. *Diabetes Care*. 2017

Outcomes in Participants Age 80+

	Intensive (N/CIF) N = 586	Standard (N/CIF) N = 581	HR (95% CI)	P interaction
1^0 CVD Outcome				
Overall	75/0.13	106/0.18	0.67 (0.50-0.90)	
MoCA higher	37/0.11	72/0.19	0.49 (0.33-0.73)	0.01
MoCA lower	35/0.16	34/0.16	1.04 (0.65-1.66)	
1^0 CVD Outcome + Death				
Overall	111/0.20	152/0.25	0.65 (0.51-0.83)	
MoCA higher	47/0.13	106/0.27	0.40 (0.28-0.57)	<0.001
MoCA lower	60/0.31	46/0.23	1.33 (0.87-2.03)	

CIF = Cumulative incidence over FU

SPRINT Systolic Blood Pressure Intervention Trial

Pajewski NM. JAGS 2020;68:496-504

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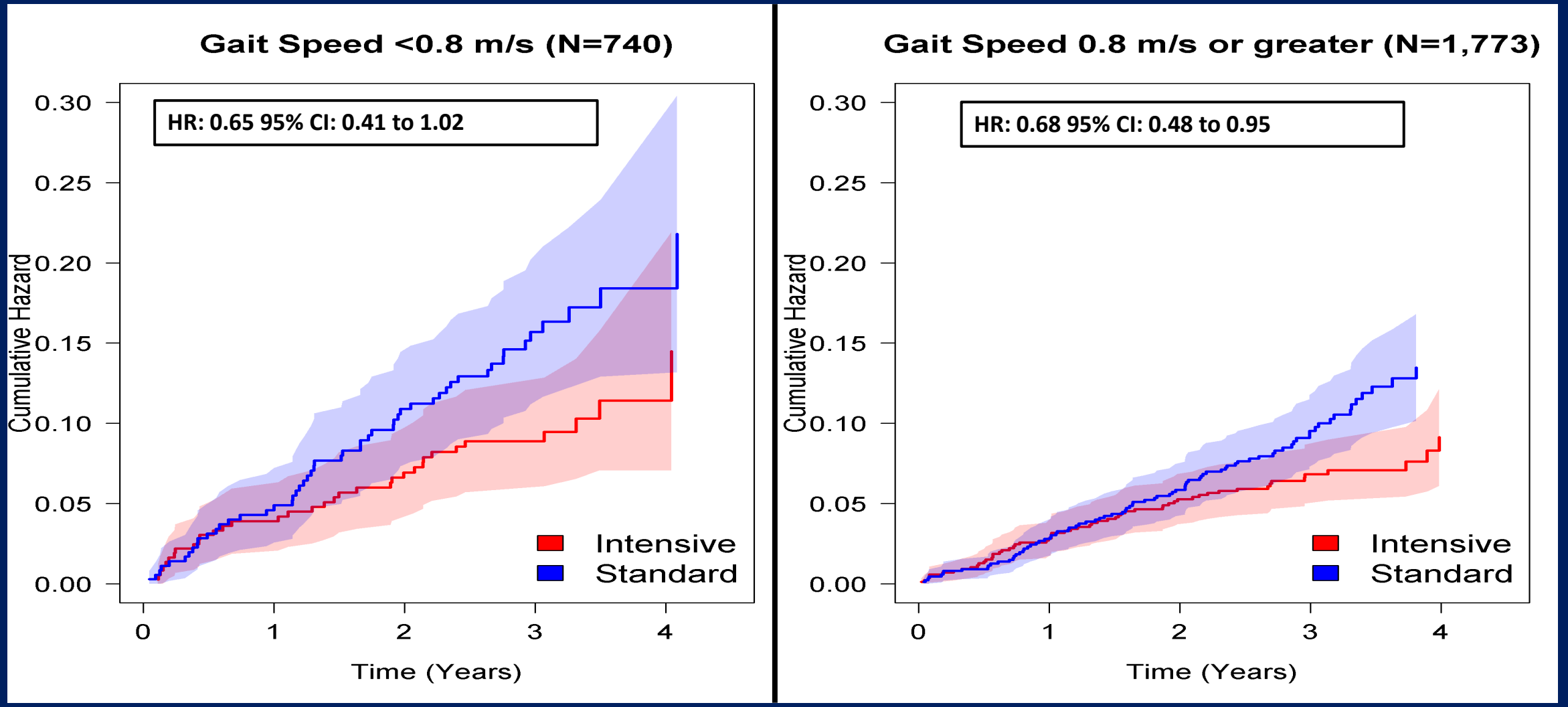
MoCA lower	60/0.31	46/0.23	1.33 (0.87-2.03)	

TAKE HOME: Intensive BP treatment may not have the Benefit for those persons who are Age 80+ with Lower Baseline Cognitive Function

CIF Cumulative incidence over FU

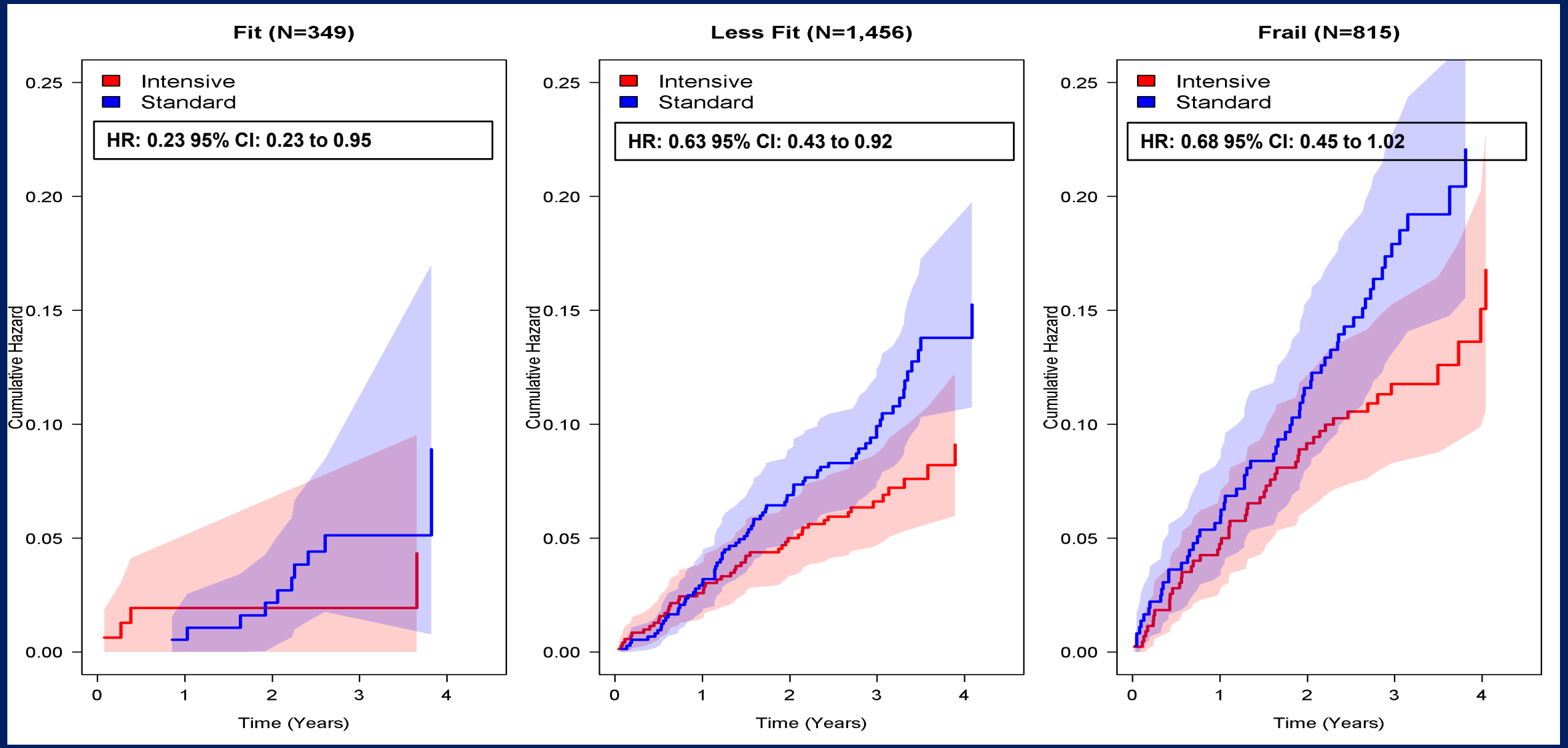
Pajewski NM. JAGS 2020;68:496-504

Cumulative Hazards for SPRINT Primary CVD Outcome by Gait Speed



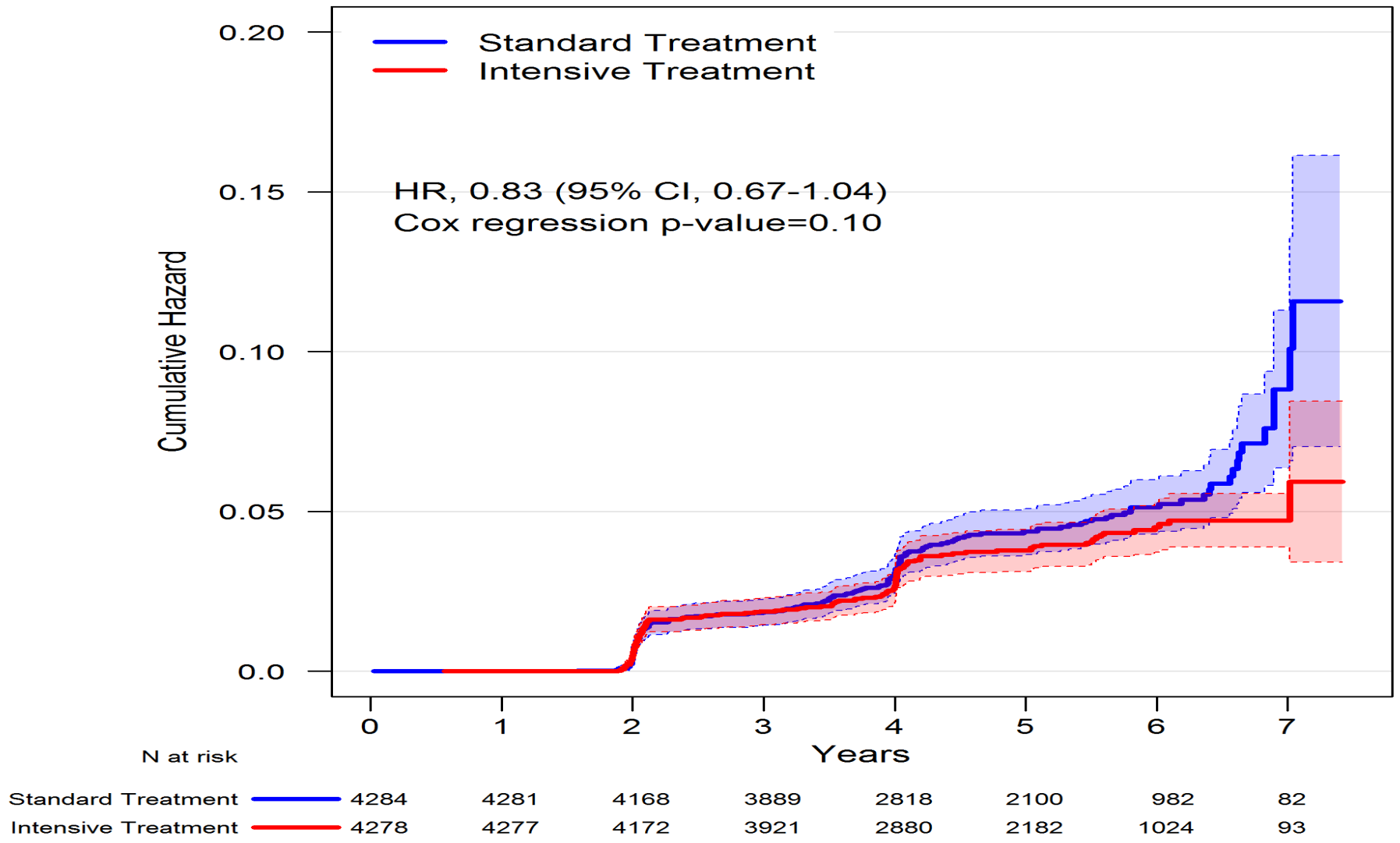
Interaction p-value = 0.732

Cumulative Hazards for SPRINT
Primary CVD Outcome by Frailty Status



Interaction p-value = 0.838

Adjudicated Probable Dementia by Treatment Group



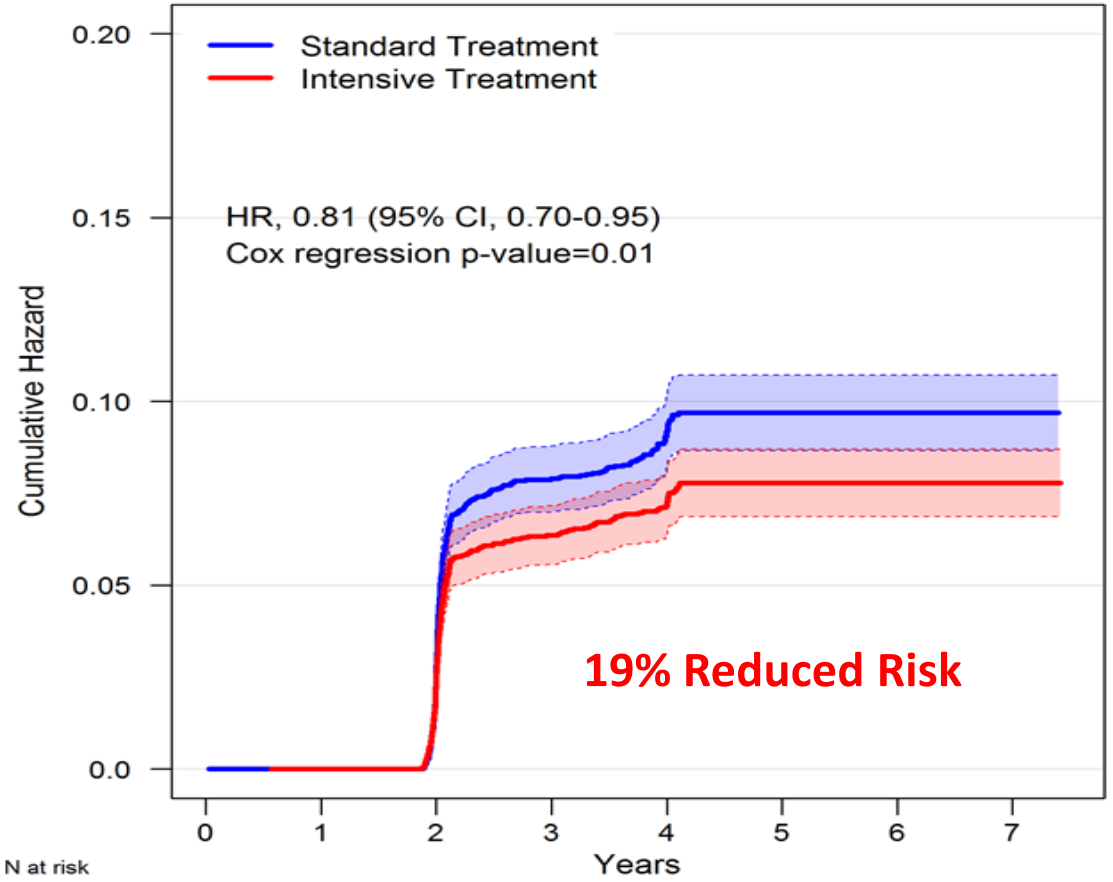
No difference between groups in probable dementia but stopping the trial early probably decreased our power to detect the dementia outcome

SPRINT Systolic Blood Pressure Intervention Trial

JAMA. 2019 Jan 28. doi: 10.1001/jama.2018.21442. [Epub ahead of print]

Adjudicated SPRINT-MIND Events

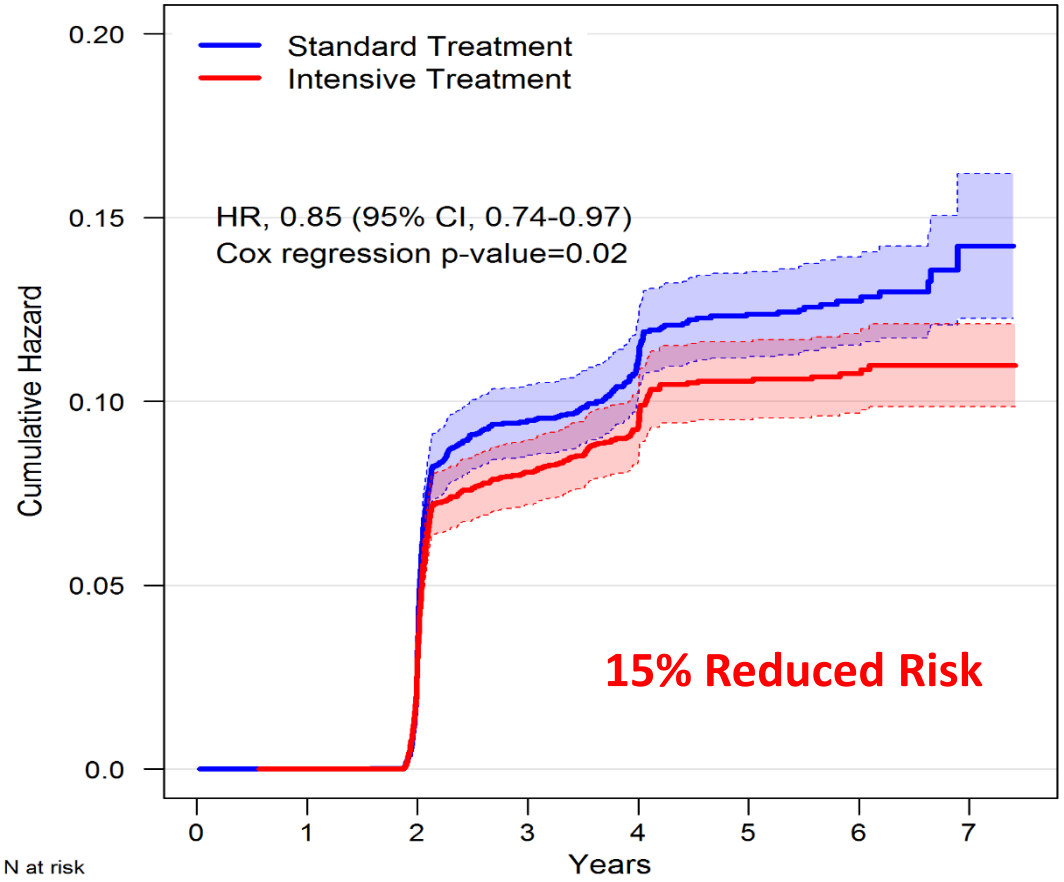
Probable Mild Cognitive Impairment (MCI)



N at risk

Standard Treatment	4131	4128	3903	3427	2456	1837	852	72
Intensive Treatment	4126	4125	3916	3532	2572	1944	917	81

MCI and Dementia



N at risk

Standard Treatment	4284	4281	4059	3596	2596	1940	906	75
Intensive Treatment	4278	4277	4071	3677	2717	2057	971	88

JAMA. 2019 Jan 28. doi: 10.1001/jama.2018.21442. [Epub ahead of print]

BRAIN OUTCOMES: Cognitive, White Matter Lesions, Blood Flow

Change	Intensive	Standard	Est. Difference in Change	P Value
White Matter Lesion volume (cm^3), asinh	0.15 (0.11-0.19)	0.28 (0.24-0.33)	-0.13 (-0.19 to -0.07)	< 0.001
Whole Brain Cerebral Blood Flow	1.46 (0.08-2.83)	-0.84 (-2.30-0.61)	2.30 (0.30-4.30)	0.02
Gray Matter Cerebral Blood Flow	2.14 (0.41-3.87)	-0.34 (-2.17-1.48)	2.49 (-0.03-5.00)	0.05
White Matter Cerebral Blood Flow	0.65 (-0.32-1.61)	-0.83 (-1.85-0.18)	1.48 (0.08-2.88)	0.04
Periventricular White Matter Cerebral Blood Flow	0.32 (-0.54-1.17)	-0.88 (-1.80-0.04)	1.20 (-0.06-2.45)	0.06

SPRINT Systolic Blood Pressure Intervention Trial

Dolui S. JAMA Neurol 2022

BRAIN OUTCOMES: Cognitive, White Matter Lesions, Blood Flow

Change	Intensive	Standard	Est. Difference in Change	P Value
WML volume (cm^3) asinh				< 0.001
Whole B Cerebral				0.02
Gray Ma Cerebral				0.05
White M Cerebral				0.04
Perivent White M Cerebral Blood Flow				0.06

TAKE HOME: Intensive Beat Standard for MCI, Composite Cognitive Outcome;
And
Slower Increase in White Matter Lesion volume, Improved Cerebral Blood Flow in Intensive Group (Not a Decrease!)

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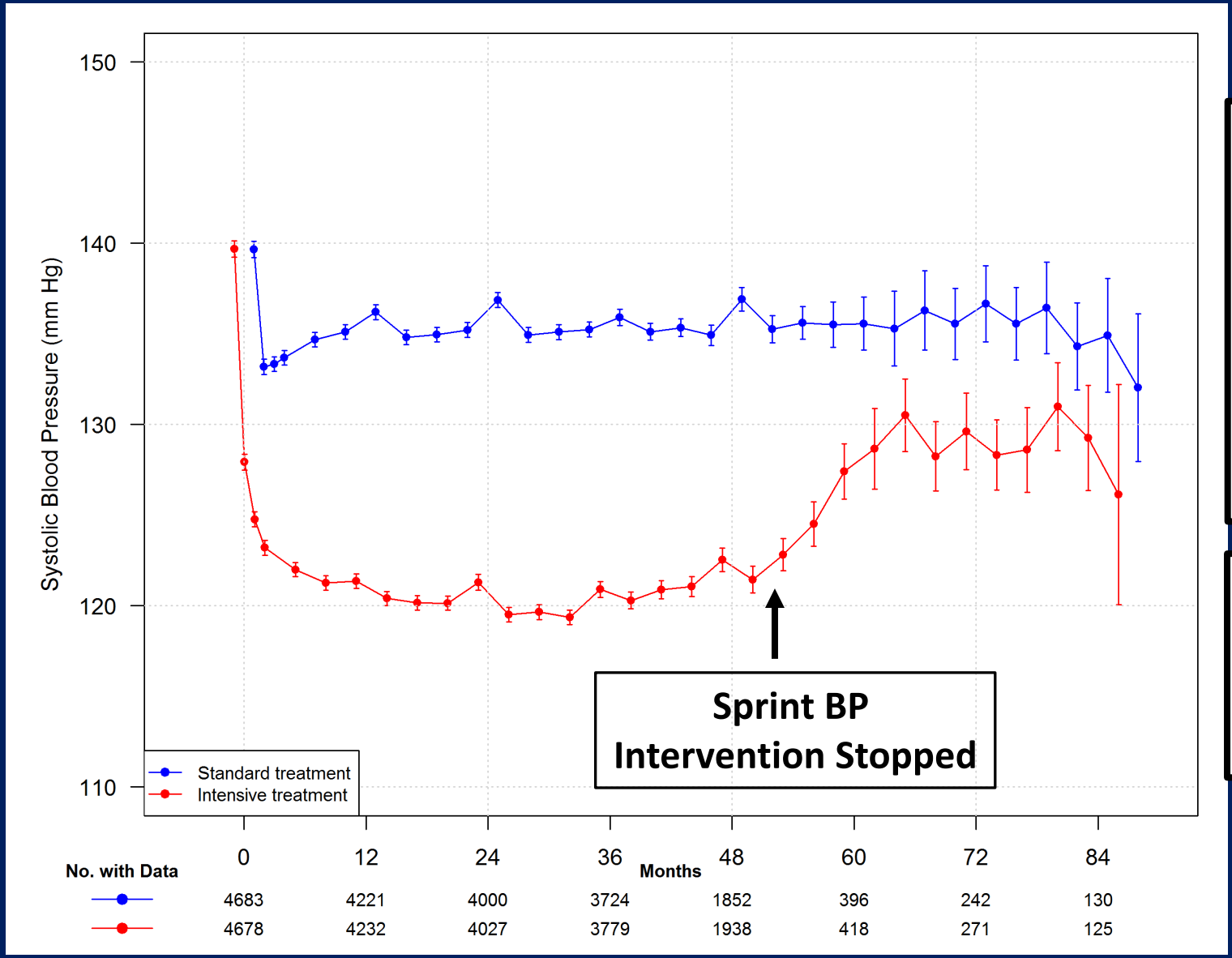
Systolic Blood Pressure Through Follow-Up



Mean Systolic Blood Pressure

Standard Treatment
135 mmHg (Intervention Period)
136 mmHg (Closeout Visits)
136 mmHg (Extended Follow-up Visits)

Intensive Treatment
122 mmHg (Intervention Period)
125 mmHg (Closeout visits)
129 mmHg (Extended Follow-up Visits)

Mean Number of Antihypertensive Medications During Intervention Period

Standard Treatment: 1.8
Intensive Treatment: 2.8

Summary and Conclusions

- SPRINT examined effects of more intensive antihypertensive therapy than currently recommended
- Rapid and sustained difference in SBP achieved between the two treatment arms
- Trial stopped early, due to benefit, after median follow-up of 3.33 years
- Incidence of primary outcome (composite of CVD events) 25% lower in Intensive compared to Standard Group and all-cause mortality reduced by 27%.
- Treatment effect similar in all six pre-specified groups of interest.
- The “number needed to treat” to prevent primary CVD outcome event was 61 or death was 90, respectively

Summary and Conclusions

- No overall difference in serious adverse events (SAEs) between treatment groups
- SAEs associated with hypotension, electrolyte abnormalities, acute kidney injury / failure were more common in Intensive Group. AKI events generally mild and largely reversible
- Overall, benefits of more intensive BP lowering exceeded the potential for harm
- Intensive control of BP in older people did not significantly reduce dementia (too short a follow-up period for dementia outcome?), but significantly reduced the risk of developing mild cognitive impairment, a precursor of early dementia, by 19%

SPRINT
Systolic Blood Pressure Intervention Trial

Conclusions

- Significant benefit of intensive vs standard SBP lowering for
  - 1^0 CVD outcome and all-cause death
  - 1^0 CVD outcome was not dependent on heart failure
  - Brain outcomes: MCI and MCI + probable dementia; change in WML volume and improvement cerebral perfusion
- Patient health related quality of life outcomes not significantly different
- Benefits of intensive control may not extend to those age 80+ with lower baseline cognitive function

SPRINT
Systolic Blood Pressure Intervention Trial

Thank you!

SPRINT
Systolic Blood Pressure Intervention Trial