Blood Pressure Measurement in SPRINT

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For the SPRINT Research Group

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SPRINT
Systolic Blood Pressure Intervention Trial

SPRINT Research Question

Examine effect of more intensive high blood pressure treatment than is currently recommended

Randomized Controlled Trial
Target Systolic BP

Intensive Treatment	**Primary Outcome Composite**	*Standard Treatment*
Goal SBP < 120 mm Hg	**MI, ACS, Stroke, CHF or Death from CVD**	*Goal SBP < 140 mm Hg*

SPRINT design details available at:

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

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Blood Pressure Measurement in SPRINT

- Similar to what has been used in virtually all recent 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

Background

- **The SPRINT clinical trial demonstrated that treatment to an intensive systolic BP goal (<120 mmHg) reduces risk of cardiovascular disease (CVD) and mortality compared with standard treatment (< 140 mm Hg)**

- **Recent publications from investigators not involved with SPRINT have stated that the BP measurement technique used in SPRINT was unattended, making the BP not comparable to other studies.**

- ***SPRINT protocol does not address the issue of staff attendance, nor have SPRINT investigators yet published information on this topic.***

SPRINT Systolic Blood Pressure Intervention Trial

Sprint Research Group. NEJM 2015;373:2103-16.

Objectives

- To present the results of a survey conducted immediately after SPRINT closeout visits were completed to inquire whether BP measurements were usually attended or unattended by staff.

- To determine whether variation in blood pressure measurement technique was associated with differences in blood pressure obtained, medication utilization, CVD or mortality outcomes, or serious adverse events (SAE).

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BP Measurement Technique Categories

- **Always Alone (4082 participants at 38 sites)**
  - ➢ **Participant alone for 5 minutes of rest and the 3 BP readings**
- **Never Alone (2247 participants at 25 sites)**
  - ➢ **Personnel in the room during the entire BP measurement period**
- **Alone for Rest (1746 participants at 19 sites)**
  - ➢ **Participant alone only during the rest period**
- **Alone for BP Measurement (570 participants at 6 sites)**
  - ➢ **Participant alone only during the BP readings**
- **Excluded from analyses (716 participants at 14 sites)**

Majority of coordinators were extremely confident or very confident in their responses to the survey

Baseline Clinical Characteristics of SPRINT Participants Stratified by Randomized Group and Blood Pressure Technique

	Always Alone (n =4082)		Never Alone (n =2247)		Alone for Rest (n =1746)		Alone for BP Measurement (n=570)	
Characteristics	Intensive	Standard	Intensive	Standard	Intensive	Standard	Intensive	Standard
No. Clinics	38		25		19		6	
No. Randomized	2037	2045	1123	1124	875	871	283	287
Age 50-64 %	35.8	37.5	50.3	49.1	34.6	34.0	46.6	45.3
65-74 %	33.1	32.1	26.5	25.8	32.7	33.0	32.9	36.2
≥75 %	31.1	30.4	23.2	25.1	32.7	33.1	20.4	18.5
Female Gender %	32.8	30.3	30.3	31.0	40.1	43.2	48.8	48.4
Black Race %	29.2	30.6	36.4	37.3	27.9	26.2	28.6	27.2
Hispanic Ethnicity %	3.1	2.2	17.2	16.2	3.0	3.0	64.7	65.2
Chronic kidney disease‡ %	31.2	31.0	25.1	24.0	29.0	29.2	20.1	23.3
Cardiovascular disease %	21.5	21.9	21.2	21.1	16.5	16.5	19.1	17.8
Framingham 10-yr CVD risk score mean	25.8	26.0	25.1	24.8	24.0	23.8	23.6	22.5

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No. Clinics	38		25		19		6	
No. Randomized	2037	2045	1123	1124	875	871	283	287
Baseline BP								
SBP mean, mmHg	139.6	139.9	139.2	138.8	140.0	140.0	142.5	141.1
DBP mean, mmHg	77.9	78.0	79.3	78.7	77.8	77.1	76.9	76.2
BMI mean, Kg/m^2	30.0	29.9	30.2	29.9	29.3	29.2	29.6	29.4
Smoking Status								
Current %	13.3	12.6	16.9	14.7	9.7	11.1	13.1	11.5
Past %	45.2	44.7	41.9	42.1	40.8	44.8	34.3	27.6
Statin use %	46.3	46.3	41.0	44.5	41.1	44.2	34.4	39.8
Aspirin use %	54.6	54.8	51.2	49.2	50.5	47.8	36.4	37.4

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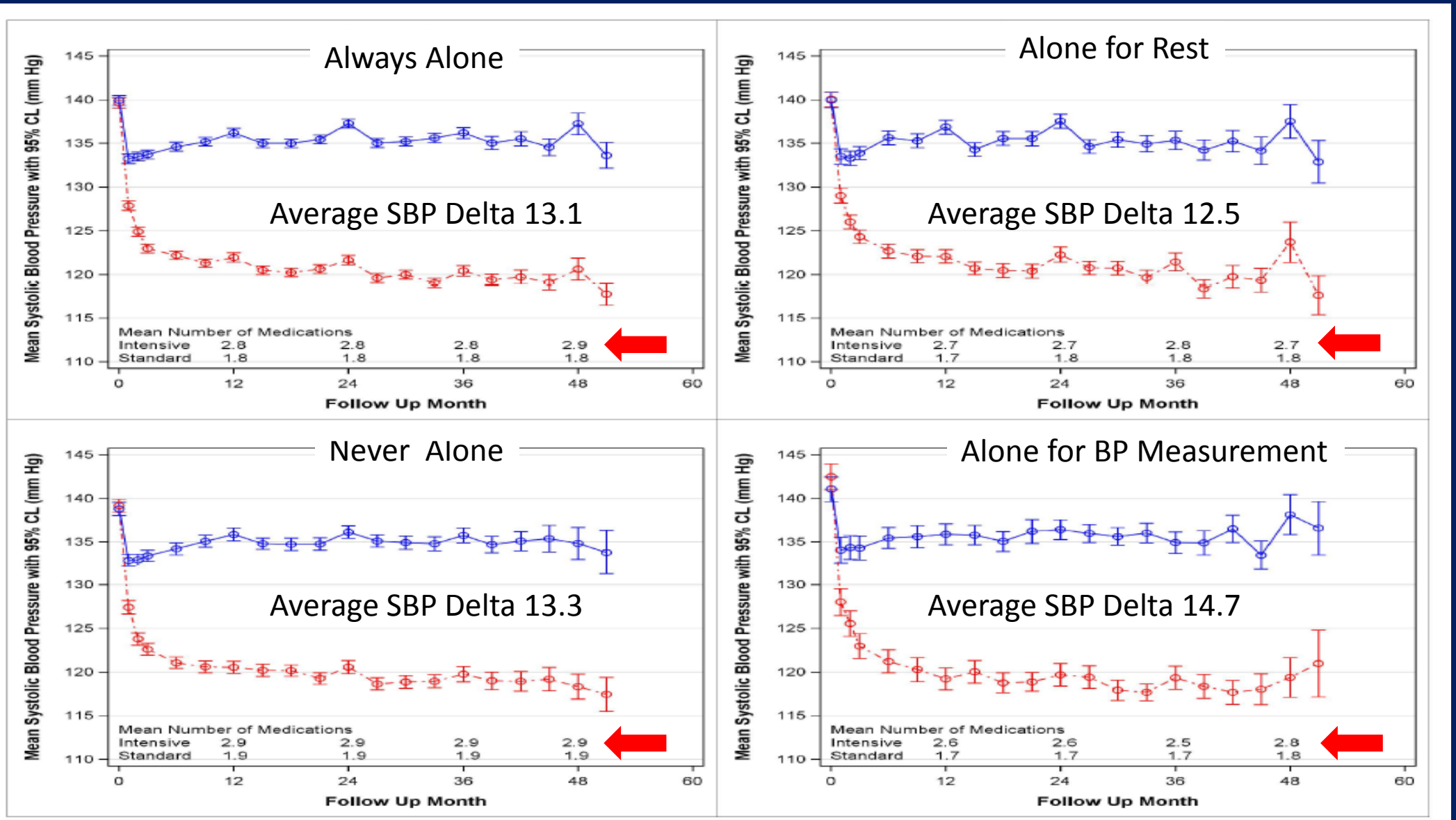
Systolic Blood Pressure by BP Measurement Technique



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Primary and all-cause mortality outcomes stratified by treatment group and blood pressure technique

		Intensive Arm		Standard Arm		Intensive vs. Standard Hazard Ratio		
Outcome	BP Technique	Events	% Per year	Events	% Per year	HR	95% CI	Interaction P-value
Primary	Always Alone	101	1.5	159	2.5	0.62	0.51,0.76	0.88
	Never Alone	68	1.9	103	3.0	0.64	0.46,0.91	
	Alone for Rest	50	1.8	51	1.9	0.98	0.76,1.25	
	Alone for BP Measurement	20	2.1	15	1.5	1.39	0.78,2.49	
Total Mortality	Always Alone	64	1.0	98	1.5	0.65	0.47,0.88	0.28
	Never Alone	46	1.3	60	1.7	0.76	0.53,1.11	
	Alone for Rest	19	0.7	32	1.1	0.59	0.37,0.94	
	Alone for BP Measurement	10	1.0	7	0.7	1.48	0.63,3.05	

Primary Outcome Composite - MI, ACS, Stroke, CHF or Death from CVD

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Serious Adverse Events (SAE) and other monitored adverse event outcomes stratified by treatment group and blood pressure technique

		Intensive Arm	Standard Arm	Intensive vs. Standard Hazard Ratio		
Outcome	BP Technique	% Per year	% Per year	HR	95% CI	Interaction P-value
Any SAE	Always Alone	15.4	15.0	1.03	0.95,1.12	0.57
	Never Alone	14.7	14.3	1.02	0.85,1.23	
	Alone for Rest	14.6	14.8	0.99	0.88,1.10	
	Alone for BP Measurement	8.9	7.7	1.16	0.96,1.41	
Syncope	Always Alone	0.8	0.4	1.79	1.20,2.68	0.14
	Never Alone	0.5	0.4	1.19	0.61,2.34	
	Alone for Rest	0.5	0.6	0.82	0.46,1.46	
	Alone for BP Measurement	0.4	0.6	0.68	0.11,4.42	
Hypotension	Always Alone	0.7	0.4	1.73	1.03,2.92	0.48
	Never Alone	0.7	0.3	2.50	1.30,4.78	
	Alone for Rest	0.6	0.5	1.22	0.55,2.71	
	Alone for BP Measurement	0.3	0.5	0.61	0.04,9.99	
Injurious Fall	Never Alone	0.8	0.8	0.95	0.57,1.59	0.64
	Always Alone	0.6	0.6	1.10	0.66,1.84	
	Alone for Rest	0.7	0.8	0.82	0.49,1.38	
	Alone for BP Measurement	0.5	0.2	2.59	0.40,16.76	

Serious Adverse Events (SAE) and other monitored adverse event outcomes stratified by treatment group and blood pressure technique

		Intensive Arm	Standard Arm	Intensive vs. Standard Hazard Ratio		
Outcome	BP Technique	% Per year	% Per year	HR	95% CI	Interaction P-value
Bradycardia	Always Alone	0.5	0.5	1.15	0.74,1.81	--
	Never Alone	0.5	0.5	1.05	0.60,1.84	
	Alone for Rest	0.4	0.6	0.70	0.31,1.58	
	Alone for BP Measurement	0.4	0	--	--	
Acute Kidney Injury	Always Alone	1.4	0.9	1.50	1.11,2.03	0.41
	Never Alone	1.3	0.6	2.08	1.16,3.75	
	Alone for Rest	1.1	0.5	2.15	1.22,3.77	
	Alone for BP Measurement	0.8	0.7	1.18	0.62,2.26	
Electrolyte Abnormal	Always Alone	1	0.7	1.38	1.04,1.83	0.38
	Never Alone	0.6	0.7	0.91	0.50,1.67	
	Alone for Rest	1	0.8	1.47	0.80,2.72	
	Alone for BP Measurement	0.6	0.2	3.10	0.78,12.38	

Limitations

- Post-hoc survey to assess BP measurement technique
- BP measurement technique classifications based on staff recall – potential for misclassification
- Unattended and attended BP measurements were not made in the same individual
- Survey was not prespecified prior to the beginning of the trial

Summary and Conclusions

- Similar BP levels and CVD risk reduction were observed in the Intensive group whether the BP measurements technique used was primarily attended (NA) or primarily unattended (AA).

- To fully realize the benefits and minimize risks associated with following the SPRINT Intensive treatment algorithm, use of a validated automated BP device, staff training to allow for a quiet rest period, proper positioning, use of proper cuff size, and averaging multiple measurements, may be more important than whether the BP measurement is attended or unattended.

- To arrive at firmer conclusions, additional research with better methods, is needed to determine whether attendance or other factors during the BP measurement affect level of BP reading.

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Acknowledgements

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  - *National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)*
  - *National Institute on Aging (NIA)*
  - *National Institute of Neurological Disorders and Stroke (NINDS)*

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