



Southeastern Collaboration to Improve Blood Pressure Control

A collaborative project between:

University of Alabama at Birmingham;
Weill Cornell Medical College of Cornell University;
University of Carolina at Chapel Hill;
East Carolina University;
North Carolina Area Health Education Centers;
Alabama Area Health Education Centers;
Health and Wellness Education Center of Livingston, AL;
West Central Alabama Community Health Improvement League of Camden,
AL;
ConnectionHealth, Birmingham, AL;
Open Water Coaching and Consulting, Cape Carteret, NC;
and 80 primary care practices,
peer coaches,
and practice facilitators living in the Black Belt region

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Study Protocol

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**Southeastern Collaboration to Improve Blood Pressure Control in the US Black Belt –
Addressing the Triple Threat**

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Statistical analysis plan: The main hypothesis test was at the individual patient level, adjusting for baseline covariates with imbalance across treatment arms and accounting for clustering using generalized estimating equations (GEE). Each intervention, alone or in combination, was compared to the enhanced usual care arm with $p < 0.05$ serving as the threshold for statistical significance. To test for differences between trial arms we used the Benjamini-Hochburg approach to control the false-discovery rate at 0.05. The secondary outcome was change in systolic blood pressure levels, which was analyzed using linear regression adjusting for characteristics that were imbalanced across trial arms, state (AL vs. NC), and days from baseline to follow-up. All analyses accounted for clustering of patients within practices.

28 **Table 1. Adjusted^a Odds ratios (95% CI) for blood pressure control at 12 months, by trial arm compared to**
 29 **enhanced usual care**

Arm	12 month OR (95% CI)
PF vs. EUC	0.97 (0.6, 1.58)
PC vs. EUC	1.3 (0.83, 2.04)
PFPC vs. EUC	1.02 (0.64, 1.64)

30 Abbreviations: CI- confidence interval; EUC-enhanced usual care; PF-practice facilitation; PC-peer coaching;
 31 PFPC- practice facilitation and peer coaching.

32 a. Adjusts for baseline SBP, DBP, PHQ8, age, state, insurance, current smoking, health literacy.

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37 **Table 2. Adjusted^a Changes (95% CI) in systolic blood pressure at 12 months, by trial arm compared with en-**
 38 **hanced usual care**

Arm	12-month Diff. (95% CI)
PF vs. EUC	-0.08 (-4.07, 3.91)
PC vs. EUC	-2.34 (-6.06, 1.38)
PFPC vs. EUC	-2.06 (-5.94, 1.82)

39 Abbreviations: CI- confidence interval; EUC-enhanced usual care; PF-practice facilitation; PC-peer coaching;
 40 PFPC- practice facilitation and peer coaching.

41 a. Adjusts for baseline SBP, DBP, PHQ8, age, state, insurance, current smoking, health literacy.

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44 **Table 3. Adjusted^a differences (95% CI) for change in Physical Component Summary (PCS) score at 12 months**

Arm	12 months		
	n ^b	Coefficient (95%CI)	p-value
EUC	312	ref	ref
PF vs. EUC	236	-1.59 (-2.96,-0.21)	0.02
PC vs. EUC	309	-0.15 (-1.43,1.13)	0.82
PFPC vs. EUC	249	-0.02 (-1.36,1.33)	0.98

45 Abbreviations: CI- confidence interval; EUC-enhanced usual care; PF-practice facilitation; PC-peer coaching;
 46 PFPC- practice facilitation and peer coaching

47 a. Adjusts for baseline PCS, SBP, DBP, PHQ8, age, state, insurance, current smoking, health literacy.

48 b. N reflects complete case numbers in adjusted model; <1% of sample missing information on covariates.

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56 **Table 4. Adjusted^a differences (95% CI) for change in mental component summary (MCS) score at 12 months**

Arm	12 months		
	Total n ppt ^b	Coefficient (95%CI)	p-value
EUC	312	Ref	Ref
PF vs. EUC	236	-0.30 (-2.09,1.49)	0.74
PC vs. EUC	309	0.54 (-1.11,2.20)	0.52
PFPC vs. EUC	249	0.81 (-0.93,2.55)	0.36

57 Abbreviations: ppt-participant; CI-confidence interval; EUC-enhanced usual care; PF-practice facilitation; PC-
58 peer coaching; PFPC-practice facilitation and peer coaching.

59 a. Adjusts for baseline MCS, SBP, DBP, age, state, insurance, PHQ-8, current smoking, and health literacy.

60 b. Total n reflects complete case numbers in fully adjusted model. <1% of sample missing information on co-
61 variates.

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Table 5. Adjusted^a differences (95% CI) for change in perceived stress (PSS) at 12 months

Arm	12 months		
	n ^b	Coefficient (95%CI)	p-value
EUC	312	ref	ref
PF vs. EUC	238	-0.10 (-0.60,0.39)	0.68
PC vs. EUC	313	-0.46 (-0.92,0.00)	0.05
PFPC vs. EUC	249	-0.22 (-0.70,0.26)	0.36

67 Abbreviations: ppt-participant; CI-confidence interval; EUC-enhanced usual care; PF-practice facilitation; PC-
68 peer coaching; PFPC-practice facilitation and peer coaching.

69 a. Adjusts for baseline PSS, baseline SBP, baseline DBP, age, state, insurance, PHQ-8, current smoking, health
70 literacy

71 b. Total n reflects complete case numbers in fully adjusted model. <1% of sample missing information on co-
72 variates

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74 **Table 6. Adjusted^a differences (95% CI) in change in patient assessment of chronic illness care (PACIC) at 12-
75 months**

Arm	12 months		
	n ^b	Coefficient (95%CI)	p-value
EUC	281	ref	ref
PF vs. EUC	221	-0.00 (-0.21,0.20)	0.97
PC vs. EUC	298	0.18 (-0.01,0.37)	0.06
PFPC vs. EUC	230	0.24 (0.04,0.44)	0.02

77 Abbreviations: ppt-participant; CI-confidence interval; EUC-enhanced usual care; PF-practice facilitation; PC-
78 peer coaching; PFPC-practice facilitation and peer coaching.

79 a. Adjusts for PACIC, baseline SBP, baseline DBP, age, state, insurance, PHQ-8, current smoking, health literacy.

80 b. Total n reflects complete case numbers in fully adjusted model. <1% of sample missing information on co-
81 variates.

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85 **Table 7. Adjusted^a odds ratios (95% CI) for ED visits at 12 months**

Arm	12 months		
	Events/total n ppt ^b	OR (95% CI)	p-value
EUC	78/320	ref	ref
PF vs. EUC	57/243	0.91 (0.53,1.56)	0.73
PC vs. EUC	65/317	0.72 (0.43,1.20)	0.21
PFPC vs. EUC	55/260	0.77 (0.45,1.32)	0.34

86 Abbreviations: ED-emergency department; ppt-participant; CI-confidence interval; EUC-enhanced usual care;
 87 PF-practice facilitation; PC-peer coaching; PFPC-practice facilitation and peer coaching; PHQ-8-patient health
 88 questionnaire depression scale.

89 a. Adjusts for baseline ED (Y/N), baseline SBP, baseline DBP, age, state, insurance, PHQ-8, current smoking,
 90 health literacy.

91 b. Total n reflects complete case numbers in fully adjusted model. <1% of sample missing information on co-
 92 variates. c. Poor health literacy defined as having problems learning about conditions because can't under-
 93 stand written information a little to all of the time.

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97 **Table 8. Adjusted^a odds ratios (95% CI) for hospitalization at 12-months**

Arm	12 months		
	Events/total n ppt ^b	OR (95% CI)	p-value
EUC	23/320	ref	ref
PF vs. EUC	35/243	2.19 (1.17,4.10)	0.01
PC vs. EUC	31/317	1.37 (0.74,2.55)	0.32
PFPC vs. EUC	30/260	1.78 (0.95,3.33)	0.07

98 Abbreviations: ppt-participant; CI-confidence interval; EUC-enhanced usual care; PF-practice facilitation; PC-
 99 peer coaching; PFPC-practice facilitation and peer coaching; PHQ-8-patient health questionnaire depression
 100 scale.

101 a. Adjusts for baseline hospitalization (Y/N), baseline SBP, baseline DBP, age, state, insurance, PHQ-8, current
 102 smoking, health literacy.

103 b. Total n reflects complete case numbers in fully adjusted model. <1% of sample missing information on co-
 104 variates.

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