



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

Funded by NHLBI
UH3 HL130691-05

Study Protocol

Version November 1, 2021
NCT02866669
Unique Protocol ID: X160722009

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

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3 **Statistical analysis plan:** The main hypothesis test was at the individual patient level, adjusting for
4 baseline covariates with imbalance across treatment arms and accounting for clustering using gener-
5 alized estimating equations (GEE). Each intervention, alone or in combination, was compared to the
6 enhanced usual care arm with $p < 0.05$ serving as the threshold for statistical significance. To test for
7 differences between trial arms we used the Benjamini-Hochberg approach to control the false-discov-
8 ery rate at 0.05. The secondary outcome was change in systolic blood pressure levels, which was ana-
9 lyzed using linear regression adjusting for characteristics that were imbalanced across trial arms,
10 state (AL vs. NC), and days from baseline to follow-up. All analyses accounted for clustering of pa-
11 tients within practices.

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

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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**

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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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