Hypertension

CLINICAL TRIAL

# Sustained Benefit of Alternate Behavioral Interventions to Improve Hypertension Control

## A Randomized Clinical Trial

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**ABSTRACT:** Little is known about the long-term effects of behavioral interventions to improve blood pressure (BP) control. We evaluated whether a telephone-delivered, behavioral stage-matched intervention (SMI), or a nontailored health education intervention (HEI) delivered for 6 months improves BP control (or lowers systolic BP) over 12 months, as well as its sustainability 6 months after intervention implementation ended, compared with usual care in participants with repeated uncontrolled BP at baseline. A 3-arm, randomized controlled trial was designed to evaluate the effectiveness of 2 interventions, each compared with a usual-care control group. Participants were 533 adults with persistent uncontrolled BP who were treated at 2 Veterans Affairs Medical Centers. The intervention was implemented for 6 months, followed by 6 months of observation. Compared with usual care, the odds of having BP under control over 12 months in SMI were 84% higher (odds ratio, 1.84 [95% CI, 1.28–2.67]; *P*=0.001), and 48% higher in HEI (odds ratio, 1.48 [95% CI, 1.02–2.14]; *P*=0.04). Over the 12 months, compared with usual care, systolic blood pressure was 2.80 mm Hg lower in SMI ([95% CI, 0.27 to 5.33]; *P*=0.03) while it was 2.58 mm Hg lower in HEI ([95% CI, −0.40 to 5.55]; *P*=0.09). From 6 to 12 months, SMI sustained improved BP control and lower systolic blood pressure, while HEI, which did not have significantly better BP control or lower systolic blood pressure at 6 months, appeared to improve BP control and lower systolic blood pressure. SMI and HEI are promising interventions that can be implemented in clinical practice to improve BP management.

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**Key Words:** adult ■ blood pressure ■ control group ■ odds ratio ■ telephone

Hypertension is highly prevalent and the primary risk factor for mortality.[1] Despite its high risk and the availability of effective treatments, only 51.8% of adults have their blood pressure under control.[2] Successful management requires persistent adherence to lifestyle and medications to bring blood pressure (BP) consistently under control and thereby lower the mortality associated with it.[3]

Successive national and international committees have reviewed the evidence and recommended individualizing treatment, simplifying the medication dosing if possible, and counseling patients about the importance of diet, exercise, and sustained weight loss if obese.[3–5] Interventions targeting multiple behaviors, such as diet, medication-taking, and exercise simultaneously are associated with stronger effects and can increase efficiency of behavioral interventions and reduce health costs.[6]

Behavioral interventions can improve BP.[7] In a previous article, we reported on the 6-month effects of a novel, tailored intervention (using the Transtheoretical Model of health behavior change)[8] or a nontailored health education intervention on BP control and systolic blood pressure (SBP).[9] At 6 months, we found that the tailored transtheoretical stage-matched intervention (SMI) significantly improved BP control by 20% and lowered SBP by 3.5 mm Hg compared with usual care (UC).

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## Novelty and Significance

### What Is New?

- This randomized trial evaluated the overall effectiveness (over 12 months) and sustainability (6 months after stopping intervention) of 2 telephone-delivered behavioral interventions on blood pressure (BP) control and systolic BP among veterans with persistent uncontrolled hypertension in the primary-care setting. The results show that stage of change-matched telephone counseling is especially effective in facilitating adherence to diet, medication, and exercise that produced clinically meaningful improvements in BP and systolic BP control, which was sustained over the course of 1 year.

### What Is Relevant?

- The stage-matched intervention group received tailored counseling that targeted multiple behaviors associated with hypertension (ie, diet, medication, and exercise), consistent with national and international recommendations. The HEI group received nontailored education about hypertension as well as other health areas (eg, the flu shot). The UC group received standard health care for hypertension.

### Summary

Overall, the stage-matched intervention had 84% greater odds of bringing BP under control while HEI had 48% greater odds of bringing BP under control compared with the usual care group over 12 months. Both the stage-matched intervention and the health education intervention were sustainable and thus are valuable approaches to lower systolic blood pressure and improve BP control rates.

### Nonstandard Abbreviations and Acronyms

| | |
|---|---|
| **BP** | blood pressure |
| **GEE** | generalized estimating equation |
| **HEI** | health education intervention |
| **SBP** | systolic blood pressure |
| **SMI** | stage-matched intervention |
| **UC** | usual care |

The nontailored Health Education Intervention (HEI) led to a nonsignificant 8.5% improved BP control rate and a nonsignificant 2.9 mm Hg lower SBP compared with UC.

According to observational data, healthful behaviors in young adults lower cardiovascular risk in middle age[10] and BP lowering in middle age lowers lifetime risk of cardiovascular disease.[11] Little is known, however, about the sustainability of BP reductions achieved through behavioral interventions.[12] This article reports on the overall effects and the sustainability of the BP effects achieved in a 3-arm randomized clinical trial, which evaluated the effectiveness of 2 behavioral interventions (a stage of change matched education and a health education without matching) and UC, in a patient population with persistent uncontrolled hypertension at baseline. The behavioral interventions were discontinued after 6 months, and 6- to 12-month sustainability of the BP effect was evaluated through prespecified analyses. Our objective was to evaluate whether the telephone-delivered, transtheoretical SMI, or the nontailored HEI that were both delivered for 6 months would lead to better BP control (or lower SBP) over 12 months as well as maintain its effects 6 months after implementation of the intervention ended (sustainability) compared with UC in participants with repeated uncontrolled BP at enrollment.

## MATERIALS AND METHODS

The data that support the findings of this study are available from the corresponding author upon reasonable request.

### Design, Setting, and Participants

We conducted a 3-arm randomized clinical trial to assess the effectiveness and sustainability of 2 active interventions on BP control and SBP, each intervention being compared with a usual-care control group with BP being measured at 0, 6, and 12 months. The study was approved by the Institutional Review Board of the New York Harbor Healthcare System, and all participants provided formal written informed consent. Participants were recruited from July 2006 through March 2009 in the outpatient clinics in Brooklyn and Manhattan with follow-up being completed by August 2011.

Participants were eligible if they had hypertension, were on antihypertensive drug therapy for ≥6 months, and had uncontrolled BP during the previous clinic visit and during current screening.[9] Consistent with the recommendations during the time period of the study (JNC VII), uncontrolled BP was defined as (1) SBP≥130 mm Hg or diastolic BP≥80 mm Hg in participants with diabetes or chronic kidney disease or (2) SBP≥140 mm Hg or diastolic BP≥90 mm Hg in all others. Participants with uncontrolled BP during their previous routine clinic visit were identified via electronic medical record search, approached during their subsequent visit, and informed about the study.[9] Interested participants had their BP checked 3 times during this screening, and those with uncontrolled BP (averaged) were invited to participate.[9,13]

Participants with recent cardiovascular disease (<6 months ago), Class III or IV heart failure, severe psychiatric illness, AIDS, tuberculosis, lupus, end-stage renal failure, or limited life

expectancy (<1 year) due to terminal illnesses were excluded as reported previously.[9] Following enrollment, participants had a simple run-in period of 4 weeks during which period they were informed again about the study responsibilities and their telephone availability confirmed.[13] After the run-in period, participants had the initial baseline assessment (month 0) during which a research assistant measured resting BP (6× over a 2-hour period using an Omron HEM-907XL automated BP machine), height, weight, and administered valid questionnaires assessing the dietary approaches to stop hypertension adherence index (using the Willett food frequency questionnaire), aerobic exercise in minutes per week (from the Sallis 7-day physical activity recall), and medication adherence (from the Morisky adherence scale). The average of the 6 readings was used in statistical analyses.[14,15] Participants also had serum and urine laboratory tests. A similar protocol was followed at 6 and 12 months. All participants were given $20 at each visit to partially reimburse them for their time and travel.

After the baseline data collection, participants were allocated to one of the 3 study arms by block randomization stratified by site (Manhattan or Brooklyn) and by dietary stage of change. At each site, randomization was in blocks of 6 such that for every 6 participants at a site, 2 were allocated to each arm. The random assignments were concealed. While participants knew that the study was evaluating telephone interventions to improve hypertension control, they did not know which of the 2 phone interventions they were receiving. This was feasible because study participants did not have contact with each other. While counselors knew of the treatment assignments, they did not know the BP and adherence outcomes. Finally, research assistants who assessed outcomes were blinded to treatment assignment. Further details about the blinding procedures are in Friedberg et al.[16]

## Intervention

All study participants received information about hypertension and its treatment. The UC group did not receive monthly phone counseling. The SMI and HEI groups received monthly telephone counseling for 6 months. Participants did not receive counseling between 6 and 12 months and completed a final visit at 12 months post-randomization to assess BP and treatment adherence after counseling had been stopped for 6 months. All phone sessions were conducted by counselors with a Master's degree or higher in psychology or a related field. Participants were randomized equally to the counselors such that each counselor conducted both HEI and SMI calls. All calls were recorded and a random sample assessed weekly for fidelity by the research team (ie, counselors, study coordinator, and PI).

Participants in SMI received tailored monthly phone counseling for exercise, diet, and medications matched to their current stage of change based on the Transtheoretical Model[8] using a computer-based intervention manual. During each call (≈30 minutes), stage of change for adherence to diet, medication, and exercise was assessed separately using validated stage of change questions.[17] Counseling was tailored based on the stage of change assessment, which was used to determine which processes of change to use, and then counseling conducted. For all participants, decisional balance, or the pros and cons of engaging in a behavior (eg, exercising regularly) was explored. Participants were also assessed for their self-efficacy[18] and then the counselor worked with the participant to problem-solve situations in which they had low self-efficacy to adhere to treatment recommendations. The dietary goal was the dietary approaches to stop hypertension diet,[19,20] which we operationalized as following the dietary approaches to stop hypertension diet for >5 days per week (>80% adherence). Before the 2008 Physical Activity Recommendations for Americans,[21] the exercise goal was 20 to 60 minutes of moderate to high-intensity exercise performed 3 or more times a week.[22] Since the majority of participants were over the age of 60 with many comorbidities in addition to hypertension, in the interest of safety, we conservatively defined appropriate exercise as 20 minutes of moderate intensity exercise for at least 3 days a week. We defined medication adherence as ≥80% adherence,[23] which we operationalized as taking the medication as prescribed >5 days per week. Participants in HEI had monthly telephone counseling (duration of ≈15 minutes) where they received nontailored information about hypertension, and guidelines for diet, medication, and exercise in hypertension from American Heart Association educational materials[24] and had a chance to ask questions. An additional health topic was added each month to approximate the amount of time and attention given to SMI participants.

## Statistical Analyses

The outcomes were BP control (dichotomous: controlled or uncontrolled) and SBP (continuous); BP was measured at the 0-, 6-, and 12-month visits. The analysis was conducted in several steps. First, $\chi^2$ and Kruskal-Wallis tests were performed to evaluate if BP control and SBP at month 0 among the randomized arms were balanced. Second, McNemar test for BP control and the Wilcoxon signed-rank test for SBP were applied to test if the changes between month 0, month 6, and month 12 were significant within the SMI, HEI, and UC arms. To evaluate sustainability of BP control, we tested the null hypothesis that the change in BP control (or SBP) is similar in the intervention and control groups.[25,26] Third, generalized estimating equations (GEEs) with logit link function were fitted to analyze the repeated measures of BP control (at both 6- and 12-month intervals), with 0-month BP control, treatment assignment, time, and interaction between treatment and time as covariates. Similarly, GEE models were applied to analyze continuous SBP with repeated measurements at 6- and 12-month intervals, adjusting for 0-month BP.

Fourth, to address the influence of missing data, we used multiple imputations under missing-at-random assumption, along with sensitivity analyses under missing-not-at-random assumption. We used multiple imputation with *P* summarized from 100 imputed datasets generated from an imputation model that included those variables that differed between those with missing and those without missing data. To obtain more robust estimates for standard errors from the multiple imputations, we also increased the number of imputations to 1000, and the results did not change. We also conducted a propensity-type analysis based only on patients being followed. To conduct this propensity analysis, we modeled the probability of missing at 6 and 12 months and then reweighted the observations by the probability of missing in the model. Then, we used weighted generalized estimating equations method that implements the

inverse probability-weighted method to account for missing data under the missing at random assumption.[27,28]

Finally, to examine if the effect of the interventions on BP control varied among prespecified subgroups, we conducted subgroup analyses where we examined whether the effect of the interventions on BP control varied among specific subgroups.

All statistical tests were evaluated at the 5% significance level, and all *P* are 2-sided. All analyses were intent-to-treat and were performed using SAS 9.4.

## RESULTS

We screened and enrolled 705 adults with repeated uncontrolled BP of whom 548 participants successfully navigated the 1-month run-in period. Another 15 participants were cancelled after the month 0 visit but before randomization for a total cancellation rate of 24.4% (172 participants). We randomized 533 participants of whom 481 completed the 6-month visit and 467 completed the 12-month visit, resulting in a 6-month missing data rate of 9.8% and a 12-month missing data rate of 11.6% (Figure 1).

The proportion of participants with controlled hypertension at baseline (month 0) after the 1-month run-in period among the SMI, HEI, and UC groups were 43%, 41%, and 45%, respectively. There were no significant differences in BP control between the 3 groups at month 0 (*P*=0.74). The mean SBP in mm Hg (with SD) at month 0 for SMI, HEI, and UC was 136 (SD=14), 137 (SD=18), and 137 (SD=15), respectively; no significant differences were found (*P*=0.66; Table 1). At 6 months, there was significantly better BP control in SMI (62.3%) compared with UC (46.5%); HEI (52.4%) was not significant. The 0-, 6-, and 12-month BP control rates and SBP levels are shown in Table 2. To evaluate sustainability of BP control from 6 to 12 months, we tested the null hypothesis that the change in BP control from 6 to 12 months is similar in the intervention and control groups. There was no significant change for any of the groups. Similarly, there was no significant change in SBP from 6 to 12 months for any of the groups. We further evaluated sustainability of the effect by testing the significance of the interaction between time and treatment, which was not significant in either GEE model indicating the change in BP control rate or systolic blood pressure from 6 to 12 months is not significantly different among the randomized groups.

Table 3 shows the mean effect of the interventions on BP control evaluated using GEE to analyze the repeated measure of BP control and adjusting for month 0 BP control. The SMI resulted in improved BP control over the duration of the trial compared with UC (*P*=0.001), with SMI having 84% greater odds of having BP under control (odds ratio, 1.84 [95% CI, 1.28–2.67). HEI also led to overall improvement in BP control compared with UC (*P*=0.04), with HEI having 48% greater likelihood of bringing BP under control (odds ratio, 1.48 [95% CI, 1.02–2.14]). When controlling for month 0 BP control, there was no significant difference in BP control between 6 and 12 months for SMI (*P*=0.86), HEI (*P*=0.07), or UC (*P*=0.25).

Table 4 depicts the mean effect of the interventions on SBP evaluated using GEE to analyze the repeated measure of SBP and adjusting for month 0 BP control. The mean effect of SMI was 2.8 mm Hg (95% CI, 0.27–5.33) lower than UC (*P*=0.03), while the mean effect of HEI was 2.6 mm Hg (95% CI, −0.40 to 5.55) lower compared with UC (*P*=0.09).

Because of loss to follow up, ≈7% to 12.5% of the data was missing at the 6-month follow-up and 10% to 13% at 12-month follow-up. We compared the sociodemographic, clinical, and comorbidity data (diabetes, heart attack, revascularization, hyperlipidemia, and estimated glomerular filtration rate) between those who completed and those who did not complete the follow-up visits. We used multiple imputation to conduct further analyses that incorporated missing data, with *P* summarized from one hundred imputed datasets generated from an imputation model that included those variables that differed between those with missing and those without missing data.[29] These variables were study group, race, hyperlipidemia, diet stage of change, exercise stage of change, and the number of medicines. Sensitivity analysis was also conducted by comparing the results under the missing-at-random assumption and the results under a scenario less favorable to the intervention arm. The results are summarized in Table 5 where we compare the findings from 3 putative missing data mechanisms: (1) missing completely at random using only the completed observations, (2) missing at random, and (3) missing not at random. For the third missing mechanism, we considered a scenario, which was less favorable to the interventions, that is, the missing observations in SMI and HEI were assumed to follow the same pattern as that of completed observations in UC.[30] We found that the intervention effects estimated under missing at random were generally bigger than those under missing completely at random, while the effects under the less favorable sensitivity analysis scenario (UC) were slightly smaller than those under missing completely at random. These indicated that the results were not sensitive to the missing mechanisms.

To assess whether the overall effect of the interventions on BP control varied among subgroups, we conducted within-subgroup analyses (Figures 2 and 3) where we restricted the sample to all participants in the subgroup and compared SMI (or HEI) to UC using logistic regression. All statistically significant comparisons are marked with asterisks. SMI had higher BP control rates than UC for 16 of the 22 comparisons across different characteristics (Figure 2A) while HEI had higher BP control rates than UC for 4 of the 22 comparisons (Figure 2B), with the magnitude of the effect (OR point

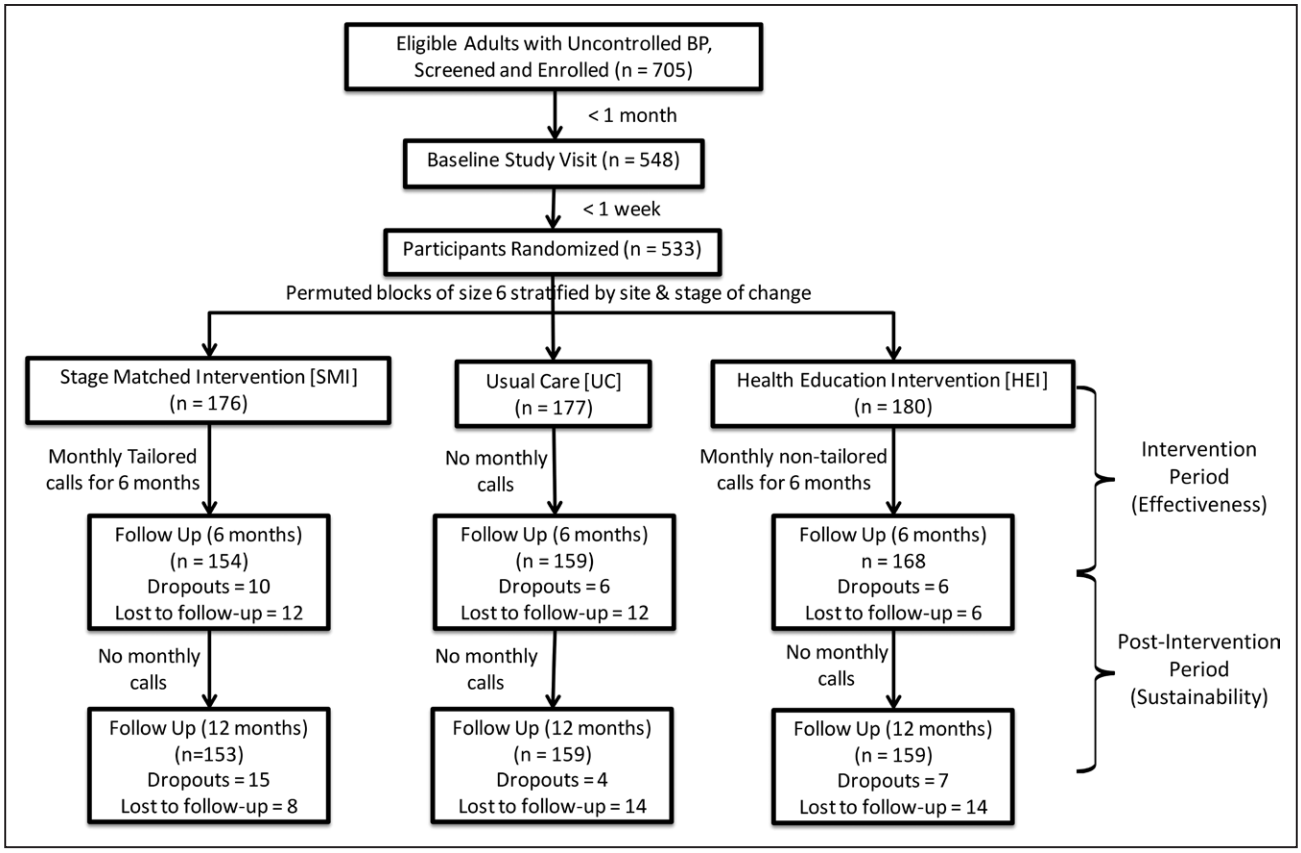


**Figure 1. CONSORT diagram with flow of participants from enrollment through 12 mo.**
The figure shows the number screened and enrolled with repeated uncontrolled blood pressure (BP), the number who successfully navigated the 1-month run-in period and the number randomized for a total cancellation rate of 24.4% (172 participants) before randomization. It depicts the number (n=481) who completed the 6-mo visit and the number (n=467) who completed the 12-mo visit, resulting in a 6-mo missing data rate of 9.8% and a 12-mo missing data rate of 11.6%. HEI indicates health education intervention; SMI, stage-matched intervention; and UC, usual care.

estimate) being consistently smaller for the HEI versus UC comparisons than for the SMI versus UC comparisons. Finally, to evaluate if there were significant differences between subgroups, we tested the interaction terms between treatments and the candidate subgroup variable in the GEE models. Between subgroup comparisons were not significant, except for the different tendencies in working versus nonworking participants ($P$=0.04).

To understand which specific behavior change was driving the improvements in BP, we looked at the change in BP-related behaviors (ie, dietary approaches to stop hypertension score for diet, Morisky score for medication use, and physical activity) from 0 to 6, 6 to 12, and 0 to 12 months (Table S1 in the Data Supplement). Mean scores for diet and medication use did increase from 0 to 12 months for SMI and HEI, but changes were only significant for medication use. Within-group mean scores for medication use did increase from 0 to 12 months for all 3 groups. However, the BP reduction in the intervention groups was not driven by medication intensification (increasing the dose of existing medication or the addition of new medications) by the clinician. To further evaluate the clinician effect, we conducted GEE analysis in which patients within the same clinician are correlated as well as the repeated measures within patient are correlated, that is, a random effect for the clinician and for patients nested within clinicians. From the GEE, the correlation between patients within clinician was very nonsignificant. In addition, we evaluated the effect of the SMI and HEI in participants with and without controlled BP at baseline (Table S2). The SMI versus UC comparison over 12 months was significant for both veterans with and without controlled BP at 0 months, while the HEI versus UC comparison over 12 months was only significant for veterans with uncontrolled BP at 0 months.

## DISCUSSION

This trial evaluated the intervention effect (effectiveness over 12 months) and sustainability (6 months after stopping intervention) of 2 telephone-delivered behavioral interventions on BP control and SBP among veterans with persistent uncontrolled hypertension in the primary-care setting. There were no significant differences between the SMI, HEI, or UC at month 0. We enrolled only patients with repeated uncontrolled

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**Table 1. Characteristics of Participants by Randomization Group at Baseline for Intervention and Sustainability**

| Variables | Intervention baseline (0 months) | | | | Sustainability baseline (6 months) | | | |
|---|---|---|---|---|---|---|---|---|
| | SMI (N=176) | HEI (N=180) | UC (N=177) | *P* | SMI (N=154) | HEI (N=168) | UC (N=159) | *P* |
| Sociodemographic and clinical characteristics | | | | | | | | |
| Age, y; mean (SE) | 66.4 (0.66) | 66.5 (0.96) | 65.4 (0.76) | 0.50 | 66.7 (0.88) | 66.4 (0.84) | 65.5 (0.80) | 0.56 |
| Male, % | 98.9 | 99.4 | 97.7 | 0.36 | 98.7 | 99.4 | 97.5 | 0.34 |
| Race | | | | 0.33 | | | | 0.43 |
| White (Non-Hispanic) | 46.0 | 33.9 | 39.6 | | 48.1 | 35.7 | 41.5 | |
| Black (Non-Hispanic) | 36.9 | 43.3 | 39.0 | | 35.7 | 43.5 | 39.0 | |
| Hispanic | 13.6 | 16.1 | 15.8 | | 12.3 | 14.3 | 15.1 | |
| Other | 3.4 | 6.1 | 5.7 | | 3.9 | 6.6 | 4.4 | |
| Married, % | 33.5 | 38.0 | 39.1 | 0.58 | 35.1 | 36.9 | 38.5 | 0.83 |
| High school grad or below, % | 40.8 | 50.3 | 48.3 | 0.15 | 40.8 | 47.9 | 48.1 | 0.34 |
| Employed | 16.3 | 22.9 | 22.5 | 0.25 | 14.7 | 22.8 | 22.6 | 0.13 |
| Manhattan Campus, % | 54.6 | 54.4 | 53.7 | 0.98 | 55.2 | 55.4 | 54.1 | 0.97 |
| Body mass index, mean (SE) | 30.5 (0.38) | 31.2 (0.47) | 30.0 (0.34) | 0.12 | 30.6 (0.43) | 30.9 (0.46) | 29.7 (0.37) | 0.16 |
| Current smoker, % | 20.1 | 18.3 | 17.9 | 0.87 | 19.0 | 18.1 | 16.4 | 0.83 |
| Comorbidities | | | | | | | | |
| Diabetes, % | 40.3 | 46.7 | 45.2 | 0.51 | 39.6 | 45.2 | 44.0 | 0.57 |
| IHD (heart attack), % | 13.1 | 12.2 | 13.0 | 0.96 | 13.1 | 11.9 | 11.3 | 0.89 |
| Revascularization, % | 15.3 | 16.1 | 17.1 | 0.93 | 16.2 | 16.1 | 15.2 | 0.96 |
| Hyperlipidemia, % | 22.0 | 21.6 | 28.7 | 0.86 | 17.7 | 19.7 | 25.9 | 0.22 |
| EGFR, mean (SE) | 79.9 (1.92) | 83.2 (3.48) | 80.6 (2.11) | 0.74 | 79.4 (2.11) | 83.7 (3.94) | 81.1 (2.23) | 0.75 |
| Baseline BP and BP-related behaviors | | | | | | | | |
| BP control, % | 42.6 | 40.6 | 44.6 | 0.50 | 62.3 | 52.4 | 46.5 | 0.02 |
| Systolic blood pressure, mm Hg, mean (SE) | 136.0 (0.89) | 137.2 (1.33) | 137.0 (0.96) | 0.65 | 131.2 (1.18) | 131.7 (1.30) | 133.9 (1.17) | 0.13 |
| Diastolic blood pressure, mm Hg, mean (SE) | 75.5 (0.70) | 76.1 (0.87) | 75.0 (0.83) | 0.66 | 72.2 (1.01) | 72.6 (0.96) | 73.2 (0.99) | 0.51 |
| Aerobic exercise, h/wk, mean (SE) | 5.3 (0.61) | 4.5 (0.44) | 5.0 (0.50) | 0.48 | 4.6 (0.36) | 4.8 (0.54) | 4.3 (0.32) | 0.73 |
| DASH score, mean (SE) | 23.6 (0.47) | 23.8 (0.45) | 24.0 (0.42) | 0.77 | 24.2 (0.49) | 23.9 (0.48) | 23.5 (0.46) | 0.55 |
| Medication adherence by Morisky scale, mean (SE) | 3.4 (0.07) | 3.2 (0.05) | 3.3 (0.07) | 0.45 | 3.6 (0.06) | 3.5 (0.06) | 3.5 (0.06) | 0.12 |
| Number of antihypertensive medications, mean (SE) | 2.7 (0.11) | 2.8 (0.10) | 2.7 (0.10) | 0.58 | 2.7 (0.12) | 2.9 (0.11) | 2.7 (0.11) | 0.11 |
| Proportion (%) in action or maintenance for: | | | | | | | | |
| Diet | 39 | 38 | 39 | 0.99 | 56 | 46 | 43 | 0.06 |
| Exercise | 71 | 62 | 60 | 0.07 | 82 | 78 | 74 | 0.25 |
| Medications | 93 | 96 | 92 | 0.42 | 95 | 98 | 96 | 0.43 |

BMI indicates body mass index; BP, blood pressure; EGFR, estimated glomerular filtration rate; HEI, health education intervention; IHD, ischemic heart disease; SE, standard error; SMI, stage-matched intervention; and UC, usual care.

BP (per documented history from primary care visits). At month 0, fewer than half of the participants in each group had their BP under control. At 6 months, participants in SMI increased their BP control and lowered their SBP, with a similar effect being observed in HEI, although without reaching statistical significance. From 6 to 12 months, participants in SMI sustained their improved BP control and lower SBP, while participants in HEI were also able to sustain and further improve their BP control and SBP. Over 12 months, participants in both SMI and HEI increased their BP control and lowered their SBP.

Our results suggest that telephone counseling, utilizing either the tailored transtheoretical intervention or (to some extent) the nontailored health education intervention, enabled participants to lower SBP and control BP relative to the usual-care group between 0 and 6 months, and to sustain control for an additional 6 months after the intervention was stopped. Mean SBP for SMI decreased at 6 months (from 136 at month 0 to 131 mm Hg at month 6) and continued to decline at 12 months (130 mm Hg). Similarly, mean SBP for HEI decreased at 6 months (from 137 to 132 mm Hg) and at 12 months mean SBP was 131 mm Hg. In light of the

**Table 2. BP Control and SBP Along With Change in BP Control and SBP Between Arms and Within Each Arm**

| Study arm | 0 mo | 6 mo | 12 mo | Δ 0–6 mo within arm (*P* value) | Δ 6–12 mo within arm (*P* value) | Δ 0 to 12 mo within arm (*P* value) | D-D 0–6 mo (95% CI; *P* value) between arms | D-D 6–12 mo (95% CI; *P* value) between arms | D-D 0–12 mo (95% CI; *P* value) between arms |
|---|---|---|---|---|---|---|---|---|---|
| BP control at 0, 6, and 12 mo with comparisons (McNemar test for within-group and *t*-test for between group) | | | | | | | | | |
| SMI | 42.86% | 62.59% | 61.90% | 19.73% (0.0001) | −0.69% (0.88) | 19.04% (0.0001) | SMI vs UC: 18.42% (5.6% to 1.3%; 0.005) | SMI vs UC: −5.3% (−18.4% to 7.9%; 0.43) | SMI vs UC: 13.2% (−0.4% to 26.8%; 0.06) |
| HEI | 39.74% | 53.85% | 60.26% | 14.11% (0.005) | 6.41% (0.13) | 20.52% (<0.0001) | HEI vs UC: 12.8% (−0.02% to 25.6%; 0.05) | HEI vs UC: 1.8% (−10.8% to 14.5%; 0.78) | HEI vs UC: 14.6% (1.1% to 28.1%; 0.03) |
| UC | 46.41% | 47.71% | 52.29% | 1.30% (0.76) | 4.58% (0.35) | 5.88% (0.24) | Comparator | Comparator | Comparator |
| Systolic BP, mm Hg (with SE) at 0, 6, and 12 mo with comparisons (Signed Rank test for within group and *t*-test for between group) | | | | | | | | | |
| SMI | 136.25 (1.13) | 130.93 (1.21) | 130.32 (1.20) | −5.33 (<0.0001) | −0.61 (0.47) | −5.94 (<0.0001) | SMI vs UC: −1.94 (−5.47 to 1.60; 0.28) | SMI vs UC: 0.16 (−3.21 to 3.53; 0.93) | SMI vs UC: −1.78 (−5.60 to 2.05; 0.36) |
| HEI | 137.06 (1.33) | 131.17 (1.36) | 130.85 (1.67) | −5.89 (<0.0001) | −0.31 (0.83) | −6.21 (0.0005) | HEI vs UC: −2.51 (−6.63 to 1.62; 0.23) | HEI vs UC: 0.46 (−3.41 to 4.32; 0.82) | HEI vs UC: −2.05 (−6.59 to 2.49; 0.38) |
| UC | 136.96 (1.18) | 133.57 (1.19) | 132.80 (1.12) | −3.39 (0.04) | −0.77 (0.59) | −4.16 (0.001) | Comparator | Comparator | Comparator |

Difference-in-difference (D-D) BP control comparisons between SMI and HEI for 0 to 6 mo was 5.6% (−7.9% to 19.2%; 0.41); 6 to 12 mo −7.1% (−19.4% to 5.2%; 0.26); and 0 to 12 mo −1.5% (−14.6% to 11.7%; 0.83). The D-D SBP comparisons (in mm Hg) between SMI and HEI for 0 to 6 mo was 0.57 (−3.45 to 4.59; 0.78); 6 to 12 mo −0.30 (−4.21 to 3.62; 0.88); and 0 to 12 mo 0.27 (−4.30 to 4.85; 0.91). BP indicates blood pressure; HEI, health education intervention; SBP, systolic blood pressure; SMI, stage-matched intervention; and UC, usual care.

fact that just a 2.2 mm Hg SBP reduction is associated with a 4% reduction in coronary death and a 6% reduction in stroke death during middle age,[31,32] this reduction is clinically significant.

A Cochrane review of 72 RCTs that focused on improving BP through different approaches reported that the success achieved in most is modest and further evaluation was needed.[33,34] Interventions utilizing behavioral counseling were not included, and educational interventions alone were considered insufficient for achieving a large net reduction in BP. Our study thus adds to the literature on BP interventions by incorporating state-of-the-art behavioral theory and intervention processes to improve adherence to lifestyle changes.

This trial has several important strengths. First, we prioritized patients with persistent uncontrolled BP and monitored both the immediate and sustained effects of the intervention as part of the clinical trial. The traditional approach (UC) has proven ineffective in reducing BP and remote behavioral interventions present a good alternative. It is estimated that $51.2 billion is spent both directly and indirectly on high BP. Thus, the widespread use of behavioral interventions could ease some of this economic burden. Moreover, other studies have shown potential sustainable effects of interventions on chronic disease risk factor levels.[35–37] Second, we focused on improving multiple aspects of dietary behavior as well as medication adherence and exercise through an intervention approach informed by the Transtheoretical Model. Third, even though we only had a small proportion of missing data, we used missing data methods currently recommended for trial analysis, and thus the statistical inferences were robust.[38]

**Table 3. Longitudinal Analysis of Intervention Effectiveness and Sustainability: Effect on BP Control**

| Comparison | Odds ratio | 95% CI | *P* value |
|---|---|---|---|
| BP control (dichotomous variable) | | | |
| SMI vs UC (over 12 mo) | 1.84 | 1.28–2.67 | 0.001 |
| HEI vs UC (over 12 mo) | 1.48 | 1.02–2.14 | 0.04 |
| SMI vs HEI (over 12 mo) | 1.25 | 0.85–1.83 | 0.26 |
| 12 vs 6 mo for SMI | 0.97 | 0.64–1.45 | 0.86 |
| 12 vs 6 mo for HEI | 1.41 | 0.98–2.04 | 0.07 |
| 12 vs 6 mo for UC | 1.28 | 0.84–1.93 | 0.25 |

The covariates in the GEE models were treatment arms, time points (6 and 12 mo), the interaction between treatments and time points, and baseline BP control. BP was measured at 0, 6, and 12 mo. BP indicates blood pressure; GEE, generalized estimating equation; HEI, health education intervention; SMI, stage-matched intervention; and UC, usual care.

**Table 4. Longitudinal Analysis of Intervention Effectiveness and Sustainability: Effect on Systolic BP**

| Comparison | Mean difference | 95% CI | *P* value |
|---|---|---|---|
| Systolic BP (continuous variable) | | | |
| SMI vs UC (over 12 mo) | −2.80 | −5.33 to −0.27 | 0.03 |
| HEI vs UC (over 12 mo) | −2.58 | −5.55 to 0.40 | 0.09 |
| SMI vs HEI (over 12 mo) | −0.22 | −3.25 to 2.80 | 0.89 |
| 12 vs 6 mo for SMI | −0.64 | −3.67 to 1.67 | 0.57 |
| 12 vs 6 mo for HEI | −0.64 | −3.67 to 2.39 | 0.68 |
| 12 vs 6 mo for UC | −0.97 | −3.27 to 1.32 | 0.41 |

The covariates in the GEE models were treatment arms, time points (6 and 12 mo), the interaction between treatments and time points, and baseline BP control. BP was measured at 0, 6, and 12 mo. BP indicates blood pressure; GEE, generalized estimating equation; HEI, health education intervention; SMI, stage-matched intervention; and UC, usual care.

**Table 5. Effects of SMI vs UC and HEI vs UC on BP Control and SBP Under Different Missing Data Scenarios**

| Outcome of interest | Comparison | MCAR estimate | *P* value | Multiple imputation estimate | *P* value | Propensity estimate | *P* value | MNAR estimate | *P* value |
|---|---|---|---|---|---|---|---|---|---|
| BP control (yes/no) | SMI vs UC | 1.85 (OR) | 0.001 | 1.85 | 0.001 | 1.91 | 0.0007 | 1.73 | 0.004 |
| | HEI vs UC | 1.48 (OR) | 0.04 | 1.48 | 0.04 | 1.46 | 0.04 | 1.43 | 0.06 |
| Systolic BP, mm Hg | SMI vs UC | −2.80 | 0.03 | −2.82 | 0.03 | −2.96 | 0.03 | −2.52 | 0.06 |
| | HEI vs UC | −2.58 | 0.09 | −2.50 | 0.10 | −2.58 | 0.10 | −2.31 | 0.13 |

The multiple imputation model used the following variables to impute BP at 6 and 12 mo sequentially: race, hyperlipidemia status, DSOC, ESOC, number of medication, baseline BP, time points, and treatment arms. MCAR missing completely at random; MAR missing at random; MNAR missing not at random. BP indicates blood pressure; DSOC, dietary stage of change; ESOC, exercise stage of change; HEI, health education intervention; MAR, missing at random; MCAR, missing completely at random; MNAR, missing not at random; OR, odds ratio; SBP, systolic blood pressure; SMI, stage-matched intervention; and UC, usual care.

*MNAR is under a less favorable usual care sensitivity analysis scenario than the intervened groups, where the missing observations in SMI and HEI were assumed to follow the same distribution as that of completed observations in the UC group.

Despite the strengths, certain potential limitations need to be noted. First, notwithstanding our best efforts, there is a small proportion of missing data (Figure 1). This was primarily due to the fact that some participants were not able to attend all visits (ie, 6 and 12 months). Second, this randomized trial was not powered to test comparisons between the active intervention arms. However, if both interventions are successful, the findings would allow a hospital or clinic to use the appropriate intervention based on their resources and needs. In some settings, implementing the tailored intervention will be feasible and justified by local resources and the high prevalence of uncontrolled hypertension; in other settings, there may not be the expertise or resources to feasibly deliver the tailored intervention, and thus a simpler intervention may be a viable alternative. Third, certain subgroups may not benefit from either of the interventions, in particular, those who were working and thus could not fully participate in the intervention. Further research is needed to find tailored interventions that will target their needs.

Although we enrolled patients with 2 consecutive uncontrolled BP measurements on 2 different days, 41% to 45% had controlled BP at the baseline visit. This could be because of regression to the mean, provider treatment intensification, placebo effects, or patient activation after enrollment. The run-in period allows us to account for regression to the mean effects. Other potential confounders should be equally distributed between the groups because of randomization. Importantly, there were no significant BP differences between groups at baseline. To reduce the likelihood of bias further, we took providers into account and controlled for baseline BP in all analyses. Although we enrolled patients who were uncontrolled at the baseline, anticipating regression to the mean, our actual power analysis assumed the BP control rate of 43% in UC at the baseline, which is consistent with what happened. The proportion of drop outs was also lesser than what we expected, which improved the power of the study.

Our findings should be interpreted while taking into account the study setting and design. Our sample is representative of US veterans with hypertension living in an urban environment (ie, being primarily male, older, and with multiple comorbidities). The Veterans Health Administration is the largest health maintenance organization in the United States and hypertension is a major issue in non-Veterans Administration and non-Health Maintenance Organization (HMO) settings throughout the United States and the world. Thus, these findings likely can be generalized to other managed-care settings that possess similar organizational characteristics and patient populations. While gains in hypertension control have been achieved using system and provider efforts, concerns remain that non-targeted behavioral approaches may lead to overtreatment and potential adverse events.[39] Therefore, a strategy that focuses on patients with persistent uncontrolled hypertension and tailors counseling to patients' behaviors to improve adherence and achieve BP targets has great promise. Moreover, the coronavirus disease 2019 (COVID-19) pandemic has created an immediate need for novel remote interventions for vulnerable and isolated populations. In addition to telephone-based intervention, both SMI and HEI could be adapted for interactive voice response, texting or other digital health communication technologies.

## PERSPECTIVES

The telephone-delivered, SMI we evaluated resulted in statistically significant and clinically meaningful improvements in BP at 6 months, with sustained benefits over 12 months. By comparison, the telephone-delivered HEI was nearly as effective over 12 months. Importantly, the interventions did not involve in-person contact; this increases the potential reach and scalability of these approaches and should reduce costs. Thus, we think SMI and HEI constitute valuable intervention approaches for improving BP control rates. Health care settings with the resources to train staff in transtheoretical model-based counseling should use the SMI while health care

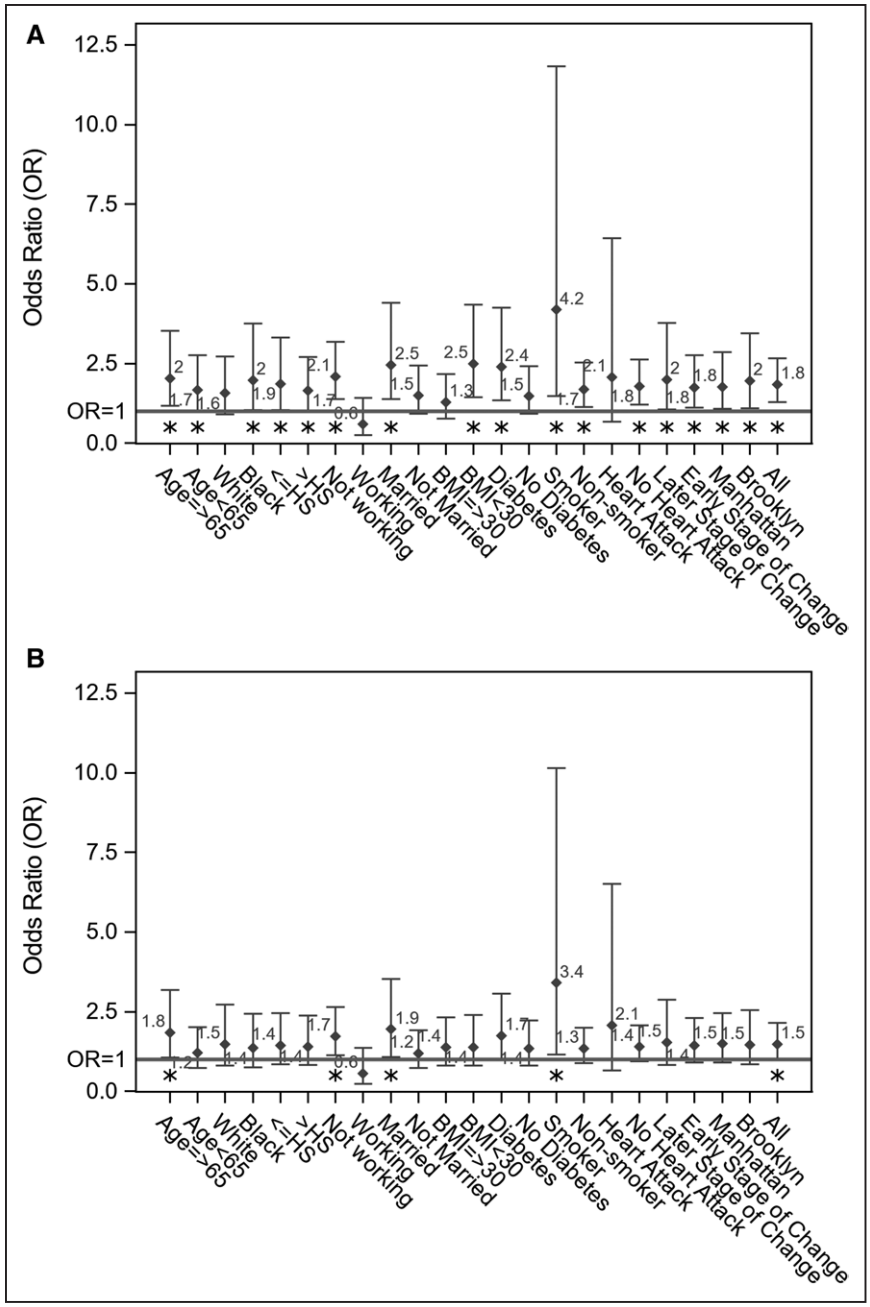


**Figure 2. Odds ratios (ORs) for blood pressure control among key participant subgroups and all participants.**
These subgroup analyses evaluate how well the interventions worked in important subgroups and are within-subgroup comparisons of intervention and control groups. The sample was restricted to each subgroup, and within each subgroup stage-matched intervention (SMI) (or health education intervention [HEI]) was compared with usual care (UC) using logistic regression. Top **A**, SMI arm compared with UC (*$P$<0.05). Lower **B**, HEI arm compared with UC (*$P$<0.05).

settings with limited resources could use the HEI. Either approach represents the proactive approach necessary to provide patients with uncontrolled hypertension with the additional behavioral self-management skills that are critical to achieve BP control.

## ARTICLE INFORMATION

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None.

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