Tailored Behavioral Intervention

Effectiveness of a Tailored Behavioral Intervention to Improve Hypertension Control
Primary Outcomes of a Randomized Controlled Trial

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Abstract—Blood pressure (BP) control rates are suboptimal. We evaluated the effectiveness of 2 behavioral interventions to improve BP control via a 3-arm, randomized controlled trial of 533 adults with repeated uncontrolled BP, despite antihypertensive drug treatment for ≥6 months. The interventions were a tailored stage-matched intervention (SMI) or a nontailored health education intervention (HEI) of 6 monthly calls targeting diet, exercise, and medication. Control was usual care (UC). There were no baseline group differences. Baseline BP control was 42.6%, 40.6%, and 44.6% in SMI, HEI, and UC (P=0.74), respectively; systolic BP (with SEs) was 136 (0.89), 137 (1.33), and 137 (0.96) mm Hg. Six-month control was 64.6% (SMI), 54.3% (HEI), and 45.8% (UC) (P values for pairwise comparisons versus UC, 0.001 [SMI] and 0.108 [HEI]). At 6 months, systolic BP (SE) was 131.2 (1.05), 131.8 (0.99), and 134.7 (1.02) for SMI, HEI, and UC, respectively (P values for pairwise comparisons versus UC, 0.009 for SMI and 0.047 for HEI). SMI led to lower systolic BP and better BP control than UC. SMI constitutes a new, potent approach to assist patients with uncontrolled hypertension to reach BP goals.

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More than 65 million American adults have hypertension.1 Diet, exercise, and drugs are mainstays of hypertension management.2 The efficacy of hypertension treatment in preventing cardiovascular events is established.2 Although the system and provider interventions have improved blood pressure (BP) control rates from the previous low rate (27%)3 to more respectable rates (51%4 to 79%5,6), the substantial proportion remains uncontrolled. However, we may have reached the maximum control achievable with nontailored interventions targeting clinics or hospitals with growing concerns that such interventions may lead to overtreatment and adverse outcomes.4-6 To optimize hypertension control further, approaches to identify and target patients at risk, to whom appropriately tailored therapy can then be offered, are needed.

Suboptimal adherence is a common, but modifiable, problem leading to inadequate hypertension control. Fewer than 10% of adults with hypertension adhere fully to diet recommendations,7 ≈35% exercise regularly,8 and only 50% to 60% are fully medication adherent.9 In-person counseling to improve adherence requires time and is labor-intensive and costly. Telephone counseling offers a promising alternate approach,10 and such counseling can be delivered at a convenient time and setting.11 Telephone interventions have improved medication adherence,12,13 physical activity,14 and diet,15 all key to lowering BP. It is not known, however, whether novel theory-based behavioral interventions can be delivered by telephone and whether they are effective in busy, clinical settings.

We conducted a randomized controlled trial to evaluate the effectiveness of targeting patients with repeated uncontrolled hypertension with either a tailored or a nontailored intervention in improving hypertension control and systolic blood pressure (SBP).

Methods

Design, Setting, and Participants
The study was a randomized controlled trial to evaluate whether a telephone-delivered, behavioral stage-matched intervention (SMI) or a nontailored health education intervention (HEI) would lead to better BP control than usual care (UC) in patients with uncontrolled BP. The study was approved by the institutional review board. All participants provided written informed consent. Procedures were...
followed in accordance with institutional guidelines. We recruit-
ed participants from July 2006 to March 2009 in Veterans Affairs
Medical Center clinics in Brooklyn and Manhattan. Follow-up was
completed in August, 2010. Patients with uncontrolled BP during
their previous visit were approached during their subsequent visit and
invited to participate. Patients were eligible if they had hypertension,1
antihypertensive drug therapy for ≥6 months, and uncontrolled BP
during screening. Uncontrolled BP was defined as SBP ≥130 mm Hg
or diastolic BP ≥80 mm Hg in diabetes mellitus (DM) or chronic kid-
ney disease, or SBP ≥140 mm Hg or diastolic BP ≥90 mm Hg in all
others as per the BP guidelines at the time of the study.

Participants with cardiovascular disease diagnosed <6 months ago,
class III or IV heart failure, severe psychiatric illness, AIDS, tuber-
culosus, lupus, end-stage renal failure, or limited life expectancy (<1
year) were excluded because of terminal illnesses. Other exclusions
included lack of a telephone, inability to follow the study protocol,
recent major surgery (<3 months), those temporarily in the area or
not available for follow-up, or inability to provide informed consent.

After enrollment, veterans had a simple “run-in period” of 4 weeks
during which we confirmed their telephone availability and reminded
them about the study and visits.16 After the run-in, participants visited
the clinic for the baseline assessment where a research assistant mea-
sured BP 6x for 2 hours using an Omron HEM-907XL automated BP
machine. The cuff was placed on the participant’s right upper arm,
with the bottom of the cuff placed 1″ above the crook of the elbow.
The standard-sized cuff (9″–13″) was used for most participants; if
there was doubt about cuff size, arm circumference was measured.
Height and weight were measured, and questionnaires were adminis-
tered. Participants also completed laboratory tests. A similar protocol
was followed for 6 months. Participants received $20 for their time
and travel for each study visit.

After the baseline, participants were allocated to the 3 study arms
by block randomization stratified by the site and dietary adherence.
The randomized assignments were concealed and computer-gen-
erated randomization was performed by the research coordinator,
who was neither involved in assessment nor counseling.17 Participants
knew that we were evaluating whether telephone interventions im-
prove hypertension management, but they did not know which active
telephone arm they were in. Counselors knew the treatment assign-
ment, but did not know the BP and adherence outcomes. Research
assistants were blinded to treatment assignment.17 Random assign-
ment was made by computer-generated randomization (using statis-
tical analysis system) to each treatment group by permuted blocks
of size 6 by the site. For all consecutive blocks of size 6 in a site, 2
subjects were in each of the 3 treatments. Patients received a phone
call from the counselor to schedule the first session 7 days after
the baseline if randomized to SMI or HEI.

Intervention

All participants received standard information about hypertension
and its treatment at enrollment. The UC group received no coun-
seling. SMI and HEI received monthly telephone counseling for 6
months. All telephone sessions were conducted by counselors with a
Master’s degree or higher in psychology or social work who were not
involved in recruitment or assessment visits. Participants were ran-
domized equally to the counselors with the same call procedures for
SMI and HEI such that each counselor conducted both SMI and HEI
calls. Calls were recorded, and a random sample was assessed weekly
for treatment fidelity by the PI, research coordinator, and counselors.

Patients in SMI received tailored monthly phone counseling for
exercise, diet, and medications based on the current stage of change,
using a computer-based intervention manual. During each call (~30
minutes), the stage of change for adherence to diet, medication, and
exercise was assessed separately using the validated stage of change
questions18 and tailored counseling based on this assessment. The
stages of change were precontemplation or no plans to adhere in <6
months; contemplation or plans to adhere in 1 to 6 months; prepara-
tion or plans to adhere within 1 month; action or adherence for ≥6
months; and maintenance or adherence for ≥6 months.

Patients were considered adherent to diet if they reported eating
the appropriate diet for hypertension (low in salt and fat with fruits,
vegetables, and low- or nonfat dairy products) ≥6 days/wk. Specific
recommendations, such as trimming visible fat from meat and ask-
ing for sauces on the side in restaurants were provided each month,
and any additional dietary questions were answered. The interven-
tion was tailored to target personal barriers and brainstorm solutions.
Medication adherence was defined as the self-report of taking BP
medications as prescribed for ≥6 days/wk. Although refill compliance
was measured, the stage of change only took self-reported adherence
into account. Exercise adherence was defined as self-reported aerobic
exercise for ≥3 days/wk for ≥220 minutes each time. We used the lower
threshold for exercise adherence to ensure patients received the
best of both worlds, as physical activity and adherence to medication
treatment benefit from one another.19 Patients received tailored
counseling for each target behavior based on their current stage of
change. SMI used the processes of change using the cognitive and
behavioral activities found to be most effective for each stage,22,23
and incorporated decisional balance and self-efficacy. For the deci-

sional balance, the pros and cons of each behavior were elicited, and
the counselor explored why each pro endorsed was important to the
participant. For each con, alternatives were explored using problem-
solving methods. Similarly, for self-efficacy, the counselor worked
with the participant to enhance confidence in ability to adhere.

Patients in HEI had monthly telephone counseling (~15 minutes)
of standard, nontailored information about hypertension, and diet,
medication, and exercise guidelines for hypertension from American
Heart Association educational materials. Although HEI did not take
the stage of change into account, it was still interactive in encour-
aging the participants to ask questions. Because the HEI is shorter
than the SMI, we included education on other healthful behaviors
(expanded hypertension information; sun safety; flu prevention; sleep
hygiene; back injury prevention; and vision and hearing) to increase
the duration of attention provided.

Other Measurements

Participants were categorized as having DM, chronic kidney disease,
or other comorbidities using established criteria. DM was determined
by chart review. Anyone with an estimated glomerular filtration rate,
calculated using the MDRD equation, of ≤60 was considered to have
chronic kidney disease. Smoking, race, marital status, education, and
employment were obtained by questionnaire. The number of antihy-
pertensive medications and antihypertensive medication intensifica-
tion (dose and number) was obtained from electronic medical records
and confirmed by the self-report.24 Exercise was obtained from
physical activity recall25 and medication adherence from the Morisky
adherence scale,26 a 4-item questionnaire scored from 0 to 4; scores
<4 are defined as nonadherent. Diet was assessed using the Willett
Food Frequency Questionnaire and adherence was summarized using
the dietary approaches to stop hypertension score, which ranges from
8 to 40, with higher scores representing greater adherence.

Statistical Analyses

The primary end points were BP control (dichotomous) and SBP
(continuous). The study was designed as an effectiveness trial of 2
active interventions, each compared with an active standard of care
control group. On the basis of our pilot data and a literature search,
we expected that 54% of patients on BP-lowering therapy would be
properly controlled with HEI and 43% with UC, whereas we expected
SI to increase this to 69% control in 6 months. With a significance
level of 0.025 (2-sided type I error rate), it was necessary to recruit
149 patients per group (~6 months; ie, 447 in total) to achieve 200%-
power using Pearson χ² to test for significant differences between the
3 groups. The study was not powered to test comparisons between the
2 active intervention arms. We controlled the possible clustering of
patient outcomes by physician in all analyses.37 Patient characteris-
tics were compared across treatment arms to assess randomization
using Rao–Scott χ² tests for categorical variables38 and generalized estima-
ting equations for continuous variables.

BP control and SBP were compared at 6 months across treatment
arms using a 2.5% type I error (Bonferroni adjustment), ie, 1.25%
for each of the 4 comparisons (SMI versus UC and HEI versus UC
for BP control and SBP separately). The BP control analysis compared the proportions of patients with BP under control at 6 months across the 3 treatment groups using Rao–Scott $\chi^2$ tests accounting for physician clustering. The SBP analysis compared the mean 6-month SBP across the 3 treatment groups using robust generalized estimating equation tests controlling for physician clustering. Additional analyses using logistic regression estimated the impact of SMI and HEI (versus UC) on BP control among subgroups, via generalized estimating equation to control for clustering by physicians. All analyses used SAS software, version 9.2 (SAS Institute). All $P$ values are 2 sided.

**Results**

We enrolled 705 individuals with uncontrolled BP at a previous clinic visit and uncontrolled BP during screening at a follow-up visit (Figure 1). After enrollment, 157 dropped out during the run-in period because of lack of interest or time (n=61), inability to be contacted (n=75), and occurrence of exclusionary events, such as myocardial infarction or stroke (n=21). Another 15 were excluded after the baseline before randomization because we could not contact them by phone (n=10) or they became ineligible (n=5). We randomized 533 participants of those 481 completed the 6-month visit, resulting in a 6-month missing data rate of <10%. Although this missing data percentage is small, to ensure study validity in case data are not missing completely at random, we used a generalized estimating equations approach that yields unbiased estimates, if the missing data are missing at random.

There were no significant baseline differences between groups (Table 1). There were 71 providers for these 533 participants (mean, 7.5 participants per provider; range 1 per provider to 36 per provider).

No significant baseline differences were found between treatment groups for BP and BP-related behaviors (Table 2). The proportion of participants with controlled hypertension at the baseline among SMI, HEI, and UC was 43%, 41%, and 45%, respectively ($P=0.74$). The mean SBP (in mmHg) was 136.0, 137.2, and 137.0 in SMI, HEI, and UC, respectively ($P=0.65$).

At 6-month follow-up (Table 3), a significantly greater number of participants in SMI had controlled BP compared with participants in HEI or UC, with 64.6%, 54.3%, and 45.8% having controlled BP in SMI, HEI, and UC, respectively. The 6-month mean SBP for each treatment group, adjusted for mean baseline SBP, indicated that patients in SMI had significantly lower mean SBP at 6 months than those in UC (131.2 versus 134.7; $P=0.009$); HEI had lower mean SBP than UC at 6 months (131.8 versus 134.7; $P=0.047$), although not significant when adjusting for multiple comparisons because we use a type I error of 0.0125 to account for the 4 main comparisons.

To evaluate the robustness of our findings, we tested whether the change in BP control and SBP was similar across arms (Table 3). The changes in BP control and SBP were both significantly better for SMI than UC. To assess this further, we tested the null hypothesis of no change in BP control from baseline.

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**Table 1. Baseline Characteristics of Participants by Randomization Group**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>SMI, n=176</th>
<th>HEI, n=177</th>
<th>UC, n=180</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y, mean (SE)</td>
<td>66.4 (0.66)</td>
<td>66.5 (0.96)</td>
<td>65.4 (0.76)</td>
<td>0.50</td>
</tr>
<tr>
<td>Men, %</td>
<td>98.9</td>
<td>99.4</td>
<td>97.7</td>
<td>0.36</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White (nonhispanic)</td>
<td>46.0</td>
<td>33.9</td>
<td>39.6</td>
<td>0.33</td>
</tr>
<tr>
<td>Black (nonhispanic)</td>
<td>36.9</td>
<td>43.3</td>
<td>39.0</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>13.6</td>
<td>16.1</td>
<td>15.8</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>3.4</td>
<td>6.1</td>
<td>5.7</td>
<td></td>
</tr>
<tr>
<td>Married, %</td>
<td>33.5</td>
<td>38.0</td>
<td>39.1</td>
<td>0.58</td>
</tr>
<tr>
<td>High school graduate or below, %</td>
<td>40.8</td>
<td>50.3</td>
<td>48.3</td>
<td>0.15</td>
</tr>
<tr>
<td>Employed</td>
<td>16.3</td>
<td>22.9</td>
<td>22.5</td>
<td>0.25</td>
</tr>
<tr>
<td>Manhattan campus, %</td>
<td>54.6</td>
<td>54.4</td>
<td>53.7</td>
<td>0.98</td>
</tr>
<tr>
<td>BMI, mean (SE)</td>
<td>30.5 (0.38)</td>
<td>31.2 (0.47)</td>
<td>30.0 (0.34)</td>
<td>0.12</td>
</tr>
<tr>
<td>Current smoker, %</td>
<td>20.1</td>
<td>18.3</td>
<td>17.9</td>
<td>0.87</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>40.3</td>
<td>46.7</td>
<td>45.2</td>
<td>0.51</td>
</tr>
<tr>
<td>IHD (heart attack)</td>
<td>13.1</td>
<td>12.2</td>
<td>13.0</td>
<td>0.96</td>
</tr>
<tr>
<td>Revascularization, %</td>
<td>15.3</td>
<td>16.1</td>
<td>17.1</td>
<td>0.93</td>
</tr>
<tr>
<td>Hyperlipidemia, %</td>
<td>22.0</td>
<td>21.6</td>
<td>28.7</td>
<td>0.86</td>
</tr>
<tr>
<td>eGFR, mean (SE)</td>
<td>79.9 (1.92)</td>
<td>83.2 (3.48)</td>
<td>80.6 (2.11)</td>
<td>0.74</td>
</tr>
</tbody>
</table>

BMI indicates body mass index; eGFR, estimated glomerular filtration rate; HEI, health education intervention; HEI, health education intervention; IHD, ischemic heart disease; SMI, stage-matched intervention; and UC, usual care.

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**Figure 1. Flow diagram of the progress through the phases of the 3-arm parallel randomized controlled trial of adults with uncontrolled hypertension. BP indicates blood pressure; HEI, health education intervention; SMI, stage-matched intervention; and UC, usual care.**
ied among subgroups, we conducted subgroup analyses with UC. There was no change for medication adherence. maintenance at follow-up for diet or exercise in SMI compared arms, a significantly greater proportion of SMI was in action or we assessed the proportion in action or maintenance across tion (dose and number) across arms was not significant. When the Morisky score, and antihypertensive medication intensifica-

versus UC, 0.32). The change in hours of exercise, change in 4. The proportion of participants in SMI was greater after the appropriate diet for hypertension than in HEI or UC, and improvement in diet can lower SBP by ≤11 mm Hg.33,34 Although we expected improvement in medication adherence, baseline medication adherence was high, and there was no significant improvement at follow-up.

Although several studies have focused on improving BP using different approaches, the success achieved has been modest.35 Our study is unique in focusing on patients with repeated uncontrolled BP and ongoing intervention tailoring to improve multiple behaviors simultaneously. Furthermore, we aimed to improve multiple aspects of dietary behavior (sodium, fat, fruits, and vegetables).

Although we enrolled patients with 2 consecutive uncontrolled BP measurements on 2 different days, 41% to 45% had controlled BP at the baseline. This could be because of regression to the mean,36,37 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 the 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 had happened. The proportion of dropped out patients was also lesser than what we expected, which improved the power of the study.

Medication adherence was relatively high. Veterans are well-educated, they have patient-centered medical homes, and medications are almost free for most patients. For all of those reasons, medication adherence tends to be high in veteran patients.

HEI, the nontailored intervention, did not lead to significantly better BP control or lower SBP when compared with UC in the primary analyses. The proportion of patients with baseline SBP further from normal SBP seemed to be greater in HEI than in SMI and UC patients. The interquartile ranges for SBP at the baseline were 126.1–145.7 for SMI, 126.2–148.5 for HEI, and 127.0–146.5 for UC. Furthermore, the DM prevalence also seemed greater (but not significantly) in HEI than in SMI, so HEI had more participants that needed to reach a lower goal (130/80). This could explain why SBP control did not significantly improve in HEI versus UC at 6 months in the primary analysis. In secondary analyses, when HEI was compared with UC, it was of borderline significance for the change in BP control outcome although it reached significance for the change in SBP outcome. Finally, the post hoc prepost comparison of BP control and SBP for HEI was significant.

This trial had several strengths. We used a rigorous experimental design and achieved similar groups by block randomization. A simple run-in period reduced the number of dropouts after randomization and careful patient monitoring with attention to data completion resulted in minimal missing data. The statistical inferences were obtained using methods currently recommended for trial analysis. The SMI used the transtheoretical model to tailor therapy delivered by telephone monthly with high fidelity among counselors. Finally, we used

### Table 2. Baseline BP Levels and BP-Related Behaviors

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>SMI</th>
<th>HEI</th>
<th>UC</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP control, %</td>
<td>42.6</td>
<td>40.6</td>
<td>44.6</td>
<td>0.50</td>
</tr>
<tr>
<td>Systolic blood pressure, mm Hg, mean (SE)</td>
<td>136.0 (0.89)</td>
<td>137.2 (1.33)</td>
<td>137.0 (0.96)</td>
<td>0.65</td>
</tr>
<tr>
<td>Diastolic blood pressure, mm Hg, mean (SE)</td>
<td>75.5 (0.70)</td>
<td>76.1 (0.87)</td>
<td>75.0 (0.83)</td>
<td>0.66</td>
</tr>
<tr>
<td>Aerobic exercise in hours per week, mean (SE)</td>
<td>5.3 (0.61)</td>
<td>4.5 (0.44)</td>
<td>5.0 (0.50)</td>
<td>0.48</td>
</tr>
<tr>
<td>DASH score, mean (SE)</td>
<td>23.6 (0.47)</td>
<td>23.8 (0.45)</td>
<td>24.0 (0.42)</td>
<td>0.77</td>
</tr>
<tr>
<td>Medication Adherence by Morisky scale, mean (SE)</td>
<td>3.4 (0.07)</td>
<td>3.2 (0.05)</td>
<td>3.3 (0.07)</td>
<td>0.45</td>
</tr>
<tr>
<td>Number of antihypertensive medications, mean (SE)</td>
<td>2.7 (0.11)</td>
<td>2.8 (0.10)</td>
<td>2.7 (0.10)</td>
<td></td>
</tr>
<tr>
<td>Proportion (%) in action or maintenance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diet</td>
<td>39</td>
<td>39</td>
<td>39</td>
<td>0.99</td>
</tr>
<tr>
<td>Exercise</td>
<td>71</td>
<td>62</td>
<td>60</td>
<td>0.07</td>
</tr>
<tr>
<td>Medications</td>
<td>93</td>
<td>96</td>
<td>92</td>
<td>0.42</td>
</tr>
</tbody>
</table>

BP indicates blood pressure; DASH, dietary approaches to stop the hypertension; HEI, health education intervention; Ischemic heart disease; SMI, stage-matched intervention; and UC, usual care.

To explore whether the effect of the interventions varied among subgroups, we conducted subgroup analyses (Figure 2). For all subgroups, SMI had higher BP control rates than UC with the pattern of odds ratios showing a consistent tendency also seemed greater (but not significantly) in HEI than in SMI and UC. The interquartile ranges for SBP at the baseline were 126.1–145.7 for SMI, 126.2–148.5 for HEI, and 127.0–146.5 for UC. Furthermore, the DM prevalence also seemed greater (but not significantly) in HEI than in SMI, so HEI had more participants that needed to reach a lower goal (130/80). This could explain why SBP control did not significantly improve in HEI versus UC at 6 months in the primary analysis. In secondary analyses, when HEI was compared with UC, it was of borderline significance for the change in BP control outcome although it reached significance for the change in SBP outcome. Finally, the post hoc prepost comparison of BP control and SBP for HEI was significant.

### Discussion

This trial evaluated the effectiveness of 2 telephone-delivered behavioral interventions on BP control and SBP among adults with repeated uncontrolled hypertension in primary care. Among such adults, rates of hypertension control at 6 months were higher and SBP was lower in SMI compared with UC.

Our findings can be explained primarily by improvements in diet. At 6 months, the proportion of participants in SMI the baseline to 6 months within each arm and found that there was 19.7% improvement in the proportion with controlled BP for SMI (P<0.0001), 11.9% for HEI (P=0.012), and 1.3% for UC (P=0.76).

We also examined the effects of the interventions on diet, exercise, and medication adherence across arms (Table 3). The change in mean dietary approaches to stop the hypertension score from the baseline to follow-up was 0.69 in SMI, −0.16 in HEI, and −0.76 in UC (P values, SMI versus UC, 0.01; HEI versus UC, 0.32). The change in hours of exercise, change in the Morisky score, and antihypertensive medication intensification (dose and number) across arms was not significant. When we assessed the proportion in action or maintenance across arms, a significantly greater proportion of SMI was in action or maintenance at follow-up for diet or exercise in SMI compared with UC. There was no change for medication adherence.

To explore whether the effect of the interventions varied among subgroups, we conducted subgroup analyses (Figure 2). For all subgroups, SMI had higher BP control rates than UC with the pattern of odds ratios showing a consistent effect of SMI across different characteristics (Figure 2A). Participants who were elderly, not working, married, not obese or with cardiovascular disease (or DM) were more likely to have BP under control in SMI compared with UC. For HEI (Figure 2B), the magnitude of the effect was consistently smaller for HEI versus UC comparisons than for SMI versus UC comparisons (Figure 2A).
the mean of 6 BP measurements, consistent with methods used in population studies.

Our findings should be interpreted taking into account the study sample and design. Our sample is representative of urban veterans with hypertension, ie, being primarily men, older, and with multiple comorbidities. Results might differ in other populations, eg, among women with hypertension. The Veterans Health Affairs system is the largest health maintenance organization in the country, and these findings likely can be generalized to other managed care settings. Hypertension is a big issue in nonveterans and non–health maintenance organization settings all over the United States as well. The aging of the population and the increasing rates of obesity and DM are likely to increase this high prevalence of hypertension further. Although gains in hypertension control have been achieved, there are concerns that system-wide interventions may lead to overtreatment and potential adverse events. Therefore, an approach targeting patients with repeated uncontrolled hypertension and tailored counseling the patients’ behaviors to improve adherence has great promise. This study provides a way to overcome the challenge of motivating patients to make behavioral changes, such as modifying dietary habits. This approach is particularly relevant and timely with the increasing integration and patient-centeredness of healthcare where many healthcare organizations have (or are now developing) infrastructure to support telephone-based care and are poised to intervene advantageously in a standardized way for patients with repeated uncontrolled hypertension. Consequently, we believe that this work has important implications for the clinical management of hypertension and could serve as a model for approaches to other chronic diseases where consistent adherence to behavioral regimens is required to produce optimal health outcomes and where the failure to do so is associated with the bulk of preventable costs in the US healthcare system.

Although this effectiveness trial was not powered to test comparisons between the active intervention arms, the intent was that the findings, if both interventions were successful, would allow a hospital or a clinic to use the appropriate intervention based on its resources and needs. For some, implementing the tailored intervention will be feasible and justified by local resources and the prevalence of uncontrolled hypertension. Others may not have the expertise to deliver the

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>SMI</th>
<th>HEI</th>
<th>UC</th>
<th>( P )-Value, Pairwise Comparisons</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary analyses</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BP control at 6 mo, %</td>
<td>64.6</td>
<td>54.3</td>
<td>45.8</td>
<td>SMI vs UC, 0.001</td>
</tr>
<tr>
<td>Systolic blood pressure at 6 mo, mmHg, mean (95% CI)</td>
<td>131.2 (129.1, 133.3)</td>
<td>131.8 (129.9, 133.7)</td>
<td>134.7 (132.7, 136.7)</td>
<td>SMI vs UC, 0.009</td>
</tr>
<tr>
<td><strong>Secondary analyses</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in proportion with BP under control from the baseline to 6 mo, %</td>
<td>19.7</td>
<td>11.8</td>
<td>1.9</td>
<td>SMI vs UC, 0.004</td>
</tr>
<tr>
<td>Change in systolic blood pressure (mmHg) from the baseline to 6 mo, mean (95% CI)</td>
<td>-4.7 (-6.9, -2.5)</td>
<td>-5.4 (-8.5, -2.3)</td>
<td>-2.7 (-5, -4)</td>
<td>SMI vs UC, 0.007</td>
</tr>
<tr>
<td><strong>Diet, exercise, and medication analyses</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in DASH score from baseline to 6 mo, mean (95% CI)</td>
<td>0.69 (-0.1, 1.5)</td>
<td>-0.16 (-1.1, 0.8)</td>
<td>-0.76 (-1.5, 0)</td>
<td>SMI vs UC, 0.013</td>
</tr>
<tr>
<td>Change in number of cardio exercise hours from baseline to 6 mo, mean (95% CI)</td>
<td>-0.29 (-1.7, 1.1)</td>
<td>0.53 (-0.6, 1.7)</td>
<td>-0.43 (-1.4, 0.6)</td>
<td>SMI vs UC, 0.880</td>
</tr>
<tr>
<td>Change in Morisky score from baseline to 6 mo, mean (95% CI)</td>
<td>0.25 (0.1, 0.4)</td>
<td>0.25 (0.1, 0.4)</td>
<td>0.14 (0, 0.3)</td>
<td>SMI vs UC, 0.306</td>
</tr>
<tr>
<td><strong>Antihypertensive medication intensification</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% that increased the number of meds or dose</td>
<td>43.8</td>
<td>45.6</td>
<td>40.1</td>
<td>SMI vs UC, 0.99</td>
</tr>
<tr>
<td>% with no change in number of meds or dose</td>
<td>41.5</td>
<td>45.0</td>
<td>49.7</td>
<td>SMI vs UC, 0.41</td>
</tr>
<tr>
<td>% that decreased the number of meds or dose</td>
<td>14.7</td>
<td>9.4</td>
<td>9.6</td>
<td>SMI vs UC, 0.011</td>
</tr>
<tr>
<td><strong>Proportion (%) in action or maintenance at 6 mo</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diet</td>
<td>56</td>
<td>46</td>
<td>43</td>
<td>SMI vs UC, 0.638</td>
</tr>
<tr>
<td>Exercise</td>
<td>82</td>
<td>78</td>
<td>74</td>
<td>SMI vs UC, 0.012</td>
</tr>
<tr>
<td>Medications</td>
<td>95</td>
<td>98</td>
<td>96</td>
<td>SMI vs UC, 0.502</td>
</tr>
</tbody>
</table>

BP indicates blood pressure; CI, confidence interval; DASH, dietary approaches to stop the hypertension; HEI, health education intervention; ischemic heart disease; SMI, stage-matched intervention; and UC, usual care.
tailored intervention, and a simpler intervention may be a viable alternative.

**Perspectives**

A telephone-delivered tailored stage of change-based intervention resulted in significant improvement in BP at 6 months. Because this trial did not involve in-person contact, it has the potential to increase scalability and reduce costs. With the current shift in health care to provide personalized care through the patient-centered medical home, health care is moving toward providing patient-centered care through the medical home model, with counseling on diet, physical activity, and medication adherence being provided through phone by a nonphysician. Another approach to provide care efficiently is through developing care coordination or Telehealth programs where nurses provide care through the phone using structured disease management protocols.

The methods and findings from this study could be used to develop a toolkit that would allow a hospital or a clinic to deliver the SMI by different disciplines (ie, social work, nursing, and pharmacy) depending on local resources and needs. For some institutions, implementing such a program may be feasible and justified by the volume of uncontrolled hypertension. An alternative approach is to have a specialized hub center for a network of hospitals and intervene in a standardized way for patients with repeated uncontrolled hypertension for the hospitals in a network.

The SMI may be a valuable additional tool to lower BP levels and improve control. It may also be a useful strategy to enhance adherence and improve outcomes in other chronic conditions, such as DM and heart failure, or in those who live further away and have difficulty attending frequent in-person medical visits.

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This work was funded by the Department of Veterans Affairs Health Services Research and Development Service Research Career Development Award 00-211 (S. Natarajan), Investigator-Initiated Research 04-170 (S. Natarajan) and Career Development Award 08-009 (J.P. Friedberg).

**Disclosures**

None.

**References**

This trial evaluated the effectiveness of 2 telephone-delivered behavioral interventions on blood pressure control (BP) and systolic BP among adults with repeated uncontrolled hypertension in primary care. It found that a telephone-delivered, stage-matched behavioral intervention (SMI) led to higher rates of hypertension control and lower SBP at 6 months compared with usual care. This intervention is novel because of its focus on patients with repeated uncontrolled BP and ongoing tailoring of the SMI to improve multiple behaviors simultaneously.

What Is Relevant?
Suboptimal adherence to treatment recommendations is a common, but modifiable, problem that leads to inadequate hypertension control. The improvements in BP resulting from SMI are primarily driven by improvements in diet, which is a difficult area in which to change for many patients with hypertension. The intervention led to improvements in BP via telephone rather than in-person counseling, which potentially increases scalability and reduces costs.

**Novelty and Significance**

- This trial evaluated the effectiveness of 2 telephone-delivered behavioral interventions on blood pressure control (BP) and systolic BP among adults with repeated uncontrolled hypertension in primary care. It found that a telephone-delivered, stage-matched behavioral intervention (SMI) led to higher rates of hypertension control and lower SBP at 6 months compared with usual care.

- This intervention is novel because of its focus on patients with repeated uncontrolled BP and ongoing tailoring of the SMI to improve multiple behaviors simultaneously.

- Suboptimal adherence to treatment recommendations is a common, but modifiable, problem that leads to inadequate hypertension control. The improvements in BP resulting from SMI are primarily driven by improvements in diet, which is a difficult area in which to change for many patients with hypertension. The intervention led to improvements in BP via telephone rather than in-person counseling, which potentially increases scalability and reduces costs.

**Summary**
A telephone-delivered SMI resulted in significant clinical and statistical improvement in BP at 6 months. This SMI may be a valuable additional tool for improving BP control rates.
Effectiveness of a Tailored Behavioral Intervention to Improve Hypertension Control: Primary Outcomes of a Randomized Controlled Trial
Jennifer P. Friedberg, Maria A. Rodriguez, Michelle E. Watsula, Iris Lin, Judith Wylie-Rosett, John P. Allegrante, Stuart R. Lipsitz and Sundar Natarajan

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罐装饮料和血压（摘要）

与摄入罐装饮料相关的双酚A暴露可升高血压：一项随机交叉试验
Exposure to Bisphenol A From Drinking Canned Beverages Increases Blood Pressure:
Randomized Crossover Trial
Sanghyuk Bae, Yun-Chul Hong
杨雪楠 译 罗素新 审校

双酚A（BPA）是一种常用于塑料瓶和饮料罐（易拉罐）内涂层的化学物质，与此同时，BPA暴露几乎无处不在。之前的研究所发现，BPA与高血压及心率变异性降低有关，而本研究的目的是观察摄入罐装饮料而增加BPA暴露是否更显著地影响了血压及心率变异性。为此，本研究在普普通通社区居民进行了一项随机交叉试验，受试者年龄均≥60岁且全部来自当地一个社区中心，试验中将相同的饮料分别装入2个玻璃瓶、2个饮料罐（易拉罐）或者1个玻璃瓶、1个饮料罐（易拉罐）中给受试者饮用，并且每次只随机替换其中一组饮料，共有20人完成了全部3次试验。在受试者摄入饮料2小时后监测其尿BPA浓度，血压和心率变异性，并以配对检验及混合模型来比较各组结果间的差异。结果发现，与摄入玻璃饮料相比，摄入罐装饮料2小时后尿BPA浓度升高大于1600%，收缩压（调整每日变异后）则升高约4.5 mmHg，此差异有统计学意义。心率变异性的差异则无统计学意义。本研究证明了摄入罐装饮料增加BPA暴露后会使血压迅速升高。

（Hypertension. 2015;65:313-319.）

个性化行为干预（摘要）

个性化行为干预在提高血压控制率中的作用：一项随机对照试验的主要结果
Effectiveness of a Tailored Behavioral Intervention to Improve Hypertension Control: Primary Outcomes of a Randomized Controlled Trial
Jennifer P. Friedberg, Maria A. Rodriguez, Michelle E. Wattsula, Iris Lin, Judith Wylie-Rosett, John P. Allegrante, Stuart R. Lipsitz, Sundar Natarajan
苏国海 译

目前，高血压患者的血压控制率仍不理想。本研究选取533例血压控制不佳的高血压患者（经抗高血压药物治疗≥6个月），采用三支随机对照试验的方法，给予2种行为干预来提高血压控制率。干预组采用个体化、阶段匹配式干预（stage-matched intervention, SMI）及非个性化健康教育干预（health education intervention, IHEI）的方式，给予目标饮食、运动及药物治疗6个月。对照组采用常规护理（UC）。各组的血压基线水平无差别。SMI组、HEI组、UC组的基线血压控制率分别为42.6%、40.6%及44.6%（P=0.74），收缩压（SE）分别为136（0.89）、137（1.33）及137（0.96）mmHg。三组6个月时的血压控制率分别为64.6%（SMI）、54.3%（HEI）及45.8%（UC）[与UC进行两两比较，P值分别为0.001（SMI）和0.108（HEI）]。6个月后，SMI组、HEI组、UC组收缩压（SE）分别为131.2（1.05）、131.8（0.99）及134.7（1.02）mmHg[与UC进行两两比较，P值分别为0.009（SMI）和0.047（HEI）]。较UC而言，SMI组与UC组相比可以更好的降低收缩压并使血压控制率提高。对于血压控制不佳的高血压患者而言，SMI是一种全新、有效的方法去帮助其血压达标。

（Hypertension. 2013;65:440-446.）