Hypertension is a major risk factor for cardiovascular disease. Although control rates have improved over time, racial/ethnic disparities in hypertension control persist. Self-blood pressure monitoring, by itself, has been shown to be an effective tool in predominantly white populations, but less studied in minority, urban communities. These types of minimally intensive approaches are important to test in all populations, especially those experiencing related health disparities, for broad implementation with limited resources.

Methods and Results—The New York City Health Department in partnership with community clinic networks implemented a randomized clinical trial (n=900, 450 per arm) to investigate the effectiveness of self-blood pressure monitoring in medically underserved and largely black and Hispanic participants. Intervention participants received a home blood pressure monitor and training on use, whereas control participants received usual care. After 9 months, systolic blood pressure decreased (intervention, 14.7 mm Hg; control, 14.1 mm Hg; P=0.70). Similar results were observed when incorporating longitudinal data and calculating a mean slope over time. Control was achieved in 38.9% of intervention and 39.1% of control participants at the end of follow-up; the time-to-event experience of achieving blood pressure control in the intervention versus control groups were not different from each other (logrank P value =0.91).

Conclusions—Self-blood pressure monitoring was not shown to improve control over usual care in this largely minority, urban population. The patient population in this study, which included a high proportion of Hispanics and uninsured persons, is understudied. Results indicate these groups may have additional meaningful barriers to achieving blood pressure control beyond access to the monitor itself.

Clinical Trial Registration: http://clinicaltrials.gov. Unique Identifier: NCT01123577

(Circ Cardiovasc Qual Outcomes. 2015;8:138-145. DOI: 10.1161/CIRCOUTCOMES.114.000950.)

Key Words: blood pressure monitoring ■ clinical trial ■ hypertension ■ lifestyle ■ population
WHAT IS KNOWN

- Self-blood pressure monitoring has been shown to be an effective tool in the management of hypertension.
- Most studies have been conducted in white race populations.

WHAT THE STUDY ADDS

- This study used an innovative method of screening and randomizing patients directly in the electronic health record, which may be applied in several different clinic-based settings and for varying health-related research questions.
- This trial tested the effect of administering self-blood pressure monitors to a mostly Hispanic, foreign-born, and uninsured population and found it not to be effective beyond usual care in these groups.
- Additional services such as appropriate language support or cultural tailoring may be necessary for achieving BP control in these populations.

Methods

The study design was a randomized clinical trial conducted in a large health center network (6 sites) and 2 small, independent community health centers (1 site each), for a total of 8 clinic sites. These sites treat populations that are medically underserved; the large network which included 6 sites and one of the smaller centers were federally qualified health centers. The design and implementation of this study incorporated aspects of participatory action research,15 in that it was a collaborative effort between the Health Department and community clinic networks. The healthcare networks were using the same EHR, eClinicalWorks, and receiving technical assistance on systems changes from Health Department staff. All eClinicalWorks practices have BP quality and decision support measures that allow for monitoring of their patient populations. The trial consisted of 2 study arms: an intervention arm where participants received automatic home BP monitors with modems capable of transmitting (or uploading) home BP readings via phone line to a secure database for evaluation and a control arm where participants received usual care. The Department of Health and Mental Hygiene collaborated with iMetrikus/Numera to provide a mechanism for uploading and collecting the participants’ home readings.

The target sample size for enrollment was 996 or 498 participants in each arm. This would have allowed for the detection of a 3.3 mm Hg (SD, 17 mm Hg) difference in systolic BP between intervention and control arms after 9 months at 80% power and 99.8% power to detect BP control over time using time-to-event analysis, both accounting for study participant attrition (13.6% over 9 months). The original study design sought to recruit Hispanics, non-Hispanic blacks, and non-Hispanic whites evenly (33% of study sample of each race/ethnicity) using stratified, block randomization. With even distribution of study arms across 3 race/ethnic groups (n=165 per arm, per race/ethnicity), a difference of 5.7 mm Hg in systolic BP would be detectable within race/ethnic group; detection of BP control over time using time-to-event analysis was powered at 80%. In the planning process, study sites were selected based on having sufficient information technology infrastructure and provider interest which limited the demographics of the final recruited sample. The percentage of Hispanics was 62%, blacks 28%, and whites 10%. Between-race/ethnic comparisons (eg, Hispanic versus white) were not performed given limited sample size.

Participant Recruitment and Randomization With the Electronic Health Record

Participants needed to meet all eligibility criteria: (a) age ≥18 years; (b) diagnosis of hypertension for ≥6 months; (c) last visit BP uncontrolled (systolic BP ≥140 mm Hg or diastolic BP ≥90 mm Hg); (d) not currently measuring BP at home; (e) access to a land [telephone] line; (f) Hispanic, black, or white; (g) capacity to use the home monitor and record readings as determined by the provider; and (h) BP uncontrolled. Criteria ‘a’ through ‘c’ were built into the EHR, such that only those who met those criteria were approached and screened for the study. All other criteria were assessed by a smartform, as described below.

Participants’ eligibility was determined, and participants were automatically randomized into the intervention or control group by a smartform, a software tool residing within the EHR. The study smartform was developed by Health Department staff in collaboration with the EHR vendor for use in this study. The smartform is a tool that provides a method of query-able structured data collection and performs basic study logic and calculations. Although some providers had used similar smartforms in the past to collect patient histories for depression/smoking, providers and nonprovider/nursing staff at participating clinics did receive some training to become familiar and comfortable with the new smartform and the workflow that it entailed.

Patients were enrolled from June 7, 2010, through October 7, 2011. A typical screening workflow proceeded in the following manner. After the vital signs were taken by the medical assistant, the provider would answer the next 3 questions on the smartform (eligibility criteria g and h, and verification of CKD or diabetes mellitus diagnoses). If all 3 answers were yes, the patient was sent back to the nurse to complete enrollment, including obtaining consent, randomization by answering yes to the last question, and training if in the intervention arm. The information from the
smartform was passed to an integrated study protocol EHR module responsible for enrolling a randomized and balanced cohort of patients for each race/ethnicity for each control/intervention arm. All patients screened and enrolled in the study were tracked in a master study participants table within the EHR database, which prevented duplicate enrollments and facilitated study data collection efforts throughout the program. The screening and consent process was adapted to fit each clinic's setting (age at baseline, sex, race/ethnicity, activity, body mass index, primary insurance [self-pay, Medicare, other]), systolic and diastolic BP at each clinic visit, and mean number of clinic visits (defined as having a clinic BP reading in the EHR). Clinic BP values were those BP readings that were taken at the start of the clinic visit as a part of vital signs measurements and were pulled from this field in the EHR. Given the applied design of this trial, a clinic visit specifically for the study was not required. Nativity was defined as US born or foreign born; those born in Puerto Rico were categorized as US born because they are more likely to have health insurance.² potentially owing to their US citizenship status. Relevant comorbidities (diabetes mellitus diagnosis, CKD diagnosis, personal history of heart disease, and of stroke) were assessed using corresponding International Classification of Disease (ninth edition, ICD-09) codes for each condition (diabetes mellitus, 250; CKD, 585; heart disease, 393–398, 402, 404–429; stroke, 430–438 [but not 435]).

Outcomes assessed were change in systolic and diastolic BP from baseline to follow-up, the slope of BP over the follow-up period, in- cluding all available BP measurements, and achievement of BP con- trol. Control was defined as systolic BP <140 mm Hg and diastolic BP <90 mm Hg and diastolic BP <90 mm Hg. After randomization, participants in both arms were asked to return to the clinic as per their regularly scheduled visits. Intervention arm participants received BP monitors, educational materials on hypertension, and a tote bag. They were trained on how to use their moni- tors, record their BP, and upload their home readings (transmitting them electronically to the secured database) and were encouraged to share their BP readings with their doctors. Control arm partici- pants received usual care, and as an incentive, a BP monitor at the end of study follow-up. The planned follow-up period was 9 months, longer than the majority of previous studies on SBPM,³ to demon- strate persistence and maintenance of improvement over time. The Institutional Review Board of each participating institution approved this study; informed consent from the patient was required to partici- pate in the trial.

Data and Variable Definitions

Clinic data for analysis was pulled from the EHRs in all clinic sites with the assistance of Health Department staff and the clinic informa- tion technology staff in September and October 2012. Data included demographic characteristics (age at baseline, sex, race/ethnicity, activity, body mass index, primary insurance [self-pay, Medicare, other]), systolic and diastolic BP at each clinic visit, and mean number of clinic visits (defined as having a clinic BP reading in the EHR). Clinic BP values were those BP readings that were taken at the start of the clinic visit as a part of vital signs measurements and were pulled from this field in the EHR. Given the applied design of this trial, a clinic visit specifically for the study was not required. Nativity was defined as US born or foreign born; those born in Puerto Rico were categorized as US born because they are more likely to have health insurance.² potentially owing to their US citizenship status. Relevant comorbidities (diabetes mellitus diagnosis, CKD diagnosis, personal history of heart disease, and of stroke) were assessed using corresponding International Classification of Disease (ninth edition, ICD-09) codes for each condition (diabetes mellitus, 250; CKD, 585; heart disease, 393–398, 402, 404–429; stroke, 430–438 [but not 435]).

Outcomes assessed were change in systolic and diastolic BP from baseline to follow-up, the slope of BP over the follow-up period, in- cluding all available BP measurements, and achievement of BP con- trol. Control was defined as systolic BP <140 mm Hg and diastolic BP <90 mm Hg (<130/80 for those with diabetes mellitus or CKD). Because participants were not asked to come back specifically for this study but according to the clinic’s regular schedule of follow-up visits for patients with hypertension, the window for a follow-up visit was defined as a range of 7 to 10 months. Follow-up was enumerated in 2 ways. First, any participant who had ≥1 BP measurement during the 10 month follow-up time was enumerated as having ≥1 follow-up visit and was included in analyses of change in BP slope and in the time-to-event (achieving BP control) analyses. Second, a participant who had ≥1 visit in the 7 to 10 month interval was included in analy- ses of change in baseline to follow-up BP comparisons; the first value in the 7 to 10 month interval was used. Specific participant flow is described in the Results below.

Analytic Methods

Participant characteristics at baseline were compared between the inter- vention and control groups and stratified by race/ethnicity to verify comparability of the 2 study arms. Differences were assessed using t test and the Wilcoxon Rank-Sum test for normal and non-normal continuous variables, respectively, and the χ² test and Fisher exact test for categorical variables.

Owing to the multisite nature of the study design, the strength of clustering and the degree of dependence was measured by the intra- cluster correlation coefficient. The intraclass correlation coefficients showed some, albeit minor, statistically significant evidence of hier- archical clustering of individuals within sites (intraclass correlation coefficient =0.03, P<0.001 for systolic BP and intraclass correla- tion coefficient =0.05, P<0.001 for diastolic BP). Therefore, changes in systolic and diastolic BP were assessed by intervention group, by race/ethnicity, and by home upload status and were compared using multilevel linear mixed models with 1 between subjects factor (in- tervention group – intervention versus control) and 1 within-subjects factor (time – baseline and follow-up) accounting for nonindepen- dence and correlation of the BP measurements within patients and hierarchical clustering of patients within clinic sites. The change in BP measurements from baseline to follow-up was directly measured by the groupxtime interaction term within each intervention group and then compared between the 2 intervention groups. Separate mod- els were developed for systolic BP and diastolic BP. Several residual covariance structures were tested by using likelihood ratio test, the Akaike’s Information Criterion, and Bayesian Information Criterion measures and models with an unstructured correlation structure showed to be the best fitted models.

Because the clustering effect in our data was unintentional and not an explicit part of the study design, a secondary sensitivity analysis was conducted by using an alternative simpler approach of analysis of covariance on BP change (follow-up – baseline measurements) con- trolling for the baseline BP measurements ignoring the hierarchical site clustering effect. Separate models were developed for systolic BP and diastolic BP. This sensitivity analysis, however, produced similar inferences to the mixed model approach for the level of statistical significance of change in BP between the study groups and thus, for brevity, are not included in this report.

The slopes of BP over the follow-up period were calculated and compared using random coefficient models accounting for the longi- tudinal correlation of BP measurements within patients, overall, and by race/ethnicity. Percent achieving control in the study period was assessed using time-to-event analysis, overall and by race/ethnicity. The comparison of interest was the time (months) that it took the intervention and control groups to achieving BP control for the first time. Differences in the time-to-event experience were compared using the Kaplan–Meier survival distribution function, survival curves, and log-rank tests.

To assess whether frequency of BP measurements at home affected clinic results in the intervention group, intervention arm participants were additionally stratified by whether they uploaded their home readings. This prespecified analysis was performed to determine best patterns of home BP monitor use. Intervention-uploaders were de- fined as intervention arm participants who uploaded (n=182); inter- vention-non-uploaders were defined as intervention arm participants who did not upload (n=224). Intervention-uploaders were stratified as measuring BP 2+ times/day (n=96) or <2 times/day (n=86); this cutoff was decided post hoc based on the distribution of the data.

All statistical analyses were conducted using SAS software version 9.2 (SAS Institute, Inc., Cary, North Carolina).

Results

Ninety-one percent (409) of intervention and 93% (419) of control participants had a baseline visit and ≥1 follow-up visit within 10 months, which meant they were included in the analysis of BP slope over time and the time-to-event analy- sis. Seventy-three percent (329) in the intervention group and 74% (332) in the control group had a follow-up visit in the 7 to 10 months follow-up window only; analyses of change from baseline to follow-up BP included only these individuals. A participant flow diagram, which also includes the breakdowns by race/ethnicity, is displayed in Figure 1.

The median number of visits per participant was 5 (inter- quartile range, 3–8 visits) in both study arms.
The majority of the study population was female (68%), Hispanic (63%), foreign born (51%), had diabetes mellitus (59%), and were self-pay/uninsured (69%). Characteristics of participants by interventions arm are displayed in Table 1.

The intervention and control groups were similar with respect to age, sex, race/ethnicity, nativity, body mass index, diabetes mellitus, CKD, personal history of heart disease and stroke, and primary insurance. Diastolic BP at baseline was slightly higher in the intervention versus control group (83.9±11.2 mmHg versus 82.3±10.6 mmHg, \( P =0.04 \)). No significant differences were found between intervention arms by race/ethnicity (results not shown), other than a higher prevalence of diabetes mellitus among black participants in the intervention (60.4%) versus control group (43.9%, \( P =0.02 \)). Additionally, whites in the intervention group had a higher mean systolic BP at baseline compared with the white control group (157.7±16.6 mmHg versus 150.8±14.2 mmHg, \( P =0.04 \)).

Mean systolic and diastolic BP at baseline and follow-up and changes in values are displayed in Table 2. Overall, systolic BP decreased 14.7 mmHg (\( P<0.001 \)) in the intervention group and 14.1 mmHg (\( P<0.001 \)) in the control group, with no significant difference between these decreases (\( P=0.70 \)). When stratified by race/ethnicity, the difference in systolic BP decrease was significant in white participants only (\( P=0.01 \)) and not in blacks (\( P=0.95 \)) or Hispanics (\( P=0.56 \)). Similar results were observed with diastolic BP values, with the only significant effect of the intervention being observed in whites. There was no difference in the slope over the follow-up period between the intervention and control groups (Table 2), but again, differences were apparent in the whites only.

BP control was achieved in 38.9% of intervention and 39.1% of control participants after 10 months, though the time-to-event experience of intervention versus control were not different from each other (logrank \( P \) value =0.91; Figure 2). Achieving BP control did not differ for intervention versus control for any of the race/ethnic groups (logrank \( P \) values, whites \( P=0.50 \), blacks \( P=0.11 \), Hispanics \( P=0.64 \)).

**Home Data Results**

Overall, those in the intervention group who uploaded their readings (uploaders) and those who did not upload their readings (nonuploaders) were similar to each other on key demographic characteristics, including age, sex, race/ethnicity, nativity, body mass index, diabetes mellitus, CKD, history of cardiovascular disease, and insurance status. When considering uploaders only, uploaders who took BP measurements >2× per day were more likely to achieve BP control in the clinic compared with uploaders who took BP measurements ≤2× per day (log rank \( P \) value =0.02) and had a larger change in systolic BP over time (decrease in uploaders, >2× per day=1.06 mmHg; <2× per day =0.48 mmHg, \( P=0.05 \)). When comparing intervention-uploaders, intervention-nonuploaders, and control, there were no differences in achieving BP control (log rank \( P \) value =0.38) or in slope over time.

**Discussion**

Overall, the distribution of self BP monitors was not shown to be more effective in reducing BP over time or in improving BP control above and beyond usual care in this largely minority sample of NYC adults from medically underserved communities. The intervention was not found to be effective among...
Hispanic and black participants for any BP outcomes. It was effective among white participants in reducing BP compared with the control group, but not in achieving control over time. The participants in this study represent a unique subset of individuals typically understudied in the literature: predominantly Hispanic (≈70%); foreign born (≈60%); and uninsured or self-pay patients (≈70%). Although the recent studies include emerging information on predictors or correlates of BP control in Hispanics,3,4,18,19 to our knowledge, this is one of first randomized clinical trials to evaluate SBPM in an urban, medically underserved population. Consistent with the Agency for Healthcare Research and Quality review published in January 2012 on the effectiveness of SBPM, we conclude that SBPM alone was not effective in our study sample under existing conditions.

### Table 1. Study Participant Characteristics by Intervention Group

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (n=409)</th>
<th>Control (n=419)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at baseline, y (mean±SD)</td>
<td>61.3±11.9</td>
<td>61.3±12.2</td>
<td>0.98</td>
</tr>
<tr>
<td>Female sex, n (%)</td>
<td>275 (67.2)</td>
<td>285 (68.0)</td>
<td>0.81</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td>0.87</td>
</tr>
<tr>
<td>Non-Hispanic white</td>
<td>43 (10.5)</td>
<td>44 (10.5)</td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic black</td>
<td>111 (27.1)</td>
<td>107 (25.5)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>255 (62.4)</td>
<td>268 (64.0)</td>
<td></td>
</tr>
<tr>
<td>Country of birth, n (%)*</td>
<td></td>
<td></td>
<td>0.70</td>
</tr>
<tr>
<td>US born</td>
<td>134 (35.9)</td>
<td>108 (37.4)</td>
<td></td>
</tr>
<tr>
<td>Foreign born</td>
<td>239 (64.1)</td>
<td>181 (62.6)</td>
<td></td>
</tr>
<tr>
<td>BMI, kg/m², n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal, 18.5 to &lt;25</td>
<td>57 (14.1)</td>
<td>48 (11.6)</td>
<td>0.51</td>
</tr>
<tr>
<td>Overweight, 25 to &lt;30</td>
<td>123 (30.4)</td>
<td>136 (32.9)</td>
<td></td>
</tr>
<tr>
<td>Obese, 30+</td>
<td>225 (55.6)</td>
<td>230 (55.6)</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus diagnosis, n (%)</td>
<td>255 (62.4)</td>
<td>235 (56.1)</td>
<td>0.07</td>
</tr>
<tr>
<td>Chronic kidney disease diagnosis, n (%)</td>
<td>12 (2.9)</td>
<td>11 (2.6)</td>
<td>0.79</td>
</tr>
<tr>
<td>Personal history of heart disease, n (%)</td>
<td>115 (28.1)</td>
<td>138 (32.9)</td>
<td>0.13</td>
</tr>
<tr>
<td>Personal history of stroke, n (%)</td>
<td>53 (13.0)</td>
<td>57 (13.6)</td>
<td>0.78</td>
</tr>
<tr>
<td>Primary insurance, n (%)</td>
<td></td>
<td></td>
<td>0.84</td>
</tr>
<tr>
<td>Self-pay</td>
<td>283 (69.2)</td>
<td>289 (69.0)</td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>18 (4.4)</td>
<td>22 (5.3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>108 (26.4)</td>
<td>108 (25.8)</td>
<td></td>
</tr>
<tr>
<td>Systolic BP at baseline, mean±SD</td>
<td>151.5±16.4</td>
<td>152.1±15.0</td>
<td>0.58</td>
</tr>
<tr>
<td>Diastolic BP at baseline, mean±SD</td>
<td>83.9±11.2</td>
<td>82.3±10.6</td>
<td>0.04</td>
</tr>
<tr>
<td>NO. of visits, median (25% to 75% IQR)</td>
<td>5 (3–8)</td>
<td>5 (3–8)</td>
<td>0.65</td>
</tr>
</tbody>
</table>

BMI indicates body mass index; BP, blood pressure; and IQR, interquartile range.
*Values here are not adjusted for clustering and thus differ from BP mean change analyses displayed in Table 2.

### Table 2. Baseline and Follow-Up Comparison and Slopes of Mean Systolic and Diastolic BPs Between Intervention and Control Groups, Overall, and by Race/Ethnicity

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Baseline (Mean±SE)</th>
<th>Follow-up (Mean±SE)</th>
<th>Change (Mean±SE)</th>
<th>Slope Over Time</th>
<th>Baseline (Mean±SE)</th>
<th>Follow-up (Mean±SE)</th>
<th>Change (Mean±SE)</th>
<th>Slope Over Time</th>
<th>P Value</th>
<th>P† Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic BP</td>
<td>150.7±1.5</td>
<td>136.0±1.6</td>
<td>−14.7±1.1</td>
<td>−0.86</td>
<td>151.0±1.5</td>
<td>137.0±1.6</td>
<td>−14.1±1.1</td>
<td>−1.02</td>
<td>0.70</td>
<td>0.25</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>84.1±1.0</td>
<td>78.4±1.0</td>
<td>−5.8±0.6</td>
<td>−0.38</td>
<td>82.5±1.0</td>
<td>77.7±1.0</td>
<td>−4.8±0.6</td>
<td>−0.36</td>
<td>0.24</td>
<td>0.81</td>
</tr>
<tr>
<td>White</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic BP</td>
<td>157.4±2.9</td>
<td>135.9±3.7</td>
<td>−21.5±3.6</td>
<td>−1.45</td>
<td>149.0±2.9</td>
<td>140.9±3.7</td>
<td>−8.1±1.3</td>
<td>−0.39</td>
<td>0.01</td>
<td>0.01</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>86.1±2.4</td>
<td>77.8±2.0</td>
<td>−8.3±1.9</td>
<td>−0.59</td>
<td>81.1±2.4</td>
<td>79.8±2.0</td>
<td>−1.3±1.9</td>
<td>0.02</td>
<td>0.01</td>
<td>0.001</td>
</tr>
<tr>
<td>Black</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic BP</td>
<td>152.7±2.4</td>
<td>141.4±2.5</td>
<td>−11.3±2.3</td>
<td>−0.82</td>
<td>151.3±2.4</td>
<td>140.3±2.6</td>
<td>−11.1±2.4</td>
<td>−0.83</td>
<td>0.95</td>
<td>0.97</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>86.5±1.1</td>
<td>83.3±1.2</td>
<td>−3.2±1.3</td>
<td>−0.19</td>
<td>84.7±1.2</td>
<td>81.9±1.2</td>
<td>−2.9±1.3</td>
<td>−0.18</td>
<td>0.86</td>
<td>0.98</td>
</tr>
<tr>
<td>Hispanic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic BP</td>
<td>148.7±1.6</td>
<td>133.8±1.7</td>
<td>−14.9±1.4</td>
<td>−0.76</td>
<td>151.0±1.5</td>
<td>135.1±1.7</td>
<td>−16.0±1.3</td>
<td>−1.14</td>
<td>0.56</td>
<td>0.03</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>81.9±0.7</td>
<td>75.6±0.6</td>
<td>−6.3±0.7</td>
<td>−0.41</td>
<td>81.1±0.7</td>
<td>75.2±0.6</td>
<td>−5.9±0.7</td>
<td>−0.46</td>
<td>0.70</td>
<td>0.56</td>
</tr>
</tbody>
</table>

*P value comparing change in intervention group to change in control group.
†P value comparing slope over time in intervention group to slope over time in control group.
In both the intervention and control groups, BP reductions corroborate the magnitude of BP reduction observed in the evaluation of the SBPM program, where we observed an 18.7 mm Hg reduction in systolic BP and a 8.5 mm Hg reduction in diastolic BP using a prepost design (systolic BP 9.0 mm Hg reduction, diastolic BP 3.4 mm Hg reduction after adjustment for regression to the mean). However, in the current study, the magnitude of the effect in the intervention group was not greater than the effect observed in the control group. Because this study was randomized at the participant level and not the provider or practice level, providers may have been engaging with participants in both the intervention and control arms similarly with respect to activities around BP control. As a part of EHR implementation, the Health Department provided technical assistance, and all eClinicalWorks practices had enhanced BP quality and decision support measures that allowed for monitoring of their patient populations. Further, the clinic network from which our largest percentage (85%) of participants came from additionally was able to achieve Level 3 status as a Patient Centered Medical Home (in part because of their participation in the current study). These activities included improvements in BP measurements through training of medical assistants on appropriate cuff sizes and increased education on BP generally among nurses. This may partially explain the large decrease observed in the control group because this may have affected usual care. Additionally, it may be that simply enrolling in the study, with or without the BP monitor, may have been a factor in some participants being able to lower their BP and achieve BP control.

The high percentage of uninsured participants bears implication on interpretation of the study results. Lack of insurance has been shown to be associated with lower rates of BP control, owing in part to decreased regular access to BP medications or lower access to BP monitoring. Prior studies have demonstrated less use of a BP monitor in lower income groups, providing evidence that the cost of the monitor may be a meaningful barrier to use. Through our study design, participants had access to a BP monitor, but facilitated access to other resources related to BP management, such as behavioral counseling above and beyond what is provided by the clinic staff or reduced cost medications, was not provided. Therefore, in this patient population with a high prevalence of being uninsured, supplying the BP monitor itself may not be sufficient to produce the anticipated benefits in BP outcomes.

By enrolling those who are both uninsured and foreign born, we may have captured a population that is known to have additional barriers, such as reduced communication with their provider or restrictions in access to other health resources. Further, it has been suggested that Hispanics are less likely than whites or non-Hispanic blacks to benefit from community interventions targeting hypertension owing in part to barriers to access to care and treatment, dietary patterns, acculturation levels, and communication barriers. Thus, it may be that the dissemination of SBPM in this population should be accompanied by additional support services, which might include education, appropriate language support, and cultural tailoring for achieving BP control. This should be a topic of further study.

Few studies to date have explored patient-related patterns of home use and the optimal schedule for readings using a home monitor. We collected and evaluated home data to address...
this limitation in the current literature and found that those who were measuring their BP 2+ times/day versus <2 times/day were more likely to achieve BP control. However, our small sample size limits the conclusions that can be made from these results. Another interesting finding is that only one half of those who received monitors actually engaged in uploading information, even with the additional support provided through participation in this research study. In this current era of expanding the use of technology in medical care, much attention has been given to the idea of efficiently increasing provider reach to patients in between office visits through the remote uploading of patient information. Our study suggests that the practical realities of this strategy in populations, such as ours, should be carefully considered.

There are several strengths worth highlighting in our study design. The innovative use of the smartform to screen eligible patients and to randomize to treatment arms minimized bias on the part of the provider. To our knowledge, this is one of the first studies to use this mechanism. Further, the EHR enabled us to collect systematic, longitudinal data on all study participants, including detailed data on comorbidities, such as diabetes mellitus, CKD, and a detailed assessment of past history of cardiovascular disease through ICD-09 codes in the EHR rather than self-report. Finally, we leveraged existing electronic systems and relationships to maximize efficiency in study conduct, factors strongly indicated by national institutions for cardiovascular disease research.26

In terms of limitations, there may have been bias operating at the study site level. At the largest study site, the BP-related quality improvements described above were being implemented, which may have influenced the control group. A second limitation was that medication data for our largest study site was irretrievable. Therefore, any behaviors related to medication intensification by the providers or whether the medication intensification had an effect on the results were not assessed. Third, we were unable to assess whether participants understood their readings or incorporated self-monitoring into their daily routines. Although we assessed this in the focus groups and embedded a question on BP readings in the EHR, both modalities yielded low compliance and are thus not reported on in the present article. Fourth, any potential differences in the frequency of BP measurements between the intervention and control groups could have led to differing probabilities of control by chance alone; however, this seems to have had a minimal effect to current results. Finally, the small sample size of whites in this study limit the conclusions that can be made in this race/ethnic subgroup, in addition to the significantly higher baseline systolic BP in whites in the intervention versus control group.

The SBPM intervention was not found to be impactful on lowering BP beyond usual care in this study population composed primarily of Hispanics, foreign born individuals, and those who lacked insurance, as has been observed in predominantly white populations. Although SBPM may be effective in some populations, it did not seem to have a meaningful effect under the conditions of the current study. In settings where several quality improvement activities are occurring, any improvements that may be observed by the provision of a BP monitor by itself (ie, low-level intervention) may not be observable. We view these results as a starting point for expanding current strategies on BP control in specific subgroups, as an example of collaborative applied clinical research and as a model for efficient study design and methods using the EHR.

Acknowledgments

We thank Kimberly Rasch, Rachel Abramczyk, Molly Jung, Seth Guthartz, Gail Goldstein, Mehul Dalal, and Gita Chhabra for their support throughout the development of this project, data collection, and in preparing the contents of this article. We thank eClinicalWorks for donating their time to help build the study’s smartform.

Sources of Funding

This study was made possible by funding from the Robert Wood Johnson Foundation and Finding Answers: Disparities Research for Change and New York City tax levy dollars. This funding was administered by the Fund for Public Health in New York, a private nonprofit organization that supports innovative initiatives of the New York City Department of Health and Mental Hygiene. The contents of this article are solely the responsibility of the authors and do not necessarily represent the official view of the funders. The New York University Center for the Study of Asian American Health is supported by the National Institute of Health/National Institute on Minority Health and Health Disparities cooperative agreement number 2P60MD000538-10.

Disclosures

None.

References

Self-Blood Pressure Monitoring in an Urban, Ethnically Diverse Population: A Randomized Clinical Trial Utilizing the Electronic Health Record
Stella S. Yi, Bahman P. Tabaei, Sonia Y. Angell, Anne Rapin, Michael D. Buck, William G. Pagano, Frank J. Maselli, Alvaro Simmons and Shadi Chamany

Circ Cardiovasc Qual Outcomes. 2015;8:138-145; originally published online March 3, 2015; doi: 10.1161/CIRCOUTCOMES.114.000950
Circulation: Cardiovascular Quality and Outcomes is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2015 American Heart Association, Inc. All rights reserved.
Print ISSN: 1941-7705. Online ISSN: 1941-7713

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circoutcomes.ahajournals.org/content/8/2/138

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation: Cardiovascular Quality and Outcomes can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation: Cardiovascular Quality and Outcomes is online at:
http://circoutcomes.ahajournals.org//subscriptions/