

ORIGINAL PAPER

A texting-based blood pressure surveillance intervention

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Abstract

The authors examined whether using home BP measurements collected via a custom-built bi-directional-texting platform incorporated into patients' electronic medical records would lead to treatment calibration and improved BP management. Patients were randomized to either the intervention group and collected home measurements based on reminders and reported via bi-directional texting, or to the control group, with home BP measurement reporting via standard practice (eg, phone, electronic medical record portal) and instructed to return 7 morning and 7 evening BP measurements. Outcomes included number of BP measurements submitted, the number of medication changes, reduction in BP, and BP control. 72% of the intervention group submitted at least 14 readings, compared with 45% of the control group. BP control improved in both groups. However, the authors found no statistically significant difference in BP or the number of BP-medication changes at 1, 3, or 6 months compared with the control group.

1 | INTRODUCTION

Having patients take their own BP at home can facilitate the timely diagnosis and appropriate management of HTN by reducing diagnostic uncertainty.¹ In fact, home BP measurements are at least as

reproducible as clinic readings.² Home measurements are a better indicator of stroke and cardiovascular mortality than clinic measurements³⁻⁵ and are also more closely correlated with end-organ damage from HTN than clinic measurements.^{6,7} The availability of home BP measurements may also help physicians overcome barriers related to clinical inertia, where HTN remains untreated even in the face of repeated elevated measurements.⁸

Previous Presentations: This work has not been previously presented in whole or in part.

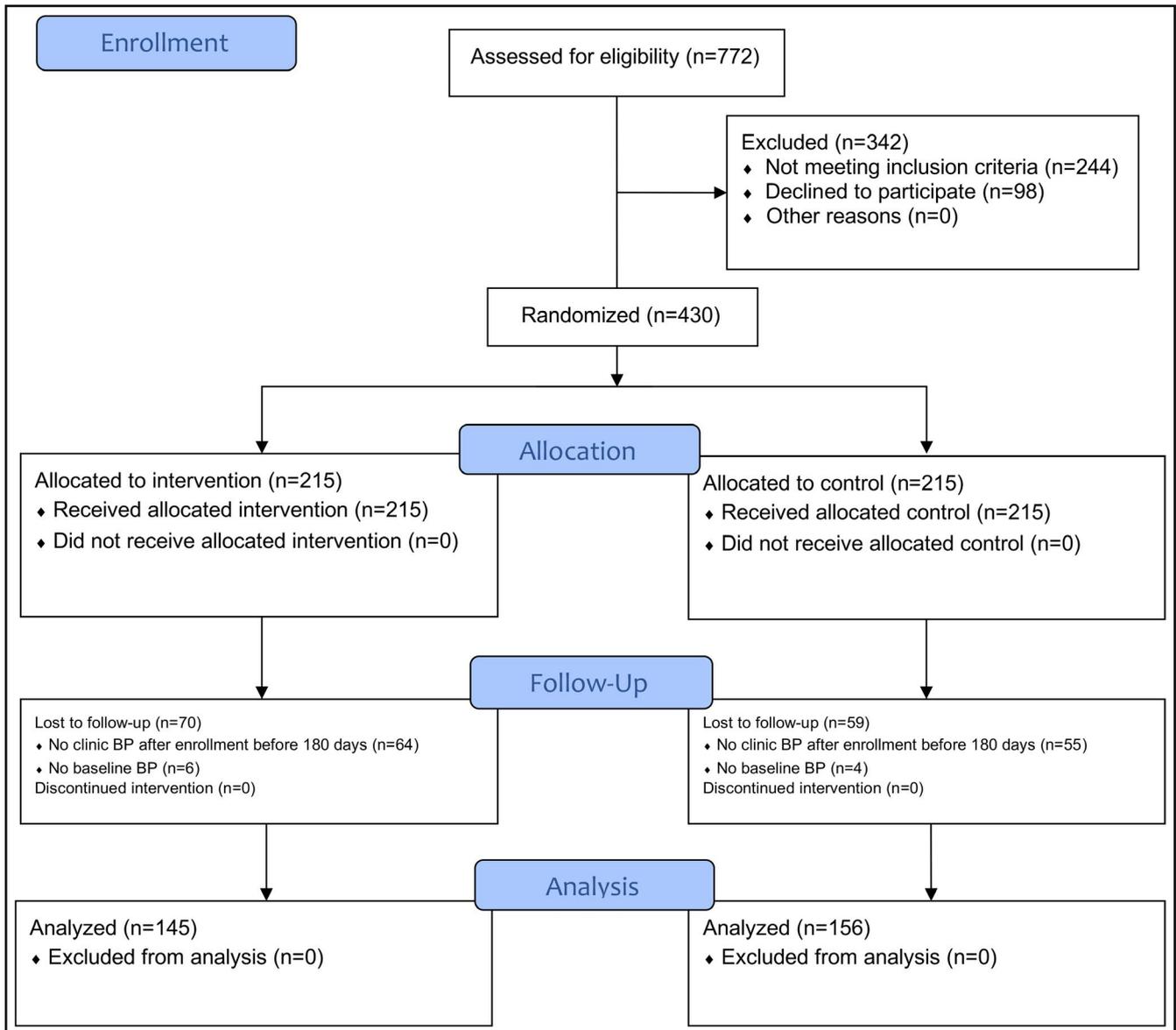


FIGURE 1 CONSORT 2010 flow diagram

Patients' self-monitoring of BP is cost-effective and well-tolerated.⁹ However, using home BP measurements requires careful follow-up on the part of both patients and health care providers. Patients must take, record, and communicate their BP measurements, either on paper or, more recently, through web-based interfaces, either of which may present significant challenges for the elderly or medically underserved populations. Thus, there is a critical need for an easier and more reliable means to accurately record and communicate home BP measurements between patients and health care providers.

To facilitate HTN diagnosis and treatment, we developed an m-health solution, a custom-built bi-directional SMS-based (short message service or texting) platform. In previous work, we have shown that bi-directional texting is effective for collecting home BP measurements.¹⁰ In this study, we examined whether using the home BP measurements collected via bi-directional texting and subsequently

incorporated into patients' electronic medical records would lead to treatment calibration and improved BP management.

2 | METHODS

2.1 | Data collection

This study was a two-armed randomized controlled trial. Patients were recruited from the University of Iowa Internal Medicine Clinic between December 10, 2015, and August 23, 2016; data collection was completed on July 31, 2017. We approached patients with a previous clinic BP reading of >140 mm Hg (SBP) or >90 mm Hg (DBP) recorded in their electronic medical record during the previous 6 months. Exclusion criteria were as follows: lack of a cellphone with text-messaging ability, unwillingness to send BP measurements via text, active or acute mental health problem,

significant cognitive impairment, lack of fluency in speaking or understanding English, and pregnancy. Patients signed consent forms and were enrolled in private clinic rooms. Patients were randomized by choosing one of two envelopes, with group assignment obscured. Half were randomized to the intervention group, who collected home measurements based on reminders and reported via bi-directional texting, with the remaining half randomized to the control group, with home BP measurement reporting via MyChart (an Internet-based web-portal connected to the patient's electronic medical record), mail, phone, or fax. Patients in both groups were provided a home BP monitor (Omron Upper-Arm BP Monitor, Series 5) and were shown how to use it. All were asked to return the BP cuff at the end of the study and were compensated \$20 when the cuff was returned. This study was approved by the University of Iowa Institutional Review Board (#201509761). A CONSORT diagram for this study is shown in Figure 1.

2.1.1 | Power analysis

Our primary outcome was the difference in the changes in SBP over 6 months. A randomized trial of a pharmacist-delivered intervention suggests a 12-month reduction in SBP between the intervention group, and usual care is approximately 5.7 mm Hg with a standard deviation of approximately 18 mm Hg.¹¹ Based on these values, to have 80% power at 95% confidence for a two-sample t test, we would need 157 participants per group. Because our study is comparing BP at 6 months and not 12 months, we increased this number by 10% to account for a potentially smaller change in BP during the shorter interval and by an additional 20% to account for dropout and loss to follow-up. These adjustments indicated approximately 430 participants would be required.

2.1.2 | Data collection for texting group

A research assistant recorded the patient's cell phone number through the bi-directional-texting administrative interface. Patients selected 7 morning and 7 evening times that were convenient for them to measure and send BP measurements. We chose this number because the literature recommends that 12-14 home measurements, with morning and evening readings, may be needed before making a diagnosis of hypertension.¹²

After the patient left the clinic, at the pre-specified times and dates, the bi-directional-texting system sent the patient a text message with specific instructions such as "Please remember to check your BP this morning at 7AM! Reply to this message with your BP and time it was taken." The patient returned a short text with his/her BP measurements and the time they were taken: for example, "150/90 and 145/88 7AM" If the patient did not respond to 7 morning and 7 evening BP requests, reminders were sent to the patient until 2 weeks elapsed. Once the pre-specified number of measurements (seven days' worth of measurements) were received or 2 weeks had elapsed, a summary document was generated with BP measurements and sent to the patient's physician.

2.1.3 | Data collection for the control group

Patients randomized to the control group were also instructed to return 7 morning and 7 evening BP measurements. They were asked to choose a method for returning BP measurements. Methods included entering their BP measurement in MyChart, calling the clinic, mailing, or faxing their BP measurements to their physician.

2.1.4 | Data collection from the electronic medical record

We obtained the following information from the patient's medical record at baseline: latest BP measurements, BP medications, latest cholesterol measurements, cholesterol medications, latest glucose measurement, other chronic medical conditions, other medications, insurance, race, age, gender, marital status, height, and weight.

Medical records were also accessed 6 months after enrollment to identify any change in medical management that occurred after sending BP readings. Time and type of interventions were recorded, including adding a new medication or increasing a current medication dose. Also, BP readings during the subsequent clinic visits (3-6 months after enrollment) were recorded. Outcomes included number of readings reported (ideally 14), morning readings (ideally 7), evening readings (ideally 7), changes in SBP/DBP at 6 months (closest visit until 180 days from enrollment, ≤ 180 days), number of changes to medications (until 180 days from enrollment), and percentage with controlled BP at baseline and 6 months, where control is defined as in JNC-7 as SBP >140 mm Hg or DBP >90 mm Hg.¹³

2.2 | Statistical analysis

2.2.1 | Number of BP readings collected

The number of readings was aggregated by patient. We used the percentage of total potential readings to compare the propensity to report any readings, at least 14 readings, at least seven readings in the morning, at least seven readings in the evening, and at least seven readings in the morning *and* at least seven readings in the evening. We also compared the percentage of patients who returned readings by each of the different methods. We compared the propensity to report the readings using a Pearson chi-squared test.

2.2.2 | Number of medication changes

The number of medication changes for each patient between enrollment and 180 days after enrollment was counted. The addition of a new medication, discontinuation of a medication, or change in dose of a medication all are considered to be a medication change event. Note, switching between two drugs of the same class counted as two events—a discontinuation and a starting event both occurred. We

Variable	Intervention (n = 215)	Control (n = 215)	P-value
Age	56.5 (13.0)	64.1 (11.6)	<.001
Female	118 (54.9%)	125 (58.1%)	.496
White Race	191 (90.5%) [4]	192 (91.4%) [5]	.745
Married	134 (66.0%) [6]	129 (61.7%) [12]	.365
Publicly insured	67 (31.2%)	95 (44.2%)	.006
BMI	32.9 (8.7) [6]	31.4 (7.2) [1]	.062
Time to "6-month" visit (days)	134.4 (58.0) [37]	133.3 (44.5) [43]	.843
Days between trigger BP and enrollment	46.0 (58.7) [12]	48.9 (56.4) [19]	.624
SBP at trigger	150.3 (8.6) [20]	151.8 (9.6) [12]	.106
DBP at trigger	86.5 (9.5) [20]	86.7 (9.1) [12]	.772
SBP at baseline	138.9 (15.8) [4]	142.3 (16.3) [8]	.030
DBP at baseline	84.0 (9.2) [4]	84.1 (11.5) [8]	.986
Percent controlled at baseline	101 (48.8%) [4]	88 (41.7%) [8]	.146

TABLE 1 Baseline characteristics by study group. Values are mean (SD) or count (%) as appropriate. The number included in [] is the number of patients with missing observations; it is omitted when the value is zero

compared the mean number of medication changes and the mean number of medication changes among patients with any change between the two groups using two-sample *t* tests. We compared the percentage of patients with any change between the arms using a chi-squared test.

2.2.3 | BP measurement

We computed the change in BP for each patient between the initial baseline visit and the visit closest to 180 days and compared whether the change in BP was greater in the intervention group compared with the controls using a two-sample *t* test. Because of the wide range of times of visits labeled as "6 months" in our data, we conducted a sub-group analysis using only visits between 150 and 180 days after enrollment.

3 | RESULTS

A total of 430 patients were recruited. At baseline, the two groups were similar, except for a difference in age and payer type, Table 1. Controls were, on average, 7.6 years older than those in the intervention group, a difference that was statistically significant (95% CI for the mean age difference between the intervention group and the controls: 5.2-9.9 years). Consequentially, the rates of public insurance were different ($P = .006$) due to the larger utilization of Medicare among the controls. For other factors (sex, race, marital status, BMI), the intervention and control groups were similar. The mean SBP and DBP measurements taken from the electronic medical record that determined eligibility did not differ significantly between the intervention and control groups ($P = .11$ and 0.77 , respectively). The mean number of days from the triggering reading to enrollment was also similar ($P = .62$). At enrollment, mean systolic BP was slightly higher (142.3 vs 138.9) in controls

TABLE 2 The number and percent of the sample reporting at least one reading, at least 14 readings, at least seven readings in the morning, at least seven readings in the afternoon, and at least seven readings in each the morning and afternoon

Outcome	Intervention number (%)	Control number (%)	P-value
Any readings	204 (94.9)	112 (52.1)	<.0001
14+ readings	155 (72.1)	97 (45.1)	<.0001
7+ in the AM	148 (68.8)	91 (42.3)	<.0001
7+ in the PM	168 (78.1)	84 (39.1)	<.0001
7+ in the AM and 7+ in the PM	121 (56.3)	73 (34.0)	<.0001

($P = .03$) but there was no statistically significant difference in mean DBPs ($P = .97$) or rates of BP control ($P = .15$). The mean time until the "6-month" visit did not significantly differ between the groups ($P = .84$).

3.1 | Number of BP readings collected

Patients randomized to report readings using text messaging were much more likely to report the requested measurements (see Table 2). The intervention patients were much more likely to report at least one home BP reading (94.9% vs 52.1%, $P < .0001$). Additionally, they were more likely to report 14 or more readings (72.1% vs 45.1%), the requested 7+ readings in the morning (68.8% vs 42.3%), evening (78.1% vs 39.1%), and 7+ in both the morning and evening (56.5% vs 34.0%) (with all P -values <.0001). Among the control group, 118 (55%) elected to return their BP measurements via MyChart, 50 (23%) via US mail, 44 (20%) via telephone, and 3 (1%) via fax. About half of each group returned BP measurements (see Table 3), and there were no statistically significant differences among the groups ($P = .21$).

TABLE 3 The number and percentage of control patients who returned BP measurements by return method chosen

Return method (chosen by patient)	Total number of patients	Number (%) of patients who returned BP measurements	Number of patients who did not return BP measurements
MyChart	118	63 (54)	50
US Mail	50	26 (52)	24
Telephone	44	20 (45)	24
Fax	3	3 (100)	0
Total	215	112 (52)	103

3.2 | Number of medication changes

The summary of medication changes is in Table 4. The mean number of changes was 1.46 (95% CI 1.21-1.70) in the intervention group and 1.53 (95% CI 1.28-1.77) among the controls. Differences between these means were not statistically significant ($P = .69$). After conditioning on having at least one change, there was also no statistically significant difference in the sub-group means ($P = .37$). Finally, the proportion of patients within each group with at least one change did not differ between the two arms of the study ($P = .69$).

3.3 | BP measurement

Average BP readings that triggered enrollment at baseline and 6 months are shown in Figure 2. The average BP readings at baseline and six months, as well as the results of the hypothesis tests, are shown in Table 5. There was no significant difference between the mean readings at baseline and 6 months for SBP ($P = .66$) or DBP ($P = .85$). As our model defines the "6-month" measurement as the measurement taken the greatest number of days after enrollment with a maximum of 180, the actual timing of the measurement was variable (range 0-180, mean of 124.0 days from enrollment). Restricting the definition of "6 months" to the range 150-180 days did not alter the results, showing no differential change in means between the groups for SBP ($P = .41$) or DBP ($P = .37$). Considering only patients who were not controlled at baseline also reveals no effect for SBP ($P = .56$) or DBP ($P = .42$) 150-180 days later. BP control at six months also did not differ between the intervention and control groups: 89 (60.1%) of the participants assigned to the intervention group had controlled BP compared with 97 (62.2%) of the controls (62 intervention and 55 control participants lacked a 180-day BP).

TABLE 4 Number of medication changes

Outcome	Intervention	Control	P-value
Mean number of medication changes (SD)	1.46 (1.81)	1.53 (1.81)	.690
Mean number of medication changes, conditional on having at least 1 change (SD)	2.39 (1.77)	2.58 (1.68)	.370
Number of patients with a medication change (%)	131 (60.6%)	127 (59.1%)	.694

4 | DISCUSSION

Our bi-directional texting intervention was successful in terms of collecting home BP measurements compared with the control group: 95% of patients in the intervention group returned at least one BP measurement, compared with only 52% of patients in the control group. In addition, 72% of the intervention group submitted at least 14 readings, compared with only 45% of the control group. However, we found no evidence of increased BP-medication changes or improved BP management in the intervention group. Specifically, we found no statistically significant difference in the mean number of BP-medication changes at 1, 3, or 6 months compared with the control group nor did we detect any statistically significant difference in BP management.

Although we did not observe a difference in BP control between groups, BP improved for patients in both the control group and the intervention group, and these changes were clinically significant. SBP among the intervention group was reduced from a mean of 150 mg Hg systolic that made them eligible for the study, to a mean of 136 mg Hg taken from the electronic medical record 6 months later. For the control group, SBP was reduced from a mean of 152 mg Hg that determined eligibility to 135 mg Hg at 6 months. These findings suggest that self-measurement of BP alone may be sufficient to activate patients to change behavior and possibly seek additional care from their physician.

There are at least three potential reasons the control group experienced an improvement in BP. First, the control group was not truly standard of care. Patients randomized to the control group were enrolled in a BP study and signed the same consent form prior to randomization. As a result, this process may have helped patients understand the importance of BP control, monitoring, and treatment and resulted in behavior change. Second, both intervention

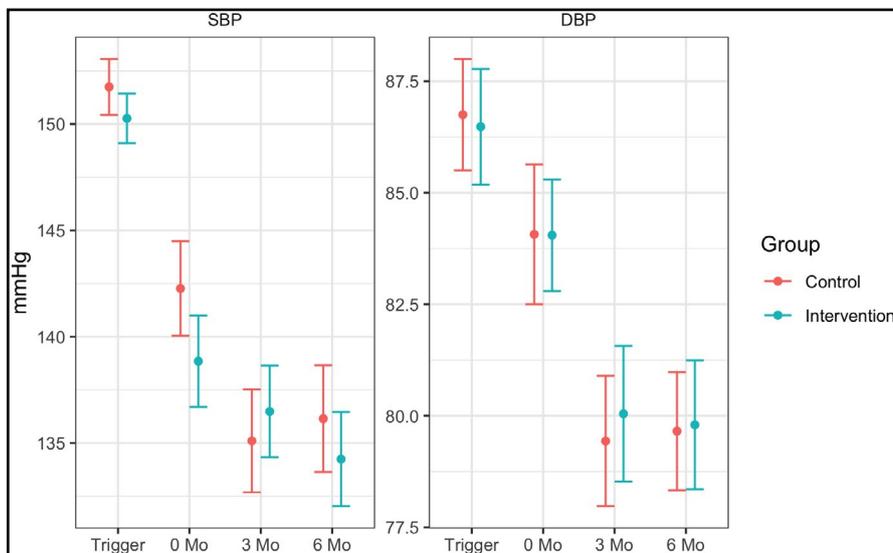


FIGURE 2 BP for the intervention and control groups over time. Dots are means, and the bars represent 95% confidence intervals. Notice that BP was reduced for both groups during the study period, but there was no difference between the groups

Outcome	Group	Nearest to 180 days	150-180 days	Uncontrolled at baseline, 150-180 days
Number of patients	Intervention	145	58	26
	Control	156	50	27
SBP at baseline	Intervention	139.2 (1.3)	137.3 (2.1)	151.8 (2.2)
	Control	142.2 (1.3)	139.6 (2.2)	150.6 (1.8)
DBP at baseline	Intervention	84.3 (0.8)	82.8 (1.2)	86.9 (2.0)
	Control	83.9 (0.9)	82.2 (1.9)	87.0 (1.6)
SBP at 180 days	Intervention	134.5 (1.4)	133.5 (2.4)	137.6 (4.0)
	Control	136.5 (1.5)	139.5 (3.0)	140.0 (4.7)
DBP at 180 days	Intervention	80.0 (0.9)	79.2 (1.2)	77.6 (1.9)
	Control	79.8 (0.8)	80.8 (1.3)	80.0 (2.0)
P-value	SBP	.658	.411	.56
	DBP	.851	.366	.424

TABLE 5 Mean BP at baseline and 6-months for patients with final BP measurements. Value in the parenthesis is the standard error of the mean. Notice that the results do not depend on the sample

and control patients received a home BP monitor with instructions on how to measure their BP, further highlighting the importance of BP control. In fact, 42% of patients in the control group returned the requisite number of BP measurements, and 52% sent at least one measurement. From anecdotal reports, this appears to be a large increase over standard of practice (although there is no way to establish such a baseline retrospectively). Finally, simply conducting this study likely affected clinic physicians by increasing the emphasis on BP. Because physicians had patients in both arms of the study, they may well have paid more attention to BP in patients assigned to both the control and intervention groups. In support of this informal hypothesis, we observed that patients in both groups had similar numbers of visits after enrollment: 3.7 in the control group and 3.8 in the intervention group. Also, most patients had BP medication changes during the study period. However, we cannot determine whether these numbers are different from historical levels of patient visits and medication changes.

Home-measured BP may have led to improvements in both groups. Home BP readings to supplement clinic readings may help overcome clinical inertia.⁸ McManus and colleagues (2005) found that home self-monitoring itself reduced systolic BP for 6 months by 4.3 mm Hg,⁹ and these results are similar to ours. There have been many previous SMS- or telehealth-based hypertension studies, but most have used a team-based approach including a nurse or pharmacist. Team-based interventions have been successful,¹⁴⁻¹⁶ but non-team-based interventions have had mixed results. For example, in a study of hypertension and telehealth by Green and colleagues (2008), there were three groups: usual care, home BP with a dedicated website, and home BP with a dedicated website and pharmacist intervention. The resulting increase BP control in the first two groups was similar (31% vs. 36%), but in the pharmacist group, BP control increased by 56%.¹⁷ In our intervention group, BP control increased by 23%, which is lower than that of Greene's telehealth-only group. The closest study to ours was Carrasco and colleagues

(2008), where patients were instructed to text their BP measurements. However, providers had to login to a separate website to obtain the measurements. They found that systolic BP decreased by 15.5 mm Hg in the texting group versus 11.9 in the control group, but this difference was not statistically significant.¹⁸ Systolic BP in our study decreased a little more than in Carrasco, but our results, like theirs, were statistically insignificant.

Our results are subject to limitations. Beyond our control group not representing standard of care, our pragmatic approach did not require patients to return for a final research-related interview. Thus, we were limited to using only BP measurements from the patients' medical records. Accordingly, we did not get 6-month clinic-based BP measurements for many patients (only 64 patients in the intervention group and 60 patients in the control group had BP measurements recorded between 150 and 180 days after enrollment). Thus, by relying on usual care for follow-up, we effectively reduced our sample size and our ability to detect a difference in BP control. Additionally, the reports were returned soon after the patient's clinic visit, and most patients did not return to the clinic soon after the readings were recorded in the chart. So, the report may not have been at the forefront of the physician's mind when the patient returned for a follow-up appointment, and our 6 months of follow-up might not have been long enough to measure many medication changes. Also, although all patients had elevated BP, many were close to control. Future research should include only patients with uncontrolled BP on the baseline visit who require the most intense interventions. Finally, this study was conducted before the new AHA/ACC guidelines were published so providers were not as likely to focus on a goal BP <130/80 mm Hg.¹⁹ These lower BP goals will require additional strategies to achieve BP control.

Our bi-directional-texting intervention successfully collected BP measurements and sent them to the patients' physicians. BP reduction occurred for both the intervention and control groups during the study period. However, BP was not reduced more for the intervention group, nor were they more likely to be controlled or have medication changes than the control group. Thus, even minimal interventions—loaning patients' home BP monitors and instructing them to return their measurements—may improve BP control.

CONFLICTS OF INTEREST

All authors report no conflicts.

AUTHOR CONTRIBUTIONS

All authors have approved the final version of the manuscript and are accountable for all aspects of the work. Specifically, Roula Zahr helped acquire the data for this study and helped draft and revise the manuscript. Chris Anthony contributed to the design of the study and helped revise the manuscript. Philip Polgreen designed the study, helped acquire the data for the study, interpreted the data, and drafted and revised the manuscript. Jacob Simmering

analyzed and interpreted the data, and drafted and revised the manuscript. Christopher Goerdts contributed to the design of the study and helped revise the manuscript. Angela Hoth helped acquire the data for this study and helped revise the manuscript. Michelle Miller helped acquire the data for this study and helped revise the manuscript. Manish Suneja contributed to the design of the study, helped acquire the data for the study, and helped revise the manuscript. Alberto Segre contributed to the design of the study, helped acquire the data for the study, and helped revise the manuscript. Barry Carter contributed to the interpretation of the data and revised the manuscript. Joseph Cavanaugh contributed to the interpretation of the data and revised the manuscript. Linnea Polgreen contributed to the design of the study, analyzed and interpreted the data, and drafted and revised the manuscript.

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