

ORIGINAL RESEARCH

Empowering Low-Income Patients with Home Blood Pressure Monitors to Improve Hypertension Control

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Introduction: Effective management of hypertension (HTN) is a priority in primary care. With telehealth now considered a staple care delivery method, uninsured and low-income patients without home blood pressure (BP) monitors may need additional attention and resources to achieve successful HTN control.

Methods: This prospective study at an underserved community clinic assessed the impact of distributing free BP monitors on patients' HTN control and therapy adherence. Enrollees were randomized into 2 groups, both completing 4 primary care physician (PCP) visits over a 6-month study period. Intervention participants collected home BP readings to report to their PCP and comparison participants completed an equivalent number of visits without having home BP data available for their PCP to review. Both groups completed an initial and final Therapy Adherence Scale (TAS) questionnaire.

Results: 263 patients were invited and 200 participants (mean age 50, 60% female, 19% Black, 67% Hispanic) completed the study. Intervention and comparison subjects featured comparable initial BP levels and TAS scores. After adjusting for age, race, ethnicity, sex, presence of diabetes and therapy adherence, intervention participants experienced higher odds of controlled HTN (OR 4.0; 95% Confidence Interval 2.1 to 7.7). A greater proportion of participants achieved BP control in the intervention arm compared with the comparison arm (82% vs 54% of participants, $P < .001$). TAS scores were higher in the intervention group (Mean = 44.1 vs 41.1; $P < .001$).

Discussion: The provision of free home BP monitors to low-income patients may feasibly and effectively improve BP control and therapy adherence. (J Am Board Fam Med 2024;37:187–195.)

Keywords: Blood Pressure, Hypertension, Minority Health, Patient Adherence, Primary Health Care, Prospective Studies, Surveys and Questionnaires, Telemedicine, Vulnerable Populations

Introduction

As hypertension (HTN) represents the commonest chronic condition seen in adult primary care practices, every touchpoint of patient interaction presents an opportunity to improve blood pressure (BP)

control and reduce cardiovascular disease risk.¹ Although the diagnostic threshold of HTN differs throughout guidelines, a BP of 140/90 mmHg or higher for adults ages 18 to 59 is universally considered uncontrolled.^{2,3} Low-income individuals are 3 times more likely to have poor BP control compared with the average American.⁴ As uncontrolled HTN increases the risk of heart disease, kidney disease, stroke, and cognitive decline, BP management is one of the most important roles of primary care physicians (PCPs).

Since the onset of the COVID-19 pandemic, family physicians have been challenged by the goal of safely and effectively managing patients' chronic medical conditions. Although telephone and video communication are widely available to conduct primary care visits, successful virtual care remains

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limited by availability of objective data such as vital signs. With telehealth persisting as a staple modality of delivering care, more physicians rely on home BP monitoring (HBPM) to manage patients' HTN.⁵ Atop considerable other health inequities, home ownership of BP machines is an economic barrier for low-income and medically underserved patients at community health centers throughout the nation. Furthermore, receiving care at a publicly funded primary care clinic is associated with lower medication adherence.⁶ Another notable consideration for patients of safety-net health care systems is higher clinical inertia – whereby limited access to clinicians results in suboptimal dosage intensification.⁷

At the time of writing, limited studies have assessed the role of virtual BP management on therapy adherence and BP control within low-income and other medically underserved people. One small study used a multidisciplinary team of specialists and pharmacists to intensively manage 31 patients using a similar design.⁸ Those patients were older than 65 and a small fraction of participants were enrolled from a community health clinic environment.

Literature on the effects of HBPM on HTN control have shown mixed results. In one review, HBPM was associated with a moderate increase in achieving BP targets when patients were permitted to self-titrate medication dosages and were provided counseling, education, and adherence contracts.⁹

In a review of telemedicine interventions on chronic conditions, a significant and clinically meaningful impact on BP levels was not observed.¹⁰ In patients with high engagement and health literacy, virtual primary care visits were preferred by patients and led to better BP control.¹¹ HBPM has not been widely used or studied in medically underserved settings due to device costs. Physicians are more likely to recommend HBPM to patients who have insurance, high health literacy and high therapy engagement levels.¹²

Two factors have been theorized to contribute the most to HTN control – clinician prescription of an adequate number and dosage of antihypertensive medications and patient adherence with therapy recommendations.^{13,14} This campaign evaluated the benefit of providing free BP monitors to low-income, primarily Hispanic, patients with uncontrolled HTN. The study's 2 hypotheses were (1) subjects in the intervention group with access to home BP readings will achieve control in greater proportion than patients in a

comparison group and (2) intervention group participants will achieve better therapy adherence as measured by a validated tool.

Methods

This study was conducted at an urban, underserved community health center which serves as the continuity clinic for a family medicine residency program. Eight attending physicians and 22 resident physicians were briefed on the use of a standardized protocol. Four faculty and 6 resident physicians elected to participate in this study. Patients were screened for enrollment as they presented to the clinic for regularly scheduled primary care visits. Two hundred BP monitors were purchased through philanthropic grant funding.

Subject Enrollment

Participants were offered inclusion into the study if they were ages 18 to 59 with uncontrolled HTN – defined as a SBP >140 or DBP >90 mmHg during the current, in-office PCP visit with a known history of HTN. For patients that consented to enrollment, that initial PCP visit was considered their first study visit. The upper age limit served to ensure a consistent BP target across various clinical guidelines. Patients with obesity, diabetes and chronic kidney disease were included. Patients were excluded if they were pregnant, homeless, incarcerated, had uncontrolled psychiatric illness, had a stroke in the past 30 days, or were on dialysis.

Enrollees' preferred languages were English or Spanish. Participants received care through a county-funded financial assistance program for low-income, uninsured, and medically underserved patients. Enrollees' household incomes were generally below 150% of the Federal Poverty Level. Due to cost barriers, nearly all patients at the study site did not own a home BP monitor machine.

Description of the Intervention

Two hundred participants were randomized into an intervention group (n = 100) and a comparison group (n = 100). Randomization occurred at the time of enrollment into the study based on whether the last digit of the patient's medical record number was odd or even. Subjects in both groups completed a total of 4 PCP visits addressing HTN within a study period of 6 months. For all participants, the

first and fourth visits occurred in-office whereas the second and third visits were conducted virtually with the patient at home. In accordance with similar studies, a 35-day grace period was available to all participants to accommodate study completion barriers such as access to care, reliable transportation, time off work and the global pandemic.¹⁵

During the initial visit, participants in both groups signed a written informed consent form, completed a preintervention therapy adherence scale (TAS) survey, and recorded an initial in-office BP reading (Table 1). To maximize consistency, BP data utilized for statistical analysis were collected in-office by a trained medical assistant. Patients were counseled on accurate data collection methods for their home readings. Patients were not observed collecting their own readings.

For all participants, the second and third PCP visits were conducted virtually. In the fourth visit, approximately 6 months after the initial visit, patients completed a postintervention TAS survey and recorded a final, in-office BP reading as the postintervention outcome variable.

Participants in the intervention group received a free BP monitor during their initial PCP visit and were instructed to record 4 BP measurements weekly—2 morning readings and 2 evening readings. Patients in the intervention group reported

these 4 BP readings to their physician during their second and third PCP visits. Comparison group members received the usual standard of virtual care during their second and third visits, which may have included assessing for symptoms of end organ damage as a proxy for BP readings. Physicians were not blinded to participants' group membership as intervention group subjects revealed their home BP readings to their provider as part of the intervention. Comparison group patients received a free BP monitor after their study period.

Participants in both groups were encouraged to follow standard pharmacologic and nonpharmacologic recommendations such as reducing salt intake and attending follow-up appointments. Treatment and management of patients in either group did not differ in any proscribed way. Providers followed evidence-based treatment algorithms for subjects in both groups using low-cost, single daily dose, guideline-recommended medications, prescribed with a 90-day supply. Study providers were asked to apply consistent clinical decision making and follow-up appointment scheduling for all participants. Members of both groups received informational handouts regarding the consequences of uncontrolled HTN and nonpharmacologic strategies to lower blood pressure.

Table 1. Therapy Adherence Scale (TAS) Questions

Scoring:

1. All of the Time
2. Most of the Time
3. Some of the Time
4. None of the Time

Dietary Compliance

1. How often do you eat salty food?
2. How often do you shake salt on your food before you eat it?
3. How often do you eat fast food?

Appointment Keeping

4. How often do you make the next appointment before you leave the doctor's office?*
5. How often do you miss scheduled appointments?

Medication Adherence

6. How often do you forget to take your high blood pressure medicine?
7. How often do you skip your high blood pressure medicine before you go to the doctor?
8. How often do you forget to get prescriptions filled?
9. How often do you decide NOT to take your high blood pressure medicine?
10. How often do you run out of high blood pressure pills?
11. How often do you miss taking your high blood pressure pills when you feel better?
12. How often do you miss taking your high blood pressure pills when you feel sick?
13. How often do you take someone else's high blood pressure pills?
14. How often do you miss taking your high blood pressure pills when you are careless?

*Reverse coding.

As standard of care, comparison group participants were welcome—and even encouraged—to purchase a BP machine or check their BP at a public amenity at any time. If any patient elected this route, they were asked to notify their provider to discontinue participation in the study.

By inclusion, participants from both groups had initial BP levels in the uncontrolled range. This study's primary outcome was achievement of BP control defined as a final reading $\leq 140/90$ mmHg. This threshold is aligned with the national Health care Effectiveness Data and Information Set (HEDIS) benchmarks. Physicians in this study targeted a BP lower than 140/90 mmHg for all patients.

The secondary outcome was change in therapy adherence scale (TAS) score over a 6-month period for participants undergoing HBPM compared with subjects practicing the usual standards of care without BP data.

Acquisition of BP Monitors and BP Readings

BP monitors were purchased through community research grants. Home BP was self-measured in intervention group participants with a validated, automatic oscillometric device (Omron model 3-series, Omron Corp, Tokyo, Japan) according to the current guidelines.¹⁶ Intervention group members were provided with materials on obtaining accurate home BP readings.¹⁷

Participants in the intervention group were provided a written log to record their readings. Subjects in either group were permitted to check their BP at any time. As the availability of BP information was a variable being specifically evaluated in this study, participants in the usual care group were asked to report whether they elicited any BP data outside the study parameters. Although checking BP was not discouraged, those usual care participants would be excluded from data analysis.

Direct integration of BP measurements from the monitor into an electronic medical record (EMR) was not feasible in this study. A substantial number of participants do not own smartphones with requisite Bluetooth capabilities. In addition, the Omron 3-series monitor was selected due to low cost and simple usage. Validated BP monitors at the entry-level price range do not have EMR embedding features.

Therapy Adherence Scale Data

In the initial visit, participants from both groups completed a preintervention questionnaire about their baseline therapy adherence according to the

validated, 14-item Hill-Bone Compliance with High Blood Pressure Therapy scale.¹⁸ In this study, the compliance survey is referred to as the Therapy Adherence Scale (TAS).

The questionnaire consists of 14 items with 3 domains: (1) reducing sodium intake, (2) appointment keeping, and (3) medication taking, with each item rated on a 4-point Likert scale (1 = all the time, 2 = most of the time, 3 = some of the time, and 4 = none of the time). The score ranges from a minimum of 14 to 56 (maximum). The sodium domain consists of 2 items to assess dietary intake of salty foods; the appointment keeping domain consists of 3 items to assess appointments for doctor visits and prescription refills, and the medication-taking domain consists of 9 items to assess medication-taking behavior.

Although shorter medication adherence questionnaires, like the 4-item Morisky Green Levine Scale, have been studied, the selected TAS offers a comprehensive and multi-dimensional view of therapy adherence beyond pharmacologic adherence.¹⁹

Statistical Analysis

BP data utilized in our statistical analysis was collected in-office by a trained medical assistant following established principles of accurate data collection. The endpoints for each patient were defined as the in-office BP and TAS recorded on their last visit.

We initially examined the raw unadjusted changes in proportion of patients controlled and changes in SBP and DBP using standard 2-group comparisons (Chi-Squared test). As patients could be seen by different providers, it was not possible to account for individual provider effects.

To conduct an adjusted analysis, a multivariable logistic regression analysis was performed using BP control as a binary dependent variable and study arm, patient age, sex, race, ethnicity, and presence of diabetes as independent variables. We performed a second multivariate logistic regression analysis with study arm (intervention or comparison group) and baseline therapy adherence scales (dichotomized as low or high adherence) as predictors and postintervention therapy adherence (low or high adherence) as the outcome. Akin to other studies using the TAS, high adherence was defined as a score equal to or greater than the group mean score.²⁰

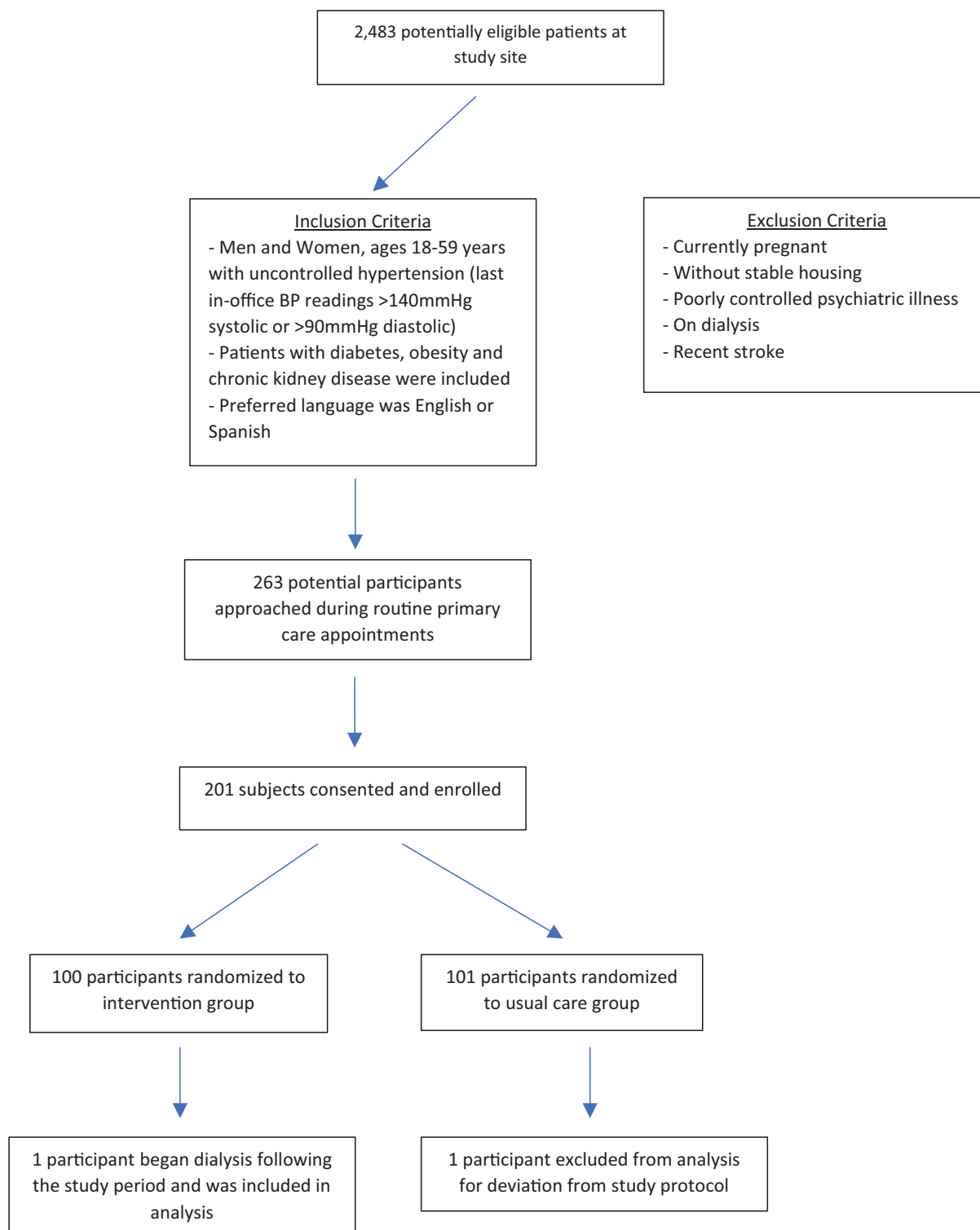
Data analysis was performed using SPSS, version 28. This study was approved by the Baylor College of Medicine IRB and passed administrative review by Harris Health System.

Results

Two hundred sixty-three patients that met inclusion criteria were approached to participate in the study (Figure 1). Two hundred one patients were

consented and enrolled between April 2021 to January 2023. The most often-cited reason for declining participation was uncertainty of ability to attend 4 appointments within the study period.

Figure 1. Participant enrollment. *Abbreviation:* BP, blood pressure.



One subject in the intervention group began dialysis shortly after completing their study period. As they did not meet exclusion criteria during the time of their participation, their data were included in the analysis.

One subject in the usual care group was excluded from the study after their initial visit as they reported collecting an out-of-office BP reading. Having only been consented without any follow-up visits or data collection, the participant was replaced and excluded from data analysis. No other participants in the comparison group reported obtaining extraneous BP readings outside the study parameters.

A total of 200 subjects successfully completed the study requirements of 4 appointments within the study period. At baseline, the intervention and comparison group featured highly similar demographic composition with comparable systolic and diastolic BP levels. [Table 2]

Change in status of BP “control” was the primary outcome. BP readings of all patients were uncontrolled in the baseline period. In the intervention group, systolic and diastolic blood pressure levels improved by 13.3% and 11.3%, respectively. In the usual care group, systolic and diastolic blood pressure levels improved by 9.1% and 6.8%, respectively. Stated another way, the proportion of patients with controlled hypertension was significantly higher in the intervention group than in the control group (82% vs 54% respectively, $P < .001$).

As a secondary outcome, changes to participants’ TAS scores were evaluated. The mean initial TAS in the intervention group was 38.7. After the intervention, the final TAS for this group was 42.6. After adjusting for baseline adherence, the adherence was significantly higher in the intervention

group than in the control group. Considering both outcomes together, improved therapy adherence was likely the main driver of increases in blood pressure control.

In the multivariable logistic regression analysis, adjusted for age, sex, race, ethnicity and presence of diabetes, the odds ratio of hypertension control in intervention versus control group was 4.0 (95% Confidence Interval 2.1 to 7.7, P value < 0.001). The value of Akaike Information Criterion (AIC) for the final model using BP control as a binary dependent variable and study arm, patient age, sex, race, ethnicity, and presence of diabetes as independent variables was 241.5.

Using a previously described approach, we created a binary variable describing “good adherence” as TAS scores above the mean and “poor adherence” referring to scores below the group mean.²⁰ A multivariate logistic regression analysis was performed with study group (intervention/comparison) and baseline adherence (dichotomized) as predictors and postintervention adherence (dichotomized) as the outcome. The odds ratio of good adherence in the intervention versus comparison group was 17.0 (95% Confidence Interval 8.1 to 35.7, P value < 0.001). [Table 3]

Although statistical trends were observed with changes to the dietary compliance and appointment keeping subscales, the medication adherence subscale showed greatest improvement as a result of the intervention.

Certain TAS items had little variance among subjects. For example, the item inquiring, “How often do you take someone else’s high blood pressure

Table 2. Baseline Characteristics of Participants (n = 200)

	Intervention	Usual Care
Age (mean, SD)	50.5 (± 7.5)	49.9 (± 7.6)
Female (%)	60	61
Systolic BP (mean, SD)	155 (± 16)	154 (± 13)
Diastolic BP (mean, SD)	87 (± 11)	87 (± 12)
Therapy Adherence Scale score, (mean, SD)	39.2 (6.6)	38.1 (7.0)
Black or African American (%)	18	20
Hispanic or Latino (%)	66	68
Comorbid Diabetes (%)	35	30

Abbreviation: SD, standard deviation.

Table 3. Post-Intervention Outcomes (n = 200)

	Intervention	Usual Care
Systolic BP lowering (%)	13.3	9.1
Diastolic BP lowering (%)	11.3	6.8
Initial Therapy Adherence Score (mean)	38.7	38.1
Final Therapy Adherence Score (mean)	44.1	41.1
BP became controlled ($< 140/90$) (%)	82	54
Odds ratio for BP control (intervention vs usual care)	4.0 (95% Confidence Interval 2.1 to 7.7)	
Odds ratio for good therapy adherence (intervention vs usual care)	17.0 (95% Confidence Interval 8.1 to 35.7)	

Abbreviation: BP, blood pressure.

pills?” was nearly universally recorded as “None of the time.” Similarly, very few patients admitted to shaking salt on their food. There was ambiguity amid many respondents regarding which restaurants qualify as “fast food.” Survey administrators were instructed to ask patients to use their best judgment.

Discussion

This campaign demonstrated a potential benefit to providing free BP monitors to medically underserved patients with uncontrolled HTN. A significantly greater proportion of subjects in the intervention group achieved BP control compared with the usual standards group. Our data support greater therapy adherence as the mechanism for this difference between groups. This mechanism is consistent with dozens of previous studies across various demographic cross-sections.

Notably, the extent to which adherence played a role in achieving BP control was greater in this study population—predominantly low-income, Hispanic and female—compared with data from practice settings with insured patients.^{21–23}

Several study clinicians reported patients remarked that they were previously motivated to check their home BP and simply did not have the financial bandwidth to procure a home monitor. Provision of a free device to individuals already interested in advancing their self-efficacy likely resulted in a large improvement to BP control.

Patients were more likely to be adherent with their medications in the intervention group. One proposed mechanism for this effect is that by measuring their blood pressure, patients were less likely to forget or skip their antihypertensive dose. Of the 3 subscales, Medication Adherence, was found to differ the greatest among the intervention and comparison group.

Tighter BP control was achieved at least in part due to better therapy adherence as determined by the compliance survey. BP reduction may have also been achieved through clinician titration of antihypertensive medications. Because physicians had access to BP measurements obtained throughout the week, physicians were comfortable with up-titrating medications with no adverse side effects. Effective care and control of BP cannot be achieved without patient medication adherence.²⁴ TAS scores are a reliable, valid, and cost-effective method to assess patient adherence.

For patients with insurance, physicians may consider prescribing a BP monitor. A 2020 joint policy

statement by the American Heart Association and American Medical Association reviewed insurance coverage and reimbursement for home BP devices.²⁵ Although there was significant variability in coverage of BP monitors for patients with commercial or government-sponsored insurance programs, prescription of BP monitors generally reduced patients’ out-of-pocket cost. Without insurance, the average cost of a validated BP device in the US from supermarkets or drug stores ranges from \$40 to \$100.²⁶

Limitations

As in any multi-component intervention, it is difficult to separate how much of intervention effect is attributable to enhanced patient engagement versus effective virtual primary care appointments. The study was not blinded, which could have influenced participants’ reporting of subjective therapy adherence scores. Reasons for poor medication adherence were not explored.

The confidence intervals for the 2 reported odds ratios are wide. The sample size of this study was limited by available funding to purchase BP monitors. Future iterations of this program aim to purchase 500 BP monitors.

Meta-analyses have demonstrated that, compared with usual care, the use of HBPM alone without cointerventions leads to modest reductions in systolic and diastolic BP at 6 months but no difference at 12 months.²⁷ Further studies should follow patients longitudinally to see if benefits are sustained beyond a period where patients know that they are being specifically monitored.

Conclusion

Telemonitoring and virtual care titration provide an alternative to seeing clinicians in person. This format is especially helpful when assisting medically underserved and lower-income patients. Although HBPM allows for a more practical and convenient way of controlling BP, factors such as cost, insurance coverage, operator training, and accuracy of readings continue to pose significant barriers. By empowering patients with free home BP monitors, clinicians can improve therapy adherence and achieve superior BP control.

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To see this article online, please go to: <http://jabfm.org/content/37/2/187.full>.

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