Effective Health Care Program

Comparative Effectiveness Review
Number 45

Self-Measured Blood Pressure Monitoring: Comparative Effectiveness

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting Comparative Effectiveness Reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealth care.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

We welcome comments on this CER. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Self-Measured Blood Pressure Monitoring: Comparative Effectiveness

Structured Abstract

Background. Hypertension often requires lifelong treatment. Self-measured blood pressure (SMBP) monitoring, the regular measurement of blood pressure (BP) by the patient at home, has been proposed as a means of improving treatment adherence and BP control.

Purpose. To systematically review the trial evidence on the comparative effectiveness of hypertension management with versus without SMBP monitoring, and of different additional support interventions with SMBP. To determine predictors of adherence with SMBP monitoring.

Data Sources. MEDLINE®, Cochrane Central Register of Controlled Trials, existing systematic and narrative reviews, recent conference proceedings, and the Food and Drug Administration.

Study Selection. To address comparative effectiveness, we included prospective comparative studies of SMBP with or without additional support versus usual care or an alternative SMBP intervention. We included studies that used arm (not wrist) monitors for at least 8 weeks and excluded studies of pregnant women or people on hemodialysis. We also included longitudinal cohort studies in addressing adherence predictors.

Data Extraction. Details on design, patients, interventions, outcomes, and quality were extracted into standard forms. We standardized extraction by training on multiple articles, after which each study was extracted by one methodologist and the extraction reviewed by at least one other.

Data Synthesis. In total, 49 studies met eligibility criteria. There were 24 comparisons of SMBP alone versus usual care, 24 of SMBP plus additional support versus usual care, 12 of SMBP plus additional support versus SMBP without additional support or with less intense additional support, and 1 study evaluating predictors of adherence to SMBP. No studies of SMBP monitoring in children were identified. For SMBP alone versus usual care, the strength of evidence is moderate and supports a lower BP with SMBP (SBP/DBP -3.1/-2.0 mmHg at 6 months). For SMBP plus additional support versus usual care, the strength of evidence is high and supports a lower BP with SMBP use (SBP/DBP -3.4 to -8.9/-1.9 to -4.4 mmHg) up to 12 months. For SMBP plus additional support versus SMBP alone or with less intense additional support, the strength of evidence is low, failing to support a difference in BP. For all comparisons, evidence for clinical outcomes was insufficient; for all other outcomes (surrogate and intermediate outcomes, and health care encounters) strength of evidence was low, thus failing to support a difference. No trials compared different SMBP devices or provided evidence on the relationship between BP control and clinical or surrogate outcomes. There is insufficient evidence concerning predictors of SMBP adherence.

Limitations. Very few trials evaluated objective clinical outcomes. The trials were greatly heterogeneous, varying in population, intervention, and outcome measures and definitions. Many studies were of moderate to poor quality and had short followup periods. No studies evaluated children.

Conclusions. SMBP with or without additional support may confer a small benefit in BP control compared with usual care, but the BP effect beyond 12 months and the attendant long-term clinical consequences remain unclear. Given clinical heterogeneity and limited head to head comparisons, the evidence limits our ability to draw definitive conclusions about the incremental effect of any specific additional support. Future research should standardize patient inclusion criteria, BP treatment targets for home BP, and SMBP and additional support protocols to maximize the interpretability and applicability of SMBP trials.

Contents

Tables

Figures

Appendixes

Executive Summary

Background

High blood pressure (BP), or hypertension, is a common, long-term health condition, particularly among older adults. Untreated or ineffectively treated hypertension leads to increased cardiovascular morbidity and mortality, and increased consumption of health care resources, thus levying high human and financial costs to society. In adults, hypertension is defined as a persistently elevated BP equal to or greater than 140/90 mmHg.[1] In children, the diagnosis is made from an average of three or more BP readings greater than the 95th percentile for age, sex, and height.[2,3] The Seventh Joint National Committee (JNC 7) guideline recommends a BP goal of 140/90 mmHg or less in the general population and a lower threshold of 130/80 mmHg or less in patients with diabetes mellitus or chronic kidney disease.[1]

The World Health Report 2002 estimates that over 1 billion people have high BP and that hypertension is responsible for 4.5 percent of the global disease burden.[4] Within the United States alone, about 76.4 million adults are affected.[5] Despite improvements in the quality of health care and life expectancy, it is expected that the prevalence of hypertension will continue to rise worldwide. The World Health Organization ranks high BP as the third highest risk factor for burden of disease, highlighting the contribution of hypertension directly and indirectly to the development of numerous diseases.[4] Hypertension has been identified as a major risk factor for cardiovascular disease,[6] and is an important modifiable risk factor for coronary artery disease, stroke, peripheral vascular disease, congestive heart failure, and chronic kidney disease.[1] High BP directly results in 7 million deaths every year.[7]

Effective management of BP has been shown to dramatically decrease the incidence of stroke, heart attack, and heart failure.[1,8-13] However, hypertension is usually a lifelong condition, and long-term adherence to lifestyle modification (such as smoking cessation, regular exercise, and weight loss) and medication treatment remains a challenge in the management of hypertension. Thus an increasing focus has been placed on developing strategies that can improve adherence and result in satisfactory BP control with the goal of improving health outcomes for hypertensive patients.

One such proposed method is self-measured blood pressure (SMBP) monitoring. SMBP refers to the regular self-measurement of a patient's BP at home or elsewhere outside the office or clinic setting. However, while patient self-participation in chronic disease management appears promising, the sustainability and clinical impact of this strategy remain uncertain. Also its impact on health care utilization is uncertain, since it may replace office visits for BP checks but may increase overall intensity of surveillance and treatment.

Objectives

The primary objective of this review is to evaluate whether the use of SMBP monitoring influences outcomes in adults and children with hypertension, and to what extent these changes in outcomes can be attributable to the use of self-monitoring devices alone or the use of SMBP plus additional support or attention. The intention of this report is to inform physicians' decisionmaking as to whether to encourage the use of SMBP monitoring alone or along with additional support, and to assist health care policymakers and payers with decisions regarding coverage and promotion of SMBP monitoring.

The topic nomination provided the general parameters (population, modes of treatment, alternative approaches, outcomes of interest, etc.) that defined the scope of this report. Using these parameters, Key Questions were developed to address the questions of interest. Five Key Questions are addressed in this report. Four pertain to the comparative effectiveness of using SMBP as part of a strategy of BP monitoring (Key Questions 1–4). The remaining Key Question concerns associations between baseline patient characteristics and adherence to SMBP (Key Question 5).

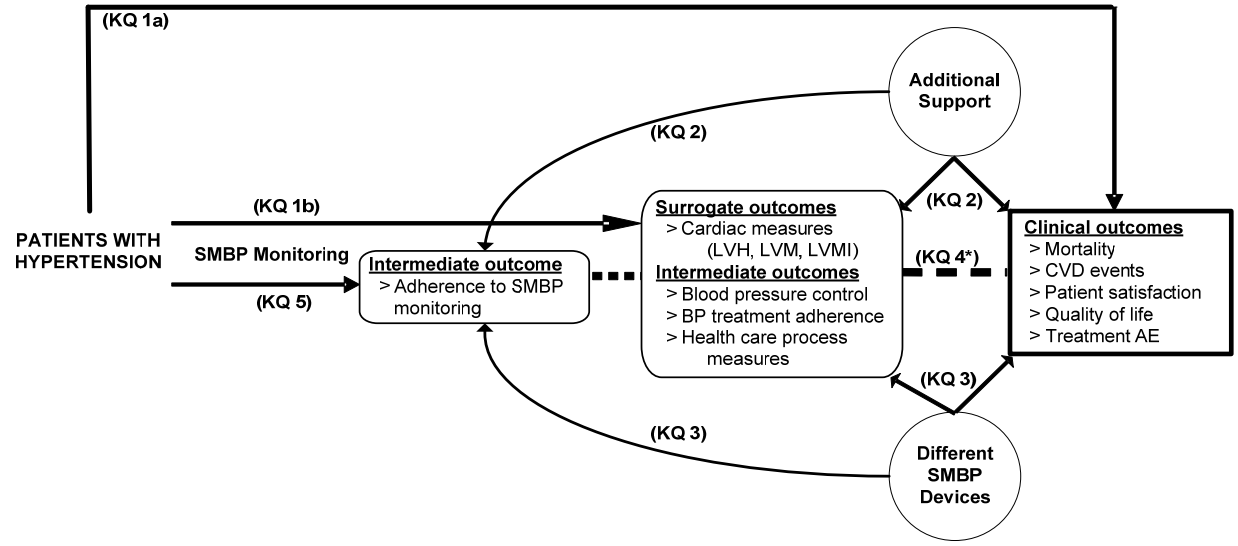
Key Questions

1. In people with hypertension (adults and children), does self-measured blood pressure (SMBP) monitoring, compared with usual care or other interventions without SMBP, have an effect on clinically important outcomes?
   a. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents)?
   b. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH [left ventricular hypertrophy], LVM [left ventricular mass], LVMI [left ventricular mass index]) and intermediate outcomes (blood pressure [BP] control, BP treatment adherence, or health care process measures)?
2. In trials of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?
3. How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic vs. manual) in their effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?
4. In trials of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?
5. How does adherence with SMBP monitoring vary by patient factors?

Analytic Framework

To guide the development of Key Questions, we generated an analytic framework (Figure A) that maps the specific linkages associating the populations and subgroups of interest, interventions (for both diagnosis and treatment), and outcomes of interest (intermediate outcomes, health-related outcomes, compliance, and adverse effects). Specifically, this analytic framework depicts the chain of logic that evidence must support to link interventions to improved health outcomes.

Figure A. Analytic framework for evaluation of SMBP monitoring



*Key Question 4 relates to the link between the intermediate outcome blood pressure control and either surrogate outcomes (cardiac measures) or clinical outcomes.
Note: AE = adverse event; BP = blood pressure; CVD = cardiovascular disease; KQ = Key Question; LVH = left ventricular hypertrophy; LVM = left ventricular mass; LVMI = left ventricular mass index; SMBP = self-measured BP.

Methods

Input From Stakeholders

During a topic refinement phase, the initial questions were refined with input from a panel of Key Informants. Key Informants included experts in hypertension, general internal medicine, pediatrics, and cardiology; representatives from both New York State and New York City Medicaid; and the Agency for Healthcare Research and Quality (AHRQ) Task Order Officer.

After a public review of the proposed Key Questions, the clinical experts from among the Key Informants were reconvened to form the Technical Expert Panel, which served to provide clinical and methodological expertise and comments that were considered to further refine Key Questions, identify important issues, and define parameters for the review of evidence, including study eligibility criteria.

Data Sources and Selection

We conducted literature searches of studies in MEDLINE® (from inception through July 19, 2011) and both the Cochrane Central Trials Registry® and Cochrane Database of Systematic Reviews®. All studies enrolling human subjects were screened to identify articles relevant to each Key Question. The search strategy included terms for self-measurement, home measurement, telemonitoring, self-care, and relevant research designs. The reference lists of related systematic reviews, selected narrative reviews, and primary articles were also reviewed, and relevant articles were screened. Following screening of abstracts, full-text articles were retrieved for all potentially relevant articles and rescreened for eligibility. A gray literature search of recent conference proceedings and of the Food and Drug Administration Web site was conducted for additional unpublished or non–peer-reviewed evidence.

For all Key Questions, we included all prospective comparative studies of SMBP versus any other intervention, including SMBP in adults or children already diagnosed with hypertension. We excluded studies of pregnant women or of patients on dialysis. We considered only arm (not wrist) SMBP monitors that were used for at least 8 weeks. For Key Question 5, we also included prospective or retrospective longitudinal studies that analyzed at least 100 adults or at least 10 children who used SMBP monitoring for at least 8 weeks.

Data Extraction and Quality Assessment

Study data were extracted into customized forms. Together with information on study design, patient and intervention characteristics, outcome definitions, and study results, the methodological quality of each study was rated from A (highest quality, least likely to have significant bias) to C (lowest quality, most likely to have significant bias).

Data Synthesis and Analysis

The Comparative Effectiveness Review from which this Executive Summary is derived is a systematic review of the published scientific literature using established methodologies outlined in the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews (www.effectivehealthcare.ahrq.gov). Evidence tables in the full report summarize study and baseline patient characteristics, detailed descriptions of the SMBP monitors and other interventions used, study quality, and relevant study results. For Key Questions 1 and 2, we graphed all the trial results for BP outcomes in forest plots. When there were three or more studies of SMBP alone versus usual care at any given time point, we performed random effects model meta-analyses. Sensitivity analyses were run excluding the quality C studies.

We graded the strength of the body of evidence according to the AHRQ methods guide.[14] We assessed the evidence for each question (or comparison of interventions) based on the risk of bias, study consistency, directness of the evidence, and precision of the findings. Based on these factors, we graded the overall strength of evidence as high, moderate, low, or insufficient for the following outcome categories: (1) BP (continuous and categorical outcomes); (2) other clinical events, other clinical outcomes such as quality of life and satisfaction, surrogate and intermediate outcomes; and (3) number of health care encounters.

Results

We identified 48 comparative studies addressing Key Question 1 or Key Question 2 and one study addressing Key Question 5. (Please refer to the reference list in the full report for full documentation of statements contained in the Executive Summary.) No studies relevant to Key Questions 3 or 4 were found. No studies of SMBP monitoring in children were identified.

Key Question 1

In people with hypertension (adults and children), does self-measured blood pressure monitoring, compared with usual care or other interventions without SMBP, have an effect on clinically important outcomes?

a. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents)?

b. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH, LVM, LVMI) and intermediate outcomes (BP control, BP treatment adherence, or health care process measures)?

SMBP Alone Versus Usual Care: Clinical Outcomes

The strength of evidence is *insufficient* regarding a difference between SMBP versus usual care for clinical outcomes. No studies reported on clinical outcomes.

SMBP Alone Versus Usual Care: BP Outcomes

The strength of evidence is *moderate* for a small improvement in BP control using SMBP alone compared with usual care, based on statistically significant findings at 6 months and a trend at 12 months. Of 24 studies that compared SMBP alone versus usual care, 22 were randomized controlled trials (RCTs) and 2 were quasi-RCTs. The studies were heterogeneous in terms of the brand and type of SMBP monitor, followup duration, and baseline BP control.

Individual studies mostly found greater (although nonsignificant) rates of achieving BP control with SMBP monitoring alone than with usual care, but meta-analysis of the small number of available studies showed that SMBP alone was not associated with a significantly increased probability of achieving a predefined BP target at either 6 or 12 months. Sixteen studies reported continuous outcomes of net changes in clinic systolic BP (SBP) and diastolic BP (DBP). Meta-analyses revealed no significant effect at 2 months followup. Statistically significant differences favoring SMBP monitoring alone over usual care were, however, found at 6 months for SBP and DBP (SBP/DBP -3.1/-2.0 mmHg), but not at 12 months (SBP/DBP -1.2/-0.8 mmHg). Meta-analyses showed statistical heterogeneity at 6 and 12 months. The meta-analyses for 6- and 12-month BP outcome included five and six studies, respectively, with one quality A study in each meta-analysis. Only one RCT reported followup data beyond 12 months; significant reductions were found in SBP and DBP at 24 months with SMBP.

Comparisons of SMBP alone with usual care for the outcomes of ambulatory BP measurements (24 hour, awake, and asleep) were based on a small number of studies that reported contradictory results. Meta-analysis of a small number of studies for the net changes in 24-hour ambulatory SBP and DBP at 2 months found no significant differences between SMBP alone and usual care. There were not enough studies to be subjected to meta-analysis for longer durations of followup. The studies of awake and asleep ambulatory BP fairly consistently favored SMBP alone over usual care, although most did not find a statistically significant difference.

SMBP Alone Versus Usual Care: Surrogate and Intermediate Outcomes

The strength of evidence is *low* and fails to support a difference between SMBP alone versus usual care for surrogate and intermediate outcomes. Other outcomes examined included quality of life (in three trials), medication number and dosage (in eight trials), medication adherence (in seven trials), left ventricular mass index (in one trial), and patient satisfaction with health care service (in one trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.

SMBP Alone Versus Usual Care: Number of Health Care Encounters

The strength of evidence is *low* and fails to support a difference between SMBP alone versus usual care for the number of health care encounters. Six studies reported on health care encounters. The majority of studies found no difference between SMBP alone and usual care in the number of health care encounters; however, there was some inconsistency, as one study found an increase and two found a decrease in office visits in the SMBP versus usual-care groups.

SMBP Plus Additional Support Versus Usual Care: Clinical Outcomes

The strength of evidence is *insufficient* regarding a difference between SMBP plus additional support versus usual care for clinical outcomes. One quality C study reported on mortality and end-stage renal disease.

SMBP Plus Additional Support Versus Usual Care: BP Outcomes

The strength of evidence is *high* and supports an improvement in BP control using SMBP with some form of additional support compared to usual care, based on consistent findings in quality A trials. Thirteen of 24 studies reported a statistically significant reduction in either SBP or DBP at followup favoring the SMBP with additional support intervention. All six quality A trials reported a significant mean net reduction in SBP (ranging from -3.4 to -8.9 mmHg) or DBP (ranging from -1.9 to -4.4 mmHg) in the intervention group compared with usual care at up to 12 months followup. The modalities of support added to SMBP in these six trials were telemonitoring and counseling on patient adherence to antihypertensive medications; Web-based pharmacist counseling; telemonitoring with self-titration of antihypertensive medications; telemonitoring with nurse videoconference; behavioral management; and medication management. The remaining seven studies reporting results favoring SMBP with additional support (in both SBP and DBP) used similarly diverse modes of support. Four studies provided results after 12 months. The single quality A trial found no difference between groups at 18 months followup; the other three trials each reported statistically significant mean net BP reductions for followup periods of 18 to 60 months.

Across studies, it is not possible to state with certainty whether one form of additional support is superior, as the modalities of additional support examined varied in their primary intent, ancillary equipment and educational materials, followup personnel, and algorithms for medication adjustments. In addition, no form of additional support was examined by more than one trial.

SMBP Plus Additional Support Versus Usual Care: Surrogate and Intermediate Outcomes

The strength of evidence is *low* and fails to support a difference between SMBP plus additional support versus usual care for surrogate and intermediate outcomes. Additional support included counseling, education, and Web support. Outcomes examined included quality of life (in 3 trials), medication number and dosage (in 11 trials), medication adherence (in 6 trials), and adverse drug reactions (in 1 trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.

SMBP Plus Additional Support Versus Usual Care: Number of Health Care Encounters

The strength of evidence is *low* and fails to support a difference between SMBP plus additional support versus usual care for the number of health care encounters. Eight studies reported on health care encounters. Results were mixed, with five studies finding no difference between groups, one study finding fewer visits in the SMBP plus additional support group, one finding more visits in the SMBP plus additional support group, and one reporting mixed findings. The quality of included studies for this outcome was poor, and the results were inconclusive.

Key Question 2

In trials of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?

SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Clinical Outcomes

The strength of evidence is *insufficient* regarding a difference between SMBP plus additional support versus SMBP without additional support or with less intense additional support for clinical outcomes. No studies reported on clinical outcomes.

SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Blood Pressure Outcomes

The strength of evidence is *low* and fails to support a difference in BP effects between SMBP plus additional support versus SMBP with no additional support or with less intense additional support. This rating is based on the findings of the majority of comparisons, which failed to show a difference for the additional support or the more intense support. In addition, the studies that indicated benefit included only one rated as quality A. Of the 12 studies, 11 were RCTs and 1 was a quasi-RCT. The studies were highly heterogeneous, primarily in the types of additional support used. Additional support consisted of a mixture of behavioral interventions or disease management by a nurse or pharmacist, medication management, educational interventions, electronic transmission of BP measurements, Web sites/training portals for patient-provider communication, BP recording cards, BP and medication tracking tool, hypertension information leaflets, and home visits. Change in medication management as a result of the monitoring could be initiated by the patient, nurse, pharmacist, or primary care physician.

Four trials found statistically significant benefits favoring more intense additional support for either SBP, DBP, BP control, or combinations thereof. Only one study was rated quality A. It showed consistent benefit for continuous SBP and DBP outcomes and for a categorical BP outcome. The additional support examined in this study was pharmacist counseling added to SMBP plus use of personalized Web training. The other eight trials (seven full reports and one abstract) were indeterminate. Two studies provided results beyond 12 months. These were nonsignificant or of uncertain statistical significance. Across studies, no clear patterns could be discerned to explain the heterogeneity in results. The small number of studies and their distribution across different categories of additional support make it impossible to draw

conclusions regarding the potential effects of any specific additional support or its interactions with SMBP.

SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Surrogate and Intermediate Outcomes

The strength of evidence is *low* and fails to support a difference between SMBP plus additional support versus SMBP without additional support or with less intense additional support for clinical, surrogate, and intermediate outcomes. Outcomes examined included quality of life (two trials), mental health (one trial), medication number and dosage (five trials), medication adherence (three trials), and adverse drug reactions (one trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.

SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Number of Health Care Encounters

The strength of evidence is *low* and fails to support a difference for number of health care encounters between groups receiving SMBP plus additional support versus SMBP without additional support or with less intense additional support. Five trials reported number of health care encounters. Additional support included counseling by a nurse or pharmacist, behavioral intervention, medication management, and telemedicine. None of the studies found a difference in number of health care encounters through visits or hospitalizations. One study found that communication via email or telephone increased in those assigned to a pharmacist in addition to SMBP with Web training.

Key Question 3

How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic vs. manual) in their effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?

No trial addressed this Key Question.

Key Question 4

In trials of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?

No trial addressed this Key Question.

Key Question 5

How does adherence with SMBP monitoring vary by patient factors?

There is an *insufficient* level of evidence regarding predictors of SMBP adherence. One study investigated predictors for adherence to SMBP monitoring (with telephonic transmission of BP measurements, hypertension education, and telephone counseling by a nurse) and its relationship to BP control in 377 middle-aged Korean Americans. Older age was independently associated

with greater adherence to SMBP monitoring, and the presence of depression was independently associated with lower adherence.

Discussion

Summary

This review identified 48 comparative studies that examined the impact of SMBP with or without additional support in the management of hypertension and 1 study that evaluated predictors of adherence to SMBP. Overall, the benefit of SMBP for BP reduction appears to be modest and is not consistent across studies. We examined the role of additional support in combination with SMBP by setting up comparisons as: (1) SMBP alone versus usual care; (2) SMBP plus additional support versus usual care; and (3) SMBP plus additional support versus SMBP with no additional support or less intense additional support Findings are summarized in Table A. Twenty-four trials compared SMBP alone versus usual care. Meta-analysis showed a statistically significant reduction in clinic SBP and DBP (SBP/DBP -3.1/-2.0 mmHg) at 6 months but not at 12 months. Only one RCT reported followup beyond 12 months; findings indicated significant reductions in SBP and DBP at 24 months in favor of SMBP.

The comparison of SMBP plus additional support versus usual care was examined in 24 studies, with 11 of 21 randomized trials and 2 of 3 nonrandomized studies reporting a statistically significant benefit in BP reduction favoring SMBP plus additional support. Four studies provided results after 12 months. The only quality A trial found no difference between groups at 18 months followup; the other three trials reported statistically significant mean net BP reductions for followup periods of 18 to 60 months.

Although the observed reductions in BP with SMBP with or without additional support were small in size, they may still reflect a clinically relevant effect, since observational data on a population level show a decreased risk of cardiovascular disease with even small differences in BP in the hypertensive range.[15] On the other hand, the reductions in BP found with SMBP are modest compared to those estimated to occur with other lifestyle interventions.1 Evidence for other surrogate or clinical outcomes or health care processes was sparse, of low strength, or not conclusive.

Twelve trials compared SMBP plus additional support (or more intense additional support) versus SMBP without additional support (or plus less intense additional support). Only four of these trials reported a significantly greater reduction in BP in the SMBP plus additional (or more intense) support groups. Two studies provided results beyond 12 months. Both reported findings that were nonsignificant or of uncertain statistical significance.

Clinical Heterogeneity

Despite the ostensible similarity in research questions across studies, great clinical heterogeneity across the examined publications limited the conclusions that could be drawn. There was a large degree of variability in SMBP monitoring protocols and implementation, use of and response to BP data, and types of additional support provided to patients. We grouped the additional support interventions into categories based predominantly on education, counseling, Web support, or other support. However, the types of additional support were too heterogeneous and overlapping to be neatly categorized. Further, no two studies used exactly the same mode of

additional support, and even the studies that used SMBP without additional support varied in their methods.

While it should be noted that evidence from indirect comparisons is much inferior to evidence from direct comparisons within trials, the evidence appears to suggest that additional support is synergistic with SMBP to achieve BP control. However, the heterogeneity of additional support with regard to the primary intent, ancillary equipment, educational materials, followup personnel, and algorithms for medication adjustments make it impossible to draw conclusions regarding the potential effects of specific modalities or particular components of additional support or their interactions with SMBP. Further, there were too few subgroup analyses in these trials for each potential effect modifier, such as sex, race, comorbid disease, socioeconomic status, blood pressure control, or compliance at baseline, to allow detection of consistent signals for subgroups that might preferentially benefit.

Applicability

Reviewed studies were all conducted in an outpatient setting and included only adults with uncontrolled hypertension or on antihypertensive medication. Patients had to be willing and able to participate in SMBP, or, in a small number of studies, have a companion to conduct the home BP measurement. Most studies included individuals with uncomplicated hypertension, without recent acute cardiovascular disease events, terminal illnesses, or advanced kidney disease. Most studies were conducted in Western Europe and North America. Minorities were underrepresented, although a few studies focused on African Americans.

Limitations

Given the clinical heterogeneity stemming from the variation in the populations, interventions, and outcomes examined, in many cases only one or two studies were available for specific comparisons. Many studies were rated as quality C and likely were underpowered, even for BP outcomes. There were no studies in children. Duration of followup was limited and in most instances less than 12 months. Data on clinical event outcomes were lacking.

There are multiple possible reasons that these studies generally found no significant effects or reported relatively small effect sizes. Existing trials did not evaluate patients regarding their pattern of home and clinic BPs prior to inclusion. Each study may have included varying proportions of individuals with uncontrolled hypertension, white coat hypertension (elevated BP in the office setting but not at home), or masked hypertension (elevated BP at home but not in the office). Study participants with different patterns of BP abnormalities will differ in when they trigger treatment thresholds, depending on whether BP management in a trial is guided by home or clinic BP; thus the same treatment targets may result in different actions in terms of medication titration and achieved BP levels. Therefore, SMBP may have resulted in opposing effects on medication management and clinic BP within and across trials.

A question of interest to this review was how the type of BP device (particularly automated versus semiautomated or manual devices) impacted BP control. However, no study comparing different SMBP devices was identified. Automated electronic oscillometric devices are presently the devices most widely used for SMBP monitoring, although a number of these digital BP devices have yet to undergo rigorous independent validation.16 Nevertheless, we are unlikely to get more data on this comparison due to the widespread adoption of automatic devices, despite the difference in cost and the dilemma this presents for policymakers.

It stands to reason that adherence to SMBP is a necessary intermediate outcome in deriving any benefit from SMBP. However, observational data on predictors of adherence to SMBP were sparse, precluding any in-depth analysis.

Future Research

On a population level, home BP is lower than clinic BP, but the exact relationship between home and clinic BP levels varies from person to person. As noted earlier, it can be expected that patients with white coat hypertension or masked hypertension will be managed differently based on SMBP than those with average BP behavior. Thus the strategies to measure and control elevated BP may need to differ based on an individual's discrepancy between home and clinic BP. Individuals with elevated BP at home and in the clinic require more intense BP treatment, while those with elevated BP only in the clinic do not. Therefore, future studies on SMBP ought to be clear as to whether their primary goals are lowering BP in individuals with uncontrolled hypertension or avoiding overtreatment in individuals with white coat hypertension. To accomplish this, patients should be evaluated regarding their pattern of BP abnormality prior to study enrollment. Subgroups of interest in studies are older persons and those with important clinical comorbidities, including cardiovascular and cerebrovascular disease, diabetes mellitus, and chronic kidney disease.

Better standardization is needed regarding how patients use SMBP and the types of additional support that are employed. While we do not suggest that incremental improvements in how SMBP is deployed should cease, we have found that it is of limited value for every study to have a unique protocol for SMBP monitoring and additional support. To reduce the heterogeneity of interventions, researchers should consider which already-investigated method of SMBP monitoring and additional support they believe is most promising and implement that protocol. Furthermore, the interpretability of future studies would be enhanced by the use of "usual care" protocols that most closely resemble the true usual care of the patients being studied, as well as by pragmatic trials that would inform real-world effectiveness.

Self-measuring BP can be burdensome over time. Future studies of SMBP should compare different monitoring schedules to determine the least burdensome protocol(s). Other important areas for future research include examining the role of various measures for improving the accuracy of and adherence to SMBP, as well as improving the transmission of SMBP information for decisionmaking. Investigations should also be made into further use of telemedicine for patient-provider interaction regarding SMBP results and medication management. Given the paucity of data for clinical event outcomes, future studies examining the effects of SMBP on clinical events should also be made. Other recommendations for future SMBP research include examining characteristics that predict adherence to SMBP; establishing targets for home BP; and consistently reporting complete information on the name, type, and accreditation of the SMBP device used.

Conclusion

SMBP may confer a small benefit in blood pressure control, but the BP effect beyond 12 months and the attendant long-term clinical consequences remain unclear. Future research should standardize patient inclusion criteria, BP treatment targets for home BP, and protocols for SMBP and additional support to maximize the interpretability and applicability of SMBP trials.

Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 1: SMBP Alone Versus Usual Care ***Overall***	--	• Twenty-four studies compared SMBP alone versus usual care (22 RCTs and 2 quasi-RCTs). In total, 5,400 patients with hypertension were included. Four studies were graded quality A; 6, quality B; 13, quality C; and 1 conference abstract was not graded. • The studies were heterogeneous in terms of the brands and types of SMBP monitors; followup duration (2–36 months); baseline hypertension control (across studies, mean SBP/DBP: 124-167/70-109 mmHg); patient ages (across studies, mean 47–73 years). All patients were adults, most were male, and the most commonly cited comorbid conditions in these studies were type 1 or 2 diabetes, obesity, dyslipidemia, and cardiovascular disease.
Key Question 1: SMBP Alone Versus Usual Care ***Clinical Outcomes***	Insufficient	• No study reported clinical outcomes. • **Conclusion**: There is insufficient comparative study evidence regarding clinical outcomes in trials of SMBP versus usual care.
Key Question 1: SMBP Alone Versus Usual Care ***Blood Pressure***	Moderate (favoring SMBP)	• Twenty-three of the 24 studies that compared SMBP alone versus usual care reported BP outcomes (4 quality A, 5 quality B, 13 quality C, and 1 conference abstract that was not graded). See the "Overall" summary above regarding the study heterogeneity. • Thirteen studies reported categorical changes in BP control, mostly defined as achieving a BP of <130-140/80-90 mmHg (sometimes with lower thresholds for patients with diabetes). Although all but one study found greater rates of achieving BP control with SMBP monitoring, meta-analyses of the subset of trials that examined achieving a BP target found no significant effects at 6- and 12-month followup. • Twenty-one studies reported continuous BP outcomes. Seventeen studies reported clinic BP outcomes; 5 reported 24-hour ambulatory BP; 6, awake (day) ambulatory BP; and 5, asleep (night) ambulatory BP. In meta-analyses, no significant effect was found at 2 months followup; statistically significant differences for clinic BP favoring SMBP monitoring were found at 6 months (SBP/DBP: -3.1/-2.0 mmHg), but these differences were not statistically significant at 12 months (-1.2/-0.8 mmHg). The meta-analyses were statistically heterogeneous at 6 and 12 months. Only 1 RCT reported followup data beyond 12 months, and it found significant reductions in SBP and DBP at 24 months with SMBP. The studies reporting 24-hour ambulatory BP had inconsistent findings favoring either SMBP or usual care. However, the studies of awake and asleep ambulatory BP fairly consistently favored SMBP, although most did not find a statistically significant difference. • Subgroup analyses were reported by 4 trials. One study found no differences in the relative effect of SMBP monitoring in patients treated or untreated for hypertension at baseline. Another found no difference by age, sex, or diagnosis with diabetes. A third study found significant reductions in clinic and 24-hour ambulatory DBP in men but not women. A study looking at differences by race did not have consistent findings. Across studies, no clear patterns could be discerned to explain the heterogeneity in results. • **Conclusion**: Based primarily on the consistent findings of the quality A and B studies examining the impact of SMBP versus usual care in clinic BP measurements and the corresponding results from meta-analyses, the strength of evidence is moderate for a small improvement in BP using SMBP compared with usual care.

Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 1: SMBP Alone Versus Usual Care ***Surrogate and Intermediate Outcomes (Not Blood Pressure)***	Low (failing to support a difference)	• Thirteen of the 24 studies that compared SMBP alone versus usual care reported surrogate and intermediate outcomes that were not BP. See the "Overall" summary above regarding the study heterogeneity. • Eight studies reported data on categorical and continuous outcomes related to number of medications and dosage (1 quality A, 5 quality B, 2 quality C). Studies variously reported increases or decreases in number of medications, medication dose, added medication classes, number of treatment modifications by physicians, physician assessment of strength of medication regimen, number of antihypertensive medications used, and medication changes. The majority of studies found no difference in medication outcomes, although a minority found significantly greater changes in medication treatment with SMBP monitoring. Weak evidence favors no difference in medication use with SMBP monitoring. • Three studies reported on quality-of-life outcomes (2 quality B, 1 quality C). Studies used the SF-36 quality-of-life assessment tool. In general, studies found no difference in quality of life between SMBP and usual care. • Seven studies reported on medication adherence using a variety of different definitions of adherence, including both categorical and continuous outcomes (3 quality B, 4 quality C). A wide variety of definitions were used for medication adherence across studies. Three studies reported some significantly better measures of adherence with SMBP (although not always for all evaluated measures of adherence); the remaining 4 studies found no difference. Overall, there was weak evidence that medication adherence may be better among patients using SMBP monitoring. • Only a single study each reported on patient satisfaction (quality C) and left ventricular mass index (quality B). No differences were found between SMBP and usual care. There is insufficient evidence for either of these outcomes. • **Conclusion**: The evidence is weak or insufficient for these outcomes. Thus, overall the strength of evidence is low and fails to support a difference between SMBP alone versus usual care for surrogate and intermediate outcomes.
Key Question 1: SMBP Alone Versus Usual Care ***Health Care Encounters***	Low (failing to support a difference)	• Six of the 24 studies that compared SMBP alone versus usual care reported number of health care encounters (1 quality A, 3 quality B, and 2 quality C). See the "Overall" summary above regarding the study heterogeneity. • The majority of studies found no difference in number of physician visits between groups, 2 studies found no difference in number of hypertension-related telephone calls, and 1 study found no difference in number of medical procedures received for hypertension. • One study found that patients using SMBP had more office visits and 2 studies found that patients using SMBP had fewer visits. • **Conclusion**: Based on the lack of agreement in study results, the strength of evidence is low and fails to support a difference between SMBP alone versus usual care for health care encounters.

Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 1: SMBP + Additional Support Versus Usual Care ***Overall***	--	• Twenty-four studies compared SMBP plus additional support versus usual care (19 RCTs, 2 quasi-RCTs, and 3 nonrandomized studies). In total, 6,187 patients with hypertension were included. Six studies were graded quality A; 5, quality B; and 13, quality C. Four of these studies also provided data for SMBP alone versus usual care. • The studies were heterogeneous in terms of the brands and types of SMBP monitors; followup duration (2–36 months); baseline hypertension control (across studies, mean SBP/DBP: 124-163/70-103 mmHg); patient ages (across studies, mean 47–77 years). All patients were adults, most were male, and the most commonly cited comorbid conditions in these studies were type 1 or 2 diabetes, obesity, dyslipidemia, and cardiovascular disease. • No form of additional support was examined by more than one trial. The studies were highly heterogeneous in the types of additional support used. They included educational materials, Web resources, telephone monitoring with electronic transmission of BP data, nurse or pharmacist visits, calendar pill packs and/or compliance contracts, and behavioral management and/or medication management. Change in medication management as a result of the monitoring could be initiated by patient, nurse, pharmacist, or primary care physician.
Key Question 1: SMBP + Additional Support Versus Usual Care ***Clinical Outcomes***	Insufficient	• One quality C trial found significantly lower mortality with SMBP plus self-titration versus usual care, and lower composite mortality and end-stage renal disease. End-stage renal disease alone was not significantly different. • **Conclusion**: There is insufficient comparative study evidence regarding clinical outcomes in trials of SMBP plus additional support versus usual care.
Key Question 1: SMBP + Additional Support Versus Usual Care ***Blood Pressure***	High (favoring SMBP)	• All 24 studies that compared SMBP plus additional support versus usual care reported BP outcomes. See the "Overall" summary above regarding the study heterogeneity. • All 6 quality A trials reported a significant mean net reduction in SBP (ranging from -3.4 to -8.9 mmHg) or DBP (ranging from -1.9 to -4.4 mmHg) in the intervention group compared with usual care at up to 12 months followup. Four studies provided results after 12 months. The only quality A trial found no difference between groups at 18 months followup; the other 3 trials reported statistically significant mean net BP reductions for followup periods of 18 to 60 months. • **Conclusion**: The strength of evidence is high for an improvement in BP control using SMBP with some form of additional support compared to usual care. By examination across studies, it is not possible to state with certainty whether one form of additional support is superior, as the additional supports examined across studies varied in primary intent, ancillary equipment and educational materials, followup personnel, and algorithms for medication adjustments. The studies were too heterogeneous in numerous ways to allow an explanation of differences in results across studies.

Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 1: SMBP + Additional Support Versus Usual Care ***Surrogate and Intermediate Outcomes (Not Blood Pressure)***	Low (failing to support a difference)	• Fourteen of the 24 studies that compared SMBP plus additional support versus usual care reported surrogate and intermediate outcomes that were not BP. See the "Overall" summary above regarding the study heterogeneity. • Eleven studies reported data on categorical and continuous outcomes related to medication number and dosage (3 quality A, 2 quality B, 6 quality C). Studies variously reported increases or decreases in medication number, medication inertia (no change in regimen), physician assessment of strength of medication regimen, treatment modification by physician, discontinuation of medication, and number of medication classes used or tablets taken. Studies were split between finding no difference in medication outcomes and finding either an increase or decrease in medications with patients using SMBP with additional support. The contradictory findings in the evidence overall favor no difference in medication use with SMBP monitoring plus additional support. • Three studies (2 quality A and 1 quality C) reported on quality-of-life outcomes. These studies found no difference in SF-12, Consumer Assessment of Healthcare Providers and Systems score, Anxiety score, or Euro QoL 5D score. The studies all found no difference in quality of life. • Six studies reported on medication adherence using a variety of different definitions of adherence, including both categorical and continuous outcomes (1 quality A, 2 quality B, 3 quality C). The studies had inconsistent findings, with half finding no difference in medication adherence and half finding greater adherence with SMBP plus additional support. Overall, there was weak evidence that medication adherence may be better among patients using SMBP monitoring. • One study found no difference in adverse drug reactions across three groups with different forms of additional support. • **Conclusion**: The evidence is weak or insufficient for these outcomes. Thus, overall the strength of evidence is low and fails to support a difference between SMBP plus additional support versus usual care for surrogate and intermediate outcomes.
Key Question 1: SMBP + Additional Support Versus Usual Care ***Health Care Encounters***	Low (failing to support a difference)	• Eight of the 24 studies that compared SMBP plus additional support versus usual care reported number of health care encounters. All were graded quality C. • The studies were highly heterogeneous, primarily in the types of additional support used. Additional support included education, alerts, medication monitoring, self-titration, Web training, pharmacist counseling, medication management, and behavioral management. All reported on number of physician (or physician and nurse) visits. One study additionally reported on telephone and Web encounters. • Six studies found no difference in number of visits, 1 found fewer visits, and 1 found more visits with SMBP plus additional support compared to usual care. • One study found mixed results with respect to telephone and Web encounters. • **Conclusion**: Given the discordant findings as well as the low study quality, the strength of evidence is low and fails to support a difference between groups.

Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 2: SMBP + Additional Support Versus SMBP ***Overall***	--	• Twelve studies compared SMBP plus additional support versus SMBP without additional support or with less intense additional support, of which 11 were RCTs and 1 was quasi-randomized. In total, 3,311 patients with hypertension were included. Two trials were graded quality A; 4, quality B; and 5, quality C; and 1 conference abstract was not graded. • The studies were highly heterogeneous, primarily in the types of additional support used. Additional support consisted of a mixture of behavioral interventions or disease management by a nurse or pharmacist, medication management, educational interventions, electronic transmission of BP measurements, Web sites/training for patient-provider communication, telemonitoring, BP recording cards or hypertension information leaflets, BP and medication tracking tool, and home visits. Change in medication management as a result of the monitoring could be initiated by patient, nurse, pharmacist, or primary care physician. Other sources of heterogeneity included the brands and types of SMBP monitors; followup duration (3–24 months, although mostly ≤12 months); baseline hypertension control (across studies, mean SBP/DBP: 126-179/70-103 mmHg); patient ages (across studies, mean 50–72 years. All patients were adults, most were male, and the most commonly cited comorbid condition was type 2 diabetes.
Key Question 2: SMBP + Additional Support Versus SMBP ***Clinical Outcomes***	Insufficient	• No study reported clinical outcomes. • **Conclusion**: There is insufficient comparative study evidence regarding clinical outcomes in trials of SMBP versus usual care.

Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 2: SMBP + Additional Support Versus SMBP ***Blood Pressure***	Low (failing to support a difference)	• All 12 studies that compared SMBP plus an additional support versus SMBP without the additional support or with less intense additional support reported BP outcomes. See the "Overall" summary above regarding the study heterogeneity. • Eight studies reported categorical changes in BP control, mostly defined as achieving a BP of <120-140/80-90 mmHg (sometimes with lower thresholds for patients with diabetes). Six trials showed no significant difference or were indeterminate for a difference in rates of achieving BP control. One trial of SMBP plus pharmacist counseling plus training in use of a patient Web portal vs. SMBP plus training in use of a patient Web portal found a significant effect favoring, more intensive additional support. Another trial comparing SMBP plus medication monitoring plus educational material versus SMBP plus educational material also found benefit for the more intense additional support. • Ten studies reported continuous BP outcomes. Six trials found no significant difference. Four favored the more intense support in addition to SMBP, comparing pharmacist counseling plus training in use of a patient Web portal versus training in use of a patient Web portal, medication monitoring plus educational material versus educational material, medication monitoring plus educational material versus educational material, and telemonitoring versus SMBP alone. Two studies provided results beyond 12 months. These studies reported findings that were nonsignificant or of uncertain statistical significance. • Four trials reported subgroup analyses by control of BP at baseline (controlled or not controlled), degree of adherence (lower adherence), or race (white vs. predominantly African American). Two of these studies did not provide analyses for the comparisons of SMBP plus additional support versus SMBP without additional support or with another type of additional support, and two studies did not provide complete subgroup analysis data. • **Conclusion**: Overall the strength of evidence is low and fails to support a difference in BP effects between SMBP plus additional support versus SMBP with no additional support or with less intense additional support.

Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 2: SMBP + Additional Support Versus SMBP ***Surrogate and Intermediate Outcomes (Not Blood Pressure)***	Low (failing to support a difference)	• Seven of the 12 studies that compared SMBP plus additional support versus SMBP without additional support reported surrogate and intermediate outcomes that were not BP. See the "Overall" summary above regarding the study heterogeneity. • Two trials reported on quality of life or anxiety (1 quality A, 1 quality B). The studies used SF-36, SF-12, and the State-Trait Anxiety Inventory, a mental health questionnaire. Both found no differences using any quality-of-life measure. • Five trials reported data on categorical and continuous medication number and dosage (2 quality A, 2 quality B, 1 quality C). Studies reported numbers of patients taking 2 or more classes of medications, medical inertia (defined as no medication change vs. either an increase or decrease in medications), and number of medication drug classes. Four trials using additional support consisting of nurse counseling, home visits for BP measurement, telemonitoring, or education found no difference between SMBP plus additional support and usual care. One trial found a somewhat greater mean number of medication drug classes with SMBP plus Web training plus pharmacist counseling. Weak evidence suggests no difference in medication use. • Three quality C trials reported on medication adherence. Using different measures in each study, none found a significant difference in medication adherence. One trial also found no difference in a subgroup of individuals with lower baseline adherence. • Two trials looked at miscellaneous outcomes. One quality C trial found no difference in adverse drug reactions across four groups with different forms of additional support or usual care. One quality A trial found no difference in consumer satisfaction measured with the Consumer Assessment of Healthcare Providers and Systems instrument. • **Conclusion**: The evidence is weak due to inconsistency across studies or poor-quality studies, or it is insufficient. Thus, overall the strength of evidence is low and fails to support a difference between SMBP plus additional support versus SMBP without additional support or with less intense additional support for surrogate and intermediate outcomes.
Key Question 2: SMBP + Additional Support Versus SMBP ***Health Care Encounters***	Low (failing to support a difference)	• Five of the 12 studies that compared SMBP plus an additional support versus SMBP without the additional support reported number of health care encounters. All were quality C. See the "Overall" summary above regarding the study heterogeneity. • All reported on outpatient primary care visits, 2 reported on hospital admissions or inpatient or urgent care/emergency use, and 3 reported on cardiac and other specialist visits. • None found a difference in the numbers of outpatient visits or hospital admissions between patients receiving SMBP with or without additional support. • One study found more electronic and telephonic communication with SMPB plus pharmacist counseling plus training in use of a patient Web portal compared to SMBP plus training in use of a patient Web portal. • **Conclusion**: Despite the consistency across trials, because of their small number and poor quality, overall the strength of evidence is low and fails to support a difference in number of health care encounters when using additional support with SMBP compared to SMBP without additional support or with less intense additional support.

Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 3: Different SMBP Devices	Insufficient	• No eligible study provided data to address this question. • **Conclusion**: There is insufficient comparative study evidence regarding the comparison of different SMBP devices.
Key Question 4: Blood Pressure Control Relationship With Clinical and Surrogate Outcomes	Insufficient	• No eligible study provided data to address this question. • **Conclusion**: There is insufficient comparative study evidence regarding the relationship of BP control with SMBP and clinical and surrogate outcomes.
Key Question 5: Predictors of SMBP Adherence	Insufficient	• One quality B study addressed how adherence to SMBP monitoring varies by patient factors. The study included 377 middle-aged Korean Americans using SMBP with telephonic transmission of BP measurements, hypertension education, and telephone counseling by a nurse. Adherence was defined as transmitting a minimum of 12 readings per week for at least 24 weeks of the 48-week study. • Age ≥ 60 years was significantly associated with better adherence with SMBP, and greater depression (measured on a scale specific to Korean Americans) was significantly associated with worse adherence. Other factors explored for their relationship to adherence that did not show significant influences were marital status, education, work status, medication, duration of hypertension, comorbidity, family history of hypertension, body mass index, and knowledge and awareness regarding hypertension. • **Conclusion**: There is insufficient evidence regarding predictors of SMBP adherence.

Note: BP = blood pressure; DBP = diastolic blood pressure; Euro QoL 5D = Euro QoL Group 5-Dimension Self Report Questionnaire; RCT = randomized controlled trial; SBP = systolic blood pressure; SF-12/36 = Short Form-12/36 Health Survey; SMBP = self-measured blood pressure (monitoring).

Methodological Quality Ratings:

A (good). Quality A studies have the least bias, and their results are considered valid. They generally possess the following: a clear description of the population, setting, interventions, and comparison groups; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; clear reporting of dropouts and a dropout rate of less than 20 percent; and no obvious bias. For treatment studies, only RCTs may receive a grade of A.

B (fair/moderate). Quality B studies are susceptible to some bias, but not sufficiently to invalidate results. They do not meet all the criteria in category A due to some deficiencies, but none likely to introduce major bias. Quality B studies may be missing information, making it difficult to assess limitations and potential problems.

C (poor). Quality C studies have been adjudged to carry a significant risk of bias that may invalidate the reported findings. These studies have serious errors in design, analysis, or reporting and contain discrepancies in reporting or have large amounts of missing information.

Evidence Ratings:

High. There is a high level of assurance that the findings of the literature are valid with respect to the relevant comparison. No important scientific disagreement exists across studies. At least two quality A studies are required for this rating.

Moderate. There is a moderate level of assurance that the findings of the literature are valid with respect to the relevant comparison. Little disagreement exists across studies. Moderately rated bodies of evidence contain fewer than 2 quality A studies or such studies lack long-term outcomes of relevant populations.

Low. There is a low level of assurance that the findings of the literature are valid with respect to the relevant comparison. Underlying studies may report conflicting results. Low rated bodies of evidence could contain either quality B or C studies.

Insufficient. Evidence is either unavailable or does not permit estimation of an effect due to lacking or sparse data. In general, when only one study was published, the evidence was considered insufficient, unless the study was particularly large, robust, and of good quality.

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Introduction

High blood pressure (BP), or hypertension, is a common, long-term health condition, particularly among older adults. Untreated or ineffectively treated hypertension leads to increased cardiovascular morbidity and mortality in individuals, increased consumption of health care resources, high financial and human costs to society. In otherwise healthy adults, hypertension is defined as a persistently elevated BP equal to or greater than 140/90 mmHg.[1] The recommended BP measurement technique is to average two readings taken in a person after 5 minutes quietly seated in chair.[1] In children, the diagnosis is made from an average of three or more BP readings greater than the 95th percentile for age, sex, and height.[2,3] The Seventh Joint National Committee (JNC 7) guideline recommends a BP goal of 140/90 mmHg or less in the general population and a lower goal of 130/80 mmHg or less in patients with diabetes mellitus or chronic kidney disease.[1]

Background

Burden of Hypertension

One study estimated that the global prevalence of hypertension in 2000 was 26 percent in the adult population. It predicted a rise by 24 percent in developed countries and 80 percent in developing countries by 2025.[4] The World Health Report 2002 estimates that over 1 billion people have hypertension, which is estimated to cause 4.5 percent of the global disease burden.[5] In addition, high BP directly results in 7 million deaths annually.[6] Within the United States, about 76.4 million adults are affected.[7] Data from the National Health and Nutrition Examination Surveys (NHANES) from 1999 to 2008 indicated that 30 percent of all adults in the U.S. 18 years and older were hypertensive, with a higher prevalence among African Americans and the elderly.8 The prevalence of verified hypertension in children is more than 3 percent.[2] A study from 2002 reported a lifetime risk of developing hypertension among adults aged 55 to 65 years in the U.S. as greater than 90 percent.[9] Despite improvements in the quality of health care and life expectancy, it is expected that the prevalence of hypertension will continue to rise as the population ages.

Hypertension is a major risk factor for cardiovascular disease and mortality and accounts for an estimated 14 percent of cardiovascular deaths worldwide and 18 percent in developed countries.[10] It is an important modifiable risk factor for coronary artery disease, stroke, chronic kidney disease, congestive heart failure, and peripheral vascular disease.[1] The World Health Organization ranks high BP as the third highest risk factor for burden of disease, after underweight and unsafe sex, highlighting the contribution of hypertension directly and indirectly to the development of numerous diseases.5

Hypertension also imposes a heavy financial burden on society at large. The direct and indirect cost of high BP and its complications has been estimated at more than $43.5 billion in 2007 in the U.S.[7] Thus, it cannot be viewed simply as an individual health issue given the large public health impact and the potential for cost savings with effective prevention or treatment.

Numerous health professional and government organizations have developed various guidelines for BP management. The choice of treatment is largely dependent on the cause of hypertension, severity of the condition, as well as the presence or absence of existing comorbid states. Recommended management strategies for BP control include lifestyle and behavior modification (such as smoking cessation, moderation of alcohol consumption, salt restriction and

other dietary modifications, regular exercise, and weight loss in obese persons), usually combined with the use of antihypertensive medication. Effective BP control has been shown to decrease incidence for stroke by 35 to 40 percent, myocardial infarction by 20 to 25 percent, and heart failure more than 50 percent.11,12 Systematic reviews have also shown the beneficial effects of lowering BP on reducing fatal and nonfatal stroke, cardiac events, and total among individuals with severe hypertension or at increased risk (such as of older age or with other comorbid risk factors).11,13,14 A decrease of 5 mmHg in systolic BP has been estimated to result in a 14 percent overall reduction in mortality due to stroke, 9 percent reduction in mortality due to chronic heart disease and 7 percent reduction in all-cause mortality.1,15,16 However, long-term adherence to lifestyle modification and medication remains a challenge in the management of hypertension, which is usually a lifelong condition.

BP Measurement Strategies

Strategies aimed at the control of high BP as well as adherence to medication continue to be of foremost concern to providers and patients, health care payers, policymakers, and governments worldwide. For appropriate diagnosis and therapy, accurate BP measurement is of great importance. However, consistently attaining reliable BP measurements is problematic. There is within-individual biological variability as well as measurement error. Repeated measurements are needed to facilitate accurate classification of patients. Other factors that can improve accuracy include the use of an appropriately sized cuff and slow cuff deflation. Measurements can be read by a person or provided digitally by a device. Readings by a person can be affected by observer training, preference, and bias. For example, terminal digit preference (i.e., preference for 0, 5, and even numbers) and single number preference (i.e., preference for specific values such as 130/80 or 140/90 mmHg) can lead to inaccuracies in measurement readings and variability across observers.[17,18] This can be prevented when machines provide readings automatically.

Current settings for BP measurement include BP measurement in a healthcare setting, or BP measurement in a patient's usual environment with either ambulatory BP monitoring, or self-measured BP (SMBP) monitoring. BP as recorded in the office or clinic setting at medical encounters is the most commonly used approach for measurement of BP. Reliable clinic measurements require an adequate rest period prior to measurement in order to enhance the consistency of BP readings. However, even when measured according to established guidelines, clinic BP measurements have several limitations. Clinic measurements may not reflect the usual BP outside of the clinic setting throughout a day. BP may rise in the clinic in response to the medical environment (referred to as white coat hypertension), or may be normal in the clinic but not outside of the clinic (referred to as masked hypertension).[19,20] Prevalence of white coat hypertension ranges from 10 to more than 20 percent,[21,22] and the prevalence of masked hypertension (MH) reaches 40 percent in some studies.[23] The prognostic significance of either is unclear.[24]

There are two BP monitoring strategies that can currently be used at home: Ambulatory and SMBP monitoring. In brief, ambulatory BP monitoring is a noninvasive, fully automated technique in which BP is recorded over an extended period of time, typically 24 hours. A BP cuff is placed around the upper arm and left in place for approximately 24 hours. A connected monitor is preprogrammed to regularly record BP, usually every 15 to 20 minutes while awake and every 20 to 30 minutes while asleep. Patients are instructed to keep an activity log throughout the testing period for evaluation of stress- and activity-related BP changes.

Ambulatory BP monitoring requires a technologist to program the machine, fit it on the patient, remove it and download the results and a physician to interpret them. Measurements may interfere with a patient's activity or sleep. Given the inconvenience and expense of setting up and using the device, ambulatory BP monitoring is predominantly used to diagnose white coat or masked hypertension, to identify people with abnormal daily BP patters, or to help with management of hard to control or highly variable BP. In addition, ambulatory BP monitoring is often used in research studies as an outcome, since many consider it to be more accurate than clinic-based BP measurement. It has been the subject of a 2002 Evidence Practice Center (EPC) Evidence Report.[25] A fuller description of ambulatory BP monitoring can be found there. The current report evaluates ambulatory BP monitoring only as an outcome measurement tool, not as an intervention of interest.

Self-measured BP (SMBP) monitoring is another option that allows for more frequent measurements, and possibly more accurate readings of a patient's typical BP.

Self-Measured Blood Pressure Monitoring

Technically, SMBP monitoring refers to regular measurement by the patient of his or her own BP. More broadly, though, it is the regular use of a BP measurement device that is owned by (or lent to) the patient to be used outside the office/clinic setting. The actual BP measurement can be done either by the patient, or less frequently by a companion, who is usually not a medical professional. SMBP measurements can be obtained from the upper arm, wrist, or fingers (or, if necessary, the lower extremity); however, experts recommend the use of upper arm devices due to the lack of validation and the high number of inaccurate measurements from the wrist and finger devices.[26-28] Models for SMBP devices range from mechanical aneroid gauges (sphygmomanometers), which require self-inflation and auscultation ("manual" devices), to manually-inflated sphygmomanometers with automatic displays ("semiautomated" devices), to fully automated configurations that automatically inflate the sphygmomanometer and measure the BP ("automated" devices). Many SMBP devices are commercially available. Many have undergone validation according to the recommendations of the American Association of Medical Instrumentation, the European Society of Hypertension or the British Hypertension Society.[25,29] Generally, the use of validated devices is preferred. Patients may require some instruction on how to use SMBP devices.[30,31]

Generally, individuals with hypertension would use such devices at home to measure their own BP and provide written lists of readings to their provider at office visits. Newer SMBP devices can automatically store readings and some are equipped to electronically transmit readings to a provider. This may facilitate direct communication with a provider via phone call or email and result in shorter turn-around times in responding to a BP reading and thus ultimately to better BP control.

Proposed Advantages of Self-Measured Blood Pressure Monitoring

Self-measured blood pressure (SMBP) has been used in the treatment of hypertension with three major aims: 1) to avoid undertreatment of hypertension 2) to enhance self-participation in disease management and to enhance adherence; and 3) to avoid overtreatment in those with lower BP out of the clinic compared with in the clinic[26]

SMBP is being used to avoid undertreatment of hypertension. SMBP monitoring can provide more frequent BP readings and if these are transmitted back to the provider, they can be used for more rapid and frequent adjustments in blood pressure medication to ensure adequate BP control.

With training, additional support and treatment algorithms, patients may be able to self adjust medications based on SMBP results. However, there is uncertainty about the appropriate home BP targets for guiding treatment decisions and whether these should be based on the same cut-points from clinic BP or from ABPM for defining hypertension.[32]

SMBP monitoring may be used as a tool for disease self-management and to improve adherence with lifestyle and diet modification, or with drug treatment. While patient self-participation in chronic disease management appears promising, the sustainability and clinical impact of SMBP remains uncertain. Finally, SMBP may be useful in preventing overtreatment in individuals with white coat syndrome, orthostatic BP changes, or hypotensive episodes from medication.

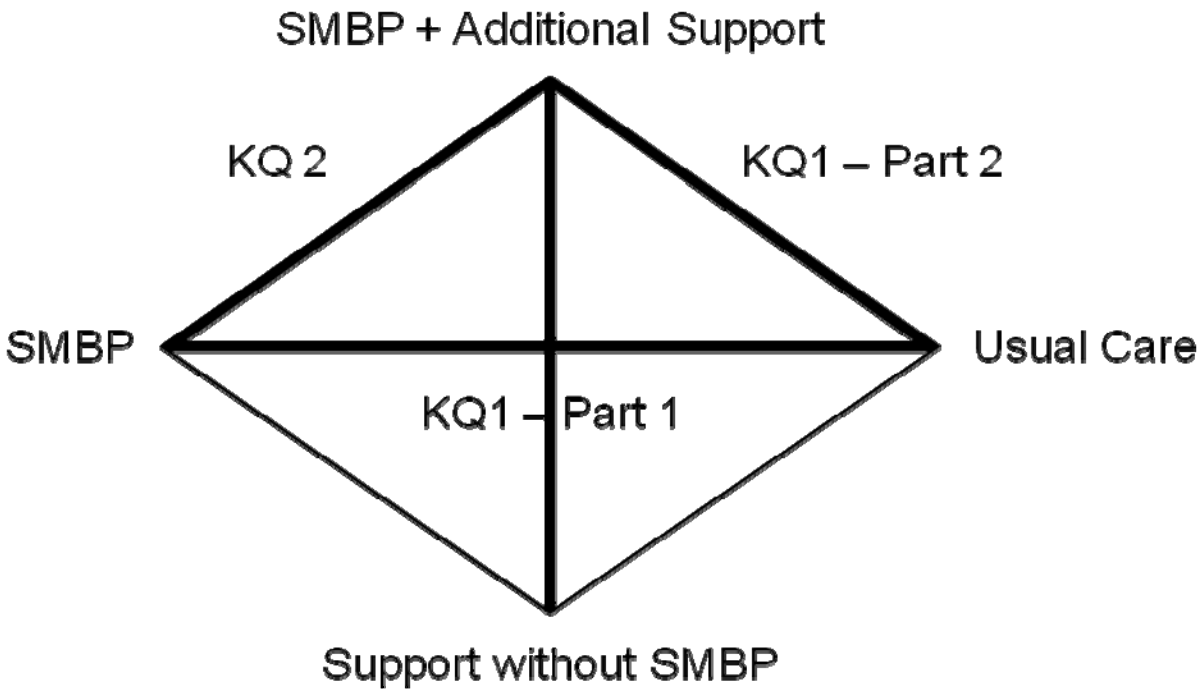
Whether or not to advise the use of an SMBP monitoring device for a patient with hypertension is a common clinical question for clinicians. The cost of a home BP monitor ranges between $40 to $150, and the insurance coverage and approval for these devices vary across states.[33] However, provision of the device could be cost-saving if it resulted in a reduced number of office visits for BP measurement or management or resulted in improved BP, which could translate into reduced morbidity and health care utilization. On the other hand, if more frequent home BP measurements lead to more encounters for counseling, modification of lifestyle behaviors, drug treatments along with management of adverse effects, SMBP may actually increase cost, at least in the short term, since it takes several years for improved BP control to improve clinical outcomes.

Current Uncertainties About Self Measured Blood Pressure Monitoring

There is no consensus on the precise protocol for SMBP monitoring in the management of hypertension regarding timing, frequency and duration. Neither is there consensus on how many serial measurements should be taken and which ones should be used or averaged to derive an accurate reading. SMBP monitoring may not be suitable in certain patients, such as those with arrhythmias and ectopic beats, large arm circumferences (as a too-small cuff size may give falsely elevated BP readings), with physical or mental disabilities that interfere with device operation. In addition, SMBP may carry the risk of unreliable BP readings if not obtained in a standard fashion, inappropriate self adjustments of antihypertensive medications, as well as increased anxiety in susceptible patients. As self-measurement requires patient participation, certain patient characteristics may affect compliance with SMBP monitoring, such as the willingness and ability to self-monitor BP and the technical literacy in operating the device or an interface for telemonitoring.

Further debate focuses on the role of additional support needed to enhance adherence with SMBP monitoring and, possibly, achieve the clinical benefit from it. For example it is unclear whether simply providing a device for SMBP will improve BP control or whether this needs to be combined with additional support such as the telemetric transmission of readings to a provider to allow more frequent titration of drugs, regular nursing contact, or other types of interactions with a provider regarding hypertension management. Figure 1 shows possible comparisons between SMBP, SMBP plus additional support, support without SMBP, and usual care. The bold lines indicate the comparisons addressed in the Key Questions (see below).

Figure 1. Possible comparisons between SMBP, SMBP plus additional support, support without SMBP, and usual care



SMBP = self-measured BP; KQ = Key Question
The figure shows a schematic of possible comparisons between SMBP, SMBP plus additional, support without SMBP, and usual care. The bold lines correspond to the comparisons covered in this report: SMBP versus usual care (Key Question 1, part 1); SMBP plus additional support versus support without SMBP (also Key Question 1, part 1); SMBP plus additional support versus usual care (Key Question 1, part 2); SMBP plus additional support versus SMBP (Key Question 2).

Statement of Work

In light of the potential health care benefits and knowledge gaps highlighted above, a topic titled "Self Blood Pressure Monitoring" was developed through the processes of topic identification, selection, and refinement for Comparative Effectiveness Review (CER) within the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care program.[34]

This report focuses on SMBP monitoring as a strategy to help patients and clinicians to better manage and control hypertension while avoiding under- or overtreatment or treatment-related hypotension. This review does not explore the validity, reproducibility, or comparability of BP measurements across devices or techniques (which was addressed by the 2002 EPC report[25]), or the use of SMBP as a diagnostic tool. For the purpose of this report, BP measurement by the patient in the office/clinic/pharmacy or a health unit at work is not included under SMBP monitoring since it does not reliably overcome the problem of white coat hypertension nor provide the privacy and opportunity for more frequent measurements of home self measurement. Thus an alternative term for SMBP monitoring which better captures the application of self measurement for this report is the term home BP monitoring; however since the term is relatively rarely used in the literature, we will continue to use SMBP. Regular BP measurement by visiting nurses or other health care professionals at home is not considered to be SMBP monitoring.

The primary objective of this review is to evaluate whether the use of SMBP monitoring influences outcomes in adults and children with hypertension and to what extent these changes in

outcomes can be attributable to the use of self monitoring devices alone or the use of SMBP with additional support or attention provided. The population of interest is the general population of people with hypertension, excluding pregnant women or those receiving dialysis.

This report addresses questions regarding the clinical value of SMBP monitoring with or without additional support and what factors may predict adherence with SMBP monitoring. The goals of this report, therefore, are to inform physicians' decision whether to encourage the use of SMBP monitoring alone or along with additional support and to assist health care policymakers and payers with decisions regarding coverage and promotion of SMBP monitoring.

Key Questions

1. In people with hypertension (adults and children), does self-measured blood pressure (SMBP) monitoring, compared with usual care or other interventions without SMBP, have an effect on clinically important outcomes?
    a. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents)?
    b. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH [left ventricular hypertrophy], LVM [left ventricular mass], LVMI [left ventricular mass index]) and intermediate outcomes (BP control, BP treatment adherence, or health care process measures)?
2. In studies of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?
3. How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic versus manual) in their effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?
4. In studies of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?
5. How does adherence with SMBP monitoring vary by patient factors?

Methods

The present Comparative Effectiveness Review (CER) evaluates the effects of self-measured blood pressure (SMBP) monitoring in hypertensive patients. The Evidence-based Practice Center (EPC) reviewed the existing body of evidence on the effects of SMBP on clinical, surrogate, and intermediate outcomes in the management of hypertension. The CER is based on a systematic review of the published scientific literature using established methodologies as outlined in the Agency for Healthcare Research and Quality's (AHRQ) Methods Guide for Comparative Effectiveness Reviews (Agency for Healthcare Research and Quality. Methods Guide for Comparative Effectiveness Reviews [posted November 2008]. Rockville, MD.), which is available at: http://effectivehealth care.ahrq.gov/healthInfo.cfm?infotype=rr&ProcessID=60.

AHRQ Task Order Officer

The AHRQ Task Order Officer (TOO) was responsible for overseeing all aspects of this project. The TOO facilitated a common understanding among all parties involved in the project, resolved ambiguities, and fielded all EPC queries regarding the scope and processes of the project. The TOO and other staff at AHRQ reviewed the report for consistency, clarity, and to ensure that it conforms to AHRQ standards.

External Expert Input

During a topic refinement phase, the initial questions that had previously been nominated for this report were refined with input from a panel of Key Informants. Key Informants included experts in hypertension, general internal medicine, pediatrics, and cardiology, as well as representatives from both New York State and New York City Medicaid, and the TOO. After a public review of the proposed Key Questions, the clinical experts were reconvened to form the Technical Expert Panel (TEP), which served in an advisory capacity to help refine Key Questions, identify important issues, and define parameters for the review of evidence. Discussions among the EPC, TOO, and Key Informants, and, subsequently, the TEP occurred during a series of teleconferences and via email. In addition, input from the TEP was sought during compilation of the report when questions arose about the scope of the review.

Key Questions

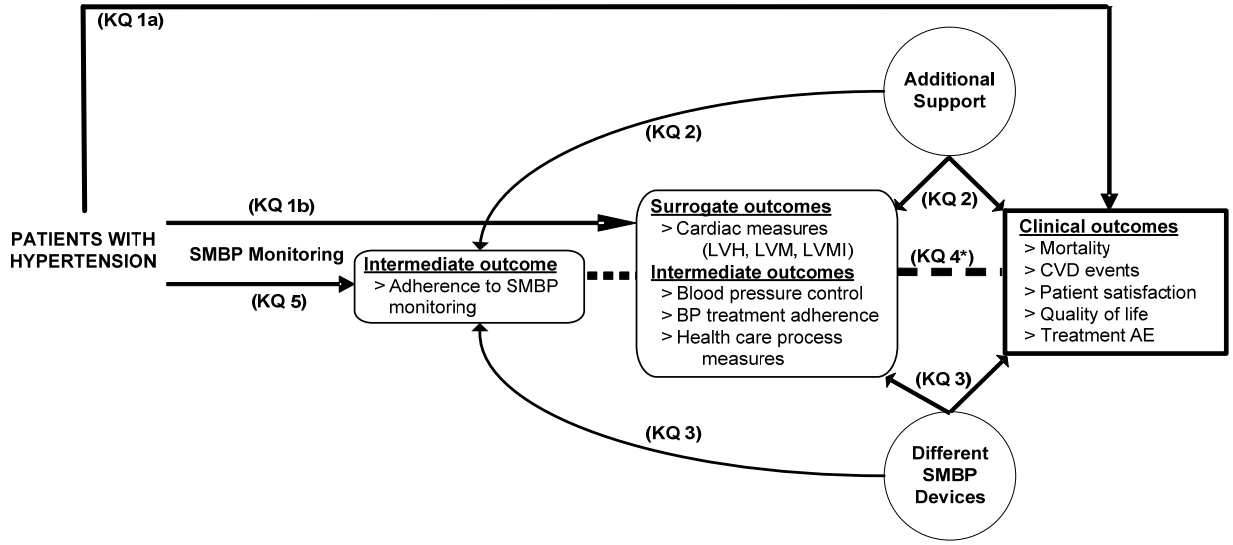
Key Questions were further refined in cooperation with the TEP and take into account the patient populations, interventions, comparators, outcomes, and study designs (PICOD) that are clinically relevant for the use of SMBP in hypertensive patients. Five Key Questions are addressed in the present report. Four pertain to outcomes in patients using SMBP devices (Key Questions 1–4); and one addresses associations between patient factors and adherence with SMBP monitoring (Key Question 5). The Key Questions are listed at the end of the Introduction.

Analytic Framework

To guide the development of the Key Questions for the evaluation of SMBP, we developed an analytic framework (Figure 2) that maps the specific linkages associating the populations of interest, the interventions, and the outcomes of interest (intermediate outcomes, surrogate

outcomes, and clinical outcomes). Specifically, this analytic framework depicts the chain of logic that evidence must support to link the interventions to improved health outcomes.

Figure 2. Analytic framework for evaluation of SMBP monitoring



AE = adverse events; BP = blood pressure; CVD = cardiovascular disease; KQ = Key Question; LVH = left ventricular hypertrophy; LVM = left ventricular mass; LVMI = left ventricular mass index; SMBP = self-measured BP
* Key Question 4 relates to the link between the specific intermediate outcome blood pressure control and either surrogate outcomes (cardiac measures) or clinical outcomes.

Literature Search

We conducted literature searches of studies in MEDLINE® (inception–July 19, 2011) and both the Cochrane Central Trials Registry®, and Cochrane Database of Systematic Reviews® (through 2nd Quarter, 2011). All studies, regardless of language and study participant age, were screened to identify articles relevant to each Key Question. Our search included terms for self-measurement, home measurement, telemonitoring, self-care, and relevant research designs (see **Appendix A** for complete search strings). We also reviewed the reference lists from recently published systematic reviews for potentially eligible studies. In addition, articles suggested by TEP members were screened for eligibility using the same criteria as for the original articles.

We also conducted a focused grey literature search to find unpublished or non-peer-reviewed data, in particular the Food and Drug Administration 510(k) database and abstracts from recent relevant scientific meetings of professional societies. We searched the Food and Drug Administration 510(k) database (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm) for all listed blood pressure (BP) measurement systems with Product Code DXN in February 2011. We limited the search to products that received approval since 1976. With the assistance of the TEP, we also compiled a list of professional organization meetings that were most likely to have published oral presentations and poster abstracts on hypertension management. Based on this list we retrieved and screened abstracts from conferences in 2009 through March 2011 from the American College of Cardiology (published in the Journal of the American College of Cardiology), the American Heart Association (published in Circulation), the American Heart Association High Blood Pressure Council (published in Hypertension), the American Society of Hypertension (published in the Journal of Clinical Hypertension), and the European Society of Hypertension (published in the Journal of Hypertension). We used the same eligibility criteria as for the full-text articles. In addition, we searched for ongoing research on SMBP in the

Clinicaltrials.gov registry on March 21, 2011 to identify observational and interventional studies of SMBP. We used the terms [blood pressure OR hypertension] as a "condition" search string combined with the following search terms for interventions [(home OR ambulatory OR self) AND (monitor* OR telemonitoring OR measure* OR manage*)]. Protocols of retrieved entries were reviewed for use of interventions and outcomes relevant to the Key Questions of the current CER. Protocols of relevant studies were tabulated.

An effort was made to collect information on accreditation of the devices used in studies that ultimately met eligibility criteria. When the information was not reported in the study reports, relevant references in the articles were checked first. Next, when necessary, a search of grey literature was conducted by searching the device name in Google, PubMed, manufacturer or company Web sites, and the FDA database. For each device, findings were tabulated according to the accreditation criteria of the British Hypertension Society, American Association of Medical Instruments, and European Society of Hypertension.

An attempt was made to supplement the literature search by solicited Scientific Information Packets. A sister organization, also under contract with AHRQ, solicited industry stakeholders, professional societies, and other interested researchers for research relevant to the Key Questions. However, we received no Scientific Information Packets.

Study Selection and Eligibility Criteria

The EPC has developed a computerized screening program, Abstrackr, to automate the screening of abstracts to include eligible articles for full-text screening.[35] The program uses an active learning algorithm to screen for articles most relevant to the key questions. Relevance was established by manually double-screening 250 abstracts to train the program. Subsequently, abstracts selected by the program were screened by one researcher. The results of each group of abstracts that were manually screened (and classified as accept or reject) were iteratively fed into the program for further training prior to generation of the next group of abstracts to be manually screened. This process continued until the program was left with only abstracts it rejected. In addition, abstracts tagged "reject" by a researcher were rescreened by a second researcher. Any abstract tagged as "accept" by either researcher was considered an accepted abstract. Using Abstrackr, we reduced by 40 percent the number of abstracts we needed to manually screen prior to starting the subsequent steps of the systematic review. While the review was subsequently being conducted, all abstracts rejected by the program were also manually screened. (All abstracts rejected by Abstrackr were also rejected by manual screening.) Full text articles were retrieved for all potentially relevant articles. These were rescreened for eligibility. The reasons for excluding these articles were tabulated in **Appendix B.**

Eligible studies were further segregated using the following selection criteria: population and condition of interest; interventions, predictors, and comparators of interest; outcomes of interest; study designs; and duration of follow-up.

Population and Condition of Interest

We included studies conducted in both adults (≥18 years) and children with hypertension, Hypertension in adults is generally defined as an untreated (or pretreatment) BP >140/90 mmHg.[1] In children, it is generally defined as either a BP above a cut-off for age, sex and height reference. We allowed any clinically reasonable definition of hypertension, including existing treatment with antihypertensive medications. By consensus with the TEP, we excluded studies in which participants were on dialysis or had gestational hypertension. Hypertension in these

special populations has a different pathophysiology, different duration, and different outcomes of interest. We also excluded studies where SMBP was part of a comprehensive disease management for heart failure or for weight loss, regardless of the presence of hypertension.

Interventions, Predictors, and Comparators of Interest

SMBP Monitoring (All Key Questions)

We included only SMBP upper arm monitors and excluded wrist monitors except in cases where they were used as a default for selected patients with large arm circumference. All varieties of SMBP monitors (manual, semiautomated, automated) were included. We included all monitors, regardless of whether they have been accredited or validated, or whether they are commercially available. We excluded studies where self measurement was not undertaken at home, for example if the participant self measured in the clinic, office, pharmacy, or workplace. We allowed studies that used home measurement devices where the measurement was done by a family member or a companion of the patient. SMBP had to be used as a medical intervention, not solely as a measurement tool for a BP outcome (e.g., a trial of antihypertensive medications where the BP outcome was measured with SMBP). SMBP monitoring had to be conducted for at least 8 weeks.

Additional Support

We included studies of SMBP monitoring with (or without) any type of additional support. Studies of additional support had to include at least one group who used SMBP monitoring. The study abstract and/or title must have suggested that SMBP monitoring was used as a principle part of the intervention. We did not screen all studies of ancillary interventions to find those that happened to use SMBP monitoring. Additional support included but was not limited to educational training, reminders, nursing interventions, telemonitoring, algorithms for medication titration, and additional physician consultation.

Key Question 1 was limited to studies that compared SMBP monitoring (with or without additional support) to usual care (any office or clinic BP monitoring). From studies that included groups who used SMBP alone, SMBP with additional support, additional support alone, and usual care, we evaluated three comparisons for this Key Question: SMBP alone versus usual care; SMBP with additional support versus additional support alone; and SMBP with additional support versus usual care.

Key Question 2 was limited to studies that compared SMBP monitoring with additional support to either SMBP without additional support or SMBP with an alternative additional support.

Key Question 3 was limited to studies that compared SMBP monitoring (with or without additional support) with one SMBP device (or type of device, e.g., manual) with another SMBP device (or type of device, e.g., automated).

Key Question 4 included studies that evaluated any SMBP. We evaluated the effect of SMBP on BP control as a predictor of clinical and surrogate outcomes.

Key Question 5 included studies that addressed the outcome of adherence with any type of SMBP monitoring. A prerequisite was that studies had to evaluate adherence rates based on specific predictors. We included any predictors of adherence with SMBP monitoring, with a primary interest in patient factors (e.g., demographics, medical or comorbid conditions, care setting).

Outcomes of Interest

Key Questions 1–4

The outcomes of interest were classified into three categories: clinical outcomes (e.g., mortality and cardiovascular events), surrogate outcomes (e.g., left ventricular hypertrophy and left ventricular mass index), and intermediate outcomes (e.g., BP control and number and change of antihypertensive medications).

Clinical outcomes (Key Questions 1a, 2, 3, & 4)

- Cardiovascular events (myocardial infarction, angina, congestive heart failure, stroke, transient ischemic attack, peripheral vascular disease diagnosis or events)
- Cardiovascular mortality (as defined by studies)
- All-cause mortality
- Patient satisfaction (any measurement tool, including satisfaction specifically with SMBP device)
- Quality of life
- Adverse events related to treatment with antihypertensive agents (e.g., hypotensive episodes or orthostatic falls)

Surrogate outcomes (Key Questions 1b, 2, 3, & 4)

- Cardiac measures
    - Left ventricular hypertrophy by echocardiography
    - Left ventricular mass by echocardiography
    - Left ventricular mass index by echocardiography

Intermediate outcomes (Key Questions 1b, 2, & 3)

- BP control (also predictor in Key Question 4)
    - Achieving a predefined change in BP (e.g., systolic BP reduction by 10 mmHg) or a predefined threshold (e.g., systolic BP <140 mmHg)
    - Systolic and diastolic BP or mean arterial pressure which must be measured the same way in both groups. SMBP measured BP can be outcome only for Key Questions 2 & 3.
        - Clinic or other measurement by a health care professional
        - Ambulatory BP (as either mean wake or daytime, mean sleep or nighttime, or mean 24 hour BPs)
    - Number and dose of hypertension medications or number of medication changes

N.B. We did not extract or analyze data regarding how the BP was measured (beyond whether it was clinic, self-measured, or ambulatory). We did not extract body position (seated, prone), mandated rest periods, which readings were discarded, or whether

measurements were based on single readings or averages of multiple readings, or other such BP measurement protocols.

- Adherence to hypertension treatment.
    - *Not:* adherence to BP monitoring (for Key Questions 1–4)
- Health care process measures such health care encounters (visits or calls)
- *Not:*
    - Diagnosis of hypertension
    - Diagnosis of white coat or masked hypertension
    - Diagnostic accuracy

Adherence with SMBP monitoring (Key Question 5)

- Adherence (or compliance) with SMBP monitoring, including any measurements used by the studies

Eligible Study Designs

We included both published, peer-reviewed articles from the formal literature search and recent abstracts and other reports from the grey literature (unpublished and nonpeer-reviewed data), though abstracts were described only in the text and were not included in Summary Tables. We included articles in any language (and used Google Translate [http://translate.google.com] and consulted foreign-language-speaking colleagues, when necessary).

SMBP Monitoring (Key Questions 1–4)

We included all comparative studies, including randomized controlled trials (RCTs), quasi-RCTs, and nonrandomized prospective studies. We excluded retrospective longitudinal studies. Studies must have had at least 8 weeks of followup. There was no minimum sample size threshold.

Adherence (Key Question 5)

We included prospective or retrospective longitudinal studies that analyzed at least 100 adults or at least 10 children who used SMBP monitoring for at least 8 weeks. The sample size threshold for adult studies was chosen to allow for adequate statistical analysis of the predictors. A lower threshold was chosen for pediatric studies due to expected sparseness of studies in this population. Case-control studies were excluded. Studies must have evaluated adherence rates based on predictors (for example age group ≥65 versus <65 years old), not predictor values based on adherence (for example adherers were on average X years old and nonadherers were on average Y years old). We included both univariable and multivariable analyses.

Data Extraction and Summaries

Two articles were extracted simultaneously by all researchers for training. Subsequently, each study was extracted by one experienced methodologist. The extraction was reviewed and confirmed by at least one other methodologist. Data were extracted into customized forms in Microsoft Word, designed to capture all elements relevant to the Key Questions. Separate forms were used for questions related to SMBP outcomes (Key Questions 1–4), and adherence with SMBP (Key Question 5) (see **Appendix C** for the data extraction forms). The forms were tested on several studies and revised before commencement of full data extraction.

Items common to both forms included first author, year, country, sampling population, recruitment method, whether multicenter or not, enrollment years, funding source, study design, inclusion, and exclusion criteria, specific population characteristics including demographics such as age and sex, and BP. Both forms also included information on baseline medication use, additional interventions, and device accreditation.

For each outcome of interest, baseline, followup, and change from baseline data were extracted, including information of statistical significance. We either extracted data from all timepoints or, if a large number of timepoints were reported, selected those timepoints most common with other studies, and noted that other timepoint data are available. Adverse event data related to antihypertensive treatment or safety of treatment were extracted, if available.

For studies that reported analyses of predictors of adherence with SMBP (Key Question 5), full data were extracted for each reported predictor when analyses were performed from the perspective of the predictor (i.e., baseline age as a predictor of death, not the mean age of those who lived and died). All analyses (e.g., univariable and multivariable) were extracted.

Quality Assessment

We assessed the methodological quality of studies based on predefined criteria. We used a three-category grading system (A, B, or C) to denote the methodological quality of each study as described in the AHRQ methods guide.[36] This grading system has been used in most of the previous evidence reports generated by the EPC. This system defines a generic grading scheme that is applicable to varying study designs including RCTs, nonrandomized comparative trials, cohort, and case-control studies. For RCTs, we primarily considered the methods used for randomization, allocation concealment, and blinding as well as the use of intention-to-treat analysis, the report of dropout rate, and the extent to which valid primary outcomes were described as well as clearly reported. For treatment studies, only RCTs could receive an A grade. Nonrandomized studies and prospective and retrospective cohort studies could be graded either B or C. For all studies, we used (as applicable): the report of eligibility criteria, the similarity of the comparative groups in terms of baseline characteristics and prognostic factors, the report of intention-to-treat analysis, crossovers between interventions, important differential loss to followup between the comparative groups or overall high loss to followup, and the validity and adequacy of the description of outcomes and results.

A (good). Quality A studies have the least bias, and their results are considered valid. They generally possess the following: a clear description of the population, setting, interventions, and comparison groups; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; clear reporting of dropouts and a dropout rate less than 20 percent dropout; and no obvious bias. For treatment studies, only RCTs may receive a grade of A.

B (fair/moderate). Quality B studies are susceptible to some bias, but not sufficiently to invalidate results. They do not meet all the criteria in category A due to some deficiencies, but none likely to introduce major bias. Quality B studies may be missing information, making it difficult to assess limitations and potential problems.

C (poor). Quality C studies have been adjudged to carry a significant risk of bias that may invalidate the reported findings. These studies have serious errors in design, analysis, or reporting and contain discrepancies in reporting or have large amounts of missing information.

Data Synthesis

We summarized all included studies in narrative form as well as in summary tables (see below) that condense the important features of the study populations, design, intervention, outcomes, and results. We divided study groups (or arms) into three categories: SMBP alone; SMBP and additional support: and control. For Key Question 1, we considered SMBP versus usual care. This included studies that compared SMBP alone versus usual care (or a reasonable variation of usual care), SMBP plus additional support versus usual care, and SMBP plus an additional support versus the same additional support. Thus, a study that compared SMBP plus an education program versus use of the education program alone was treated as a comparison of SMBP versus usual care (where the education program "cancels out"). In addition, in studies that included three or more groups (specifically either [1] SMBP alone, SMBP plus additional support, and control or [2] SMBP plus an additional support, SMBP plus a different additional support, and control), the direct comparisons of SMBP with control were treated as independent despite the reuse of the control. For Key Question 2, we considered both [1] SMBP plus additional support versus SMBP alone and [2] SMBP plus an additional support versus SMBP plus a different additional support. Again, we cancelled out additional supports that were used in both study groups (e.g., use of an educational leaflet) and allowed multiple comparisons with the same comparator group.

For Key Questions 1 to 4, which evaluate the effect of an intervention on intermediate and clinical outcomes, we performed DerSimonian & Laird random effects model meta-analyses of differences of continuous variables between interventions where there were at least three studies that were deemed to be sufficiently similar in population and had the same comparison of interventions and the same outcomes.[37] In practice this meant that meta-analyses were restricted to the comparison of SMBP monitoring alone (with no additional support) versus usual care. We did not attempt to meta-analyze the SMBP with heterogeneous additional support versus control comparisons. For each specific BP outcome, we performed separate meta-analyses at specific timepoints (e.g., 3 months, 1 year), chosen based on available relevant data. All timepoints with reported data from each study were included in the forest plots.

We preferentially evaluated the net change BP (the difference between the change in BP from baseline between the intervention of interest and the control intervention). However, when the net change could not be calculated (or if the study used a crossover design), we assessed the difference between final BP measurements.

However, a large number of studies did not report full statistical analyses of the net change or difference of final values. Where sufficient data were reported, we calculated these values and estimated their confidence intervals (CI). These estimates were included in the summary tables and were used for meta-analyses. In the summary tables we include only the P-values reported by the studies (not estimated P-values). If a study reported an exact P-value for the difference, we calculated the CI based on the P-value. When necessary, standard errors of the differences were estimated from reported standard deviations (or standard errors) of baseline and/or final values. For parallel trials, we arbitrarily assumed a 50 percent correlation of baseline and final values in patients receiving a given intervention. Likewise for crossover trials, we assumed a 50 percent correlation between final values after interventions (among the single cohort of patients). Thus in both cases we used the following equation to estimate the standard error (SE):

$$SE^2_{difference} = (SE_A)^2 + (SE_B)^2 - 2 \cdot r \cdot (SE_A) \cdot (SE_B)$$

where r=0.5 and A & B are the correlated values.

For each meta-analysis the statistical heterogeneity was assessed with the I^2 statistic, which describes the percentage of variation across studies that is due to heterogeneity rather than chance.[38,39]

We performed two sets of sensitivity meta-analyses: first by including data from conference proceeding abstracts (which had not been included in the primary analyses)—this sensitivity analysis is presented in relevant forest plots (see Results); and second by excluding quality C studies to draw inferences from syntheses of quality A and B studies only—because this sensitivity analysis found no difference from the primary analysis, its results are described in the text only.

Evidence Tables

Evidence tables succinctly report measures of the main outcomes evaluated. The decision about which data to include in the evidence tables was made in consultation with the TEP. We included information regarding sampled population, country, study design, interventions, demographic information on age and sex, the study setting, number of subjects analyzed, dropout rate, and study quality. For continuous outcomes, we included the time point of ascertainment, the baseline values, the within-group changes (or final values for crossover studies), the net difference (or difference between final values) and its 95 percent CI and P-value. For categorical (dichotomous) outcomes, we report the time point of ascertainment, the number of events and total number of patients for each intervention and (usually) the risk difference and its 95 percent CI and P-value. If results were given for several timepoints, we included the longest timepoint up to and including 1 year as well as the longest timepoint beyond 1 year. If adjusted results were provided, we preferentially included these in the evidence tables and the meta-analyses, noting covariates for adjustment.

Each set of tables includes a study and patient characteristics table (which is organized in alphabetical order by first author). Results are presented in separate evidence tables for each outcome. Within these tables, the studies are ordered alphabetically. It should be noted that the P-value column includes the P-value reported in the articles for the difference in effect between the two interventions of interest. The table also includes the 95 percent CI about the net difference (or difference in final values, from crossover studies); however, in the large majority of cases, these numbers were estimated by the EPC based on reported standard deviations, standard errors, and P-values. This is noted in each table.

Grading a Body of Evidence for Each Key Question

We graded the strength of the body of evidence as per the AHRQ methods guide.[36] Based on the division of outcomes within the Key Questions, we determined the strengths of evidence for the following three categories of outcomes: 1) BP (continuous and categorical outcomes); 2) other clinical, surrogate and intermediate outcomes, including quality of life and satisfaction; and 3) outcomes related to resource use. We further divided Key Question 1 into two sections: SMBP alone versus usual care; and SMBP and additional support versus usual care.

Risk of bias was defined as low, medium, or high based on the study design and methodological quality. We assessed the consistency of the data as either “no inconsistency” or “inconsistency present” (or not applicable if only one study). The direction, magnitude, and statistical significance of all studies were evaluated in assessing consistency, and logical explanations were provided in the presence of equivocal results.

We also assessed the relevance of evidence. Studies with limited relevance either included populations which related poorly to the general population of adults with hypertension or that contained substantial problems with the measurement of the outcomes of interest. (As will be shown in the Results section, we found no studies conducted in children.) We also assessed the precision of the evidence based on the degree of certainty surrounding an effect estimate. A precise estimate was considered an estimate that would allow a clinically useful conclusion. An imprecise estimate was one for which the CI is wide enough to preclude a conclusion.

We rated the strength of evidence for a particular comparison for each outcome category using one of the following four labels (as per the AHRQ methods guide): High, Moderate, Low, or Insufficient. Ratings were assigned based on our level of confidence that the evidence reflected the true effect for the major comparisons of interest. Ratings were defined as follows:

High. There is a high level of assurance that the findings of the literature are valid with respect to the relevant comparison. No important scientific disagreement exists across studies. At least two quality A studies are required for this rating.

Moderate. There is a moderate level of assurance that the findings of the literature are valid with respect to the relevant comparison. Little disagreement exists across studies. Moderately rated bodies of evidence contain fewer than two quality A studies or such studies lack long-term outcomes of relevant populations.

Low. There is a low level of assurance that the findings of the literature are valid with respect to the relevant comparison. Underlying studies may report conflicting results. Low rated bodies of evidence could contain either quality B or C studies.

Insufficient. Evidence is either unavailable or does not permit estimation of an effect due to lacking or sparse data. In general, when only one study has been published, the evidence was considered insufficient, unless the study was particularly large, robust, and of good quality.

Overall Summary Table

To aid discussion, we summarized all studies and findings into one table in the Summary and Discussion (and the Executive Summary). Separate cells were constructed for each key question and subquestion. The table also includes the strength of evidence to support each conclusion.

Peer Review

The initial draft report was pre-reviewed by the TOO and an AHRQ Associate Editor (a senior member of a sister EPC). Following revisions, the draft report was sent to invited peer reviewers and was simultaneously uploaded to the AHRQ Web site where it was available for public comment for 30 days. All reviewer comments (both invited and from the public) were collated and individually addressed. The revised report and the EPC's responses to invited and public reviewers' comments were again reviewed by the TOO and the Associate Editor prior to completion of the report. The authors of the report had final discretion as to how the report was revised based on the reviewer comments, with oversight by the TOO and the Associate Editor.

Results

The literature search yielded 10,331 citations. From these, 334 articles were provisionally accepted for review based on abstracts and titles (Figure 3). After screening their full texts, 46 studies, published in 49 articles, were judged to have met the inclusion criteria. One additional study was found in the reference lists of previous reviews. The grey literature search yielded two conference abstracts but no additional studies from the Food and Drug Administration database. Thus a total of 49 studies (in 52 articles) are reviewed herein. The Summary Tables, with the descriptions and results of each study (except the two abstracts), are in **Appendix D.**

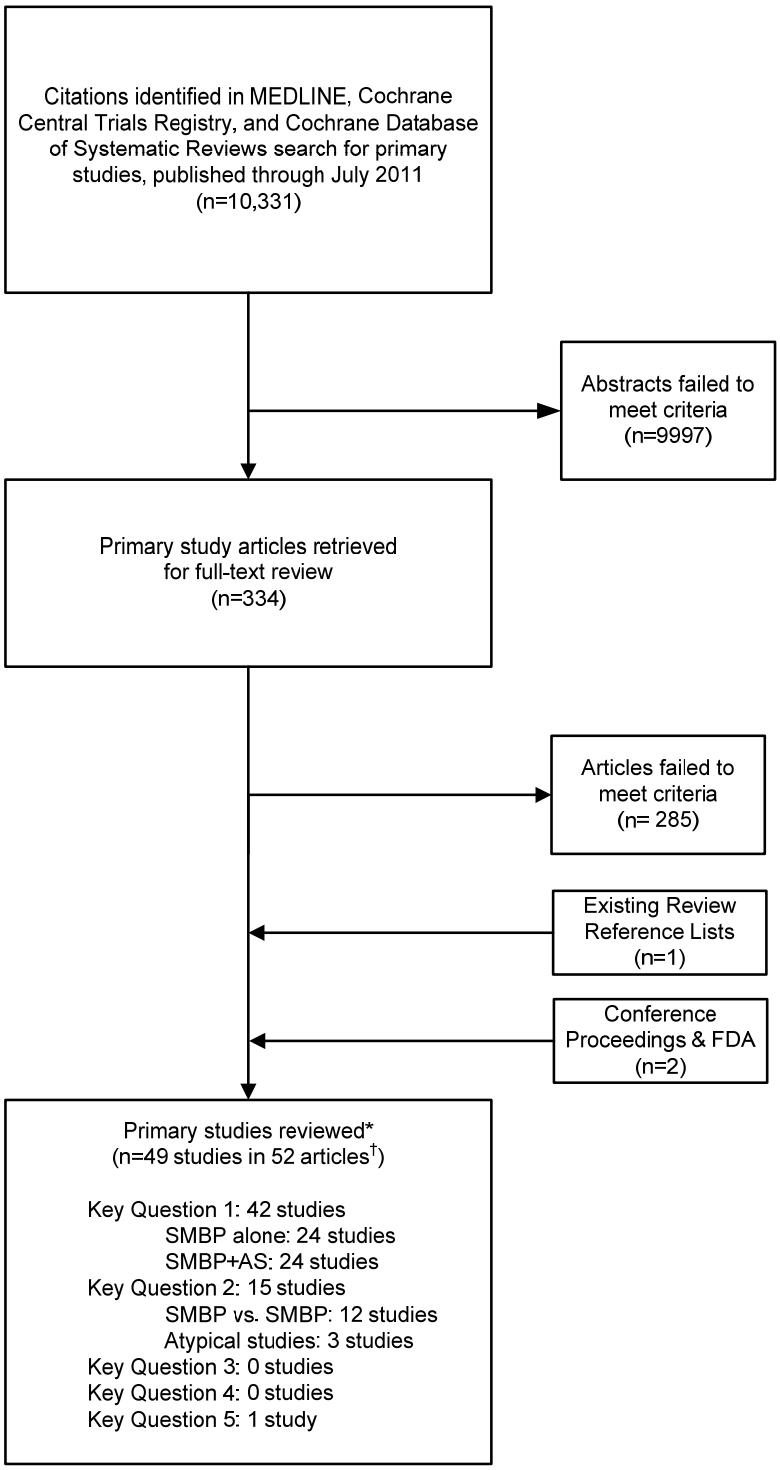
The remaining 285 retrieved articles were rejected for not meeting eligibility criteria; one additional study retrieved from the reference list of a previous review also did not meet eligibility criteria (see **Appendix B** for the list of rejected articles and the rationale for their rejection). The most common reasons for article rejection were that the analyzed intervention was not self-measured blood pressure (SMBP), the cohort study did not evaluate predictors of adherence with SMBP and/or was too small, SMBP monitoring was used for less than 8 weeks, the article was not a primary study, SMBP monitoring was being performed to diagnose hypertension (or white coat hypertension), and the accuracy or validity of an SMBP device was being measured.

None of the studies were conducted in children. The applicability for each section is thus with reference to adults with hypertension.

Devices used for SMBP monitoring in the 49 studies (including the two conference abstracts) are shown in Table D-1 in **Appendix D**, along with information that could be retrieved on their validation or accreditation according to the American Association of Medical Instruments, British Hypertension Society, or European Society of Hypertension. In the following we tabulate the information on the device type and accreditation only for the upper arm monitors, although two studies also provided a wrist monitor as a default for individuals with large arm circumference. Regarding devices, 28 studies used automated devices, 2 semi-automated, 4 manual devices, and in 15 the information on the devices was not sufficient to determine the device type.

Regarding accreditation, in 32 studies it appeared that the device was accredited by at least one of the accreditation bodies. However, in 6 of these 30 studies it was not clear if the device for which accreditation information was cited or could be found was identical to the one used in the study, in three studies accreditation was claimed based on other or unpublished data that could not be clearly tracked to formal accreditation criteria, in one study, question remained as to if accreditation criteria were satisfied and one study used a collection of 30 different monitors with incomplete information on device accreditation except for the four main devices. In the remaining 21 studies, there was information on device accreditation.

Figure 3. Literature flow



FDA = Food and Drug Administration Web site; SMBP = self-measured blood pressure; SMBP+AS = self-measured blood pressure with additional support

* The numbers of studies for each Key Question do not sum to the total number of studies as several studies addressed both Key Questions 1 and 2.

† Including two conference abstracts.

Key Question 1

In people with hypertension (adults and children), does self-measured blood pressure (SMBP) monitoring, compared with usual care or other interventions without SMBP, have an effect on clinically important outcomes?

a. **How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents)?**
b. **How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH [left ventricular hypertrophy], LVM [left ventricular mass], LVMI [left ventricular mass index]) and intermediate outcomes (BP control, BP treatment adherence, or health care process measures)?**

For Key Question 1, we included only studies of interventions using SMBP monitoring as a principal part of the medical intervention in individuals with hypertension. The first part in this section discusses studies that compared SMBP alone with usual care. The second part discusses studies that compared SMBP with additional support versus usual care. Descriptions of all studies that addressed Key Question 1 (for both parts of the write-up) are summarized in **Appendix D** Table 2 (descriptions of the interventions) and Table 3 (descriptions of the study characteristics).

Comparison of SMBP Alone Versus Usual Care

We identified 24 studies (23 reported in 24 articles and 1 study reported as a conference abstract) that contributed data to the comparison of SMBP monitoring alone versus usual care.[20,42-44,47,48,51,53,56,58,59,62,64,67,68,71,72,77,79,83,85-88,90] These studies have been published over the past 35 years (1975 to 2010), with seven published before 1990. Of the 24 identified studies, 21 concerned comparisons of SMBP alone versus usual care, and five provided data for the comparison of SMBP plus some additional support (including education, telecounseling, or home visitor measurement in each study) versus the same additional support alone.[43,44,53,64,77] The latter comparison was considered to correspond to a "SMBP versus usual care" comparison because the additional support interventions are common in both arms and thus their effects can be considered to cancel out. Thus a total of 26 comparisons were considered.

Of the 24 examined studies, 22 were randomized controlled trials (RCTs) and two were quasi-RCTs (Pierce 1984; Stahl 1984). Of the 22 RCTs, one was of a crossover design (Fitzgerald 1985) and the remaining were parallel group studies. Two of the trials (Dalfo i Baqué 2005 and Godwin 2010) used a cluster randomization scheme, randomizing clinics or physicians, rather than individual patients, to each group.

The examined SMBP interventions utilized a variety of monitor types (11 studies used automated monitors, while the remaining employed manual or semiautomated monitors) (Table D-1 in **Appendix D**) and applied different followup protocols with respect to frequency of blood pressure (BP) measurements, clinic visits, and types of BP recording and transmission (patient recorded versus centralized automatic transmission) (Table D-2). Usual care typically consisted of the standard-of-care management of hypertension in outpatient and general practice settings, as defined by the current standards of practice in each study.

Nineteen studies included patients with hypertension irrespective of whether these patients were on antihypertensive treatment at study enrollment (Table D-3). Four studies[58,59,64,67] included only patients with poorly controlled hypertension despite being on antihypertensive medication, and one study included only patients that had not received antihypertensive treatment for at least one year (Stahl 1984). Thirteen of the 24 studies explicitly defined that the patients included had essential hypertension, whereas the remaining 11 studies[20,43,44,47,48,53,58,64,67,72,85,90] did not clarify whether patients with secondary hypertension were included as well. Mean baseline systolic BP (SBP) ranged from 124 to 167 mmHg and diastolic BP (DBP) ranged from 70 to 109 mmHg. The mean age of patients ranged from 47 to 73 years, and men accounted for the majority of participants in 12 of 24 studies. The sample sizes of the intervention groups of interest in the included studies ranged from 12 to 1,325 patients (total = 5400 across studies). The most commonly cited comorbid conditions in these studies were type 1 or 2 diabetes, obesity, dyslipidemia, and cardiovascular disease.

Four studies were rated quality A, six studies were rated quality B, and 13 quality C. The conference abstract (Fuchs 2010) was not graded for quality due to insufficient data. The primary methodological concerns included small sample sizes with multiple testing, lack of power calculations, high dropout rates without adjustments for missing data, and incomplete or inconsistent reporting of data.

Clinical Events

None of the studies examined clinical event outcomes.

Blood Pressure Outcomes

BP outcomes were reported by 23 studies (25 comparisons in total). Four studies were rated quality A, 5 studies were rated quality B, and 13 quality C. The conference abstract was not graded for quality due to insufficient data. Followup durations ranged from 2 to 36 months, with only two studies (Bosworth 2009; Stahl 1984) having one of more than a year. Reported BP outcomes included both categorical outcomes, where the outcomes were defined as achieving a predefined BP target (e.g., clinic SBP <140 mmHg), and continuous outcomes, where net differences of SBP and DBP between baseline and final measurements (or, in some studies, differences between final values) were calculated. Clinic BP and ambulatory (24-hour, awake, and asleep) BP measurements were reported.

Categorical BP Outcomes (Table D-4, Figure 4)

Thirteen studies reported categorical BP outcomes.[20,44,51,53,58,62,67,68,71,77,79,85,87] Six RCTs provided data for the outcome of reaching a predefined BP threshold (considered as "adequate" BP control) at 6-month followup. The SBP thresholds used by studies considering the whole population or only nondiabetic patients ranged from 130 to 140 mmHg and DBP thresholds from 80 to 95 mmHg. Three studies specified lower BP thresholds for diabetic patients, however, reporting values which ranged from 125 to 130 mmHg for SBP and 75 to 85 mmHg for DBP.

Meta-analysis of six studies (two quality A, one quality B and three quality C studies) at 6 months followup revealed a nonstatistically significant increase in the probability of achieving adequate BP control with SMBP monitoring (summary relative risk [RR] 1.24; 95 percent confidence interval [CI] 0.94 to 1.63), with statistically significant heterogeneity (I^2 = 73 percent). All studies reported a point estimate indicating a favorable effect of SMBP monitoring, with the exception of Dalfo i Baqué 2005, which reported a nonsignificant odds ratio (OR) of

0.79 (95 percent CI 0.56 to 1.12) favoring usual care. In a sensitivity meta-analysis that included only the three quality A or B studies, a statistically significant summary RR of 1.53 (95 percent CI 1.22 to 1.93) favoring SMBP was found, with no statistical heterogeneity (I^2 = 0 percent).

Three RCTs (all rated as quality B studies) reported data for the adequate BP control outcome at 12 months (defined as <140/90 mmHg in one study, and as <140/90 mmHg for nondiabetic and <130/80 mmHg for diabetic patients in the other two studies). Meta-analysis of these results indicated that the summary estimate did not show a statistically significant effect of SMBP monitoring (summary RR 1.18; 95 percent CI 0.95 to 1.46) and that extensive statistical heterogeneity was present (I^2 = 86 percent). Two comparisons from the same trial (Bosworth 2009) also reported nonsignificant SMBP effects at 24 months followup; however, this study had a more than 20 percent dropout rate at this timepoint.

Four studies reporting categorical BP outcomes were not included in the aforementioned meta-analyses. Pierce 1984 and Stahl 1984 were not included because these were quasi-RCTs; Fuchs 2010 was excluded because the categorical BP outcome was evaluated at 2 months only; and Rogers 2001 was excluded because the reported outcome was the proportion of patients with reductions in SBP and DBP from baseline and not the achievement of a predefined BP target. None of the Pierce 1984, Stahl 1984 and Fuchs 2010 studies found that the use of SMBP was associated with a significant increase in the probability of achieving adequate BP control (for SBP and DBP in Pierce 1984 and Fuchs 2010 and DBP in Stahl 1984). However, Rogers 2001 reported that SMBP use resulted in significantly increased odds of experiencing reductions in SBP (OR 2.52; 95 percent CI 1.13 to 5.64) and DBP (OR 2.32; 95 percent CI 1.05 to 5.15).

Continuous BP Outcomes

In total, 21 studies provided data for continuous BP outcomes.[20,42-44,47,48,53,56,58,59,62,64,67,68,71,72,79,83,85,87,88]

Clinic BP (Table D-5, Figure 5)

Seventeen studies examined net changes in clinic SBP and DBP between the SMBP and control arms from baseline to final measurements. Three of the studies provided data for BP changes at 2 months. Meta-analysis of these three quality C studies revealed no significant difference in the net change of SBP and DBP between SMBP and usual care: SBP summary net change = 0.1 mmHg (95 percent CI -4.1, 4.3; nonsignificant [NS]); DBP summary net change = 0.1 mmHg (95 percent CI -1.5, 1.7; NS).

For the comparison at 6 months followup, seven RCTs provided data for SBP net changes (one quality A, four quality B and two quality C studies) and nine RCTs for DBP (one quality A, four quality B and four quality C studies). By meta-analysis of these studies, a statistically significant reduction for both SBP and DBP was found favoring SMBP: SBP summary net change = -3.1 mmHg (95 percent CI -5, -1.2; P = 0.002), with low statistical heterogeneity (I^2 = 24 percent); DBP summary net change = -2.0 mmHg (95 percent CI -3.2, -0.8; P = 0.001), with moderate heterogeneity (I^2 = 41 percent). All studies had point estimates indicating a favorable effect of SMBP over usual care for both SBP and DBP, with the exception of DeJesus 2009 and Johnson 1978B that showed nonsignificant net changes in DBP favoring usual care over SMBP. In sensitivity meta-analyses that included only quality A and B studies, no material changes in the magnitude and statistical significance of the summary net changes for SBP and DBP were found.

For the 12-month followup data, seven RCTs (one quality A, five quality B and one quality C) were synthesized by meta-analysis (three of them having also contributed data for the 6

month meta-analysis). In the 12-month meta-analysis, no statistically significant net change was evident for SBP or DBP: SBP summary net change = -1.2 mmHg (95 percent CI –3.5, 1.2), with moderate heterogeneity (I^2 = 66 percent); DBP summary net change = –0.8 (95 percent CI -2.5, 1.0), with high heterogeneity (I^2 = 81 percent). These summary estimates remained essentially unchanged in sensitivity meta-analyses that included only quality A and B studies.

Beyond 12 months of followup, data were provided only by two comparisons from the same trial (Bosworth 2009). Significant reductions for SBP and DBP with SMBP were found at 24 months only in the comparison of SMBP plus telecounseling versus telecounseling alone.

Stahl 1984, a quasi-RCT not included in the aforementioned meta-analyses, reported a significant reduction in DBP favoring SMBP at 7–12 months followup. The reduction in DBP was no longer statistically significant at subsequent followup times up to 36 months, which were characterized by large proportions of dropouts (>20 percent).

24 Hour Ambulatory BP (Table D-6, Figure 6)

For the net change in 24 hour ambulatory BP measurement, five studies contributed data; however, the followup durations varied from 2 to 12 months, thus no meta-analysis was feasible for this outcome. At 2 months, three studies (one quality A, one quality C and one conference abstract not rated for quality) reported significant differences in SBP measurements between SMBP monitoring and usual care but different directions of effects were noted. By meta-analysis, no statistically significant net change was found for 2 hour ambulatory SBP or DBP: SBP summary net change = -1.3 mmHg (95 percent CI -8.5, 5.9), with high heterogeneity (I^2 = 84 percent); DBP summary net change = –2.7 (95 percent CI -5.9, 0.4), with moderate heterogeneity (I^2 = 63 percent). Of these three studies, Rogers 2001 was rated as quality A and reported significant results favoring SMBP for both 24 hour ambulatory SBP and DBP. Of the two studies reporting 12 month followup data, Goodwin 2010 showed a significant net change in DBP favoring SMBP (-2.0 mmHg), whereas Verberk 2007 reported that the 24 hour ambulatory SBP and DBP were significantly higher in the SMBP group (SBP: +2.1 mmHg; DBP: +1.1 mmHg), thus favoring the usual care arm.

Awake (or day) Ambulatory BP (Table D-7, Figure 7)

Six studies reported awake ambulatory BP. The majority of reported comparisons between the SMBP and usual care arms were nonsignificant in individual studies. Statistically significant results were reported only for SBP by Bailey 1999 (2 months) favoring usual care, for DBP by the conference abstract by Fuchs 2010 (2 months) favoring SMBP, and for both SBP and DBP by Verberk 2007 (12 months) favoring usual care.

Asleep (or Night) Ambulatory BP (Table D-8, Figure 8)

A similar pattern of results was also observed for the net change in asleep ambulatory BP in four studies published in full reports, with all but one comparison for SBP and DBP showing no significant differences between SMBP and usual care arms; a marginally statistically significant result was reported by Verberk 2007 showing a 2.2 mmHg net change in SBP with SMBP at 12 months, favoring usual care. The conference abstract by Fuchs 2010 reported a statistically significant change in both SBP and DBP at 2 months, favoring SMBP.

Medication Dosage (Tables D-9&10)

Eight studies provided data on outcomes relating to the number of medications prescribed and dosage (1 quality A, 5 quality B, and 2 quality C).[42,62,72,77,86-88,90] The followup duration in

these studies ranged from 2 to 12 months. Reported medication outcomes included both categorical outcomes (Table D-9), where the outcomes were defined as the number of patients with a specified change in medication (e.g., an increase in dosage or ceasing treatment with a particular class of medication), and continuous outcomes (Table D-10), which included number of medications and dosages. Due to the heterogeneity in outcome definitions between studies, no meta-analyses were feasible.

Six out of these eight studies reported categorical medication outcomes.[42,72,77,87,88,90] Medication changes were reported in a variety of ways. Three examined an increase in medications, defined variously as either an increase in medication number, medication dose, an added medication class, or physician assessment of strength of medication regimen; none found a significant different between groups.[42,67,77] Four looked at medication inertia, defined as no change in medication regimen; none of the four found a difference between groups,[67,77,87,88] Two studies reported on a decrease of medication, either as a lower strength of mediation regiment as assessed by a physician or by a cessation of treatment with a particular class of medication.[42,77] Neither found a difference between groups. In addition, Midanik 1991 found no difference in the number of patients using medication after study completion at 12 months.

Four of seven studies reported continuous medication outcomes.[62,86,88,90] Two compared the number of antihypertensive medications used per patient between SMBP and usual care groups; neither found a significant difference.[88,90] Halme 2005 reported no difference between groups in the number of medication changes per patient. van Onzenoort 2010 found the SMBP group to be prescribed 1.9 daily doses of antihypertensive medication compared to 2.4 in the usual care group (P = 0.001).

Medication Adherence (Tables D-11&12)

Seven studies in total provided data on outcomes relating to medication adherence (3 quality B and 4 quality C).[42,47,68,71,77,86,88] Followup durations in these studies ranged from 2 to 12 months. Reported medication outcomes included both categorical outcomes (Table D-11), where the outcomes were defined as the number of patients with a specified level of medication adherence, and continuous outcomes (Table D-12), where adherence was measured on a continuous scale (e.g. tablet count).

Five of these seven studies reported categorical medication adherence outcomes.[42,47,68,77,86] In Marquez-Contreras 2006, patients with SMBP exhibited significantly different rates of adherence compared to those with usual care (P<0.001). Most notably, patients using SMBP were less likely to have adherences <80 percent as assessed by tablet count (RR 0.31; 95 percent CI 0.15, 0.65). Pierce 1984 found that the SMBP group was less likely to be rated as poor at medication adherence by a visiting nurse (RR 0.54; 95 percent CI 0.21, 1.37). However, neither Bailey 1999 (assessed by tablet count), van Onzenoort 2010 (electronic pill box monitoring), or Broege 2001 found any difference in medication adherence between groups (no specific adherence assessment method described).

Four studies reported continuous medication adherence outcomes.[68,71,86,88] Mehos 2000 did not find a difference between groups in adherence as defined by percent of prescribed medications refilled. However, Marquez-Contreras 2006 found the SMBP group to take antihypertensive medication correctly on a greater percentage of study days (difference = 5.7 percent; 95 percent CI 2.87, 8.71; P<0.001), as did van Onzenoort 2010 (difference = 1.4 percent; P = 0.043). Marquez-Contreras 2006 also found that a greater percentage of patients using SMBP took medication at the prescribed time (88.1 versus 79.9 percent; P = 0.006).

Zarnke 1997 found no difference between SMBP with self-titration versus usual care in the number of drug doses missed.

Quality of Life (Table D-13)

Three studies provided data on outcomes relating to quality of life (2 quality B and 1 quality C).[47,71,90] Followup durations in these studies ranged from 3 to 6 months. Mehos 2000 found no difference between groups in any domain of the Short Form-36 Health Survey (SF-36), while Broege 2001 found no difference between groups in SF-36 total score. Madsen 2008 found the SMBP group to fare better in bodily pain compared to the usual care group, as measured by the SF-36 (Scale 0–100, with higher score indicating better health; net difference = 7.0; P = 0.026), but did not find a significant difference between groups in any other SF-36 domain. Madsen 2008 also found that significantly fewer patients in the SMBP group felt that their health was worse after a year.

Health Care Encounters (Tables D14&15)

Six quality C studies provided data on outcomes relating to health care encounters.[42,71,72,83,87,88] Only one of these provided categorical data on health care encounters: Soghikian 1992 found no difference between groups in number of patients with no office visits for hypertension. However, each of the six studies provided continuous data on health care encounters.[42,71,72,83,88] Two of these found no difference in the number of visits with a primary care or an otherwise unspecified provider,[42,71] while two found no difference in the number of visits specifically related to hypertension.[72,83] In Soghikian 1992, the difference remained nonsignificant after adjustment for age, race, sex, baseline DBP, use of baseline antihypertensive meds, and use of outpatient services for hypertension care in the prior year. Zarnke 1997 found that patients in the SMBP with self-titration group had 0.85 more physician visits than the usual care group over a period of eight weeks (95 percent CI 0.30, 1.40; P=0.045). Varis 2010 found that patients in the SMBP group had significantly fewer extra visits than the usual care group (1.4 versus 5.3, $P < 0.05$). Soghikian 1992 found no difference between groups in the number of medical procedures received for hypertension, but did find the SMBP group to have 1.3 fewer outpatient visits over the one year study period (no statistical comparison performed).

Three studies looked at the number of hypertension-related telephone calls made by study subjects, and found no difference between groups.[72,83,87] In Soghikian 1992, the difference remained nonsignificant after adjusting for the aforementioned factors (i.e., age, race, etc.).

Miscellaneous Outcomes (Table D-16)

Two studies reported miscellaneous outcomes.[20,51] Dalfó i Baqué 2005, a quality C study, did not find a difference between SMBP and usual care in patient satisfaction (not defined). Verberk 2007, a quality B study, did not find a significant difference in left ventricular mass index change in the SMBP group compared to the usual care group.

Subgroups and Heterogeneity

BP Outcomes

Four trials reported results from subgroup analyses: Broege 2001 (quality C), Madsen 2008 (quality A), Godwin 2010 (quality B), and Bosworth 2011, an update of Bosworth 2009 (quality B).[44,47,59,67,91] However, only the update of Bosworth 2009 performed formal statistical tests, and

thus inferences for any differences in effects across subgroups were evaluated qualitatively for the other studies. Broege 2001 reported nonsignificant reductions in SBP and DBP for both the SMBP and usual care (nurse measurement) arms overall. By breaking down their analysis into patients previously treated and untreated, they found that patients previously treated experienced significant increases in BP with both SMBP and usual care, while previously untreated patients exhibited BP reductions in both groups. This discrepancy could be attributed to the fact that a relatively lenient BP target was set for this study (<150/90 mmHg), with previously treated patients meeting this target before study entry and thus possibly being more likely to experience an increase in BP. Nevertheless, the net changes in BP between SMBP and usual care were not statistically significant in either of these two subgroups.

Madsen 2008 examined the effect of SMBP versus usual care on awake and asleep ambulatory BP in subgroups defined by age (< or ≥60 years old), sex, and diagnosis with diabetes. Findings in these subgroups were consistent with the overall analysis. Godwin 2010 examined the effect of the patients' sex on ambulatory and clinic BP measurements. A lack of a statistically significant net change was observed in systolic and diastolic awake ambulatory BP (primary outcome) in both subgroups, which was consistent with the negative finding in the overall trial. However, there was a statistically significant net change in 24-hour ambulatory and clinic DBP favoring SMBP monitoring in men (no significant net changes were observed in women).

A post hoc data analysis of Bosworth 2009 reported a subgroup analysis by whites versus nonwhites, where nonwhites were 95 percent African American. There was no significant difference in SBP or DBP between SMBP and usual care groups at either 12 or 24 months of followup. In contrast, nonwhite patients in the SMBP group had significantly lower SBP and DBP at 12 months, compared with the usual care group. However, at the 24 month followup, these differences were no longer significant.

The summary estimates derived from meta-analyses were characterized by statistically significant heterogeneity in all cases. The small number of studies included in each meta-analysis (ranging from three to nine studies) did not allow a formal exploration of sources of heterogeneity with meta-regression techniques. We aimed to identify potential outliers by examining the pattern of results in the meta-analyses' forest plots. For the categorical outcome of adequate BP control at 6 months, the only study that had a point estimate favoring usual care was Dalfo i Baqué 2005, which was a large, cluster-randomized trial rated quality C due to methodological issues and reporting problems. The clinical characteristics of the patients included in this study were similar to other studies; however, the intervention consisted of SMBP measurements conducted only over two fortnight periods and not throughout the study followup period. Studies synthesized for the continuous BP outcomes displayed a consistent pattern of results favoring SMBP over usual care, although the majority of individual study estimates for SBP and DBP were not statistically significant. For the outcome of net change in clinic SBP and DBP at 12 month followup, Varis 2010 was an outlier showing a statistically significant net change favoring usual care for both SBP and DBP. By excluding this study from the meta-analysis at 12 months, a statistically significant summary net change of -2.0 mmHg (95 percent CI -3.8, -0.2; P = 0.027) for SBP was found favoring SMBP, whereas the summary net change for DBP remained non-significant. The remaining few studies that displayed nonstatistically significant effect estimates favoring usual care over SMBP had generally small sample sizes and their estimates were not precise.

Summary

Clinical Events

No studies of SMBP versus usual care provide evidence regarding the effect of SMBP monitoring on clinical outcomes. Thus, there is insufficient evidence regarding clinical events.

BP Outcomes

Twenty-three studies (four quality A, five quality B, 13 quality C, and conference abstract that was not graded for quality) provided data on BP outcomes. Meta-analysis of a small number of available studies for the outcome of adequate BP control showed that SMBP was not associated with a significantly increased probability of achieving a predefined BP target compared to usual care, at both 6 and 12 months. By restricting these meta-analyses to quality A and B studies only, a statistically significant result for adequate BP control at 6 months was found favoring SMBP. Meta-analyses for the continuous outcomes of net changes in clinic SBP and DBP showed significant effects favoring SMBP. Although there was no significant net change between SMBP and usual care in the meta-analysis at 2 months, SMBP monitoring was associated with statistically significant net changes in both SBP and DBP at 6 months, with summary point estimates that signify small, but clinically relevant reductions on a population level (-3.1 mmHg and -2.0 mmHg for SBP and DBP, respectively). However, these net changes were no longer significant in the meta-analysis of studies at 12 months followup point estimates of -1.2 mmHg and -0.8 for SBP and DBP, respectively). These summary estimates at 6 and 12 months were derived from syntheses of studies that included two quality A studies, six quality B and five quality C studies in total; the summary estimates were essentially unchanged in sensitivity analyses that were restricted to quality A or B studies only. The comparisons of SMBP with usual care for the outcomes of ambulatory BP measurements (24-hour, awake, and asleep) were based on a small number of studies which reported contradictory results. Overall, the studies were too heterogeneous along a variety of criteria (including populations, settings, interventions, control treatment, duration of followup and quality) to allow for a consistent explanation as to the differences in results observed across studies.

Due to the consistency of findings in studies with quality A and B examining the impact of SMBP versus usual care in clinic BP measurements, as well as those of the corresponding meta-analyses, the strength of evidence for an improvement in BP using SMBP compared to usual care is rated as moderate.

Surrogate and Intermediate Outcomes (not Blood Pressure)

Eight (one quality A, five quality B, and two quality C) studies reported data related to the number of medications prescribed and dosage.[42,62,72,77,86,88,90] Evidence largely indicated no difference in number of medications and dose between SMBP and usual care groups. The majority of studies were rated as B or C quality. However, McManus 2010 did find the SMBP group to be prescribed a greater number of additional medications than the usual care group, and it was the largest trial (with 580 total participants), as well as the only A quality study. Thus there is a weak level of evidence for a lack of difference in medication dose between SMBP and usual care, primarily due to conflicting results and the differing methodologies employed between studies in assessing outcomes.

Seven studies (three quality B, four quality C) reported on medication adherence using a variety of different definitions of adherence.[42,47,68,71,77,86,88] Studies were split: four found no

difference between groups[42,47,71,88] while two reported significantly greater adherence in the SMBP group,[68,77] and one found patients in the SMBP group to take medication correctly on a greater percentage of days but did not find a difference in adherence using electronic pill box monitoring[86] Given the wide variety of different definitions used and overall low study quality, the level of evidence that medication adherence was better among patients using SMBP monitoring is rated as weak.

Three studies (two quality B, one quality C) reported on quality of life outcomes.[47,71,90] A moderate level of evidence points to no difference between SMBP and usual care, as only a single subdomain of one measurement tool in one study found a difference between groups, however, with an important caveat. The quality of life measurement tools were not specifically targeted towards hypertension, and may not capture components of quality of life that are relevant in hypertensive patients who use SMBP devices.

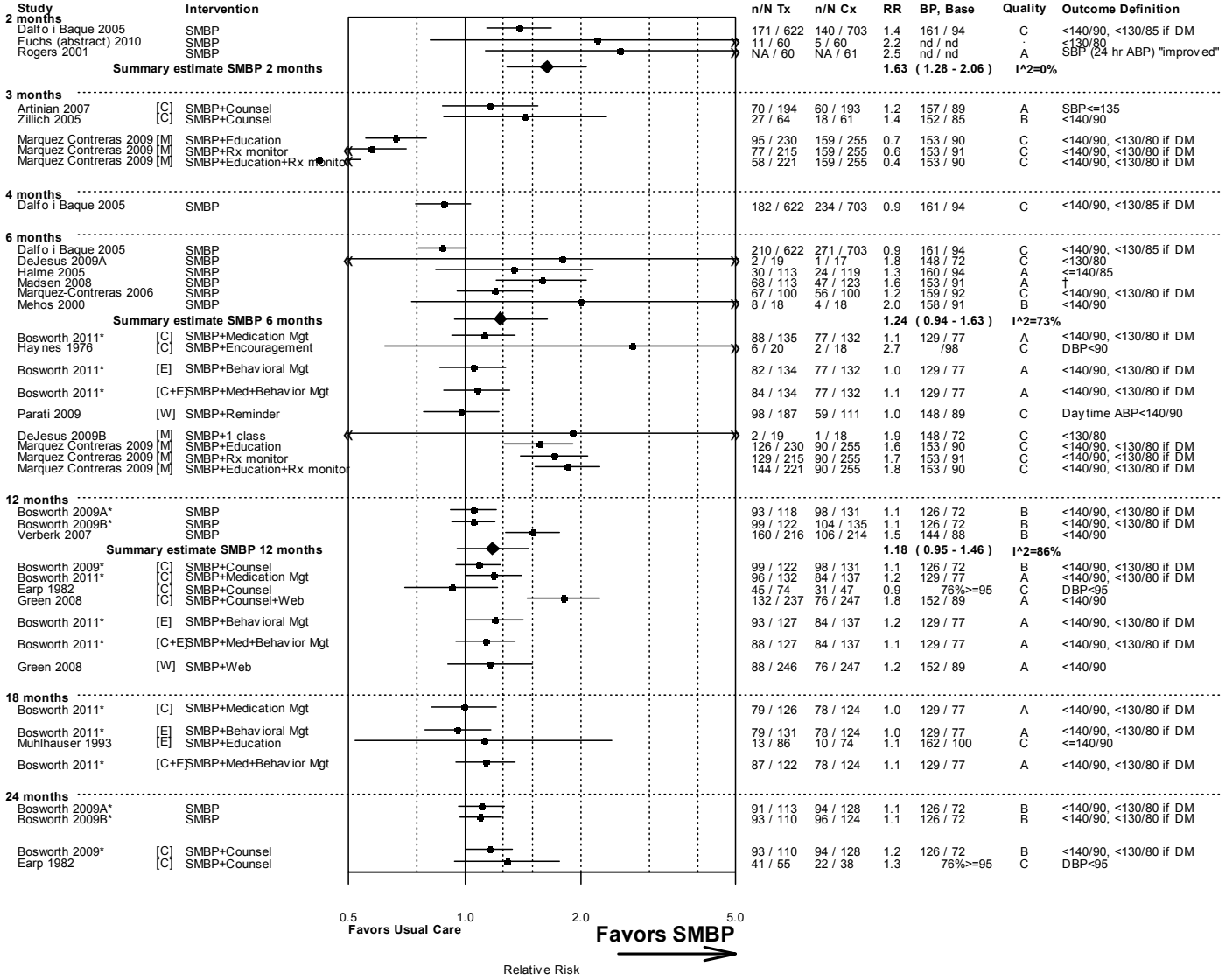
Evidence indicating no difference in patient satisfaction and left ventricular mass index is insufficient, as only one quality C and one quality B study, respectively, were found per outcome.[20,51]

Due to the inconsistency of findings, as well as heterogeneity of outcome definitions used, the strength of evidence for failing to find a difference between SMBP and usual care is rated as low across surrogate and intermediate outcomes.

Health Care Encounters

Six quality C studies reported on health care encounter outcomes.[42,71,72,83,87,88] Evidence was mixed, with the majority of outcomes showing evidence of no difference in effect, although one trial found patients using SMBP to have more visits[88] and two trials found the SMBP group to have fewer visits.[83,87] Given the inconsistency in findings, the strength of evidence that health care encounters were unchanged in patients using SMBP monitoring versus usual care is rated as low.

Figure 4. Forest plot, with meta-analyses, of relative risk of "adequate" BP at followup in RCTs of SMBP with or without additional support versus usual care, by time of outcome measurement (Note: Estimates favoring SMBP are to the right, in contrast to Figures 5-9 & 11.)



Black circles indicate relative risk for each study. Black diamonds indicate summary estimates of relative risk. Bold numbers in the right columns aligned with the summary estimates are the summary relative risk, their P-values, and the I2 measures of statistical heterogeneity. The letters in brackets to the left of interventions with additional support refer to the categories in Table 1.

ABP = ambulatory blood pressure; Behavior = behavioral; BP = blood pressure (systolic/diastolic); Counsel = counseling; DBP = diastolic blood pressure; DM = coexisting diabetes mellitus; Med = medication; Mgt = management; NA (nd) = not available (no data); n/N Cx = the number of participants with adequate BP control/total in the control (usual care) group; n/N Tx = the number of participants with adequate BP control/total in the intervention (SMBP) group; RR = relative risk; RCT = randomized controlled trial; Rx = prescription; SMBP = self measured blood pressure monitoring; Tele = telemonitoring

* Studies with same name and intervention, with an asterisk, represent the same study arms at different followup times.

† SMBP group (home): <135/85, <125/75 if DM. Usual care group: (clinic) <140/90, <130/80 if DM

Notes:

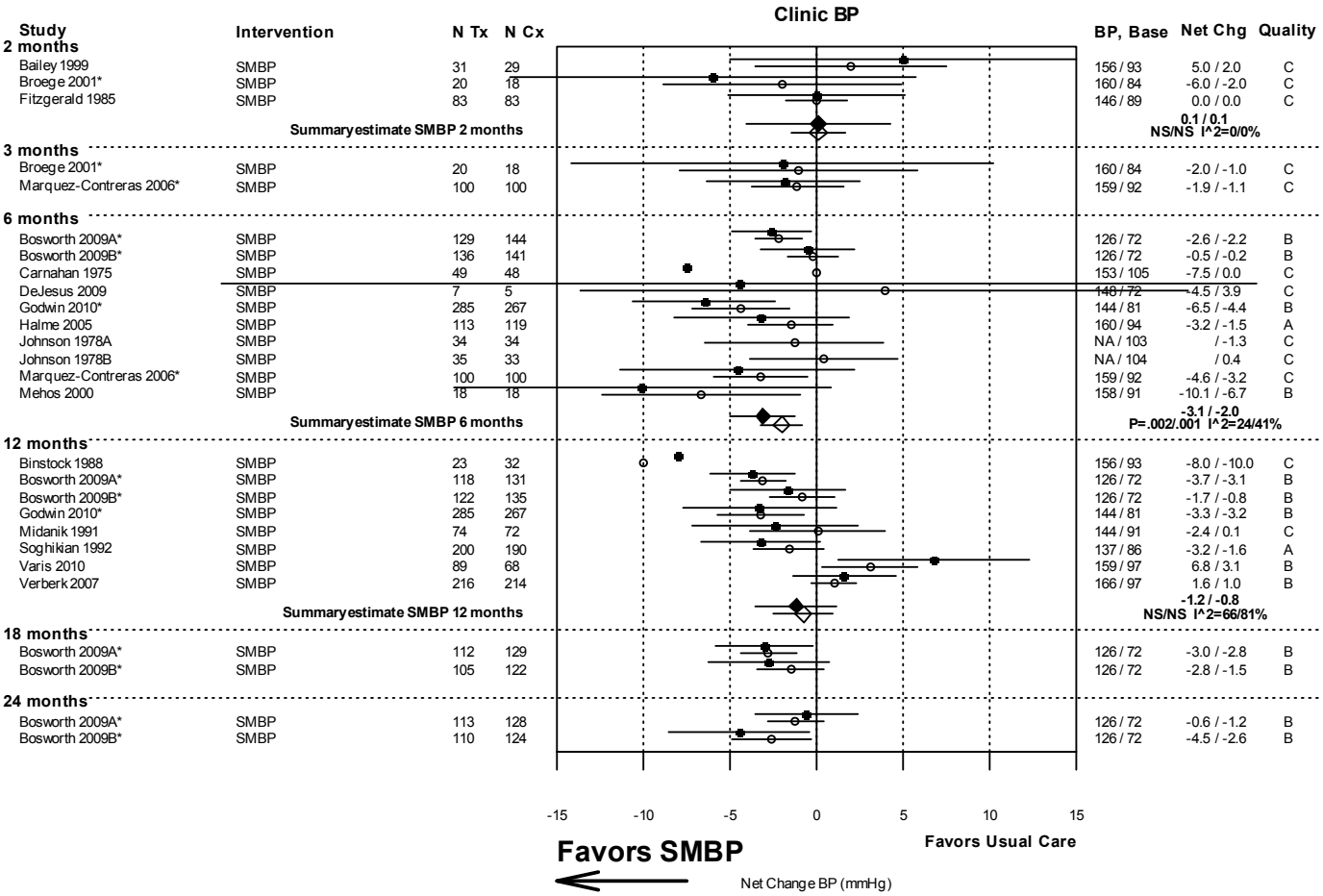
Bosworth 2009B[44] Both groups had behavioral intervention (control group is really behavioral intervention group).

Bosworth 2011[45] Reported as differences in BP control (from a regression model). RR values derived from figure of estimated proportion in BP control.

DeJesus 2009A[53] Both groups had education (control group is really education group).

Earp 1982[55] Both groups had home visits.

Figure 5. Forest plot, with meta-analyses, of net change clinic BP in RCTs of SMBP alone versus usual care, by time of outcome measurement



Black and white circles indicate systolic and diastolic blood pressures, respectively. Black and white diamonds indicate summary estimate systolic and diastolic blood pressures, respectively. Bold numbers in the right columns aligned with the summary estimates are the summary net change systolic/diastolic blood pressure, the P-values of the net change, and the I2 measures of statistical heterogeneity. Studies without 95 percent confidence intervals did not report variance data (and were not included in the meta-analyses).

BP = blood pressure (systolic/diastolic); N Cx = the number of participants in the control (usual care) group; N Tx = the number of participants in the intervention (SMBP) group; NA = not available (no data); Net Chg = net change in systolic/diastolic blood pressure; NS = nonsignificant; RCT = randomized controlled trials; SMBP = self measured blood pressure monitoring

* Studies with same name and intervention, with an asterisk, represent the same study arms at different followup times.

Notes:

Binstock 1988[43] Both groups had education.

Bosworth 2009B[44] Both groups had behavioral intervention (control group is really behavioral intervention arm).

Broege 2001[47] Average during month 2.

DeJesus 2009A[53] Both groups had education (control group is really education arm).

Figure 6. Forest plot of net change 24 hour ambulatory BP in RCTs of SMBP alone versus usual care, by time of outcome measurement (see notes below Figure 8)

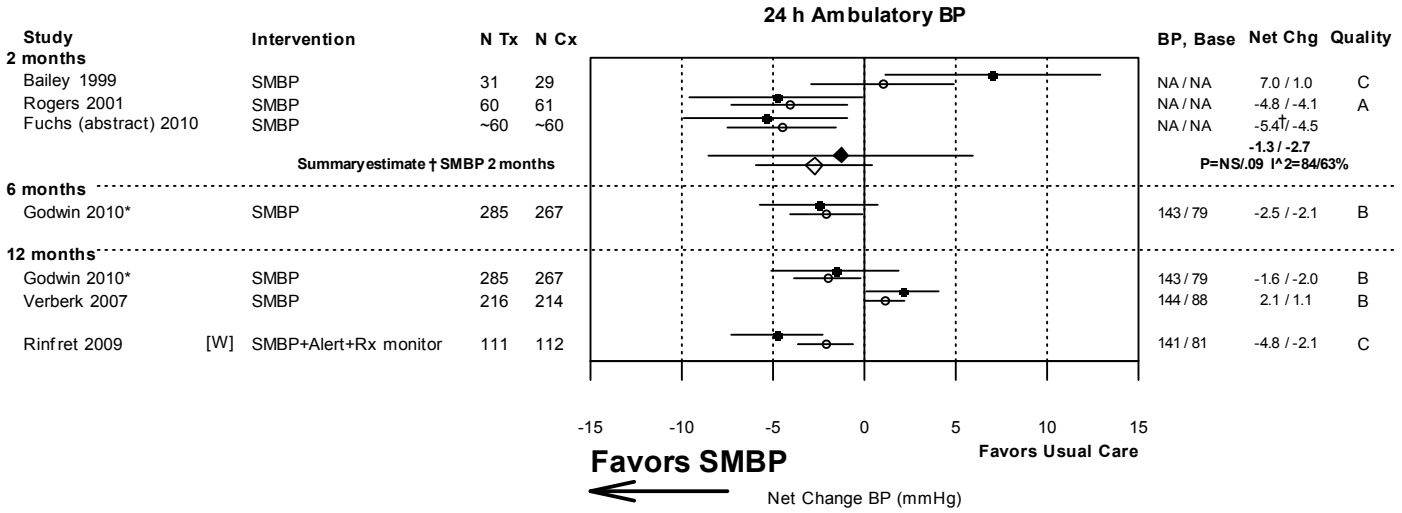


Figure 7. Forest plot of net change awake (day) ambulatory BP in RCTs of SMBP alone versus usual care, by time of outcome measurement (see notes below Figure 8)

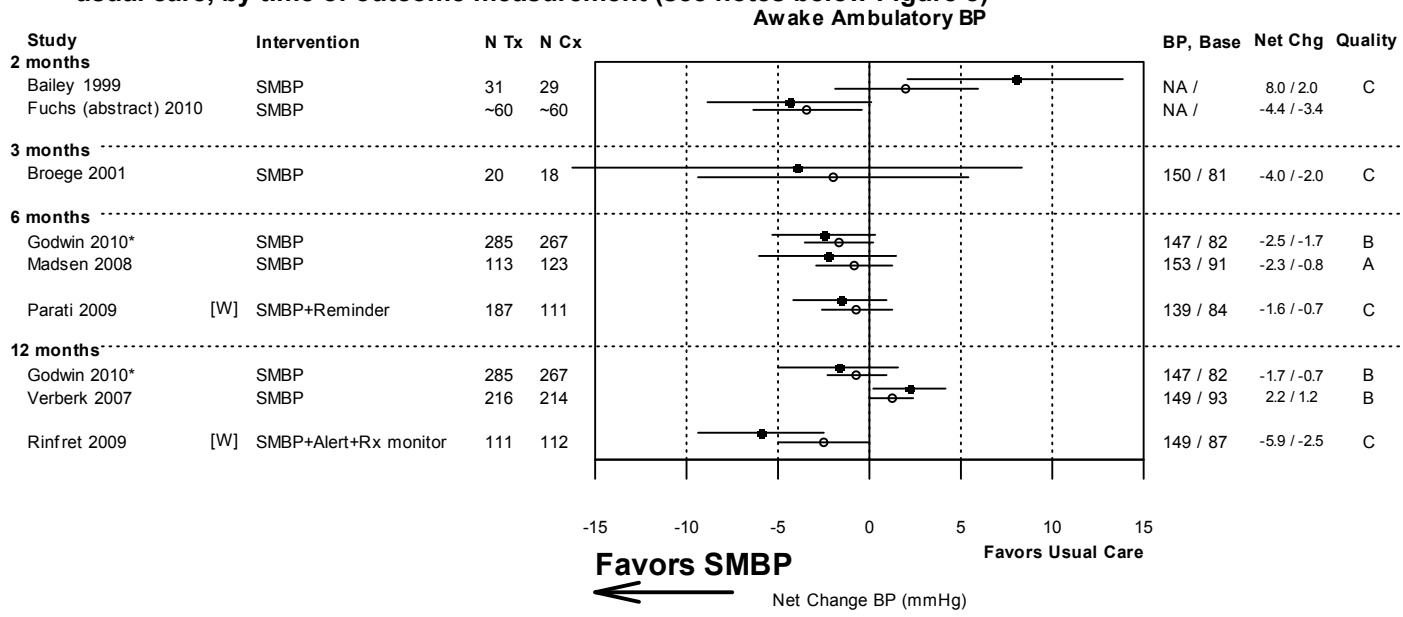
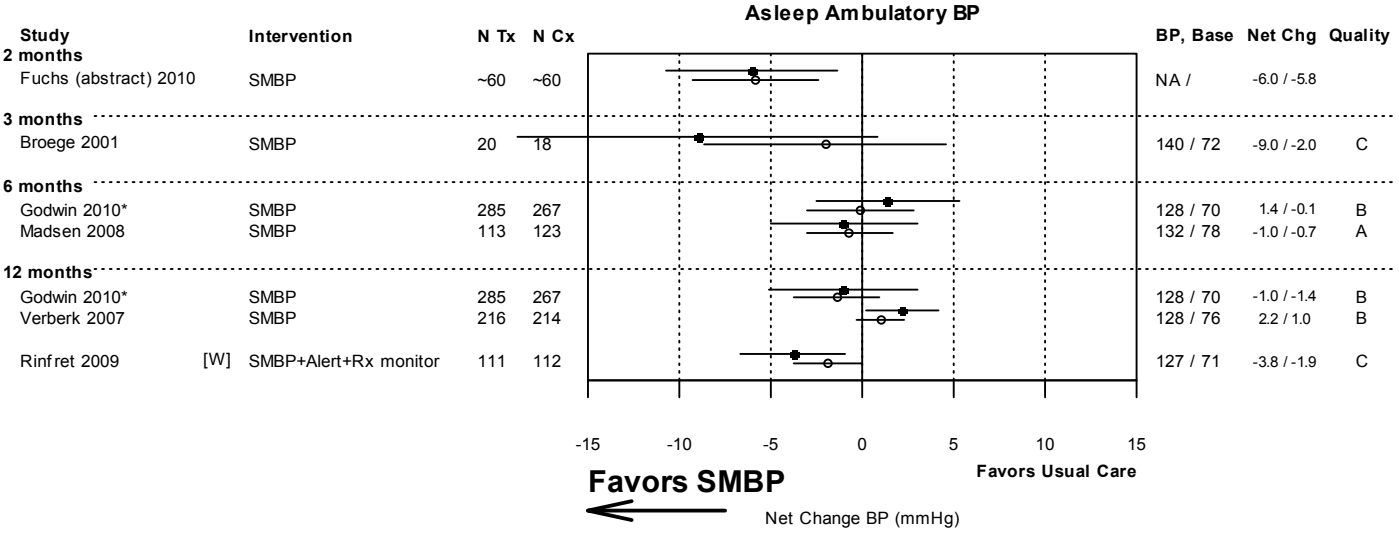


Figure 8. Forest plot of net change asleep (night) ambulatory BP in RCTs of SMBP alone versus usual care, by time of outcome measurement (see notes below)



Figures 6–8:
Black and white circles indicate systolic and diastolic blood pressures, respectively. The letters in brackets to the left of interventions with additional support refer to the categories in Table 1.
BP = blood pressure (systolic/diastolic); N Cx = the number of participants in the control (usual care) group; N Tx = the number of participants in the intervention (SMBP) group; NA = not available (no data); Net Chg = net change in systolic/diastolic blood pressure; RCT = randomized controlled trial; SMBP = self measured blood pressure monitoring
* Studies with same name and intervention (within each figure), with an asterisk, represent the same study arms at different followup times.
† Sensitivity meta-analysis that includes the conference proceeding abstract by Fuchs 2010[58]
Notes (for figures 6–8):
Bailey 1999[42] Difference of final values (not net change).
Godwin 2010[59] Difference of final values (not net change).

Comparison of SMBP Plus Additional Support Versus Usual Care

We identified 24 studies (reported in 25 articles)[40,41,43-45,53-55,57,60,61,63,64,69,70,73,75-78,80-82,89,93] that compared SMBP monitoring plus a variety of additional support with usual care (Tables D-2&3). Five studies were published before 1990.[43,55,63,64,77] Nineteen were RCTs,[40,43-45,53,55,57,61,64,69,70,73,75,78,80,82,89,93] two were quasi-RCTs,[63,77] and three were nonrandomized comparisons.[60,76,81] Additional support included educational materials, letters to patients and providers on treatment recommendations, Web resources, phone monitoring with electronic transmission of BP data, telecounseling, behavioral management, medication management with decision support, nurse or pharmacist visits, calendar pill packs, and/or compliance contracts. Change in medication management as a result of the monitoring could be initiated by study personnel such as a nurse or pharmacist, the patient, or the primary care physician. Concerning SMBP monitoring methods (Table D-1 and D-2 in **Appendix D**): 14 studies used automated devices; 5 used auscultatory methods;[55,60,63,64,77] and 4 did not provide detailed descriptions.[43,73,76,81]

All the patients enrolled in these studies had uncontrolled hypertension or were on antihypertensive medications at baseline. Mean age of the participants was 37 years in one study that enrolled only patients with type 1 diabetes and kidney disease.[81] In the rest of the studies, the mean age ranged from 47 to 77 years. The proportion of male participants varied from 11 to 100 percent. Mean baseline SBP ranged from 124 to 163 mmHg and DBP ranged from 70 to 103 mmHg. The commonly cited comorbidities in these studies were type 1 or 2 diabetes, obesity,

dyslipidemia, and cardiovascular disease. The sample size of the studies ranged from 15 to 1406 (total = 6187 across studies). Six studies were rated quality A, five were rated quality B, and 13 studies were rated quality C for the BP outcome. The primary methodological concerns included small sample sizes, the lack of a power calculation, high dropout rates, and incomplete reporting. Overall, the studies are applicable to adults with hypertension in the outpatient setting with the ability to self-monitor BP and with limited comorbid conditions.

Clinical Events

Sawicki 1995, in a quality C trial of 91 patients with Type 1 diabetes and diabetic kidney disease, found lower mortality in the SMBP plus self-titration plus education group (4 percent and 28 percent respectively; RR 0.16; 95 percent CI 0.04, 0.66), with the difference remaining significant after adjustment for proteinuria, age, and creatinine clearance (P=0.047).[81] The study also found a lower composite of mortality and end-stage renal disease (RR 0.27; 95 percent CI 0.11, 0.66; P=0.006). This result also remained statistically significant after adjustment for DBP and age (P=0.018). However, incidence of end-stage renal disease by itself was not significantly different between groups (RR 0.41; 95 percent CI 0.14, 1.21).

Blood Pressure Outcomes

All 24 studies provided data on BP outcomes. The majority of the studies had followup durations of no more than 12 months. Seven studies also reported followup data of more than 12 months.[44,45,55,60,73,81,93] Reported BP outcomes included both categorical outcomes, where the outcomes were defined as achieving a predefined BP target (e.g., clinic SBP/DBP ≤140 mmHg), and continuous outcomes, where net differences of SBP and DBP between baseline and final measurements (or, in some instances, differences between final values) were calculated.

Nearly all studies reported clinic BP measurements; in two studies BP measurements were taken at home by research personnel.[57,64]. Two studies also reported ambulatory (24 hour, awake, or asleep) BP measurements.[75,78] Meta-analyses were not performed due to the great heterogeneity of the interventions.

Categorical BP Outcomes (Table D-17, Figure 4)

Eleven studies reported categorical BP outcomes.[41,44,45,53,55,61,63,69,73,75,89] Five trials reported that significantly higher proportions of patients achieved controlled BP target at followup in the intervention group compared with usual care.[41,45,61,69,75] Márquez Contreras 2009 found that about twice as many patients achieved BP control (<140/90 mmHg or <130/80 mmHg in those with diabetes) using SMBP plus combinations of educational materials and/or medication monitoring compared with usual care (ANOVA P=0.01).[69] Green 2008 also found that about twice as many patients achieved BP control (≤140/90 mmHg) using SMBP plus Web training with pharmacist counseling compared with usual care (57 versus 31 percent; P<0.001).[61] Parati 2009 also reported a statistically significant difference in the proportion of patients achieving BP control (awake BP <130/80 mmHg) favoring SMBP plus reminder compared to usual care (62 versus 50 percent; P<0.05).[75] Artinian 2007 reported that significantly higher proportion of patients achieved diastolic BP control (64 versus 53 percent; P=0.04) but no significant difference for systolic BP control.[41] Bosworth 2011 reported that a significantly higher proportion of patients in the behavioral management group and in the medication management with decision support group had improvement in BP control compared to usual care at 12 months (estimated difference 12.8 percent; 95 percent CI 1.6, 24.1, P=0.03 [behavioral]; 12.5 percent; 95

percent CI 1.3, 23.6, P=0.03 [medication]), but there was no significant difference at 18 months.[45] There was also no significant difference between combined medication-behavioral management and usual care at any of the time points. The rest of the studies did not report statistically significant differences between usual care and SMBP plus additional support.

Continuous BP Outcomes

In total, 24 studies (reported in 25 articles) provided data for continuous BP outcomes.[40,41,43-45,53-55,57,60,61,63,64,69,70,73,75-78,80-82,89,93]

Clinic BP (Table D-18, Figure 9)

All 24 studies reported clinic-measured BP outcomes or home BP measured by research personnel. Eleven trials reported statistically significant greater reductions in either the clinic SBP or DBP at followup favoring the SMBP intervention with additional support compared to usual care.[41,44,45,57,61,70,73,78,80,82,89] The additional support examined in these 11 trials were telecounseling;[41,44,57,80] Web training with pharmacist counseling;[61] self-titration plus provider alert;[70] education;[73] medication monitoring with provider alert;[78] personalized Web site plus videoconference counseling;[82] pharmacist counseling;[89] and combined medication-behavioral management (as needed whenever there were inadequate BP control).[45]

For followup from 3 to 12 months, the mean net change in SBP ranged from -1.6 to -8.5 mmHg, favoring SMBP with additional support; the mean net change in DBP ranged from -1.9 to -4.4 mmHg. Of note, one trial comparing SMBP plus behavioral and medication management against usual care reported statistically a significant reduction of SBP at 12 months (net change -4.3 mmHg; 95 percent CI -8.5, -0.2, P=0.04), but not at 18 months.[45] However, in this study, the other interventions (SMBP plus either behavioral management or medication management) did not differ from usual care at any timepoint. Three of four trials reported statistically significant mean net BP reductions for followup periods of 18 to 60 months. With the exception of the single quality A study, Bosworth 2011[45] at 18 months, net changes in SBP ranged from -2.6 to -5.0 mmHg and in DBP from -1.3 to -4.0 mmHg.[44,73,93]

Statistical analyses for the between-group differences were not reported in five trials.[40,43,53,54,77] Meta-analysis was not undertaken because of the heterogeneity of the interventions across trials. An examination of the forest plot suggests a pattern of reduction in either the SBP or DBP favoring the intervention at longer term followup (12 months and beyond) but not at shorter term followup (3 or 6 months).

Two[76,81] of three nonrandomized studies[60,76,81] also reported a statistically significant greater reduction in either the SBP or the DBP at followup favoring the intervention (personalized Web site plus nurse counseling[76] or self-titration plus education[81]).

Ambulatory BP (Table D-19, Figures 6–8)

Two trials also provided outcomes on ambulatory continuous BP measurements.[75,78] Rinfret 2009 reported a statistically significant greater reduction in 24 hour ambulatory BP (mean net change SBP: -4.8 mmHg; P<0.001; DBP: -2.1 mmHg; P=0.007); awake BP (mean net change SBP: -5.9 mmHg; P<0.001; DBP: -2.5 mmHg; P=0.05); and asleep time BP (mean net change SBP: -3.8 mmHg; P<0.001; DBP: -1.9 mmHg; P=0.05) at 12 months followup favoring those with SMBP plus medication monitoring with provider alert compared to usual care.[78] Parati 2009 reported a statistically significant greater reduction of awake SBP in those who had SMBP plus reminder compared to usual care (mean net change: -1.6 mmHg; P<0.05).[75] No statistically significant difference was reported for awake DBP.

Medication Dosage (Tables D-20 and 21)

Eleven studies provided data on outcomes relating to the number of medications prescribed and dosage (three quality A, two quality B, and six quality C).[41,61,69,70,73,75,77,78,80,81,89] The followup durations in these studies ranged from 2 to 60 months. Reported medication outcomes included both categorical outcomes (Table D-20), where the outcomes were defined as the number of patients with a specified change in medication (e.g. an increase in medication dosage or cessation of a class medication) and continuous outcomes (Table D-21), which reported on quantities of medication or number of medication classes used. Due to the heterogeneity in outcome definitions between studies, no meta-analyses were feasible.

Five of these ten studies reported categorical medication outcomes.[73,75,77,80,89] Among these, Pierce 1984 and Zillich 2005 both examined an increase in medications. Pierce 1984 found no difference between SMBP plus education versus usual care in physician assessment of the strength of medication regimen, while Zillich 2005 found that more subjects in the SMBP plus pharmacist counseling group exhibited an increase in the amount of medication used or number of medications compared with the pharmacist BP measurement group (RR 2.26; 95 percent CI 1.42, 3.61; P>0.05). Pierce 1984 reported on medication inertia, defined as no change in medication regimen, and did not find a difference between groups. Rudd 2004 however found more patients having SMBP plus counsel to report no change in drug therapy (RR 0.05; 95 percent CI 0.01, 0.20). With respect to physician assessment of decreased medication, Pierce 1984 found no difference between groups; however, Muhlhauser 1993 found more patients in the SMBP plus education group to show a decrease in the number of medications prescribed than in the usual care group.(RR 0.3; 95 percent CI 0.17, 0.43; P<0.001). Additionally, Zillich 2005 found no difference between groups in the number of patients discontinuing medication after the study. Rudd 2004 found more patients in the SMBP plus counsel group to be taking two or more drugs (RR 1.53; 95 percent CI 1.13, 2.07) or no drugs (RR 1.77; 95 percent CI 1.04, 3.03) at the completion of the 6 month study. Parati 2009 found no difference between groups in percentage of visits at which physicians modified their patient's treatment, but did find that the SMBP group had a significantly smaller percent of visits at which patients were found to have modified their own treatment schedule (P = 0.04).

Seven of 11 reported continuous medication outcomes.[41,61,69,70,78,80,81] Four of these reported on the number of hypertension medication classes used.[61,70,78,81] Green 2008 found that both the SMBP plus Web training with pharmacist counseling group and the SMBP plus Web training used a greater number of medication classes than the usual care group (SMBP plus Web with pharmacy versus usual care difference: 0.5; 95 percent CI 0.3, 0.6; P<0.05. SMBP plus Web versus usual care difference: 0.3; 95 percent CI 0.1, 0.4; P<0.05). Rinfret 2009 found that the SMBP plus provider alert with medication monitoring group used an average of 1 more medication class than the usual care group (adjusted P = 0.007) and also had 1 more physician-driven medication change (adjusted P=0.03). McManus 2010 found that patients in the SMBP plus alert with self-titration group were prescribed a greater number of additional antihypertensive medications (net difference = 0.46; 95 percent CI 0.34, 0.58; P = 0.001), and Sawicki 1995 found that patients in the SMBP plus education with self-titration group were prescribed a greater number of antihypertensive medications (net difference = 0.46; 95 percent CI 0.34, 0.58; P = 0.001). Marquez-Contreras 2009 found no difference between either SMBP plus educational material, SMBP plus medication monitoring, or SMBP plus educational material with medication monitoring in comparison to usual care with respect to the number of tablets taken per day. Rudd 2004 found a greater number of medication changes in the SMBP

plus counsel group (net difference = 2.0; P<0.01). Artinian 2007 found no difference in Treatment Intensity Score, which approximates dosage strength, between SMBP plus telecounseling versus enhanced usual care.

Medication Adherence (Tables D-22 and 23)

Six studies provided data on outcomes relating to medication adherence (one quality A, two quality B, and three quality C).[57,63,77,78,80,89] The followup durations in these studies ranged from 2 to 12 months. Reported medication outcomes included both categorical outcomes (Table D-22), where the outcomes were defined as the number of patients with a specified level of medication adherence, and continuous outcomes (Table D-23), where adherence was measured on a continuous scale (e.g., tablet count).

Three of these six studies provided data on categorical medication adherence outcomes.[63,77,89] Haynes 1976 found that SMBP plus encouragement resulted in greater medication adherence, defined as a patient having greater adherence at study completion than at baseline, as assessed by a surreptitious pill count conducted by a home visitor (RR 2.06; 95 percent CI 1.11, 3.82; P<0.05). Pierce 1984 found no significant difference in medication adherence between SMBP plus education versus usual care, as assessed by medication count and nurse-administered survey. Zillich 2005 found no difference between SMBP plus pharmacist counseling versus pharmacist BP measurement, as assessed by self-report.

Four of six studies examined continuous medication adherence outcomes.[57,63,78,80] Haynes 1976 found that patients in the SMBP plus encouragement group showed a greater increase in percentage of prescribed pills taken than the usual care group (net difference: 23 percent; 95 percent CI 2.9, 43; P=0.025). Friedman 1996 found greater medication adherence in terms of percentage of pills taken in the SMBP plus telecounseling group compared with the usual care group (net difference: 6 percent; 95 percent CI 0.6, 2.8; P=0.03) after adjustment for age, sex, and baseline adherence. Rudd 2004 found the SMBP plus counsel group to take antihypertensive medication correctly on a greater percentage of study days (difference = 11.3 percent; P = 0.03). Rinfret 2009 found no difference between SMBP plus provider alert plus medication monitoring and usual care in "continuous measure of medication acquisition" (cumulative days supply of medication obtained divided by the total days to the next prescription refill, based on pharmacy data) and "continuous measure of medication gaps" (total days of treatment gaps divided by the total days to the next prescription refill, based on pharmacy data). (Outcome definitions are based on the cited reference.[94])

Quality of Life (Table D-24)

Three studies provided data on quality of life outcomes (two quality A, one quality C).[61,70,75] Followup durations in these studies ranged from 3 to 12 months. Green 2008 found no difference in either the SMBP plus Web training or SMBP plus Web training with pharmacist counseling group compared to usual care with regards to SF-12 score or the Consumer Assessment of Healthcare Providers and Systems score. Parati 2009 found no difference between SMBP plus reminder versus usual care in the Short Form-12 Health Survey (SF-12) score. McManus 2010 found no difference between SMBP plus alert with self-titration in Anxiety score (a six item scale of the State Trait Anxiety Inventory) or Euro Quality of Life Group 5-Dimension Self Report Questionnaire (Euro QoL 5D) score.

Health Care Encounters (Table D-25)

Eight quality C studies provided data on outcomes relating to health care encounters.[45,53,61,70,73,78,81,89] DeJesus 2009 found no difference between the SMBP plus one class versus usual care groups in the number of physician and nurse visits. The remaining seven studies provided data on the number of physician visits per study group.[45,61,70,73,78,81,89] Five studies found no difference compared to usual care, when looking at SMBP plus education, SMBP plus provider alert with medication monitoring, SMBP plus self-titration with provider alert, and SMBP plus medication management and/or behavioral management.[45,61,70,73,78] Zillich 2005 found that patients in the SMBP plus pharmacist counseling group had 0.61 fewer visits than the pharmacist BP measurement group, over a period of 3 months (P=0.007). Sawicki 1995 found that the SMBP group had 2.5 more visits, over a study period of five years (P<0.001). Green 2008 found no difference between either group versus usual care in terms of inpatient and emergency care use.

Green 2008 also found that patients using SMBP plus Web training did not have a different number of message threads or phone encounters compared to the usual care group over a period of 12 months. Patients using SMBP plus Web training with pharmacy counseling had a greater number of message threads (net difference = 19.9, P<0.05) and phone encounters (net difference = 3.5, P<0.001) compared to the usual care group. Patients using SMBP plus Web training had a greater number of patient-initiated message threads compared to the usual care group (net difference = 0.9, P=0.01), as did patients using SMBP plus Web training with pharmacy counseling (net difference = 2.4, P<0.01).

Miscellaneous Outcomes (Table D-26)

One study (quality C), Marquez-Contreras 2009, found no difference between groups with regards to adverse drug reactions, when comparing usual care, SMBP plus medication monitoring, SMBP plus educational material, and SMBP plus medication monitoring with educational material using an ANOVA analysis across the three intervention groups.[69]

Subgroups and Heterogeneity

BP Outcomes (Table 1)

Seven trials reported results from subgroup analyses: Friedman 1996 (quality A), DeJesus 2009 (quality C), McManus 2010 (quality A), Green 2008, (quality A), Bosworth 2011 (quality A), Shea 2006 (quality A), and a second Bosworth 2011, which is an update of Bosworth 2009 (quality B) 44,45,53,61,70,82,91. Friedman 1996 reported that patients who were nonadherent with their antihypertensive medications at baseline were most affected by SMBP with computer-controlled telephone system intervention.57 Mean DBP decreased by 6 mmHg in this group versus an increase of 2.8 mmHg in the usual care group (P=0.01). Quantitative analysis for the adherent group was not reported. DeJesus 2009, using a multivariate logistic model, did not find that body mass index, number of nurse or physician visits, or baseline SBP or DBP predicted the achievement of target BP in a study of patients with diabetes comparing SMBP and nurse education with usual care.53 McManus 2010 reported a greater reduction in SBP in those with higher socioeconomic status who had SMBP plus telemonitoring compared to those with lower socioeconomic status (net difference: -5.7 mmHg at 6 months, P=0.05; -5.4 mmHg at 12 months, P=0.08).70 Green 2008 reported that the subgroup of patients with baseline SBP ≥160 mmHg who had SMBP plus Web-based pharmacist counseling had lower SBP (-13.2 mm, P<0.001) and

DBP (-4.6 mm, P<0.001) compared to those with usual care at 12 months followup.61 Quantitative analysis for those with baseline SBP <160 mmHg was not reported. Bosworth 2011 compared 348 patients with adequate BP control (≤140/90 mmHg in patients without diabetes or ≤130/80 mmHg in those with diabetes) to 243 patients with inadequate control in a post hoc analysis.45 The study reported that patients with adequate control at baseline continued to remain in control over the 18 months of the study. For those with inadequate control, comparing SMBP plus behavioral management with usual care, SBP net change was -8.3 mmHg (95 percent CI -15.1, -1.6, P=0.02) at 12 months, but there was no significant difference at 18 months. Comparing SMBP plus medication management with usual care, SBP net change was -7.9 mmHg (95 percent CI -14.5, -1.4, P=0.02) at 12 months and DBP net change was -4.2 mmHg (95 percent CI -8.3, -0.2, P=0.04) at 18 months. Comparing SMBP plus combined medication-behavioral management with usual care, SBP net change was -14.8 mmHg (95 percent CI -21.8, -7.8, P<0.001) at 12 months and 8 mmHg (95 percent CI -15.5, -0.5, P=0.04) at 18 months; DBP was lowered by 5.3 mmHg (95 percent CI -9.5, -1.2, P=0.01) at 12 months and 5.5 mmHg (95 percent CI -9.7, -1.2, P=0.01) at 18 months.

Shea 2006, an RCT of SMBP plus personalized Web site and videoconference counseling versus usual care, also analyzed separately the 12 months outcomes from patients recruited in the Upstate New York area and those from the New York City regions and reported similar magnitude of effects in the two regions for BP outcomes.82 For upstate New York, the adjusted mean net difference for SBP was -3.98 mmHg (ANCOVA P=0.006) versus -2.76 mmHg (ANCOVA P=0.06) for New York City region. For DBP, the adjusted mean net difference in upstate New York was -2.13 mmHg (ANCOVA P=0.003) versus -1.73 mmHg (ANCOVA P=0.02) for New York City region.

As noted in the previous section on SMBP versus usual care, a post hoc data analysis of Bosworth 2009 reported a subgroup analysis by whites versus nonwhites, where nonwhites were 95 percent African American.44,91 In white patients, there was no significant difference in SBP or DBP between the SMBP plus telecounseling group versus the usual care group at either 12 or 24 months of followup. In contrast, nonwhite patients in the SMBP plus telecounseling group had significantly lower (P< 0.05) SBP and DBP at 12 months, compared to the usual care group. These differences remained significant at the 24-month followup.

To try to gain an insight into the heterogeneous nature of the additional supports across studies, we have post hoc classified the various interventions for each group into four categories, which are described in Table 1. This was based on our assessment of the key component, since the categories are not exclusive. Five of the nine studies in category “C” (Counseling with regular one-on-one encounters with study personnel) reported statistically significant reductions in either the SBP or the DBP at followup favoring the additional support with SMBP.41,44,61,80,89 The mean net change in SBP ranged from -3.3 to -8.9 mmHg; the mean net change in DBP ranged from -2.2 to -3.2 mmHg. Green 2008 also reported a significantly higher proportion of patients achieved controlled BP target at followup in the intervention group compared with usual care (57 percent versus. 31 percent; P<0.001).61 Three of five studies in category “E” (Education offered in regular hypertension education classes) reported statistically significant reduction in either the SBP or the DBP at followup favoring those who attended the classes in addition to SMBP.45,73,81 Two studies were conducted by the same group of investigators.73,81 The mean net changes of SBP were -5 mmHg (95 percent CI -10, 0; NS) in the first study73 and -19 mmHg (95 percent CI -33, -5.2; P=0.007) in the second study.81 The mean net changes of DBP were -4 mmHg (95 percent CI -7, -1; P=0.018) in the first study73

and -6.1 mmHg (95 percent CI -13.1, 0.9; NS) in the second study.81 Bosworth 2011 reported an estimated net change in SBP of -4.3 mmHg (95 percent CI -8.5, 0.2; P=0.04) in the combined medication-behavioral management group (versus usual care) at 12 months, but no significant difference at 18 months.45 The estimated net change in DBP was -0.01 mmHg (95 percent CI -2.6, 2.6; P=NS) at 12 months. Six of seven studies in category "W" (Web-based or telephonic tools) reported statistically significant reductions in either the SBP or the DBP at followup favoring those who had additional support.57,61,70,75,76,78,82 The mean net change in SBP ranged from -1.6 to -5.4 mmHg; the mean net change in DBP ranged from -1.9 to -4.4 mmHg. The seventh study reported a significantly higher proportion of patients achieved controlled BP target at followup in the intervention group compared with usual care (62 percent versus. 50 percent; P<0.05).75 Four studies were in category "M" (Miscellaneous).43,53,54,69 The additional support in one study was a single class offered by a diabetes educator and instruction by a nurse on SMBP monitoring.53 The second study used leaflet with educational materials on hypertension and/or a card for recording BP and pill counts.69 Neither study reported a statistically significant difference in continuous BP outcomes. Márquez Contreras 2009 reported a significantly higher proportion of patients achieved controlled BP target at followup in the intervention group compared with usual care (65 percent versus. 35 percent; P=0.01).69 The third study compared SMBP plus contract plus pill pack with control and both groups received education.43 The fourth study compared SMBP via telephone upload with letters for treatment recommendation to patients and providers with usual care.54 Statistical analyses for the between-group differences in the last two studies were not reported.

Summary

Clinical Events

Only one C quality study reported on clinical events, finding lower mortality and composite of mortality and end-stage renal disease in patients using SMBP, but no difference in end-stage renal disease by itself.[81] This study was conducted in individuals with Type 1 diabetes and diabetic kidney disease and therefore has limited applicability. Due to the paucity of evidence, the strength of evidence is insufficient to make a determination as to the clinical event outcomes when comparing SMBP plus additional support to usual care.

BP Outcomes

Eleven of 21 trials and two of three nonrandomized studies reported statistically significant reduction in either SBP or DBP at followup favoring the SMBP with additional support intervention. The patients in these studies all had baseline uncontrolled hypertension with or without antihypertensive medications. Two trials enrolled only patients with diabetes.[54,82] All six quality A trials reported a significant mean net changes in SBP (ranging from -3.4 to -8.9 mmHg) or DBP (ranging from -1.9 to -4.4 mmHg) in an SMBP plus additional support group compared with usual care at up to 12 months followup. [41,45,57,61,70,82] There were mixed results at 18 months and two studies found significant net reductions in SBP and DBP at 24 to 60 months.[45,93] These changes were measured in the clinic[45,61,70] and at home.[57] The support in addition to SMBP in these six trials were: telemonitoring and counseling on patient adherence to antihypertensive medications;[41,57] Web-based pharmacist counseling;[61] telemonitoring with self-titration of antihypertensive medications;[70] telemonitoring with nurse videoconference,[82] and combined medication-behavioral management.[45] Three quality B[44,80,89] and two quality C

trials[73,78] also reported significant reductions in SBP or DBP using similarly diverse supports. Overall, the studies were too heterogeneous along a variety of axes to allow for a consistent explanation as to the differences in results observed across studies. It is not possible to state with certainty whether one form of additional support is superior as the additional supports examined across studies varied in the primary intents, ancillary equipments and educational materials, followup personnel, and algorithms for medication adjustments. No form of additional support was examined by more than one trial. Key Question 2 will address trials that performed direct comparisons of SMBP with additional support and SMBP alone.

Overall, in light of the consistent findings in all six quality A trials, the strength of evidence is rated as high in favor of an improvement in BP control using SMBP with some form of additional support compared to usual care.

Surrogate and Intermediate Outcomes (no Blood Pressure)

Eleven studies (three quality A, two quality B, and six quality C) reported data related to the number of medications prescribed and dosage.[41,61,69,70,73,75,77,78,80,81,89] Evidence was mixed, with some trials finding no difference in number of medications and dose between SMBP and usual care groups, and others finding either an increase or decrease in medications with patients using SMBP with additional support. Half of studies were rated as C quality. Thus there is a weak level of evidence for lack of difference in medication dose between SMBP and usual care, primarily due to conflicting results, low study quality, and the differing methodologies employed between studies in assessing outcomes.

Six studies (one quality A, two quality B, and three quality C) reported on medication adherence using a variety of different definitions of adherence.[57,63,77,78,80,89] Studies were split between finding no difference between groups and finding significantly greater adherence in the SMBP group. Given the wide variety of different definitions used and overall low study quality, the level of evidence that medication adherence was better among patients using SMBP monitoring is rated as weak.

Three studies (two quality A, one quality C) reported on quality of life outcomes.[61,70,75] A moderate level of evidence points to no difference between SMBP and usual care, as no studies found a difference between groups using a variety of assessment tools, however, with an important caveat. The quality of life measurement tools were not specifically targeted towards hypertension, and may not capture components of quality of life that are relevant in hypertensive patients who use SMBP devices.

Evidence for no difference in adverse drug reactions is limited, as only one C quality study was found for this outcome.[69]

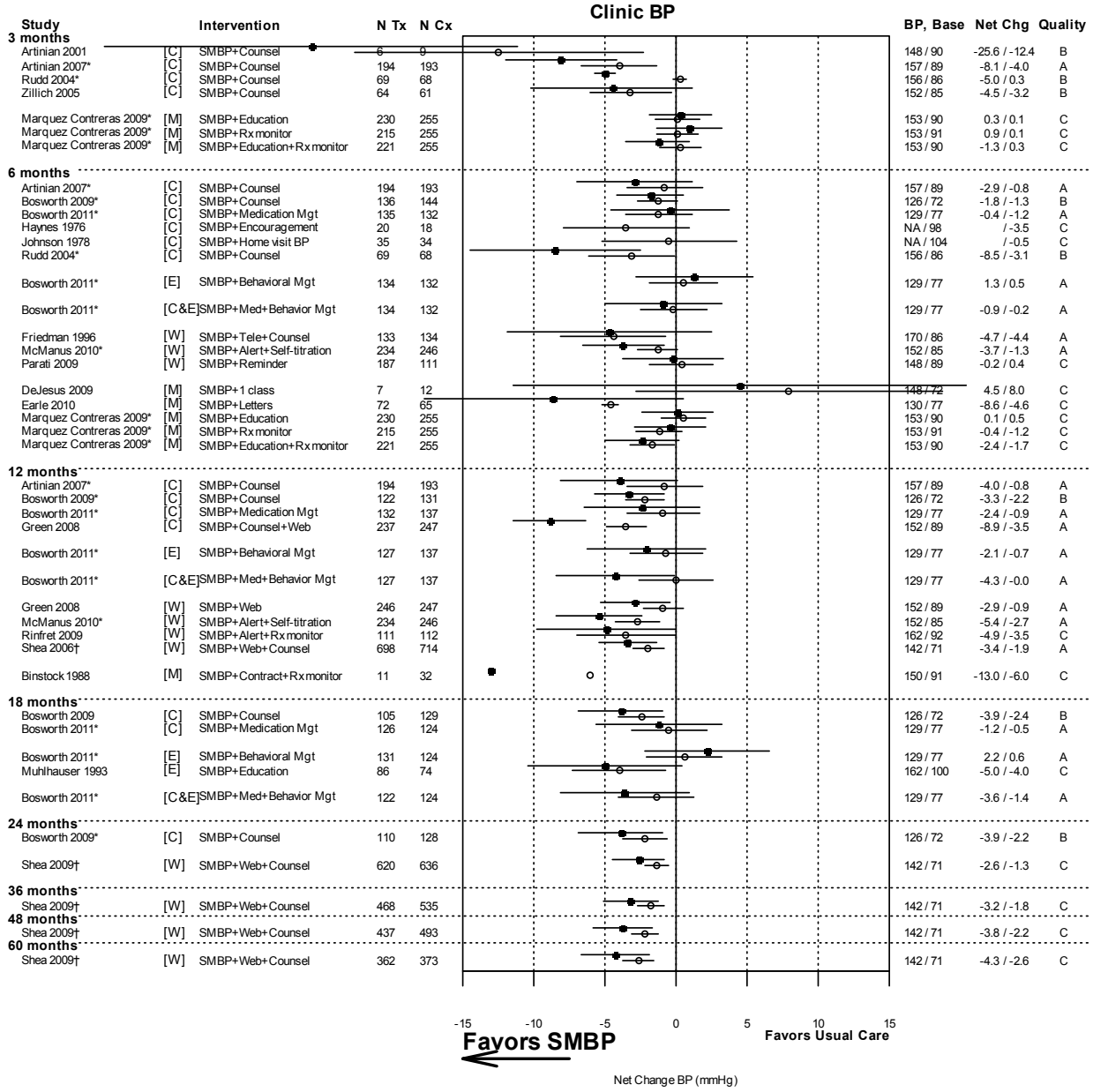
Due to the inconsistency of findings, as well as heterogeneity of outcome definitions used, the strength of evidence for failing to find a difference between SMBP with some form of additional support versus usual care is rated as low across surrogate and intermediate outcomes.

Health Care Encounters

Seven quality C studies reported on health care encounter outcomes.[53,61,70,73,78,81,89] Evidence was mixed, with five studies showing no difference in effect, one outcome showing SMBP to have more visits, and one outcome showing SMBP to have fewer health care provider visits. One study looking at electronic or phone communication found more encounters with pharmacist counseling plus Web training compared to usual care, but not with Web training compared to usual care.[61] Given the inconsistency in findings, the strength of evidence that health care

encounters were not different in patients using SMBP monitoring versus usual care is rated as low.

Figure 9. Forest plot, with meta-analyses, of net change clinic BP in RCTs of SMBP monitoring with additional support versus usual care, by time of outcome measurement



Black and white circles indicate systolic and diastolic blood pressures, respectively. Studies without 95 percent confidence intervals did not report variance data. The letters in brackets to the left of interventions with additional support refer to the categories in Table 1.

BP = blood pressure (systolic/diastolic); N Cx = the number of participants in the control (usual care) group; N Tx = the number of participants in the intervention (SMBP) group; NA = not available (no data); Net Chg = net change in systolic/diastolic blood pressure; RCT = randomized controlled trial; SMBP = self measured blood pressure monitoring

* Studies with same name and intervention, with an asterisk, represent the same study arms at different followup times.

† The same trial with different followup durations (Shea 2006,[82] Shea 2009[93]).

Notes:

Binstock 1988[43] Both groups had education.

Zillich 2005[89] Both groups had pharmacist.

Table 1. Post hoc categorization of types of additional support reported in studies

Category[a]	Definition of Additional Support	Key Question 1 Studies	Key Question 2 Studies
C	Face to face or telecounseling with regular one-on-one encounters with study personnel (nurse, pharmacist, or others) on a regular basis during the course of the intervention. During these encounters, there may be opportunities for education and disease management, or these encounters could simply be for checking BP alone.	Bosworth, 2009 Bosworth, 2011[b] Green, 2008[c] Johnson, 1978 Artinian, 2001 Artinian, 2007 Earp, 1982 Haynes, 1976 Rudd, 2004 Zillich, 2005	Bosworth, 2009 Bosworth, 2011[b] Green, 2008[c] Johnson, 1978 Brennan, 2010 Cheltsova, 2010
E	Education offered in regular classes on hypertension during the course of the study. No regular one-on-one contact with a professional was reported. The classes covered a variety of topics, such as self-management and nondrug therapies including behavioral and lifestyle modifications to nutrition and weight loss.	Bosworth, 2011[b] Pierce, 1984 Gran, 1991 Muhlhauser, 1993 Sawicki, 1995	Bosworth, 2011[b] Pierce, 1984
W	Web-based or telephonic tools with or without counseling support by a professional or preprogrammed computer. The studies offered neither regular one-on-one encounter nor regular educational classes.	Friedman, 1996 Green, 2008[c] McManus, 2010 Parati, 2009 Park, 2009 Rinfret, 2009 Shea, 2006	Carrasco, 2008 Neumann, 2011
M	Miscellaneous types of additional support. A single class offered by a diabetes educator and instruction by a nurse on SMBP monitoring. A leaflet with educational materials on hypertension and/or a card for recording BP and pill counts. A contract on a behavior related to hypertension and calendar pill packs Letter to patients and providers on treatment recommendations	Binstock, 1988[d] Márquez Contreras, 2009 DeJesus, 2009 Earle, 2010	Binstock, 1988[d] Márquez Contreras, 2009 Dawes, 2010

BP = blood pressure; C = Counseling; E = Education; M = Miscellaneous additional supports; SMBP = self-measured blood pressure; W = Web-based or telephonic tools[a] These are the categories noted in square brackets in the forest plots.
[b] Bosworth 2011 provides both a category C and a category E comparison for Key Question 2.
[c] Green 2008 provides both a category C comparison and a category W comparison for Key Question 1.
[d] All groups in Binstock 1998, including control, also participated in an educational program.

Key Question 2

In studies of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?

For Key Question 2, we included only studies of interventions using SMBP monitoring as a principal part of the medical intervention in individuals with hypertension. The first portion of this section discusses studies that compared SMBP with additional support versus SMBP without additional support or with different additional support. The second discusses atypical studies that did not clearly fit into the context of Key Question 2 but used SMBP or home BP monitoring in all patients and were sufficiently relevant for inclusion. Descriptions of all studies that addressed

Key Question 2 are summarized in Table D-27 (descriptions of the interventions) and Table D-28 (descriptions of the study characteristics).

Comparison of SMBP With Versus Without Additional Support

Twelve RCTs (11 full reports[43-46,49,52,61,64,69,74,77] and one conference abstract[50]) directly compared SMBP plus additional support versus SMBP alone or with less intensive additional support. Eleven were RCTs and one was a quasi-randomized study. Two studies were rated quality A, four quality B, and five quality C. The conference abstract was not graded for quality due to insufficient data. Three studies were published before 1990.[43,64,77]

The types of additional support varied widely across trials with regards to what, how, and by whom it was delivered. Modalities of additional support consisted of a mixture of educational interventions, behavioral interventions or disease management by a nurse or pharmacist, medication management based on decision support, a hypertension informational leaflet, a BP and medication recording card, electronic transmission of SMBP measurements, Web sites/training for patient provider communication, or home visits. Change in medication management as a result of monitoring could be initiated by study personnel such as a nurse or pharmacist, the patient, or the primary care physician. Seven studies used automated SMBP devices (i.e., devices that automatically inflate the sphygmomanometer and measure BP),[44-46,49,52,61,74] while the remainder did not describe the monitor type (Table D-1 in **Appendix D**).[43,50,64,69,77]

All studies explicitly qualified that patients had essential hypertension. Studies included patients with hypertension irrespective of whether these patients were on antihypertensive treatment upon study entry. Six included only patients with poorly controlled hypertension despite being on antihypertensive medication.[43,45,50,61,69,74]

Across relevant trial groups, mean baseline SBP ranged from 126 to 179 mmHg and DBP ranged from 70 to 103 mmHg. The mean age of patients ranged from 50 to 72 years and the proportion of men ranged from 33 to 92 percent. The size of the studies (excluding study groups not relevant for this Key Question) ranged from 34 to 828 (total = 3311 across studies). Six studies did not report the prevalence of comorbid conditions. Five studies reported on the prevalence of diabetes, which ranged from 22 and 43 percent.[44-46,49,52] Other comorbid conditions reported included cardiovascular disease in one study (15 percent in Carrasco 2008) and chronic kidney disease in another (7 percent in Brennan 2010).

The primary methodological concerns of the reviewed studies included high dropout rates and incomplete reporting. Overall, the studies are applicable to adults with hypertension in the outpatient setting with the ability to self-monitor BP and with limited comorbid conditions.

Clinical Events

No trial examined clinical event outcomes.

Blood Pressure Outcomes

All 12 studies provided data on BP outcomes. Followup durations ranged from 3 to 24 months, with only Bosworth 2009 and Bosworth 2011 having followup periods longer than 1 year. The BP outcome was based on clinic BP in nine studies,[43-45,49,50,52,61,69,77] home BP in one study,[64] both in one study[46] and 24 hour ABPM in one study[74] . Reported BP outcomes included both categorical outcomes, where the outcomes were defined as achieving a predefined BP target (e.g., clinic SBP <140 mmHg), and continuous outcomes, where net differences of SBP and DBP

between baseline and final measurements, or, in one study, differences between final values were given. Meta-analyses were not performed due to the great heterogeneity of interventions across trials.

Categorical BP Outcomes (Table D-29, Figure 10)

Eight studies reported findings for categorical BP outcomes, which consisted of seven fully reported RCTs (two quality A study, 4 quality B studies and one quality C study), and one quasi-randomized study graded quality C.[44-46,49,61,69,74,77] BP targets varied from <120/80 to <140/90 mmHg across studies, and in one study consisted of discrete reductions in SBP and DBP.[77] In three studies, BP targets were lower for individuals with diabetes (clinic BP <130/80 rather than 140/90 mmHg).[44,45,69]

Green 2008 reported a significantly higher proportion of patients achieving a BP target with the addition of pharmacist counseling to combined SMBP plus Web training (56 versus 36 percent; RR 1.54; 95 percent CI 1.26, 1.88; P<0.001). Marquez Contreras 2009 reported that individuals using SMBP who also received a card for medication monitoring were more likely to achieve BP control at 6 months than those who received the educational material (RR 1.2; 95 percent CI 1.02, 1.38), though the study did not explicitly analyze this comparison. In the same study, comparisons of SMBP plus leaflet with educational material versus SMBP alone or of SMBP plus the card for medication monitoring versus SMBP plus the leaflet with educational material were not statistically significant. Differences in six other studies were not statistically significant or were indeterminate. In these studies, the additional types of support consisted of telecounseling, telemonitoring, educational material, medication monitoring, Web training, physician counseling, nurse counseling, behavior or medication management. One of these studies contained three relevant groups for this Key Question: SMBP plus combined behavior and medication management, SMBP plus behavior management, and SMBP plus medication management.[45] The comparisons between these groups were not prespecified, and since the results were reported as adjusted risk differences in percent of patients with BP control, it was not possible to calculate CIs. However, a higher proportion of patients in the SMBP plus behavior and medication management group achieved improvement in BP control compared to SMBP plus medication management at 18 months (estimated difference 8 percent). A higher proportion of patients in the SMBP plus behavior and medication management group achieved BP control compared to SMBP plus behavior management at 18 months (estimated difference 11 percent). And a higher proportion of patients in the SMBP plus medication management group achieved BP control compared to SMBP plus behavior management at 18 months (estimated difference 2.6 percent). Based on relative risk values derived from a figure of estimated proportions in BP control, none of the risk ratios appeared to differ statistically.

Continuous BP Outcomes

Ten studies reported continuous clinic BP outcomes. Two studies were rated quality A, three quality B, and four quality C. The conference abstract was not graded for quality due to insufficient data.[43-46,49,50,52,61,64,69] One quality B study provided results for continuous 24 hour ABPM.[74]

Clinic BP (Table D-30, Figure 11)

Ten trials reported changes in clinic BP.[43-46,49,50,52,61,64,69] Seven found no evidence or did not provide a measure of statistical difference for a change in BP with the addition of nurse telecounseling, behavioral management, medication management, Web plus physician

counseling, telemedicine, home visitor for BP measurement, compliance contracts plus calendar pill packs plus education, or educational material plus BP and medication tracker.[43-45,49,50,52,64] One of the studies reporting indeterminate results was Bosworth 2011, which included three intervention groups of SMBP plus medication and behavioral management, SMBP plus medication management, and SMBP plus behavioral management.[45] Again, the comparisons of interest for Key Question 2 were not the comparisons for the study's primary analysis, and while the net differences for BP could be calculated, the confidence intervals could not. The largest net difference was for the comparison of SMBP plus combined medication and behavioral management versus SMBP plus behavioral management (-5.8 for SBP and -2.0 for DBP at 18 mos). The remaining three trials showed some benefit for BP reduction from more intense additional support.[46,61,69] Brennan 2010 showed statistically lower BP for SMBP plus counseling by a nurse versus SMBP for SBP at 12 months (mean difference -3.0; P=0.03), but no statistically significant difference for DBP. Green 2008 reported statistically significant results favoring the addition of pharmacist counseling to SMBP plus a Web training for SBP and DBP at 12 months. Results were consistently significant before and after adjustment for baseline BP, sex, having a home BP monitor before trial, and clinic (mean difference for adjusted SBP -6.0 mmHg; P<0.001 and for adjusted DBP -2.6 mmHg; P<0.001). Márquez Contreras 2009 reported statistically significant results for DBP (mean net difference -2.2; 95 percent CI -3.9, -0.5) but not SBP at 6 months favoring the addition of a card for recording BP and monitoring of medication pill counts to SMBP plus educational material on a leaflet, though the study did not explicitly analyze this comparison. However, comparisons of the SMBP with and without the educational material or of SMBP plus the card for medication monitoring versus SMBP plus educational material on a leaflet groups were not statistically significant.

Only two studies provided results regarding more intensive versus less intensive additional support in addition to SMBP beyond 12 months. These were nonsignificant or of uncertain statistical significance.[44,45] In Bosworth 2009, the loss to followup was 30 percent at 24 months.

Ambulatory BP (Table D-31)

One study evaluated SMBP with telemonitoring versus SMBP and examined 24 hour SMBP and DBP on ABPM.[74] The study showed a statistically significant net difference for SBP of -7.2 (95 percent CI -13.8, -0.6, P=0.032) in favor of SMBP with telemonitoring, but not for DBP (-2.0, 95 percent CI -6.2, 2.2, P=0.35).

Quality of Life (Table D-32)

Two studies reported continuous outcomes for quality of life and for mental health.[49,61] The quality of life instruments were SF-36 and SF-12 questionnaires, the mental health instrument the State-Trait Anxiety Inventory for Adults with the "state anxiety" and "trait anxiety" components.

Green 2008, a quality A trial, had a followup of 1 year, and compared SMBP plus Web training with pharmacist counseling versus SMBP plus Web training. Carrasco 2008 (quality B) had a followup of 6 months, and compared SMBP plus Web plus physician counseling versus SMBP alone. Both studies found no statistically significant differences in comparative outcomes concerning quality of life or anxiety.

Medication Dosage (Tables D-33 and 34)

Five studies reported outcomes related to medication prescriptions, three of which reported categorical outcomes and two a continuous outcome.[46,64,74,77] Two studies were rated quality A,

two quality B and one quality C for these outcomes. Followup durations ranged from 3 to 13 months.

Brennan 2010 compared SMBP plus nurse counseling versus SMBP alone and found no statistically significant difference in the proportion of patients taking two or more antihypertensive medication drug-classes as reported by the patient or determined by pharmacy claims after a mean followup of 13 months. Johnson 1978 and Pierce 1984 looked at medical inertia (defined as no medication change versus either an increase or decrease in medication). In addition to SMBP, Johnson 1978 used home visits for BP measurement and Pierce 1984 used education. Neither found any statistically significant difference between groups.

Green 2008 reported that the number of hypertension medication drug-classes used after 1 year followup was greater with the addition of pharmacist counseling to combined SMBP plus Web training (net difference 0.2; 95 percent CI 0.1, 0.4; P<0.01). Neumann 2011 reported "No significant change was observed during the study period" in number of HTN medication classes.

Medication Adherence (Tables D-35 and 36)

Three quality C trials provided data on outcomes related to medication adherence.[44,64,77] Duration of followup ranged from 6 to 24 months. Measures for medication adherence were proportion of individuals returning their logs with BP recordings (Bosworth 2009), proportion of prescribed pills that were consumed (Johnson 1978), or undefined (Pierce 1984). None of the three studies found a statistically significant difference between groups in medication adherence.

Health Care Encounters (Table D-37 and 38)

Five studies provided data on health care encounters.[44-46,49,61] All five studies were graded quality C for these outcomes. Followup durations ranged from 6 to 24 months. In four studies, the addition of a behavioral intervention had no statistically significant effect on the number of outpatient encounters and the proportion of hospitalized individuals over 2 years; the addition of disease management had no effect the number of primary care visits, cardiac visits, or specialist visits per patient per year; the addition of telemedicine had no effect on the median number of consultations or number of hospital admissions; and the number of primary care and specialty care encounters over 18 months was similar across 4 groups of SMBP plus medication and behavioral management, SMBP plus medication management, SMBP plus behavioral management and usual care without SMBP. In the fifth study, Green 2008, there was also no statistically significant difference for primary care visits, or for inpatient and urgent care/emergency use. The study reported a modest but significant decrease in the percentage of patients with office visits to a specialist in 12 months in the SMBP plus Web training plus pharmacist counseling group relative to baseline and to patients in the other arms but the statistical significance was not clear.

Green 2008 also looked at communication and found a statistically significantly higher number of electronic message thread (P nd), patient initiated electronic message threads (P<0.01) and phone encounters (P<0.001) in the SMBP plus Web training plus pharmacist counseling group than in the SMBP plus Web training group.

Miscellaneous Outcomes (Tables D-26 and 39)

Two trials reported miscellaneous outcomes.[61,69] Marquez Contreras 2009 (quality C) provided data on adverse drug reactions after 6 months. These did not differ statistically

significantly across all four study groups of SMBP plus use of educational leaflet, SMBP plus use of card for recording of medication, SMBP plus use of leaflet plus card, and usual care.

Green 2008 (quality A) reported consumer satisfaction concerning patient's experiences and satisfaction with health care service measured with the Consumer Assessment of Healthcare Providers and Systems instrument after 1 year. This study found no statistically significant differences when comparing SMBP plus Web training with pharmacist counseling versus SMBP plus Web training.

Subgroups and Heterogeneity

Four trials reported results from subgroup analyses: Bosworth 2011 (quality A), Green 2008 (quality A), Johnson 1978 (quality C), and a second Bosworth 2011, which is an update of Bosworth 2009 (quality B).[44,45,61,64,91] Bosworth 2011 compared subgroups of 348 patients with adequate BP control (≤140/90 mmHg in patients without diabetes or ≤130/80 mmHg in those with diabetes) to 243 patients with inadequate control in a post hoc analysis.[45] The study reported that patients with adequate control at baseline continued to remain in control over the 18 months of the study. For those with inadequate control, SBP net change was -1.4 mmHg at 18 months, and DBP net change was -1.3 mmHg (comparing SMBP plus combined medication and behavioral management with SMBP plus medication management). Comparing SMBP plus combined medication and behavioral management with SMBP plus behavioral management, SBP net change was -8.3 mmHg at 18 months and DBP net change was -6.6 mmHg. Comparing SMBP plus medication management with SMBP plus behavioral management, SBP net change was -6.9 mmHg at 18 months; DBP net change was -5.3 mmHg. For these comparisons, a confidence interval or P value could not be calculated as the study reported adjusted results with usual care being the reference group.

Green 2008 reported categorical and continuous BP outcomes from the subgroup of patients whose SBP at baseline was ≥160 mmHg. In this subgroup, the addition of pharmacist counseling to combined SMBP plus Web training resulted in better BP control at 12 months (RR 2.11; CI 1.22, 3.65; P<0.001) and greater reductions in SBP and DBP. This was consistently found for unadjusted SBP outcomes and after adjustment for baseline BP, sex, having a home BP monitor before trial, and clinic (net difference for adjusted SBP was not provided but P<0.001). For the DBP the unadjusted comparison was not statistically significantly different (P=0.10), although the adjusted analysis was (P<0.03). In the overall group, all 12-month BP outcomes (SBP and DBP, unadjusted and adjusted) were significantly different. However, data for the subgroup with SBP <160 mmHg at baseline were not reported, limiting the interpretability of their subgroup finding.

Johnson 1978 reported changes in adherence among subjects with initial adherence of less than 80 percent. In this subgroup, the percentage of prescribed pills that had been consumed did not differ with the addition of a visitor taking home BP measurement. This was consistent with the results in the entire study. Again, the lack of data on the study subjects with better initial adherence limits the interpretability of these findings.

As noted in the previous section on SMBP versus usual care, a post hoc data analysis of Bosworth 2009 reported a subgroup analysis by whites versus nonwhites, where nonwhites were 95 percent African American.[44,91] At both 12 and 24 months of followup, white patients in the SMBP plus telecounseling group had a similar SBP and DBP compared with those in the SMBP group. In non-white patients, SBP and DBP were also similar at 12 months in the two groups. However, at 24 months, SBP was 8.8 mmHg lower and DBP was 2.9 mmHg lower in the SMBP

plus telecounseling group compared with the SMBP group. These results were not statistically analyzed.

We attempted to gain an insight into the heterogeneous nature of the additional modalities of support across comparisons using the classification scheme described in Table 1. This scheme was based on our assessment of the key component differing between the two groups, as the categories are not exclusive. Six studies examined the addition of an intervention from category "C" (Counseling with regular one-on-one encounters with study personnel).[44-46,50,61,64] Two of these studies showed some benefit for BP control or BP reduction.[46,61] As described above, Green 2008 reported a significantly higher proportion of patients achieving a BP target at 12 months and lower SBP and DBP at 12 months with the addition of pharmacist counseling. Brennan 2010 also showed a benefit with the addition of counseling by a nurse at 12 months, albeit only for SBP and not for DBP. Two other studies showed no benefit with addition of telephonic counseling by a nurse[44] or home visits.[64] The conference abstract by Cheltsova 2010 examined the addition of telephonic counseling by a nurse and also found no difference. The findings from Bosworth 2011 were indeterminate for the comparison of SMBP plus combined medication and behavioral management (C+E) versus SMBP plus behavioral management (E).

Two studies[45,77] examined the addition of an intervention from category "E" (Education offered in regular hypertension education classes), the addition of four educational classes. Pierce 1984 found no difference. Bosworth 2011 compared SMBP plus combined medication and behavioral management (C+E) versus SMBP plus medication management (C). The results were indeterminate.

Two studies[49,74] examined the addition of an intervention from category "W" (Web-based or telephonic tools). Carrasco 2008 study added a Web site and physician counseling to SMBP, but failed to detect a difference in BP at 6 months. Neumann 2011 with addition of telemonitoring to SMBP showed statistically significant greater net change for SBP on 24 hour ABPM at 3 months but not for DBP.

One study compared SMBP with an intervention from category "C" to and intervention from category "E". The findings from Bosworth 2011 were indeterminate for the comparison of SMBP plus medication management (C) versus SMBP plus behavioral management (E).

Three studies were placed in category "M" (Miscellaneous).[43,69] Binstock 1988 examined the addition of compliance contract plus calendar pill packs to SBMP plus education and found effect estimates in favor of the less intensive treatment group, but did not provide statistical testing. Marquez Contreras 2009 compared addition of a leaflet with educational materials on hypertension in one group, a card for recording BP and pill counts in another group, and a combination of both in a third group. The combination of the card plus leaflet compared to the addition of the leaflet only resulted in significantly lower DBP at 6 months (SBP did not differ significantly between groups). The addition of the card plus leaflet versus just the leaflet also resulted in better BP control. However, as previously mentioned, the study did not explicitly analyze this comparison. Further, comparisons of the SMBP plus the leaflet containing educational material versus SMBP, or of SMBP plus the card for medication monitoring versus SMBP plus the leaflet containing educational material were not statistically significant. Finally, Dawes 2010 found no difference in BP when comparing SMBP plus educational material plus a BP and medication tracking tool with SMBP plus educational material alone.

Summary

Clinical Events

No studies of SMBP plus additional support versus SMBP without additional support (or plus a less intensive additional support) provide evidence on clinical event outcomes. Thus, there is insufficient evidence regarding clinical events.

BP Outcomes

Twelve trials of SMBP plus additional support versus SMBP without additional support (or plus a less intensive additional support) provided BP results across five separate timepoints ranging from 3 to 24 months.[43,44,46,49,50,52,61,64,69,77] In total, 3311 patients with hypertension were included. Two trials were graded quality A, four quality B, and five quality C, and one conference abstract was not graded. Additional support consisted of a mixture of behavioral interventions or disease management by a nurse or pharmacist, medication management, educational interventions, electronic transmission of BP measurements, Web sites/training for patient-provider communication, telemonitoring, BP recording cards, BP and medication tracking tool, hypertension information leaflets, or home visits. Change in medication management as a result of the monitoring could be initiated by the patient, nurse, pharmacist, or the primary care physician. The most commonly cited comorbid condition in these studies was type 2 diabetes. Nine studies reported clinic BP outcomes, one study reported only home BP, one study reported both and one reported ABPM.[43,44,46,49,50,52,61,64,69,77] I Meta-analysis was not undertaken due to clinical heterogeneity.

Four trials found statistically significant benefits for the more intensive additional support for either SBP, DBP, BP control, or combinations thereof.[46,61,69] Green 2008 was the only study rated quality A, and showed consistent benefit for SBP, DBP continuous outcomes and for categorical BP outcome. The additional support examined in this study was pharmacist counseling added to SMBP plus use of Web training. The other eight trials (six full reports and one abstract) were indeterminate for a difference. Across studies, no clear patterns could be discerned to explain the heterogeneity in results. The small number of studies and their distribution across different categories of additional support makes it impossible to draw conclusions regarding the potential effects of specific additional support or its interactions with SMBP. Overall, the strength of evidence is rated as low and fails to support a difference between SMBP plus additional support versus SMBP with no additional support or with less intensive additional support in BP.

Four trials reported subgroup analyses by control of baseline BP at baseline (controlled or not controlled), degree of adherence (lower adherence) or race (white versus predominantly African American). Two of these studies did not provide analyses for the comparisons of SMBP plus additional support versus SMBP without additional support or with another type of additional support and two studies did not provide complete subgroup analyses data.

Surrogate and Intermediate Outcomes (not Blood Pressure)

Five trials of SMBP plus additional support versus SMBP without additional support (or plus a less intensive additional support) reported data on categorical and continuous medication number and dosage (two quality A and two quality B, one quality C).[46,61,64,77] Studies reported the numbers of patients taking two or more classes of medications, medical inertia (defined as no medication change versus either an increase or decrease in medications), and the number of

medication drug-classes. Four trials using additional support consisting of nurse counseling, home visits for BP measurement, telemonitoring or education found no difference between SMBP plus additional support versus SMBP. One trial found a somewhat greater mean number of medication drug-classes with SMBP plus pharmacist care plus Web training. A weak level of evidence suggests no difference in medication use.

Two trials reported quality of life or anxiety outcomes (one quality A and one quality B). The studies used the SF-36 and SF-12 quality of life instruments and the State-Trait Anxiety Inventory, a mental health questionnaire. Both found no differences using these measures. A weak level of evidence fails to support a difference in quality of life or anxiety outcomes.

Three trials (all quality C) reported on medication adherence.[44,64,77] Using different measures in each study, none found a significant difference in medication adherence. One trial also found no difference in a subgroup of individuals with lower baseline adherence.[64] A weak level of evidence fails to support a difference in medication adherence.

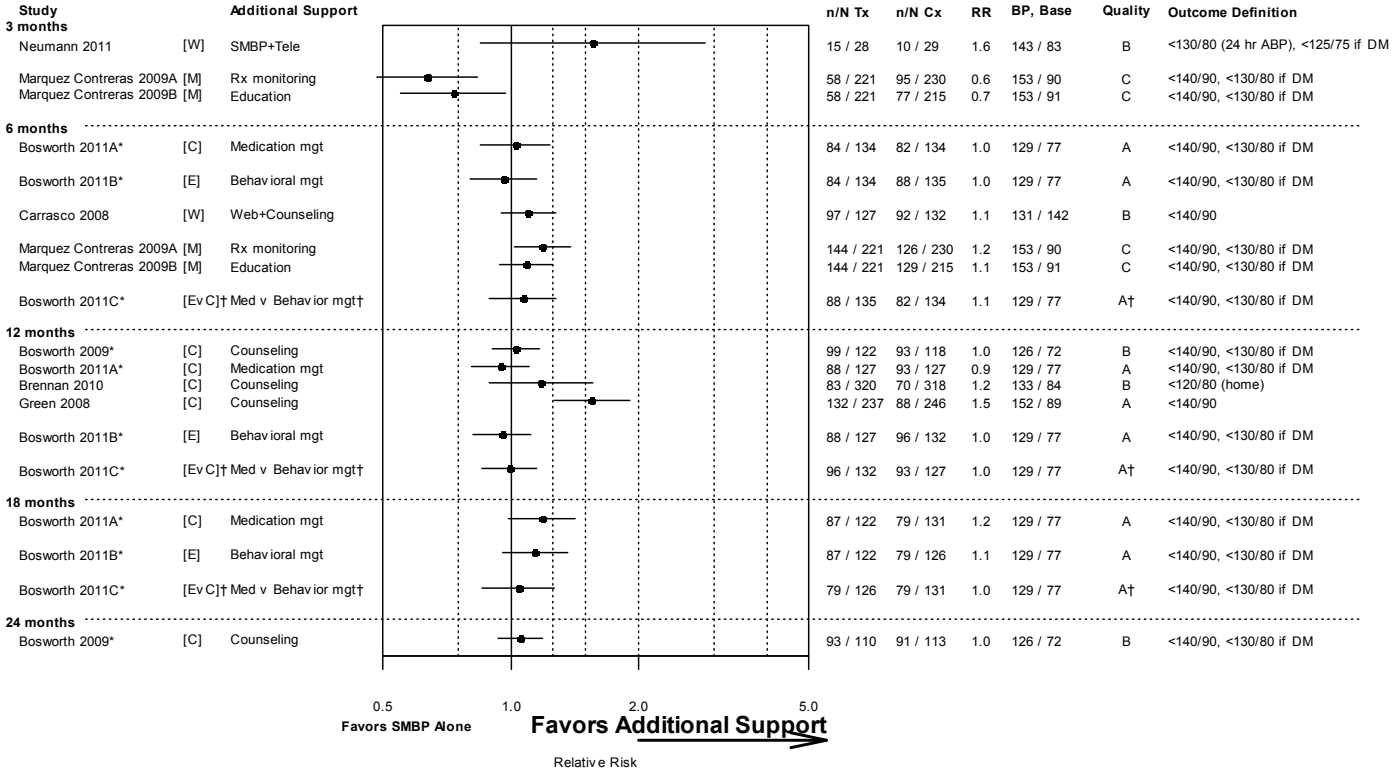
Two trials reported miscellaneous outcomes. One study (quality C) found no difference in adverse drug reactions across four groups with different forms of additional support or usual care.[69] One study (quality A) found no difference for consumer satisfaction measured by the Consumer Assessment of Healthcare Providers and Systems instrument.[61] The level of evidence is insufficient for miscellaneous outcomes.

Due to the inconsistency of findings, as well as heterogeneity of outcome definitions used, the strength of evidence for failing to find a difference between SMBP with some form of additional support versus usual care is rated as low across surrogate and intermediate outcomes.

Health Care Encounters

Five quality C trials compared SMBP plus additional support to SMBP without additional support and reported results for health care encounters. Additional support included counseling by a nurse or pharmacist, behavioral intervention, medication management, Web training or telemedicine. All reported on outpatient primary care visits, two reported on hospital admissions, and three reported on cardiac and other specialist visits. No study found a difference in the numbers of outpatient visits or hospital admissions between patients receiving SMBP with or without additional support. One study found a higher number of any or patient initiated electronic message threads or phone encounters with the addition of pharmacist counseling to SMBP plus Web training. Despite the consistency across trials for visits, due to their small number and general poor quality, overall, the strength of evidence is rated as low and fails to support a difference for health care utilization by the addition of auxiliary support to SMBP compared to SMBP without additional support or with less intensive additional support. One study showed that the addition of pharmacist counseling to training in a patient Web portal increased electronic and telephonic communication.

Figure 10. Forest plot of relative risk of "adequate" BP at followup in RCTs of SMBP with additional support versus SMBP monitoring alone, by time of outcome measurement



ABP = ambulatory blood pressure; BP = blood pressure (systolic/diastolic); DBP = diastolic blood pressure; DM = coexisting diabetes mellitus; n/N Cx = the number of participants with adequate BP control/total in the control (SMBP alone) group; n/N Tx = the number of participants with adequate BP control/total in the intervention (SMBP with additional support) group; RCT = randomized controlled trial; RR = relative risk; SMBP = self measured blood pressure monitoring

Black circles indicate relative risk for each study. The letters in brackets to the left of interventions with additional support refer to the categories in Table 1.

* Studies with same name and intervention, with an asterisk, represent the same study arms at different followup times.

† Comparator is not SMBP alone; comparison is SMBP+Medication Management versus SMBP+Behavioral management.

Notes:

Estimates favoring additional support (the more intensive intervention) are to the right, in contrast to Figures 5-9 & 11.

Bosworth 2011[45] Reported as differences in BP control (from a regression model). RR values derived from figure of estimated proportion in BP control.

Bosworth 2011A[45] Both groups had behavioral management.

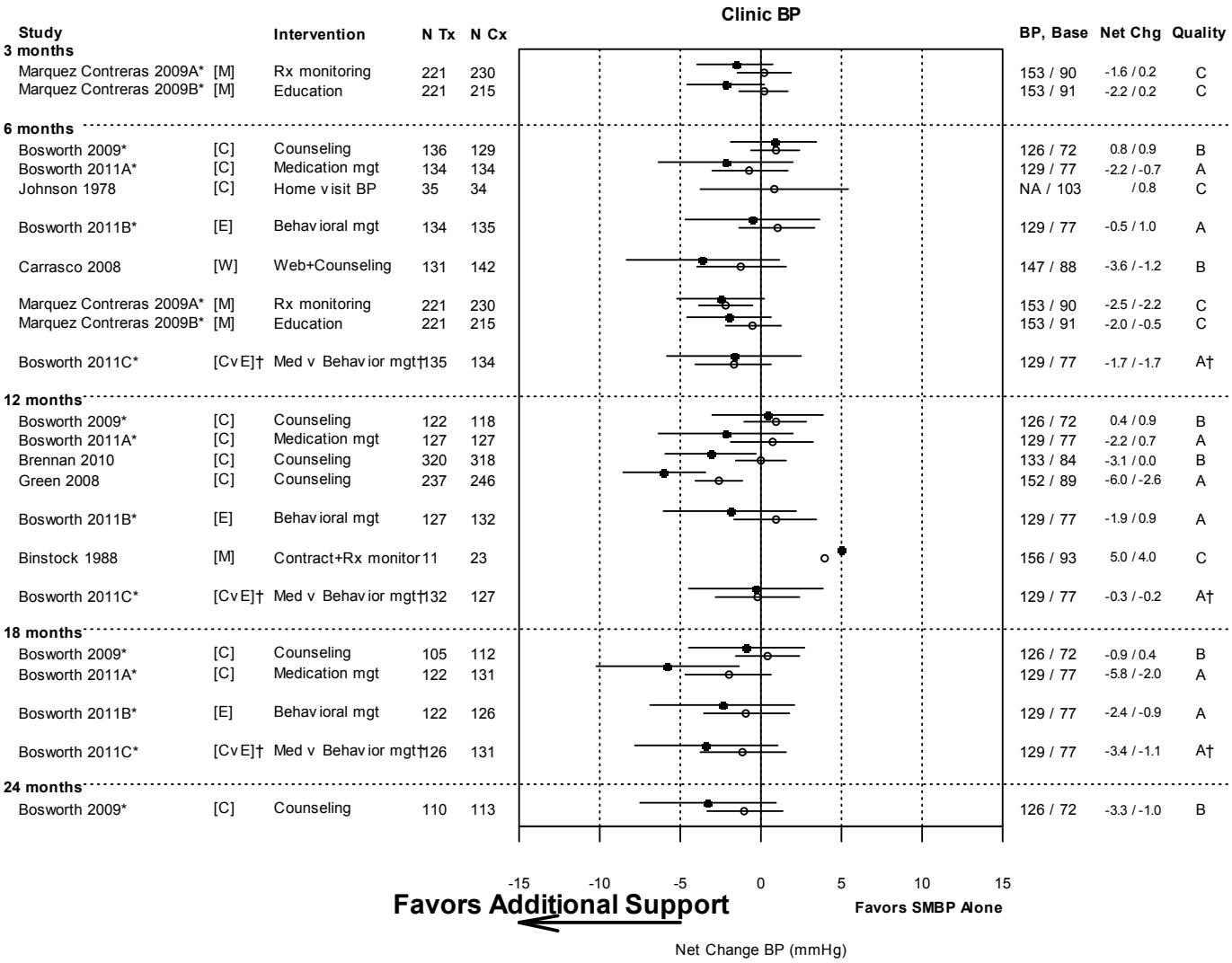
Bosworth 2011B[45] Both groups had medication management.

Marquez Contreras 2009A[69] Both groups had leaflet.

Marquez Contreras 2009B[69] Both groups had card.

Green 2008[61] Both groups had Web site.

Figure 11. Forest plot of net change clinic BP in RCTs of SMBP with additional support versus SMBP monitoring alone, by time of outcome measurement



Black and white circles indicate systolic and diastolic blood pressures, respectively. Studies without 95 percent confidence intervals did not report variance data. The letters in brackets to the left of interventions with additional support refer to the categories in Table 1.

BP = blood pressure (systolic/diastolic); Med = medication; N Add = the number of participants in the SMBP with additional support group; N Cx = the number of participants in the control (SMBP alone) group; NA = not available (no data); Net Chg = net change in systolic/diastolic blood pressure; RCT = randomized controlled trial; Rx = prescription; SMBP = self measured blood pressure monitoring

* Studies with same name and intervention, with an asterisk, represent the same study arms at different followup times.† Comparator is not SMBP alone; comparison is SMBP+Medication Management versus SMBP+Behavioral management.

Notes:

Bosworth 2011A[45] Both groups had behavioral management.

Bosworth 2011B[45] Both groups had medication management.

Green 2008[61] Both groups had Web site.

Marquez Contreras 2009A[69] Both groups had leaflet. Intervention is the same as the 2009B analysis.

Marquez Contreras 2009B[69] Both groups had card. Intervention is the same as the 2009A analysis.

Atypical Studies Using SMBP Monitoring in all Groups

Three RCTs did not clearly fit into the context of Key Question 2, but were nonetheless of sufficient interest for inclusion.[65,84,85] These studies are discussed individually below, and are summarized in Table D-27 (descriptions of the interventions) and Table D-28 (descriptions of the study characteristics).

SMBP With Graphical Display Versus SMBP Without Graphical Display (Tables D-40 Through 42)

Kabutoya 2009, a quality C RCT, compared SMBP plus a graph-equipped SMBP monitor versus use of the SMBP monitor without the graphic display. The graph-equipped SMBP monitor displayed weekly and monthly averaged BPs, while in the control group the same SMBP monitor displayed only a single BP-value. The study included 65 patients, and was rated quality C because of incomplete and selective reporting.

At 6 months, the percentage of patients with home BP below 135⁄85 mmHg in the graph-equipped SBPM group did not differ from that in the conventional SMBP group (Table D-40). However, the graph-equipped monitor group displayed better BP control at 2 months (41 versus 13 percent, P<0.05), 4 months (40 versus 11 percent, P<0.05), and 5 months (37 versus 16 percent, P<0.05).

At 6 months, continuous home DBP and SBP did not differ between groups (Table D-41). However, at 2 months, home SBP was significantly lower in the group with the graph-equipped SMBP monitor than in the control monitor group (estimated mean difference in home SBP approximately -6.3 mmHg; P<0.05). Clinic BP results were incompletely reported. It was stated only that clinic SBP was significantly lower in the graph-equipped SMBP group at 3 months (net difference -9.7 mmHg; P<0.05), and presumably did not differ at the other time points.

The number of medications was significantly greater in the graph-equipped SMBP group than in the conventional SMBP group at 5 and 6 months (3.74 versus 2.76 at 6 months; P<0.02) (Table D-42). It was not explicitly reported for other timepoints, presumably because it did not differ.

This study provides insufficient evidence for use of a graphical display along with SMBP.

SMBP With BP Medication Titration Based on Home BP Versus SMBP With Titration Based on Clinic BP (Tables D-41 Through 43)

Staessen 2004 randomized a total of 400 patients into two groups. Both groups used SMBP and had their BPs transmitted to study personnel. This was followed by blinded stepwise medication titration to reach the same BP target: a target DBP between 80 and 89 mmHg, but in one group drug treatment was adjusted based on home BP, while in the other group, it was adjusted based on clinic BP. This study was rated quality A for all outcomes except for those related to left ventricular hypertrophy, for which it was rated quality C.

At 12 month followup, BP in the home BP titration group was significantly higher than in the clinic BP titration group (Table D-41). This was consistent for all BP outcomes. For clinic BP, the differences were 6.8 mmHg for SBP (95 percent CI 3.6, 9.9; P<0.001) and 3.5 mmHg for DBP (95 percent CI 1.9, 5.1; P<0.001). For home BP, the differences were 4.9 mmHg for SBP (95 percent CI 2.5, 7.4; P<0.001) and 2.9 mmHg for DBP (1.5, 4.4; P<0.001). For daytime ambulatory BP, the differences were 5.3 mmHg for SBP (95 percent CI 2.6, 7.9; P<0.001) and 3.2 mmHg for DBP (95 percent CI 1.5, 4.8; P<0.001). For nighttime ambulatory BP, the differences were 4.8 mmHg for SBP (95 percent CI 2.1, 7.5; P<0.001) and 3.0 mmHg for DBP

(95 percent CI 1.3, 4.7; P<0.001). For 24 hour ABPM, the differences were 4.9 mmHg in SBP (95 percent CI 2.5, 7.4; P<0.001) and 2.9 mmHg in DBP (95 percent CI 1.4, 4.4; P<0.001).

The antihypertensive treatment score, which measured the intensity of equipotent drugs, was significantly lower with home BP titration than with clinic BP titration (P=0.007 at last visit, approximately after 12 months) (Table D-42). Adverse events as assessed by symptom score did not differ significantly between groups.

The number of patients who permanently stopped antihypertensive treatment was significantly greater in the home BP titration group than in the clinic BP titration group (RR 2.34; 95 percent CI 1.48, 3.69; P<0.01) (Table D-43). The proportion of patients proceeding to multiple-drug treatment was not significantly different between the two groups (RR 0.84; 95 percent CI 0.66, 1.06).

Also reported were left ventricular hypertrophy outcomes in a subgroup of patients in both groups. Serial electrocardiograms were available in 355 patients, as well as echocardiographic results in 54 patients. Outcome measures were left ventricular wall thickness, fractional shortening, and the ratio of the peak left ventricular inflow velocities in early diastole and at atrial contraction. After adjustment for baseline values, sex, age, and body mass index, the between-group differences in the changes in most electrocardiographic and echocardiographic measurements were small and statistically nonsignificant. The only statistically significant finding was a marginal clinical benefit for the echocardiographic ratio of the peak left ventricular inflow velocities in early diastole and at atrial contraction (between group difference -0.22; 95 percent CI -0.39, 0.05; P=0.02) in the clinic BP titration versus the home BP titration group.

This study provides insufficient evidence to clarify whether medication titration should be based on SMBP or clinic BP. But it highlights the challenge of selecting a BP target for SMBP since SMBP is generally lower than clinic BP. In a response to a letter to the editor about their study, the study authors suggest that a lower limit for the diastolic blood pressure needs to be chosen for adjusting antihypertensive drug treatment based on SMBP than on clinic BP if the same clinic BP is to be achieved.[32] Another study, Verberk 2007, included under KQ1, also adjusted antihypertensive therapy in a blinded fashion based on the same BP target of 120-140/80-90 for either SMBP or clinic BP.[20] It also showed a reduction in the number of drugs, with a trend for worse clinic BP control in the SMBP group.

Home BP Monitoring by a Family Member Versus SMBP (Tables D-40 and 41)

Stahl 1984 was a quasi-RCT of 202 patients assigned either to home BP monitoring by a family member or SMBP by the patient. This study was rated quality C due to a lack of randomization, a dropout rate of 67 percent at 36 months, and apparent reporting errors. There was no clear pattern for consistent differences in BP control (Table D-40) or DBP (Table D-41) between groups over time. Although a significantly greater reduction in DBP was observed in the SMBP group versus the family measured group for the 7–12 months interval, this effect reversed at subsequent followup.

There is insufficient evidence to clarify whether the efficacy for BP reduction depends on home BP measurement by a family member versus the patient.

Key Question 3

How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic versus manual) in their effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?

For Key Question 3, we searched for studies that directly compared SMBP monitoring devices. We found no study comparing devices that were of a priori interest to the reviewers or the Technical Expert Panel. Most devices used in the trials reviewed for Key Question 1 and 2 used automated devices. There is insufficient evidence comparing SMBP monitors.

Key Question 4

In studies of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?

In order to address Key Question 4, we searched for studies that reported both BP control outcomes and clinical or surrogate outcomes with sufficient data. Sawicki 1995 was the only eligible study that reported on clinical outcomes (death, kidney, and diabetes-related outcomes).[81] However, the study provided no data on how many patients achieved BP control nor other data relevant to this Key Question.

Based on the studies reviewed, the evidence is insufficient regarding how achieving BP control relates to clinical and surrogate outcomes under an SMBP monitoring regime.

Key Question 5

In people with hypertension how does adherence with SMBP monitoring vary by patient factors?

To address Key Question 5, our literature search was restricted to studies that addressed the outcome of adherence with SMBP monitoring and employed a longitudinal design with at least 100 participants followed for at least 8 weeks. As a prerequisite, studies also had to evaluate adherence rates based on predictors. Only one study met criteria.[66]

Adherence With SMBP Monitoring

Kim 2010, a quality B study, investigated predictors for adherence with SMBP monitoring and its relationship to BP control in 377 middle-aged Korean Americans. SMBP was employed as part of an intervention that consisted of education about hypertension and its management, SMBP with telephonic transmission of BP measurements, and telephone counseling by a nurse. Participants were required to measure their BP twice daily. Participants were considered adherent if they had transmitted a minimum of 12 readings per week for at least 24 weeks of the 48-week study. The cohort consisted of equal numbers of men and women, more than half of whom had a college education or higher and more than half of whom were employed either full or part time. Adherence with SMBP was observed in 60 of 377 (16 percent) participants.

Multivariable analysis that adjusted for demographic variables, hypertension characteristics, comorbidity, body mass index, psychosocial variables and ancillary interventions, showed that age >60 years was associated with better adherence with SMBP (OR 5.3; 95 percent CI 1.8, 15.8) compared to younger age groups. The authors noted that older age may have been a surrogate for other factors such as work status or lifestyle patterns. Patients with depression scores of greater severity (>90th percentile) rated on a depression scale specific for Korean Americans were less likely to be adherent (OR 0.2; 95 percent CI 0.04, 0.9). Notably, the study

also found that patients with higher depression scores were less likely to have knowledge and awareness regarding hypertension. Other factors explored for their relationship to adherence that did not show significant influences were marital status, education, work status, medication, duration of hypertension, comorbidity, family history (presumably for hypertension, though this was not specified in the paper), body mass index, and knowledge and awareness regarding hypertension.

Summary

In a single study of Korean Americans, older age was independently associated with greater adherence to SMBP monitoring, and the presence of depression was independently associated with lower adherence. Other tested factors were not associated with adherence. As data are limited to that of a single study, the strength of evidence is insufficient regarding predictors of adherence with SMBP monitoring.

Summary and Discussion

Summary

Table 2 summarizes the main findings addressing the five Key Questions of this systematic review. Discussion regarding the report and recommendations for future research follow.

Table 2. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 1: SMBP Alone Versus Usual Care **Overall**	--	• Twenty-four studies compared SMBP alone versus usual care (22 RCTs and 2 quasi-RCTs). In total, 5,400 patients with hypertension were included. Four studies were graded quality A; 6, quality B; 13, quality C; and 1 conference abstract was not graded. • The studies were heterogeneous in terms of the brands and types of SMBP monitors; followup duration (2–36 months); baseline hypertension control (across studies, mean SBP/DBP: 124-167/70-109 mmHg); patient ages (across studies, mean 47–73 years). All patients were adults, most were male, and the most commonly cited comorbid conditions in these studies were type 1 or 2 diabetes, obesity, dyslipidemia, and cardiovascular disease.
Key Question 1: SMBP Alone Versus Usual Care **Clinical Outcomes**	Insufficient	• No study reported clinical outcomes. • **Conclusion:** There is insufficient comparative study evidence regarding clinical outcomes in trials of SMBP versus usual care.

Table 2. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 1: SMBP Alone Versus Usual Care **Blood Pressure**	Moderate (favoring SMBP)	• Twenty-three of the 24 studies that compared SMBP alone versus usual care reported BP outcomes (4 quality A, 5 quality B, 13 quality C, and 1 conference abstract that was not graded). See the "Overall" summary above regarding the study heterogeneity. • Thirteen studies reported categorical changes in BP control, mostly defined as achieving a BP of <130-140/80-90 mmHg (sometimes with lower thresholds for patients with diabetes). Although all but one study found greater rates of achieving BP control with SMBP monitoring, meta-analyses of the subset of trials that examined achieving a BP target found no significant effects at 6- and 12-month followup. • Twenty-one studies reported continuous BP outcomes. Seventeen studies reported clinic BP outcomes; 5 reported 24-hour ambulatory BP; 6, awake (day) ambulatory BP; and 5, asleep (night) ambulatory BP. In meta-analyses, no significant effect was found at 2 months followup; statistically significant differences for clinic BP favoring SMBP monitoring were found at 6 months (SBP/DBP: -3.1/-2.0 mmHg), but these differences were not statistically significant at 12 months (-1.2/-0.8 mmHg). The meta-analyses were statistically heterogeneous at 6 and 12 months. Only 1 RCT reported followup data beyond 12 months, and it found significant reductions in SBP and DBP at 24 months with SMBP. The studies reporting 24-hour ambulatory BP had inconsistent findings favoring either SMBP or usual care. However, the studies of awake and asleep ambulatory BP fairly consistently favored SMBP, although most did not find a statistically significant difference. • Subgroup analyses were reported by 4 trials. One study found no differences in the relative effect of SMBP monitoring in patients treated or untreated for hypertension at baseline. Another found no difference by age, sex, or diagnosis with diabetes. A third study found significant reductions in clinic and 24-hour ambulatory DBP in men but not women. A study looking at differences by race did not have consistent findings. Across studies, no clear patterns could be discerned to explain the heterogeneity in results. • **Conclusion:** Based primarily on the consistent findings of the quality A and B studies examining the impact of SMBP versus usual care in clinic BP measurements and the corresponding results from meta-analyses, the strength of evidence is moderate for a small improvement in BP using SMBP compared with usual care.

Table 2. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 1: SMBP Alone Versus Usual Care **Surrogate and Intermediate Outcomes (Not Blood Pressure)**	Low (failing to support a difference)	• Thirteen of the 24 studies that compared SMBP alone versus usual care reported surrogate and intermediate outcomes that were not BP. See the "Overall" summary above regarding the study heterogeneity. • Eight studies reported data on categorical and continuous outcomes related to number of medications and dosage (1 quality A, 5 quality B, 2 quality C). Studies variously reported increases or decreases in number of medications, medication dose, added medication classes, number of treatment modifications by physicians, physician assessment of strength of medication regimen, number of antihypertensive medications used, and medication changes. The majority of studies found no difference in medication outcomes, although a minority found significantly greater changes in medication treatment with SMBP monitoring. Weak evidence favors no difference in medication use with SMBP monitoring. • Three studies reported on quality-of-life outcomes (2 quality B, 1 quality C). Studies used the SF-36 quality-of-life assessment tool. In general, studies found no difference in quality of life between SMBP and usual care. • Seven studies reported on medication adherence using a variety of different definitions of adherence, including both categorical and continuous outcomes (3 quality B, 4 quality C). A wide variety of definitions were used for medication adherence across studies. Three studies reported some significantly better measures of adherence with SMBP (although not always for all evaluated measures of adherence); the remaining 4 studies found no difference. Overall, there was weak evidence that medication adherence may be better among patients using SMBP monitoring. • Only a single study each reported on patient satisfaction (quality C) and left ventricular mass index (quality B). No differences were found between SMBP and usual care. There is insufficient evidence for either of these outcomes. • **Conclusion:** The evidence is weak or insufficient for these outcomes. Thus, overall the strength of evidence is low and fails to support a difference between SMBP alone versus usual care for surrogate and intermediate outcomes.
Key Question 1: SMBP Alone Versus Usual Care **Health Care Encounters**	Low (failing to support a difference)	• Six of the 24 studies that compared SMBP alone versus usual care reported number of health care encounters (1 quality A, 3 quality B, and 2 quality C). See the "Overall" summary above regarding the study heterogeneity. • The majority of studies found no difference in number of physician visits between groups, 2 studies found no difference in number of hypertension-related telephone calls, and 1 study found no difference in number of medical procedures received for hypertension. • One study found that patients using SMBP had more office visits and 2 studies found that patients using SMBP had fewer visits. • **Conclusion:** Based on the lack of agreement in study results, the strength of evidence is low and fails to support a difference between SMBP alone versus usual care for health care encounters.

Table 2. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 1: SMBP + Additional Support Versus Usual Care **Overall**	--	• Twenty-four studies compared SMBP plus additional support versus usual care (19 RCTs, 2 quasi-RCTs, and 3 nonrandomized studies). In total, 6,187 patients with hypertension were included. Six studies were graded quality A; 5, quality B; and 13, quality C. Four of these studies also provided data for SMBP alone versus usual care. • The studies were heterogeneous in terms of the brands and types of SMBP monitors; followup duration (2–36 months); baseline hypertension control (across studies, mean SBP/DBP: 124-163/70-103 mmHg); patient ages (across studies, mean 47–77 years). All patients were adults, most were male, and the most commonly cited comorbid conditions in these studies were type 1 or 2 diabetes, obesity, dyslipidemia, and cardiovascular disease. • No form of additional support was examined by more than one trial. The studies were highly heterogeneous in the types of additional support used. They included educational materials, Web resources, telephone monitoring with electronic transmission of BP data, nurse or pharmacist visits, calendar pill packs and/or compliance contracts, and behavioral management and/or medication management. Change in medication management as a result of the monitoring could be initiated by patient, nurse, pharmacist, or primary care physician.
Key Question 1: SMBP + Additional Support Versus Usual Care **Clinical Outcomes**	Insufficient	• One quality C trial found significantly lower mortality with SMBP plus self-titration versus usual care, and lower composite mortality and end-stage renal disease. End-stage renal disease alone was not significantly different. • Conclusion: There is insufficient comparative study evidence regarding clinical outcomes in trials of SMBP plus additional support versus usual care.
Key Question 1: SMBP + Additional Support Versus Usual Care **Blood Pressure**	High (favoring SMBP)	• All 24 studies that compared SMBP plus additional support versus usual care reported BP outcomes. See the "Overall" summary above regarding the study heterogeneity. • All 6 quality A trials reported a significant mean net reduction in SBP (ranging from -3.4 to -8.9 mmHg) or DBP (ranging from -1.9 to -4.4 mmHg) in the intervention group compared with usual care at up to 12 months followup. Four studies provided results after 12 months. The only quality A trial found no difference between groups at 18 months followup; the other 3 trials reported statistically significant mean net BP reductions for followup periods of 18 to 60 months. • **Conclusion:** The strength of evidence is high for an improvement in BP control using SMBP with some form of additional support compared to usual care. By examination across studies, it is not possible to state with certainty whether one form of additional support is superior, as the additional supports examined across studies varied in primary intent, ancillary equipment and educational materials, followup personnel, and algorithms for medication adjustments. The studies were too heterogeneous in numerous ways to allow an explanation of differences in results across studies.

Table 2. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 1: SMBP + Additional Support Versus Usual Care **Surrogate and Intermediate Outcomes (Not Blood Pressure)**	Low (failing to support a difference)	• Fourteen of the 24 studies that compared SMBP plus additional support versus usual care reported surrogate and intermediate outcomes that were not BP. See the "Overall" summary above regarding the study heterogeneity. • Eleven studies reported data on categorical and continuous outcomes related to medication number and dosage (3 quality A, 2 quality B, 6 quality C). Studies variously reported increases or decreases in medication number, medication inertia (no change in regimen), physician assessment of strength of medication regimen, treatment modification by physician, discontinuation of medication, and number of medication classes used or tablets taken. Studies were split between finding no difference in medication outcomes and finding either an increase or decrease in medications with patients using SMBP with additional support. The contradictory findings in the evidence overall favor no difference in medication use with SMBP monitoring plus additional support. • Three studies (2 quality A and 1 quality C) reported on quality-of-life outcomes. These studies found no difference in SF-12, Consumer Assessment of Healthcare Providers and Systems score, Anxiety score, or Euro QoL 5D score. The studies all found no difference in quality of life. • Six studies reported on medication adherence using a variety of different definitions of adherence, including both categorical and continuous outcomes (1 quality A, 2 quality B, 3 quality C). The studies had inconsistent findings, with half finding no difference in medication adherence and half finding greater adherence with SMBP plus additional support. Overall, there was weak evidence that medication adherence may be better among patients using SMBP monitoring. • One study found no difference in adverse drug reactions across three groups with different forms of additional support. • **Conclusion:** The evidence is weak or insufficient for these outcomes. Thus, overall the strength of evidence is low and fails to support a difference between SMBP plus additional support versus usual care for surrogate and intermediate outcomes.
Key Question 1: SMBP + Additional Support Versus Usual Care **Health Care Encounters**	Low (failing to support a difference)	• Eight of the 24 studies that compared SMBP plus additional support versus usual care reported number of health care encounters. All were graded quality C. • The studies were highly heterogeneous, primarily in the types of additional support used. Additional support included education, alerts, medication monitoring, self-titration, Web training, pharmacist counseling, medication management, and behavioral management. All reported on number of physician (or physician and nurse) visits. One study additionally reported on telephone and Web encounters. • Six studies found no difference in number of visits, 1 found fewer visits, and 1 found more visits with SMBP plus additional support compared to usual care. • One study found mixed results with respect to telephone and Web encounters. • **Conclusion:** Given the discordant findings as well as the low study quality, the strength of evidence is low and fails to support a difference between groups.

Table 2. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 2: SMBP + Additional Support Versus SMBP **Overall**	--	• Twelve studies compared SMBP plus additional support versus SMBP without additional support or with less intense additional support, of which 11 were RCTs and 1 was quasi-randomized. In total, 3,311 patients with hypertension were included. Two trials were graded quality A; 4, quality B; and 5, quality C; and 1 conference abstract was not graded. • The studies were highly heterogeneous, primarily in the types of additional support used. Additional support consisted of a mixture of behavioral interventions or disease management by a nurse or pharmacist, medication management, educational interventions, electronic transmission of BP measurements, Web sites/training for patient-provider communication, telemonitoring, BP recording cards or hypertension information leaflets, BP and medication tracking tool, and home visits. Change in medication management as a result of the monitoring could be initiated by patient, nurse, pharmacist, or primary care physician. Other sources of heterogeneity included the brands and types of SMBP monitors; followup duration (3-24 months, although mostly ≤12 months); baseline hypertension control (across studies, mean SBP/DBP: 126-179/70-103 mmHg); patient ages (across studies, mean 50-72 years. All patients were adults, most were male, and the most commonly cited comorbid condition was type 2 diabetes.
Key Question 2: SMBP + Additional Support Versus SMBP **Clinical Outcomes**	Insufficient	• No study reported clinical outcomes. • **Conclusion:** There is insufficient comparative study evidence regarding clinical outcomes in trials of SMBP versus usual care.

Table 2. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 2: SMBP + Additional Support Versus SMBP **Blood Pressure**	Low (failing to support a difference)	• All 12 studies that compared SMBP plus an additional support versus SMBP without the additional support or with less intense additional support reported BP outcomes. See the "Overall" summary above regarding the study heterogeneity. • Eight studies reported categorical changes in BP control, mostly defined as achieving a BP of <120-140/80-90 mmHg (sometimes with lower thresholds for patients with diabetes). Six trials showed no significant difference or were indeterminate for a difference in rates of achieving BP control. One trial of SMBP plus pharmacist counseling plus training in use of a patient Web portal vs. SMBP plus training in use of a patient Web portal found a significant effect favoring, more intensive additional support. Another trial comparing SMBP plus medication monitoring plus educational material versus SMBP plus educational material also found benefit for the more intense additional support • Ten studies reported continuous BP outcomes. Six trials found no significant difference. Four favored the more intense support in addition to SMBP, comparing pharmacist counseling plus training in use of a patient Web portal versus training in use of a patient Web portal, medication monitoring plus educational material versus educational material, medication monitoring plus educational material versus educational material, and telemonitoring versus SMBP alone. Two studies provided results beyond 12 months. These studies reported findings that were nonsignificant or of uncertain statistical significance. • Four trials reported subgroup analyses by control of BP at baseline (controlled or not controlled), degree of adherence (lower adherence), or race (white vs. predominantly African American). Two of these studies did not provide analyses for the comparisons of SMBP plus additional support versus SMBP without additional support or with another type of additional support, and two studies did not provide complete subgroup analysis data. • **Conclusion:** Overall the strength of evidence is low and fails to support a difference in BP effects between SMBP plus additional support versus SMBP with no additional support or with less intense additional support.

Table 2. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 2: SMBP + Additional Support Versus SMBP **Surrogate and Intermediate Outcomes (Not Blood Pressure)**	Low (failing to support a difference)	• Seven of the 12 studies that compared SMBP plus additional support versus SMBP without additional support reported surrogate and intermediate outcomes that were not BP. See the "Overall" summary above regarding the study heterogeneity. • Two trials reported on quality of life or anxiety (1 quality A, 1 quality B). The studies used SF-36, SF-12, and the State-Trait Anxiety Inventory, a mental health questionnaire. Both found no differences using any quality-of-life measure. • Five trials reported data on categorical and continuous medication number and dosage (2 quality A, 2 quality B, 1 quality C). Studies reported numbers of patients taking 2 or more classes of medications, medical inertia (defined as no medication change vs. either an increase or decrease in medications), and number of medication drug classes. Four trials using additional support consisting of nurse counseling, home visits for BP measurement, telemonitoring, or education found no difference between SMBP plus additional support and usual care. One trial found a somewhat greater mean number of medication drug classes with SMBP plus Web training plus pharmacist counseling. Weak evidence suggests no difference in medication use. • Three quality C trials reported on medication adherence. Using different measures in each study, none found a significant difference in medication adherence. One trial also found no difference in a subgroup of individuals with lower baseline adherence. • Two trials looked at miscellaneous outcomes. One quality C trial found no difference in adverse drug reactions across four groups with different forms of additional support or usual care. One quality A trial found no difference in consumer satisfaction measured with the Consumer Assessment of Healthcare Providers and Systems instrument. • **Conclusion:** The evidence is weak due to inconsistency across studies or poor-quality studies, or it is insufficient. Thus, overall the strength of evidence is low and fails to support a difference between SMBP plus additional support versus SMBP without additional support or with less intense additional support for surrogate and intermediate outcomes

Table 2. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)

Key Question	Strength of Evidence	Summary/Conclusions/Comments
Key Question 2: SMBP + Additional Support Versus SMBP **Health Care Encounters**	Low (failing to support a difference)	• Five of the 12 studies that compared SMBP plus an additional support versus SMBP without the additional support reported number of health care encounters. All were quality C. See the "Overall" summary above regarding the study heterogeneity. • All reported on outpatient primary care visits, 2 reported on hospital admissions or inpatient or urgent care/emergency use, and 3 reported on cardiac and other specialist visits. • None found a difference in the numbers of outpatient visits or hospital admissions between patients receiving SMBP with or without additional support. • One study found more electronic and telephonic communication with SMPB plus pharmacist counseling plus training in use of a patient Web portal compared to SMBP plus training in use of a patient Web portal. • **Conclusion:** Despite the consistency across trials, because of their small number and poor quality, overall the strength of evidence is low and fails to support a difference in number of health care encounters when using additional support with SMBP compared to SMBP without additional support or with less intense additional support.
Key Question 3: Different SMBP Devices	Insufficient	• No eligible study provided data to address this question. • **Conclusion:** There is insufficient comparative study evidence regarding the comparison of different SMBP devices.
Key Question 4: Blood Pressure Control Relationship With Clinical and Surrogate Outcomes	Insufficient	• No eligible study provided data to address this question. • **Conclusion:** There is insufficient comparative study evidence regarding the relationship of BP control with SMBP and clinical and surrogate outcomes.
Key Question 5: Predictors of SMBP **Adherence**	Insufficient	• One quality B study addressed how adherence to SMBP monitoring varies by patient factors. The study included 377 middle-aged Korean Americans using SMBP with telephonic transmission of BP measurements, hypertension education, and telephone counseling by a nurse. Adherence was defined as transmitting a minimum of 12 readings per week for at least 24 weeks of the 48-week study. • Age ≥60 years was significantly associated with better adherence with SMBP, and greater depression (measured on a scale specific to Korean Americans) was significantly associated with worse adherence. Other factors explored for their relationship to adherence that did not show significant influences were marital status, education, work status, medication, duration of hypertension, comorbidity, family history of hypertension, body mass index, and knowledge and awareness regarding hypertension. • **Conclusion:** There is insufficient evidence regarding predictors of SMBP adherence.

BP = blood pressure; DBP = diastolic blood pressure; Euro QoL 5D = Euro QoL Group 5-Dimension Self Report Questionnaire; RCT = randomized controlled trial; SBP = systolic blood pressure; SF-12/36 = Short Form-12/36 Health Survey; SMBP = self-measured blood pressure (monitoring)

Discussion

General Discussion

Self-measured blood pressure (SMBP) has been used in the treatment of hypertension with three major aims: (1) to avoid undertreatment of hypertension by allowing shorter cycles of BP measurement and treatment adjustment than are possible with clinic BP measurements alone; (2) to enhance self-participation in disease management and to enhance patients' adherence with lifestyle interventions and medication treatment; and (3) to avoid overtreatment in those with lower BP out of the clinic compared with in the clinic. This review identified 48 comparative studies that examined the impact of SMBP with or without additional support in the management of hypertension (plus one study on predictors of SMBP adherence). Overall, the benefit of SMBP for BP reduction appears to be modest, but this is not consistent across studies. We examined the role of additional support in combination with SMBP by setting up comparisons as: (1) SMBP alone versus usual care; (2) SMBP with additional support versus usual care; and (3) SMBP plus additional support versus SMBP with no additional support or a less intense additional support (Figure 1). Across studies, however, there was a very large degree of clinical heterogeneity in SMBP monitoring protocols, as well as a lack of consistency in the way SMBP monitoring was implemented and used by patients and in the types of additional support either provided to or expected from the patients. No two studies used the same additional support, and even the studies that used SMBP without additional support varied in their methods. This great heterogeneity limits the conclusions that can be drawn from this systematic review.

Summary of Findings for Key Questions 1 and 2

Twenty-four trials compared SMBP alone versus usual care. Meta-analysis showed a statistically significant reduction in clinic SBP and DBP (SBP/DBP -3.1/-2.0 mmHg) at 6 months, but not at 12 months. Only one RCT reported followup beyond 12 months; findings indicated significant reductions in SBP and DBP at 24 months in favor of SMBP.

The comparison of SMBP plus additional support versus usual care was examined in 24 studies with 11 of 21 randomized trials and 2 of 3 nonrandomized studies reporting a statistically significant benefit in BP reduction favoring SMBP plus additional support. Four studies provided results after 12 months. The only quality A trial found no difference between groups at 18 months followup; the other three trials reported statistically significant mean net BP reductions for followup periods of 18 to 60 months

We found 12 trials of SMBP plus additional support (or more intensive additional support) versus SMBP without additional (or with less intensive additional support). Only four of these trials reported a significantly greater reduction in BP in the SMBP plus additional (or more intensive) support groups. Two studies provided results beyond 12 months. These studies reported findings that were nonsignificant or of uncertain statistical significance.

To answer the question regarding the role of additional support in combination with SMBP, we attempted to look across the three comparisons of SMBP alone versus usual care, SMBP plus additional support versus usual care, and SMBP plus additional support versus SMBP without additional support or with less intensive additional support. While it should be noted that evidence from indirect comparisons is much inferior to evidence from direct comparisons within trials, the evidence appears to suggest that additional support is synergistic with SMBP to achieve BP control. However, the heterogeneity of additional support with regards to the primary

intents, ancillary equipments, educational materials, followup personnel, and algorithms for medication adjustments make it impossible to draw conclusions regarding the potential effects of specific modalities or particular components of additional support or their interactions with SMBP. Further, subgroup analyses in the trials were too few in number for each potential effect modifier, such as sex, race, comorbid disease, socioeconomic status, blood pressure control or compliance at baseline, to allow detection of consistent signals for subgroups that might preferentially benefit.

The observed reduction in BP with SMBP was statistically significant at 6 months but clinically only of small to modest size. Nevertheless, this may reflect a clinically relevant effect on a population level. Observational data suggest that each increase of 20 mmHg SBP or 10 mmHg DBP is associated with a 50 to 100 percent increase in mortality from cardiovascular disease, depending on age.95 In those 60 to 69 years of age, a 10 mmHg lower systolic BP is associated with about one-fifth lower risk of a coronary heart disease event.96 On the other hand, the BP reduction achieved with SMBP is modest compared to the reduction in blood pressure estimated to occur with other lifestyle interventions.[1] However, effective lifestyle interventions must be high frequency and intensive and therefore may not feasible in many clinical practice settings. In comparison, SBPM may be a simpler intervention to introduce in the clinical setting.

Results on clinical outcomes for all comparisons were sparse or absent. A small number of studies reported quality of life or mental health outcomes but were inconclusive regarding the effect of SMBP. Other surrogate and intermediate outcomes and outcomes related to health care encounters were also inconsistently studied and reported across studies, further limiting the conclusions that can be drawn. For the comparisons of SMBP versus control and SMBP plus additional support versus control, there was weak evidence that medication adherence may be better among patients using SMBP monitoring. For the comparison of SMBP plus additional support versus SMBP alone or with another type of additional support, the evidence was weak and failed to show a difference

Clinical Heterogeneity

Despite the ostensible similarity in research questions across studies, great clinical heterogeneity across the examined publications limits the conclusions that can be drawn. There was a large degree of variability in SMBP monitoring protocols and implementation, use of and response to BP data, and the types of additional support, either provided to or expected from patients. We grouped the additional support interventions into categories based predominantly on education, counseling, Web support, or other support. However, the types of additional support were too heterogeneous and overlapping to be neatly categorized. Further, no two studies used the exact same mode of additional support, and even the studies that used SMBP without additional support varied in their methods.

Studies employed a variety of SMBP monitors, for example. Older studies used manual devices, while more recent studies used semiautomated or automated machines. Protocols for self-measurement varied in frequency and timing of measurements. Further, studies varied regarding how many serial measurements were taken on each occasion, and which measurements were chosen or averaged. The methods of recording and transmitting BP readings were similarly diverse, including ad hoc or structured self-recording into fixed forms; automatic storage of readings; presentation of the readings to the physician, a nurse, or a research coordinator; manual or automatic transmission of readings via telephone or Web site; and other variations. The response to the BP reading also varied with respect to the responder, the timing of treatment

regimen changes, and how such changes were implemented. Responders could be the patients' regular providers, study clinicians, nurses, pharmacists, or the patients themselves. Responses in drug management were based either on SMBP results, or clinic BP results, and the actual response could entail counseling on lifestyle modification, general encouragement and support, advice on medication adherence, or changes in medication number, type, and dose. Medication changes could either be prescribed by standardized algorithms, or be deferred to the clinical provider's discretion. Further, even the "usual care" groups varied across studies, ranging from true usual care to study-standardized "usual care" to enhanced care including education or consistent followup.

Given the potential interaction between SMBP, additional support, and the clinical heterogeneity detailed above, it was not possible to confidently sort out which particular feature of SMBP or additional support could provide the greatest impact on reducing BP.

Summary of Findings for Key Questions 3, 4, and 5

No study comparing different SMBP devices (particularly automated, semiautomated or manual devices) was identified to answer Key Question 3. Automated electronic oscillometric devices are presently the devices most widely used for SMBP monitoring; manual or semi-automated devices were only used in a few older studies.

None of the comparative studies reviewed addressed Key Question 4 by examining the relationship between achieving BP control and clinical or surrogate outcomes.

The data on predictors of adherence with SMBP were scant. One study in a special population of Korean Americans showed older age was independently associated with greater adherence to SMBP monitoring, and that a greater degree of depression was independently associated with lower adherence. Since SMBP is a tool for patient participation, it is likely that its adoption by a patient is affected by a patient's attitudes and preferences for self-participation in disease management. We found no study exploring patients' self-reported attitudes towards participation in disease management and how this would impact SMBP adherence.

Limitations

As discussed above, the present systematic review is subject to several important limitations. Given the clinical heterogeneity stemming from the variation in the populations, interventions, and outcomes examined, only one or two studies were often available for specific comparisons. Many studies were rated as quality C and likely underpowered, even for BP outcomes. There were no studies in children. Duration of followup was limited and in most instances less than 12 months. Data on clinical event outcomes were lacking.

There are multiple possible reasons possible for why these studies generally found no significant effects and/or relatively small effect sizes. Existing trials did not evaluate patients regarding their pattern of home and clinic BPs prior to inclusion. Each study may have included varying proportions of individuals with uncontrolled hypertension, white coat hypertension, or masked hypertension. Depending on the particular home and clinic BP abnormalities in a specific patient, and whether BP management was guided by home or clinic BP in a trial, SMBP may have resulted in opposing effects on medication management and clinic BP within and across trials. Staessen 2004 and Verberk 2003 have both shown that adjusting BP medication to achieve the same BP target measured either by SMBP or by clinic BP will lead to less medication but higher clinic BP in the groups managed with SMBP.[20,32,84] Consequently, SMBP may lead to (1) an intensified drug treatment in the patients with elevated clinic and home BP,

thus lowering their clinic and home BP or (2) a reduction in medication in the patients with elevated clinic but normal or low home BP, thus (appropriately) raising their clinic and home BP.

Overall, such opposing medication titrations resulting from inclusion of patients with different clinic and home BP patterns and from different BP management protocols may cancel out effects on BP within and across trials. Thus the actual difference in BP may not fully reflect the potential benefit from SMBP in patients with more homogeneous BP abnormalities, such as in cases of either uncontrolled or refractory hypertension, or in patients with white coat hypertension (patients with typically normal BP whose BP rises to the abnormal range in the clinic, possibly due to anxiety). Further, given the short-term biological variability of BP within a patient and random measurement error, SMBP allows potentially for repeated measurements that provides greater certainty in the assessment of BP level.[97]

Medication adherence is an important intermediate outcome for primary care providers. It stands to reason that adherence to SMBP is a necessary intermediate outcome in deriving any benefit from SMBP, and that nonadherence to SMBP schedules is a key limitation in the successful application of this intervention in hypertension management. However, adherence itself has not been defined in a consistent fashion, and studies examining predictors of adherence were sparse, precluding any in-depth analysis.

Though it was of interest to this report to address how the particular type of BP device impacted BP control, no study comparing different SMBP devices was identified. Most studies used automated SMBP devices, although a number of these digital BP devices have yet to undergo rigorous independent validation.[98] Nevertheless, these devices are not associated with observer bias or terminal digit preference and can be used with minimal training by most patients, even those with physical limitations. Given the widespread adoption of automatic devices, we are unlikely to get more data on manual versus automated devices, despite the difference in cost and the dilemma this presents for policymakers.

Applicability

Reviewed studies were all conducted in an outpatient setting, mostly in Western Europe and North America. They included only adults with uncontrolled hypertension or on antihypertensive medication, with various eligibility criteria for BP at entry. Patients had to be willing and able to participate in SMBP. In two studies, the home BP monitoring could be conducted by a companion of the patient, usually a family member. Some studies required the patient to have a phone or computer with Web access. The prevalence of comorbid conditions was not consistently reported. Some studies specifically stated exclusion of individuals with active acute illness or recent hospital admissions. Minorities were underrepresented, although a few studies focused on African Americans. These eligibility criteria likely selected groups of patients with lesser severities of illness, better functional and cognitive status, higher socio-economic status, and better family support, thus limiting applicability to the general population of adults under treatment for hypertension.

A few studies reported the effect of various patient characteristics on BP outcomes. These included control of baseline BP, degree of adherence, socioeconomic status, and race. These subgroup analyses were limited by the small number of analyses per subgroup characteristic, and incomplete reporting for all subgroups or statistical analyses. Thus, no overall conclusion could be drawn on the effect of patient characteristics on BP outcomes.

Evidence from studies using manual devices and self-recording of BP on paper may become less and less applicable in the modern era. SMBP in conjunction with modern avenues for provider-patient communication has the potential to impact effectiveness and resource utilization. Telemedicine and Web-based tools have expanded the possibilities for patient-provider interactions to support 'self-titration' of BP medication,[70] and SMBP plus telemedicine may shift encounters from conventional in-person clinic visits to virtual on-demand encounters that may more flexibly accommodate patient preferences regarding timing of interaction and intensity. SMBP as a component of telemedicine constitutes a major change in delivery of care for individuals with hypertension, and requires rigorous evaluation regarding feasibility, patient and provider preferences, logistical and infrastructural demands, and ethical considerations. The impact of reimbursement structures, in particular fee-for-service versus capitated systems, needs to be evaluated for such a potential shift.[99]

Context of Findings

Our findings are consistent with four recently published systematic reviews examining the effect of SMBP identified in our search.[100-103] Agarwal 2011 examined 37 trials, Bray 2010 examined 25 trials, Cappuccio 2004 examined 18 trials, and Glynn 2010 examined 14 trials.

In contrast to our review, these reviews did not require a minimum duration of followup of 2 months, and two also included studies in chronic hemodialysis patients; however, all excluded nonrandomized studies, which we allowed. All four reviews also found a modestly significant effect of SMBP on BP reduction, with net differences ranging from -2.5 to -4.2 mmHg for SBP and -1.4 to -2.4 mmHg for DBP. Agarwal 2011 also specifically studied the effect of SMBP on therapeutic inertia, defined as unchanged medication despite elevated BP, and reported less therapeutic inertia (greater number of medication changes) with SMBP compared to control. However, it is unclear how the definition of therapeutic inertia was standardized across studies for the purpose of meta-analysis.

Current clinical practice guidelines recommend the use of SMBP as an adjunct modality in the long-term clinical management of hypertension to supplement the readings obtained in the clinic setting.1 The American Heart Association (AHA) recommends SMBP for the majority of hypertensive patients in order to assess response to treatment and possibly improve adherence, as well as for some patients with prehypertension for the purpose of detecting masked hypertension. Of note, our review did not evaluate SMBP as a diagnostic tool. The AHA also mentions that SMBP may be of increased value in certain populations, such as diabetic patients, who require tight BP control.[104]

Ongoing Research

A search in the ClinicalTrials.gov registry yielded 25 active (recently completed or ongoing) studies examining SMBP that are potentially relevant to the Key Questions in our report. No study entry provided results. One study was observational; the remaining 24 were interventional, of which 23 were RCTs. These studies are primarily examining the effects of various types of additional support along with SMBP versus control on BP control. The protocols of these studies are summarized in Table D-44 in **Appendix D**.

An ongoing trial in Japan, the HOMED-BP study, aims to determine an optimal target BP level on the basis of SMBP at home.[105,106] Patients are randomized to either a more intensive BP-lowering group (home SBP <125 mmHg and DBP <80 mmHg) or a less intensive group (home SBP in the range 134-125 and DBP 84-80 mmHg). Patients will be followed until approximately

2013. This trial is expected to inform the choice of the home BP target, although it does not appear that it will provide evidence as to the effect of SMBP monitoring, per se.

Future Research

On a population level, home BP is lower than clinic BP, but the exact relationship between home and clinic BP levels vary from person to person; thus the strategies to measure and control elevated BP may need to differ based on an individual's discrepancy between home and clinic BP. Individuals with elevated BP at home and in the clinic require more intense BP treatment, while those with elevated BP only in the clinic do not. Therefore, future research on SMBP ought to separate studies according to the primary study goal, either aimed at lowering BP in individuals with uncontrolled hypertension, or avoiding overtreatment in individuals with white coat hypertension. Studies should then evaluate patients according to their pattern of BP abnormality prior to study enrollment. Patients may be characterized as having uncontrolled hypertension, white coat hypertension, or masked hypertension.

In individuals with uncontrolled hypertension, future studies should examine the combined effects of SMBP with frequent cycles of drug titration based on home BP when BP is not yet controlled. Outcomes of interest are control of home and clinic BPs, and medication adherence. Populations of interest include individuals with newly diagnosed hypertension, individuals with hypertension "refractory" to treatment, or individuals with low adherence to medication. Subgroups of interest in studies are older persons and those with important clinical comorbidities, including cardiovascular and cerebrovascular disease, diabetes mellitus, and chronic kidney disease. Other subgroups of interest include racial and ethnic minorities, low SES groups and individuals receiving care in safety-net and non-academic settings. Further, the role of SMBP needs to be examined in children.

In individuals with white coat hypertension, future trials should examine the effects of SMBP and drug treatment based on home BP on the adequacy of home BP control and avoidance of over-treatment. Future studies in individuals with masked hypertension should examine the effect of self-management of home BP on the adequacy of home BP control.

Further there is a need to test SMBP as an adjunct to in-office BP management and use it for validation of clinical impression of BP control in willing patients.

Better standardization is needed regarding how patients use SMBP and the types of additional support that are employed. While we do not suggest that incremental improvements in how SMBP is deployed should cease, we have found that it is of limited value for every study to have a unique SMBP monitoring and additional support protocol. To reduce the heterogeneity of interventions, researchers should consider which already-investigated method of SMBP monitoring and additional support they believe is most promising, and implement that protocol. Similarly, retesting previously examined forms of additional support would be likely to advance the field more than introducing completely new protocols. Furthermore, the interpretability of future studies would be enhanced by the use of "usual care" protocols that most closely resemble the true usual care of the patients being studied as well as by pragmatic trials that would inform real world effectiveness.

Self-measuring BP can be burdensome over time. Future studies of SMBP should, therefore, also compare different monitoring schedules, with the goal of finding the least burdensome protocol. Studies can also evaluate the acceptance and effects of dynamic approaches that tailor measurement frequency to the degree of BP control, e.g., more frequent measurement when not at target and less frequent when in range.

A key question for this report was how different SMBP devices compare against each other, specifically automated, semi-automated, or a manual devices. While we could not identify any RCT with a head-to-head comparison of different devices, most recent studies used automated devices. Automated devices are widely available and require less dexterity on the part of the patient. If the question of cost difference between different types of devices is of interest, then future research on this question may be considered and should evaluate any tradeoffs between cost and user acceptance.

Other important areas for future research include examining the role of various measures for improving the accuracy of and adherence with SMBP, as well as improving the transmission of SMBP information for decisionmaking. Investigations should also be made into further use of telemedicine for patient-provider interaction regarding SMBP results and medication management.

Given the paucity of data for clinical event outcomes in this review, future studies should also examine the effects of SMBP on clinical events in addition to BP control. This will require followup durations greater than 1 year. A 5- to 10-year followup appears more appropriate for a chronic disease like hypertension to obtain more information on vascular outcomes and longer follow up on the effects on BP, adherence with SMBP and medication. In uncomplicated hypertension, it may be challenging to extend trial followup long enough to obtain precise effect estimates for objective clinical outcomes. Echocardiographic changes in left ventricular hypertrophy may be an appropriate vascular surrogate outcome. It should also be possible to nest studies comparing SMBP use versus no SMBP use in other cohort studies or link them to clinical outcome registries. If consistent clinical benefit can be established, the cost-effectiveness of SMBP monitoring should be evaluated by patient group and clinical setting.

Many clinicians consider self-monitoring of BP to be an educational tool to help patients become aware of their disease process, increase their commitment to BP normalization, recognize the importance of antihypertensive therapy, and increase adherence and persistence to BP lowering therapy. Therefore, another outcome of interest to be examined in future comparative studies of SMBP is patients' understanding of disease and how this correlates with adherence to antihypertensive medication and with BP control.

The effectiveness of SMBP may vary by patient characteristics or attitudes. Observational and experimental studies should, therefore, examine characteristics that are associated with adherence with SMBP. Data gathered should encompass demographic, psychosocial, educational, economic, and geographic factors, in addition to clinical variables. Candidate variables of interest include age, sex, race and ethnicity, socioeconomic status, and burden of disease comorbidity. Future research should also explore patient attitudes and values towards self-participation as factors that impact preference for SMBP. It may be possible to glean information on potential candidate variables from other instances of patient self-participation in chronic disease management, for example self-monitoring of blood sugar, self-measurement of anticoagulation, and self-management of asthma. Future studies may assess heterogeneity of treatment effects based on patient attitudes and preferences regarding SMBP.

Of particular importance for future SMBP research is the need to establish targets for home BP based on observational and RCT data. Observational studies should compare risk information from home BP, ambulatory BP measurement, and clinic BP levels. RCTs are needed to compare treatment to different home BP targets and their effect on clinical outcomes.

There is also a need to enhance the transparency of reporting of future research studies of SMBP. At a minimum, studies should consistently report complete information on the SMBP

device used (including brand name), type, and accreditation. If necessary, the authors should also comment on how devices used in a study are similar or different to those used in existing validation studies. Further standardization in reporting is needed for how many serial measurements were taken and which ones were used to respond to. Future studies of SMBP should report detail on prescribed and achieved frequency and timing of measurements, how results are recorded or transmitted, and who responds to results and how.

Conclusion

SMBP may confer a small benefit in blood pressure control, but the BP effect beyond 12 months and the attendant long-term clinical consequences remain unclear. Future research should standardize patient inclusion criteria, BP treatment targets for home BP, and SMBP and additional support protocols to maximize the interpretability and applicability of SMBP trials.

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Acronyms and Abbreviations

AHA	American Heart Association
AHRQ	Agency for Healthcare Research and Quality
BP	blood pressure
CER	comparative effectiveness review
CI	confidence interval
DBP	diastolic blood pressure
EPC	Evidence-based Practice Center
Euro QoL 5D	Euro Quality of Life Group 5-Dimension Self Report Questionnaire
FDA	Food and Drug Administration
JNC-7	Seventh Joint National Committee (guideline on hypertension)
NHANES	National Health and Nutrition Examination Surveys
OR	odds ratio
PICOD	populations, interventions, comparators, outcomes, and study designs
RCT	randomized controlled trial
RR	relative risk
SBP	systolic blood pressure
SE	standard error
SF-36 (or 12)	Short Form-36 (or 12) Health Survey
SMBP	self-measured blood pressure (monitoring)
TEP	Technical Expert Panel
TOO	Task Order Officer

Appendix A. Literature Search Strategy

Databases: Ovid MEDLINE, MEDLINE(R) In-Process, Cochrane Controlled Trials Register (CCTR) Last run 2/17/2010

#	Searches	
1	exp Blood Pressure Monitoring, Ambulatory/	SMBP
2	exp Blood Pressure Monitors/	
3	exp Blood Pressure/	
4	exp hypertension/	
5	exp Self Care/	
6	(3 or 4) and 5	
7	((blood pressure or hypertens$) and self and (measure$ or monitor$ or care or manage$)).mp.	
8	**1 or 2 or 6 or 7**	
9	randomized controlled trial.pt.	Comparative Studies (KQ 1-3)
10	controlled clinical trial.pt.	
11	randomized controlled trials/	
12	Random Allocation/	
13	Double-blind Method/	
14	Single-Blind Method/	
15	clinical trial.pt.	
16	Clinical Trials.mp. or exp Clinical Trials/	
17	(clinic$ adj25 trial$).tw.	
18	((singl$ or doubl$ or trebl$ or tripl$) adj (mask$ or blind$)).tw.	
19	Placebos/	
20	placebo$.tw.	
21	random$.tw.	
22	trial$.tw.	
23	(randomized control trial or clinical control trial).sd.	
24	(latin adj square).tw.	
25	Comparative Study.tw. or Comparative Study.pt.	
26	exp Evaluation studies/	
27	Follow-Up Studies/	
28	Prospective Studies/	
29	(control$ or prospectiv$ or volunteer$).tw.	
30	Cross-Over Studies/	
31	**or/9-30**	
32	exp cohort studies/ or exp prospective studies/ or exp retrospective studies/ or exp epidemiologic studies/ or exp case-control studies/	Cohorts (KQ 4)
33	(cohort or retrospective or prospective or longitudinal or observational or follow-up or followup or registry).af.	
34	case-control.af. or (case adj10 control).tw.	
35	ep.fs.	
36	**32 or 33 or 34 or 35**	
37	**8 and (31 or 36)**	Limits
38	limit 37 to humans [Limit not valid in CDSR,CCTR; records were retained]	
39	limit 38 to yr="1888 - 2000"	
40	remove duplicates from 39	
41	limit 37 to yr="2001-2008"	
42	remove duplicates from 41	
43	limit 37 to yr="2009-current"	
44	remove duplicates from 43	

#	Searches	
45	**or/40, 42, 44**	Final
46	(home adj20 blood pressure).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	Added Terms
47	or/9-45	
48	46 and 47	
49	(exp telemedicine/ or exp self-examination/) and (exp Blood pressure/ or exp Hypertension/)	
50	47 and 49	
51	**45 or 48 or 50**	

Appendix B. Excluded Studies

Studies are listed in alphabetical order by author. The reason for rejection for each study is indicated in italics below the corresponding reference.

Home monitoring aids in blood pressure control. *Johns Hopkins Medical Letter, Health After 50.* 2006;18:7.
Not a study

Abe K, Tsunoda K, Sato T. [Measurement and evaluation of home blood pressure monitoring with particular emphasis on evaluating anti-hypertensive effects using a home blood pressure distribution diagram]. [Japanese]. *Nippon Jinzo Gakkai Shi.* 2006;48:354-364.
Cohort without data on predictors of adherence

Aberg H, Tibblin G. Addition of non-pharmacological methods of treatment in patients on antihypertensive drugs: results of previous medication, laboratory tests and life quality. *Journal of Internal Medicine.* 1989;226:39-46.
SMBP not analyzed intervention

AbuDagga A, Resnick HE, Alwan M. Impact of blood pressure telemonitoring on hypertension outcomes: a literature review. [Review]. *Telemedicine Journal & E-Health.* 2010;16:830-838.
Systematic review (reference list reviewed)

Agarwal R. Home and ambulatory blood pressure monitoring in chronic kidney disease. [Review] [60 refs]. *Current Opinion in Nephrology & Hypertension.* 2009;18:507-512.
Not a study

Agarwal R, Andersen MJ. Prognostic importance of clinic and home blood pressure recordings in patients with chronic kidney disease. *Kidney International.* 2006;69:406-411.
Cohort without data on predictors of adherence

Alborzi P, Patel N, Agarwal R. Home blood pressures are of greater prognostic value than hemodialysis unit recordings. *Clinical Journal of The American Society of Nephrology: CJASN.* 2007;2:1228-1234.
Dialysis patients

Andersen AR, Nielsen PE. Home readings of blood pressure in hypertension. *Scandinavian Journal of Primary Health Care.* 1985;3:71-77.
<8 week of SMBP

Anderson CS, Huang Y, Wang JG et al. Intensive blood pressure reduction in acute cerebral haemorrhage trial (INTERACT): a randomised pilot trial. *Lancet Neurology.* 2008;7:391-399.
SMBP not analyzed intervention

Antonicelli R, Partemi M, Spazzafumo L, Amadio L, Paciaroni E. Blood pressure self-measurement in the elderly: differences between automatic and semi-automatic systems. *Journal of Human Hypertension.* 1995;9:229-231.
Accuracy/validation study

Antony I, Asmar R, Carette B, Demolis P, Vaisse B. [The REVEIL study: feasibility study of blood pressure self-monitoring. Preliminary results and patient opinions]. [French]. *Archives des Maladies du Coeur et des Vaisseaux.* 2001;94:897-900.
<8 week of SMBP

Aoki Y, Asayama K, Ohkubo T et al. Progress report on the HOMED-BP Study: hypertension objective treatment based on measurement by electrical devices of blood pressure study. *Clinical & Experimental Hypertension (New York).* 2004;26:119-127.
SMBP not analyzed intervention

Appel LJ, Stason WB. Ambulatory blood pressure monitoring and blood pressure self-measurement in the diagnosis and management of hypertension. [Review] [140 refs]. *Annals of Internal Medicine.* 1993;118:867-882.
Systematic review (reference list reviewed)

Arnesen E. Comparative study of the blood-pressur-lowering effect of combined therapy with chlorthalidone and metoprolol or alpha-methyldopa, judged by self-monitoring of blood pressure. *Current Therapeutic Research Clinical and Experimental.* 1978;24:899.
SMBP not analyzed intervention

Asayama K, Ohkubo T, Kikuya M et al. Use of 2003 European Society of Hypertension-European Society of Cardiology guidelines for predicting stroke using self-measured blood pressure at home: the Ohasama study. *European Heart Journal.* 2005;26:2026-2031.
Cohort without data on predictors of adherence

Asayama K, Ohkubo T, Kikuya M et al. Prediction of stroke by home "morning" versus "evening" blood pressure values: the Ohasama study. *Hypertension.* 2006;48:737-743.
Cohort without data on predictors of adherence

Asayama K, Ohkubo T, Sato A et al. Proposal of a risk-stratification system for the Japanese population based on blood pressure levels: the Ohasama study. *Hypertension Research - Clinical & Experimental.* 2008;31:1315-1322.
Diagnosis study

Ashida T. [Improvement in medication compliance by home blood pressure measurement]. [Review] [10 refs] [Japanese]. *Nippon Rinsho - Japanese Journal of Clinical Medicine.* 2006;64:29-32.
Not a study

Ashida T, Sugiyama T, Okuno S, Ebihara A, Fujii J. Relationship between home blood pressure measurement and medication compliance and name recognition of antihypertensive drugs. *Hypertension Research - Clinical & Experimental.* 2000;23:21-24.
Cross-sectional

Ashida T, Yokoyama S, Ebihara A, Sugiyama T, Fujii J. Profiles of patients who control the doses of their antihypertensive drugs by self-monitoring of home blood pressure. *Hypertension Research - Clinical & Experimental.* 2001;24:203-207.
Cross-sectional

Atallah A, Mourad JJ, Inamo J et al. [Self monitoring of blood pressure in Guadeloupe in 2005 results of the PRETRAHGUAD enquiry]. [French]. *Archives des Maladies du Coeur et des Vaisseaux.* 2006;99:1225-1229.
Cross-sectional

Aylett M, Marples G, Jones K. Home blood pressure monitoring: its effect on the management of hypertension in general practice. *British Journal of General Practice.* 1999;49:725-728.
Cohort without data on predictors of adherence

Bachmann LM, Steurer J, Holm D, Vetter W. To what extent can we trust home blood pressure measurement? A randomized, controlled trial. *Journal of Clinical Hypertension.* 2002;4:405-407.
<8 week of SMBP

Badskjaer J, Nielsen PE. Clinical experience using home readings in hypertensive subjects (indirect technique). *Acta Medica Scandinavica - Supplementum.* 1982;670:89-95.
Accuracy/validation study

Bayo Llibre J, Roca SC, Dalfo BA et al. [Effectiveness of self-monitoring of blood pressure in white coat hypertension diagnosis. Rationale and design]. [Spanish]. *Atencion Primaria.* 2005;35:208-212.
Diagnosis study

Bayo Llibre J, Roca SC, Dalfo BA, Verdu Rotellar JM, Martin-Baranera MM. [White-coat hypertension indicators diagnosed through self-measurement of blood pressure at home]. [Spanish]. *Atencion Primaria.* 2007;39:507-509.
Diagnosis study

Beitelshees AL, Gong Y, Bailey KR et al. Comparison of office, ambulatory, and home blood pressure antihypertensive response to atenolol and hydrochlorthiazide. *Journal of Clinical Hypertension.* 2010;12:14-21.
SMBP not analyzed intervention

Bobrie G, Chatellier G, Genes N et al. Cardiovascular prognosis of "masked hypertension" detected by blood pressure self-measurement in elderly treated hypertensive patients. *JAMA.* 2004;291:1342-1349.
Diagnosis study

Bobrie G, Postel-Vinay N, Delonca J, Corvol P, SETHI I. Self-measurement and self-titration in hypertension: a pilot telemedicine study. *American Journal of Hypertension.* 2007;20:1314-1320.
Cohort without data on predictors of adherence

Boreu QF, de Tuero GC, Rodriguez-Poncelas A et al. Proportion of isolated clinical hypertension in primary care settings. Comparison of target organ damage in patients with isolated clinical hypertension and patients with sustained arterial hypertension. *Blood Pressure.* 2007;16:354-361.
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Accuracy/validation study

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SMBP not analyzed intervention

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SMBP not analyzed intervention

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Not comparative, N<100

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SMBP not analyzed intervention

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Cohort without data on predictors of adherence

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Not comparative, N<100

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Diagnosis study

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SMBP not analyzed intervention

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SMBP not analyzed intervention

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Cohort without data on predictors of adherence

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Cohort without data on predictors of adherence

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Cohort without data on predictors of adherence

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Cross-sectional

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Abstract

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SMBP not analyzed intervention

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SMBP not analyzed intervention

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Cohort without data on predictors of adherence

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SMBP not analyzed intervention

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SMBP not analyzed intervention

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SMBP not analyzed intervention

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Not a comparative study

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Cohort without data on predictors of adherence

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Not comparative, N<100

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SMBP not analyzed intervention

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SMBP not analyzed intervention

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<8 week of SMBP

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Cohort without data on predictors of adherence

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Diagnosis study

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SMBP not analyzed intervention

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SMBP not analyzed intervention

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Cohort without data on predictors of adherence

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<8 week of SMBP

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Cohort without data on predictors of adherence

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Diagnosis study

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<8 week of SMBP

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Cross-sectional

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Study protocol

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Diagnosis study

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<8 week of SMBP

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Diagnosis study

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Diagnosis study

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Diagnosis study

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Cohort without data on predictors of adherence

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SMBP not analyzed intervention

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Cohort without data on predictors of adherence

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Not a study

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Not a study

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Not a study

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No outcomes or analyses of interest

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Diagnosis study

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Not comparative, N<100

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SMBP not analyzed intervention

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SMBP not analyzed intervention

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Not comparative, N<100

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SMBP not analyzed intervention

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SMBP not analyzed intervention

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<8 week of SMBP

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SMBP not analyzed intervention

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Not a study

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Accuracy/validation study

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SMBP not analyzed intervention

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Cohort without data on predictors of adherence

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No outcomes or analyses of interest

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Cohort without data on predictors of adherence

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Heart failure. SMBP used as part of telemonitoring

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Not a study

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Cohort without data on predictors of adherence

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Diagnosis study

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Not a study

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Diagnosis study

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Not a study

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Diagnosis study

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Not a study

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Not a study

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Accuracy/validation study

Stepien M, Stepien A, Matusewicz W. [Evaluation of self-measurement of blood pressure im ambulatory monitoring of hypertension therapy]. [Polish]. *Przeglad Lekarski.* 2002;59:756-758.
Accuracy/validation study

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Not a study

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Not a study

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Diagnosis study

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Diagnosis study

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<8 week of SMBP

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<8 week of SMBP

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Diagnosis study

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Study protocol

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SMBP not analyzed intervention

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SMBP not analyzed intervention

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<8 week of SMBP

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Cohort without data on predictors of adherence

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No outcomes or analyses of interest

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Cross-sectional

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Not a study

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No SMBP in intervention

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Accuracy/validation study

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Cross-sectional

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<8 week of SMBP

Torrisi G, Di MS, Spallina G, Campisi M, Leotta C, Malaguarnera M. A diary model for monitoring blood pressure in the elderly. *European Review for Medical & Pharmacological Sciences.* 1997;1:119-124.
SMBP not analyzed intervention

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SMBP not analyzed intervention

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Cross-sectional

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Study protocol

Vaisse B, Genes N, Vaur L et al. [The feasibility of at-home self-monitoring blood pressure in elderly hypertensive patients]. [French]. *Archives des Maladies du Coeur et des Vaisseaux.* 2000;93:963-967.
<8 week of SMBP

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Systematic review (reference list reviewed)

Verberk WJ, Thien T, Kroon AA et al. Prevalence and persistence of masked hypertension in treated hypertensive patients. *American Journal of Hypertension.* 2007;20:1258-1265.
Diagnosis study

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Wrist SMBP measurement

Viera AJ, Cohen LW, Mitchell CM, Sloane PD. Use of home blood pressure monitoring by hypertensive patients in primary care: survey of a practice-based research network cohort. *Journal of Clinical Hypertension.* 2008;10:280-286.
Cohort without data on predictors of adherence

Warren RE, Marshall T, Padfield PL, Chrubasik S. Variability of office, 24-hour ambulatory, and self-monitored blood pressure measurements. *British Journal of General Practice.* 2010;60:675-680.
Cohort study without adherence data

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Not a study

Weintraub A, Gregory D, Patel AR et al. A multicenter randomized controlled evaluation of automated home monitoring and telephonic disease management in patients recently hospitalized for congestive heart failure: the SPAN-CHF II trial. *Journal of Cardiac Failure.* 2010;16:285-292.
Heart failure. SMBP used as part of telemonitoring

Weiss JJ, Osorio G, Ryan E, Marcus SM, Fishbein DA. Prevalence and patient awareness of medical comorbidities in an urban AIDS clinic. *AIDS Patient Care & Stds.* 2010;24:39-48.
SMBP not analyzed intervention

Welin L, Svardsudd K, Tibblin G. Home blood pressure measurements--feasibility and results compared to office measurements. The study of men born in 1913. *Acta Medica Scandinavica.* 1982;211:275-279.
Accuracy/validation study

Wetzels GE, Nelemans PJ, Schouten JS et al. Electronic monitoring of adherence as a tool to improve blood pressure control. A randomized controlled trial. *American Journal of Hypertension.* 2007;20:119-125.
SMBP not analyzed intervention

White WB, Asmar R, Imai Y et al. Task force VI: Self-monitoring of the blood pressure. [Review] [67 refs]. *Blood Pressure Monitoring.* 1999;4:343-351.
Not a study

Xue F, Yao W, Lewin RJ. A randomised trial of a 5 week, manual based, self-management programme for hypertension delivered in a cardiac patient club in Shanghai. *BMC Cardiovascular Disorders.* 2008;8:10.
<8 week of SMBP

Yamasue K, Tochikubo O, Kono E, Maeda H. Self-monitoring of home blood pressure with estimation of daily salt intake using a new electrical device. *Journal of Human Hypertension.* 2006;20:593-598.
Cohort without data on predictors of adherence

Yan IR, Poon CC, Zhang YT. A protocol design for evaluation of wearable cuff-less blood pressure measuring devices. *Conf Proc IEEE Eng Med Biol Soc.* 2009;2009:7045-7047.
Accuracy/validation study

Yasui D, Asayama K, Ohkubo T et al. Stroke risk in treated hypertension based on home blood pressure: the Ohasama study. *American Journal of Hypertension.* 2010;23:508-514.
Cohort without data on predictors of adherence

Yavuz BB, Yavuz B, Tayfur O et al. White coat effect and its clinical implications in the elderly. *Clinical & Experimental Hypertension (New York).* 2009;31:306-315.
SMBP not analyzed intervention

Yen LL, Patrick WK, Chie WC. Comparison of relaxation techniques, routine blood pressure measurements, and self-learning packages in hypertension control. *Preventive Medicine.* 1996;25:339-345.
SMBP not analyzed intervention

Yin TT, Williams N, Burton C et al. Hypertension, fetal growth restriction and obstructive sleep apnoea in pregnancy. *European Journal of Obstetrics, Gynecology, & Reproductive Biology.* 2008;141:35-38.
SMBP not analyzed intervention

Yoshitomi Y, Nagakura C, Miyauchi A. Significance of mean blood pressure for blood pressure control. *International Heart Journal.* 2005;46:691-699.
Cohort without data on predictors of adherence

Zhuo S, Wen W, Li-Yuan M, Shu-Yu W, Yi-Xin W. Home blood pressure measurement in prehypertension and untreated hypertension: comparison with ambulatory blood pressure monitoring and office blood pressure. *Blood Pressure Monitoring.* 2009;14:245-250.
Accuracy/validation study

Zutz A, Ignaszewski A, Bates J, Lear SA. Utilization of the internet to deliver cardiac rehabilitation at a distance: a pilot study. *Telemedicine Journal & E-Health.* 2007;13:323-330.
SMBP not analyzed intervention

Appendix C. Data Extraction Forms

SMBP Data Extraction Form

Key Questions 1 &2

A. GENERAL INFORMATION

Author, Year				**Intervention 1**	
PMID*		**RefID**		**Intervention 2**	
Key Question(s)				**Intervention 3**	
Study Design †				**Control**	
Extractor					
Funding source				**Country**	

* or Cochrane number

Intervention: SMBP with upper arm BP monitor, other SMBP monitor except wrist monitors

Control: No SMBP monitoring, co interventions, other devices, usual care

† RCT; Quasi RCTs, NRCS, (prospective longitudinal studies N≥ 100 (≥10 for children) KQ5 alone)

Write "nd" (no data), or "–" (not applicable), when necessary. Please do not leave blank

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS:

Inclusion	Exclusion	Enrollment Years	Power calculation?(Y/N)	outcome	effect size	Min sample size

C. BASELINE CHARACTERISTICS:

	Group	N enrolled (analyzed)	Male, %	Children, %	Age, yrs	Race	Systolic BP*	Diastolic BP*	HTN %	BMI	
Tx											
Cx											
Total											
		CVD , % (specify)	**DM, %**	**Smoking status, % (define)**	**Hyperlipidemia, (define) %**	**Mental health status (define) ∞, %**	**Socioeconomic status**		**Other relevant Comorbidities, % (specify)**	**Setting*** **	**Is this special population? Y/N (Define)**
Tx											
Cx											
Total											
		Current antihypertensive medication data (category, name, dose, number)**					**Other (if necessary)**				
Tx											
Cx											
Total											

* Mean±SD. If median, SE, range, IQR, or other, specify these.

**Diuretics, ACE inhibitors, calcium channel blockers, Beta blockers, others

*** Hospital outpatient, Workplace, Community, Hospital outpt or general practice, not clear

∞ Depression, anxiety, substance abuse, alcohol abuse, other psychiatric disorders

Comments on Baseline Characteristics	

SMBP Data Extraction Form

Key Questions 1 &2

D. INTERVENTIONS

	Specific Intervention	Details of BP measurement frequency*:	How were the BP measurements recorded ‡	Describe the training and the intensity of any education received	Additional Detail or Comments
1					
2					
Control					

*Number of times of SMBP used per day or week (etc.)
‡ **e.g.** written down by patient in a diary, stored & transmitted electronically

D2: ADDITIONAL INTERVENTION

How was BP acted upon and by whom? *	Other Training†	Other Ancillary Intervention ‡	Comments

* **e.g.** Self titration of BP medication; Health care provider adjustment of BP
† **e.g.** Training for self-titration of medication (self-management)
‡ **e.g.** Nursing management, counseling, phone calls, reminders, etc.

E. DEVICE ACCREDITATION

Brand Name or Equivalent	Arm or Wrist*?	Type**	Any Accreditation, Y/N	BHS grade, A - D	AAMI grade, pass/fail	ESH grade, recommended, Not recommended, Questionable.	Details on accreditation

BHS = British HTN Society; AAMI = Association for the Advancement of Medical Instrumentation, ESH = European Society of Hypertension
* include wrist only if arm circumference ≥ 18 inches
**automated, semi automated, manual, other

F. CO-INTERVENTIONS FOR ALL GROUPS

Co-intervention all participants	Description

G. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

Outcome Category*	Specific Outcome	Time points measured‡	Definition of Outcome

***outcomes category:**

- **clinical:-** CVD or all cause mortality, CVD events (MI, new onset angina, stroke, TIA, peripheral vascular events or diagnosis), patient satisfaction, QOL,
- **adverse events** related to anti-HTN treatment; safety of treatment
- **surrogate:-** LVH (left ventricular hypertrophy), LVM (left ventricular mass), LVMI(left ventricular mass index);
- **Intermediate: -**number and dose of hypertension medication, number of medication changes, change in blood pressure, blood pressure control, adherence to prescribed medication, adherence to SMBP monitoring, health care process measures (visits or calls), measure of consumer acceptance, ease of use of device;

‡ At least 8 weeks follow up

SMBP Data Extraction Form

Key Questions 1 &2

H. RESULTS (dichotomized or categorical outcomes) **If a value is calculated by us (not reported), highlight yellow**

Leave an empty row between outcomes data

Author, Year PMID	Outcome		Intervention	Time point	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

I. RESULTS (continuous measures) **If a value is calculated by us (not reported), highlight yellow** **

Leave an empty row between outcomes data

Author, Year PMID	Outcome	Unit		Intervention	Time point	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE/CI*	Value	SD/SE/CI*	Value	SD/SE/CI*	P	Value	SD/SE/CI*	P
			Tx													
			Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.

** If data is presented graphically, please reference the appropriate figure,

J. RESULTS (other reporting)

Author, Year PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

K. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT

Intervention	% Dropout	How defined	Reasons

L.SUBGROUPS:

Subgroups	Outcome	Qualitative summary	Figure or Table # (or text location)

M. Adherence:

Adherence with SMBP prescription	

N. ADVERSE EVENTS (Major adverse events directly related to usage of SMBP)
If data are clearly presented in a Table, copy the Table and insert.

Author, Year UI	Adverse Event	Follow-up	Arm	n/N	Arm	n/N	Arm	n/N

Comments on Adverse events	

O. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n)	Clear Reporting with No Discrepancies (y/n)

	Were Eligibility Criteria Clear? (y/n)	Is there some reason to think that the groups being compared are different? (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)

Other Issues:	
Overall Study Quality (A, B, C)	
Reasons for downgrading overall study quality	
Lower quality for certain outcomes? If so specify outcome and grade and reasons for downgrading	

P. SPECIFIC COMMENTS CONCERNING THE STUDY (including applicability)

Comments

Q. ANY DATA ON FACTORS ASSOCIATED WITH ADHERENCE WITH SMBP MONITORING? Y/N

SMBP Data Extraction Form

Key Question 5

A. GENERAL INFORMATION

Author, Year				**Intervention 1**	
PMID*		**RefID**		**Intervention 2**	
Key Question(s)	KQ5			**Intervention 3**	
Study Design †				**Control**	
Extractor					
Funding source				**Country**	

* or Cochrane number

Intervention: SMBP with upper arm BP monitor, other SMBP monitor except wrist monitors
Control: No SMBP monitoring, co interventions, other devices, usual care

† prospective longitudinal studies N≥ 100 (≥10 for children)

Write "nd" (no data), or "–" (not applicable), when necessary. Please do not leave blank

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	Enrollment Years	Power calculation?(Y/N)	outcome	effect size	Min sample size

C. BASELINE CHARACTERISTICS:

	Group	N enrolled (analyzed)	Male, %	Children, %	Age, yrs	Race	Systolic BP*	Diastolic BP*	HTN %	BMI	
Tx											
Cx											
Total											
		CVD , % (specify)	**DM, %**	**Smoking status, % (define)**	**Hyperlipidemia, (define) %**	**Mental health status (define) ∞, %**	**Socioeconomic status**		**Other relevant Comorbidities, % (specify)**	**Setting*** **	**Is this special population? Y/N (Define)**
Tx											
Cx											
Total											
		Current antihypertensive medication data (category, name, dose, number)**					**Other (if necessary)**				
Tx											
Cx											
Total											

* Mean±SD. If median, SE, range, IQR, or other, specify these.
**Diuretics, ACE inhibitors, calcium channel blockers, Beta blockers, others
*** Hospital outpatient, Workplace, Community, Hospital outpt or general practice, not clear
∞ Depression, anxiety, substance abuse, alcohol abuse, other psychiatric disorders

Comments on Baseline Characteristics	

D. DEVICE ACCREDITATION

Brand Name or Equivalent	Arm or Wrist*?	Type**	Any Accreditation, Y/N	BHS grade, A - D	AAMI grade, pass/fail	ESH grade, recommended, Not recommended, Questionable.	Details on accreditation

BHS = British HTN Society; AAMI = Association for the Advancement of Medical Instrumentation, ESH = European Society of Hypertension
* include wrist only if arm circumference ≥ 18 inches
**automated, semi automated, manual, other

E. CO-INTERVENTIONS FOR ALL GROUPS

Co-intervention all participants	Description

F. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	
Multivariate	

G. PREDICTORS TESTED

	Predictor	Definition	Follow-up duration	Strata*	Tested in Univariate Analysis?	Tested in Multivariate Analysis?	Comment
1							
2							
3							
4							
5							
6							
	Criteria Used to Test Predictors in Multivariable Analysis						

*Continous; categorical strata

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

Outcome Category*	Specific Outcome	Time points measured‡	Definition of Outcome

***outcomes category:**

- adherence to SMBP monitoring,

‡ At least 8 weeks follow up

SMBP Data Extraction Form

Key Question 5

I. RESULTS (dichotomized or categorical outcomes) **If a value is calculated by us (not reported), highlight yellow**

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Baseline	Final				Metric*	Result	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:

* RR, OR, HR, RD

J. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	

K. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons

M.SUBGROUPS:

	Outcome	Qualitative summary	Figure or Table # (or text location)
Subgroup Results			

N. Adherence:

Adherence with SMBP prescription	

O. ADVERSE EVENTS (Major adverse events directly related to usage of SMBP)
If data are clearly presented in a Table, copy the Table and insert.

Author, Year UI	Adverse Event	Follow-up	Arm	n/N	Arm	n/N	Arm	n/N

Comments on Adverse events	

P. SPECIFIC COMMENTS CONCERNING THE STUDY (including applicability)

Comments

Appendix D. Additional Tables

Table D-1. Information on SMBP device accreditation

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Artinian 2001[40] 11343005	A&D UA 767PC	Arm	Automated	Yes	A SBP A DBP	Pass		*Provided by authors (For AAMI grade):* Elwood C. UA-767 validation study. Menlo Park CA): A&D Medical; 1996. *Found by EPC:* Verdeccia, P, Angeli, F, Poeta, F, REboldi, GP, Borgioni, C, Pittavini, L, and Porcellati, C. Validation of the A&D UA-774 (UA-767Plus) device for self-measurement of blood pressure. Blood Pressure Monitoring 2004, 9 (4): 225-229:	A&D UA-767PC is a derivative of UA-774 and UA-767 Plus. It has a BHS grade of A/A according to the BHS website.
Artinian 2007[41] 17846552	Omron HEM-737 Intellisense, (Omron Healthcare, Inc., Vernon Hills, IL)	Arm	Automated	Yes	B SBP B DBP	Pass		*Provided by authors:* Dabl Educational Trust. (2005). Device table: Upper arm devices for self-measurement of blood pressure. Retrieved January 3, 2005, from http://www.dableducational.com/sphygmomanometers.html	
Bailey 1999[42] 10100064	Omron HEM 706	Arm	nd	Yes	B SBP C DBP	Pass		*Found by EPC:* Foster C, McKinley S, Cruickshank JM, Coats AJS. Accuracy of the Omron HEM 706 portable monitor for home measurement of blood pressure. J Hum Hypertens 1994; 8:661 -664.	
Binstock 1988[43] 3415798	No data on monitor								
Bosworth 2009[44] 19920269	Omron HEM 773AC	Arm	Automated						No validation studies regarding Omron HEM 773AC could be found.

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
	Omron HEM 637	Wrist (if arm circumference >17 in and wrist <8.5 in)	Automated	Yes			Recommended	*Found by EPC:* Topouchian JA et al. Validation of two automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension: the Omron M6 (HEM-7001-E) and the Omron R7 (HEM 637-IT). Blood Press Monit 2006; 11(3): 165-71.	It is assumed that Omron HEM 637, used in the study, is the same model as Omron HEM 637-IT, for which a validation reference is provided.
Bosworth 2011[45] 21747013	A&D UA-767PC	Arm	Automated	Yes	A SBP A DBP	Pass		*Found by EPC:* *For AAMI grade:* Elwood C. UA-767 validation study. Menlo Park CA): A&D Medical; 1996. *For BHS grade:* Verdeccia, P, Angeli, F, Poeta, F, REboldi, GP, Borgioni, C, Pittavini, L, and Porcellati, C. Validation of the A&D UA-774 (UA-767Plus) device for self-measurement of blood pressure. Blood Pressure Monitoring 2004, 9 (4): 225-229:	A&D UA-767PC is a derivative of UA-774 and UA-767 Plus. It has a BHS grade of A/A according to the BHS website.

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Brennan 2010 [46] 20415618	Omron ComFit Cuff HEM-780	Arm	Automated	Yes	A SBP A DBP	Pass		*Found by EPC:* Coleman A, Steel S, Freeman P, de Greeff A, Shennan A. Validation of the Omron M7 (HEM-780-E) oscillometric blood pressure monitoring device according to the British Hypertension Society. Blood Pressure Monitoring 2008, 13:49-54	It is assumed that Omron HEM-780, used in the study, is the same model as HEM 780-E, for which a validation reference is provided.
	Omron with advance positioning sensor Model HED-637	Wrist (if arm circumference was too large for the arm cuff)	Automated	Yes			Recommended	*Found by EPC:* Topouchian JA et al. Validation of two automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension: the Omron M6 (HEM-7001-E) and the Omron R7 (HEM 637-IT). Blood Press Monit 2006; 11(3): 165-71.	The device used is reported to be Omron HED-637. Likely that there is a typo in the name and the device should have been Omron HEM-637. It is assumed that Omron HEM-637, is the same model as HEM 637-IT, for which a validation reference is provided.

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Broege 2001[47] 11518836	Omron HEM-702	Arm	Semi-automated	Yes	B SBP C DBP	Pass		*Provided by authors:* Foster C, McKinley S, Cruickshank JM, Coats AJS. Accuracy of the Omron HEM 706 portable monitor for home measurement of blood pressure. J Hum Hypertens 1994; 8:661 -664.	While the device used in the study is Omron HEM-702, the device for which the authors provide a reference is Omron HEM 706. It is assumed that Omron HEM-702, is the same model as HEM 706, for which a validation reference is provided.
Carnahan 1975[48] 1130437	No data on monitor								
Carraso 2008[49] 19000959	Omron M4-I	Arm	Automated	Yes	A SBP A DBP	Pass		*Found by EPC:* Declaration of Blood Pressure Measuring Device Equivalence 2006 from the dabl®Educational Trust stating that there are no differences that will affect blood pressure measuring accuracy between the Omron M4-I and Omron 705IT, which has previously been validated.	
Cheltsova 2010[50]	No data on monitor								abstract

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Dalfo i Baque 2005[51] 15802109	Omron HEM-705CP	Arm	Automated	Yes	B SBP A DBP	Pass		*Found by EPC:* O'Brien E, Waeber B, Parati G, Staessen J, Myers MG, for the European Society of Hypertension Working Group on Ambulatory Blood Pressure Monitoring. Blood pressure measuring devices: recommendations of the European Society of Hypertension. BMJ.2001;322:531-536.	
Dawes 2010[52] 20631056	30 different models (14 manufacturers) of home BP monitor were used. The commonest three were: Omron HEM 711, LifeSource UA-767-PAC and Omron HEM 773.	Arm	Automated	Yes	HEM 711: B SBP A DBP LifeSource UA-767-PAC: A SBP A DBP (see comment) Omron HEM 773: nd	HEM 711: Pass LifeSource UA-767-PAC: Nd Omron HEM 773: nd		*Provided by EPC:* HEM 711: Artigao LM, Llavador JJ, Puras A, López Abril J, Rubio MM, Torres C, Vidal A, Sanchis C, Divisón JA, Naharro F, Caldevilla D, Fuentes G. Evaluation and validation of Omron Hem 705 CP and Hem 706/711 monitors for self-measurement of blood pressure. Aten Primeria 2000; 25(2):96-102. Life Source UA-767 Plus: Verdecchia P, Angeli F, Poeta F, Reboldi GP, Borgioni C, Pittavini L, Porcellati C. Validation of the A&D UA774 (UA-767Plus) device for self measurement of blood pressure. Blood Press Monit 2004;9:225-229.	UA-767-PAC is the same model as Life Source UA-767 Plus.
DeJesus 2009[53] 19756162	Life Source UA-767 Plus	Arm	Automated	Yes	A SBP A DBP			*Found by EPC:* Verdecchia P, Angeli F, Poeta F, Reboldi GP, Borgioni C, Pittavini L, Porcellati C. Validation of the A&D UA774 (UA-767Plus) device for self measurement of blood pressure. Blood Press Monit 2004;9:225-229.	Life Source UA-767 Plus and A&D UA-767 Plus is the same device. A&D Medical manufactures LifeSource blood pressure monitors.

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Earle 2010[54] 20597833	UA-767BT, A&DMedical, San Jose, CA	Arm	Automated	Yes (see comment)	A SBP A DBP			*Found by EPC:* Verdecchia P, Angeli F, Poeta F, Reboldi GP, Borgioni C, Pittavini L, Porcellati C. Validation of the A&D UA774 (UA-767Plus) device for self measurement of blood pressure. Blood Press Monit 2004;9:225-229.	According to manufacturer's website, UA-767BT is a derivative of UA-767 Plus with an extra BluetoothR wireless feature. Hence, it is validated as UA-767 Plus.
Earp 1982[55] 7114339	No data on monitor								
Fitzgerald 1985[56] 4044205	nd	Arm	Manual						Validation for manual instruments was not verified.
Friedman 1996[57]	Omron (no further data)	Arm (implied)	Automated						Insufficient information about device to check for validation
Fuchs 2010[58]	No data on monitor								abstract
Godwin 2010[59] 20032170	A&D UA-767	Arm	Automated	Yes	A SBP A DBP	Pass		*Found by EPC:* Rogoza AN Rogoza AN, Pavlova TS, Sergeeva MV. Validation of A&D UA-767 device for the self-measurement of blood pressure. Blood Press Monit. 2000;5(4):227-31.	
Gran 1991[60] 1891656	Ortho Konsult Tensomat	Arm	nd						Insufficient information about device to check for validation

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Green 2008[61] 18577730	Omron HEM-705CP	Arm	Automated	Yes	B SBP A DBP	Pass		*Provided by authors*: O'Brien E, Waeber B, Parati G, Staessen J, Myers MG, for the European Society of Hypertension Working Group on Ambulatory Blood Pressure Monitoring. Blood pressure measuring devices: recommendations of the European Society of Hypertension. BMJ.2001;322:531-536.	
Halme 2005[62] 16280273	Omron M4	Arm	Automated	Yes	A SBP A DBP	Pass		*Found by EPC:* O'Brien E, Waeber B, Parati G, Staessen J, Myers MG, for the European Society of Hypertension Working Group on Ambulatory Blood Pressure Monitoring. Blood pressure measuring devices: recommendations of the European Society of Hypertension. BMJ.2001;322:531-536.	
Haynes 1976[63] 73694	Nelkin sphygmomanometer 204M and separate stethoscope	Arm	Manual						Validation for manual instruments was not verified.
Johnson 1978[64] 369673	Taylor Sybron Corporation (no further data)	Arm (implied)	nd	nd					Insufficient information about device to check for validation

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Kabutoya 2009[65] 19695029	Omron HEM-737 IntelliSense	Arm	Automated	Yes	B SBP B DBP	Pass		*Provided by authors (For AAMI grade):* Anwar YA, Giacco S, McCabe EJ, et al. Evaluation of the efficacy of the Omron HEM-737 IntelliSense device for use on adults according to the recommendations of the association for the advancement of medical instrumentation. Blood Press Monit. 1998;3:261–265. *Found by EPC* (For BHS grade): O'Brien E, Waeber B, Parati G, Staessen J, Myers MG, for the European Society of Hypertension Working Group on Ambulatory Blood Pressure Monitoring. Blood pressure measuring devices: recommendations of the European Society of Hypertension. BMJ.2001;322:531-536.	-
Kim 2010[66] 20433546	No data on monitor								
Madsen 2008[67] 18568696	Omron 705 IT	Arm	Automated	Yes	A SBP A DBP	Pass		*Provided by authors*: El Assaad MA, Topouchian JA, Asmar RG. Evaluation of two devices for self measurement of blood pressure according to the international protocol: The Omron M5-I and the Omron 705IT. Blood press Monit. 2001;8(3):127-33	According to study, Omron 705 IT is described as semiautomatic. However, manufacturer classifies Omron 705 IT as automated.

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Marquez-Contreras 2006[68] 16331115	Omron M4	Arm	Automated	Yes	A SBP A DBP	Pass		*Found by EPC:* O'Brien E, Waeber B, Parati G, Staessen J, Myers MG, for the European Society of Hypertension Working Group on Ambulatory Blood Pressure Monitoring. Blood pressure measuring devices: recommendations of the European Society of Hypertension. BMJ.2001;322:531-536.	
Marquez-Contreras 2009[69] 19482378	Omron (no further data)	Arm	nd	nd					Insufficient information about device to check for validation
McManus 20010[70] 20619448	Omron 705 IT	Arm	Automated	Yes	A SBP A DBP	Pass		*Provided by authors*: Coleman A, Freeman P, Steel S, Shennan A. Validation of the Omron 705IT HEM-759-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol. Blood Press Monit 2006; 11: 27–32	
Mehos 2000[71] 11079287	UA-702	Arm	Manual					*Provided by authors:* Anonymous. Blood pressure monitors: convenience doesn't equal accuracy. Consumer Report 1996;61:50, 53-5	Validation for manual instruments was not verified.
Midanik 1991[72] 1899945	Tycos Self Check Model 7052-08	Arm	Automated	Yes (informal)				*Provided by authors:* Unpublished data by J. Terdiman and L. Hurley, of the Division of Research, Kaiser Permanente Medical Care Program, Oakland, CA	
Muhlhauser 1993[73] 8467308	No data on monitor								

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Neumann 2011[74] 21228822	Stabil-O-Graph, Ltd, Corporation, I.E.M. GmbH, Stollberg Germany	Arm	Automated	Yes	A SBP A DBP	Pass	Nd	*Found by EPC:* Ten Oever G, Cortez-Campeao, Bour, J. Validation of Stabil-O-Graph® device for self-measurement of blood pressure according to the British Hypertension Society (BHS) standards and protocols. APC Cardiovascular Ltd. 2011. 11 Aug. 2011. <http://www.apccardiovascular.co.uk/nl/pdf/16-2.pdf>	
Parati 2009[75] 19145785	Tenisiomed Tensiophone	Arm	Automated	Yes	A SBP A DBP	Pass		*Provided by authors:* Nemeth Z, Moczar K, Deak G. Evaluation of the Tensioday ambulatory blood pressure monitor according to the protocols of the British Hypertension Society and the Association for the Advancement of Medical Instrumentation. Blood Press Manit 2002; 7:191-197.	
Park 2009[76] 19643661	No data on monitor								
Pierce 1984[77] 6377291	ND (device by Merck Sharpe & Dohme)	Arm	nd	nd					Insufficient information about device to check for validation

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Rinfret 2009[78] 20031834	Omron HEM-711AC	Arm	Automated	Yes (see comment)	B SBP A DBP	Pass		*Provided by EPC:* Artigao LM, Llavador JJ, Puras A, López Abril J, Rubio MM, Torres C, Vidal A, Sanchis C, Divisón JA, Naharro F, Caldevilla D, Fuentes G. Evaluation and validation of Omron Hem 705 CP and Hem 706/711 monitors for self-measurement of blood pressure. Aten Primeria 2000; 25(2):96-102.	It is assumed that Omron HEM-711AC, used in the study is the same model as Omron HEM 711, for which a validation reference is provided.
Rogers 2001[79] 11388815	Welch Allyn, Inc. Model 52500	Arm	Automated	Yes (see comment)	A SBP A DBP	Pass		*Provided by authors:* Rogoza AN, Pavlova TS, Sergeeva MV. Validation of A&D UA-767 device for the self-measurement of blood pressure. Blood Press Monit. 2000;5:227-31.	While the device used in the study is Welch Allyn Inc Model 52500, the device for which the authors provide a reference is A&D UA-767. It is assumed that Welch Allyn Inc Model 52500 is the same model as A&D UA-767, for which a validation reference is provided.

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Rudd, 2004[80] 15485755	UA 751; A&D	Arm	Semi-Automated	Yes (see comment)		Unclear (see comment)		*Provided by authors:* Jamieson MJ, Webster J, Witte K, Huggins MM, MacDonald TM, de Beaux A, Petrie JC: An evaluation of the A&D UA-751 semi automated cuff-oscillometric sphygmomanometer. J Hypertens 1990;8: 377–381.	The validation study reports that "there was an acceptable level of agreement between the results, according to the criteria suggested by the Association for the Advancement of Medical Instrumentation (range of differences systolic: mean - 0.9 to 1.4 mmHg, s.d. 4.6-9.8 mmHg; diastolic: mean - 0.6 to 1.3 mmHg, s.d. 2.9-5.1 mmHg), although there were sizeable discrepancies in individual subjects." However, the SD cut point of 9.8 mmHg is above the criterion for fulfilling the AAMI protocol.

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Sawicki 1995[81] 8557972	nd	Arm	nd					*Provided by authors:* Muhlhauser I , Sawicki PT, Didjurgeit U, Jorgens V, Berger M. Uncontrolled hypertension in type 1 diabetes: assessment of patients' desires about treatment and improvement of blood pressure control by a structured treatment and teaching programme. Diabet Med 1988, 5:693-698.	Insufficient information about device to check for validation
Shea 2006[82] 16221935	UA-767	Arm	Automated	Yes	A SBP A DBP	Pass		*Found by EPC:* Rogoza AN, Pavlova, TS, Sergeeva, MV. Validation of A&D UA-767 device for the self-measurement of blood pressure. Blood Press Monit. 2000;5(4):227-31.	
Soghikian 1992[83] 1518317	Tycos Self Check Model 7052-08	Arm	Automated	Yes (informal)				*Found by EPC:* Same device as in Midanik, LT et al. Home Blood Pressure Monitoring for Mild Hypertensives. Public Health Reports. 1991 Jan-Feb 106(1):85-89., which references unpublished data.	
Staessen 2004[84] 14982911	Omron HEM-705CP	Arm	Automated	Yes	B SBP A DBP	Pass		*Provided by authors*: O'Brien E, Waeber B, Parati G, Staessen J, Myers MG, for the European Society of Hypertension Working Group on Ambulatory Blood Pressure Monitoring. Blood pressure measuring devices: recommendations of the European Society of Hypertension. BMJ.2001;322:531-536.	
Stahl 1984[85] 6742256	Mercury sphygmomanometer	Arm (implied)	Manual	nd					Validation for manual instruments was not verified.

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
van-Onzenoort 2010[86] 19952780	Omron HEM-705CP	Arm	Automated	Yes	B SBP A DBP	Pass		*Provided by authors:* O'Brien E, Mee F, Atkins N, Thomas M. Evaluation of three devices for self-measurement of blood pressure according to the revised British Hypertension Society Protocol: the Omron HEM-705CP, Philips HP5332, and Nissei DS-175. Blood Press Monit. 1996:55– 61.	
Varis 2010[87] 20367560	Omron 1C	Arm	Automated	Yes (see comment)	Omron HEM 722C: A SBP A DBP Omron HEM 735C: B SBP A DBP	Omron HEM 722C: Pass Omron HEM 735C: Pass		*Provided by authors:* Bortolotto L, Henry O, Hanon O, Sikias P, Mourad JJ, Girerd X. Validation of two devices for self-measurement of blood pressure by elderly patients according to the revised British Hypertension Society Protocol: The Omron HEM-722C and HEM-735C. Blood Press Monit. 1999;4:21-25.	While the device used in the study is Omron 1C, the devices for which the authors provide a reference are Omron HEM-722C and HEM-735C. It is assumed that Omron 1C is the same or equivalent to one or both of these two models for which a validation reference is provided.
Verberk 2007[20] 17938383	Omron HEM-705CP	Arm	Automated	Yes	B SBP A DBP	Pass		*Provided by authors:* O'Brien E, Mee F, Atkins N, Thomas M. Evaluation of three devices for self-measurement of blood pressure according to the revised British Hypertension Society Protocol: the Omron HEM-705CP, Philips HP5332, and Nissei DS-175. Blood Press Monit. 1996:55– 61.	

Paper Reference	Brand Name or Equivalent	Arm or Wrist*?	Type**	Accreditation?	BHS Grade (AD)	AAMI Grade (Pass/ Fail)	ESH Grade (Recommended, Not recommended, Questionable)	Reference	Comments
Zarnke 1997[88] 9008249	Marshall 85 oscillometric, Omron	Arm	nd	Yes (informal)				*Provided by authors*: Smith CV, Selig CL, Rayburn WF, Yi PF: Reliability of compact electronic monitors for hypertensive pregnant women. J Reprod Med 1990;35: 399–401.	The reference states: "The accuracy of the device was considered as accurate as a mechanical aneroid unit available at the same retail stores."
Zillich 2005[89] 16423096	Omron HEM-737A	Arm	Automated	Yes (see comment)	B SBP B DBP	Pass		*Provided by authors:* O'Brien E, Waeber B, Parati G, Staessen J, Myers MG. Blood pressure measuring devices: recommendations of the European Society of Hypertension. BMJ. 2001;322:531–6.	While the device used in the study is Omron HEM-737A, the device for which the authors provide a reference is Omron HEM-737 Intellisense. It is assumed that Omron HEM-737A is the same model as HEM-737 Intellisense, for which a validation reference is provided.

Table D-2. Description of study interventions: Key Question 1

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	BP Transmission	Target BP, mmHg	Clinic or Study Visit Frequency	Medication Titration
Artinian 2001[40] 11343005	SMBP + Counsel	Telecounseling[a]	BPLink UA 767PC (Automated)	3x/wk	Electronic transmission	nd	Community center 3x/wk	Physician
	Usual care							
Artinian 2007[40] 17846552	SMBP + Counsel	Telecounseling[b]	LifeLink Monitoring	3x/wk	Electronic transmission	<135/85	nd	Physician
	Enhanced usual care							
Bailey 1999[42] 10100064	SMBP		Omron HEM 706 (nd)	2x/d	nd	nd	0, 8 wk	Physician
	Usual Care							
Binstock 1988[43] 3415798	SMBP + Contract + Rx monitor + Education	Compliance contracts[c]+ Calendar pill packs + Education[d]	nd	nd	nd	nd	0, 12 mo	nd
	SMBP + Education	Education[d]						
	Education	Education[d]						
Bosworth 2009[44] 19920269	SMBP + Counsel	Telecounseling[e]	Omron HEM-773AC[f] (Automated)	3x/wk	Mailed every 2 mo	Clinic<140/90 (<130/80 DM)	0, 6, 12, 18, 24 mo	Physician
	SMBP							
	Counsel	Telecounseling[e]						
	Usual care							
Bosworth 2011[45] 21747013	SMBP + Medication management + Behavioral management	Medication management[g1] + Behavioral management[h1]	A&D Medical Digital Blood Pressure (UA-767PC)	Every 2 d	Electronic transmission	Clinic<140/90 (<130/80 DM)	0, 6, 12, 18 mo	Physician
	SMBP + Medication management	Medication management [g1]						
	SMBP + Behavioral management	Behavioral management [h1]						
	Usual care							
Broege 2001[47] 11518836	SMBP		Omron HEM-702 (Semi-automated)	Every 2 d	Study nurse phoned every 2 wk	Home<150/90	Every mo for 3 mo[g]	Physician

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	BP Transmission	Target BP, mmHg	Clinic or Study Visit Frequency	Medication Titration
	Nurse BP			Every 2 wk		Clinic<150/90	Every 2 wk	
Carnahan 1975[48] 1130437	SMBP		Ultrasphyg, Lumiscope company (Semi-automated)	2x/d		Clinic DBP<90	Every mo	Nurse
	Usual care							
Dalfo i Baque 2005[51] 15802109	SMBP		Omron HME-705CP (Automated)	2 x 15-day periods: wk 6-8 and 14-16	Brought to office	Clinic<140/90 (<130/85 DM)	0, 8, 16, 24 wk	nd
	Usual Care							
DeJesus 2009[53] 19756162	SMBP + 1 Class	1 Class education[h]	Life Source UA-767 Plus (Automated)	nd	Patient recorded	Clinic<130/80	0, 6 mo	nd
	1 Class	1 Class education[h]						
	Usual Care							
Earp 1982[55] 7114339	SMBP[i] + Counsel	In-home counseling[j]	nd	1/d or several times/wk	Brought to office	Clinic DBP<95	0, 12, 24 mo	nd
	Counsel	In-home counseling[j]						
	Usual Care							
Fitzgerald, 1985[56] 4044205	SMBP		50% patients used manual mercury and 50% used manual aneroid	2x/d	Brought to office	nd	Every 3 wk	nd
	Clinic BP						nd	
Freidman 1996[57] 8722429	SMBP + Telecounseling	Telecounseling[k]	Omron Health Care (Automated)	1x/wk	Phone-linked computer system	nd	0, 6 mo	Physician
	Usual Care							
Fuchs 2010[58] NA	SMBP		nd (Automated)	nd	nd	Clinic<130/80	0, 4, 8 wk	nd
	Usual care							

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	BP Transmission	Target BP, mmHg	Clinic or Study Visit Frequency	Medication Titration
Godwin 2010[59] 20032170	SMBP		A&D UA-767 (Automated)	Minimum 1/wk	Brought to office	Clinic<140/90	0, 6, 12 mo	Physician
	Usual Care							
Gran 1991[60] 1891656	SMBP + Lifestyle interventions	Lifestyle interventions[l]	Tensomat, Ortho Konsult AB (nd)	14x/mo	nd	Clinic DBP≤90	0, 12, 24 mo	Physician
	Usual Care							
Green 2008[61] 18577730	SMBP + Counsel + Web training	Pharmacist counseling + Web training[m]	Omron HEM-705CP (Automated)	≥2x/wk	Emailed to physician	Home<135/85	0, 12 mo	Pharmacist and Physician
	SMBP + Web training	Web training[m]						Physician
	Usual Care							
Halme 2005[62] 16280273	SMBP		Omron M4 (Automated)	2x/d, for 7d at 0, 2, 4, 6 mo	Brought to office	Clinic<140/85 Home<135/80	0, 6 mo	Physician
	Usual care							
Haynes 1976[63] 73694	SMBP + Encouragement	Encouragement[n]	Nelkin 204M and separate stethoscope (Manual)	1/d	Brought to office	Clinic DBP<90	0, 6 mo	Physician
	Usual Care							
Johnson 1978[64] 369673	SMBP + Home visit BP	Home visitor BP measurement[o]	Blood pressure kit by Taylor Sybron (nd)	1/d	Brought to office	nd	0, 6 mo	Physician
	SMBP							
	Home visit BP	Home visitor BP measurement[o]						
	Usual Care							
Madsen 2008[67] 18568696 Madsen 2008[90] 18815937	SMBP		Omron 705 IT (Automated)	3x/wkfor first 3 mo and 1/wk during last 3 mo	Recording on PDA and transmitted to central server	Home<130/85 (<125/75 DM)	0, 6 mo	Physician
	Usual care					Clinic<140/90 (<130/80 DM)		
Marquez-Contreras 2006[68] 16331115	SMBP		Omron M4 (Automated)	3x/wk	Patient recorded on a card	Clinic<140/90	4 visits	Physician

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	BP Transmission	Target BP, mmHg	Clinic or Study Visit Frequency	Medication Titration
	Usual Care							
Marquez-Contreras 2009[69] 19482378	SMBP + Education + Rx monitor	Educational materials[p] + Medication monitoring[q]	Omron (nd)	3x/wk	Brought to office	Clinic<140/90 (<130/80 DM)	0, 3, 6 mo	Physician
	SMBP + Rx monitor	Medication monitoring[q]			Special card			
	SMBP + Education	Educational materials[p]			Special card			
	Usual Care							
McManus 2010[70] 19220913 McManus 2010[66] 20619448	SMBP + Alert+ Self-titration	Provider alert + Self titration	Omron 705IT (Automated)	1/d 1st wk of each mo	Electronic transmission	Home<130/85 (<130/75 DM, CKD)	Clinic visit if extreme BP, or after 2 Rx changes by patient	Patient, according to predetermined medication titration plan[r]
	Usual care					Clinic <140/90	Minimum annual visit	Physician
Mehos 2000[71] 11079287	SMBP[s]		UA-702 (Manual)	1/d	Brought to office (Predated diary)	Clinic<140/90	0, 6 mo	Physician Pharmacist made recommendation if mean monthly BP-values ≥140/90
	Usual care							Physician
Midanik 1991[72] 1899945	SMBP		Tycos Self-Check digital device (Automated)	2x/wk	Mailed every 4 wk	nd	0, 12 mo	Physician
	Usual care							
Muhlhauser 1993[73] 8467308	SMBP + Education	Education[t]	nd	2x/d for 1st week, less frequent when BP at target	Brought to office	nd	0, 18 mo	Physician
	Usual Care						0, 19 mo	
Parati 2009[75] 19145785	SMBP + Reminder	Reminder[u]	Tensiophone device, Tenisiomed Budapest (Automated)	nd	Electronic transmission	Home<135/85	0, 2, 4, 12, 24 wk	Physician
	Usual Care					Clinic<140/90		

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	BP Transmission	Target BP, mmHg	Clinic or Study Visit Frequency	Medication Titration
Park 2009[76] 19643661	SMBP + Web+ Counsel	Personalized Web site + Nurse counseling[v]	nd	nd	Electronic transmission	nd	0, 8 wk	Physician
	Usual Care							
Pierce 1984[77] 6377291	SMBP + Education	Education[w]	Aneroid sphygmomanometer (Manual)	1x/d	Brought to office	nd	0, 6 mo	Physician
	SMBP							
	Education	Education[w]						
Rinfret 2009[78] 20031834	SMBP + Alert + Rx monitor	Provider alert + Medication monitoring[x]	Omron HEM-711AC (Automated)	nd	Electronic transmission 1x/wk	Clinic<140/90	0, 12 mo	Physician
	Usual Care							
Rogers 2001[79] 113888152	SMBP		Welch Allyn Model 52500 (Automated)	3x/wk for minimum 8wk	Electronic transmission 1x/wk	nd	nd	Physician
	Usual Care							
Rudd 2004[80] 15485755	SMBP + Counsel	Telecounseling[y]	UA 751; A&D (Semi-automated)	2x/d	Mailed printed report every 2wk	Home<130/85	0, 3 mo	Nurse, per protocol
	Usual Care					nd		Physician
Sawicki 1995[81] 8557972	SMBP + Education + Self-titration	Education[z]+ Self- titration	Aneroid manometers (Manual)	At least 2x/d	nd	Home<140/90	nd	Patient, per protocol
	Usual Care			nd		nd	nd	Physician
Shea 2006[82] 16221935 Shea 2007[92] 18528511 Shea 2009[93] 19390093	SMBP + Web+ Counsel	Personalized Web site + Videoconference counseling[aa]	UA-767 (Automated)	nd	Transmitted electronically	nd	0, 12 mo	Physician
	Usual Care							
Soghikian 1992[83] 1518317	SMBP		Tycos Self Check Model 7052-08 (Manual)	2x/wk	Mailed every 4 wk. Computer reports generated for physician	nd	0, 12 mo	Physician
	Usual Care							

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	BP Transmission	Target BP, mmHg	Clinic or Study Visit Frequency	Medication Titration
Stahl 1984[85] 6742256	SMBP		nd (mercury sphygmomanometer	nd	Brought to office	Clinic DBP≤95	Every 2-4 wk until BP controlled, then every 2 mo	Nurse practitioner
	Usual Care							
Van Onzenoort 2010[86] 19952780	SMBP		Omron HEM-705 CP (Automated)	1x/d for 1 wk prior to clinic visit	Patient recorded	Home 120-139/80-89	7x/1y	Stepwise titration by physician at the coordination center
	Usual Care					Clinic 120-139/80-89	7x/1 y	Physician
Varis 2010[87] 20367560	SMBP		Omron 1c (Automated)	3x/wk	Patient recorded in a diary	135/85	nd	Titration by physician
	Usual care					Clinic 140/90	10x/1 y	Titration by physician
Verberk 2007[20] 17938383	SMBP		Omron HEM-705 CP (Automated)	6x/d for 7dprior to clinic visit	nd	Home 120-140/80-90	8x/1 y	Titration by physician at the coordination center
	Usual Care					Clinic 120-140/80-90	10x/1 y	Physician
Zarnke 1997[88] 9008249	SMBP		Marsall 85 oscillometric, Omron (Semiautomated)	2x/d	Patient recorded in a diary	nd	0, 8 wk	Patient per protocol[bb] Physician
	Usual Care							Physician
Zillich 2005[89] 16423096	SMBP + Counsel	Pharmacist counseling[cc]	Omron HEM-737A (Automated)	2x/d for 4 wk, then 2-4 wk break, and then another 4 wk	Brought to office (log book)	Home<140/90 (<130/80DM, CKD)	0, 1, 3 mo	Recommendations given by pharmacist Physician
	Pharmacist BP	Pharmacist BP measurement[dd]	BP measured in the pharmacy	4x in 3 mo	Brought to office (log book)			

BP = blood pressure; CKD = chronic kidney disease; DBP = diastolic blood pressure; DM = diabetes mellitus; nd = no data; SMBP = self-measured blood pressure.

[a] Weekly phone counseling by trained nurse on lifestyle modification and medication adherence.
[b] Weekly phone counseling by trained nurse on lifestyle modification and medication adherence.

[c] Each patient identified a specific behavior related to hypertension, recorded it for a defined period of time and established his or her own rewards for compliance and signed a contract.
[d] Bimonthly educational program by clinical nurse on hypertension and Rx options.
[e] Bimonthly phone counseling by nurse on improving adherence to diet, weight loss and lifestyle modification.The nurse also discussed patient's perceived risk for hypertension, social support, relationships with health care providers and side effects of medication.
[f] Omron HEM-637 wrist monitor, if arm circumference >17 inches and wrist circumference <8.5 inches.
[g1] Out of range BPs triggered nurse recommendation for medication change based on a decision support software; these were reviewed with and prescribed by study physician. Follow-up by nurse after 3 weeks via telephone to get reports of adverse effects and address patient questions.
[h1] Behavioral management delivered via telephone by a nurse, with 11 tailored health behavior modules focused on improving hypertension self-management. Verbal information as well as handouts.
[g] Clinic BP not used to make medication decisions.
[h] One-time class by DM educator focusing on hypertension in diabetes.
[i] Significant other BP monitoring: 50% chose spouse, 25% son or daughter, 7% chose nonrelative as "significant other."
[j] In home counseling was done by nurse or pharmacist (5-6 visits).
[k] Phone-linked computer counseling once/wk (~4 min) with BP input by patient. BP data transmitted to patient' physicians with clinically significant information highlighted.
[l] Patient had to choose ≥1 of 14 lifestyle intervention for BP reduction (e.g.: exercise, weight reduction, low sodium diet, low-fat diet, smoking cessation, alcohol restriction, improved sleep, noise reduction, reducing stress causes) including SMBP. 87% chose SMBP at baseline, 85% after 1 y, and 80% after 24 mo. Every 6mo information session on study results and more info on various nondrug approach.
[m] Web services for medication refill, appointments, view portions of their medical record and secure messaging to contact health care team members.
[n] Every 2 wk in-person review of BP-values of medication compliance by a high school graduate and encouragement for better BP control.
[o] Home visits every 1 mo to check BP.
[p] Patient education kit (leaflets) on general aspects of hypertension and compliance promotion.
[q] Card for BP measurements recording and medication reminder.
[r] After two consecutive months of readings above target (≥4 above-target readings in 2 consecutive months), patients self titrated medication in accordance with 2 step titration schedule prescribed in advance by physician. After each set of two changes had been implemented, patients returned to their family doctor for a future titration schedule if blood pressure remained above target. Monthly summaries of each patients' readings were sent to their family doctor.
[s] Clinical pharmacist contacted each patient monthly by phone to evaluate BP response. If mean monthly > target, physicians were informed and treatment adjusted as needed.
[t] Four consecutive weekly class taught by physician assistants; education on hypertension and nondrug treatment.
[u] Auto-electronic BP (phone) load with electronic reminders. If extreme BP-values a nurse called the patient.
[v] Medication and lifestyle modification info during visit by nurse and Internet monitoring weekly (patient input BP data, education on diet, medications, exercise, etc)
[w] Four educational meetings on nonpharmacological approach to lower BP.
[x] Phone transmission of patient's recorded home BP and of monthly pharmacy refill data to physician and study nurse. Nurse contacted subjects if poor BP control after 4wk or nonadherence.
[y] Patient mails BP report every 2 wk to nurse. Nurse follows by phone 4x (~10 min each call) with counseling on drug adherence and side effect.
[z] Four teaching sessions about hypertension, self-monitoring, nonpharmacological measures taught by a paramedic. Patients were instructed to titrate medications until normotensive.
[aa] Auto-electronic BP upload. Nurse videoconferencing via Web (no prespecified usage requirement) after reviewing BP and glucose data.
[bb] Self-titration based on medication-specific algorithms. Thresholds for medication change of 160/95 mmHg x 2 wk or >110/70 mmHg x 1 wk.
[cc] Four patient-pharmacist meetings over 3 mo for SMBP training and hypertension education. Pharmacists made recommendations to physicians about medication; treatment plans developed with physicians and implemented by pharmacist.
[dd] Four patient-pharmacist meetings over 3 mo: BP measured and patient was told if BP over the target and asked to contact physician. BP measurements faxed to physician.

Table D-3. Study characteristics: Key Question 1

Author Year PMID	Country (Enrollment Years)	Interventions[a]	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout[b], % (Timepoint)	Other Quality Issues
Artinian 2001[40] 11343005	US (nd)	SMBP + Counsel	59	11.5	nd	Community	Urban African Americans, majority women	12% (3 mo)	Pilot study, unbalanced randomization
		Usual care							
Artinian 2007[40] 17846552	US (2002-04)	SMBP + Counsel	60.2	30.1	25.8	General practice	Urban African Americans, majority women	14% (12 mo)	
		Enhanced usual care						12% (12 mo)	
Bailey 1999[42] 10100064	Australia (nd)	SMBP	54	48	nd	General practice		3% (8 wk)	No power calculation, not clear how many patients in each group and how many analyzed, interventions poorly defined, outcomes not clearly defined
		Usual care						3% (8 wk)	
Binstock 1988[43] 3415798	US (nd)	SMBP + Contract + Rx monitor + Education	nd	40	nd	nd		nd	No data frequency of SMBP and device type, sparse information on baseline characteristics, no statistical testing done, no information on dropouts
		SMBP + Education						nd	
		Education						nd	
Bosworth 2009[44] 19920269	US (2004-05)	SMBP + Counsel	61	34	36	Hospital outpatient		31% (24 mo)	Dropout rate, numbers in the figure do not always match the numbers reported in the text
		SMBP						28% (24 mo)	
		Counsel						22% (12 mo)	
		Usual care						19% (24 mo)	
Bosworth 2011[45] 21747013	US (2006)	SMBP + Medication management + Behavioral management	64	92	43	Hospital outpatient	Predominantly male	17% (18 mo)	
		SMBP + Medication management						15% (18 mo)	
		SMBP + Behavioral management						11% (18 mo)	
		Usual care						16% (18 mo)	
Broege 2001[47] 11518836	US (nd)	SMBP	73	65	nd	Hospital outpatient	Age ≥65	15% (3 mo)	Small sample size. Short period of followup. Heterogeneous mix of previously treated and untreated patients.
		Nurse BP							

Author Year PMID	Country (Enrollment Years)	Interventions[a]	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout[b], % (Timepoint)	Other Quality Issues
Carnahan 1975[48] 1130437	US (nd)	SMBP Usual care	56.9	98	nd	Outpatient		3% (6 mo)	Sparse baseline data, little explanation of intervention group details
Dalfo i Baque 2005[51] 15802109	Spain (nd)	SMBP Usual care	62	42	20	General practice		nd nd	Unclear, inadequate reporting to check or calculate estimates. Text and table do not match. High drop out for surveys. Surveys not defined or referenced properly.
DeJesus 2009[53] 19756162	US (nd)	SMBP + 1 class 1 class Usual care	17% ≤60; 83% >60	58	63	General practice	Diabetic	63% (6 mo) 71% (6 mo) 33% (6 mo)	Very high dropout rate, no data on SMBP frequency, unclear how baseline measurements were obtained for ITT analysis
Earp 1982[55] 7114339	US (1975-76)	SMBP + Counsel Counsel Usual care	47	49	nd	Hospital outpatient	Predominantly African-American	44% (24 mo) 39% (24 mo) 40% (24 mo)	Unclear descriptions of intervention groups, no data on device type or instructions for use, high dropout rate
Fitzgerald, 1985[56] 4044205	Ireland (nd)	SMBP Usual care	54.3	57	nd	Hospital outpatient or general practice	Uncomplicated hypertension	17% (9 wk)	Results poorly reported. Imprecise figure only.
Freidman 1996[57] 8722429	USA (nd)	SMBP + Tele + Counsel Usual care	77	21	16	Community	Older patients	11% (6 mo)	
Fuchs 2010[58] NA	Brazil (2002-05)	SMBP Usual care	nd	nd	nd	nd	nd	11% (8 wk)	Quality was not graded due to insufficient data (study published only as conference abstract)
Godwin 2010[59] 20032170	Canada (2002-05)	SMBP Usual care	68.8	48.7	29	General practice		12% (12 mo) 21% (12 mo)	High and uneven loss to followup: control 21% vs intervention 12%
Gran 1991[60] 1891656	Sweden (1986)	SMBP + Lifestyle interventions Usual care	51.3	31	nd	Clinic		11% (24 mo)	Not RCT. Selection bias. Control group were hypertensive patients who did not agree to take part in any intervention, Adoption of SMBP was optional in intervention group No data on frequency or timing during day for SMBP Baseline BP different between groups and not accounted for No data on control group's care (assume it's usual care)

Author Year PMID	Country (Enrollment Years)	Interventions[a]	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout[b], % (Timepoint)	Other Quality Issues
Green 2008[61] 18577730	US (2005)	SMBP + Counsel + Web training SMBP + Web training Usual care	59.1	47.8	0	Primary care clinics	No DM, CVD, kidney disease or other serious diseases	9.1% (12 mo) 5% (12 mo) 4.2% (12 mo)	
Halme 2005[62] 16280273	Finland (nd)	SMBP Usual care	57.1	35.3	15.1	Outpatient		14% (6 mo) 14% (6 mo)	
Haynes 1976[63] 73694	Canada (nd)	SMBP + Encouragement Usual care	nd	100	nd	Workplace	Steelworkers All noncompliant with poorly controlled BP at baseline.	0% (6 mo) 5.3% (6 mo)	Not RCT, problem with reporting
Johnson 1978[64] 369673	Canada (nd)	SMBP + Home visit BP SMBP Home visit BP Usual care	53	60	nd	Home (recruited from screening in shopping centers)		3% (6 mo) 3% (6 mo)	No information on frequency or other instructions given to SMBP group. No definition of compliance and "strength of therapy" outcomes.
Madsen 2008[67] 18568696 Madsen 2008[90] 18815937	Denmark (2004-06)	SMBP Usual care	56.7	52	8.8	General Practice		7% (6 mo) 4% (6 mo)	Baseline ABPM carried forward if no final ABPM No analysis for clustering of patients by 10 practitioners For QOL: no blinding, only QOL measurement at end of study, not at baseline
Marquez-Contreras 2006[68] 16331115	Spain (nd)	SMBP Usual care	59	51	nd	Primary care (hospital outpatient)		20% (6 mo)	SMBP group had more diseases than control, unclear reporting with discrepancies between text & table Unclear outcome definition High dropout rates
Marquez-Contreras 2009[69] 19482378	Spain (2006-07)	SMBP + Education + Rx monitor SMBP + Rx Monitor	62	45	nd	General practice	Uncontrolled on single drug therapy	17% (6 mo)	Unclear what the baseline number of drugs were. Patients withdrawn in failed to take drugs >20%. Unclear methods sentence about not advising drug changes

Author Year PMID	Country (Enrollment Years)	Interventions[a]	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout[b], % (Timepoint)	Other Quality Issues
		SMBP + Education							Unclear what the educational or "card" interventions were. No data on specific monitor used
		Usual care							
McManus 2010[70] 19220913 McManus 2010[66] 20619448	UK (2007-08)	SMBP + Alert + Self-titration	66.2	47	7	General practice		11% (12 mo)	
		Usual care						7% (12 mo)	
Mehos 2000[71] 11079287	US (nd)	SMBP	58	38	22	Hospital outpatient clinic		10% (6 mo)	Randomization with a deck of cards. Uneven baseline characteristics between groups
		Usual care							
Midanik 1991[72] 1899945	US (nd)	SMBP	47	53	nd	Hospital outpatient		27% (12 mo)	High dropout rates, incomplete eligibility criteria
		Usual care						29% (12 mo)	
Muhlhauser 1993[73] 8467308	Germany (nd)	SMBP + Education	51	43	nd	General practice		20% (18 mo)	Intervention group, as analyzed, included both patients that had agreed to SMBP + education and those that presumably did not agree to participate. Dropout rate was high in both groups, and over 20% in usual care group. SMBP portion of intervention was not described.
		Usual care							
Parati 2009[75] 19145785	Italy (nd)	SMBP + Reminder	58.1	54.1	nd	General practice		9% (6 mo)	Analysis reported as ITT but is actually per protocol, the interventions are not clearly defined, did not account for multiple centers (within center correlations)
		Usual care							
Park 2009[76] 19643661	South Korea (nd)	SMBP + Web + Counsel	55	43	nd	Outpatient	Obese	20% (2 mo)	Not RCT
		Usual care						16% (2 mo)	
Pierce 1984[77] 6377291	Australia (1977-78)	SMBP + Education	58	38	nd	General practice		2% (12 mo)	Dropout>20%, compliance outcome by survey, lack of statistical comparisons between study groups
		SMBP							
		Education							
		Usual care							
Rinfret 2009[78] 20031834	Canada (2004-07)	SMBP + Alert + Rx Monitor	57	54	10	Primary care		ABPM ≥16% Office ≥14% (12 mo)	Large dropout rates.

Author Year PMID	Country (Enrollment Years)	Interventions[a]	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout[b], % (Timepoint)	Other Quality Issues
		Usual care						ABPM 22% Office 16% (12 mo)	
Rogers 2001[79] 113888152	US (1999-2000)	SMBP	60.3	55.7	26.3	Outpatient		0.7% (11 wk)	Exact time point for outcome measurement by ABPM is not clear, at least 8 weeks, median 11 weeks.
		Usual care						10% (11 wk)	
Rudd 2004[80] 15485755	US (nd)	SMBP + Counsel	60	44	14	Outpatient		7% (6 mo)	No adjustment for two clinics.
		Usual care						10% (6 mo)	
Sawicki 1995[81] 8557972	Germany (1984-87)	SMBP + Education + Self-titration	37	52	100	Tertiary care hospital	Type 1 DM with diabetic kidney disease	7% (60 mo)	Not RCT Individuals in intensive treatment group were those living closer to the study center and had more followup visits over the course of the observation.
		Usual care						4% (60 mo)	
Shea 2006[82] 16221935 Shea 2007[92] 18528511 Shea 2009[93] 19390093	USA (2000-02)	SMBP + Web + Counsel	70	37.9	100	Primary care physician	Diabetic, underserved	18% (12 mo)	ITT analysis unclear. Numbers inconsistent between table and text. Baseline values carried forward as final values for a large number of patients during follow up visits No details on intensity of training of telemedicine system, frequency of BP monitoring
		Usual care						52% (60 mo)	
Soghikian 1992[83] 1518317	US (1984-85)	SMBP	54.7	50.2	nd	Hospital outpatient		7% (12 mo)	
		Usual care						12% (12 mo)	
Stahl 1984[85] 6742256	US (nd)	SMBP	48	43	nd	Hospital outpatient	Inner city Indianapolis (low income and Black)	8.3% (12 mo) [23% (36 mo]	Not RCT. Some potential for bias in randomization based on ability to self measure or availability of family.
		Family BP						2.5% (12 mo) [31% (36 mo]	
Van Onzenoort 2010[86] 19952780	Netherlands (2001-05)	SMBP	57	49	7	Outpatient and general practice			No data about the drop out rate
		Usual care							
Varis 2010[87]	Finland	SMBP	nd	37.6	5.7	Outpatient		14% (52 wk)	The numbers of patients randomized

Author Year PMID	Country (Enrollment Years)	Interventions[a]	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout[b], % (Timepoint)	Other Quality Issues
20367560	(nd)	Usual care						20% (52 wk)	to each group were uneven
Verberk 2007[20] 17938383	Netherlands (nd)	SMBP	55	55	nd	Hospital outpatient		19% (12 mo)	Incomplete eligibility criteria , no power calculation
		Usual care						27% (12 mo)	
Zarnke 1997[88] 9008249	Canada (nd)	SMBP	52	36	nd	Community		nd	Very small number of drug changes.
		Usual care						9% (2 mo)	
Zillich 2005[89] 16423096	US (nd)	SMBP + Counsel	66.1	61	20	Pharmacy		11% (3 mo)	
		Pharmacist BP						2% (3 mo)	

ABPM = ambulatory blood pressure monitoring; BP = blood pressure; DM = diabetes mellitus; nd = no data; RCT = randomized controlled trial; SMBP = self-measured blood pressure.

[a] For details, see "Interventions" table (Table D-2).
[b] For blood pressure outcomes in the whole study at "primary" timepoint (longest reported timepoint with <20% dropout, except as noted). In square brackets is the dropout rate for the longest reported timepoint. Any substantial differences in dropout rates across study arms are noted.

Table D-4. Categorical BP: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Result[b]	95% CI	P Btw	Study Quality
Bosworth 2009A[44] 19920269	124/70	12 mo[c]	BP <140/90 mmHg (<130/80 DM)	SMBP	93[d]	118	RR	1.05	0.92, 1.21	NS	B
				Usual care	98[d]	131					
Bosworth 2009B[44] 19920269	124/71			SMBP + Counsel	99[d]	122	RR	1.05	0.93, 1.19	NS	
				Counsel	104[d]	135					
Dalfo i Baque 2005[51] 15802109	162/94	6 mo	BP <140/90 mmHg (<130/85 DM)	SMBP	210[d]	622	OR	0.79[e]	0.56, 1.12	NS	C
				Usual care	271[d]	703					
			SBP <140 mmHg (<130 DM)	SMBP	245[d]	622	RR[f]	1.15	0.95, 1.39[g]	NS	
				Usual care	242[d]	703					
			DBP <90 mmHg (<85 DM)	SMBP	427[d]	622	RR[f]	1.06	0.95, 1.18[g]	NS	
				Usual care	455[d]	703					
DeJesus 2009[53] 19756162	149/79	6 mo	BP <130/80 mmHg	SMBP + Education	2	19	RR	1.79[h]	0.18, 18.0	NS	C
				Education	1	17					
Fuchs 2010[58] NA	nd	8 wk	BP <130/80 mmHg	SMBP	13	68	RR	2.17	0.87, 5.37	NS	Not graded
				Usual care	6	68					
Halme 2005[62] 16280273	160/95	6 mo	BP <140/85 mmHg	SMBP	31	113	RR	1.34	0.84, 2.14	NS	A
				Usual care	24	119					
Madsen 2008[67] 18568696	152/91	6 mo	Awake ABPM<135/85 mmHg (<130/85 DM)	SMBP	32	113	RR	0.76	0.52, 1.10	NS	A
				Usual care	46	123					
			Home or clinic target BP[i]	SMBP	68	113	RR	1.57	1.20, 2.06	<0.001	
				Usual care	47	123					
Marquez-Contreras 2006[68] 16331115	157/91	6 mo	BP <140/90 mmHg	SMBP	67	100	RR	1.20	0.96, 1.49	NS	C
				Usual care	56	100					
Mehos 2000[71] 11079287	154/90	6 mo	BP <140/90 mmHg	SMBP	8	18	RR	2.00	0.73, 5.47	NS	C
				Usual care	4	18					
Pierce 1984[77] 6377291	179/103	6 mo	SBP decrease ≥40 mmHg	SMBP	11	25	RR	0.91	0.51, 1.63	NS	C
				Usual care	14	29					
			DBP decrease ≥25 mmHg	SMBP	6	25	RR	0.99	0.38, 2.57	NS	
				Usual care	7	29					
Rogers 2001[79] 113888152	nd	>8 wk (median 11 wk)	24 hr SBP "Improved"[j]	SMBP	nd	60	OR	2.52	1.13, 5.64	nd	A
				Usual care	nd	61					
			24 hr DBP "Improved"[j]	SMBP	nd	60	OR	2.32	1.05, 5.15	nd	
				Usual care	nd	61					

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Result[b]	95% CI	P Btw	Study Quality
Stahl 1984[85] 6742256	167/109	7-12 mo	DBP ≤95 mmHg	SMBP	89	125	RR	1.12	0.95, 1.32	NS	C
				Usual care	95	149					
Verberk 2007[20] 17938383	165/98	12 mo	BP <140/90 mmHg	SMBP	160	216	RR	1.50	1.28, 1.75	0.001	B
				Usual care	106	214					

ABPM = ambulatory blood pressure monitoring; BP = blood pressure; CI = confidence Interval; DBP = diastolic blood pressure; DM = diabetes mellitus; nd = no data; NS = not significant; OR = odds ratio; P Btw = P-value between groups; RR = relative risk; SBP = systolic blood pressure; SMBP = self-measured blood pressure; NA = not available.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Top row intervention vs. bottom row intervention.
[c] Data are reported for 24 mo followup; however, the drop-out rate for this timepoint is >20%.
[d] Estimated from reported %.
[e] Inverse of reported OR. Text and table do not match. Reported OR (per Table 2) is Control vs Intervention.
[f] RR calculated from reported percentages. Estimated ORs from reported data do not exactly match reported ORs, therefore RRs were calculated.
[g] Estimated from reported P-value.
[h] Estimated from reported data for the ITT analysis.
[i] Target home BP in SMBP group < 130/85 mmHg for nondiabetics and 125/75 mmHg for diabetics; target office BP in control group <140/90 mmHg for nondiabetics and <130/80 mmHg for diabetics.
[j] Decrease in pressure from baseline to final.

Table D-5. Clinic BP: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	
Bailey 1999[42] 10100064	155/95	7 wk	SMBP	31	156 (4[b])	-8	+5	-4, 15[c]	<0.05	93 (2[b])	-4	+2	-3, 7[c]	NS	C
			Usual care	29	155 (4[b])	-13				95 (2[b])	-6				
Binstock 1988[43] 3415798	151/90	12 mo	SMBP + Education	23	156 (nd)	-21	-8	nd	nd	93 (nd)	-11	-10	nd	nd	C
			Education	32	151 (nd)	-13				90 (nd)	-1				
Bosworth 2009A[44] 19920269	124/70	12 mo	SMBP	118	126 (15)	-5	-3.7[d]	-6.1, -1.2	0.004	72 (11)	-4	-3.1[d]	-4.4, -1.8	<0.001	B
			Usual care	131	124 (18)	0				70 (10)	0				
Bosworth 2009B[44] 19920269	124/71		SMBP + Counsel	122	126 (20)	-4.5	-1.7	-5.0, 1.6[c]	NS	72 (12)	-3.1	-0.8	-2.7, 1.1[c]	NS	
			Counsel	135	124 (18)	-1				71 (10)	-1.3				
Broege 2001[47] 11518836	144/82	3 mo	SMBP	20	165 (24[e])	4	-2	-16.1, 12.1[c]	NS	84 (10[e])	2	-1	-7.4, 5.4[c]	NS	C
			Nurse monitor	18	153 (25[e])	6				87 (12[e])	3				
Carnahan 1975[48] 1130437	157/104	6 mo	SMBP	49	152.7 (nd)	-18	-7.5	-14.9, -0.03[f]	<0.05	101.7 (nd)	-10.4	0	nd	NS	C
			Usual care	48	156.6 (nd)	-10.5				103.6 (nd)	-10.4				
DeJesus 2009[53] 19756162	149/79	6 mo	SMBP + Education	7[g]	145.4 (5.3)	-3.29	nd	nd	NS	68.4 (11.6)	5.71	nd	nd	NS	C
			Education	5[g]	156 (11.7)	1.2				78.8 (2.7)	1.8				
Fitzgerald, 1985[56] 4044205	146/89	9 wk	SMBP	83	146 (19.9)	(149)	(0)	-5, 5[c]	NS	89 (10.3)	(93)	(0)	-2, 2[c]	NS	C
			Clinic measure	83	146 (19.9)	(149)				89 (10.3)	(93)				
Godwin 2010[59] 20032170	144/81	12 mo	SMBP	285	144.0 (18.9)	(132.8)	(-3.3)	-7.7, 1.1[h]	NS	80.8 (10.8)	(75.1)	(-3.2)	-5.7, -0.7[h]	0.01	B
			Usual care	267	144.3 (16.1)	(136.1)				82.1 (12.0)	(78.3)				
Halme 2005[62]	160/95	6 mo	SMBP	113	159.5 (17.5)	-12.7	-3.2	-8.2, 1.8[c]	NS	94.1 (6.8)	-7.1	-1.5	-4.0, 1.0[c]	NS	A

Author Year PMID	Baseline BP[a], mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	
16280273			Usual care	119	159.5 (18.9)	-9.5				94.6 (7.5)	-5.6				
Johnson 1978A[64] 369673	nd/103	6 mo	SMBP	34	nd	nd	nd	nd	nd	102.6 (1.2[b])	-8.9	-1.3	-6.4, 3.6[c]	NS	C
			Usual care	34						103.2 (1.7[b])	-7.6				
Johnson 1978B[64] 369673	nd/104		SMBP + Home visitor	35	nd	nd	nd	nd	nd	104.2 (1.1[b])	-8.1	0.4	-3.9, 4.7[c]	NS	
			Home visitor	33						103.9 (1.1[b])	-8.5				
Marquez-Contreras 2006[68] 16331115	156/91	6 mo	SMBP	100	159.1 (16.6)	-23.5	-4.6	-11.4, 2.2[f]	NS	92.4 (10.8)	-12.9	-3.2	-5.4, -1.0[f]	<0.005	C
			Usual care	100	155.6 (14.6)	-18.9				91.0 (9.7)	-9.7				
Mehos 2000[71] 11079287	154/90	6 mo	SMBP	18	157.9 (16.4)	-17.1	-10.1	-21.0, 0.8[f]	0.07	91.1 (10.8)	-10.5	-6.7	-12.4, -1.0[f]	0.02	C
			Usual care		153.9 (14.6)	-7.0				89.6 (9.8)	-3.8				
Midanik 1991[72] 1899945	144/93	12 mo	SMBP	74	144.4 (15.7)	-1.6	-2.4	-7.2, 2.4[f]	NS	91.3 (9.1)	1.0	0.1	-3.8, 4.0[f]	NS	C
			Usual care	72	144.0 (16.8)	0.8				92.7 (7.7)	0.9				
Soghikian 1992[83] 1518317	140/86	12 mo	SMBP	200	137.4 (1.2[b])	-1.4	-3.2	-6.7, 0.2	NS	86.1 (0.6[b])	0.1	-1.6	-3.6, 0.4	NS	A
			Usual care	190	140.2 (1.3[b])	1.8				86.3 (0.8[b])	1.7				
Stahl 1984[85] 6742256	167/109	7-12 mo	SMBP	125	nd	nd	nd	Nd	nd	109.7 (nd)	-20.1	-3.4	nd	<0.05	C
			Usual care	149						108.6 (nd)	-17.0				
Verberk 2007[20] 17938383	165/98	12 mo	SMBP	216	166.2 (19.3)	-22.4	1.6[i]	-2.0, 5.3	NS	97.8 (10.8)	-13.5	1.0[i]	-0.9, 2.9	NS	B
			Usual care	214	165.1 (20.8)	-22.9				97.1 (9.9)	-11.7				
Varis 2010[87] 20367560	159/97	12 mo	SMBP	89	159.4 (18.3)	-4.2	6.8	-0.1, 13.7[j]	NS	97.4 (8.9)	-4.6	3.1	nd	NS	B
			Usual care	68	158.8 (16.8)	-11				97.2 (9.1)	-7.7				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

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[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Reported SE.
[c] Estimated from reported data.
[d] Estimate based on a general linear model.
[e] Physician measured BP-values. The authors also provide nurse-measured BP-values, which were similarly nonsignificant.
[f] Estimated from reported P-value.

[g] Per protocol analysis; ITT analysis data available were also reported, and yielded similar results.

[h] Estimated based on reported P-values. Reported 95% CIs were asymmetric and narrower than the calculated CIs.

[i] Difference in blood pressure adjusted for baseline blood pressure values, center, age, gender, BMI, smoking, anti-hypertensive drugs at baseline, run-in-period, and setting of patient recruitment.

[j] Estimated from reported P-value.

Table D-6. Ambulatory BP, 24 hour: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	
Bailey 1999[42] 10100064	155/95	7 wk	SMBP	31	nd	(137)	(+7)	1, 13[b]	<0.05	nd	(79)	(+1)	-3, 5[b]	NS	C
			Usual care	29	nd	(130)				nd	(78)				
Fuchs 2010[58] NA	nd	8 wk	SMBP	68	nd	-8.8	-5.4	-0.9, -9.8	0.018	nd	-5.5	-4.5	-1.6, -7.4	0.003	Not graded
			Usual care	68	nd	-5.5				nd	-1.0				
Godwin 2010[59] 20032170	144/81	12 mo	SMBP	285	142.6 (11.6)	(136.1)	(-1.6)	-5.1, 1.9[c]	NS	79.2 (7.0)	(75.0)	(-2.0)	-3.8, -0.2[c]	0.03	B
			Usual care	267	143.9 (10.7)	(137.7)				80.0 (7.4)	(77.0)				
Rogers 2001[79] 11388815 2	nd	>8 wk (median 11 wk)	SMBP	60	nd	-4.9	-4.8	-0.10, -9.4	0.047	nd	-2.0	-4.1	-0.9, -7.1	0.01	A
			Usual care	61	nd	-0.1				nd	+2.1				
Verberk 2007[20] 17938383	165/98	12 mo	SMBP	216	143.7 (13.8)	-17.8	2.1[d]	0.0, 4.3	0.04	88.1 (9.7)	-10.9	1.1[d]	-0.4, 2.7	0.05	B
			Usual care	214	143.4 (13.5)	-19.6				88.4 (8.8)	-12.3				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Estimated from reported data.
[c] Estimated based on reported P-values. Reported 95% CIs were asymmetric and narrower than the calculated CIs.
[d] Difference in blood pressure adjusted for baseline blood pressure values, center, age, gender, BMI, smoking, anti-hypertensive drugs at baseline, run-in-period, and setting of patient recruitment.

Table D-7. Ambulatory BP, awake: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	
Bailey 1999[42] 10100064	155/95	7 wk	SMBP	31	nd	(141)	(+8)	2, 14[b]	<0.05	nd	(83)	(+2)	-20, 8[b]	NS	C
			Usual care	29	nd	(133)				nd	(81)				
Broege 2001[47] 11518836	144/82	3 mo	SMBP	20	150 (22)	-4	-4	-15.4, 7.4[b]	NS	81 (12)	-1	-2	-9.2, 5.2[b]	NS	C
			Nurse monitor	18	144 (20)	0				82 (13)	1				
Fuchs 2010 NA	nd	8 wk	SMBP	68	nd	nd	-4.4	0.1, -8.8	NS	nd	nd	-3.4	-0.4, -6.3	0.025	Not graded
			Usual care	68	nd	nd				nd	nd				
Godwin 2010[59] 20032170	144/81	12 mo	SMBP	285	146.9 (10.7)	(141.1)	(-1.7)	-5.0, 1.6[c]	NS	82.0 (7.4)	(78.7)	(-0.7)	-2.3, 0.9[c]	NS	B
			Usual care	267	148.2 (10.4)	(142.8)				82.8 (7.5)	(79.4)				
Madsen 2008[67] 18568696	152/91	6 mo	SMBP	113	153.1 (13.2)	-11.9	-2.3	-6.1, 1.5	NS	91.2 (8.1)	-6.2	-0.8	-3.1, 1.4	NS	A
			Usual Care	123	152.2 (13.7)	-9.6				90.5 (8.9)	-5.4				
Verberk 2007[20] 17938383	165/98	12 mo	SMBP	216	149.3 (14.8)	-18.1	2.2[d]	-0.02, 4.5	0.03	92.7 (10.5)	-11.1	1.2[d]	-0.5, 2.9,	0.05	B
			Usual care	214	149.5 (14.5)	-20.4				93.6 (9.3)	-13.2				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Estimated from reported data.
[c] Estimated based on reported P-values. Reported 95% CIs were asymmetric and narrower than the calculated CIs.
[d] Difference in blood pressure adjusted for baseline blood pressure values, center, age, gender, BMI, smoking, anti-hypertensive drugs at baseline, run-in-period, and setting of patient recruitment.

Table D-8. Ambulatory BP, asleep: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	
Broege 2001[47] 11518836	144/82	3 mo	SMBP	20	140 (21)	-8	-9	-18.8, 0.8[b]	NS	72 (13)	-2	-2	-8.6, 4.6[b]	NS	C
			Nurse monitor	18	127 (13)	1				71 (9)	0				
Fuchs 2010 NA	nd	8 wk	SMBP	68	nd	nd	-6.0	-1.3, -10.7	0.012	nd	nd	-5.8	-2.5, -9.0	0.001	Not graded
			Usual care	68	nd	nd				nd	nd				
Godwin 2010[59] 20032170	144/81	12 mo	SMBP	285	127.7 (18.4)	(127.2)	(-1.0)	-5.1, 3.1[c]	NS	69.9 (8.7)	(68.4)	(-1.4)	-3.8, 1.0[c]	NS	B
			Usual care	267	128.7 (16.5)	(128.2)				70.2 (8.8)	(69.8)				
Madsen 2008[67] 18568696	152/91	6 mo	SMBP	113	132 (15.6)	-9.4	-1.0	-5.0, 3.0	NS	77.6 (8.7)	-5.8	-0.7	-2.9, 1.6	NS	A
			Usual Care	123	133.7 (16.6)	-8.5				77.8 (9.5)	-5.2				
Verberk 2007[20] 17938383	165/98	12 mo	SMBP	216	127.9 (14.5)	-15.6	2.2[d]	-0.1, 4.5	0.03	76.2 (10.5)	-9.8	1.0[d]	-0.7, 2.6	NS	B
			Usual care	214	127.6 (15.8)	-17.5				76.1 (10.4)	-10.6				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Estimated from reported data.
[c] Estimated based on reported P-values. Reported 95% CIs were asymmetric and narrower than the calculated CIs.

[d] Difference in blood pressure adjusted for baseline blood pressure values, center, age, gender, BMI, smoking, anti-hypertensive drugs at baseline, run-in-period, and setting of patient recruitment.

Table D-9. Categorical medication dose and number outcomes: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	Inc	No Δ	Dec	Other	N Total	RR (95% CI) P-value Increase	No Δ	Decrease	Other	Study Quality
Bailey 1999[42] 10100064	155/95	8 wk (8 wk)	Medication dose	SMBP	5				31	0.58 (0.22, 1.58) nd				C
				Usual care	8				29					
			A medication class started	SMBP	2				31	0.31 (0.03, 2.83) nd				
				Usual care	0				29					
			A medication class ceased	SMBP			1		31			0.31 (0.03, 2.83) nd		
				Usual care			3		29					
Madsen 2008[67] 18568696	152/91	6 mo (6 mo)	Number of medications	SMBP	46	65			113	0.96 (0.71, 1.30) nd	1.01 (0.81, 1.26) NS			B
				Usual care	52	70			123					
Midanik 1991[72] 1899945	144/93	12 mo (12 mo)	Medication use (patients taking medication at the end of study)	SMBP				18	102				1.06 (0.58, 1.94) nd	C
				Usual care				17	102					
Pierce 1984[77] 6377291	179/103	1 yr (1 yr)	Medication change (Physician assessme	SMBP	3	10	7		27	0.40 (0.12, 1.36)[b] nd	0.90 (0.46, 1.72)[b] nd	1.50 (0.54, 4.17)[b] nd		C

Author Year PMID	Baseline BP[a], mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	Inc	No Δ	Dec	Other	N Total	RR (95% CI) P-value Increase	No Δ	Decrease	Other	Study Quality
			nt of change of "strength" of medications for each patient)	Usual care	8	12	5		29					
Zarnke 1997[88] 9008249	MAP 100	8 wk	Number of patients who did not change drug therapy	SMBP		15			20		0.83 (0.60, 1.16)[b] NS			B
				Usual care		9			10					

Δ = change; BP = blood pressure; CI = confidence Interval; Dec = decreased; Inc = increased; nd = no data; NS = not significant; RR = relative risk; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Calculated from reported data.

Table D-10. Continuous medication dose and number outcomes: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Halme 2005[62] 16280273	160/95	6 mo (6 mo)	Number of changes in medication per patient (either an increase in the dose of the drug used or an addition of a new antihypertensive agent)	SMBP	113	-	(0.75)	(0.14)	nd	NS	B[b]
				Usual care	119	-	(0.61)				
Madsen 2008[90] 18815937	152/91	6 mo (6 mo)	Number of antihypertensive medications	SMBP	113	1.0[c]	(1.9)	(-0.1)	nd	NS	A
				Usual care	123	0.5	(2.0)				
Marquez-Contreras 2006[68] 16331115	156/91	6 mo (6 mo)	Percentage of patients taking medication at prescribed time	SMBP	100	-	(88.1%)	(8.2%)	nd	0.006	C
				Usual care	100	-	(79.9%)				
Van Onzenoort 2010[86] 19952780	169/99	12 mo	Number of daily doses of antihypertensive medications prescribed (daily doses of antihypertensive drugs – defined as the assumed average maintenance dose per day for a drug used for its main indications in adults)	SMBP	114	-	(1.9)	(-0.5)	nd	0.001	B
				Usual care	114	-	(2.4)				
Zarnke 1997[88] 9008249	MAP 100	8 wk	Number of antihypertensive agents used (Sum of assigned proportional units for each drug [e.g., HCTZ 12.5 mg = 0.5 units])	SMBP	20	nd	(0.05)	(0)	-0.23, 0.23[d]	NS[e]	B
				Usual care	10	nd	(0.05)				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.

[b] Study quality was downgraded from A to B for this outcome because it was unclear if the medication change was a dose increase or an addition of another drug.

[c] Median.
[d] Calculated from reported data.
[e] Adjusted for baseline BP.

Table D-11. Categorical medication adherence: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	n Events			N Total	Outcome Metric	Result[b]	95% CI	P Btw	Study Quality
Bailey 1999[42] 10100064	155/95	8 wk (8 wk)	Medication compliance % (by tablet count)	SMBP		27		31	RR	0.94	0.79, 1.11	NS	C
				Usual care		27		29					
Broege 2001[47] 11518836	153/87	3 mo	Medication compliance (no description given)	SMBP		nd		20	nd	nd	nd	NS	C
				Nurse BP		nd		18					
Marquez-Contreras 2006[68] 16331115	156/91	6 mo (6 mo)	Medication compliance <80%, 80-90%, >90% (tablets assumed to have been taken divided by tablets that should have been taken)	SMBP	8	15	77	100	nd	nd	nd	0.0003	C
				Usual care	26	4	70	100					
Pierce 1984[77] 6377291	179/103	1 yr (1 yr)	Medication compliance-good/fair/poor (Unannounced nurse-administered survey identifying drugs and counting hypertensive meds)	SMBP	7	13	5	27	nd	nd	nd	nd	C
				Usual care	7	12	10	29					
Van Onzenoort 2010[86] 19952780	169/99	12 mo	Adequate adherence to treatment (measured with electronic pill box monitoring)	SMBP		92		114	RR	1.10	0.95, 1.26	NS	
				Usual care		84		114					

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Top row intervention vs. bottom row intervention.

Table D-12. Continuous medication adherence: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Marquez-Contreras 2006[68] 16331115	156/91	6 mo (6 mo)	Percentage of days on which antihypertensives were taken correctly	SMBP	100	-	(89.4)	(5.7)	2.87, 8.71	0.0001	C
				Usual care	100	-	(83.7)				
Mehos 2000[71] 11079287	154/90	6 mo (6 mo)	Percentage compliance= number of tablets or capsule refilled divided by the amount prescribed during the study	SMBP	18	-	(82%)	(-7%)		0.29	B
				Usual care	18	-	(89%)				
Van Onzenoort 2010[86] 19952780	169/99	12 mo	Percentage of days adherent to treatment (measured with electronic pill box monitoring system)	SMBP	114	-	(92.3)[b]	(1.4)[c]		0.04	B
				Usual care	114	-	(90.9)				
Zarnke 1997[88] 9008249	100.4[d]	8 wk	Number of drug doses missed	SMBP	20	-	(0.05)	-0.15	-0.4, 0.1[e]	NS	B
				Usual care	10	-	(0.2)				

BP = blood pressure; CI = confidence Interval; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Median for both arms.
[c] Difference in medians.
[d] MAP, by daytime ABPM.
[e] Calculated from reported data.

Table D-13. Quality of life: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Broege 2001[47] 11518836	153/87	3 mo	SF-36 total score (no description given)	SMBP	20	nd	nd	nd	nd	NS	C
				Nurse BP	18	nd	nd				
Madsen 2008[90] 18815937	152/91	6 mo (6 mo)	Physical functioning SF 36 (score 0-100)	SMBP	118	nd	(88.2)	(0.0)		0.08	B[b]
				Usual care	105	nd	(88.2)				
			Role physical SF 36 (score 0-100)	SMBP	118	nd	(80.0)	(2.7)		NS	
				Usual care	105	nd	(77.3)				
			Bodily pain SF36 (score 0-100)	SMBP	118	nd	(85.3)	(7.0)		0.03	
				Usual care	105	nd	(78.3)				
			General health SF36 (score 0-100)	SMBP	118	nd	(77.1)	(3.6)		NS	
				Usual care	105	nd	(73.5)				
			Vitality SF36 (score 0-100)	SMBP	118	nd	(68.8)	(1.0)		NS	
				Usual care	105	nd	(67.8)				
			Social functioning SF36	SMBP	118	nd	(89.5)	(-2.1)		NS	
				Usual care	105	nd	(91.6)				
			Role emotional SF36	SMBP	118	nd	(83.8)	(-0.7)		NS	
				Usual care	105	nd	(84.5)				
			Mental health SF36	SMBP	118	nd	(79.3)	(-2.2)		NS	
				Usual care	105	nd	(81.5)				
Mehos 2000[71] 11079287	154/90	6 mo (6 mo)	SF-36 score (range 0-100, higher score is better, all domains)	SMBP	18	-	-	-	-	NS[c]	B
				Usual care	18	-	-				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Study quality was downgraded from A to B for this outcome because there were baseline quality of life data that were not reported.
[c] No domains showed a significant difference.

Table D-14. Categorical health care resource use: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Result[b]	95% CI	P Btw	Study Quality
Soghikian 1992[83] 1518317	140/86	1 yr	Patients with no office visits for hypertension	SMBP	78	211	RR	2.25	1.58, 3.21[c]	nd	A
				Usual care	34	207					

BP = Blood pressure; CI = confidence Interval; nd = no data; P Btw = P-value between groups; RR = relative risk.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Top row intervention vs. bottom row intervention.
[c] Calculated from reported data.

Table D-15. Continuous health care resource use: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Bailey 1999[42] 10100064	155/95	8 wk (8 wk)	Frequency of doctor visits (no definition)	SMBP	31	nd	nd	nd	nd	NS	C
				Usual care	29	nd	nd				
Mehos 2000[71] 11079287	154/90	6 mo (6 mo)	Number of office visits per patient (with primary care provider)	SMBP	18	-	(2.72)	-1.72		0.08	C
				Usual care	18	-	(4.44)				
Midanik 1991[72] 1899945	144/93	12 mo (12 mo)	Office visits (hypertension related)	SMBP	102	-	(2.5)	0.2		NS	C
				Usual care	102	-	(2.3)				
			Phone calls (hypertension related)	SMBP	102	-	(0.2)	-0.1		NS	
				Usual care	102	-	(0.3)				
Soghikian 1992[83] 1518317	140/86	1 yr	Office visits for hypertension for the year	SMBP	211	3.2[b]	-1.7	-0.9		NS[c]	C
				Usual care	207	3.5	-0.8				
			Office visits for hypertension for the year, adjusted[d]	SMBP	211	nd	nd	nd	nd	NS[c]	
				Usual care	207	nd	nd				
			Number of telephone calls for hypertension	SMBP	211	0.6[b]	0.9	0.8		NS[c]	
				Usual care	207	0.7	0.1				
			Number of telephone calls for hypertension, adjusted[d]	SMBP	211	nd	nd	nd	nd	NS[c]	
				Usual care	207	nd	nd				
			Medical procedures for hypertension	SMBP	211	0.9[b]	0.0	0.1	0.0, 0.4	NS	
				Usual care	207	0.8	-0.1				
			Number of outpatient visits	SMBP	211	nd	(6.1)	(-1.3)		ND	
				Usual care	207	nd	(7.4)				
Zarnke 1997[88] 9008249	MAP 100	8 wk	Number of physician visits	SMBP	20	-	(1.05)	(0.85)	0.30, 1.40[e]	0.045	C
				Usual care	10	-	(0.20)				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Prior year measurement for both arms.
[c] P < 0.05 for difference in final values.
[d] Adjusted for age, race, sex, baseline DBP, use of baseline antihypertensive meds, use of outpatient services for hypertension care in the prior year.
[e] Calculated from reported data.

Table D-16. Continuous miscellaneous outcomes: SMBP alone versus usual care

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Dalfó i Baqué, 2005[51] 15802109	162/94	24 wk (24 wk)	Patient satisfaction (Score range 7-30, higher better)	SMBP	367	nd	(20.6	(4.3)	4.2, 12.8[b]	nd	C
				Usual care	408	nd	(16.3)				
Verberk 2007[20] 17938383	165.1/97.8	12 mo (12 mo)	LVMI	SMBP	216	98.3 (nd)	-6.5	-0.9	nd	0.72	B
				Usual care	214	96.4 (nd)	-5.6				

BP = blood pressure; CI = confidence interval; LVMI = left ventricular mass index; nd = no data; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Calculated from reported data.

Table D-17. Categorical BP: SMBP plus additional support versus usual care

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Result[b]	95% CI	P Btw	Study Quality
Bosworth 2009[44] 19920269	124/70	12 mo	BP <140/90 mmHg (<130/80 DM)	SMBP + Behavioral	99[c]	122	RR	1.08	0.95, 1.24[d]	nd	B
				Usual care	98c	131					
Bosworth 2011[45] 21747013	129/77	18 mo	BP ≤140/90 mmHg (≤130/80 DM)	SMBP + Behavioral management[s]	nd	131	RD[r]	-2.9%	-15.0%, 9.3%	NS	A
				Usual care	nd	124					
				SMBP + Medication management[s]	nd	126	RD[r]	-3%	-12.4%, 11.9%	NS	
				Usual care	nd	124					
				SMBP + Medication management[s] + Behavioral management[s]	nd	122	RD[r]	7.7%	-4.1%, 19.5%	NS	
				Usual care	nd	124					
DeJesus 2009[53] 19756162	149/74	6 mo	BP <130/80 mmHg	SMBP + Education	2	19[e]	nd	nd	nd	NS[f]	C
				Usual care	1	18					
Earp 1982[55] 7114339	63% in usual care DBP <95	12 mo	DBP <95 mmHg	SMBP[g] + Home visits	29	74	adj RD[n]	-0.03	nd	NS	C
				Usual care	16	47					
		24 mo		SMBP[g]+ Home visits	14	55	adj RD[l]	-0.15	-0.3, 0.01[d]	NS[l]	
				Usual care	16	38					
Green 2008[61] 18577730	152/89	12 mo	BP ≤140/90 mmHg	SMBP + Counsel +Web training	149[k]	261	adj RR[l]	1.84	1.48, 2.29	<0.001	A
				Usual care	80k	258					
				SMBP + Web training	99k	259	adj RRl	1.22	0.95, 1.56	NS	
				Usual care	80k	258					
Haynes[m] 1976[63] 73694	nd/98	6 mo	DBP <90	SMBP + Encouragement	6	20	RR	2.70	0.62, 11.72d	nd	C
				Usual care	2	18					
Marquez-Contreras 2009[69] 19482378	153/91	6 mo	BP <140/90 mmHg (<130/80 DM)	SMBP + Leaflets	126	230	RR	1.55	1.27, 1.90	0.01[n]	C
				Usual care	90	255					
				SMBP + Card	129	215	RR	1.70	1.39, 2.07	0.01n	
				Usual care	90	255					
				SMBP + Leaflets + Card	144	221	RR	1.85	1.52, 2.24	0.01n	
				Usual care	90	255					
Muhlhauser 1993[73] 8467308	163/100	18 mo	BP ≤140/90 mmHg	SMBP + Education	13d	86	RR	1.12d	0.52, 2.40	nd	C
				Usual care	10d	74					

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Result[b]	95% CI	P Btw	Study Quality
Parati 2009[75] 19145785	149/89	6 mo	Awake ABPM <130/80 mmHg	SMBP + Telemonitoring	116	187	RD	0.12	0, 0.24[o]	<0.05	C
				Usual care	56[p]	111					
Artinian 2007[41] 17846552	156/89	3 mo	SBP <135	SMBP + Telecounseling	70	194	RR	1.16	nd	NS	A
				Enhanced usual care	60	193					
			DBP<85	SMBP + Telecounseling	124	194	RR	1.21	nd	0.04	
				Enhanced usual care	102	193					
Zillich 2005[89] 16423096	152/85	3 mo	BP ≤140/90 mmHg	SMBP + Pharmacist education	27	64	RR	1.43	0.88, 2.32[q]	NS	B
				Pharmacist, no education	18	61					

BP = blood pressure; CI = confidence Interval; DM = diabetes mellitus; nd = no data; NS = not significant; P Btw = P-value between groups; RD = risk difference; RR = relative risk; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Top row intervention vs. bottom row intervention.
[c] Estimated from figure 2 in paper.
[d] Calculated from reported data.
[e] ITT data; per protocol data not available.
[f] Pearson's chi-squared including a 3rd group, education only.
[g] Performed by significant other.
[h] Adjusted for baseline BP, gender, # of anti-hypertensives at entry, hx of side effects 1st yr, provider setting, time since diagnosis.
[i] Adjusted for provider setting, # of anti-hypertensives at end of 1st yr, race, education, age, difficulty paying for care.
[j] Adjusted RD, NS; unadjusted RD -0.17, P=0.05.
[k] Estimated from adjusted RR and value reported in paper.
[l] Adjusted for BMI, sex, baseline home BP monitor availability, baseline SBP, clinic site.
[m] Quasi-RCT.
[n] ANOVA, favoring SMBP plus additional support.
[o] Estimated from P-value.
[p] Or 55 (reported as 50% of 111).
[q] Calculated directly from reported group data; differed from estimates based on reported P-value of 0.45.
[r] Estimated from logistic mixed-effects regression model.
[s] Additional intervention only instituted whenever mean BP exceeds threshold over a period of 2 weeks.

Table D-18. Clinic BP: SMBP plus additional support versus usual care

Author Year PMID	Base BP[a], mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	
Artinian 2001[40] 11343005	142/91	3 mo	SMBP + counsel	6	148.8 (13.8)	-24.7	-25.7	-40, -11	nd	90.2 (5.8)	-14.6	-12.5	-23, -2.3	nd	B
			Usual care	9	142.4 (16.5)	1				91.2 (8.7)	-2.2				
Binstock 1988[43] 3415798	151/90	12 mo	SMBP + contract + Rx monitor + education	11	150 (nd)	-16	-13	nd	nd	91 (nd)	-7	-6	nd	nd	C
			Education	32	151 (nd)	-3				90 (nd)	-1				
Bosworth 2009[44] 19920269	124/70	12 mo	SMBP + counsel	159[b]	126 (20)	-4.5[c]	-3.3	-5.7, -0.8	0.009	72 (12)	-3.1c	-2.2	-3.5, -0.8	0.001	B
			Usual care	159[d]	124 (18)	0c				70 (10)	0c				
Bosworth 2011[45] 21747013	129/77	18 mo	SMBP + Behavioral management[s]	131	129 (19)	nd	2.2[r]	-2.2, 6.6	NS	77 (12)	nd	0.6[r]	-2.0, 3.3	NS	A
			Usual care	124	128 (17)	nd				78 (14)	nd				
			SMBP + Medication management[s]	126	132 (21)	nd	-1.2[r]	-5.7, 3.2	NS	78 (14)	nd	-0.5[r]	-3.2, 2.1	NS	
			Usual care	124	128 (17)	nd				78 (14)	nd				
			SMBP + Medication management + Behavioral management[s]	122	127 (21)	nd	-3.6[r]	-8.1, 0.9	NS	77 (13)	nd	-1.4[r]	-4.0, 1.3	NS	
			Usual care	124	128 (17)	nd				78 (14)	nd				
DeJesus 2009[53] 19756162	149/74	6 mo[e]	SMBP + 1 class	7	145.4 (5.3)	-3.3	4.5	-11, 20	nd	68.4 (11.6)	5.7	8	-3.5, 19.5	nd	C
			Usual care	12	149.2 (7)	-7.8				73.9 (13.8)	-2.3				
Friedman 1996[57] 8722429	167/84	6 mo	SMBP + tele + counsel	133	169.5 (nd)	-11.5[f]	-4.7	-112 2.5[g]	NS	86.1 (nd)	-5.2f	-4.4	-8.1, -0.7g	0.02	A
			Usual care	134	167 (nd)	-6.8f				84 (nd)	-0.8f				
Green 2008[61] 18577730	152/89	12 mo	SMBP + Counsel + Web training	237	152.2 (10.4)	-14.2[h]	-8.9	-14, -3.6g	<0.001	88.9 (8.1)	-7h	-3.5	-5.6, -1.4g	<0.001	A
			Usual care	247	151.3 (10.6)	-5.3h				89.4 (8.0)	-3.5h				

Author Year PMID	Base BP[a], mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	
			SMBP + Web training	246	152.2 (10.0)	-8.2h	-2.9	-5.3, -0.4 g	0.02	89.0 (7.9)	-4.4h	-0.9	-2.3, 0.5g	NS	
			Usual care	247	151.3 (10.6)	-5.3h				89.4 (8.0)	-3.5h				
Haynes[i] 1976[63] 73694	nd/98	6 mo	SMBP + encouragement	20	nd	nd	nd	nd	nd	98.5 (5.8)	-5.4	-3.5	-7.9, 0.9g	NS	C
			Usual care	18	nd	nd				98.3 (6.4)	-1.9				
Johnson 1978[64] 369673	nd/103	6 mo	SMBP + home visit BP	35	nd	nd	nd	nd	nd	104.2 (6.5)	-8.1[j]	-0.5	nd	NS	C
			Usual care	34	nd	nd				103.2 (10.2)	-7.6j				
Marquez-Contreras 2009[69] 19482378	153/91	6 mo	SMBP + education	230	152.9 (13.8)	-16.4	0.1	-2, 2.2[k]	nd	89.7 (9.8)	-9	0.5	-1, 2.0k	nd	C
			Usual care	255	153.2 (12)	-16.5				91.01 (7.9)	-9.5				
			SMBP + Rx monitor	215	152.9 (14.6)	-16.9	-0.4	-2.6, 1.8k	nd	90.9 (8.8)	-10.7	-1.2	-2.6, 0.2k	nd	
			Usual care	255	153.2 (12)	-16.5				91.0 (7.9)	-9.5				
			SMBP + education + Rx monitor	221	152.5 (14.1)	-18.9	-2.4	-4.5, -0.3 k	nd	90.4 (8.4)	-11.2	-1.7	-3.1, -0.3k	nd	
			Usual care	255	153.2 (12)	-16.5				91.0 (7.9)	-9.5				
McManus 2010[70] 19220913	152/84	12 mo	SMBP + alert + self-titration	234	151.9 (nd)	-17.6	-5.4[l]	-8.5, -2.4	0.0004	85.2 (nd)	-7.5	-2.7l	-4.2, -1.1	0.001	A
			Usual care	246	152 (nd)	-12.2				84.7 (nd)	-4.8				
Muhlhauser 1993[73] 8467308	163/100	18 mo	SMBP + education	86	162 (14)	-8	-5	-10, 0	0.071	100 (7)	-6	-4	-7, -1	0.018	C
			Usual care	74	161 (13)	-3				98 (7)	-2				
Parati 2009[75] 19145785	149/89	6 mo	SMBP + reminder	187	148.4 (12.6)	-10.9	-0.2	-3.7, 3.3k	NS	88.7 (7.4)	-5.1	0.4	-1.8, 2.6k	NS	
			Usual care	111	148.7 (11.7)	-10.7				88.8 (8.6)	-5.5				
Rinfret 2009[78] 20031834	162/90	12 mo	SMBP + alert + Rx monitor	111	162 (16)	-18.7	-4.9	-9.8, 0g	0.05	91 (12)	-9.1	-3.5	-6.4, -0.6g	0.02	C
			Usual care	112	162 (17)	-13.8				90 (12)	-5.6				
Rudd 2004[80] 15485755	155/87	6 mo	SMBP + counsel	69	155.9[m] (19.9)	-14.2	-8.5	-15, -2g	<0.01	86.3m (10)	-6.5	-3.1	-6.2, -0.01 g	<0.05	B
			Usual care	68	154.8m (17.3)	-5.7				87.4m (9.1)	-3.4				

Author Year PMID	Base BP[a], mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	
Artinian 2007[41] 17846552	156/89	12 mo	SMBP + Telecounseling	167	156.8 (19.6)	-11.8	-4	nd	<0.0001	89.5 (14)	83.8	-0.8	nd	<00001	A
			Enhanced usual care	169	155.9 (19.2)	-7.8				88.4 (13)	83.5				
Earle 2010[54] 20597833	132/77	6 mo	SMBP + letters	72	130.5 (15.1)	-6.5	-8.6	nd	nd	76.9 (9.4)	-2.6	-4.7	nd	nd	C
			Usual care	65	131.8 (19.7)	2.1				76.6 (11.3)	2.1				
Shea 2006[82] 16221935	142/71	12 mo	SMBP + Web + counsel	697	142.1 (23.1)	-4.7	-3.4j	-5.5, -1.4 g	0.001	71.4 (11.2)	-3	-1.9j	-3.1, -0.8g	<0.001	A
			Usual care	709	141.8 (23.4)	-1.1				70.9 (10.4)	-0.9				
Zillich 2005[89] 16423096	152/85	3 mo	SMBP + counsel	64	151.5 (15.6)	-13.4	-4.5[n]	-10, 1.2g	NS	85.3 (11.6)	-8.8	-3.2n	-6.1, -0.3g	0.03	B
			Pharmacist BP	61	151.6 (12.9)	-9				85.3 (10.7)	-5.6				
Nonrandomized studies															
Gran 1991[60] 1891656	156/96	24 mo	SMBP + lifestyle interventions	122[o]	150.6 (13.4)	-9.3	-9.9	-2.9, 0.7	nd	95.2 (5.8)	-3.8	-0.9	-2.6, 0.8	nd	C
			Usual care	82	155.5 (12.8)	0.6				96.3 (6.1)	-2.9				
Park 2009[76] 19643661	134/91	2 mo	SMBP + Web + counsel	28	135.7 (8.8)	-9.1	-11.9	--19, -4.8 g	0.001	90.4 (6.7)	-7.2	-7.6	-12, -3.1g	0.001	B
			Usual care	21	133.9 (9.3)	2.8				91 (9.9)	0.4				
Sawicki 1995[81] 8557972	143/87	60 mo	SMBP + education + self-titration	34	154[p] (19)	-3.7	-19.1	-33, -5.2g	0.007	92[q] (12)	-5.8	-6.1	-13, 0.9g	0.088	C
			Usual care	25	143p (22)	15.4				87q (11)	0.3				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] ITT, actual number at 12 mo: 122.
[c] Estimated from Figure 2 in paper.
[d] ITT, actual number at 12 mo: 131.
[e] Per protocol analysis; ITT analysis also reported, with similar results.
[f] Adjusted for age, sex, baseline adherence, baseline BP.
[g] Estimated from P-value.
[h] Adjusted for baseline value, sex, baseline home BP monitor, clinic site.

[i] Quasi-RCT.
[j] Adjusted for baseline value.
[k] Calculated from reported data.
[l] Adjusted for sex, general practice, baseline SBP >150, DM, and chronic kidney disease status.
[m] Estimated from Fig 1 in paper.
[n] Adjusted for treatment group, age, sex, dyslipidemia, baseline SBP.
[o] Only 73% used SMBP.
[p] Based on original sample of 45.
[q] Based on original sample of 46.
[r] Estimated from a longitudinal data model with an unstructured covariance matrix.
[s] Additional intervention only instituted whenever mean BP exceeds threshold over a period of 2 weeks.

Table D-19. Ambulatory BP: SMBP plus additional support versus usual care

Author Year PMID	Base BP[a], mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	
Parati 2009[75] 19145785	149/89	6 mo	SMBP + reminder	187	Awake 139.4 (11)	-14.8	-1.6	-3.2, -0.01[b]	<0.05	83.9 (8)	-8.6	-0.7	nd	NS	C
			Usual care	111	140.3 (10.5)	-13.2				84.3 (8.2)	-7.9				
Rinfret 2009[78] 20031834	162/90	12 mo	SMBP + alert + Rx monitor	111	24 h 141 (11)	-11.9	-4.8	-7.7, -1.9[b]	<0.001	81 (9)	-6.6	-2.1	-3.6, -0.6[b]	0.007	C
			Usual care	112	140 (9)	-7.1				80 (10)	-4.5				
	147/85		SMBP + alert + Rx monitor	111	Awake 148.5 (11)	-13.4	-5.9	-9.4, -2.4[b]	<0.001	86.5 (10)	-7.6	-2.5	-4.2, -0.8[b]	0.005	
			Usual care	112	146.8 (9)	-7.5				85 (11)	-5.1				
	125/69		SMBP + alert + Rx monitor	111	Asleep 127 (18)	-9.0	-3.8	-6.7, -0.9[b]	0.01	71 (11)	-5.0	-1.9	-3.8, 0.0[b]	0.05	
			Usual care	112	125.3 (18)	-5.2				69 (13)	-3.1				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Estimated from P-value.

Table D-20. Categorical medication dose and number outcomes: SMBP plus additional support versus usual care

Author Year PMID	Baseline BP[a], mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	Inc	No Δ	Dec	Other	N Total	RR (95% CI) P-value Increase	No Δ	Decrease	Other	Study Quality
Muhlhauser 1993[73] 8467308	160/98	18 mo (18 mo)	Number of hypertension medications	SMBP + education			39		86			0.3 (0.17, 0.43) <0.001		C
				Usual care			11		74					
Parati 2009[75] 19145785	149/89	24 wk (24 wk)	Visits with a treatment modification by physician	SMBP + reminder				75	187 (561 visits)				SMBP: 13.4% of visits Usual care: 15.3% of visits NS	C
				Usual care				51	111 (333 visits)					
			Visits finding a treatment modification by patient	SMBP + reminder				49	187 (561 visits)				SMBP: 8.7% of visits Usual care: 13.5% of visits P = 0.04	
				Usual care				45	111 (333 visits)					
Pierce 1984[77] 6377291	179/103	1 yr (1 yr)	Medication change (Physician assessmen	SMBP + education	5	11	7		30	0.6 (0.22, 1.63)[b] nd	0.89 (0.47, 1.68)[b] nd	1.35 (0.48, 3.78)[b] nd		C

Author Year PMID	Baseline BP[a], mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	Inc	No Δ	Dec	Other	N Total	RR (95% CI) P-value Increase	No Δ	Decrease	Other	Study Quality
			t of change of "strength" of medications for each patient)	Usual care	8	12	5		29					
Rudd 2004[80] 15485755	1547/88	6 mo (6 mo)	Patients reporting two or more drugs	SMBP + counsel				48	69				1.53 (1.13, 2.07)[b] nd	B
				Usual care				31	68					
			Patients reporting no drug therapy	SMBP + counsel				27	69				1.77 (1.04, 3.03)[b] nd	
				Usual care				15	68					
			Patients reporting no change in drug therapy	SMBP + counsel		2			69		0.05 (0.01, 0.20)[b] nd			
				Usual care		39			68					
Zillich 2005[89] 16423096	152/85	3 mo	Increase in amount of a medication or number of medications	SMBP + counsel	38				64	2.26 (1.42, 3.61)[b] nd				B
				Pharmacist BP	16				61					
			Medication discontinued	SMBP + counsel				9	64				2.86 (0.88, 2.32)[b] nd	
				Pharmacist BP				3	61					

Δ = change; BP = blood pressure; CI = confidence Interval; dec = decrease; inc = increase; nd = no data; RR = relative risk; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Calculated from reported data.

Table D-21. Continuous medication dose and number outcomes: SMBP plus additional support versus usual care

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Artinian 2007[41] 17846552	156/88	9 mo	Number of additional medications[b]	SMBP + Counsel	234	nd	(2.1)	0.46	0.34, 0.58	0.001	A
				Enhanced usual care	246	nd	(1.7)				
Green 2008[61] 18577730	151/89	12 mo	Number of hypertension medication classes	SMBP + Counsel + Web training	237	1.64 (0.85)	0.52	0.5	0.3, 0.6	<0.05	A
				Usual care	247	1.64 (0.85)	0.05				
			Number of hypertension medication classes	SMBP + Web training	246	1.64 (0.85)	0.3	0.3	0.1, 0.4	<0.05	
				Usual care	247	1.64 (0.85)	0.05				
Marquez-Contreras 2009[69] 19482378	153/91	6 mo (6 mo)	Number of tablets taken per day	SMBP + education	230	1 (nd)	2.6	0[c]	-0.2, 0.2	nd	C
				SMBP + Rx monitor	215	1 (nd)	2.7	0.1	-0.1, 0.3	nd	
				SMBP + education + Rx monitor	221	1 (nd)	2.5	-0.1	-0.3, 0.1	nd	
				Usual Care	255	1 (nd)	2.6			nd	
McManus 2010[70] 19220913	152/85	12 mo (12 mo)	Number of additional medications[d]	SMBP + alert + self-titration	234	nd	(2.1)	0.46	0.34, 0.58	0.001	A
				Usual care	246	nd	(1.7)				
Rinfret 2009[78] 20031834	162/90	1 yr	Antihypertensive drug classes used	SMBP + alert + Rx monitor	111	-	(2)[e]	(1)	nd	0.007[f]	C
				Usual care	112	-	(1)				
			Physician-driven Rx changes	SMBP + alert + Rx monitor	111	-	(1)[e]	(1)	nd	0.03[f]	
				Usual care	112	-	(0)				
Rudd 2004[80] 15485755	155/88	6 mo (6 mo)	Number of medication changes (self-reported)	SMBP + counsel	69	-	(2.69)	(2.00)	nd	<0.01	B
				Usual care	68	-	(0.69)				
Sawicki 1995[81] 8557972	143/87	5 yr (5 yr)	Number of prescribed antihypertensive agents per patient (mean)	SMBP + education + self-titration	42	1.1 (1.1)	1.1	0.5	0.01, 0.99	NS	C
				Usual care	44	1.0 (1.0)	0.6				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Adjusted for sex, general practice, baseline systolic BP>150 mmHg, diabetes and chronic kidney disease.
[c] Compared to Usual care group.
[d] Adjusted for sex, general practice, baseline systolic BP>150 mmHg, diabetes and chronic kidney disease.
[e] Median.
[f] Adjusted for newly diagnosed, pharmacologically untreated versus uncontrolled pharmacologically treated hypertension, and also for pharmacologically treated concomitant disease(s) or not.

Table D-22. Categorical medication adherence: SMBP plus additional support versus usual care

Author Year PMID	Baseline BP[a], mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Result[b]	95% CI	P Btw	Study Quality
Haynes 1976[63] 73694	nd/98	6 mo (6 mo)	Increased medication compliance (surreptitious pill count by home visitor)	SMBP + encouragement	16	20	RR	2.06	1.11, 3.82[c]	<0.05	C
				Usual care	7	18					
Pierce 1984[77] 6377291	179/103	1 yr (1 yr)	Medication compliance-good/fair/poor (Unannounced nurse-administered survey identifying drugs and counting hypertensive meds)	SMBP + education	9 15	6 30	RR[d]	0.58	0.24, 1.39	nd	C
				Usual care	7 12	10 29					
Zillich 2005[89] 16423096	151.6/85.3	3 mo (3 mo)	High medication adherence (Scored according to Moritsky scale, self-reported)	SMBP + counsel	56	64	RR	1.05	0.91, 1.21	NS	B
				Pharmacist BP	51	61					

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Top row intervention vs. bottom row intervention.
[c] Calculated from reported data.
[d] RR for "poor" compliance.

Table D-23. Continuous medication adherence: SMBP plus additional support versus usual care

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Friedman 1996[57] 8722429	167/84	6 mo (6 mo)	Medication adherence % (medication dispensed divided by medication taken)	SMBP + tele + counsel	133	93	2.4	2.8	-2.4, 8.0[b]	NS	A
				Usual care	134	94	-0.4				
			Adjusted medication adherence % (medication dispensed divided by medication taken)[c]	SMBP + tele + counsel	133	93	17.7	6	0.6, 2.8[b]	0.03	
				Usual care	134	94	11.7				
Haynes 1976[63] 73694	nd/98	6 mo (6 mo)	Medication compliance (% of pills taken)	SMBP + encouragement	20	44.5 (5.6)	21.3	22.8	2.9, 42.7[b]	0.025	C
				Usual care	18	44.7 (7.1)	-1.5				
Rinfret 2009[78] 20031834	162/90	1 yr	Continuous medication availability (proportion of time medication available)	SMBP + alert + Rx monitor	111	-	(0.95)[d]	(0.04)		0.07[e]	C
				Usual care	112	-	(0.91)				
			Continuous medication gaps (proportion of time medication not available)	SMBP + alert + Rx monitor	111	-	(0.04)[d]	(-0.05)		NS[e]	
				Usual care	112	-	(0.09)				
Rudd 2004[80] 15485755	155/88	6 mo (6 mo)	Percentage of days patients took prescribed number of doses	SMBP + Counsel	69	-	(80.5%)	(11.3%)		0.03	B
				Usual care	68	-	(69.2%)				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Calculated from reported P-value.
[c] Adjusted for age, sex, baseline adherence.
[d] Median.
[e] Adjusted for newly diagnosed, pharmacologically untreated versus uncontrolled pharmacologically treated hypertension, and also for pharmacologically treated concomitant disease(s) or not.

Table D-24. Quality of life: SMBP plus additional support versus usual care

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Green 2008[61] 18577730	151/89	12 mo	SF-12 General Health score (score 1-100, higher score better)	SMBP + Counsel + Web training	237	67.1 (20.4)	-0.5	-0.1	-4.0, 3.8	NS	A
				Usual care	247	67.1 (20.4)	-0.4				
			SF-12 General Health score (score 1-100, higher score better)	SMBP + Web training	246	67.1 (20.4)	-0.5	-0.1	-4.0, 3.7	NS	
				Usual care	247	67.1 (20.4)	-0.4				
			SF-12 Physical Health score (score 1-100, higher score better)	SMBP + Counsel + Web training	237	80.6 (27)	0.4	2.8	-2.3, 8.0	NS	
				Usual care	247	80.6 (27)	-2.7				
			SF-12 Physical Health score (score 1-100, higher score better)	SMBP + Web training	246	80.6 (27)	-2.9	-0.4	-5.6, 4.7	NS	
				Usual care	247	80.6 (27)	-2.7				
			SF-12 Emotional Health score (score 1-100, higher score better)	SMBP + Counsel + Web training	237	71.6 (16.8)	0.1	0.1	-3.2, 3.4	NS	
				Usual care	247	71.6 (16.8)	-0.1				
			SF-12 Emotional Health score (score 1-100, higher score better)	SMBP + Web training	246	71.6 (16.8)	0.5	0.5	-3.2, 3.4	NS	
				Usual care	247	71.6 (16.8)	-0.1				
			Consumer Assessment of Healthcare Providers and Systems (CAHPS) score (score 1-10)	SMBP + Counsel + Web training	237	7.9 (1.5)	0.4	0.2	-0.1, 0.5	NS	
				Usual care	247	7.9 (1.5)	0.2				
			Consumer Assessment of Healthcare Providers and Systems (CAHPS) score (score 1-10)	SMBP + Web training	237	7.9 (1.5)	0.2	0.2	-0.0, 0.5	NS	
				Usual care	247	7.9 (1.5)	0.2				
McManus 2010[70] 19220913	152/85	12 mo (12 mo)	Anxiety score (six item scale of the State Trait Anxiety Inventory, scale ranges from 6 to 24, with higher scores indicating greater anxiety)	SMBP + alert + self-titration	234	10.1 (3.3)	0.6	-0.1		NS	A
				Usual care	246	9.7 (3.1)	0.7				

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
			EQ5D (Euro QoL Group 5-Dimension Self Report Questionnaire score, with higher scores indicating better health)	SMBP + alert + self-titration	234	0.809 (nd)	0.024	0.028	0.01, 0.06	nd	
				Usual care	246	0.847 (nd)	-0.004				
			EQ5D (Euro QoL Group 5-Dimension Self Report Questionnaire score, with higher scores indicating better health)[b]	SMBP + alert + self-titration	234	0.801	0.024	0.027	0.004, 0.065	nd	
				Usual care	246	0.841	-0.003				
Parati 2009[75] 19145785	149/89	24 wk (24 wk)	Quality of Life (SF-12 survey, higher score better)	SMBP + Reminder	187	37.7 (4.8)	0.7	0.6		NS	C
				Usual care	111	38.2 (4.5)	0.1				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Adjusted for sex, general practice, baseline systolic BP>150 mmHg, diabetes and chronic kidney disease.

Table D-25. Continuous health care resource use: SMBP plus additional support versus usual care

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Bosworth 2011[45] 21747013	129/77	18 mo	Number of primary care visits	SMBP + Medication management + Behavioral management	122	nd	(4)[e]	nd	nd	0.21	C
				SMBP + Medication management	126	nd	(4)[e]	nd	nd		
				SMBP + Behavioral management	131	nd	(4)[e]	nd	nd		
				Usual care	124	nd	(4)[e]				
			Number of specialty care visits	SMBP + Medication management + Behavioral management	122	nd	(5 to 6)[e]	nd	nd	0.12	
				SMBP + Medication management	126	nd	(5 to 6)[e]	nd	nd		
				SMBP + Behavioral management	131	nd	(5 to 6)[e]	nd	nd		
				Usual care	124	nd	(5 to 6)[e]				
DeJesus 2009[53] 19756162			Number of RN and MD visits during study period	SMBP + 1 class	19	nd	nd	nd	nd	NS	C
				Usual care	18	nd	nd				
Green 2008[61] 18577730	151/89	12 mo	Message threads	SMBP + Counsel + Web training	237	nd	(3.3)	(2.8)	nd	>0.05	C
				SMBP + Web training	246	nd	(22.3)	(5.6)	nd	<0.05	
				Usual care	247	nd	(2.4)				
			Patient-initiated message threads	SMBP + Counsel + Web training	237	nd	(2.7)	(2.9)	nd	0.01	
				SMBP + Web training	246	nd	(4.2)	(1.8)	nd	<0.01	
				Usual care	247	nd	(1.8)				
			Phone encounters	SMBP + Counsel + Web training	237	nd	(3.8)	(0.2)	nd	>0.05	
				SMBP + Web training	246	nd	(7.5)	(4.5)	nd	<0.01	
				Usual care	247	nd	(4.0)				
			Primary care visits	SMBP + Counsel + Web training	237	nd	(3.0)	nd	nd	NS	
				SMBP + Web training	246	nd	(3.2)	nd	nd	NS	

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
				Usual care	247	nd	(3.2)				
			Inpatient and emergency care use	SMBP + Counsel + Web training	237	nd	nd	nd	nd	nd	
				SMBP + Web training	246	nd	nd	nd	nd	nd	
				Usual care	247	nd	nd				
			Specialist office visits	SMBP + Counsel + Web training	237	nd	nd	nd	nd	nd	
				SMBP + Web training	246	nd	nd	nd	nd	nd	
				Usual care	247	nd	nd				
McManus 2010[70] 19220913	152/85	12 mo (12 mo)	Number of primary care consultations	SMBP + alert + self-titration	234	nd	(3.2)	(-0.3)		0.08	C
				Usual care	246	nd	(3.5)				
Muhlhauser 1993[73] 8467308	160/98	18 mo (18 mo)	Physician visits per patient	SMBP + Education	86	-	(12)	0		NS	C
				Usual care	74	-	(14)				
Rinfret 2009[78] 20031834	162/90	1 yr	Physician office visits	SMBP + alert + Rx monitor	111	-	(2)[b]	(0)		NS[c]	C
				Usual care	112	-	(2)				
Sawicki 1995[81] 8557972	143/87	5 yr (5 yr)	Mean number of visits to study center per year	SMBP + education + self-titration	42	-	(3.2)	(2.5)		<0.001	C
				Usual care	44	-	(0.7)				
Zillich 2005[89] 16423096	152/85	3 mo	Physician visits	SMBP + counsel	64	-	(0.31)[d]	(-0.61)		0.007	C
				Pharmacist BP	61	-	(0.92)[d]				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Median.
[c] Adjusted for newly diagnosed, pharmacologically untreated versus uncontrolled pharmacologically treated hypertension, and also for pharmacologically treated concomitant disease(s) or not.
[d] Calculated from reported data, number of patients not explicitly given.
[e] Median number of visits for all study groups

Table D-26. Categorical miscellaneous outcomes: SMBP plus additional support versus usual care

Author Year PMID	Baseline BP[a], mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Result[b]	95% CI	P Btw	Study Quality
Marquez-Contreras 2009[69] 19482378	153/91	6 mo (6 mo)	Adverse drug reactions	SMBP + education	0	230				nd[c]	C
				SMBP + Rx monitor	4	215				nd	
				SMBP + education + Rx monitor	3	221				nd	
				Usual care	6	255					

BP = blood pressure; CI = confidence Interval; nd = no data; P Btw = P-value between groups; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Top row intervention vs. bottom row intervention.
[c] ANOVA between groups = not significant.

Table D-27. Description of study interventions: Key Question 2

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	BP Transmission	Target BP, mmHg	Clinic or Study Visit Frequency	Medication Titration
Binstock 1988[43] 3415798	SMBP + Contract + Rx monitor + Education	Compliance contracts[a] + Calendar pill packs + Education[b]	nd	nd	nd	nd	0, 12 mo	nd
	SMBP + Education	Education						
Bosworth 2009[44] 19920269	SMBP + Counsel	Telecounseling[c]	Omron HEM-773AC[d]	3x/wk	Mailed every 2 mo	Clinic<140/90 (<130/80 DM)	0, 6, 12, 18, 24 mo	Physician
	SMBP							
Bosworth 2011[45] 21747013	SMBP + Medication management + Behavioral management	Medication management[g1] + Behavioral management[h1]	A&D Medical Digital Blood Pressure (UA-767PC)	Every 2 d	Electronic transmission	Clinic<140/90 (<130/80 DM)	Clinic<140/90 (<130/80 DM)	Physician
	SMBP + Medication management	Medication management [g1]						
	SMBP + Behavioral management	Behavioral management [h1]						
Brennan 2010[46] 20415618	SMBP + Counsel	Counseling by nurse	Omron HEM-780	"At regular intervals"[e]	Collected by nurse Quarterly reports sent to PCP	Home<120/80	nd	Physician
	SMBP				Mailed at 6mo and end of the study			
Carrasco 2008[49] 15564986	SMBP + Telemedicine + Counsel	Telemedicine + Physician Counseling	Omron M4-I	2x/d, 4x/wk	Transmitted via cell phone to provider	Clinic≤140/90	Routine	Physician
	SMBP				Patient recorded BP			
Cheltsova 2010[50]	SMBP + Counsel	Counseling by nurse[f]	nd	nd	nd	nd	3,6 mo	nd
	SMBP							

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	BP Transmission	Target BP, mmHg	Clinic or Study Visit Frequency	Medication Titration
Dawes 2010[52] 20631056	SMBP + Education + Rx monitor	Educational Materials + Medication monitoring[g]	Mostly Omron 711, LifeSource UA-767-PAC, Omron HEM 773	nd	BP tracking tool brought to office	nd	0, 12 wk	Physician
	SMBP + Education	Educational leaflet			nd			
Green 2008[61] 18577730	SMBP + Counsel+ Web[h]	Pharmacist counseling + Web training[i]	Omron HEM-705CP	≥2x/wk	Emailed to physician	Home<135/85	0,12 mo	Pharmacist per protocol
	SMBP + Web[h]	Web training[i]						Physician no protocol
Johnson 1978[64] 369673	SMBP + Home visit BP	Home visitor BP measurement[j]	BP kit by Taylor Sybron (nd)	1x/d	Brought to office	nd	nd	Physician
	SMBP							
Marquez-Contreras 2009[69] 19482378	SMBP + Education + Rx monitor	Educational materials[k] + Medication monitoring[l]	Omron (nd)	3x/wk	Brought to office	Clinic<140/90 (<130/80 DM)	0,3, 6 mo	Physician
	SMBP + Rx monitor	Medication monitoring[l]			Special card			
	SMBP + Education	Educational materials[k]			Special card			
Neuman 2011[74] 21228822	SMBP + Tele	Telemonitoring	Stabil-O-Graph	1x/d	Transmitted via cell phone to server or to provider, if abnormal	nd	nd	Physician
	SMBP		nd					
Pierce 1984[77] 6377291	SMBP + Education	Education[m]	Aneroid device (Manual)	1x/d	Brought to office	nd	nd	nd
	SMBP							
Atypical Studies								
Kabutoya, 2009[65] 19695029	SMBP + Graph	Graphic display of weekly and monthly averaged BP	Omron HEM-737	2x/d	No	Home<135/85	nd	Physician
	SMBP							

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	BP Transmission	Target BP, mmHg	Clinic or Study Visit Frequency	Medication Titration
Staessen 2004[84] 1498211	SMBP + Home Titration	Stepwise medication titration based on home BP	Omron HEM-705CP	SMBP: 2x/d for 7d 2x/mo; Clinic: 2x/mo	Patient recorded and printed BP-values	Home DBP 80-89	2x/mo	Physician per protocol
Den Hond 2004[94] 15564986	SMBP + Clinic Titration	Stepwise medication titration based on clinic BP				Clinic DBP 80-89		
Stahl 1984[85] 6742256	SMBP Family BP measurement		nd (mercury sphygmomanometer)	nd	Patient	Clinic DBP ≤95	1-2x/mo until BP controlled, then every 2 mo	Nurse practitioner "stepped approach"

BP = blood pressure; DM = diabetes mellitus; nd = no data; SMBP = self-measured blood pressure.

[a] Each patient identified a specific behavior related to hypertension, recorded it for a defined period of time and established his or her own rewards for compliance and signed a contract.
[b] Bimonthly educational program by clinical nurse on hypertension and Rx options .
[c] Bimonthly phone counseling by nurse on improving adherence to diet, weight loss and lifestyle modification. The nurse also discussed patient's perceived risk for hypertension, social support, relationships with health care providers and side effects of medication.
[d] Omron HEM-637 wrist monitor, if arm circumference >17 inches and wrist circumference < 8.5 inches.
[e] Weekly or more: 28%, <Weekly: 72 %.
[f] Phone calls by a nurse.

[g] Treatment arm received educational booklet included educational leaflet on hypertension and tracking tool to record BP, side effects and medication. Control arm received educational leaflet on hypertension.
[h] All received educational pamphlet on hypertension.
[i] Web services for medication refill, appointments, view portions of their medical record and secure messaging to contact health care team members.
[j] Home visits every 1 mo to check BP.
[k] Patient education kit (leaflets) on general aspects of hypertension and compliance promotion.
[l] Card for BP measurements recording and medication reminder.
[m] Four educational meetings on nonpharmacological approach to lower BP.

Table D-28. Study characteristics: Key Question 2

Author Year PMID	Country (Enrollment Years)	Interventions[a]	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout[b], %, (Timepoint) [Longest]	Other Quality Issues
Binstock 1988[43] 3415798	US (nd)	SMBP + Contract + Rx monitor + Education	nd	40	nd	nd		nd	No data frequency of SMBP and device type, sparse information on baseline characteristics, no statistical testing done, no information on dropouts
		SMBP + Education						nd	
Bosworth 2009[44] 19920269	US (2004-05)	SMBP + Counsel	61	34	36	Hospital outpatient		23% (12 mo) [31% (24 mo)]	Dropout rate, numbers in the figure do not always match the numbers reported in the text
		SMBP						15 % (12 mo) [29% (24 mo)]	
Bosworth 2011[45] 21747013	US (2006)	SMBP + Medication management + Behavioral management	64	92	43	Hospital outpatient	Predominantly male	17% (18 mo)	
		SMBP + Medication management						15% (18 mo)	
		SMBP + Behavioral management						11% (18 mo)	
Brennan 2010[46] 20415618	US (2006)	SMBP + Counsel	56	33	25	Community	African American, private health insurance (higher education, income)	22% (12 mo)	Outcome timing and collection unclear. High dropout. Unclear timing.
		SMBP						26% (12 mo)	
Carrasco 2008[49] 15564986	Spain (2004-2006)	SMBP Telemedicine + Counsel	62	59.2	22	General practice		8% (6 mo)	No adjustment for clustering
		SMBP						1% (6 mo)	
Cheltsova 2010[50]	US (nd)	SMBP + Counsel	nd	nd	nd	Outpatient urban community clinic		18% (6 mo)	Abstract with limited information
		SMBP							
Dawes 2010[52] 20631056	Canada (nd)	SMBP+Education + Rx monitor	66	53	21	General practice		24% (12 wk)	Unclear loss to follow up for BP. No results by group. Not aimed to look at BP outcome.
		SMBP+Education						20% (12 wk)	
Green 2008[61] 18577730	US (nd)	SMBP + Counsel + Web training	59.1	47.8	nd	General practice		9% (12 mo)	
		SMBP + Web training						15% (12 mo)	
Johnson 1978[64]	Canada (nd)	SMBP + Home visitor	53	60	nd	Home (recruited from screening in		3% (6 mo)	No information on frequency or other

Author Year PMID	Country (Enrollment Years)	Interventions[a]	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout[b], %, (Timepoint) [Longest]	Other Quality Issues
369673		SMBP				shopping centers)			instructions given to SMBP group. No definition of compliance and "strength of therapy" outcomes.
Marquez-Contreras 2009[69] 19482378	Spain (nd)	SMBP + Education+ Rx monitor SMBP + Education SMBP + Rx monitor	62	45	nd	General practice		20% (6 mo) 17% (6 mo) 22% (6 mo)	Unclear what the baseline number of drugs were. Patients withdrawn in failed to take drugs >20%. Unclear methods sentence about not advising drug changes Unclear what the educational or "card" interventions were. No data on specific monitor used
Neuman 2011[74] 21228822	Germany (nd)	SMBP + Telemonitoring SMBP	56	54	nd	Nephrology Practice		5% (3 mo)	No information on SMBP device in control group. No description of randomization, allocation concealment, power calculation
Pierce 1984[77] 6377291	Australia (nd)	SMBP + Education SMBP	58	38	nd	General Practice		23% (6 mo)	No randomization. Dropout>20%, compliance outcome by survey. Lack of statistical comparisons between study groups
Atypical Studies									
Kabutoya, 2009[65] 19695029	Japan (nd)	SMBP + Graph SMBP	67	46	nd	Hospital outpatient		nd	No data on numbers of patients analyzed at each time point or how frequently seen in clinic. Text reported only statistically significant results and graph did not provide variance.

Author Year PMID	Country (Enrollment Years)	Interventions[a]	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout[b], %, (Timepoint) [Longest]	Other Quality Issues
Staessen 2004[84] 1498211 Den Hond 2004[94] 15564986	Belgium and Ireland (1997-2002)	SMBP + Home Titration SMBP + Clinic Titration	54	48	nd	56 general practice and 3 hospital outpatient clinics in Belgium and 1 specialized hypertension clinic in Dublin, Ireland 77% enrolled from general practice		13.3% (12 mo) 13.2 % (12 mo)	
Stahl 1984[85] 6742256	US	SMBP Family BP measurement	48	43	nd	Hospital outpatient	Inner city Indianapolis (low income and Black)	8.3% (12 mo) [22.8% (36 mo] 2.5% (12 mo) [30.6% (36 mo]	Potential for bias in randomization based on ability to self measure or availability of family.

BP = blood pressure; DM = diabetes mellitus; nd = no data; SMBP = self-measured blood pressure.

[a] For deatails, see "Interventions" table (Table D-2).
[b] For blood pressure outcomes in the whole study at "primary" timepoint (longest reported timepoint with <20% dropout, except as noted). In square brackets is the dropout rate for the longest reported timepoint. Any substantial differences in dropout rates across study arms are noted.

Table D-29. Categorical BP: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Result[b]	95% CI	P Btw	Study Quality
Bosworth 2009[44] 19920269	126/72	12 mo	BP <140/90 mmHg, <130/80 mmHg if DM	SMBP + Counsel	99[c]	122	RR	1.03	0.91, 1.17	nd	B
				SMBP	93[d]	118					
Bosworth 2011[45] 21747013	129/77	18 mo	BP ≤140/90 mmHg (≤130/80 DM)	SMBP + Medication management[e] + Behavioral management[e]	87	122	RD	8.0%[f]	nd	nd	A
				SMBP + Medication management[e]	79	126					
				SMBP + Medication management[e] + Behavioral management[e]	87	122	RD	11%[f]	nd	nd	
				SMBP + Behavioral management[e]	79	131					
				SMBP + Medication management[e]	79	126	RD	2.6%[f]	nd	nd	
				SMBP + Behavioral management[e]	79	131					
Brennan 2010[46] 20415618	133/84	Mean 13 mo	BP <120/80 mmHg Adjusted[g]	SMBP + Counsel	83	320	OR	1.50	0.99, 2.27	0.05	B
				SMBP	70	318					
Carrasco 2008[49] 15564986	147/87	6 mo	BP ≤140/90 mmHg (per protocol analysis)	SMBP Telemedicine + Counsel	97	127	RR[h]	1.10	0.94, 1.27	nd	B
				SMBP	92	132					
Green 2008[61]	152/89	12 mo	BP <140/90	SMBP + Counsel+ Web training	132[j]	237	nd	nd	nd	<0.001	A

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Result[b]	95% CI	P Btw	Study Quality
18577730			mmHg Adjusted[i]	SMBP + Web training	88 or 89[k]	246					
Marquez-Contreras 2009[69] 19482378	153/90	6 mo	BP <140/90 mmHg (<130/80 mmHg if DM)	SMBP + Education+ Rx monitor	144	221	RR	1.19	1.02, 1.38	nd	C
				SMBP + Education	126	230					
				SMBP + Education+ Rx monitor	144	221	RR	1.09	0.94, 1.26	nd	
				SMBP + Rx monitor	129	215					
				SMBP + Rx monitor	129	215	RR	1.10	0.93, 1.29	nd	
				SMBP + Education	126	230					
Neuman 2011[74] 21228822	145/85[l]	3 mo	24h ABPM <130/80 mmHg, <125/75 mmHg if DM or CKD)	SMBP Telemonitoring	15[m]	28	nd	nd	nd	nd	C
				SMBP	10[n]	29					
Pierce 1984[77] 6377291	184/106	6 mo	SBP reduction mmHg	mmHg	>40	10-40	<10		RR	1.04[o]	0.81, 1.34	nd	C
				SMBP + Education	12	13	5	30					
				SMBP	11	9	5	25					
			DBP reduction mmHg		>25	10-25	<10		RR	1.20[p]	0.91, 1.60	nd	
				SMBP + Education	11	15	4	30					
				SMBP	6	12	7	25					

BP = blood pressure; CI = confidence Interval; CKD = Chronic Kidney Disease; DBP = diastolic blood pressure; DM = diabetes mellitus; nd = no data; OR = odds ratio; P Btw = P-value between groups; RR = relative risk; SBP = systolic blood pressure; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Top row intervention vs. bottom row intervention.
[c] N estimated from reported 81%.
[d] N estimated from reported 79%.
[e] Additional intervention only instituted whenever mean BP exceeds threshold over a period of 2 weeks.
[f] Estimated from logistic mixed-effects regression model.
[g] Adjusted for education level, ≥2 drug classes at baseline, BP <120/80 at baseline.

[h] Study reported OR for BP >140/90.
[i] Adjusted for BMI, sex, already having a home BP monitor before trial, baseline BP, clinic.
[j] N estimated from reported 56%.
[k] N estimated from reported 36%.
[l] mean daytime BP on ABP.
[m] N estimated from reported 54%.
[n] N estimated from reported 34%.
[o] SBP reduction ≥ 10 vs <10 mmHg.
[p] DBP reduction ≥ 10 vs <10 mmHg.

Table D-30. Clinic BP: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Base BP[a], mmHg	Timepoint	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Δ	Net Diff	95% CI	P Btw	Base (SD)	Δ	Net Diff	95% CI	P Btw	
Binstock 1988[43] 3415798	156/93	12 mo	SMBP+Contract+Rx monitor+Education	11	150	-16	5	nd	nd	91	-7	4	nd	nd	C
			SMBP + Education	23	156	-21				93	-11				
Bosworth 2009[44] 19920269	126/72	12 mo	SMBP + Counsel	122	126 (20)	-4.5	0.4	nd	nd	72 (12)	-3.1	0.9	nd	nd	A
			SMBP	118	126 (15)	-5				72 (11)	-4				
Bosworth 2011[45] 21747013	129/77	18 mo	SMBP + Medication management[s] + Behavioral management[s]	122	127 (21)	nd	-2.4	nd	nd	77 (13)	nd	-0.9	nd	nd	A
			SMBP + Medication management[s]	126	132 (21)	nd				78 (14)	nd				
			SMBP + Medication management[s] + Behavioral management[s]	122	127 (21)	nd	-5.8	nd	nd	77 (13)	nd	-2.0	nd	nd	
			SMBP + Behavioral management[s]	131	129 (19)	nd				77 (12)	nd				
			SMBP + Medication management[s]	126	132 (21)	nd	-3.4	nd	nd	78 (14)	nd	-1.1	nd	nd	
			SMBP + Behavioral management[s]	131	129 (19)	nd				77 (12)	nd				
Brennan 2010[46] 20415618	133/84	Mean 13 mo	SMBP + Counsel	320	133 (17.9)	-6.4	-3.0	nd	0.03	85 (11)	-4	-0.5	nd	NS	B
			SMBP	318	133 (21)	-3.4				84 (12)	-3.5				
Carrasco 2008[49] 15564986	147/87	6 mo	SMBP Telemedicine + Counsel	131	146 (16)	-15.5	-3.6	nd	0.13	89 (9)	-9.6	-1.2	nd	NS	B
			SMBP	142	147 (18)	-11.9				88 (10)[b]	-8.4				
Cheltsova 2010[50]	nd	6 mo	SMBP + Counsel	86[c]	nd	nd	nd	nd	0.62[d]	nd	nd	nd	nd	0.12[e]	Ungraded
			SMBP												
Dawes, 2010[52] 20631056	139/80	12 wk	SMBP +Education + Rx monitor	56	14	-6.36	nd[f]	nd	NS	83	-3.66	nd[f]	nd	NS	C
			SMBP +Education	53	140					81					

Author Year PMID	Base BP[a], mmHg	Timepoint	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Δ	Net Diff	95% CI	P Btw	Base (SD)	Δ	Net Diff	95% CI	P Btw	
Green 2008[61] 18577730	152/89	12 mo	SMBP + Counsel+ Web training	237	152 (10)	-14.2[b]	-6	nd	<0.001	89 (9)	-7[b]	-2.6	nd	<0.001	A
			SMBP + Web training	246	152 (10)	-8.2[b]				89 (8)	-4.4[b]				
Johnson 1978[64] 369673	nd/103	6 mo	SMBP + Home visitor	35	nd	nd				104.2	-8.1	0.8	nd	nd	C
			SMBP	34	nd	nd				102.6	-8.9				
Marquez-Contreras 2009[69] 19482378	153/91	6 mo	SMBP + Education+ Rx monitor	221	153 (14)	-18.9	-2.5	-5.2, 0.2[g]	nd	90 (8)	-11.2	-2.2	-3.9, -0.5[g]	nd	C
			SMBP + Education	230	153 (14)	-16.4				89 (10)	-9.0				
			SMBP + Education+ Rx monitor	221	153 (14)	-18.9	-2.0	-4.6, 0.6[g]	nd	90 (8)	-11.2	-0.5	-2.2, 1.2[g]	nd	C
			SMBP + Rx monitor	215	153 (15)	-16.9				91 (9)	-10.7				
			SMBP + Rx monitor	215	153 (15)	-16.9	-0.5	-3.1, 2.1[g]	nd	91 (9)	-10.7	-1.7	-3.5, 0.05[g]	nd	C
			SMBP + Education	230	153 (14)	-16.4				90 (10)	-9.0				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Adjusted for baseline BP, sex, already having a home BP monitor before trial, and clinic.
[c] Data were not provided by arm.
[d] There was no significant decrease from baseline (P= 0.22), and no difference between groups (P=0.62).
[e] DBP readings at the clinic decreased significantly from baseline to 6 months (P=0.0148), but there was no difference between the TM and control groups (P=0.12).
[f] Data were not provided by arm, but the study commented that the reduction was greater in the intervention group.
[g] Calculated from reported data.

Table D-31. Ambulatory BP: SMBP plus additional support versus SMBP alone (or with other additional support)

Author Year PMID	Base BP[a], mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	Base (SD)	Change (Final)	Net Diff (Diff of Final)	95% CI	P Btw	
Neumann 2011[74] 21228822	145/85[b]	3 mo	SMBP + Telemonitoring	28	143.3 (11.1)	-17.0	-7.2	-13.8, -0.6	0.032	82.6 (9.9)	-9.0	-2.0	-6.2, 2.2	0.356	C
			SMBP	29	142.5 (13.5)	-9.8				82.6 (6.5)	-7.0				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] mean daytime BP on ABP.

Table D-32. Quality of life: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Carrasco 2008[49] 15564986	147/87	6 mo (6 mo)	SF-36 physical component (score 0-100)	SMBP + Telemedicine + Counsel	131	47.3 (7.5)	0.2	1.2	nd	0.25	B
				SMBP	142	45.5 (8.1)	-1.0				
			SF-36 mental component	SMBP + Telemedicine + Counsel	131	49.3 (8.6)	-0.4	-1.1	nd	0.52	
				SMBP	142	48.3(10.6)	0.7				
			Mental health questionnaire-STAI (state anxiety)	SMBP Telemedicine + Counsel	131	19.3 (10.6)	-1.1	-2.0	nd	0.38	
				SMBP	142	20.7(9.6)	0.9				
			Mental health questionnaire-STAI (trait anxiety)	SMBP + Telemedicine + Counsel	131	21.3(9.9)	0.9	0.2	nd	0.76	
				SMBP	142	23.4(9.2)	-1.1				
Green 2008[61] 18577730	152/89	1 yr (1 yr)	General health, SF12 mean (SD)	SMBP + Counsel+ Web training	237	67.1 (20.4)	-0.5	0	−3.9, 3.9[b]	NS	A
				SMBP + Web training	246	67.1 (20.4)	-0.5				
			Physical health, SF12 mean (SD)	SMBP + Counsel+ Web training	237	80.6 (27)	0.4	3.3	-1.9, 8.5[b]	NS	
				SMBP + Web training	246	80.6 (27)	-2.9				
			Emotional health, mean (SD)	SMBP + Counsel+ Web training	237	71.6 (16.8)	0.1	-0.4	−3.7, 2.9[b]	NS	
				SMBP + Web training	246	71.6 (16.8)	0.5				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Calculated from reported data.

Table D-33. Categorical medication dose and number outcomes: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BP[a], mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	Inc	No Δ	Dec	Other	N Total	OR/RR (95% CI) P-value Increase	No Δ	Decrease	Other	Study Quality
Brennan 2010[46] 20415618	133/84	Mean 13 mo (Mean 13 mo)	# of patients taking ≥2 drug classes, self reported, adjusted	SMBP + Counsel				139	320				OR 1.08. (0.76, 1.53) NS	B
				SMBP				146	318					
			# of patients taking ≥2 drug classes, pharmacy records, adjusted	SMBP + Counsel				214	~297				OR 1.45 (0.93, 2.25) NS	
				SMBP				214	~300					
Johnson 1978[64] 369673	nd/103	6 mo (6 mo)	Change in therapy strength	SMBP + Home visitor	12	17	7		36				NS	C
				SMBP	8	18	7		33					
Pierce 1984[77] 6377291	184/106	6 mo (6 mo)	Medication change	SMBP + Education	5	11	7		23				RR 1.30 (0.70, 2.42) NS	C
				SMBP	3	10	7		20					

Δ = change; BP = blood pressure; CI = confidence Interval; Inc = increase; Dec = decrease; nd = no data; NS = not significant; OR = odds ratio; RR = relative risk; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.

Table D-34. Continuous medication dose and number outcomes: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Green 2008[61] 18577730	152/89	1 yr (1 yr)	Number of HTN med classes	SMBP + Counsel+ Web training	237	1.64 (0.85)	0.52	0.2	0.1, 0.4[b]	<0.01	A
				SMBP + Web training	246	1.64 (0.85)	0.3				
Neuman 2011[74] 21228822	145/85[c]	3 mo (3 mo)	Number of HTN med classes	SMBP + telemonitoring	28	3.6 (1.7)		nd	nd	nd[d]	C
				SMBP	29	3.2 (1.8)					

BP = blood pressure; CI = confidence Interval; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Calculated from reported data.
[c] Mean day BP from ABP
[d] Study reports: "No significant change was observed during the study period"

Table D-35. Categorical medication adherence: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BP[a], mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	n Events			N Total	Outcome Metric	Result[b]	95% CI	P Btw	Study Quality
Bosworth 2009[44] 19920269	126/72	24 mo (24 mo)	% of logs with ≥1 recorded BP reading turned in	SMBP + Counsel	65[c]			110	RR	0.93[d]	0.75, 1.14[d]	nd	C
				SMBP	72[e]			113					
Pierce 1984[77] 6377291	184/106	6 mo (6 mo)	Medication compliance	SMBP + Education	Good 7	Fair 13	Poor 6	30	RR	1.07[f]	0.47, 2.46[d]	nd	C
				SMBP	7	13	5	25					

BP = blood pressure; CI = confidence Interval; nd = no data; P Btw = P-value between groups; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Top row intervention vs. bottom row intervention.
[c] Calculated from reported data 59%.
[d] Calculated from reported data.
[e] Calculated from reported data 64%.
[f] Compliance good versus fair or poor.

Table D-36. Continuous medication adherence: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year Ref ID PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Johnson 1978[64] 369673	nd/103	6 mo (6 mo)	Compliance (% of pills consumed out of prescribed)	SMBP + home visits	35	65.5 (5.4)	10.1	-1.7	-4.2, 0.86[b]	nd	C
				SMBP	34	65.8 (6.1)	11.8				

BP = blood pressure; CI = confidence Interval; nd = no data; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Calculated from reported data.

Table D-37. Categorical health care resource use: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BP[a], mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	Final	P Btw	Study Quality
Bosworth 2009[44] 19920269	126/72	24 mo (24 mo)	% of hospitalized patients	SMBP + Counsel	nd[b]	NS	C
				SMBP			

BP = blood pressure; nd = no data; NS = not significant; P Btw = P-value between groups; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Proportion ranged from 19.5% to 22.6% across all 4 study groups, p=0.91 across all four groups.

Table D-38. Continuous health care resource use: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Bosworth 2009[44] 19920269	126/72	24 mo (24 mo)	Number of outpatient encounters	SMBP + Counsel	nd	nd	(nd[b])	nd	nd	NS	C
				SMBP	nd	nd	Nd				
Bosworth 2011[45] 21747013	129/77	18 mo	Number of primary care visits	SMBP + Medication management + Behavioral management	122	nd	(4)[c]	nd	nd	0.21	C
				SMBP + Medication management	126	nd	(4)[c]	nd	nd		
				SMBP + Behavioral management	131	nd	(4)[c]	nd	nd		
			Number of specialty care visits	SMBP + Medication management + Behavioral management	122	nd	(5 to 6)[c]	nd	nd	0.12	
				SMBP + Medication management	126	nd	(5 to 6)[c]	nd	nd		
				SMBP + Behavioral management	131	nd	(5 to 6)[c]	nd	nd		
Brennan 2010[46] 20415618	133/84	Mean 13 mo	PCP visits per person/y	SMBP + Counsel	320	3.8 (2.4)	-0.5	0.9	0.4, 1.3[d]	NS	C
				SMBP	318	3.8 (2.8)	-1.4				
			Cardiac visits per person/y	SMBP + Counsel	320	0.2 (0.7)	0.1	0	-0.1, 0.1	NS	
				SMBP	318	0.2 (0.7)	0.1				
			Specialist visits per person/y	SMBP + Counsel	320	0.4 (1.0)	0.1	0	-0.1, 0.1	NS	
				SMBP	318	0.4 (1.1)	0.1				
Carrasco 2008[49] 15564986	147/87	6 mo	Consultations (#, median)	SMBP Telemedicine + Counsel	131	nd	(2 [range 0, 20])	nd	nd	NS	C
				SMBP	142	nd	(3 [range 0, 23])				
			Hospital admissions (#)	SMBP Telemedicine + Counsel	131	nd	(4)	nd	nd	NS	
				SMBP	142	nd	(3)				
Green 2008[61] 18577730	152/89	1 yr (1 yr)	Message Threads (#)	SMBP + Counsel+ Web training	237	nd	(22.3)	nd	nd	nd	C
				SMBP + Web training	246	nd	(3.3)				
			Patient-initiated message	SMBP + Counsel+ Web training	237	nd	(4.2)	nd	nd	<0.01	C
				SMBP + Web	246	nd	(2.7)				

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
			threads (#)	training							
			Phone Encounters (#)	SMBP + Counsel+ Web training	237	nd	(7.5)	nd	nd	<0.01	C
				SMBP + Web training	246	nd	(3.8)				
			Primary Care Visits (#)	SMBP + Counsel+ Web training	237	nd	(3.2)	nd	nd	NS	C
				SMBP + Web training	246	nd	(3.0)				
			Inpatient and emergency care use (nd)	SMBP + Counsel+ Web training	237	nd	nd	nd	nd	NS	C
				SMBP + Web training	246	nd	nd				
			Decrease in percentage of patients with specialist office visits over 12 months compared to baseline (#)	SMBP + Counsel+ Web training	237	nd	nd	nd	nd	unclear[e]	C
				SMBP + Web training	246	nd	nd				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; PCP = primary care physician; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Median ranged from 13 to 15 across all 4 study groups, p=0.73 across all four groups.
[c] Median number of visits for all study groups.
[d] Calculated from reported data.
[e] Study reported that there was a modest but significant decrease in the percentage of patients in the BPM-Web-Pharm group with office visits to a specialist in 12 months (P=.04) relative to baseline and to patients in the other arms.

Table D-39. Continuous miscellaneous outcomes: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Green 2008[61] 18577730	152/89	1 yr (1 yr)	CAHPS, Assessment of Healthcare Providers and Systems	SMBP + Counsel+ Web training	237	7.9 (1.5)	0.4	0.2	−0.0, 0.5[b]	NS	A
				SMBP + Web training	246	7.9 (1.5)	0.2				

BP = blood pressure; CI = confidence Interval; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Calculated from reported data.

Table D-40. Categorical BP: Atypical studies

Author Year PMID	Baseline BP[a], mmHg	Timepoint	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Result[b]	95% CI	P Btw	Study Quality
Kabutoya, 2009[65] 19695029	153/79	6 mo	Home BP<135/85 mmHg	SMBP + Graph	33	nd	RR	~1.2	nd	NS	C
				SMBP	32	nd					
Stahl 1984[85] 6742256	167/109	7-12 mo	DBP ≤95	SMBP	47[c]	77	RR	0.87	0.70, 1.07	<0.05	C
				Family BP measurement	89[d]	125					

BP = blood pressure; CI = confidence Interval; DBP = diastolic blood pressure; nd = no data; NS = not significant; P Btw = P-value between groups; RR = relative risk; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Top row intervention vs. bottom row intervention.
[c] N estimated from reported 61%.
[d] N estimated from reported 71%.

Table D-41. Continuous BP: Atypical studies

Author Year PMID	Base BP[a], mmHg	Timepoint	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Quality
					Base (SD)	Δ	Net Diff	95% CI	P Btw	Base (SD)	Δ	Net Diff	95% CI	P Btw	
Kabutoya, 2009[65] 19695029	153/79	6 mo	SMBP + Graph	33	153	~-12.9	~-0.1	nd	NS	~80	~-6.2	~-0.4	nd	NS	C
			SMBP	32	153	~-12.8				~79	~-5.8				
Staessen 2004[84] 1498211	159/102	12 mo, end of followup	SMBP + Home Titration	203	Clinic 161	-15.3	6.8	3.6, 9.9	<0.001	102	-10.5	3.5	1.9, 5.1	<0.001	A
			SMBP + Clinic Titration	197	160	-22.0				102	-14.0				
			SMBP + Home Titration	203	Home 147	-11.1	4.9	2.5,7.4	<0.001	92	-7.3	2.9	1.5, 4.4	<0.001	
			SMBP + Clinic Titration	197	146	-16.0				92	-10.2				
			SMBP + Home Titration	203	Awake 149	-11.3	5.3	2.6,7.9	<0.001	94	-7.9	3.2	1.5,4.8	<0.001	
			SMBP + Clinic Titration	197	148	-16.5				94	-11.1				
			SMBP + Home Titration	203	Asleep 130	-8.2	4.8	2.1,7.5	<0.001	78	-6.1	3.0	1.3,4.7	<0.001	
			SMBP + Clinic Titration	197	128	-13				77	-9.1				
			SMBP + Home Titration	203	24 h 142	-9.9	4.9	2.5,7.4	<0.001	88	-7.1	2.9	1.4,4.4	<0.001	
			SMBP + Clinic Titration	197	141	-14.8				88	-10.0				
Stahl 1984[85] 6742256	167/109	7-12 mo	Family BP measured	77	nd	nd	nd	nd	nd	107	-16.7	3.4	nd	nd	C
			SMBP	125	nd	nd				110	-20.1				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.

Table D-42. Non-BP continuous outcomes: Atypical studies

Author Year PMID	Baseline BP[a], mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Kabutoya, 2009[65] 19695029	153/79	6 mo (6 mo)	No. of medications	SMBP + Graph	≤33	1.9 (1.0)	1.84 (3.74)	1.0	nd	<0.02[b]	C
				SMBP	≤32		0.86 (2.76)				
Den Hond 2004[94] 15564986	159/102	1 yr (1 yr)	Intensity of drug treatment[c]	SMBP + Home Titration	203	nd	1.03	-0.44	nd	0.001	A
				SMBP + Clinic Titration	197	nd	1.47				
Staessen 2004[84] 1498211	159/102	1 yr (1 yr)	Symptom score	SMBP + Home Titration	203	1.60	-0.10	0	nd	NS	A
				SMBP + Clinic Titration	197	1.52	-0.10				

BP = blood pressure; CI = confidence Interval; nd = no data; NS = not significant; P Btw = P-value between groups; SD = standard deviation; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] For difference in final values.
[c] Treatment scores are calculated by assigning a value of 1 to equipotent doses of various study medications as an annotation.

Table D-43. Categorical non-BP outcomes: Atypical studies

Author Year PMID	Baseline BP[a], mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	Inc	No Δ	Dec	Other	N Total	RR (95% CI) P-value Increase	No Δ	Decrease	Other	Study Quality
Staessen 2004[84] 1498211	159/102	1 yr (1 yr)	Pts who permanently stopped antihypertensive treatment	SMBP + Home Titration	53				203	2.34 (1.48, 3.69) P<0.001				A
				SMBP + Clinic Titration	22				197					
			Proportion of patients proceeding to multiple-drug treatment	SMBP + Home Titration	77				203	0.84 (0.66, 1.06) NS				
				SMBP + Clinic Titration	89				197					

Δ = change; BP = blood pressure; CI = confidence Interval; Dec = decrease; Inc = increase; NS = not significant; SMBP = self-measured blood pressure.

[a] Mean clinic blood pressure in control group, unless otherwise indicated.

Table D-44. Ongoing research on SMBP identified through ClinicalTrials.gov

NCT ID	Title	Recruitment	Interventions	Enrollment	Study Types	Study Designs
NCT00237692	Hypertension Intervention Nurse Telemedicine Study (HINTS)	Completed	*Behavioral:* Nurse Behavioral intervention with Home BP Telemonitoring *Behavioral:* Nurse Medication Management with Home BP Telemonitoring *Behavioral:* Nurse Combined intervention with Home BP Telemonitoring	591	Interventional	*Allocation:* Randomized *Control:* Active Control *Endpoint Classification:* Efficacy Study *Intervention Model:* Factorial Assignment *Masking:* Open Label *Primary Purpose:* Treatment
NCT00781365	Home Blood Pressure Telemonitoring and Case Management to Control Hypertension	Recruiting	*Other:* Telemonitors and pharmacy management	450	Interventional	*Allocation:* Randomized *Intervention Model:* Parallel Assignment *Masking:* Open Label *Primary Purpose:* Prevention
NCT00935441	Effect of Case-Management Using Home Monitoring on Diabetes and Blood Pressure Outcomes	Recruiting	*Behavioral:* case management with telemonitoring *Behavioral:* usual case management	460	Interventional	*Allocation:* Randomized *Control:* Active Control *Endpoint Classification:* Efficacy Study *Intervention Model:* Parallel Assignment *Masking:* Open Label *Primary Purpose:* Treatment
NCT01145742	Controlling Hypertension in Diabetes- Feasibility Study	Completed	*Behavioral:* home health/primary care collaboration	56	Interventional	*Allocation:* Randomized *Intervention Model:* Single Group Assignment *Primary Purpose:* Health Services Research
NCT01300338	Blood Pressure Telemonitoring and Goal Blood Pressure in Diabetes	Not yet recruiting	*Device:* blood pressure with telemetry *Device:* Home blood pressure monitor without telemetry	50	Interventional	*Allocation:* Randomized *Control:* Active Control *Endpoint Classification:* Efficacy Study *Intervention Model:* Parallel Assignment *Masking:* Open Label *Primary Purpose:* Health Services Research

NCT ID	Title	Recruitment	Interventions	Enrollment	Study Types	Study Designs
NCT01035554	Behavioral Study to Control Blood Pressure	Recruiting	*Other:* Self-Paced Programmed Instruction (SPPI) *Device:* Home Blood Pressure Monitor *Other:* Usual Care *Other:* Printed Materials	250	Interventional	*Allocation:* Randomized *Endpoint Classification:* Efficacy Study *Intervention Model:* Parallel Assignment *Masking:* Single Blind (Outcomes Assessor) *Primary Purpose:* Treatment
NCT00921791	Efficacy of Home Blood Pressure Monitoring (MONITOR Study)	Completed	*Device:* HBPM *Device:* HBPM and Pharmaceutical care *Behavioral:* Pharmaceutical care *Other:* Usual care	136	Interventional	*Allocation:* Randomized *Endpoint Classification:* Efficacy Study *Intervention Model:* Factorial Assignment *Masking:* Single Blind (Outcomes Assessor) *Primary Purpose:* Treatment
NCT00662753	A Study in the Use of Home Blood Pressure Monitoring and Telephone Follow-up to Control Blood Pressure	Recruiting	*Device:* Home blood pressure monitor *Other:* monitor and phone call	150	Interventional	*Allocation:* Randomized *Endpoint Classification:* Efficacy Study *Intervention Model:* Parallel Assignment *Masking:* Open Label *Primary Purpose:* Treatment
NCT00334724	Home Blood Pressure-guided Antihypertensive Intervention for Elderly (HBP-GUIDE) Study	Completed	*Procedure:* Home blood pressure measurement *Procedure:* Office blood pressure measurement	200	Interventional	*Allocation:* Randomized *Control:* Active Control *Endpoint Classification:* Safety/Efficacy Study *Intervention Model:* Parallel Assignment *Masking:* Double Blind (Investigator, Outcomes Assessor) *Primary Purpose:* Treatment
NCT01123577	Evaluation of Integrating Self Blood Pressure Monitoring Into Urban Primary Care Practices	Enrolling by invitation	*Other:* Home Blood Pressure Monitor Group *Other:* Control Group	996	Interventional	*Allocation:* Randomized *Intervention Model:* Parallel Assignment *Masking:* Open Label *Primary Purpose:* Treatment

NCT ID	Title	Recruitment	Interventions	Enrollment	Study Types	Study Designs
NCT00123058	Comparison of Two Programs to Improve Blood Pressure Treatment Adherence	Active, not recruiting	*Behavioral:* Health Education Program *Device:* BP Monitor	636	Interventional	*Allocation:* Randomized *Control:* Active Control *Endpoint Classification:* Efficacy Study *Intervention Model:* Factorial Assignment *Masking:* Single Blind (Outcomes Assessor) *Primary Purpose:* Treatment
NCT00514800	Home Blood Pressure Monitoring Trial	Recruiting	*Behavioral:* Intervention - a validated home BP monitor and support from the specialist nurse *Behavioral:* Control - usual care (BP monitoring by their practice)	360	Interventional	*Allocation:* Randomized *Control:* Active Control *Endpoint Classification:* Efficacy Study *Intervention Model:* Parallel Assignment *Masking:* Single Blind (Outcomes Assessor) *Primary Purpose:* Prevention
NCT00211666	Improving Hypertension Control in East and Central Harlem	Completed	*Behavioral:* Nurse management, home blood pressure monitors, and a chronic disease self management course.	480	Interventional	*Allocation:* Randomized *Control:* Active Control *Endpoint Classification:* Efficacy Study *Intervention Model:* Single Group Assignment *Masking:* Open Label *Primary Purpose:* Treatment
NCT00968786	Home Monitoring in the Management of Hypertension and Diabetes Mellitus	Enrolling by invitation	*Device:* Home monitoring	100	Interventional	*Allocation:* Randomized *Intervention Model:* Parallel Assignment *Masking:* Single Blind (Subject) *Primary Purpose:* Prevention
NCT00299468	The Effect of the Patient Activation Measure on Chronic Care	Completed	*Behavioral:* Patient Activation Measure Intervention Package	283	Interventional	*Allocation:* Randomized *Control:* Active Control *Endpoint Classification:* Efficacy Study *Intervention Model:* Single Group Assignment *Masking:* Open Label *Primary Purpose:* Treatment

NCT ID	Title	Recruitment	Interventions	Enrollment	Study Types	Study Designs
NCT01155050	Louisiana State University Health Care Services Division (LSUHSCD) Tele-Health Projects: Weight Loss in Chronic Disease Patient Population	Recruiting	*Device:* Tele-health Home Monitoring *Behavioral:* TrestleTree Telephone Coaching *Device:* Tele-health Home Monitoring Plus Trestle Telephone Coaching	240	Interventional	*Allocation:* Randomized *Control:* Active Control *Endpoint Classification:* Efficacy Study *Intervention Model:* Single Group Assignment *Masking:* Open Label *Primary Purpose:* Health Services Research
NCT01282957	Way to Health, Healthy Measures	Enrolling by invitation	*Behavioral:* Financial Incentive Group I *Behavioral:* Financial Incentive Group II	60	Interventional	*Allocation:* Randomized *Control:* Active Control *Intervention Model:* Parallel Assignment *Masking:* Open Label *Primary Purpose:* Health Services Research
NCT00202137	Home Blood Pressure Monitoring and Blood Pressure Control	Completed	*Behavioral:* Home blood pressure monitoring *Behavioral:* Physician monitoring of blood pressure	597	Interventional	*Allocation:* Randomized *Control:* Active Control *Endpoint Classification:* Efficacy Study *Intervention Model:* Parallel Assignment *Masking:* Open Label *Primary Purpose:* Treatment
NCT01233193	The Effect of Pharmacist Intervention on Blood Pressure Control	Active, not recruiting	*Behavioral:* Health education, Home blood pressure monitoring	140	Interventional	*Allocation:* NonRandomized *Endpoint Classification:* Efficacy Study *Intervention Model:* Parallel Assignment *Masking:* Open Label *Primary Purpose:* Supportive Care
NCT00802152	Using Health Information Technology (HIT) to Improve Ambulatory Chronic Disease Care: Smart Device Substudy	Active, not recruiting	*Device:* In-home "smart" diagnostic devices	108	Interventional	*Allocation:* Randomized *Endpoint Classification:* Efficacy Study *Intervention Model:* Parallel Assignment *Masking:* Open Label *Primary Purpose:* Treatment

NCT ID	Title	Recruitment	Interventions	Enrollment	Study Types	Study Designs
NCT01167920	Virtual Hypertension Clinic	Active, not recruiting	*Other:* Virtual Hypertension Clinic	74	Interventional	*Allocation:* Randomized *Endpoint Classification:* Efficacy Study *Intervention Model:* Parallel Assignment *Masking:* Open Label *Primary Purpose:* Treatment
NCT00233220	Blood Pressure Control in African Americans	Recruiting	*Behavioral:* Multicomponent, multi-level intervention targeted at physicians and patients *Behavioral:* Usual Care	990	Interventional	*Allocation:* Randomized *Intervention Model:* Parallel Assignment *Masking:* Open Label *Primary Purpose:* Treatment
NCT00760110	A Cohort Study of Morning Home Blood Pressure Measurement in Type 2 Diabetic Patients	Completed	*Device:* blood pressure measurements based on HBP or CBP	400	Observational	*Observational Model:* Cohort *Time Perspective:* Prospective
NCT00224861	Hypertension Telemanagement in African Americans	Completed	*Behavioral*: Self-Management *Behavioral*: Adherence	nd	Interventional	*Allocation*: Randomized *Primary Purpose*: Treatment
NCT01013857	Treating to Target for Patients With Hypertension	Active, not recruiting	*Behavioral*: Health coaching *Behavioral*: Health coaching plus home titration	240	Interventional	*Allocation*: Randomized *Endpoint Classification*: Efficacy Study *Intervention Model*: Parallel Assignment *Masking*: Open Label *Primary Purpose*: Treatment

Search was conducted on 03/21/2011.

BP = blood pressure; CBP = clinic blood pressure; HBP = home blood pressure; HBPM = home blood pressure monitoring; nd = no data; SPPI = Self-Paced Programmed Instruction.