Draft Comparative Effectiveness Review

Number XX (Provided by AHRQ)

Comparative Effectiveness Review of Self-Measured Blood Pressure Monitoring

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Contract No. [REDACTED]

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Suggested Citation: pending

None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.

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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 State Children's Health Insurance Program (SCHIP).

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 http://effectivehealth care.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 e-mail list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

Acknowledgements

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Appendixes cited in this report are available at http://ahrq.gov/XXXXX **[AHRQ will supply the rest of the information for this statement.]**

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 or without SMBP monitoring, and to evaluate the effectiveness of different additional support interventions in combination with SMBP. Also, to determine the 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: For questions regarding comparative effectiveness, we included prospective comparative studies of SMBP with or without additional support versus usual care or an alternative SMBP intervention. Only studies that used arm (not wrist) monitors for at least 8 weeks were reviewed. We excluded studies of pregnant women or people on hemodialysis. For adherence predictors, longitudinal cohort studies were also included.

Data extraction: A standardized protocol was used to extract details on design, patients, interventions, outcomes, and quality.

Data synthesis: In total, 44 studies met eligibility criteria (38 compared SMBP with or without additional support versus usual care, 12 compared different SMBP interventions, and one evaluated adherence predictors). For SMBP alone versus usual care, the strength of evidence is moderate and supports a small improvement in BP with SMBP. For SMBP plus additional support versus usual care, the strength of evidence is high and supports a small improvement in BP with SMBP use. In studies of both SMBP plus additional support and alone versus usual care, for non-BP clinical, surrogate, and intermediate outcomes, as well as for health care encounters, the strength of evidence is low and fails to support a difference. For SMBP plus additional support versus SMBP alone or with less intense additional support, the strength of evidence is low and fails to support a difference for all outcomes. 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. Studies were generally of moderate to poor quality and often had short followup periods, high dropout rates, and poor analyses and reporting. No studies evaluated children.

Conclusions: SMBP with or without additional support results in a small reduction in BP compared with usual care. The evidence does not support an incremental effect of generic additional support, but the great variety of specific additional support interventions tested precludes any definitive conclusion as to their individual benefits. The evidence is weak or insufficient for other outcomes, generally failing to support a difference between SMBP and usual care, or among different SMBP interventions.

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 health 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 goal of 130/80 mmHg or less in patients with diabetes mellitus or chronic kidney disease.[1]

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 US 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 US 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 US.[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 pateint'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]

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.[21] 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.[22-24] 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). Although many SMBP devices are commercially available, few have been independently validated as recommended by the American Association of Medical Instrumentation or the British Hypertension Society.[21] Patients may require some instruction on how to use SMBP devices.[25,26]

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.

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.

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[22]

SMBP is being used to avoid undertreatment of hypertension. SMBP monitoring can provide more frequent BP readings and if these are trasmitted 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.[27]

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 usefulto avoid 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.[28] 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 there is a decades-long lag between improved BP control and better clinical outcomes.

Statement of Work

In light of the potential health care benefits and knowledge gaps highlighted above, a topic entitled “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.[29]

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[21]), 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 to usual care or other interventions without SMBP, have an effect on clinically important outcomes?
    a. How does SMBP monitoring compare to 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 to 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)?
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?

* Left ventricular hypertrophy, left ventricular mass, left ventricular mass index.

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 1**) 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.

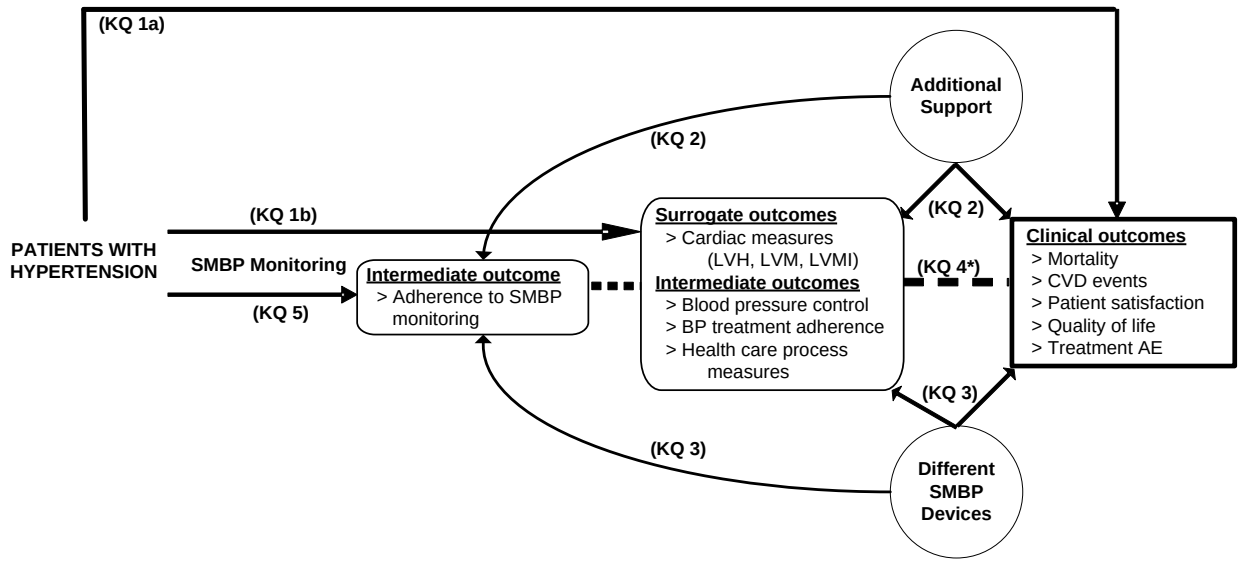
Literature Search

We conducted literature searches of studies in MEDLINE® (inception – September 2010) and both the Cochrane Central Trials Registry®, and Cochrane Database of Systematic Reviews® (through 2nd Quarter, 2010). [This search will be updated in April 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. 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 and 2010 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). [Abstracts from the March 2011 meeting of the American College of Cardiology will also be screened during the literature search update.] 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.

Figure 1. 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 the health outcomes, in addition to the surrogate outcome cardiac measures.

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.[30] 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, 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 vs <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 (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 (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.[31] 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.[32] 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.[33,34]

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.[31] 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

[To be added after peer review]

Results

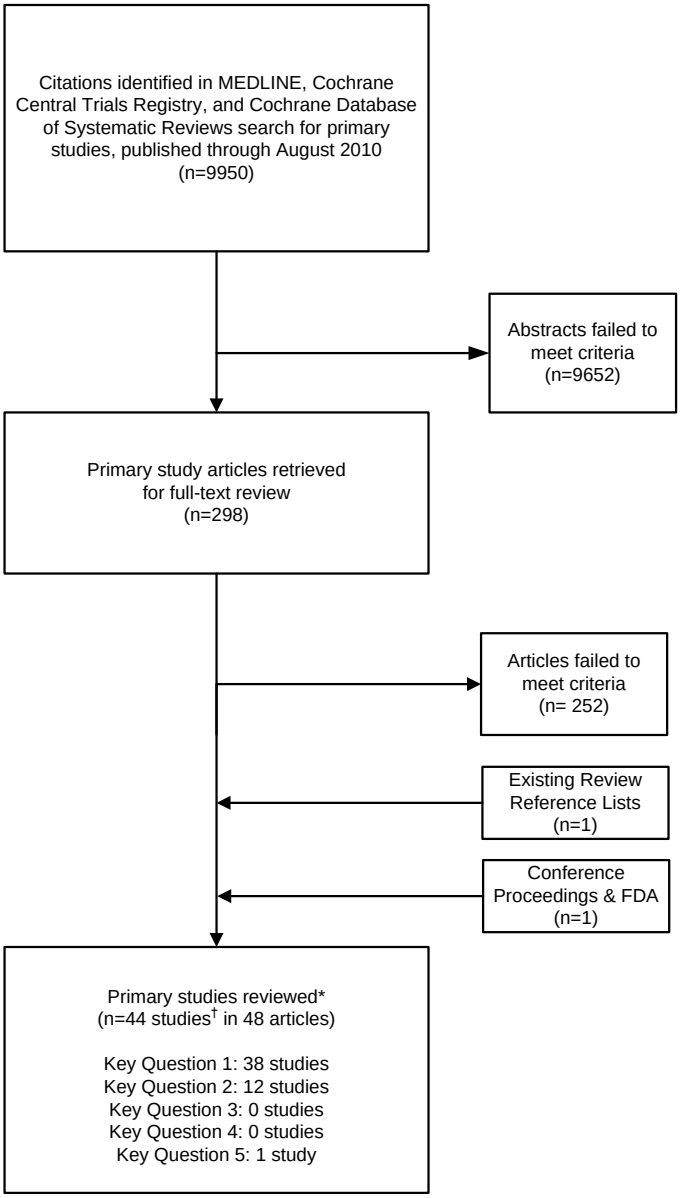
The literature search yielded 9550 citations. From these, 298 articles were provisionally accepted for review based on abstracts and titles (Figure 2). After screening their full texts, 42 studies, published in 46 articles, were judged to have met the inclusion criteria. One additional study was gleaned from reference lists of previous reviews. One conference abstract was also included from the grey literature search. Thus a total of 44 studies (in 48 articles) are reviewed herein.

The remaining 252 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 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 43 fully reported studies (excluding the one study published as an abstract) 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. Six studies provided no information on the device used; in six other studies, the information provided was insufficient to check validation. Twenty five studies described the monitor used as an automated device, two as a semiautomated device, and four as a manual device. In 22 studies it appeared that the device was accredited by at least one of the accreditation bodies although in five 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. Three studies claimed accreditation by 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. In the remaining 17 studies, there was no information on device accreditation.

Figure 2. Literature flow



FDA = Food and Drug Administration Web site.

* The numbers of studies for each Key Question do not sum to the total number of studies as 7 studies addressed both Key Questions 1 and 2.
† including one conference abstract.

Key Question 1

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

- **a. How does SMBP monitoring compare to 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 to 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)?**

*** LVH, left ventricular hypertrophy; LVM, left ventricular mass; LVMI, left ventricular mass index.**

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 writeup) are summarized in Table 1 (descriptions of the interventions) and Table 2 (descriptions of the study characteristics).

Comparison of SMBP alone versus usual care

We identified 22 studies (reported in 23 articles) that contributed data to the comparison of SMBP monitoring alone versus usual care.[20,35-56] These studies have been published over the past 35 years (1975 to 2010), with seven published before 1990. Of the 22 identified studies, 19 concerned comparisons of SMBP alone versus usual care, and five [36,37,41,45,51] 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. 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 24 comparisons were considered.

Of the 22 examined studies, 20 were randomized controlled trials (RCTs) and two were quasi-RCTs (Pierce 1984; Stahl 1984). Of the 20 RCTs, one was of a crossover design (Fitzgerald 1985) and the remaining were parallel group studies. Two of the trials (Dalfo i Baque 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 (nine 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 1). 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.

Eighteen studies included patients with hypertension irrespective of whether these patients were on antihypertensive treatment at study enrollment (Table 2). Three studies [43,45,46] 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). Twelve of the 22 studies explicitly defined that the patients included had essential hypertension, whereas the remaining ten studies [20,36-39,41,45-47,50,54] 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 22 studies. The sample sizes of the intervention groups of interest in the included studies ranged from 12 to 1325 patients (total = 5122 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, five studies were rated quality B, and 13 quality C. 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 21 studies (23 comparisons in total). Four studies were rated quality A, four studies were rated quality B, and 13 quality C. 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 h, awake, and asleep) BP measurements were reported.

Categorical BP outcomes (Table 3, Figure 3)

Twelve studies reported categorical BP outcomes.[20,37,40,41,44,46,48,49,51,52,54,57] 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 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] 0.94-1.63), 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 Baque 2005, which reported a nonsignificant odds ratio (OR) of 0.79 (95 percent CI 0.56-1.12) favoring usual care.

Three RCTs 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 0.95-1.46) 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.

Three 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, 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. Neither Pierce 1984 nor Stahl 1984 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 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 1.13-5.64) and DBP (OR 2.32; 95 percent CI 1.05-5.15).

Continuous BP outcomes

In total, 19 studies provided data for continuous BP outcomes.[20,35-39,41-46,48-50,52-54,56]

Clinic BP (Table 4, Figure 4)

Sixteen 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 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 and nine RCTs for DBP. 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 non significant net changes in DBP favoring usual care over SMBP.

For the 12-month followup data, six RCTs were synthesized by meta-analysis (three of them having also contributed data for the 6 month meta-analysis). In the 12-month meta-analysis, statistically significant net change was evident only for SBP: SBP summary net change = -2.0 mmHg (95 percent CI -3.8, -0.2; P = 0.027), with moderate heterogeneity (I^2 = 40 percent). The summary estimate for the net change in DBP, however, was no longer significant: DBP summary net change = -1.3 mmHg (95 percent CI -2.9, 0.3), with high heterogeneity (I^2 = 78 percent).

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 5, Figure 5)

For the net change in 24 h ambulatory BP measurement, four 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, two studies reported significant differences in SBP measurements between SMBP monitoring and usual care but in different directions. Bailey 1999 showed a significant net change of +7 mmHg and Rogers 2001 reported a significant net change of -4.8 mmHg. A similar divergence of results was also observed for the two studies reporting 12 month followup data, Goodwin 2010 and Verbek 2007, with the Goodwin study showing a significant net change in DBP favoring SMBP (-2.0 mmHg), whereas the Verbek study reported that the 24 h 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 6, Figure 6)

Five 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) and for both SBP and DBP by Verberk 2007 (12 months). In all cases the results were in favor of usual care.

Asleep (or night) ambulatory BP (Table 7, Figure 7)

A similar pattern of results was also observed for the net change in asleep ambulatory BP in four studies, 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.

Medication dosage (Tables 8&9)

Seven studies provided data on outcomes relating to the number of medications prescribed and dosage (1 quality A, 4 quality B, and 2 quality C).[35,44,47,50,51,55,56] The followup duration in these studies ranged from 2 to 12 months. Reported medication outcomes included both categorical outcomes (Table 8), 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 9), which included number of medications and dosages. Due to the heterogeneity in outcome definitions between studies, no meta-analyses were feasible.

Five out of these seven studies reported categorical medication outcomes.[35,47,50,51,56] 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.[35,46,51] Three looked at medication inertia, defined as no change in medication regimen; none of the three found a difference between groups,[46,51,56]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.[35,51] 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.[44,47,55,56] Two compared the number of antihypertensive medications used per patient between SMBP and usual care groups; neither found a significant difference [47,56] 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 10&11)

Seven studies in total provided data on outcomes relating to medication adherence (3 quality B and 4 quality C).[35,38,48,49,51,55,56] Followup durations in these studies ranged from 2 to 12 months. Reported medication outcomes included both categorical outcomes (Table 10), where the outcomes were defined as the number of patients with a specified level of medication adherence, and continuous outcomes (Table 11), where adherence was measured on a continuous scale (e.g. tablet count).

Five of these seven studies reported categorical medication adherence outcomes.[35,38,48,51,55] 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) and were more likely to take medication at the prescribed time (RR 1.1; 95 percent CI 0.97, 1.24; P = 0.006). 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.[48,49,55,56] 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). Zarnke 1997 found no difference between SMBP with self-titration versus usual care in the number of drug doses missed.

Quality of life (Table 12)

Three studies provided data on outcomes relating to quality of life (2 quality B and 1 quality C).[38,47,49] 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 13&14)

Five studies provided data on outcomes relating to health care encounters (1 quality A, 2 quality B, and 2 quality C).[35,49,50,53,56] 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 five studies provided continuous data on health care encounters.[35,49,50,53,56] Two of these found no difference in the number of visits with a primary care or an otherwise unspecified provider[35,49], while two found no difference in the number of visits specifically related to hypertension.[50,53]. 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). 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). Midanik 1991 and Soghikian 1992 both looked at the number of hypertension-related telephone calls made by study subjects, and found no difference between groups. In Soghikian 1992, the difference remained nonsignificant after adjusting for the aforementioned factors (i.e., age, race, etc.).

Miscellaneous outcomes (Table 15)

Two studies reported miscellaneous outcomes.[20,40] 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

Among the studies examining BP outcomes, three (Broege 2001, Godwin 2010, Madsen 2008) performed subgroup analyses to examine how patient characteristics might affect BP outcomes. However, none of these studies performed a formal test for treatment-by-subgroup interactions, and thus inferences for any differences in effects across subgroups were evaluated qualitatively. 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 h ambulatory and clinic DBP favoring SMBP monitoring in men (no significant net changes were observed in women).

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 Baque 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. A small number of studies displayed nonstatistically significant effect estimates in the opposing direction, favoring usual care; however, these studies had small sample sizes and 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-one studies (four quality A, four quality B, 13 quality C) 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. 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 attenuated in the meta-analysis of studies at 12 months followup: the summary net change was significant only for SBP (-2.0 mmHg), whereas the summary net change for DBP (-1.2 mmHg) was not statistically significant. These summary estimates at 6 and 12 months were derived from syntheses of studies that included one quality A study and four quality B studies. The comparisons of SMBP with usual care for the outcomes of ambulatory BP measurements (24 h, awake, and asleep) were based on a small number of studies that were not subjected to meta-analysis. Individual studies reported contradictory results. 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.

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.

Non-BP clinical, surrogate, and intermediate outcomes

Seven (one quality A, four quality B, and two quality C) studies reported data related to the number of medications prescribed and dosage.[35,44,47,50,51,55,56] 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.[35,38,48,49,51,55,56] Studies were split: four found no difference between groups[35,38,49,56] while two reported significantly greater adherence in the SMBP group[48,51], 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[55] 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.[38,47,49] 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.

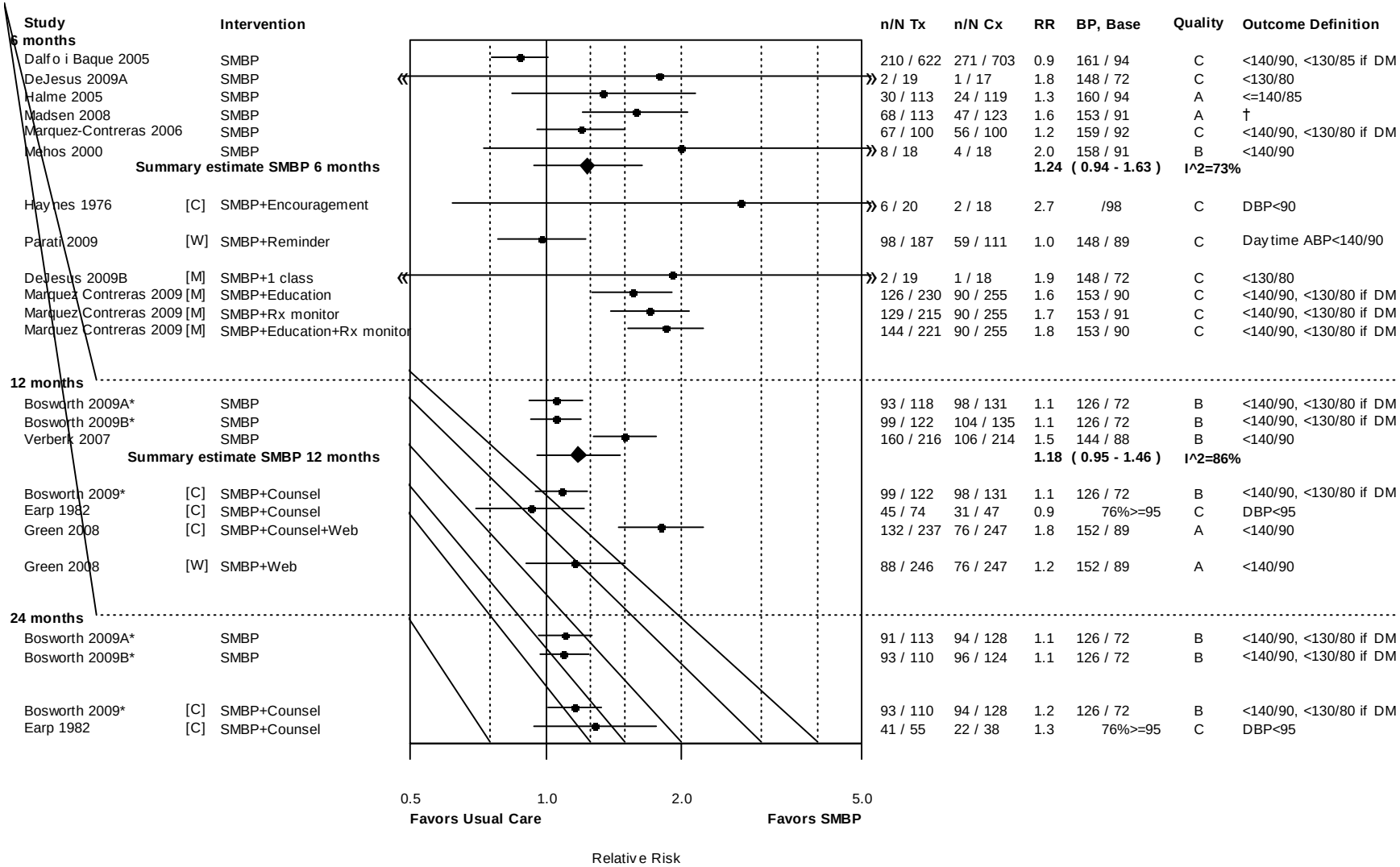
Evidence indicating no difference in patient satisfaction and left ventricular mass index is insufficient, as only one quality C and one quality B study, respectively, were found per outcome.[20,40]

Due to the inconsistency of findings, as well as heterogeneity of outcome definitions used, the strength of evidence for finding a difference between SMBP and usual care is rated as low across all non-BP clinical, surrogate and intermediate outcomes.

Health care encounters

Five studies (one quality A, two quality B, and two quality C) reported on health care encounter outcomes.[35,49,50,53,56] 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[56] and another trial found the SMBP group to have fewer visits.[53] 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 3. Forest plot, with meta-analyses, of relative risk of "adequate" BP at followup in RCTs of SMBP versus usual care, by time of outcome measurement



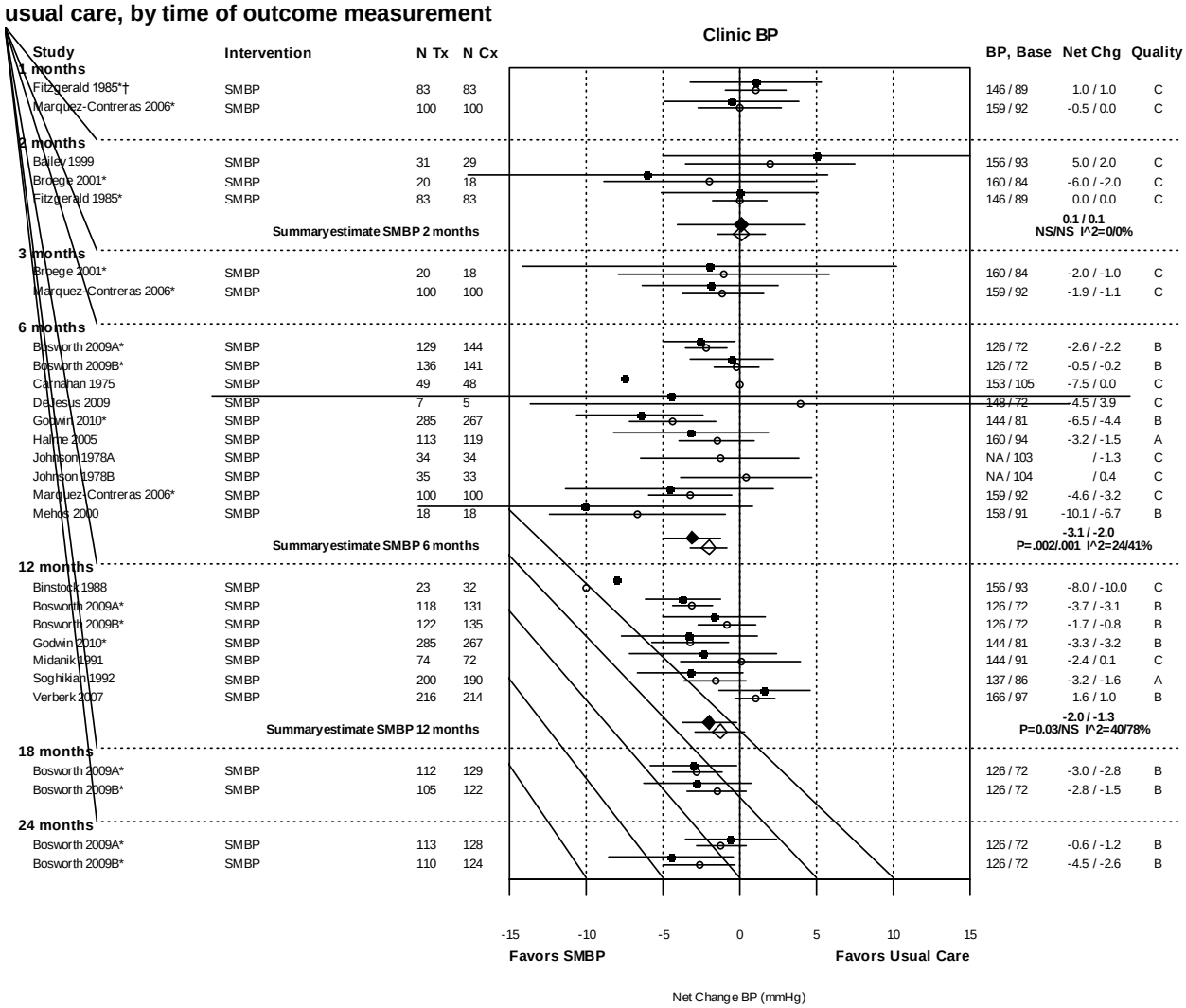
Black circles indicate relative risk for each study. Black diamonds indicate summary estimates of relative risk. Bold numbers in the right columns aligned with the summary estimates are the summary relative risk, their P values, and the I^2 measures of statistical heterogeneity. The letters in brackets to the left of interventions with additional support refer to the categories in Table 27.

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 (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, SMBP = self measured blood pressure monitoring.

* 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[37] Both groups had behavioral intervention (control group is really behavioral intervention group).
DeJesus 2009A[41] Both groups had education (control group is really education group).
Earp 1982[58] Both groups had home visits.

Figure 4. Forest plot, with meta-analyses, of net change clinic BP in RCTs of SMBP monitoring 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 I^2 measures of statistical heterogeneity. Studies without 95% 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.
† 6 weeks

Notes:
Binstock 1988[36] Both groups had education.
Bosworth 2009B[37] Both groups had behavioral intervention (control group is really behavioral intervention arm).
Broege 2001[38] Average during month 2.
DeJesus 2009A[41] Both groups had education (control group is really education arm).

Figure 5. Forest plot of net change 24 hour ambulatory BP in RCTs of SMBP monitoring versus usual care, by time of outcome measurement

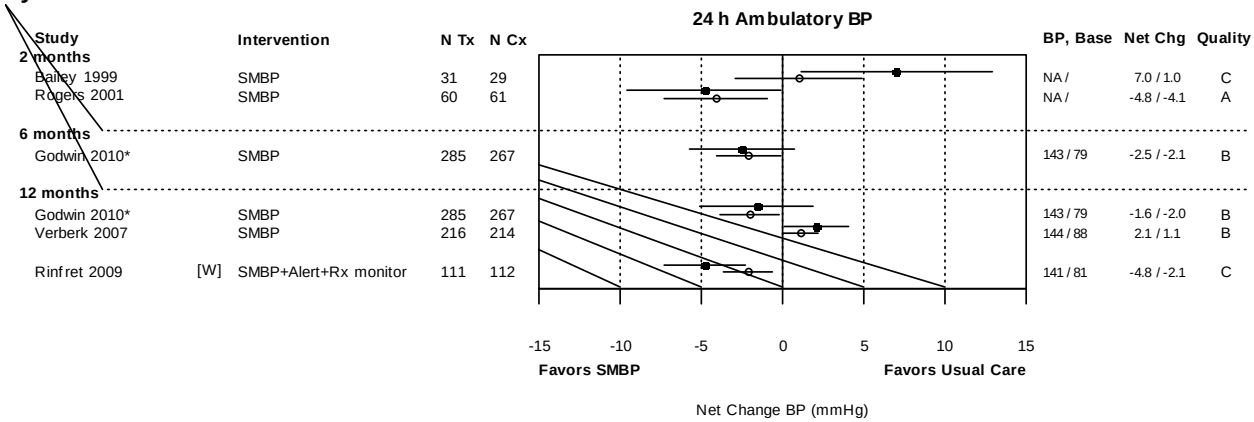


Figure 6. Forest plot of net change awake (day) ambulatory BP in RCTs of SMBP monitoring versus usual care, by time of outcome measurement

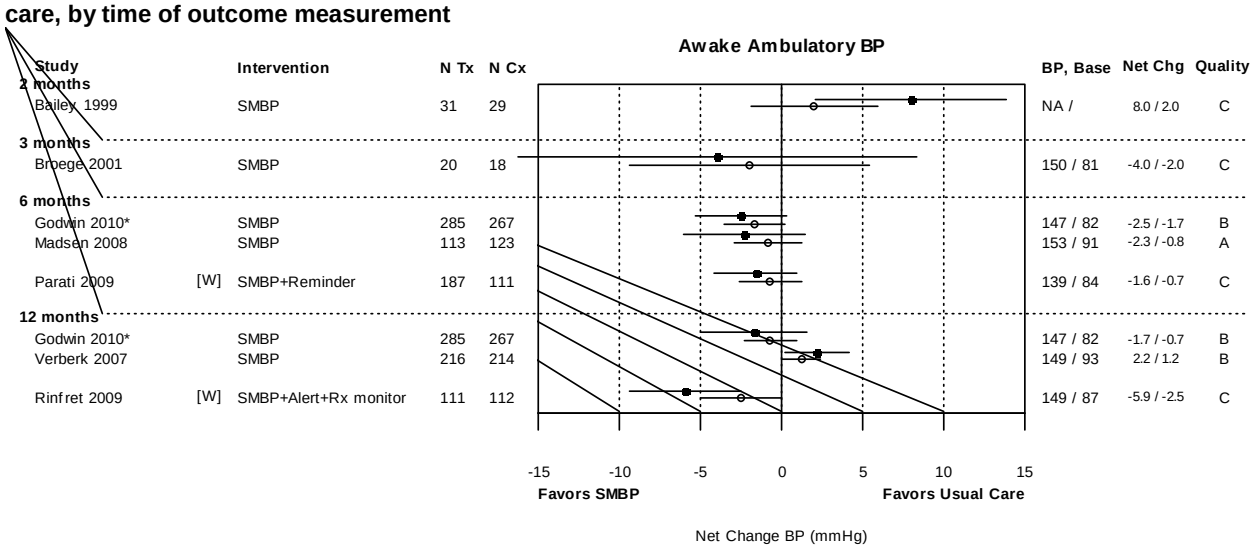
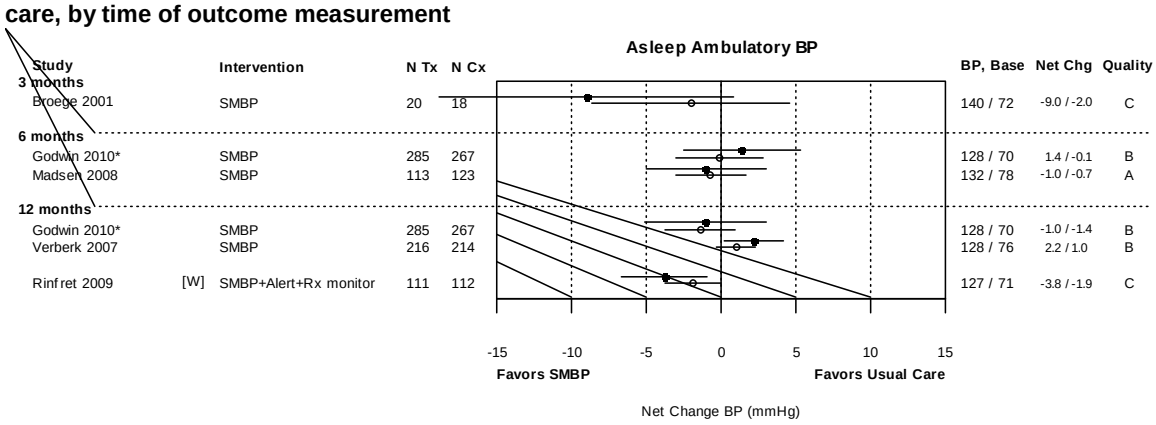


Figure 7. Forest plot of net change asleep (night) ambulatory BP in RCTs of SMBP monitoring versus usual care, by time of outcome measurement



Figures 5-7:
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 27.

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.

Notes (for figures 5-7):
Bailey 1999[35] Difference of final values (not net change).
Godwin 2010[43] Difference of final values (not net change).

Table 1. 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[59] 11343005	SMBP + Counsel	Telecounseling[a]	BPLink UA 767PC (Automated)	3x/wk	Electronic transmission	nd	Community center 3x/wk	Physician
	Usual Care							
Bailey 1999[35] 10100064	SMBP		Omron HEM 706 (nd)	2x/d	nd	nd	0, 8 wk	Physician
	Usual Care							
Binstock 1988[36] 3415798	SMBP + Contract + Rx monitor + Education	Compliance contracts[b]+ Calendar pill packs + Education[c]	nd	nd	nd	nd	0, 12 mo	nd
	SMBP + Education	Education[c]						
	Education	Education[c]						
Bosworth 2009[37] 19920269	SMBP + Counsel	Telecounseling[d]	Omron HEM-773AC[e] (Automated)	3x/wk	Mailed every 2 mo	Clinic<140/90 (<130/80 DM)	0, 6, 12, 18, 24 mo	Physician
	SMBP							
	Counsel	Telecounseling[d]						
	Usual care							
Broege 2001[38] 11518836	SMBP		Omron HEM-702 (Semi-automated)	Every 2 d	Study nurse phoned every 2 wk	Home<150/90	Every mo for 3 mo[f]	Physician
	Nurse BP			Every 2 wk		Clinic<150/90	Every 2 wk	
Carnahan 1975[39] 1130437	SMBP		Ultrasphyg, Lumiscope company (Semi-automated)	2x/d		Clinic DBP<90	Every mo	Nurse
	Usual care							
Dalfo i Baque 2005[40] 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							

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	BP Transmission	Target BP, mmHg	Clinic or Study Visit Frequency	Medication Titration
DeJesus 2009[41] 19756162	SMBP + 1 Class	1 Class education[g]	Life Source UA-767 Plus (Automated)	nd	Patient recorded	Clinic<130/80	0, 6 mo	nd
	1 Class	1 Class education [g]						
	Usual Care							
Earp 1982[58] 7114339	SMBP[h] + Counsel	In-home counseling[i]	nd	1/d or several times/wk	Brought to office	Clinic DBP<95	0, 12, 24 mo	nd
	Counsel	In-home counseling[i]						
	Usual Care							
Fitzgerald, 1985[42] 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[60] 8722429	SMBP + Telecounseling	Telecounseling[j]	Omron Health Care (Automated)	1x/wk	Phone-linked computer system	nd	0, 6 mo	Physician
	Usual Care							
Godwin 2010[43] 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[61] 1891656	SMBP + Lifestyle interventions	Lifestyle interventions[k]	Tensomat, Ortho Konsult AB (nd)	14x/mo	nd	Clinic DBP≤90	0, 12, 24 mo	Physician
	Usual Care							
Green 2008[62] 18577730	SMBP + Counsel + Web	Pharmacist counseling + Personalized website[l]	Omron HEM-705CP (Automated)	≥2x/wk	Emailed to physician	Home<135/85	0, 12 mo	Pharmacist and Physician
	SMBP + Web	Personalized website[h]						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
Halme 2005[44] 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[m]	Nelkin 204M and separate stethoscope (Manual)	1/d	Brought to office	Clinic DBP<90	0, 6 mo	Physician
	Usual Care							
Johnson 1978[45] 369673	SMBP + Home visit BP	Home visitor BP measurement[n]	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[n]						
	Usual Care							
Madsen 2008[46] 18568696	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
Madsen 2008[47] 18815937	Usual care					Clinic<140/90 (<130/80 DM)		
Marquez-Contreras 2006[48] 16331115	SMBP		Omron M4 (Automated)	3x/wk	Patient recorded on a card	Clinic<140/90	4 visits	Physician
	Usual Care							
Marquez-Contreras 2009[64] 19482378	SMBP + Education + Rx monitor	Educational materials[o] + Medication monitoring[p]	Omron (nd)	3x/wk	Brought to office	Clinic<140/90 (<130/80 DM)	0, 3, 6 mo	Physician
	SMBP + Rx monitor	Medication monitoring[p]			Special card			
	SMBP + Education	Educational materials[o]			Special card			
	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
McManus 2010[65] 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[q]
	Usual care					Clinic <140/90	Minimum annual visit	Physician
Mehos 2000[49] 11079287	SMBP[r]		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[50] 1899945	SMBP		Tycos Self-Check digital device (Automated)	2x/wk	Mailed every 4 wk	nd	0, 12 mo	Physician
	Usual care							
Muhlhauser 1993[67] 8467308	SMBP + Education	Education[s]	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[68] 19145785	SMBP + Reminder	Reminder[t]	Tensiophone device, Tenisiomed Budapest (Automated)	nd	Electronic transmission	Home<135/85	0, 2, 4, 12, 24 wk	Physician
	Usual Care					Clinic<140/90		
Park 2009[69] 19643661	SMBP + Web+ Counsel	Personalized website + Nurse counseling [u]	nd	nd	Electronic transmission	nd	0, 8 wk	Physician
	Usual Care							
Pierce 1984[51] 6377291	SMBP + Education	Education[v]	Aneroid sphygmomanometer (Manual)	1x/d	Brought to office	nd	0, 6 mo	Physician
	SMBP							
	Education	Education[v]						
Rinfret 2009[70] 20031834	SMBP + Alert + Rx monitor	Provider alert + Medication monitoring[w]	Omron HEM-711AC (Automated)	nd	Electronic transmission 1x/wk	Clinic<140/90	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
Rogers 2001[52] 113888152	SMBP		Welch Allyn Model 52500 (Automated)	3x/wk for minimum 8wk	Electronic transmission 1x/wk	nd	nd	Physician
	Usual Care							
Rudd 2004[71] 15485755	SMBP + Counsel	Telecounseling[x]	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[72] 8557972	SMBP + Education + Self-titration	Education[y]+ 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[73] 16221935 Shea 2007[74] 18528511 Shea 2009[75] 19390093	SMBP + Web+ Counsel	Personalized website + Videoconference counseling[z]	UA-767 (Automated)	nd	Transmitted electronically	nd	0, 12 mo	Physician
	Usual Care							
Soghikian 1992[53] 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							
Stahl 1984[54] 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[55] 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

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	BP Transmission	Target BP, mmHg	Clinic or Study Visit Frequency	Medication Titration
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[56] 9008249	SMBP		Marsall 85 oscillometric, Omron (Semiautomated)	2x/d	Patient recorded in a diary	nd	0, 8 wk	Patient per protocol[aa] Physician
	Usual Care							Physician
Zillich 2005[76] 16423096	SMBP + Counsel	Pharmacist counseling[bb]	OmronHEM-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[cc]	BP measured in the pharmacy	4x in 3 mo	Brought to office (log book)			

a Weekly phone counseling by trained nurse on lifestyle modification and medication adherence
b 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.
c Bimonthly educational program by clinical nurse on hypertension and Rx options
dBimonthly 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.
eOmron HEM-637 wrist monitor, if arm circumference >17 inches and wrist circumference <8.5 inches.
fClinic BP not used to make medication decisions.
g One-time class by DM educator focusing on hypertension in diabetes
hSignificant other BP monitoring: 50% chose spouse, 25% son or daughter, 7% chose nonrelative as "significant other".
i In home counseling was done by nurse or pharmacist (5-6 visits)
jPhone-linked computer counseling once/wk (~4 min) with BP input by patient. BP data transmitted to patient' physicians with clinically significant information highlighted.
k 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
lWeb services for medication refill, appointments, view portions of their medical record and secure messaging to contact health care team members.
m Every 2 wk in-person review of BP values of medication compliance by a high school graduate and encouragement for better BP control
n Home visits every 1 mo to check BP
oPatient education kit (leaflets) on general aspects of hypertension and compliance promotion.
pCard for BP measurements recording and medication reminder.

qAfter 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.
rClinical pharmacist contacted each patient monthly by phone to evaluate BP response. If mean monthly > target, physicians were informed and treatment adjusted as needed.
s Four consecutive weekly class taught by physician assistants; education on hypertension and nondrug treatment
t Auto-electronic BP (phone) load with electronic reminders. If extreme BP values a nurse called the patient.
[u]Medication and lifestyle modification info during visit by nurse and Internet monitoring weekly (patient input BP data, education on diet, medications, exercise, etc)
vFour educational meetings on nonpharmacological approach to lower BP
w 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.
x 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.
yFour teaching sessions about hypertension, self-monitoring, nonpharmacological measures taught by a paramedic. Patients were instructed to titrate medications until normotensive.
z Auto-electronic BP upload. Nurse videoconferencing via web (no prespecified usage requirement) after reviewing BP and glucose data.
aaSelf-titration based on medication-specific algorithms. Thresholds for medication change of 160/95 mmHg x 2 wk or >110/70 mmHg x 1 wk.
bb 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.
cc. 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 2. Study characteristics: Key Question 1

Author Year PMID	Country (Enrollment Years)	Interventions*	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout†, % (Timepoint)	Other Quality Issues
Artinian 2001[59] 11343005	US (nd)	SMBP + Counsel Usual care	59	11.5	nd	Community	Urban African Americans, majority women	12% (3 mo)	Pilot study, unbalanced randomization
Bailey 1999[35] 10100064	Australia (nd)	SMBP Usual care	54	48	nd	General practice		3% (8 wk) 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
Binstock 1988[36] 3415798	US (nd)	SMBP + Contract + Rx monitor + Education SMBP + Education Education	nd	40	nd	nd		nd nd nd	No data frequency of SMBP and device type, sparse information on baseline characteristics, no statistical testing done, no information on dropouts
Bosworth 2009[37] 19920269	US (2004-05)	SMBP + Counsel SMBP Counsel Usual care	61	34	36	Hospital outpatient		31% (24 mo) 28% (24 mo) 22% (12 mo) 19% (24 mo)	Dropout rate, numbers in the figure do not always match the numbers reported in the text
Broege 2001[38] 11518836	US (nd)	SMBP Nurse BP	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.
Carnahan 1975[39] 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[40] 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[41] 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[58] 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

Author Year PMID	Country (Enrollment Years)	Interventions*	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout†, % (Timepoint)	Other Quality Issues
Fitzgerald, 1985[42] 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[60] 8722429	USA (nd)	SMBP + Tele + Counsel Usual care	77	21	16	Community	Older patients	11% (6 mo)	
Godwin 2010[43] 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[61] 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)
Green 2008[62] 18577730	US (2005)	SMBP + Counsel + Web SMBP + Web 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[44] 16280273	Finland (nd)	SMBP Usual care	57.1	35.3	15.1	Outpatient		13.8% (6 mo) 13.8% (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[45] 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.

Author Year PMID	Country (Enrollment Years)	Interventions*	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout†, % (Timepoint)	Other Quality Issues
Madsen 2008[46] 18568696 Madsen 2008[47] 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[48] 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[64] 19482378	Spain (2006-07)	SMBP + Education + Rx monitor SMBP + Rx Monitor SMBP + Education Usual care	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 Unclear what the educational or "card" interventions were. No data on specific monitor used
McManus 2010[65] 19220913 McManus 2010[66] 20619448	UK (2007-08)	SMBP + Alert + Self-titration Usual care	66.2	47	7	General practice		11% (12 mo) 7% (12 mo)	
Mehos 2000[49] 11079287	US (nd)	SMBP Usual care	58	38	22	Hospital outpatient clinic		10% (6 mo)	Randomization with a deck of cards. Uneven baseline characteristics between groups
Midanik 1991[50] 1899945	US (nd)	SMBP Usual care	47	53	nd	Hospital outpatient		27% (12 mo) 29% (12 mo)	High dropout rates, incomplete eligibility criteria
Muhlhauser 1993[67] 8467308	Germany (nd)	SMBP + Education Usual care	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.
Parati 2009[68] 19145785	Italy (nd)	SMBP + Reminder Usual care	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)

Author Year PMID	Country (Enrollment Years)	Interventions*	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout†, % (Timepoint)	Other Quality Issues
Park 2009[69] 19643661	South Korea (nd)	SMBP + Web + Counsel Usual care	55	43	nd	Outpatient	Obese	20% (2 mo) 16% (2 mo)	Not RCT
Pierce 1984[51] 6377291	Australia (1977-78)	SMBP + Education SMBP Education Usual care	58	38	nd	General practice		2% (12 mo)	Dropout>20%, compliance outcome by survey, lack of statistical comparisons between study groups
Rinfret 2009[70] 20031834	Canada (2004-07)	SMBP + Alert + Rx Monitor Usual care	57	54	10	Primary care		ABPM ≥16% Office ≥14% (12 mo) ABPM 22% Office 16% (12 mo)	Large dropout rates.
Rogers 2001[52] 113888152	US (1999-2000)	SMBP Usual care	60.3	55.7	26.3	Outpatient		0.7% (11 wk) 10% (11 wk)	Exact time point for outcome measurement by ABPM is not clear, at least 8 weeks, median 11 weeks.
Rudd 2004[71] 15485755	US (nd)	SMBP + Counsel Usual care	60	44	14	Outpatient		7% (6 mo) 10% (6 mo)	No adjustment for two clinics.
Sawicki 1995[72] 8557972	Germany (1984-87)	SMBP + Education + Self-titration Usual care	37	52	100	Tertiary care hospital	Type 1 DM with diabetic kidney disease	7% (60 mo) 4% (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.
Shea 2006[73] 16221935 Shea 2007[74] 18528511 Shea 2009[75] 19390093	USA (2000-02)	SMBP + Web + Counsel Usual care	70	37.9	100	Primary care physician	Diabetic, underserved	18% (12 mo) 52% (60 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
Soghikian 1992[53] 1518317	US (1984-85)	SMBP Usual care	54.7	50.2	nd	Hospital outpatient		7% (12 mo) 12% (12 mo)	
Stahl 1984[54] 6742256	US (nd)	SMBP Family BP	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]	Not RCT. Some potential for bias in randomization based on ability to self measure or availability of family.

Author Year PMID	Country (Enrollment Years)	Interventions*	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout†, % (Timepoint)	Other Quality Issues
Van Onzenoort 2010[55] 19952780	Netherlands (2001-05)	SMBP Usual care	57	49	7	Outpatient and general practice			No data about the drop out rate
Verberk 2007[20] 17938383	Netherlands (nd)	SMBP Usual care	55	55	nd	Hospital outpatient		19% (12 mo) 27% (12 mo)	Incomplete eligibility criteria , no power calculation
Zarnke 1997[56] 9008249	Canada (nd)	SMBP Usual care	52	36	nd	Community		nd 9% (2 mo)	Very small number of drug changes.
Zillich 2005[76] 16423096	US (nd)	SMBP + Counsel Pharmacist BP	66.1	61	20	Pharmacy		11% (3 mo) 2% (3 mo)	

* For details, see “Interventions” table (Table 1).
† 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.
nd = no data reported

Table 3. Categorical BP: SMBP alone versus usual care

Author Year PMID	Baseline BPa, mmHg	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Resultb	95% CI	P Btw	Study Quality
Bosworth 2009A[37] 19920269	124/70	12 moc	BP <140/90 mmHg (<130/80 DM)	SMBP	93d	118	RR	1.05	0.92, 1.21	NS	B
				Usual care	98d	131					
Bosworth 2009B[37] 19920269	124/71			SMBP + Counsel	99d	122	RR	1.05	0.93, 1.19	NS	
				Counsel	104d	135					
Dalfo i Baque 2005[40] 15802109	162/94	6 mo	BP <140/90 mmHg (<130/85 DM)	SMBP	210d	622	OR	0.79e	0.56, 1.12	NS	C
				Usual care	271d	703					
			SBP <140 mmHg (<130 DM)	SMBP	245d	622	RRf	1.15	0.95, 1.39g	NS	
				Usual care	242d	703					
			DBP <90 mmHg (<85 DM)	SMBP	427d	622	RRf	1.06	0.95, 1.18g	NS	
				Usual care	455d	703					
DeJesus 2009[41] 19756162	149/79	6 mo	BP <130/80 mmHg	SMBP + Education	2	19	RR	1.79h	0.18, 18.0	NS	C
				Education	1	17					
Halme 2005[44] 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[46] 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 BPi	SMBP	68	113	RR	1.57	1.20, 2.06	<0.001	
				Usual care	47	123					
Marquez-Contreras 2006[48] 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[49] 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[51] 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[52] 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					
Stahl 1984[54] 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					

[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 4. Clinic BP: SMBP alone versus usual care

Author Year PMID	Base BPa, 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[35] 10100064	155/95	7 wk	SMBP	31	156 (4b)	-8	+5	-4, 15c	<0.05	93 (2b)	-4	+2	-3, 7c	NS	C
			Usual care	29	155 (4b)	-13				95 (2b)	-6				
Binstock 1988[36] 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[37] 19920269	124/70	12 mo	SMBP	118	126 (15)	-5	-3.7d	-6.1, -1.2	0.004	72 (11)	-4	-3.1d	-4.4, -1.8	<0.001	B
			Usual care	131	124 (18)	0				70 (10)	0				
Bosworth 2009B[37] 19920269	124/71		SMBP + Counsel	122	126 (20)	-4.5	-1.7	-5.0, 1.6c	NS	72 (12)	-3.1	-0.8	-2.7, 1.1c	NS	
			Counsel	135	124 (18)	-1				71 (10)	-1.3				
Broege 2001[38] 11518836	144/82	3 mo	SMBP	20	165 (24)e	4	-2	-16.1, 12.1c	NS	84 (10)e	2	-1	-7.4, 5.4c	NS	C
			Nurse monitor	18	153 (25)e	6				87 (12)e	3				
Carnahan 1975[39] 1130437	157/104	6 mo	SMBP	49	152.7 (nd)	-18	-7.5	-14.9, -0.03f	<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[41] 19756162	149/79	6 mo	SMBP + Education	7g	145.4 (5.3)	-3.29	nd	nd	NS	68.4 (11.6)	5.71	nd	nd	NS	C
			Education	5g	156 (11.7)	1.2				78.8 (2.7)	1.8				
Fitzgerald, 1985[42] 4044205	146/89	9 wk	SMBP	83	146 (19.9)	(149)	(0)	-5, 5c	NS	89 (10.3)	(93)	(0)	-2, 2c	NS	C
			Clinic measure	83	146 (19.9)	(149)				89 (10.3)	(93)				
Godwin 2010[43] 20032170	144/81	12 mo	SMBP	285	144.0 (18.9)	(132.8)	(-3.3)	-7.7, 1.1h	NS	80.8 (10.8)	(75.1)	(-3.2)	-5.7, -0.7h	0.01	B
			Usual care	267	144.3 (16.1)	(136.1)				82.1 (12.0)	(78.3)				
Halme 2005[44] 16280273	160/95	6 mo	SMBP	113	159.5 (17.5)	-12.7	-3.2	-8.2, 1.8c	NS	94.1 (6.8)	-7.1	-1.5	-4.0, 1.0c	NS	A
			Usual care	119	159.5 (18.9)	-9.5				94.6 (7.5)	-5.6				
Johnson 1978A[45] 369673	nd/103	6 mo	SMBP	34	nd	nd	nd	nd	nd	102.6 (1.2b)	-8.9	-1.3	-6.4, 3.6c	NS	C
			Usual care	34						103.2 (1.7b)	-7.6				

Author Year PMID	Base BPa, mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure Base (SD)	Systolic Change (Final)	Systolic Net Diff (Diff of Final)	Systolic 95% CI	Systolic P Btw	Diastolic Blood Pressure Base (SD)	Diastolic Change (Final)	Diastolic Net Diff (Diff of Final)	Diastolic 95% CI	Diastolic P Btw	Study Quality
Johnson 1978B[45] 369673	nd/104		SMBP + Home visitor	35	nd	nd	nd	nd	nd	104.2 (1.1b)	-8.1	0.4	-3.9, 4.7c	NS	
			Home visitor	33						103.9 (1.1b)	-8.5				
Marquez-Contreras 2006[48] 16331115	156/91	6 mo	SMBP	100	159.1 (16.6)	-23.5	-4.6	-11.4, 2.2f	NS	92.4 (10.8)	-12.9	-3.2	-5.4, -1.0f	<0.005	C
			Usual care	100	155.6 (14.6)	-18.9				91.0 (9.7)	-9.7				
Mehos 2000[49] 11079287	154/90	6 mo	SMBP	18	157.9 (16.4)	-17.1	-10.1	-21.0, 0.8f	0.07	91.1 (10.8)	-10.5	-6.7	-12.4, -1.0f	0.02	C
			Usual care		153.9 (14.6)	-7.0				89.6 (9.8)	-3.8				
Midanik 1991[50] 1899945	144/93	12 mo	SMBP	74	144.4 (15.7)	-1.6	-2.4	-7.2, 2.4f	NS	91.3 (9.1)	1.0	0.1	-3.8, 4.0f	NS	C
			Usual care	72	144.0 (16.8)	0.8				92.7 (7.7)	0.9				
Soghikian 1992[53] 1518317	140/86	12 mo	SMBP	200	137.4 (1.2b)	-1.4	-3.2	-6.7, 0.2	NS	86.1 (0.6b)	0.1	-1.6	-3.6, 0.4	NS	A
			Usual care	190	140.2 (1.3b)	1.8				86.3 (0.8b)	1.7				
Stahl 1984[54] 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	1.6i	-2.0, 5.3	NS	97.8 (10.8)	-13.5	1.0i	-0.9, 2.9	NS	B
			Usual care	214	165.1 (20.8)	-22.9				97.1 (9.9)	-11.7				

[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.

Table 5. Ambulatory BP, 24 hour: SMBP alone versus usual care

Author Year PMID	Base BPa, 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[35] 10100064	155/95	7 wk	SMBP	31	nd	(137)	(+7)	1, 13b	<0.05	nd	(79)	(+1)	-3, 5b	NS	C
			Usual care	29	nd	(130)				nd	(78)				
Godwin 2010[43] 20032170	144/81	12 mo	SMBP	285	142.6 (11.6)	(136.1)	(-1.6)	-5.1, 1.9c	NS	79.2 (7.0)	(75.0)	(-2.0)	-3.8, -0.2c	0.03	B
			Usual care	267	143.9 (10.7)	(137.7)				80.0 (7.4)	(77.0)				
Rogers 2001[52] 113888152	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	2.1d	0.0, 4.3	0.04	88.1 (9.7)	-10.9	1.1d	-0.4, 2.7	0.05	B
			Usual care	214	143.4 (13.5)	-19.6				88.4 (8.8)	-12.3				

[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 6. Ambulatory BP, awake: SMBP alone versus usual care

Author Year PMID	Base BPa, 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[35] 10100064	155/95	7 wk	SMBP	31	nd	(141)	(+8)	2, 14b	<0.05	nd	(83)	(+2)	-20, 8b	NS	C
			Usual care	29	nd	(133)				nd	(81)				
Broege 2001[38] 11518836	144/82	3 mo	SMBP	20	150 (22)	-4	-4	-15.4, 7.4b	NS	81 (12)	-1	-2	-9.2, 5.2b	NS	C
			Nurse monitor	18	144 (20)	0				82 (13)	1				
Godwin 2010[43] 20032170	144/81	12 mo	SMBP	285	146.9 (10.7)	(141.1)	(-1.7)	-5.0, 1.6c	NS	82.0 (7.4)	(78.7)	(-0.7)	-2.3, 0.9c	NS	B
			Usual care	267	148.2 (10.4)	(142.8)				82.8 (7.5)	(79.4)				
Madsen 2008[46] 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	2.2d	-0.02, 4.5	0.03	92.7 (10.5)	-11.1	1.2d	-0.5, 2.9,	0.05	B
			Usual care	214	149.5 (14.5)	-20.4				93.6 (9.3)	-13.2				

[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 7. Ambulatory BP, asleep: SMBP alone versus usual care

Author Year PMID	Base BPa, 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[38] 11518836	144/82	3 mo	SMBP	20	140 (21)	-8	-9	-18.8, 0.8b	NS	72 (13)	-2	-2	-8.6, 4.6b	NS	C
			Nurse monitor	18	127 (13)	1				71 (9)	0				
Godwin 2010[43] 20032170	144/81	12 mo	SMBP	285	127.7 (18.4)	(127.2)	(-1.0)	-5.1, 3.1c	NS	69.9 (8.7)	(68.4)	(-1.4)	-3.8, 1.0c	NS	B
			Usual care	267	128.7 (16.5)	(128.2)				70.2 (8.8)	(69.8)				
Madsen 2008[46] 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	2.2d	-0.1, 4.5	0.03	76.2 (10.5)	-9.8	1.0d	-0.7, 2.6	NS	B
			Usual care	214	127.6 (15.8)	-17.5				76.1 (10.4)	-10.6				

[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 8. Categorical medication dose and number outcomes: SMBP alone versus usual care

Author Year PMID	Baseline BPa, 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[35] 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[46] 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[50] 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[51] 6377291	179/103	1 yr (1 yr)	Medication change (Physician assessment of change of "strength" of medications for each patient)	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
				Usual care	8	12	5		29					
Zarnke 1997[56] 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					

nd = no data reported; inc = increased; dec = decreased

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

Table 9. Continuous medication dose and number outcomes: SMBP alone versus usual care

Author Year PMID	Baseline BPa, 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[44] 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	Bb
				Usual care	119	-	(0.61)				
Madsen 2008[47] 18815937	152/91	6 mo (6 mo)	Number of antihypertensive medications	SMBP	113	1.0c	(1.9)	(-0.1)	nd	NS	A
				Usual care	123	0.5	(2.0)				
Van Onzenoort 2010[55] 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[56] 9008249	MAP 100	8 wk	Number of antihypertensive agents used (Sum of assigned proportional units for each drug (eg, HCTZ 12.5 mg = 0.5 units))	SMBP	20	nd	(0.05)	(0)	-0.23, 0.23d	NSe	B
				Usual care	10	nd	(0.05)				

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Outcome downgraded from A to B- outcome does not specify if medication change is dose increase or addition of another drug
[c] Median
[d] Calculated from reported data
[e] Adjusted for baseline BP

Table 10. Categorical medication adherence: SMBP alone versus usual care

Author Year PMID	Baseline BPa, mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	n Events			N Total	Outcome Metric	Resultb	95% CI	P Btw	Study Quality
Bailey 1999[35] 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[38] 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[48] 16331115	156/91	6 mo (6 mo)	Patients taking medication at prescribed time	SMBP		88		100	RR	1.1	0.97, 1.24	0.006	C
				Usual care		80		100					
			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	
				Usual care	26	4	70	100					
Pierce 1984[51] 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[55] 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	B
				Usual care		84		114					

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

Table 11. Continuous medication adherence: SMBP alone versus usual care

Author Year PMID	Baseline BPa, 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[48] 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[49] 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[55] 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[56] 9008249	100.4d	8 wk	Number of drug doses missed	SMBP	20	-	(0.05)	-0.15	-0.4, 0.1e	NS	B
				Usual care	10	-	(0.2)				

[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 12. Quality of life: SMBP alone versus usual care

Author Year PMID	Baseline BPa, 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[38] 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[47] 18815937	152/91	6 mo (6 mo)	Physical functioning SF 36 (score 0-100)	SMBP	118	nd	(88.2)	(0.0)		0.08	Bb
				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[49] 11079287	154/90	6 mo (6 mo)	SF-36 score (range 0-100, higher score is better, all domains)	SMBP	18	-	-	-	-	NSc	B
				Usual care	18	-	-				

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Outcome downgraded from A to B- outcome assessment at end of study, not at baseline; no blinding
[c] No domains showed a significant difference

Table 13. Categorical health care resource use: SMBP alone versus usual care

Author Year PMID	Baseline BPa, mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Resultb	95% CI	P Btw	Study Quality
Soghikian 1992[53] 1518317	140/86	1 yr	Patients with no office visits for hypertension	SMBP	78	211	RR	2.25	1.58, 3.21c	nd	A
				Usual care	34	207					

[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 14. Continuous health care resource use: SMBP alone versus usual care

Author Year PMID	Baseline BPa, 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[35] 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[49] 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	B
				Usual care	18	-	(4.44)				
Midanik 1991[50] 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[53] 1518317	140/86	1 yr	Office visits for hypertension for the year	SMBP	211	3.2b	-1.7	-0.9		NSc	A
				Usual care	207	3.5	-0.8				
			Office visits for hypertension for the year, adjustedd	SMBP	211	nd	nd	nd	nd	NSe	
				Usual care	207	nd	nd				
			Number of telephone calls for hypertension	SMBP	211	0.6f	0.9	0.8		NSg	
				Usual care	207	0.7	0.1				
			Number of telephone calls for hypertension, adjustedh	SMBP	211	nd	nd	nd	nd	NSi	
				Usual care	207	nd	nd				
			Medical procedures for hypertension	SMBP	211	0.9j	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[56] 9008249	MAP 100	8 wk	Number of physician visits	SMBP	20	-	(1.05)	(0.85)	0.30, 1.40k	0.045	B
				Usual care	10	-	(0.20)				

[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] P < 0.05 for difference in final values
[f] Prior year measurement for both arms
[g] P < 0.05 for difference in final values
[h] Adjusted for age, race, sex, baseline DBP, use of baseline antihypertensive meds, use of outpatient services for hypertension care in the prior year
[i] P < 0.05 for difference in final values
[j] Prior year measurement for both arms
[k] Calculated from reported data

Table 15. Continuous miscellaneous outcomes: SMBP alone versus usual care

Author Year PMID	Baseline BPa, 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[40] 15802109	162/94	24 wk (24 wk)	Patient satisfaction (Score range 7-30, higher better)	SMBP	367	nd	(20.6	(4.3)	4.2, 12.8b	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				

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

Comparison of SMBP plus additional support with usual care

We identified 21 studies (reported in 22 articles)[36,37,41,45,51,58-65,67-73,75,76] that compared SMBP monitoring plus a variety of additional support with usual care (Tables 1&2). Five studies were published before 1990.[36,45,51,58,63] Sixteen were RCTs,[36,37,41,45,58-60,62,64,65,67,68,70,71,73,75,76] two were quasi-RCTs,[51,63] and three were nonrandomized comparisons.[61,69,72] Additional support included educational materials, Web resources, phone monitoring with electronic transmission of BP data, 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 in Appendix D and Table 1): 12 studies used automated devices; five used auscultatory methods;[45,51,58,61,63] and four did not provide detailed descriptions.[36,67,69,72]

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.[72] 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 = 5663 across studies). Four studies were rated quality A, five were rated quality B, and 12 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, 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).[72] 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 21 studies provided data on BP outcomes. The majority of the studies had followup duration of no more than 12 months. Six studies also reported followup data of more than 12 months.[37,58,61,67,72,75] 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. All studies reported clinic[1] BP measurements. Two studies also reported ambulatory (24 h, awake, or

[1] Participants in Friedman 1996[60] and Johnson 1978[45] had their measurements taken at home by research personnel.

asleep) BP measurements.[68,70] Meta-analyses were not performed due to the great heterogeneity of the interventions.

Categorical BP outcomes (Table 16, Figure 3)

Nine studies reported categorical BP outcomes.[37,41,58,62-64,67,68,76] Three trials reported that significantly higher proportions of patients achieved controlled BP target at followup in the intervention group compared with usual care.[62,64,68] 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).[64] Green 2008 also found that about twice as many patients achieved BP control (≤140/90 mmHg) using SMBP plus personalized website with pharmacist counseling compared with usual care (57 versus 31 percent; P<0.001).[62] 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).[68] The rest of the studies did not report statistically significant differences between usual care and SMBP plus additional support.

Continuous BP outcomes

In total, 21 studies (reported in 22 articles) provided data for continuous BP outcomes.[36,37,41,45,51,58-65,67-73,75,76]

Clinic BP (Table 17, Figure 8)

All 21 studies reported clinic-measured BP outcomes (with the caveat noted in the footnote on the previous page). Nine 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.[37,60,62,65,67,70,71,73,76] The additional support examined in these nine trials were telecounseling;[37,60,71] personalized website with pharmacist counseling;[62] self-titration plus provider alert;[65] education;[67] medication monitoring with provider alert;[70] personalized website plus videoconference counseling;[73] and pharmacist counseling.[76]

For followup from 3 to 12 months, the mean net reduction of SBP ranged from 1.6 to 8.5 mmHg; the mean net reduction of DBP ranged from 1.9 to 4.4 mmHg. For the three trials[37,67,75] that had followup of more than 12 months (up to 60 months), the statistically significant mean net reduction of SBP ranged from 2.6 to 4.3 mmHg; the mean net reduction of DBP ranged from 1.3 to 4 mmHg. No statistically significant difference in DBP reduction was reported in two trials.[45,63]

Statistical analyses for the between-group differences were not reported in four trials.[36,41,51,59] 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[69,72] of three nonrandomized studies[61,69,72] also reported a statistically significant greater reduction in either the SBP or the DBP at followup favoring the intervention (personalized website plus nurse counseling[69] or self-titration plus education[72]).

Ambulatory BP (Table 18, Figures 5-7)

Two trials also provided outcomes on ambulatory continuous BP measurements.[68,70] Rinfret 2009 reported a statistically significant greater reduction in 24 hour ambulatory BP (mean net

difference SBP: -4.8 mmHg; P<0.001; DBP: -2.1 mmHg; P=0.007); awake BP (mean net difference SBP: -5.9 mmHg; P<0.001; DBP: -2.5 mmHg; P=0.05); and asleep time BP (mean net difference 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.[70] Parati 2009 reported a statistically significant greater reduction of awake SBP in those who had SMBP plus reminder compared to usual care (mean net difference: -1.6 mmHg; P<0.05).[68] No statistically significant difference was reported for awake DBP.

Medication dosage (Tables 19&20)

Ten studies provided data on outcomes relating to the number of medications prescribed and dosage (two quality A, three quality B, and six quality C).[51,62,64,65,67,68,70-72,76] The followup durations in these studies ranged from 2 to 60 months. Reported medication outcomes included both categorical outcomes (Table 19), 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 20), 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.[51,67,68,71,76] 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).

Six of ten reported continuous medication outcomes.[62,64,65,70-72] Four of these reported on the number of hypertension medication classes used.[62,65,70,72] Green 2008 found that both the SMBP plus personalized Web site with pharmacist counseling group and the SMBP plus personalized Web site group 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).

Medication adherence (Tables 21&22)

Six studies provided data on outcomes relating to medication adherence (one quality A, two quality B, and three quality C).[51,60,63,70,71,76] The followup durations in these studies ranged from 2 to 12 months. Reported medication outcomes included both categorical outcomes (Table 21), where the outcomes were defined as the number of patients with a specified level of medication adherence, and continuous outcomes (Table 22), where adherence was measured on a continuous scale (e.g., tablet count).

Three of these six studies provided data on categorical medication adherence outcomes.[51,63,76] 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.[60,63,70,71] 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.[77])

Quality of life (Table 23)

Three studies provided data on quality of life outcomes (two quality A, one quality C).[62,65,68] Followup durations in these studies ranged from 3 to 12 months. Green 2008 trial found no difference in either the SMBP plus personalized website group or SMBP plus personalized website 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 24)

Six studies provided data on outcomes relating to health care encounters (one quality A, one quality B, and four quality C).[41,65,67,70,72,76]. 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 five studies provided data on the number of physician visits per study group.[65,67,70,72,76]. Three studies found no difference compared to usual care, when looking at SMBP plus education, SMBP plus provider alert with medication monitoring, or SMBP plus self-titration with provider alert.[65,67,70]. 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).

Miscellaneous outcomes (Table 25)

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.[64]

Subgroups and heterogeneity

BP outcomes (Table 26)

Four studies examined how additional patient characteristics affected the study outcomes. 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.[60] 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.[41] 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).[65] 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.[62] Quantitative analysis for those with baseline SBP <160 mmHg was not reported.

Shea 2006, an RCT of SMBP plus personalized website 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.[73] 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.

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 26. This was based on our assessment of the key component, since the categories are not exclusive. Four of the eight 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.[37,62,71,76] The mean net reduction of SBP ranged from 3.3 to 8.9 mmHg; the mean net reduction of 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 vs. 31 percent; P<0.001).[62] Two of four 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.[67,72] Both studies were conducted by the same group of investigators. The mean net changes of SBP were -5 mmHg (95 percent CI -10, 0; NS) in the first study[67] and -19 mmHg (95 percent CI -33, -5.2; P=0.007) in the second study.[72] The mean net changes of DBP were -4 mmHg (95 percent CI -7, -1; P=0.018) in the first study[67] and -6.1 mmHg (95 percent CI -13.1, 0.9; NS) in the second study.[72] 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.[60,62,65,68-70,73] The mean net reduction of SBP ranged from 1.6 to 5.4 mmHg; the mean net reduction of 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 vs. 50 percent; P<0.05).[68] Three studies were in category "M" (Miscellaneous).[36,41,64] The additional support in one study was a single class offered by a diabetes educator and instruction by a nurse on SMBP monitoring.[41] The second study used leaflet with educational materials on hypertension and/or a card for recording BP and pill counts.[64] 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 vs. 35 percent; P=0.01).[64] The third study compared SMBP plus contract plus pill pack with control and both groups received education.[36] Statistical analyses for the between-group differences 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.[72] 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

Nine of 18 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. One trial enrolled only patients with diabetes.[73] All four 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.[60,62,65,73] These changes were measured in the clinic[62,65] and at home.[60] The support in addition to SMBP in these four trials were: telemonitoring and counseling on patient adherence to antihypertensive medications;[60] Web-based pharmacist counseling;[62] telemonitoring with self-titration of antihypertensive medications;[65] and telemonitoring with nurse videoconference.[73] Three quality B[37,71,76] and two quality C trials[67,70] 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 four 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.

Non-BP clinical, surrogate, and intermediate outcomes

Ten studies (two quality A, three quality B, and six quality C) reported data related to the number of medications prescribed and dosage.[51,62,64,65,67,68,70-72,76] 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. The majority 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.[51,60,63,70,71,76] 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.[62,65,68] 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.

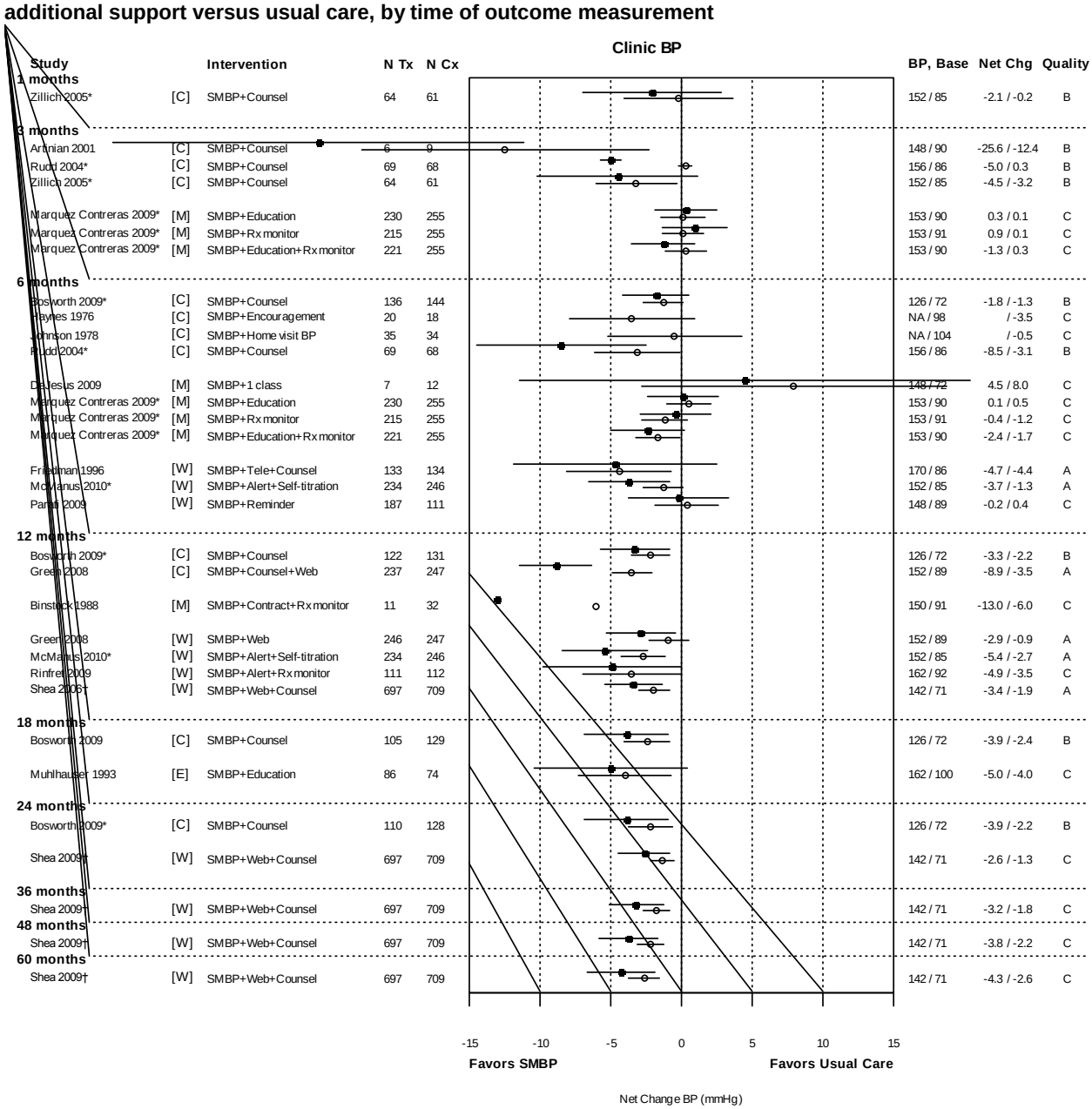
Evidence for no difference in adverse drug reactions is limited, as only one C quality study was found for this outcome.[64]

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 all non-BP clinical, surrogate and intermediateoutcomes.

Health care encounters

Six studies (one quality A, one quality B, and four quality C) reported on health care encounter outcomes.[41,65,67,70,72,76] Evidence was mixed, with four studies showing no difference in effect, one outcome showing SMBP to have more visits, and one outcome showing SMBP to have fewer visits. 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 8. 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% 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 26.

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[73], Shea 2009[75]).

Notes:
Binstock 1988[36] Both groups had education.

Zillich 2005[76] Both groups had pharmacist.

Table 16. Categorical BP: SMBP plus additional support versus usual care

Author Year PMID	Baseline BPa, mmHg	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Resultb	95% CI	P Btw	Study Quality
Bosworth 2009[37] 19920269	124/70	12 mo	BP <140/90 mmHg (<130/80 DM)	SMBP + Behavioral	99c	122	RR	1.08	0.95, 1.24d	nd	B
				Usual care	98c	131					
DeJesus 2009[41] 19756162	149/74	6 mo	BP <130/80 mmHg	SMBP + Education	2	19e	nd	nd	nd	NSf	C
				Usual care	1	18					
Earp 1982[58] 7114339	63% in usual care DBP <95	12 mo	DBP <95 mmHg	SMBPg + Home visits	29	74	adj RDh	-0.03	nd	NS	C
				Usual care	16	47					
		24 mo		SMBPg+ Home visits	14	55	adj RDi	-0.15	-0.3, 0.01d	NSj	
				Usual care	16	38					
Green 2008[62] 18577730	152/89	12 mo	BP ≤140/90 mmHg	SMBP + Web + Pharmacist	149k	261	adj RRl	1.84	1.48, 2.29	<0.001	A
				Usual care	80k	258					
				SMBP + Web	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[64] 19482378	153/91	6 mo	BP <140/90 mmHg (<130/80 DM)	SMBP + Leaflets	126	230	RR	1.55	1.27, 1.90	0.01n	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[67] 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					
Parati 2009[68] 19145785	149/89	6 mo	Awake BP <130/80 mmHg	SMBP + Telemonitoring	116	187	RD	0.12	0, 0.24o	<0.05	C
				Usual care	56p	111					
Zillich 2005[76] 16423096	152/85	3 mo	BP ≤140/90 mmHg	SMBP + Pharmacist education	27	64	RR	1.43	0.88, 2.32q	NS	diB
				Pharmacist, no education	18	61					

[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 suppport
[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

Table 17. Clinic BP: SMBP plus additional support versus usual care

Author Year PMID	Base BPa, 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[59] 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[36] 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[37] 19920269	124/70	12 mo	SMBP + counsel	159b	126 (20)	-4.5c	-3.3	-5.7, -0.8	0.009	72 (12)	-3.1c	-2.2	-3.5, -0.8	0.001	B
			Usual care	159d	124 (18)	0c				70 (10)	0c				
DeJesus 2009[41] 19756162	149/74	6 moe	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[60] 8722429	167/84	6 mo	SMBP + tele + counsel	133	169.5 (nd)	-11.5f	-4.7	-112 2.5g	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[62] 18577730	152/89	12 mo	SMBP + counsel + Web	237	152.2 (10.4)	-14.2h	-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				
			SMBP + Web	246	152.2 (10.0)	-8.2h	-2.9	-5.3, -0.4g	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[45] 369673	nd/103	6 mo	SMBP + home visit BP	35	nd	nd	nd	nd	nd	104.2 (6.5)	-8.1j	-0.5	nd	NS	C
			Usual care	34	nd	nd				103.2 (10.2)	-7.6j				
Marquez-Contreras	153/91	6 mo	SMBP + education	230	152.9 (13.8)	-16.4	0.1	-2, 2.2k	nd	89.7 (9.8)	-9	0.5	-1, 2.0k	nd	C

Author Year PMID	Base BPa, mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure Base (SD)	Systolic Change (Final)	Systolic Net Diff (Diff of Final)	Systolic 95% CI	Systolic P Btw	Diastolic Blood Pressure Base (SD)	Diastolic Change (Final)	Diastolic Net Diff (Diff of Final)	Diastolic 95% CI	Diastolic P Btw	Study Quality
2009[64] 19482378			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, -0.3k	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[65] 19220913	152/84	12 mo	SMBP + alert + self-titration	234	151.9 (nd)	-17.6	-5.4l	-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[67] 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[68] 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[70] 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[71] 15485755	155/87	6 mo	SMBP + counsel	69	155.9m (19.9)	-14.2	-8.5	-15, -2g	<0.01	86.3m (10)	-6.5	-3.1	-6.2, -0.01g	<0.05	B
			Usual care	68	154.8m (17.3)	-5.7				87.4m (9.1)	-3.4				
Shea 2006[73] 16221935	142/71	12 mo	SMBP + web + counsel	697	142.1 (23.1)	-4.7	-3.4j	-5.5, -1.4g	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[76] 16423096	152/85	3 mo	SMBP + counsel	64	151.5 (15.6)	-13.4	-4.5n	-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															

Author Year PMID	Base BPa, 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	
Gran 1991[61] 1891656	156/96	24 mo	SMBP + lifestyle interventions	122o	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[69] 19643661	134/91	2 mo	SMBP + Web + counsel	28	135.7 (8.8)	-9.1	-11.9	--19, -4.8g	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[72] 8557972	143/87	60 mo	SMBP + education + self-titration	34	154p (19)	-3.7	-19.1	-33, -5.2g	0.007	92q (12)	-5.8	-6.1	-13, 0.9g	0.088	C
			Usual care	25	143p (22)	15.4				87q (11)	0.3				

[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

Table 18. Ambulatory BP: SMBP plus additional support versus usual care

Author Year PMID	Base BPa, mmHg	Time-point (Longest)	Intervention	No. Analyzed	Systolic Blood Pressure					Diastolic Blood Pressure					Study Qualit
					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[68] 19145785	149/89	6 mo	SMBP + reminder	187	Awake 139.4 (11)	-14.8	-1.6	-3.2, -0.01g	<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[70] 20031834	162/90	12 mo	SMBP + alert + Rx monitor	111	24 h 141 (11)	-11.9	-4.8	-7.7, -1.9g	<0.001	81 (9)	-6.6	-2.1	-3.6, -0.6g	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, -2.4g	<0.001	86.5 (10)	-7.6	-2.5	-4.2, -0.8g	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, -0.9g	0.01	71 (11)	-5.0	-1.9	-3.8, 0.0g	0.05	
			Usual care	112	125.3 (18)	-5.2				69 (13)	-3.1				

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

Table 19. Categorical medication dose and number outcomes: SMBP plus additional support versus usual care

Author Year PMID	Baseline BPa, 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[67] 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[68] 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[51] 6377291	179/103	1 yr (1 yr)	Medication change (Physician assessment of change of "strength" of medications for each patient)	SMBP + education	5	11	7		30	0.6 (0.22, 1.63)b nd	0.89 (0.47, 1.68)c nd	1.35 (0.48, 3.78)d nd		C
				Usual care	8	12	5		29					
Rudd 2004[71] 15485755	1547/88	6 mo (6 mo)	Patients reporting two or more drugs	SMBP + counsel				48	69				1.53 (1.13, 2.07)e nd	B
				Usual care				31	68					
			Patients reporting no drug therapy	SMBP + counsel				27	69				1.77 (1.04, 3.03)f nd	
				Usual care				15	68					
			Patients reporting no change in drug therapy	SMBP + counsel		2			69		0.05 (0.01, 0.20)g nd			
				Usual care		39			68					

Author Year PMID	Baseline BPa, 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
Zillich 2005[76] 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)h nd				B
				Pharmacist BP	16				61					
			Medication discontinued	SMBP + counsel				9	64				2.86 (0.88, 2.32)i nd	
				Pharmacist BP				3	61					

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Calculated from reported data
[c] Calculated from reported data
[d] Calculated from reported data
[e] Calculated from reported data
[f] Calculated from reported data
[g] Calculated from reported data
[h] Calculated from reported data
[i] Calculated from reported data

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

Author Year PMID	Baseline BPa, 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[62] 18577730	151/89	12 mo	Number of hypertension medication classes	SMBP + counsel + web	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	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[64] 19482378	153/91	6 mo (6 mo)	Number of tablets taken per day	SMBP + education	230	1 (nd)	2.6	0b	-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[65] 19220913	152/85	12 mo (12 mo)	Number of additional medicationsc	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[70] 20031834	162/90	1 yr	Antihypertensive drug classes used	SMBP + alert + Rx monitor	111	-	(2)d	(1)	nd	0.007e	C
				Usual care	112	-	(1)				
			Physician-driven Rx changes	SMBP + alert + Rx monitor	111	-	(1)f	(1)	nd	0.03g	
				Usual care	112	-	(0)				
Rudd 2004[71] 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[72] 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	P>0.05	C
				Usual care	44	1.0 (1.0)	0.6				

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

Table 21. Categorical medication adherence: SMBP plus additional support versus usual care

Author Year PMID	Baseline BPa, mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Resultb	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, 3.82c	<0.05	C
				Usual care	7	18					
Pierce 1984[51] 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	RRd	0.58	0.24, 1.39	nd	C
				Usual care	7 12 10	29					
Zillich 2005[76] 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					

[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 22. Continuous medication adherence: SMBP plus additional support versus usual care

Author Year PMID	Baseline BPa, 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[60] 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, 8.0b	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, 2.8b	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, 42.7b	0.025	C
				Usual care	18	44.7 (7.1)	-1.5				
Rinfret 2009[70] 20031834	162/90	1 yr	Continuous medication availability (proportion of time medication available)	SMBP + alert + Rx monitor	111	-	(0.95)d	(0.04)		0.07e	C
				Usual care	112	-	(0.91)				
			Continuous medication gaps (proportion of time medication not available)	SMBP + alert + Rx monitor	111	-	(0.04)f	(-0.05)		NSg	
				Usual care	112	-	(0.09)				
Rudd 2004[71] 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%)				

[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
[f] Median
[g] Adjusted for newly diagnosed, pharmacologically untreated versus uncontrolled pharmacologically treated hypertension, and also for pharmacologically treated concomitant disease(s) or not

Table 23. Quality of life: SMBP plus additional support versus usual care

Author Year PMID	Baseline BPa, 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[62] 18577730	151/89	12 mo	SF-12 General Health score (score 1-100, higher score better)	SMBP + counsel + web	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	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	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	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	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	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	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	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[65] 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				
			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[68] 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				

[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 24. Continuous health care resource use: SMBP plus additional support versus usual care

Author Year PMID	Baseline BPa, mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
DeJesus 2009[41] 19756162	148/74	6 mo (6 mo)	Number of RN and MD visits during study period	SMBP + 1 class	19	nd	nd	nd	nd	NS	C
				Usual care	18	nd	nd				
McManus 2010[65] 19220913	152/85	12 mo (12 mo)	Number of primary care consultations	SMBP + alert + self-titration	234	nd	(3.2)	(-0.3)		0.08	A
				Usual care	246	nd	(3.5)				
Muhlhauser 1993[67] 8467308	160/98	18 mo (18 mo)	Physician visits per patient	SMBP + Education	86	-	(12)	0		NS	C
				Usual care	74	-	(14)				
Rinfret 2009[70] 20031834	162/90	1 yr	Physician office visits	SMBP + alert + Rx monitor	111	-	(2)b	(0)		NSc	C
				Usual care	112	-	(2)				
Sawicki 1995[72] 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[76] 16423096	152/85	3 mo	Physician visits	SMBP + counsel	64	-	(0.31)d	(-0.61)		0.007	B
				Pharmacist BP	61	-	(0.92)e				

[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] Calculated from reported data, number of patients not explicitly given.

Table 25. Categorical miscellaneous outcomes: SMBP plus additional support versus usual care

Author Year PMID	Baseline BPa, mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Resultb	95% CI	P Btw	Study Quality
Marquez-Contreras 2009[64] 19482378	153/91	6 mo (6 mo)	Adverse drug reactions	SMBP + education	0	230				ndc	C
				SMBP + Rx monitor	4	215				nd	
				SMBP + education + Rx monitor	3	221				nd	
				Usual care	6	255					

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Top row intervention vs. bottom row intervention.
[c] ANOVA between groups = NS

Table 26. Post hoc categorization of types of additional support reported in studies

Category*	Definition of Additional Support	Key Question 1 Studies	Key Question 2 Studies
C	Counseling 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 Green, 2008† Johnson, 1978 Artinian, 2001 Earp, 1982 Haynes, 1976 Rudd, 2004 Zillich, 2005	Bosworth, 2009 Green, 2008 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.	Pierce, 1984 Gran, 1991 Muhlhauser, 1993 Sawicki, 1995	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† McManus, 2010 Parati, 2009 Park, 2009 Rinfret, 2009 Shea, 2006	Carrasco 2008
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	Binstock, 1988‡ Márquez Contreras, 2009 DeJesus, 2009	Binstock 1988‡ Márquez Contreras, 2009

* These are the categories noted in square brackets in the forest plots.
† Green 2008 provides a category C comparison and a category W comparison for Key Question 1
‡ All groups, including the 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 27 (descriptions of the interventions) and Table 28 (descriptions of the study characteristics).

Comparison of SMBP with versus without additional support

Nine RCTs in eight full reports [36,37,45,51,62,64,78,79,79] and one conference abstract[80] directly compared SMBP plus additional support versus SMBP alone or with less intensive additional support. Eight were RCTs and one was a quasi-randomized study. One study was rated quality A, three quality B, and four quality C. The conference abstract was not graded for quality due to insufficient data. Three studies were published before 1990.[36,45,51]

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, a hypertension informational leaflet, a BP recording card, electronic transmission of SMBP measurements, Web sites 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. Five studies used automated SMBP devices (i.e., devices that automatically inflate the sphygmomanometer and measure BP),[37,45,62,64,78,79,79] while the remainder did not describe the monitor type (Table D-1 in Appendix D).[36,45,51,80]

All studies explicitly qualified that patients had essential hypertension. Five studies included patients with hypertension irrespective of whether these patients were on antihypertensive treatment upon study entry.[37,45,51,78,79] Two others included only patients with poorly controlled hypertension despite being on antihypertensive medication.[36,80]

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 66 percent. The size of the studies (excluding study groups not relevant for this Key Question) ranged from 34 to 828 (total = 2,701 across studies). Six studies did not report the prevalence of comorbid conditions. Three studies reported on the prevalence of diabetes, which ranged from 22 and 36 percent.[37,78,79] 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 nine studies provided data on BP outcomes. Followup durations ranged from 3 to 24 months, with only Brennan 2010 and Bosworth 2009 having followup periods longer than 1 year. The BP outcome was based on clinic BP in six studies,[36,37,51,62,64,79] home BP in one study,[45] and both in two studies.[78,80] Ambulatory (24 h, awake, and asleep) BP measurements were not reported in these studies. 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. Meta-analyses were not performed due to the great heterogeneity of interventions across trials.

Categorical BP outcomes (Table 29, Figure 9)

Seven of the nine studies reported findings for categorical BP outcomes, which consisted of five fully reported RCTs (one quality A study, 3 quality B studies and one quality C study) , one trial reported in an abstract (ungraded), and one quasi-randomized study graded quality C. [37,51,62,64,78-80] BP targets varied from <120/80 to <140/90 mmHg across studies, and in one study consisted of discrete reductions in SBP and DBP.[51] In two studies, BP targets were lower for individuals with diabetes (<130/80 rather than 140/90 mmHg).[37,64]

Green 2008 reported a significantly higher proportion of patients achieving a BP target with the addition of pharmacist counseling to combined SMBP plus a personalized Web site (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 better 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 the remaining five studies were not statistically significant. In these studies, the additional types of support consisted of telecounseling, educational material, medication monitoring, personalized Web site, physician counseling, or nurse counseling.

Continuous BP outcomes

All eight peer-reviewed trials reported continuous BP outcomes from nine comparisons. One study was rated quality A, three quality B, and three quality C. The conference abstract was not graded for quality due to insufficient data [36,37,45,62,64,78-80]

Clinic BP (Table 30, Figure 10)

All eight trials reported changes in clinic BP. Five found no evidence or did not provide a measure of statistical difference for a change in BP with the addition of nurse telecounseling, Web plus physician counseling, telemedicine, home visitor for BP measurement, or compliance contracts plus calendar pill packs plus education.[36,37,45,79,80] The remaining three trials showed some benefit for BP reduction from more intense additional support.[62,64,78] 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 personalized Web site 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.

The forest plot in Figure 10 suggests that Bosworth 2009, the only trial with more than 12 month followup, showed a nonsignificant reduction of SBP and DBP over time favoring the addition of a behavioral intervention to SMBP at 24 months. However, the loss to followup had increased to 30 percent by 24 months.

Ambulatory BP

No study evaluated ambulatory BP outcomes.

Quality of life (Table 31)

Two studies reported continuous outcomes for quality of life and for mental health.[62,79] 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 a personalized Web site plus pharmacist counseling versus SMBP plus personalized Web site. 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 32&33)

Four studies reported outcomes related to medication prescriptions, three of which reported categorical outcomes and one a continuous outcome.[45,51,78] Two studies were rated quality A and two quality B for these outcomes. Followup durations ranged from 6 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 a personalized Web site (net difference 0.2; 95 percent CI 0.1, 0.4; P<0.01).

Medication adherence (Tables 34&35)

Three quality C trials provided data on outcomes related to medication adherence.[37,45,51] 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 36&37)

Three studies provided data on health care encounters.[37,78,79] All three were graded quality C for these outcomes. Followup durations ranged from 6 to 24 months. In the three 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; and the addition of telemedicine had no effect on the median number of consultations or number of hospital admissions.

Miscellaneous outcomes (Tables 25&38)

Two trials reported miscellaneous outcomes.[62,64] 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 pharmacist counseling plus a personalized Web site versus SMBP plus personalized Web site.

Subgroups and heterogeneity

Green 2008 (quality A) and Johnson 1978 (quality C) reported results from subgroup analyses. 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 a personalized Web site 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.

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 26. This scheme

was based on our assessment of the key component differing between the two groups, as the categories are not exclusive. Five studies examined the addition of an intervention from category "C" (Counseling with regular one-on-one encounters with study personnel).[37,45,62,78,80] Two of these studies showed some benefit for BP control or BP reduction.[62,78] 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[37] or home visits.[45] The conference abstract by Chelsova 2010 examined the addition of telemedicine and also found no difference.

One study (Pierce 1984) examined the addition of an intervention from category "E" (Education offered in regular hypertension education classes), the addition of four educational classes, and found no difference.

One study, Carrasco 2008, examined the addition of an intervention from category "W" (Web-based or telephonic tools). This study added a Web site and physician counseling to SMBP, but failed to detect a difference in BP at 6 months.

Two studies were placed in category "M" (Miscellaneous).[36,64]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.

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

Nine 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.[36,37,45,51,62,64,78-80] In total, 2701 patients with hypertension were included. One trial was graded quality A, three quality B, and four 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, educational interventions, electronic transmission of BP measurements, Web sites for patient-provider communication, BP recording cards, 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. Six studies

reported clinic BP outcomes, one study reported only home BP, and two studies reported both.[36,37,45,51,62,64,78-80] Meta-analysis was not undertaken due to clinical heterogeneity.

Three trials found statistically significant benefits for the more intensive additional support for either SBP, DBP, BP control, or combinations thereof.[62,64,78] 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 a personalized Web site. The other six trials (five full reports and one abstract) were of 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.

Non-BP clinical, surrogate, and intermediate outcomes

Four 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).[45,51,62,78] 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. Three trials using additional support consisting of nurse counseling, home visits for BP measurement, 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 site. 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.[37,45,51] 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.[45] A weak level of evidence fails to support a difference in medication adherence.

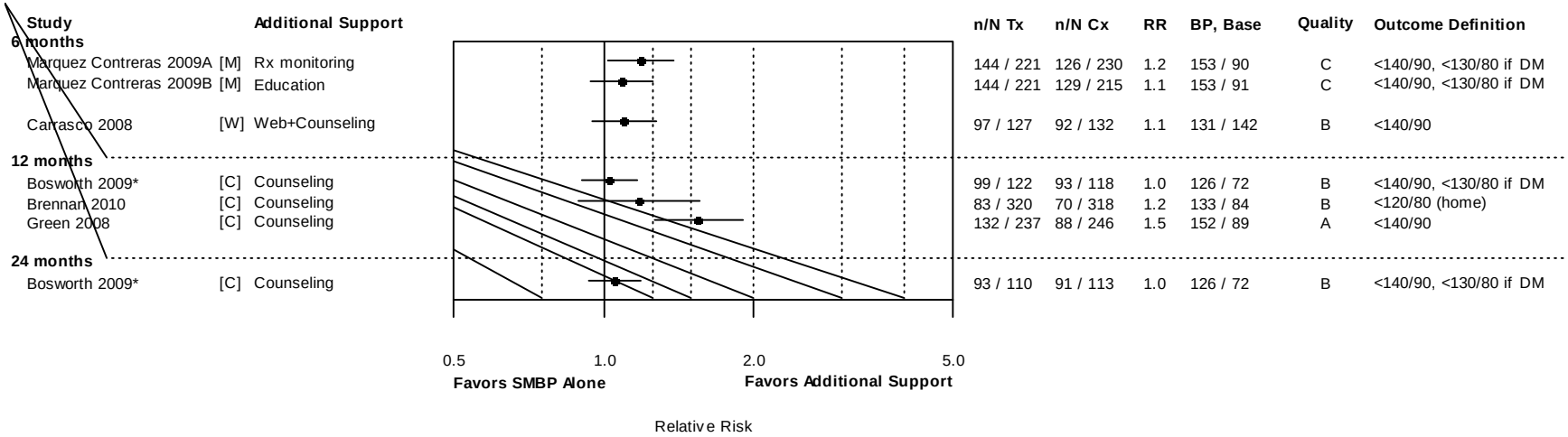
Two trials reported miscellaneous outcomes. One study (quality C) found no difference in adverse drug reactions across four groups with different forms of additional support or usual care. One study (quality A) found no difference for consumer satisfaction measured by the Consumer Assessment of Healthcare Providers and Systems instrument.[37,62] 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 all non-BP clinical, surrogate and intermediate outcomes.

Health care encounters

Three 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, behavioral intervention, or telemedicine. All reported on outpatient primary care visits, two reported on hospital admissions, and one 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. Despite the consistency across trials, 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.

Figure 9. Forest plot of relative risk of "adequate" BP at followup in RCTs of SMBP with addition support versus SMBP monitoring alone, by time of outcome measurement



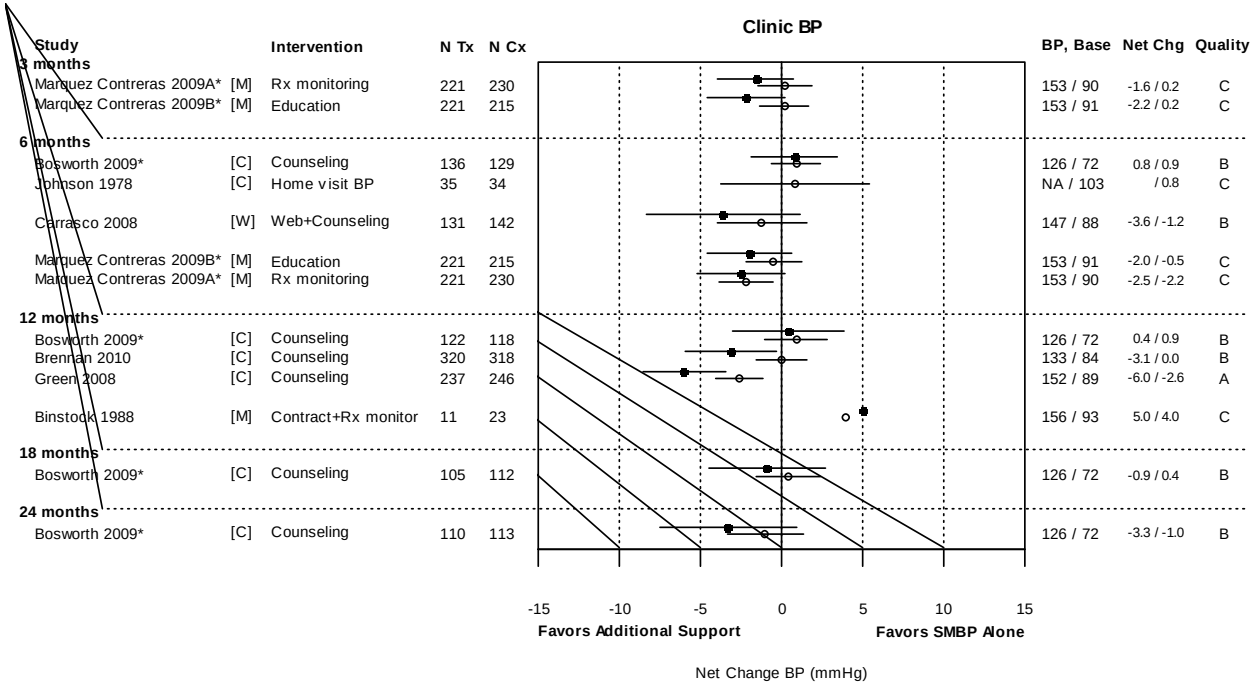
Black circles indicate relative risk for each study. The letters in brackets to the left of interventions with additional support refer to the categories in Table 26.

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.

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

Notes:
Marquez Contreras 2009A[64] Both groups had leaflet.
Marquez Contreras 2009B[64] Both groups had card.
Green 2008[62] Both groups had Web site.

Figure 10. 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% 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 26.

BP = blood pressure (systolic/diastolic), 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, 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:
Green 2008[62] Both groups had Web site.
Marquez Contreras 2009A[64] Both groups had leaflet. Intervention is the same as the 2009B analysis.
Marquez Contreras 2009B[64] Both groups had card. Intervention is the same as the 2009A analysis.

Table 27. Description of study interventions: Key Question 2

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	Target BP, mmHg	Clinic or Study Visit Frequency	BP Transmission	Medication Titration
Binstock 1988[36] 3415798	SMBP + Contract + Rx monitor + Education	Compliance contractsa + Calendar pill packs + Educationb	nd	nd	nd	0, 12 mo	nd	nd
	SMBP + Education	Educationc						
Bosworth 2009[37] 19920269	SMBP + Counsel	Telecounselingc	Omron HEM-773ACd	3x/wk	Clinic<140/90 (<130/80 DM)	0, 6, 12, 18, 24 mo	Mailed every 2 mo	Physician
	SMBP							
Brennan 2010[78] 20415618	SMBP + Counsel	Counseling by nursee	Omron HEM-780	"At regular intervals"f	Home<120/80	nd	Collected by nurse Quarterly reports sent to PCP	Physician
	SMBP						Mailed at 6mo and end of the study	
Carrasco 2008[79] 15564986	SMBP Telemedicine + Counsel	Telemedicine + Physician Counseling	Omron M4-I	2x/d, 4x/wk	Clinic≤140/90	Routine	Transmitted via cell phone to provider	Physician
	SMBP						Patient recorded BP	
Green 2008[62] 18577730	SMBP + Counsel+ Webg	Pharmacist counseling + Personalized Web siteh	Omron HEM-705CP	≥2x/wk	Home<135/85	0,12 mo	Emailed to physician	Pharmacist per protocol
	SMBP + Webg	Personalized Web site[h]						Physician no protocol
Johnson 1978[45] 369673	SMBP + Home visit BP	Home visitor BP measurementi	BP kit by Taylor Sybron (nd)	1x/d	nd	nd	Brought to office	Physician
	SMBP							
Marquez-Contreras 2009[64] 19482378	SMBP + Education + Rx monitor	Educational materialsj + Medication monitoringk	OMRON (nd)	3x/wk	Clinic<140/90 (<130/80 DM)	0,3, 6 mo	Brought to office	Physician
	SMBP + Rx monitor	Medication monitoringp					Special card	
	SMBP + Education	Educational materialso					Special card	
Pierce 1984[51] 6377291	SMBP + Education	Educationl	Aneroid device (Manual)	1x/d	nd	nd	Brought to office	nd
	SMBP							

Author Year PMID	Interventions	Additional support	Monitor Brand (Type)	BP Measurement Frequency	Target BP, mmHg	Clinic or Study Visit Frequency	BP Transmission	Medication Titration
Atypical Studies								
Kabutoya, 2009[81] 19695029	SMBP + Graph	Graphic display of weekly and monthly averaged BP	Omron HEM-737	2x/d	Home<135/85	nd	No	Physician
	SMBP							
Staessen 2004[82] 1498211	SMBP + Home Titration	Stepwise medication titration based on home BP	Omron HEM-705CP	SMBP: 2x/d for 7d 2x/mo; Clinic: 2x/mo	Home DBP 80-89	2x/mo	Patient recorded and printed BP values	Physician per protocol
Den Hond 2004[83] 15564986	SMBP + Clinic Titration	Stepwise medication titration based on clinic BP			Clinic DBP 80-89			
Stahl 1984[54] 6742256	SMBP		nd (mercury sphygmomanometer)	nd	Clinic DBP ≤95	1-2x/mo until BP controlled, then every 2 mo	Patient	Nurse practitioner' stepped approach'
	Family BP measurement							

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
cBimonthly 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] Monthly phone counseling by nurse (duration 15-20 minutes) on improving hypertension knowledge and adherence to diet, regular exercise, and DASH (Dietary Approaches to Stop Hypertension) diet. The median number of completed calls per participant was 3, with a range of 1 to 10. Educational materials were developed specifically for African Americans
[f] Weekly or more: 28%, <Weekly: 72 %
[g] All received educational pamphlet on hypertension
h Web services for medication refill, appointments, view portions of their medical record and secure messaging to contact health care team members.
[i] Home visits every 1 mo to check BP
jPatient education kit (leaflets) on general aspects of hypertension and compliance promotion.
k Card for BP measurements recording and medication reminder.
l Four educational meetings on nonpharmacological approach to lower BP

Table 28. Study characteristics: Key Question 2

Author Year PMID	Country (Enrollment Years)	Interventions*	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout†, %, (Timepoint) [Longest]	Other Quality Issues
Binstock 1988[36] 3415798	US (nd)	SMBP + Contract + Rx monitor + Education SMBP + Education	nd	40	nd	nd		nd nd	No data frequency of SMBP and device type, sparse information on baseline characteristics, no statistical testing done, no information on dropouts
Bosworth 2009[37] 19920269	US (2004-05)	SMBP + Counsel SMBP	61	34	36	Hospital outpatient		23% (12 mo) [31% (24 mo)] 15 % (12 mo) [29% (24 mo)]	Dropout rate, numbers in the figure do not always match the numbers reported in the text
Brennan 2010[78] 20415618	US (2006)	SMBP + Counsel SMBP	56	33	25	Community	African American, private health insurance (higher education, income)	22% (12 mo) 26% (12 mo)	Outcome timing and collection unclear. High dropout. Unclear timing.
Carrasco 2008[79] 15564986	Spain (2004-2006)	SMBP Telemedicine + Counsel SMBP	62	59.2	22	General practice		8% (6 mo) 1% (6 mo)	No adjustment for clustering
Green 2008[62] 18577730	US (nd)	SMBP + Counsel + Web SMBP + Web	59.1	47.8	nd	General practice		9% (12 mo) 15% (12 mo)	
Johnson 1978[45] 369673	Canada (nd)	SMBP + Home visitor SMBP	53	60	nd	Home (recruited from screening in shopping centers)		3% (6 mo)	No information on frequency or other instructions given to SMBP group. No definition of compliance and “strength of therapy” outcomes.
Marquez-Contreras 2009[64] 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
Pierce 1984[51] 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

Author Year PMID	Country (Enrollment Years)	Interventions*	Age, y Mean	Male, %	DM, %	Setting	Other Patient Characteristics	Dropout†, %, (Timepoint) [Longest]	Other Quality Issues
Atypical Studies									
Kabutoya, 2009[81] 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.
Staessen 2004[82] 1498211 Den Hond 2004[83] 15564986	Belgium and Ireland (1997-2002)	SMBP + Home Titration SMBP + Clinic Titration	54	48	nd	56 general practice and 3 hospitaloutpatient 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[54] 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]	Some potential for bias in randomization based on ability to self measure or availability of family.

* For details, see "Interventions" table (Table 1).
† 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 29. Categorical BP: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BPa, mmHg	Timepoint	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Resultb	95% CI	P Btw	Study Quality
Bosworth 2009[37] 19920269	126/72	12 mo	<140/90, <130/80 if diabetic	SMBP + Counsel	99c	122	RR	1.03	0.91, 1.17	nd	B
				SMBP	93d	118					
Brennan 2010[78] 20415618	133/84	Mean 13 mo	BP<120/80 Adjustede	SMBP + Counsel	83	320	OR	1.50	0.99, 2.27	0.05	B
				SMBP	70	318					
Carrasco 2008[79] 15564986	147/87	6 mo	BP ≤140/90 (per protocol analysis)	SMBP Telemedicine + Counsel	97	127	RRf	1.10	0.94, 1.27	nd	B
				SMBP	92	132					
Green 2008[62] 18577730	152/89	12 mo	BP<140/90 mmHg Adjustedg Yes/No %	SMBP + Counsel+ Web	132h	237	nd			<0.001	A
				SMBP + Web	88 or 89i	246					
Marquez-Contreras 2009[64] 19482378	153/90	6 mo	<140/90 (<130/80 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					
Pierce 1984[51] 6377291	184/106	6 mo	SBP reduction mmHg	mmHg	>40	10-40	<10				C
				SMBP + Education	12	13	5	30	RR	1.04j	0.81, 1.34	nd
				SMBP	11	9	5	25			
			DBP reduction mmHg		>25	10-25	<10				
				SMBP + Education	11	15	4	30	RR	1.20k	0.91, 1.60	nd
				SMBP	6	12	7	25			

[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] Adjusted for education level, ≥2 drug classes at baseline, BP <120/80 at baseline
[f] Study reported OR for BP >140/90
[g] Adjusted for BMI, sex, already having a home BP before trial, baseline BP, clinic.
[h] N estimated from reported 56%
[i] N estimated from reported 36%
[j] SBP reduction ≥ 10 vs <10 mmHg
[k] DBP reduction ≥ 10 vs <10 mmHg

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

Author Year PMID	Base BPa, 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[36] 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[37] 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				
Brennan 2010[78] 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[79] 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				
Green 2008[62] 18577730	152/89	12 mo	SMBP + Counsel+ Web	237	152 (10)	-14.2	-6	nd	<0.001	89 (9)	-7	-2.6	nd	<0.001	A
			SMBP + Web Adjusted mean change	246	152 (10)	-8.2				89 (8)	-4.4				
Johnson 1978[45] 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[64] 19482378	153/91	6 mo	SMBP + Education+ Rx monitor	221	153 (14)	-18.9	-2.5	-5.2, 0.2c	nd	90 (8)	-11.2	-2.2	-3.9, -0.5c	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, 0.6c	nd	90 (8)	-11.2	-0.5	-2.2, 1.2c	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, 2.1c	nd	91 (9)	-10.7	-1.7	-3.5, 0.05c	nd	C
			SMBP + Education	230	153 (14)	-16.4				90 (10)	-9.0				

[a] Mean clinic blood pressure control arm, unless otherwise indicated.
[b] Baseline outcome value, sex, already having a home BP monitor before trial, and clinic while assuming mean baseline covariate values
[c] Calculated from reported data

Table 31. Quality of life: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BPa, 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[79] 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[62] 18577730	152/89	1 yr (1 yr)	General health, SF12 mean (SD)	SMBP + Counsel+ Web	237	67.1 (20.4)	-0.5	0	−3.9, 3.9b	NS	A
				SMBP + Web	246	67.1 (20.4)	-0.5				
			Physical health, SF12 mean (SD)	SMBP + Counsel+ Web	237	80.6 (27)	0.4	3.3	-1.9, 8.5c	NS	
				SMBP + Web	246	80.6 (27)	-2.9				
			Emotional health, mean SD	SMBP + Counsel+ Web	237	71.6 (16.8)	0.1	-0.4	−3.7, 2.9d	NS	
				SMBP + Web	246	71.6 (16.8)	0.5				

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

Table 32. Categorical medication dose and number outcomes: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BPa, 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[78] 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[45] 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[51] 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					

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

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

Author Year PMID	Baseline BPa, 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[62] 18577730	152/89	1 yr (1 yr)	Number of HTN med classes	SMBP + Counsel+ Web	237	1.64 (0.85)	0.52	0.2	0.1, 0.4b	<0.01	A
				SMBP + Web	246	1.64 (0.85)	0.3				

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

Table 34. Categorical medication adherence: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BPa, mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Resultb	95% CI	P Btw	Study Quality
Bosworth 2009[37] 19920269	126/72	24 mo (24 mo)	% of logs with ≥1 recorded BP reading turned in	SMBP + Counsel	65c	110	RR	0.93d	0.75, 1.14e	nd	C
				SMBP	72f	113					
Pierce 1984[51] 6377291	184/106	6 mo (6 mo)	Medication compliance	SMBP + Education	Good 7, Fair 13, Poor 6	30	RR	1.07g	0.47, 2.46h	nd	C
				SMBP	Good 7, Fair 13, Poor 5	25					

[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
[f] Calculated from reported data 64%
[g] Compliance good versus fair or poor
[h] Calculated from reported data

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

Author Year Ref ID PMID	Baseline BPa, 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[45] 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, 0.86b	nd	C
				SMBP	34	65.8 (6.1)	11.8				

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

Table 36. Categorical health care resource use: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BPa, mmHg (Range)	Timepoint (Longest)	Outcome Definition	Intervention	Final	P Btw	Study Quality
Bosworth 2009[37] 19920269	126/72	24 mo (24 mo)	Number of outpatient encounters	SMBP + Counsel	ndb	NS	C
				SMBP			
			% of hospitalized patients	SMBP + Counsel	ndc	NS	
				SMBP			

[a] Mean clinic blood pressure in control group, unless otherwise indicated.
[b] Median ranged from 13 to 15 across all 4 study groups.
[c] Proportion ranged from 19.5% to 22.6% across all 4 study groups.

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

Author Year PMID	Baseline BPa, mmHg	Timepoint (Longest)	Outcome Definition	Intervention	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff (Diff of final)	95% CI	P Btw	Study Quality
Brennan 2010[78] 20415618	133/84	Mean 13 mo	PCP visits per person/y	SMBP + Counsel	320	3.8 (2.4)	-0.5	0.9	0.4, 1.3b	NS	B
				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[79] 15564986	147/87	6 mo	Consultations (#, median)	SMBP Telemedicine + Counsel	131	nd	(2 [range 0, 20])	nd	nd	NS	B
				SMBP	142	nd	(3 [range 0, 23])				
			Hospital admissions (#)	SMBP Telemedicine + Counsel	131	nd	(4)	nd	nd	NS	
				SMBP	142	nd	(3)				

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

Table 38. Continuous miscellaneous outcomes: SMBP plus additional support versus SMBP alone (or other additional support)

Author Year PMID	Baseline BPa, 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[62] 18577730	152/89	1 yr (1 yr)	CAHPS, Assessment of Healthcare Providers and Systems	SMBP + Counsel+ Web	237	7.9 (1.5)	0.4	0.2	−0.0, 0.5b	NS	A
				SMBP + Web	246	7.9 (1.5)	0.2				

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

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.[54,81,82] These studies are discussed individually below, and are summarized in Table 27 (descriptions of the interventions) and Table 28 (descriptions of the study characteristics).

SMBP with graphical display versus SMBP without graphical display (Tables 39-41)

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 39). 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 40). 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 41). 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 40-42)

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 40). 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 h 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 41). 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 42). 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.[27] 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 39&40)

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 39) or DBP (Table 40) 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.

Table 39. Categorical BP: Atypical studies

Author Year PMID	Baseline BPa, mmHg	Timepoint	Outcome Definition	Intervention	n Events	N Total	Outcome Metric	Resultb	95% CI	P Btw	Study Quality
Kabutoya, 2009[81] 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[54] 6742256	167/109	7-12 mo	DBP ≤95	SMBP	47c	77	RR	0.87	0.70, 1.07	<0.05	C
				Family BP measurement	89d	125					

[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 40. Continuous BP: Atypical studies

Author Year PMID	Base BPa, 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[81] 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[82] 1498211	159/102	12 mo, end of follow up	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[54] 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				

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

Table 41. Non-BP continuous outcomes: Atypical studies

Author Year PMID	Baseline BPa, 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[81] 19695029	153/79	6 mo (6 mo)	No. of medications	SMBP + Graph	≤33	1.9 (1.0)	1.84 (3.74)	1.0	nd	<0.02b	C
				SMBP	≤32		0.86 (2.76)				
Staessen 2004[82] 1498211	159/102	1 yr (1 yr)	Intensity of drug treatmentc	SMBP + Home Titration	203	nd	1.03	-0.44	nd	0.001	A
				SMBP + Clinic Titration	197	nd	1.47				
			Symptom score	SMBP + Home Titration	203	1.60	-0.10	0	nd	NS	
				SMBP + Clinic Titration	197	1.52	-0.10				

[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 42. Categorical non-BP outcomes: Atypical studies

Author Year PMID	Baseline BPa, 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[82] 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					

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

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. 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).[72] 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 43 summarizes the main findings addressing the five Key Questions of this systematic review. Discussion regarding the report and recommendations for future research follow.

Table 43. 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 vs. Usual Care ***Overall***	--	• 22 studies compared SMBP alone versus usual care, of which 20 were RCTs and 2 quasi-RCTs. In total, 5,350 patients with hypertension were included. 4 studies were graded quality A, 5 quality B, and 13 quality C. • The studies were heterogeneous in terms of the brands and types of SMBP monitors, followup duration (2-36 mo), 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 vs. Usual Care ***Blood Pressure***	Moderate (Favoring SMBP)	• 21 of the 22 studies that compared SMBP alone versus usual care reported BP outcomes. 4 studies were graded quality A, 4 quality B, and 13 quality C. See the "Overall" summary above regarding the study heterogeneity. • 12 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 with achieving a BP target found no significant effects at 6 and 12 month followup. • 19 studies reported continuous BP outcomes. 16 studies reported clinic BP outcomes, 4 reported 24 hour ambulatory BP, 5 awake (day) ambulatory BP, and 4 asleep (night) ambulatory BP. By meta-analyses, no significant effect was found at 2 months followup, but mostly statistically significant differences, favoring SMBP monitoring, were found at 6 months (SBP/DBP: -3.1/-2.0 mmHg) and 12 months (-2.0/-1.3 mmHg); 12 month DBP was not statistically significant. The meta-analyses were statistically heterogeneous at 6 and 12 months. Only 1 RCT reported followup data beyond 12 months and 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, though most did not find a statistically significant difference. • Incomplete subgroup analyses reported by 3 trials found no differences in the relative effect of SMBP monitoring in patients treated or untreated for hypertension at baseline in one study; by age, sex, or diagnosis with diabetes in a second study; but the third study found significant reductions in clinic and 24 hour ambulatory DBP in men but not women. 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 supporting a small improvement in BP using SMBP compared to usual care.

Key Question	Strength of evidence	Summary/Conclusions/Comments
Key Question 1: SMBP alone vs. Usual Care ***Non-BP Clinical, Surrogate, and Intermediate Outcomes***	Low (Failing to support a difference)	• 12 of the 22 studies that compared SMBP alone versus usual care reported non-BP outcomes. See the "Overall" summary above regarding the study heterogeneity. • No study reported clinical outcomes. • 7 studies reported data on categorical and continuous outcomes related to number of medications and dosage (1 quality A, 4 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, though a minority found significantly greater changes in medication treatment with SMBP monitoring. Weak evidence favors no difference in medication use with SMBP monitoring. • 3 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. • 7 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. 3 studies reported some significantly better measures of adherence with SMBP (though 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 each of these outcomes. • **Conclusion**: The evidence is weak or insufficient for all outcomes, including no evidence on clinical outcomes. Thus overall the strength of evidence is low and fails to support a difference between SMBP alone versus usual care for non-BP clinical, surrogate and intermediate outcomes.
Key Question 1: SMBP alone vs. Usual Care ***Health care encounters***	Low (Failing to support a difference)	• 5 of the 22 studies that compared SMBP alone versus usual care reported health care encounters (1 quality A, 2 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. • 1 study found patients using SMBP to have more office visits and 1 study found patients using SMBP to have 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.

Key Question	Strength of evidence	Summary/Conclusions/Comments
Key Question 1: SMBP + Additional Support vs. Usual Care ***Overall***	--	• 21 studies compared SMBP plus additional support versus usual care, of which 16 were RCTs, 2 quasi-RCTs, and 3 nonrandomized studies. In total, 5,663 patients with hypertension were included. 4 studies were graded quality A, 5 quality B, and 12 quality C. 4 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 mo), 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, phone monitoring with electronic transmission of BP data, 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 patient, nurse, pharmacist, or the primary care physician.
Key Question 1: SMBP + Additional Support vs. Usual Care ***Blood Pressure***	High (Favoring SMBP)	• All 21 studies that compared SMBP plus additional support versus usual care reported BP outcomes. See the “Overall” summary above regarding the study heterogeneity. • All four 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 • **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 the primary intents, ancillary equipments 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.

Key Question	Strength of evidence	Summary/Conclusions/Comments
Key Question 1: SMBP + Additional Support vs. Usual Care ***Clinical, Surrogate, and Intermediate Outcomes***	Low (Failing to support a difference)	• 13 of the 21 studies that compared SMBP plus additional support versus usual care reported non-BP outcomes. See the "Overall" summary above regarding the study heterogeneity. • 1 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. • 10 studies reported data on categorical and continuous outcomes related to medication number and dosage (2 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, number of medications classes used or tablets taken. Studies were split between finding no difference in medication outcomes or finding either an increase or decrease in medications with patients using SMBP with additional support. The contradictory findings in the evidence overall favors no difference in medication use with SMBP monitoring plus additional support. • 3 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 Health care Providers and Systems score, Anxiety score, or Euro QoL 5D score. The studies all found no difference in quality of life. • 6 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. • 1 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 all outcomes. Thus overall the strength of evidence is low and fails to support a difference between SMBP plus additional support versus usual care for non-BP clinical, surrogate and intermediate outcomes.
Key Question 1: SMBP + Additional Support vs. Usual Care ***Health care encounters***	Low (Failing to support a difference)	• 6 of the 21 studies that compared SMBP plus additional support versus usual care reported health care encounters (1 quality A, 1 quality B, and 4 quality C). • The studies were highly heterogeneous, primarily in the types of additional support used. Additional support included education, alerts and medication monitoring and self-titration. All reported on number of physician (or physician and nurse) visits. • 4 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. • **Conclusion**: Given the discordant findings as well as the low quality study quality, the overall strength of evidence is low, failing to support a difference between groups.

Key Question	Strength of evidence	Summary/Conclusions/Comments
Key Question 2: SMBP + Additional Support vs. SMBP *Overall*	--	• 9 studies compared SMBP plus an additional support versus SMBP without the additional support, of which 8 were RCTs and 1 was quasi-randomized. In total, 2,701 patients with hypertension were included. 1 trial was graded quality A, 3 quality B, and 4 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, educational interventions, electronic transmission of BP measurements, Web sites for patient provider communication, BP recording cards or hypertension information leaflets, or home visits. Change in medication management as a result of the monitoring could be initiated by patient, nurse, pharmacist, or the primary care physician. Other sources of heterogeneity included the brands and types of SMBP monitors, followup duration (3-24 mo, though 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, mostly male in most studies, and the most commonly cited comorbid condition was type 2 diabetes.
Key Question 2: SMBP + Additional Support vs. SMBP *Blood Pressure*	Low (Failing to support a difference)	• All 9 studies that compared SMBP plus an additional support versus SMBP without the additional support reported BP outcomes. See the "Overall" summary above regarding the study heterogeneity. • 7 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). 5 trials found no significant difference in rates of achieving BP control. 1 trial of SMBP plus Web-based pharmacist care found a significant effect favoring the SMBP. Another trial comparing SMBP plus medication monitoring plus educational material versus SMBP plus educational material also found benefit for the more intense additional support • 8 studies reported continuous BP outcomes. 5 trials found no significant difference. 3 favored the more intensive additional support, one comparing Web-based pharmacist care versus Web-based care, the second comparing medication monitoring plus educational material versus SMBP plus educational material, and the third comparing medication monitoring plus educational material versus SMBP plus educational material. • 1 trial reported incomplete subgroup analyses for BP. It showed benefit for addition of pharmacist care to SMBP plus website for those with SBP >=160 mmHg at baseline which was concordant with the main trial findings. • Across studies, no clear patterns could be discerned to explain the heterogeneity in results. • **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.

Key Question	Strength of evidence	Summary/Conclusions/Comments
Key Question 2: SMBP + Additional Support vs. SMBP ***Clinical, Surrogate, and Intermediate Outcomes***	Low (Failing to support a difference)	• 4 of the 9 studies that compared SMBP plus an additional support versus SMBP without the additional support reported non-BP outcomes. See the "Overall" summary above regarding the study heterogeneity. • No study reported clinical outcomes. • 2 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. • 4 trials reported data on categorical and continuous medication number and dosage (2 quality A, 2 quality B). Studies reported numbers of patients taking 2 or more classes of medications, medical inertia (defined as no medication change versus either an increase or decrease in medications), and number of medication drug classes. 3 trials using additional support consisting of nurse counseling, home visits for BP measurement, or education found no difference between SMBP plus additional support and usual care. 1 trial found somewhat greater mean number of medication drug classes with SMBP plus pharmacist care plus Website. Weak evidence suggests no difference in medication use. • 3 quality C trials reported on medication adherence. Using different measures in each study, none found a significant difference in medication adherence. 1 trial also found no difference in a subgroup of individuals with lower baseline adherence. • 2 trials looked at miscellaneous outcomes. 1 quality C trial found no difference in adverse drug reactions across four groups with different forms of additional support or usual care. 1 quality A trial found no difference for consumer satisfaction measured with the Consumer Assessment of Health care Providers and Systems instrument. • **Conclusion**: For each outcome the evidence is weak due to inconsistency across studies or poor quality studies, or insufficient. 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.
Key Question 2: SMBP + Additional Support vs. SMBP ***Health care encounters***	Low (Failing to support a difference)	• 3 of the 9 studies that compared SMBP plus an additional support versus SMBP without the additional support reported 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, and 1 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. • **Conclusion**: Despite the consistency across trials, because of their small number and poor quality, overall the strength of evidence is low and fails tosupport a difference for health care utilization by the use of additional support with SMBP compared to SMBP without additional support or with less intensive 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	Strength of evidence	Summary/Conclusions/Comments
Key Question 5: Predictors of SMBP adherence	Insufficient	• 1 quality B study addressed how adherence with 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.

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 43 comparative studies of SMBP with or without additional support in the management of hypertension (and one study on predictors of SMBP adherence). 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

SMBP compared to usual care resulted in a modest, but statistically significant (by meta-analysis) reduction in clinic systolic (SBP) and diastolic BP (DBP) (SBP/DBP: -3.1/-2.0 mmHg) at 6 months, as well as in clinic SBP at 12 months (-2.0 mmHg). Results at 2 months for clinic SBP and DBP and at 12 months for DBP were not statistically significant. Only one randomized controlled trial (RCT) reported followup beyond 12 months, finding significant reductions in SBP and DBP at 24 months with SMBP.

Even though 11 of 21 trials comparing SMBP plus additional support versus usual care reported a statistically significant benefit in BP reduction favoring SMBP with additional support, it is not possible to state with certainty whether one form of additional support is superior, as the modality of support varied widely across studies.

Similarly, while three of nine trials of SMBP plus additional support versus SMBP without additional support reported a significantly greater reduction in BP in the SMBP with additional

support group, the small number of studies and the heterogeneity of the mode of additional support makes it impossible to draw conclusions regarding the potential effects of specific modalities of additional support or their interactions with SMBP.

To answer the question about the role of additional support in combination with SMBP, we attempted to look across the three comparisons of SMBP versus usual care, SMBP with additional support versus usual care, and SMBP plus additional support versus SMBP. With the caveat that evidence from indirect comparisons is much inferior to evidence from direct comparisons within trials, there is a suggestion that additional support is synergistic with SMBP to achieve BP control. We grouped the different specific additional supports used into categories based predominantly on counseling, education, Web support, or other support. However, the types of additional support were too heterogeneous and overlapping to be neatly categorized. Thus, it is not possible to state with certainty which particular component is most effective.

Sources of clinical heterogeneity

Numerous sources of clinical heterogeneity across studies could be readily discerned. 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.

Studies differed in their focus on the comparison or interest either being SMBP versus control, SMBP with additional support versus control, SMBP combined with additional support versus additional support, or SMBP with additional support versus SMBP. Some studies contained more than two intervention groups, such as SMBP by itself, SMBP with additional support, SMBP with a different type of additional support, additional support alone, or usual care. Even the 'usual care' groups varied across studies ranging from true usual care, study-standardized "usual care," or 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.

Furthermore, results on clinical outcomes 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.

Interpretation of findings for Key Questions 1 and 2

Although the observed reduction in BP with SMBP was small to modest, it may reflect a clinically relevant effect on a population level. Observational data suggests 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.[84] 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.[85] On the other hand, this reduction is modest compared to that estimated to occur with other lifestyle interventions.[1]

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.[20,27,82] 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).

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. 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. However, a number of these digital BP devices have yet to undergo rigorous independent validation.[86] 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. Nonadherence to SMBP schedules is a key limitation in the successful application of this intervention in hypertension management. Indeed, adherence itself has not been defined in a consistent fashion. 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 to two studies were available for many specific comparisons. Many studies were 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.

Applicability

Reviewed studies were all conducted in an outpatient setting and 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. 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.

On the other hand, 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 expand the possibilities for patient-provider interactions to support 'self-titration' of BP medication,[65] 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. Also the impact of reimbursement structures, in particulare fee-for-service versus capitated systems needs to be evaluated for such a potential shift.[87]

Context of findings

Our findings are consistent with four recently published systematic reviews examining the effect of SMBP identified in our search.[88-91] Agarwal 2010 examined 37 trials, Bray 2010 25 trials, Cappuccio 2004 18 trials, and Glynn 2010 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 2010 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.[92]

Ongoing research

A search in the ClinicalTrials.gov registry yielded 23 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 22 were interventional, of which 21 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-2 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.[57,93] 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.

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.

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. Researchers should consider which already-investigated method of SMBP monitoring 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.

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 there was no RCT with a head-to-head comparison, most recent studies used automated devices. Thus this question may not be of high importance for future research since automated devices are widely available and require less dexterity on the part of the patient.

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, future studies should also examine the effects of SMBP on clinical events. This will require followup durations greater than 1 year. A 5 to 10-year followup appears appropriate for a chronic disease like hypertension, with its risk for clinical outcomes accruing over decades. 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 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

The effectiveness of SMBP may vary by patient characteristics or attitudes. Observational and experimental studies should, therefore, examine characteristics that predict 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, 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. There is also a need for a central database that would serve as a reference on accreditation information to support clinician-, investigator-, and consumer-selection of a device. 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 confers a small benefit for lowering BP, but its sustainability and long-term effectiveness remain uncertain. 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.

References

1. Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report.[Erratum appears in JAMA. 2003 Jul 9;290(2):197]. JAMA 2003; 289(19):2560-2572.

2. Falkner B. Hypertension in children and adolescents: epidemiology and natural history. Pediatr Nephrol 2010; 25(7):1219-1224.

3. The fourth report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents. Pediatrics 2004; 114(2 Suppl 4th Report):555-576.

4. Kearney PM, Whelton M, Reynolds K, Whelton PK, He J. Worldwide prevalence of hypertension: a systematic review. J Hypertens 2004; 22(1):11-19.

5. The world health report 2002 - Reducing Risks, Promoting Healthy Life. http://www.who.int/whr/2002/en/ . 2002. 1-31-2011.

6. Whitworth JA. 2003 World Health Organization (WHO)/International Society of Hypertension (ISH) statement on management of hypertension. J Hypertens 2003; 21(11):1983-1992.

7. Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics--2011 update: a report from the American Heart Association. Circulation 123(4):e18-e209, 2011.

8. Yoon SS, Ostchega Y, Louis T. Recent trends in the prevalence of high blood pressure and its treatment and control, 1999-2008. NCHS Data Brief 2010;(48):1-8.

9. Vasan RS, Beiser A, Seshadri S, et al. Residual Lifetime Risk for Developing Hypertension in Middle-aged Women and Men: The Framingham Heart Study. JAMA 2002; 287(8):1003-1010.

10. Ezzati M, Oza S, Danaei G, Murray CJ. Trends and cardiovascular mortality effects of state-level blood pressure and uncontrolled hypertension in the United States. Circulation 2008; 117(7):905-914.

11. Law M, Wald N, Morris J. Lowering blood pressure to prevent myocardial infarction and stroke: a new preventive strategy. Health Technol Assess 2003; 7(31):1-94.

12. Neal B, MacMahon S, Chapman N. Effects of ACE inhibitors, calcium antagonists, and other blood-pressure-lowering drugs: results of prospectively designed overviews of randomised trials. Blood Pressure Lowering Treatment Trialists' Collaboration. Lancet 2000; 356(9246):1955-1964.

13. Gueyffier F, Froment A, Gouton M. New meta-analysis of treatment trials of hypertension: improving the estimate of therapeutic benefit. J Hum Hypertens 1996; 10(1):1-8.

14. Staessen JA, Gasowski J, Wang JG, et al. Risks of untreated and treated isolated systolic hypertension in the elderly: meta-analysis of outcome trials. Lancet 2000; 355(9207):865-872.

15. Stamler R. Implications of the INTERSALT study. Hypertension 1991; 17(1 Suppl):I16-I20.

16. Whelton PK, He J, Appel LJ, et al. Primary prevention of hypertension: clinical and public health advisory from The National High Blood Pressure Education Program. JAMA 2002; 288(15):1882-1888.

17. Thavarajah S, White WB, Mansoor GA. Terminal digit bias in a specialty hypertension faculty practice. J Hum Hypertens 2003; 17(12):819-822.

18. Ghuman N, Campbell P, White WB. Role of ambulatory and home blood pressure recording in clinical practice. Curr Cardiol Rep 2009; 11(6):414-421.

19. Verberk WJ, Kroon AA, Thien T, et al. Prevalence of the white-coat effect at multiple visits before and during treatment. J Hypertension 2006; 24(12):2357-2363.

20. Verberk WJ, Kroon AA, Lenders JW, et al. Self-measurement of blood pressure at home reduces the need for antihypertensive drugs: a randomized, controlled trial. Hypertension 2007; 50(6):1019-1025.

21. Appel LJ, Robinson KA, Guallar E, et al. Utility of blood pressure monitoring outside of the clinic setting. Evid Rep Technol Assess (Summ) 2002; (63):1-5.

22. Celis H, Den HE, Staessen JA. Self-measurement of blood pressure at home in the management of hypertension. Clin Med Res 2005; 3(1):19-26.

23. O'Brien E, Asmar R, Beilin L, et al. European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement. J Hypertension 2003; 21(5):821-848.

24. Imai Y, Otsuka K, Kawano Y, et al. Japanese society of hypertension (JSH) guidelines for self-monitoring of blood pressure at home. Hypertens Res 2003; 26(10):771-782.

25. Verberk WJ, Kroon AA, Kessels AG, de Leeuw PW. Home blood pressure measurement: a systematic review. J Am Coll Cardiol 2005; 46(5):743-751.

26. Nesbitt SD, Amerena JV, Grant E, et al. Home blood pressure as a predictor of future blood pressure stability in borderline hypertension. The Tecumseh Study. Am J Hypertens 1997; 10(11):1270-1280.

27. Staessen JA, Den Hond E, O'Brien ET. Guidelines for Home- and Office-Based Blood Pressure Monitoring—Reply. JAMA 2004; 291(19):2315-2316.

28. www.consumerreportshealth.org. 2010.

29. Whitlock EP, Lopez SA, Chang S, et al. AHRQ series paper 3: identifying, selecting, and refining topics for comparative effectiveness systematic reviews: AHRQ and the effective health-care program. J Clin Epidemiol 2010; 63(5):491-501.

30. Wallace BC, Trikalinos TA, Lau J, Brodley C, Schmid CH. Semi-automated screening of biomedical citations for systematic reviews. BMC Bioinformatics 2010; 11:55.

31. Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions--agency for healthcare research and quality and the effective health-care program. Journal of Clinical Epidemiology 2010; 63(5):513-523.

32. DerSimonian R, Laird N. Meta-analysis in clinical trials. Control Clin Trials 1986; 7(3):177-188.

33. Higgins JP, Thompson SG. Quantifying heterogeneity in a meta-analysis. Stat Med 2002; 21(11):1539-1558.

34. Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. BMJ 2003; 327(7414):557-560.

35. Bailey B, Carney SL, Gillies AA, Smith AJ. Antihypertensive drug treatment: a comparison of usual care with self blood pressure measurement. J Hum Hypertens 1999; 13(2):147-150.

36. Binstock ML, Franklin KL. A comparison of compliance techniques on the control of high blood pressure. Am J Hypertens 1988; 1(3:Pt 3):t-194S.

37. Bosworth HB, Olsen MK, Grubber JM, et al. Two self-management interventions to improve hypertension control: a randomized trial. Ann Intern Med 2009; 151(10):687-695.

38. Broege PA, James GD, Pickering TG. Management of hypertension in the elderly using home blood pressures. Blood Press Monit 2001; 6(3):139-144.

39. Carnahan JE, Nugent CA. The effects of self-monitoring by patients on the control of hypertension. Am J Med Sci 1975; 269(1):69-73.

40. Dalfó i Baqué A, Capillas Peréz R, Guarch Rocarias M, et al. [Effectiveness of self-measurement of blood pressure in patients with hypertension: the Dioampa study]. [Spanish (English translation available)]. Aten Primaria 2005; 35(5):233-237.

41. Dejesus RS, Chaudhry R, Leutink DJ, et al. Effects of efforts to intensify management on blood pressure control among patients with type 2 diabetes mellitus and hypertension: a pilot study. Vasc Health Risk Manag 2009; 5:705-711.

42. Fitzgerald DJ, O'Callaghan WG, O'Brien E, et al. Home recording of blood pressure in the management of hypertension. Ir Med J 1985; 78(8):216-218.

43. Godwin M, Lam M, Birtwhistle R, et al. A primary care pragmatic cluster randomized trial of the use of home blood pressure monitoring on blood pressure levels in hypertensive patients with above target blood pressure. Fam Pract 2010; 27(2):135-142.

44. Halme L, Vesalainen R, Kaaja M, Kantola I, HOme MEasuRement of blood pressure study group. Self-monitoring of blood pressure promotes achievement of blood pressure target in primary health care. Am J Hypertens 2005; 18(11):1415-1420.

45. Johnson AL, Taylor DW, Sackett DL, Dunnett CW, Shimizu AG. Self-recording of blood pressure in the management of hypertension. Can Med Assoc J 1978; 119(9):1034-1039.

46. Madsen LB, Kirkegaard P, Pedersen EB. Blood pressure control during telemonitoring of home blood pressure. A randomized controlled trial during 6 months. Blood Press 2008; 17(2):78-86.

47. Madsen LB, Kirkegaard P, Pedersen EB. Health-related quality of life (SF-36) during telemonitoring of home blood pressure in hypertensive patients: a randomized, controlled study. Blood Press 2008; 17(4):227-232.

48. Márquez-Contreras E, Martell-Claros N, Gil-Guillén V, et al. Efficacy of a home blood pressure monitoring programme on therapeutic compliance in hypertension: the EAPACUM-HTA study. J Hypertens 2006; 24(1):169-175.

49. Mehos BM, Saseen JJ, MacLaughlin EJ. Effect of pharmacist intervention and initiation of home blood pressure monitoring in patients with uncontrolled hypertension. Pharmacotherapy 2000; 20(11):1384-1389.

50. Midanik LT, Resnick B, Hurley LB, Smith EJ, McCarthy M. Home blood pressure monitoring for mild hypertensives. Public Health Rep 1991; 106(1):85-89.

51. Pierce JP, Watson DS, Knights S, et al. A controlled trial of health education in the physician's office. Prev Med 1984; 13(2):185-194.

52. Rogers MA, Small D, Buchan DA, et al. Home monitoring service improves mean arterial pressure in patients with essential hypertension. A randomized, controlled trial. Ann Intern Med 2001; 134(11):1024-1032.

53. Soghikian K, Casper SM, Fireman BH, et al. Home blood pressure monitoring. Effect on use of medical services and medical care costs. Med Care 1992; 30(9):855-865.

54. Stahl SM, Kelley CR, Neill PJ, Grim CE, Mamlin J. Effects of home blood pressure measurement on long-term BP control. Am J Public Health 1984; 74(7):704-709.

55. van Onzenoort HA, Verberk WJ, Kroon AA, et al. Effect of self-measurement of blood pressure on adherence to treatment in patients with mild-to-moderate hypertension. J Hypertens 2010; 28(3):622-627.

56. Zarnke KB, Feagan BG, Mahon JL, Feldman RD. A randomized study comparing a patient-directed hypertension management strategy with usual office-based care. Am J Hypertens 1997; 10(1):58-67.

57. Fujiwara T, Nishimura T, Ohkuko T, Imai Y, HOMED-BP Study Group. Rationale and design of HOMED-BP Study: hypertension objective treatment based on measurement by electrical devices of blood pressure study. Blood Pressure Monitoring 2002; 7(1):77-82.

58. Earp JA, Ory MG, Strogatz DS. The effects of family involvement and practitioner home visits on the control of hypertension. Am J Public Health 1982; 72(10):1146-1154.

59. Artinian NT, Washington OG, Templin TN. Effects of home telemonitoring and community-based monitoring on blood pressure control in urban African Americans: a pilot study. Heart Lung 2001; 30(3):191-199.

60. Friedman RH, Kazis LE, Jette A, et al. A telecommunications system for monitoring and counseling patients with hypertension. Impact on medication adherence and blood pressure control. Am J Hypertens 1996; 9(4:Pt 1):t-92.

61. Gran B. Non-pharmacological methods reduce drug use in the treatment of hypertension. A two-year trial in general practice. Scand J Prim Health Care 1991; 9(2):121-128.

62. Green BB, Cook AJ, Ralston JD, et al. Effectiveness of home blood pressure monitoring, Web communication, and pharmacist care on hypertension control: a randomized controlled trial.[Erratum appears in JAMA. 2009 Nov 11;302(18):1972]. JAMA 2008; 299(24):2857-2867.

63. Haynes RB, Sackett DL, Gibson ES, et al. Improvement of medication compliance in uncontrolled hypertension. Lancet 1976; 1(7972):1265-1268.

64. Márquez Contreras E, Martel Claros N, Gil Guillén V, et al. [Control of therapeutic inertia in the treatment of arterial hypertension by using different strategies]. [Spanish]. Aten Primaria 2009; 41(6):315-323.

65. McManus RJ, Mant J, Bray EP, et al. Telemonitoring and self-management in the control of hypertension (TASMINH2): a randomised controlled trial. Lancet 2010; 376(9736):163-172.

66. Kim J, Han HR, Song H, et al. Compliance with home blood pressure monitoring among middle-aged Korean Americans with hypertension. Journal of Clinical Hypertension 2010; 12(4):253-260.

67. Muhlhauser I, Sawicki PT, Didjurgeit U, et al. Evaluation of a structured treatment and teaching programme on hypertension in general practice. Clin Exp Hypertens 1993; 15(1):125-142.

68. Parati G, Omboni S, Albini F, et al. Home blood pressure telemonitoring improves hypertension control in general practice. The TeleBPCare study. J Hypertens 2009; 27(1):198-203.

69. Park MJ, Kim HS, Kim KS. Cellular phone and Internet-based individual intervention on blood pressure and obesity in obese patients with hypertension. Int J Med Inf 2009; 78(10):704-710.

70. Rinfret S, Lussier MT, Peirce A, et al. The impact of a multidisciplinary information technology-supported program on blood pressure control in primary care. Circ Cardiovasc Qual Outcomes 2009; Cardiovascular(3):170-177.

71. Rudd P, Miller NH, Kaufman J, et al. Nurse management for hypertension. A systems approach. Am J Hypertens 2004; 17(10):921-927.

72. Sawicki PT, Muhlhauser I, Didjurgeit U, et al. Intensified antihypertensive therapy is associated with improved survival in type 1 diabetic patients with nephropathy. J Hypertens 1995; 13(8):933-938.

73. Shea S, Weinstock RS, Starren J, et al. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus. J Am Med Inform Assoc 2006; 13(1):40-51.

74. Shea S, IDEATel Consortium. The Informatics for Diabetes and Education Telemedicine (IDEATel) project. Trans Am Clin Climatol Assoc 2007; 118:289-304.

75. Shea S, Weinstock RS, Teresi JA, et al. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus: 5 year results of the IDEATel study. J Am Med Inform Assoc 2009; 16(4):446-456.

76. Zillich AJ, Sutherland JM, Kumbera PA, Carter BL. Hypertension outcomes through blood pressure monitoring and evaluation by pharmacists (HOME study). J Gen Intern Med 2005; 20(12):1091-1096.

77. Steiner JF, Prochazka AV. The assessment of refill compliance using pharmacy records: methods, validity, and applications. J Clin Epidemiol 1997; 50:105-116.

78. Brennan T, Spettell C, Villagra V, et al. Disease management to promote blood pressure control among African Americans. Popul Health Manag 2010; 13(2):65-72.

79. Carrasco MP, Salvador CH, Sagredo PG, et al. Impact of patient-general practitioner short-messages-based interaction on the control of hypertension in a follow-up service for low-to-medium risk hypertensive patients: a randomized controlled trial. IEEE Trans Inf Technol Biomed 2008; 12(6):780-791.

80. Cheltsova A, Patel S, Young H, Barr K, Katz R. A Structured Program for Hypertension Control in an Urban, High Risk Population: A Randomized Trial. Hypertension 56[5], e109. 2010.

81. Kabutoya T, Ishikawa J, Hoshide S, et al. A home blood pressure monitor equipped with a graphic function facilitates faster blood pressure control than the conventional home blood pressure monitor. J Clin Hypertens (Greenwich) 2009; 11(8):422-425.

82. Staessen JA, Den HE, Celis H, et al. Antihypertensive treatment based on blood pressure measurement at home or in the physician's office: a randomized controlled trial. JAMA 2004; 291(8):955-964.

83. Den Hond E., Staessen JA, Celis H, et al. Antihypertensive treatment based on home or office blood pressure--the THOP trial. Blood Press Monit 2004; 9(6):311-314.

84. Lewington S, Clarke R, Qizilbash N, Peto R, Collins R. Age-specific relevance of usual blood pressure to vascular mortality. The Lancet 2003; 361(9366):1391-1392.

85. Lawes CM, Bennett DA, Lewington S, Rodgers A. Blood pressure and coronary heart disease: a review of the evidence. [Review] [108 refs]. Seminars in Vascular Medicine 2(4):355-68, 2002.

86. Yarows SA, Julius S, Pickering TG. Home blood pressure monitoring. [Review] [88 refs]. Archives of Internal Medicine 160(9):1251-7, 2000.

87. Ogedegbe G. Self-titration for treatment of uncomplicated hypertension. Lancet 2010; 376(9736):144-146.

88. Agarwal R, Bills JE, Hecht TJ, Light RP. Role of home blood pressure monitoring in overcoming therapeutic inertia and improving hypertension control: a systematic review and meta-analysis. Hypertension 2011; 57(1):29-38.

89. Bray EP, Holder R, Mant J, McManus RJ. Does self-monitoring reduce blood pressure? Meta-analysis with meta-regression of randomized controlled trials. Ann Med 2010; 42(5):371-386.

90. Cappuccio FP, Kerry SM, Forbes L, Donald A. Blood pressure control by home monitoring: meta-analysis of randomised trials.[Erratum appears in BMJ. 2004 Aug 28;329(7464):499]. BMJ 2004; 329(7458):145.

91. Glynn LG, Murphy AW, Smith SM, Schroeder K, Fahey T. Interventions used to improve control of blood pressure in patients with hypertension [Systematic Review]. 2010; 3.

92. Pickering TG, Miller NH, Ogedegbe G, et al. Call to action on use and reimbursement for home blood pressure monitoring: Executive Summary. A joint scientific statement from the American Heart Association, American Society of Hypertension, and Preventive Cardiovascular Nurses Association. J Clin Hypertens (Greenwich) 2008; 10(6):467-476.

93. 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(2):119-127.

Acronyms and Abbreviations Used in Text

“C”	Counseling (see Table 26)
“E”	Education (see Table 26)
“M”	Miscellaneous additional supports (see Table 26)
“W”	Web-based or telephonic tools (see Table 26)
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