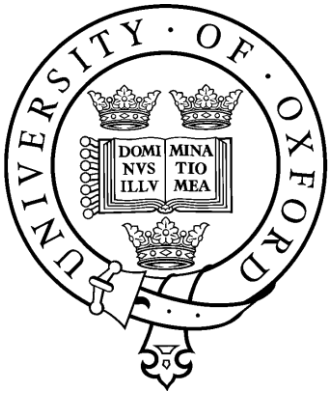
WHAT IS THE ROLE OF SELF-MONITORING OF BLOOD PRESSURE IN THE MANAGEMENT OF HYPERTENSON?



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ABSTRACT

What is the role of self-monitoring of blood pressure in the management of hypertension?

Patient self-monitoring of blood pressure (SMBP) has shown promise in contributing towards improving ongoing management of hypertension, however it has yet to be fully integrated into guidelines or routine general practice in the UK.

The aims of this thesis were to investigate the role of SMBP in the management of hypertension to better understand: patient and clinician attitudes to SMBP; what behaviour change SMBP targets in patients to bring about better BP outcomes; to what extent SMBP is utilised as part of routine hypertension management in the UK; and to understand patient preferences for hypertension management in light of effective models of care.

A mixed methods approach was used including: systematic reviews of qualitative and quantitative evidence; semi-structured interviews with patients; a cross sectional survey; and a discrete choice experiment.

Self-monitoring was associated with better medication adherence, which could have significant impact at a population level given the high proportion of non-adherent hypertensive patients.

Use of SMBP should be seen as a continuum from being used solely to inform clinical decisions, through facilitating interaction between patients and clinicians, to empowering patients to be autonomous for example in self-management.

SMBP was most effective when patients had the knowledge and skills to make improvements in their lifestyle, and this has been shown in clinical trials and through qualitative investigation.

Clinicians recognise the potential benefits of SMBP, but are concerned that patients may become burdened. Clinicians should feel encouraged that patients are supportive of self-monitoring, but they must ensure that patients who wish to self-manage are equipped with the skills to do so. Lack of facility to make positive change may lead some patients to feeling disempowered and clinicians need to be cognisant of this fact.

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CHAPTER ONE

WHAT IS THE ROLE OF SELF-MONITORING OF BLOOD PRESSURE IN THE MANAGEMENT OF HYPERTENSION

BACKGROUND AND LITERATURE REVIEW

1.1 CHAPTER OVERVIEW

This chapter summarises the background, aims, research questions, and overall structure of the thesis. It begins with a background to the epidemiology of hypertension, treatment options, and the role of out-of-office blood pressure measurement in diagnosing and managing hypertension. There is then discussion of the need for novel models of care for the management of chronic disease, in particular hypertension, along with the potential contribution that patient self-monitoring could make.

1.2 INTRODUCTION, AIMS AND RESEARCH QUESTIONS

Patient self-monitoring of blood pressure (SMBP) has in recent years proven to be an effective intervention in both the diagnosis and management of hypertension by improving clinical decision making and allowing patients to actively participate in their own health care.(1) Although there is comprehensive evidence for the effectiveness of SMBP in hypertension management, it has yet to be fully integrated into routine general practice in the UK. How SMBP can best be utilised in UK general practice is a focus of this thesis.

The aims of this thesis were to investigate the role of SMBP in the management of hypertension to better understand: patient and clinician attitudes to SMBP; what behaviour change SMBP targets in patients to bring about better BP outcomes; to what extent SMBP is utilised as part of routine hypertension management in the UK; and to understand patient preferences for hypertension management in light of other effective models of care. The aims and research questions are discussed in more depth at the end of this chapter in 1.10.

1.3 EPIDEMIOLOGY AND RISK FACTORS FOR HYPERTENSION

Since the early 1990s, high blood pressure (BP), or hypertension, has increased from the fourth to the first most important risk factor for global disease burden, leading to the World Health Organisation (WHO) describing hypertension as a "global public health crisis".(2, 3) Hypertension is a condition where BP is persistently elevated, and is the most important modifiable risk factor for stroke and heart disease, and the second leading cause for kidney disease after diabetes.(4) There are many factors that contribute to the development of hypertension including: social determinants (income, education and ageing); behavioural factors (physical inactivity, diet, alcohol and tobacco use); and metabolic factors such as

diabetes and raised blood lipids.(5) Primary hypertension, also known as essential hypertension, is due to non-specific lifestyle and genetic factors and accounts for 90-95% of cases, while secondary hypertension has an identifiable cause such as Conn's syndrome, thyroid dysfunction or use of birth control medication.

Globally non-communicable diseases have overtaken infectious diseases as the leading cause of mortality.(6) It is estimated that 17.5million people die each year as a result of cardiovascular diseases (CVD) such as heart disease and stroke, which represents 31% of all deaths (mortality), with hypertension being the most important contributing factor.(6) A 2012 study determined that high blood pressure was the leading risk factor for disease burden (morbidity) and accounted for 7% (95% uncertainty interval 6.2-7.7) of global disability adjusted life years (DALYs) in 21 regions across the globe.(2) The WHO has set a global target of a "25% relative reduction in the prevalence of raised BP or to contain the prevalence of raised BP, according to national circumstances" before 2025.

By 2008, approximately 40% of adults were thought to have hypertension worldwide; over 1 billion people.(6) In the UK currently nearly 8 million adults are recorded on hypertension registers (Quality Outcomes Framework). The Health Survey for England (HSE) is a survey that is conducted annually and collects information concerning health and health related behaviour in a representative cohort of households (c. 16,000 adults).(7) For hypertension, participants have their BP measured by a nurse, using standard methods. They are also asked if they have been diagnosed as hypertensive by their GP, and if so, whether they are on any prescribed medication. The most recently available data from the 2013 HSE showed that 31.4% of men and 26.0% of women had survey defined hypertension (measured by nurse on a single occasion). Previous surveys have shown that three fifths of those with survey defined hypertension report being diagnosed by their GP, and just over half received

treatment. The HSE also shows that almost two fifths of those receiving treatment for hypertension did not have a BP below 140/90mmHg (i.e. 'normal' BP).(8)

The "rule of halves" was developed from the findings of surveys of BP in the United States in the early 1970s, repeated in Scotland in 1990, and states that: half the hypertensive population is undetected, half of those detected are untreated, and half of those treated are uncontrolled.(9-11) Results of the Health Survey (2006) for England mirrored the rule of halves, and although there have been some improvements over the past decade, this demonstrates that there is still room for improvement in both diagnosing and treating hypertension.(12-14)

1.4 BP CLASSIFICATION, TARGETS AND VARIABILITY

Classifications of hypertension are arbitrary, and thresholds for diagnosis have progressively decreased over time, leading to more patients being treated with antihypertensive medication.(15) In the UK and elsewhere, hypertension is typically defined by clinic BP of 140/90mmHg or higher in non-diabetic patients aged under 80. Recently there has been some discussion of lowering BP targets even further, in light of results from the SPRINT trial (BP target <120/80mmHg) and a large systematic review and meta-analysis published in 2016. However these results are controversial and have yet to make an impact on guidelines.(16, 17) A more descriptive definition of hypertension was provided by Sir Muir Gray in a letter to the BMJ in 2014 (18):

> *"Having a blood pressure of a level at which there is evidence that the individual should consider taking a drug to reduce their risk of a stroke (or heart attack), if they have not been able to reduce their blood pressure by weight reduction and exercise."*

Evidence also shows that the adverse cardiovascular outcomes of hypertension depend not only on the absolute BP value, but also BP variability, with a recent review demonstrating that long-term (visit-to-visit) variability in BP was associated with cardiovascular and mortality outcomes over and above the effect of mean BP.(19, 20)

Guidelines for treatment vary internationally with regard to initiation of treatment; what BP target to treat to; what drugs to use and in what combinations. The timing of initiating pharmacologic treatment remains controversial, and a recent report has questioned the benefit of treating stage 1/mild hypertensives.(21) Uncertainty stems from the fact that trials in this population have tended to focus on BP outcomes without any data on downstream hard outcomes such as CVD and death.

A systematic review of randomised controlled trials published in 2012 showed that pharmacotherapy for low risk stage 1 hypertensives did not reduce mortality, coronary heart disease or stroke, and exposes patients to adverse drug events.(22) However, a more current review (2015) of pharmacotherapy in stage 1 hypertensives, the majority of whom also had diabetes, showed that there were benefits in terms of preventing stroke and death.(23)

If the UK were to follow the majority of international guidance and prescribe anti-hypertensives to all individuals in this low risk population group, rather than current practice of offering lifestyle advice, it could cost the NHS an additional £106-229 million per year.(24)

1.5 TREATING HYPERTENSION

The ultimate goal of antihypertensive treatment is reduction of cardiovascular risk, and trials have shown that for every 10mmHg reduction in systolic BP, risk of stroke falls by 40%,

and risk of coronary events by 20%.(25) Pharmacologic interventions and lifestyle change form the basis of treatment for reducing BP in the treatment of hypertension. The following section describes the evidence base for medication and lifestyle change on BP, as well as a summary of UK guidelines for the treatment of hypertension.

1.5.1 Anti-hypertensive medication

There are a number of effective antihypertensive medication classes, the five most commonly prescribed in the UK being: angiotensin converting enzyme inhibitors (ACEI); angiotensin receptor blockers (ARB); calcium channel blockers (CCB); beta blockers; and diuretics. There is considerable variation in prescribing internationally, most likely due to costs of medications.(26) Where necessary combining drug classes has shown to be effective: combining drugs from any two classes has approximately five times the effect of doubling the dose of one drug.(27) In addition, dual or triple therapy may be preferred to maximum dose monotherapy as this allows the medications to be used at their lowest effective doses, minimising side effects.

On average, a single blood pressure lowering drug at standard dose reduces systolic BP by 8mmHg and diastolic BP by 5mmHg, which is equivalent to approximately 25% reduction in risk of CHD and 35% reduction in risk of stroke.(28, 29) Combining two drug classes has the effect of an extra 7mmHg systolic and 5mmHg diastolic reduction in BP, equivalent to 40% reduction in CHD (additional 15% over monotherapy) and 54% reduction in stroke (additional 19%).(27)

UK guidance recommends that people under the age of 55 are first offered an ACEI or a low-cost ARB. A common cause for ACEI treatment discontinuation is chronic dry cough,

unresponsive to cough suppressant treatment. In the 15% of patients where this occurs, ACEI is changed to an ARB. While ARBs are slightly better tolerated than ACEIs, there is higher quality data supporting the use of ACEIs to prevent death, strokes and coronary heart disease (CHD), and for use in diabetic patients.(30) For patients over the age of 55, and black people of African or Caribbean origin of any age, it is recommended that a CCB is the first treatment step, due to these groups having lower plasma renin levels than the rest of the population.

If BP remains uncontrolled following monotherapy, step two involves offering CCB in combination with an ACI or ARB. For step three, a thiazide-like diuretic can be added to the treatment regime if necessary. If BP control is not established after three medications in combination, a fourth may be added, especially spironolactone and it is recommended that patients be considered for referral to a specialist for treatment for 'resistant hypertension'.

According to OpenPrescribing.net (a search interface onto the raw prescribing data files published by the Health and Social Care Information Centre), of the drugs prescribed for hypertension, ACEI/ARBs are the most commonly prescribed in the UK with over 5 million items per month at a cost of £10million, followed by CCBs with 3.2 million items per month (£10 million), and diuretics with 1.3million items per month (£2 million).(31)

1.5.2 Lifestyle modification

The UK is currently one of only three countries that recommend lifestyle advice be given before commencing pharmacological treatment in uncomplicated hypertensive patients, the other two countries being Australia and New Zealand. Many of the risk factors for high BP are modifiable and therefore potential targets for improvements.

According to NHS Choices, which provides information aimed at patients, high BP can be "prevented or reduced by eating healthily, maintaining a healthy weight, taking regular exercise, drinking alcohol in moderation and not smoking". Specifically they recommend:

- Reducing salt in diet
- Eating plenty of fresh fruit and vegetables
- Eating low-fat and high-fibre diet
- Limit alcohol intake (14 units spread over more than four days)
- Lose weight
- "Get active"
- Cut down caffeine
- Stop smoking
- "Get a good night's sleep"

The impact of diet on BP is a complex issue, with salt intake, alcohol intake, and consumption of fruits, vegetables and dairy products all thought to be key targets for intervention in hypertensive patients. The evidence from epidemiological studies is often difficult to interpret due to potential confounding factors. For example, a vegetarian diet is associated with lower BP, but vegetarians also tend to eat more fibre, have less potassium in their diet, drink less alcohol and are more physically active.(32)

There is strong evidence that reducing salt in diet can have a clinically significant impact on BP: a Cochrane review of RCTs comparing reduced salt versus usual salt showed that a modest reduction in salt intake for four weeks or more results in significant BP reduction in normotensive and hypertensive individuals, irrespective of gender or ethnic group.(33) This study found that reducing salt by 6g per day, equivalent to halving current intake from 9-12g per to 5-6g per day, was associated with a reduction in systolic BP of 5.8mmHg, (95%CI 2.5 to 9.2).

The Dietary Approaches to Stop Hypertension (DASH) study in the USA randomised participants to control diet or a diet enriched with dairy products and fruits a vegetables (8-10 servings per day), and resulted in 11.4mmHg (95%CI 6.9 to 15.9) reduction in systolic

BP in hypertensive patients.(34) Weight, salt and alcohol intake remained similar in the experimental groups, showing that these potential confounders did not account for the reductions in BP.

Increased physical activity and maintaining a healthy weight have also been shown to be important in BP control. Systolic BP has been shown to fall by 1mmHg for every 1kg weight loss in a number of trials and systematic reviews.(35, 36) All frequencies, intensities and types of aerobic exercise have been shown to have a beneficial effect on BP, with regular exercise resulting in 4mmHg systolic BP reduction.(37) A meta-analysis of fifteen RCTs demonstrated that reducing alcohol can reduce systolic BP by 3.3mmHg (95%CI 2.5 to 4.1).(38)

It is difficult to break down the relative effectiveness of individual lifestyle factors on BP and cardiovascular outcomes, however it has been estimated that a diet and weight loss approach can be at least as effective as single drug therapy at reducing BP in hypertensives.(39) Encouraging a healthy lifestyle has far-ranging benefits for general health and well-being beyond the management of hypertension.(40)

1.6 WHY DO PATIENTS REMAIN UNCONTROLLED?

Returning to the "rule of halves", to describe the problems faced in hypertension, while there is a need to improve screening to identify the large proportion of individuals as yet undiagnosed, perhaps of greater concern are those patients who have a diagnosis and are not receiving treatment, or are being treated and still have uncontrolled BP. Given the knowledge of the impact of lifestyle change on BP, and the availability of a number of

relatively cheap and effective medications, the question as to why so many patients remain uncontrolled is pertinent, and an area for improvement both in the UK and globally.

Lack of understanding of the risks of uncontrolled BP, medication non-adherence, poor primary prevention (i.e. lifestyle), are all patient factors that have an impact on BP control, however the blame should not be placed solely with patients. Redon *et al* (2016) argued that "we should stop blaming the patients, and we should not blame the drugs". They went on to set out five key areas for intervention in the successful treatment of hypertension, with a focus on what healthcare providers can impact (41):

1. Simplify the BP treatment target to less than 140/90mmHg for the majority of patients
2. Simplify treatment options
3. Decrease therapeutic inactivity/inertia
4. Improve patient empowerment
5. Involve healthcare systems and shift the focus away from cost

1.7 THE NEED FOR NEW MODELS OF CARE FOR HYPERTENSION

1.7.1 Challenges presented by chronic conditions

The National Health Service (NHS) faces different issues in 2016 than it did at its inception in the 1950s, with the emergence of chronic conditions as the dominant challenge. It is estimated that chronic conditions now account for around 70% of health care expenditure, meaning that one third of the population account for over two thirds of the costs.(42) Findings from a retrospective analysis of 100 million consultations in England between 2007-14 show a substantial increase in GP consultation rates, consultation durations and total patient facing workload in English general practice.(43) Yet over a similar period, there has been a 11% drop in GP income since 2008, while at the same time the cost of running a practice has risen by 2.3%.(44)

The problem faced by health services has been described as (45):

> *"a growing mismatch between the chronic care needs of the population and the acute care orientation of health care systems. It's as though we are trying to put a square peg in a round hole."*

New models of care are needed that involve (46):

> *"a shift away from a reactive, disease-focused, fragmented model of care towards one that is more proactive, holistic and preventative, in which [patients] are encouraged to play a central role in managing their own care."*

1.7.2 New models of care

There is a growing body of evidence that suggests health care systems that combine multidisciplinary teams, self-management support and clinical information systems lead to better care for patients with chronic conditions. The King's Fund (2007) published a report outlining a number of barriers to optimal care for people with chronic conditions:

- Single condition services
- Lack of coordination of care
- Emotional and psychological support
- Fragmented care
- Lack of informational continuity
- Reactive not predictive services
- Lack of care planning consultation

To respond to these barriers, models of care are required that fundamentally change how care is delivered. An established model of care for chronic disease that addresses these barriers is the Chronic Care Model (CCM), developed in the late 1990s in the USA, and proven to improve patient care and patient outcomes.(47, 48). The CCM targets change at personal, local/community and national levels. The CCM places an emphasis on multidisciplinary teams of healthcare professionals, and addressing the inherent challenges of this way of working, i.e. improving information systems, information sharing and

communication between HCPs. The CCM also focusses on providing support for patients for self-management and on community engagement. Patients are encouraged to become both more knowledgeable about the factors affecting their condition and more actively involved in decisions about their care.

Each study within the thesis will be discussed in the context of the CCM. In Chapter 5 the CCM was used as part of a framework exploring whether support is currently available in the UK to support SMBP. The delivery system design component of the CCM is investigated in Chapter 6 where patient preferences for hypertension care and the role of SMBP are investigated.

Although there has been more focus on new models of care for chronic disease over the past decade there remains a disconnect between those models that have been proven to be effective and what is available as part of routine care (49):

1.7.3 UK policy context

In the UK, NHS England has put forward the "House of Care" to improve the management of chronic conditions.(46) The House of Care builds on the CCM and relies on four key interdependent components, all of which must be present for person centred and coordinated care to be realised:

- Commissioning – not simply procurement but a system improvement process
- Engaged, informed individuals and carers – enabling individuals to self-manage and know how to access the services they need
- Organisational and clinical processes – structured around the needs of patients and carers using the best evidence available, co-designed with service users where possible
- Health and care professionals working in partnership

The NHS places an emphasis on greater involvement of patients in their own care. The NHS constitution (2014) states:

> *"Rather than being passive recipients of health care, patients also play a key role in managing their own health and should be actively supported by the NHS to do so."*

Patients who recognise that they have an important role to play in the management of their condition, and have the skills and confidence to do so, experience better health outcomes.(50)

Patient self-monitoring of BP is an intervention that fits well with this aim and those of the new models of care described here, by involving patients in the management of their own condition, playing an integral role in self-management support, and in providing information to support shared decision making. There is extensive evidence from clinical trials for the effectiveness of SMBP in hypertension, and this is described in the next section, however there remains uncertainty as to whether the effects from trials can be transferred to everyday care.

1.8 EVIDENCE FOR OUT-OF-OFFICE BLOOD PRESSURE MEASUREMENT AND THE ROLE OF SELF-MEASUREMENT

Traditionally hypertension has been diagnosed by physicians in the clinic environment, taking measurements on several separate occasions and treating those whose BP is consistently above the diagnostic threshold. It is now widely recognised that out-of-office measurements are prognostically superior, and allow individuals with white coat (elevated BP in clinic) and masked (normal clinic BP, but elevated home measurement) hypertension to be identified.(51-53) It has been estimated that one in three patients with uncontrolled

clinic BP can be attributed to white-coat effect, and one in three patients with controlled clinic BP have masked hypertension, leading to over- and under-treatment respectively.(54)

Ambulatory BP monitoring (ABPM) involves patients wearing a monitor for up to 24 hours, with BP measured twice every hour in the day, and once per hour at night. ABPM is seen as the gold standard for diagnosis, however ambulatory monitors are expensive, and may not be well tolerated by patients.(55-57) An alternative to ABPM is home or self-measurement where patients can measure their BP at home using a monitor similar to those used in the clinic. SMBP uses much less expensive equipment than ABPM, and is more acceptable to patients.(58) Protocols for SMBP vary, with patients most commonly asked to record BP twice daily (two consecutive measurements at least one minute apart), ideally in the morning and evening, for four to seven days. A recent study showed that increasing the number of readings beyond day five has little impact on the ability to identify patients with hypertension.(59) SMBP can be used when ambulatory monitoring is not available, or is not well tolerated by individuals. To this end, UK NICE guidelines, published in 2011, now advise general practitioners (GPs) to confirm a diagnosis of hypertension with home or ambulatory monitoring, the first set of guidelines to do so, with Canada (2015) and the USA (2014) following later.(60-62)

Beyond diagnosis, SMBP is an intervention that can be used in the management of hypertension to (63):

- Inform treatment decisions
- Determine the efficacy of antihypertensive therapy and support appropriate adjustments
- Promote medication adherence and lifestyle change
- Make patients more aware of their condition

As seen from this list, SMBP can potentially target both patients and clinicians, through overcoming clinical inertia, and making patients more aware of their condition and treatment. The latter could be particularly important due to the frequently asymptomatic presentation of hypertension, which makes the benefits of treatment difficult to perceive. Patients often think that hypertension is caused by stress, and produces symptoms, particularly headache, dizziness and sweating, and that when these symptoms are not present that treatment is not needed.(64)

While it is widely accepted that the introduction of ambulatory and self-monitoring can improve hypertension diagnosis, there is still progress to be made in proving the utility of SMBP in the management of hypertension. For example, while UK guidelines include recommendations for ABPM and SMBP in diagnosis, the same guidelines recommend that clinic measurement is used to monitor control to treatment.

A number of systematic reviews of controlled trials have explored the effectiveness of self-monitoring interventions in managing hypertension, and while they have shown it to be effective in lowering BP, the mechanisms of action remain unclear.(65-67) In perhaps the most comprehensive review to date, Uhlig *et al* concluded that SMBP, "with or without additional support lowers BP compared with usual care, but the BP effect beyond 12 months and long-term benefits remain unclear".(68)

1.9 GOING BEYOND EVIDENCE OF EFFECTIVENESS

Randomised controlled trials are the gold standard research method for determining the effectiveness of interventions. However, understanding how well an intervention works under controlled experimental conditions only tells part of the story, and translation of

interventions into everyday practice can be difficult.(69) Sir Austin Bradford Hill, an epidemiologist who developed criteria for inferring causation in his seminal paper in 1965 (70), stated:

> *"At its best a trial shows what can be accomplished with an intervention under careful observation and certain restricted conditions. The same results will not invariably or necessarily be observed when the medicine passes into general use."*

In a review summarising key factors that have interfered with translation of research to practice, four barriers were identified related to characteristics of: (a) the intervention; (b) the target setting; (c) the research/evaluation design; and (d) interactions between (a), (b) and (c).(69) In this review the authors concluded:

> *"If health researchers can develop and evaluate programs with greater attention to context and external validity and in partnership with relevant decision makers and target audiences, it will be much easier for both local practitioners and policy makers to judge program relevance."*

Ray Pawson, author of 'Realist Synthesis', a new approach to intervention/programme evaluation, described the problems faced in interpreting the results from trials of the same intervention (71):

> *"In reality, what one generally confronts in evaluations of the same [intervention] are highly discontinuous studies of subtly different implementation plans, seeking different outcomes and played out in different contexts within different policy regimes."*

In addition to this I would also add that different populations of patients and clinicians can have an effect on the outcomes.

As well as lack of mechanistic evidence for how SMBP 'works', there is also little evidence from 'real-world' use, for example how people with hypertension incorporate self-monitoring into their daily lives, how physicians use information from self-monitoring, communication between the clinicians and patients, as well which factors influence choices

around self-monitoring. While there is a wealth of information available on the effectiveness of SMBP, the results are heterogeneous, and understanding the reasons for such heterogeneity will be important in order to maximise the potential of SMBP as part of everyday practice (i.e. understanding why SMBP works well in one trial and not another).

Information from trials does not provide all the answers for a comprehensive appraisal of SMBP. Many factors that may influence the real-world effect are difficult to measure and input as variables into the data-analysis for treatment effect; as Pawson states:

> *"However lengthy, the rows and columns will always omit the crucial explanatory apparatus that is needed to understand how [interventions] work"*

When pharmacological treatments are developed, a series of stages whereby the mechanism of action, method of delivery, suitable dose and safety are evaluated before more pragmatic 'real-world' testing begins. Development of SMBP as an intervention has followed a different trajectory, with some of the earlier developmental stages bypassed, or at least not well reported. As such, evidence for some aspects of SMBP remains to be clarified, including what the best monitoring protocol is, who the intervention targets, as well as what the benefits of adding co-interventions are. Recent unpublished results from the BP SMART initiative that involves analysis of individual patient data from a number of SMBP trials, has shown that when SMBP was accompanied by a co-intervention, participants were more likely to achieve their BP target (personal communication unpublished results Dr James Sheppard 2016).

It is therefore important to take a step back and try and understand "outcome patterns" rather than "outcome regularities" among trial data, to explain why outcomes may be different in different contexts. Optimising SMBP for real-world use will depend on unpicking the mechanisms of action, and where and on whom SMBP has worked well (or not) in trials, as

well as real-world use. Looking forward this may provide some of the missing information needed for the translation of SMBP interventions into everyday care.

1.10 RESTATEMENT OF AIMS AND RESEARCH QUESTIONS

1.10.1 Overall aims

SMBP has a potential role to play in improving both the diagnosis and management of hypertension. There is significant evidence for the use of out-of-office measurement, including SMBP, to improve diagnosis of hypertension, and this evidence has been incorporated into UK guidelines. However, the role that SMBP could play in the management of hypertension is as yet less clear. As such, a better understanding of the use of SMBP in hypertension management will be a focus of this thesis, as described in the aims and objectives.

It remains to be seen whether the primary mechanism of action for SMBP interventions is changing the behaviour of patients, their clinicians or both. As such, the attitudes of both patients and clinicians as well as how they incorporate SMBP into self-management and decision making, will be explored.

Clinical trials often test a single intervention compared to a control or usual care, and the related evidence of acceptability comes from studies that look at the intervention in isolation. Yet SMBP exists within a broad range of potentially effective and acceptable interventions and models of care, and as such SMBP needs to be understood in this context. The final stage of this thesis explores patient preferences for different packages of hypertension management in order to understand the relative importance patients place on SMBP compared to other models of care.

1.10.2 Specific research questions

1) What is the effect of SMBP on medication adherence and lifestyle change?

2) What are patient and clinician attitudes to SMBP?

3) What is current practice in the UK with regard to the use of SMBP in general practice?

4) What are patient experiences of SMBP in UK general practice?

5) What are patient preferences for hypertension management including SMBP?

1.11 COMPONENT STUDIES AND STRUCTURE OF THE THESIS

To answer the research questions stated in 1.10.2 above, the structure of the thesis presents five results chapters in the order that they were completed. A mixed methods approach was taken, utilising a range of research methodologies: quantitative and qualitative systematic reviews, survey, qualitative interviews, discrete choice experiment. An overview of the thesis and how the studies fit together is presented in Figure 1.1.

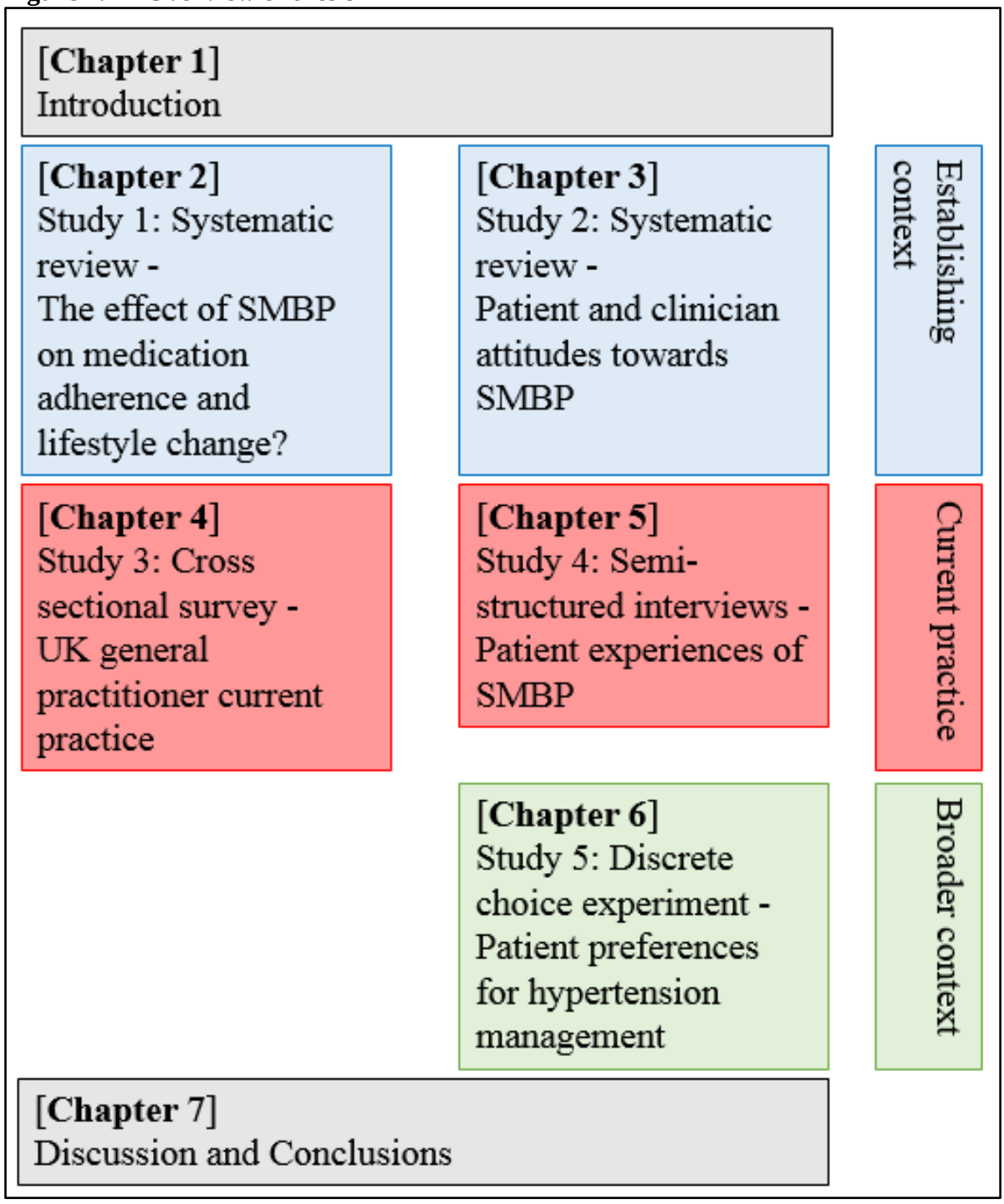
Chapter 1 introduced the background to the thesis. Chapters 2 and 3 present the results of systematic reviews: the first evaluated the impact of SMBP on patient behaviour, and the second investigated patient and clinician attitudes to SMBP. Chapter 4 presents the findings of an online survey assessing current use of SMBP by UK GPs. Chapter 5 builds on the results of Chapter 3 using qualitative interviews to assess patient experiences of SMBP. Chapter 6 presents the results of a discrete choice experiment, where patient preferences for hypertension management were evaluated. The discrete choice was developed using some

of the findings from chapter 5. Chapter 7 comprises an overall discussion of the thesis, summarises the main findings, conclusions and implications for future research and practice.

1.12 PUBLICATION OF RESULTS WITHIN THIS THESIS

The results reported in Chapters 2, 3 and 4 have been published, and as such sections of the methods, results and discussions are reproduced.(72-74) This work has not been submitted for any other course or qualification at the University of Oxford or elsewhere. The articles are available in full following the final Chapter.

Figure 1.1 – Overview of thesis



1.13 REFERENCES

1. Sheppard JP, Schwartz CL, Tucker KL, McManus RJ. Modern Management and Diagnosis of Hypertension in the United Kingdom: Home Care and Self-care. Annals of global health. 2016;82(2):274-87.
2. Lim SS, Vos T, Flaxman AD, Danaei G, Shibuya K, Adair-Rohani H, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet. 2012;380(9859):2224-60.
3. Organization. WH. A global brief on hypertension; silent killer, global public health crisis. 2013.
4. Global Burden of Metabolic Risk Factors for Chronic Diseases C. Cardiovascular disease, chronic kidney disease, and diabetes mortality burden of cardiometabolic risk factors from 1980 to 2010: a comparative risk assessment. The lancet Diabetes & endocrinology. 2014;2(8):634-47.
5. Kaplan GA, Keil JE. Socioeconomic-Factors and Cardiovascular-Disease - a Review of the Literature. Circulation. 1993;88(4):1973-98.
6. World Health Organization. Global status report on noncommunicable diseases 2014. Geneva: World Health Organization; 2014. 280 p. p.
7. Centre HaSCI. Health Survey for England - 2011, Health, social care and lifestyles. 2012.
8. England HSf. Health, social care and lifestyles. Craig RM, J., editor: Health and Social Care Information Centre; 2012.
9. Wilbur JA, Barrow JG. Hypertension: a community problem. American journal of medicine. 1972;52:653-63.
10. Wilbur JA. The problem of undetected and untreated hypertension in the community. Bull N Y Acad Med. 1973;49:510-20.
11. Smith WC, Lee AJ, Crombie IK, Tunstall-Pedoe H. Control of blood pressure in Scotland: the rule of halves. BMJ. 1990;300(6730):981-3.
12. Falaschetti E, Chaudhury M, Mindell J, Poulter N. Continued improvement in hypertension management in England: results from the Health Survey for England 2006. Hypertension. 2009;53(3):480-6.
13. Primatesta P, Brookes M, Poulter NR. Improved hypertension management and control: results from the health survey for England 1998. Hypertension. 2001;38(4):827-32.
14. Primatesta P, Poulter NR. Improvement in hypertension management in England: results from the Health Survey for England 2003. J Hypertens. 2006;24(6):1187-92.
15. Gu Q, Burt VL, Dillon CF, Yoon S. Trends in antihypertensive medication use and blood pressure control among United States adults with hypertension: the National Health And Nutrition Examination Survey, 2001 to 2010. Circulation. 2012;126(17):2105-14.
16. Group SR, Wright JT, Jr., Williamson JD, Whelton PK, Snyder JK, Sink KM, et al. A Randomized Trial of Intensive versus Standard Blood-Pressure Control. N Engl J Med. 2015;373(22):2103-16.
17. Ettehad D, Emdin CA, Kiran A, Anderson SG, Callender T, Emberson J, et al. Blood pressure lowering for prevention of cardiovascular disease and death: a systematic review and meta-analysis. Lancet. 2016;387(10022):957-67.
18. Gray M. The correct name for hypertension. BMJ. 2014;349:g6155.
19. Stevens SL, Wood S, Koshiaris C, Law K, Glasziou P, Stevens RJ, et al. Blood pressure variability and cardiovascular disease: systematic review and meta-analysis. BMJ. 2016;354:i4098.
20. Parati G, Ochoa JE, Bilo G. Blood pressure variability, cardiovascular risk, and risk for renal disease progression. Curr Hypertens Rep. 2012;14(5):421-31.
21. Martin SA, Boucher M, Wright JM, Saini V. Mild hypertension in people at low risk. BMJ. 2014;349:g5432.

22. Diao D, Wright JM, Cundiff DK, Gueyffier F. Pharmacotherapy for mild hypertension. Cochrane Database Syst Rev. 2012(8):CD006742.
23. Sundstrom J, Arima H, Jackson R, Turnbull F, Rahimi K, Chalmers J, et al. Effects of blood pressure reduction in mild hypertension: a systematic review and meta-analysis. Ann Intern Med. 2015;162(3):184-91.
24. Sheppard JP, Fletcher K, McManus RJ, Mant J. Prevalence and costs of treating uncomplicated stage 1 hypertension in primary care: a cross-sectional analysis. The British journal of general practice : the journal of the Royal College of General Practitioners. 2014;64(627):e641-8.
25. Lewington S, Clarke R, Qizilbash N, Peto R, Collins R, Prospective Studies C. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. Lancet. 2002;360(9349):1903-13.
26. Fretheim A, Oxman AD. International variation in prescribing antihypertensive drugs: its extent and possible explanations. BMC Health Serv Res. 2005;5(1):21.
27. Wald DS, Law M, Morris JK, Bestwick JP, Wald NJ. Combination therapy versus monotherapy in reducing blood pressure: meta-analysis on 11,000 participants from 42 trials. Am J Med. 2009;122(3):290-300.
28. Heran BS, Wong MM, Heran IK, Wright JM. Blood pressure lowering efficacy of angiotensin converting enzyme (ACE) inhibitors for primary hypertension. Cochrane Database Syst Rev. 2008(4):CD003823.
29. Heran BS, Wong MM, Heran IK, Wright JM. Blood pressure lowering efficacy of angiotensin receptor blockers for primary hypertension. Cochrane Database Syst Rev. 2008(4):CD003822.
30. Li EC, Heran BS, Wright JM. Angiotensin converting enzyme (ACE) inhibitors versus angiotensin receptor blockers for primary hypertension. Cochrane Database Syst Rev. 2014(8):CD009096.
31. Powell-Smith A, Goldacre B. OpenPrescribing.net 2015 [cited 2016 20 August]. Available from: https://openprescribing.net.
32. Appel LJ, Brands MW, Daniels SR, Karanja N, Elmer PJ, Sacks FM, et al. Dietary approaches to prevent and treat hypertension: a scientific statement from the American Heart Association. Hypertension. 2006;47(2):296-308.
33. He FJ, Li J, Macgregor GA. Effect of longer-term modest salt reduction on blood pressure. Cochrane Database Syst Rev. 2013(4):CD004937.
34. Appel LJ, Moore TJ, Obarzanek E, Vollmer WM, Svetkey LP, Sacks FM, et al. A clinical trial of the effects of dietary patterns on blood pressure. DASH Collaborative Research Group. N Engl J Med. 1997;336(16):1117-24.
35. Aucott L, Rothnie H, McIntyre L, Thapa M, Waweru C, Gray D. Long-term weight loss from lifestyle intervention benefits blood pressure?: a systematic review. Hypertension. 2009;54(4):756-62.
36. Neter JE, Stam BE, Kok FJ, Grobbee DE, Geleijnse JM. Influence of weight reduction on blood pressure: a meta-analysis of randomized controlled trials. Hypertension. 2003;42(5):878-84.
37. Whelton SP, Chin A, Xin X, He J. Effect of aerobic exercise on blood pressure: a meta-analysis of randomized, controlled trials. Ann Intern Med. 2002;136(7):493-503.
38. Xin X, He J, Frontini MG, Ogden LG, Motsamai OI, Whelton PK. Effects of alcohol reduction on blood pressure: a meta-analysis of randomized controlled trials. Hypertension. 2001;38(5):1112-7.
39. Hedayati SS, Elsayed EF, Reilly RF. Non-pharmacological aspects of blood pressure management: what are the data? Kidney Int. 2011;79(10):1061-70.
40. May AM, Struijk EA, Fransen HP, Onland-Moret NC, de Wit GA, Boer JM, et al. The impact of a healthy lifestyle on Disability-Adjusted Life Years: a prospective cohort study. BMC medicine. 2015;13:39.

41. Redon J, Mourad JJ, Schmieder RE, Volpe M, Weiss TW. Why in 2016 are patients with hypertension not 100% controlled? A call to action. J Hypertens. 2016;34(8):1480-8.
42. Great Britain. Department of Health., COI Communications (Agency : Great Britain). Improving the health and well-being of people with long term conditions : world class services for people with long term conditions : information tool for commissioners. London: COI for the Department of Health; 2010. 63 p. p.
43. Hobbs FD, Bankhead C, Mukhtar T, Stevens S, Perera-Salazar R, Holt T, et al. Clinical workload in UK primary care: a retrospective analysis of 100 million consultations in England, 2007-14. Lancet. 2016;387(10035):2323-30.
44. Scotland NNS. Practice Team Information (PTI) Annual Update (2012/2013). National Statistics Publication for Scotland; 2013.
45. Boult C, Karm L, Groves C. Improving chronic care: the "guided care" model. The Permanente journal. 2008;12(1):50-4.
46. Coulter A, Roberts S, Dixon A, King Edward's Hospital Fund for London. Delivering better services for people with long-term conditions : building the house of care. London: The King's Fund; 2013. 27 pages p.
47. Wagner EH. Chronic disease management: what will it take to improve care for chronic illness? Eff Clin Pract. 1998;1(1):2-4.
48. Coleman K, Austin BT, Brach C, Wagner EH. Evidence on the Chronic Care Model in the new millennium. Health Aff (Millwood). 2009;28(1):75-85.
49. Rosen R, Asaria P, Dixon A, King's Fund Centre (London England)., Commonwealth Fund. Improving chronic disease management : an Anglo-American exchange. London: King's Fund; 2007. 19 p. p.
50. Greene J, Hibbard JH. Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes. J Gen Intern Med. 2012;27(5):520-6.
51. Hansen TW, Li Y, Boggia J, Thijs L, Richart T, Staessen JA. Predictive role of the nighttime blood pressure. Hypertension. 2011;57(1):3-10.
52. Dolan E, Stanton A, Thijs L, Hinedi K, Atkins N, McClory S, et al. Superiority of ambulatory over clinic blood pressure measurement in predicting mortality: the Dublin outcome study. Hypertension. 2005;46(1):156-61.
53. Ward AM, Takahashi O, Stevens R, Heneghan C. Home measurement of blood pressure and cardiovascular disease: systematic review and meta-analysis of prospective studies. Journal of Hypertension. 2012;30(3):449-56.
54. Gorostidi M, Vinyoles E, Banegas JR, de la Sierra A. Prevalence of white-coat and masked hypertension in national and international registries. Hypertens Res. 2015;38(1):1-7.
55. Nasothimiou EG, Karpettas N, Dafni MG, Stergiou GS. Patients' preference for ambulatory versus home blood pressure monitoring. J Hum Hypertens. 2014;28(4):224-9.
56. Little P, Barnett J, Barnsley L, Marjoram J, Fitzgerald-Barron A, Mant D. Comparison of acceptability of and preferences for different methods of measuring blood pressure in primary care. BMJ. 2002;325(7358):258-9.
57. Wood S, Greenfield SM, Sayeed Haque M, Martin U, Gill PS, Mant J, et al. Influence of ethnicity on acceptability of method of blood pressure monitoring: a cross-sectional study in primary care. The British journal of general practice : the journal of the Royal College of General Practitioners. 2016;66(649):e577-86.
58. Wood S, Greenfield SM, Haque MS, Martin U, Gill PS, Mant J, et al. Influence of ethnicity on acceptability of method of blood pressure monitoring: a cross-sectional study in primary care. The British journal of general practice : the journal of the Royal College of General Practitioners. 2016.

59. Nunan D, Thompson M, Heneghan CJ, Perera R, McManus RJ, Ward A. Accuracy of self-monitored blood pressure for diagnosing hypertension in primary care. J Hypertens. 2015;33(4):755-62; discussion 62.
60. NICE. The Clinical Management of Primary Hypertension in Adults: Clinical Guideline 137. 2011.
61. Weber MA, Schiffrin EL, White WB, Mann S, Lindholm LH, Kenerson JG, et al. Clinical practice guidelines for the management of hypertension in the community: a statement by the American Society of Hypertension and the International Society of Hypertension. J Clin Hypertens (Greenwich). 2014;16(1):14-26.
62. Daskalopoulou SS, Rabi DM, Zarnke KB, Dasgupta K, Nerenberg K, Cloutier L, et al. The 2015 Canadian Hypertension Education Program recommendations for blood pressure measurement, diagnosis, assessment of risk, prevention, and treatment of hypertension. The Canadian journal of cardiology. 2015;31(5):549-68.
63. British Hypertension Society CGM. Home Blood Pressure Monitoring Protocol.
64. Marshall IJ, Wolfe CD, McKevitt C. Lay perspectives on hypertension and drug adherence: systematic review of qualitative research. BMJ. 2012;345:e3953.
65. Agarwal R, Bills JE, Hecht TJW, 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.
66. Stergiou GS, Bliziotis IA. Home blood pressure monitoring in the diagnosis and treatment of hypertension: a systematic review. American Journal of Hypertension. 2011;24(2):123-34.
67. 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.
68. Uhlig K, Patel K, Ip S, Kitsios GD, Balk EM. Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. Annals of Internal Medicine. 2013;159(3):185-94.
69. Glasgow RE, Emmons KM. How can we increase translation of research into practice? Types of evidence needed. Annu Rev Public Health. 2007;28:413-33.
70. Hill AB. The Environment and Disease: Association or Causation? Proc R Soc Med. 1965;58:295-300.
71. Pawson R. Evidence-based policy : a realist perspective. London: Sage; 2006. xi, 196 p. p.
72. Fletcher BR, Hartmann-Boyce J, Hinton L, McManus RJ. The Effect of Self-Monitoring of Blood Pressure on Medication Adherence and Lifestyle Factors: A Systematic Review and Meta-Analysis. Am J Hypertens. 2015;28(10):1209-21.
73. Fletcher BR, Hinton L, Bray EP, Hayen A, Hobbs FR, Mant J, et al. Self-monitoring blood pressure in patients with hypertension: an internet-based survey of UK GPs. The British journal of general practice : the journal of the Royal College of General Practitioners. 2016.
74. Fletcher BR, Hinton L, Hartmann-Boyce J, Roberts NW, Bobrovitz N, McManus RJ. Self-monitoring blood pressure in hypertension, patient and provider perspectives: A systematic review and thematic synthesis. Patient Educ Couns. 2016;99(2):210-9.

CHAPTER TWO

THE EFFECT OF SELF-MONITORING ON MEDICATION ADHERENCE AND LIFESTYLE FACTORS: SYSTEMATIC REVIEW AND META-ANALYSIS

2.1 CHAPTER OVERVIEW

The following chapter presents the results of the first study within the thesis (Study 1 of Figure 1.1). This was a systematic review to investigate the effect of SMBP on medication adherence and lifestyle factors.

At the time of the study design the author was focussing on the role of SMBP in facilitating behaviour change in patients. Following this review the potential for SMBP to target clinicians as well as patients became more apparent, for example through overcoming clinical inertia, and resulted in further investigation of the impact of SMBP on clinicians in subsequent thesis studies.

The chapter begins with an introduction to the study, a discussion of the importance of medication adherence in hypertension, and the rationale for the approach used. The results are followed with the findings discussed in relation to the extant literature and the strengths and weaknesses of the study. Finally suggestions are made for further research and the link to further studies within the thesis.

2.2 BACKGROUND

2.2.1 Impact of self-monitoring on patient behaviour

It is widely accepted that self-measurement of blood pressure (SMBP) contributes to improved BP control in hypertensive patients, although the mechanisms through which it achieves these effects are unclear.(1) Potential explanations include pharmacological (increased use of medication, better adherence), and non-pharmacological (diet, alcohol, exercise, weight loss) mediators. A mediator variable explains the relationship between two other variables (how and why and intervention works), and must satisfy the following: it is an event or change that happens during treatment; it has to be correlated with the treatment; it explains part of the effect of the treatment on the outcome.(2)

As hypertension is often asymptomatic, patients have difficulty tracking their response to treatment.(3) Results from a qualitative study conducted in Spain found that patient non-adherence to treatment was associated with reservations about treatment and lack of necessary knowledge on which to build an understanding of the condition and treatment.(4) Anti-hypertensive medications commonly cause side effects including dry cough (ACEI), dizziness (all medication classes), ankle swelling (CCBs), etc., which together with a lack of perceived benefit, often lead to patients discontinuing treatment.

Although the benefits of lifestyle change are well known (see section 1.5), patients often feel unable to enact change, and find advice from clinicians too general, leading to a lack of self-efficacy, and this is discussed further in the next chapter. SMBP provides patients with an opportunity to track changes in BP in relation to treatment, and thus by providing a proxy for symptoms may lead to better adherence to treatment and lifestyle change. Determining the evidence for the effect of SMBP on medication adherence and lifestyle change was the focus of this study (Research Question 1 from section 1.10.2).

The benefits of lifestyle change were described in detail in section 1.5 along with the benefits of medication; the importance of medication adherence is introduced in the next section.

2.2.2 Medication adherence

A number of terms (compliance, adherence, persistence and concordance) have been used to define different aspects of acquiring prescriptions and taking medication appropriately.(5) Definitions are presented in Box 2.1

Box 2.1 Definitions

Compliance – the extent to which patient behaviour matches the recommendation of the prescriber

Adherence – the extent to which patient behaviour matches the *agreed* recommendation of the prescriber

Persistence – the act of continuing the treatment for the prescribed duration

Concordance – collaborative decision by patient and prescriber on whether and which medication is appropriate for the patient

Compliance, included as a MeSH term (Medical Subject Heading in United States National Library of Medicine) in 1975, focussed on how well patients followed instructions given to them by prescribers. This definition however implied a lack of patient involvement, and was therefore thought to be too paternalistic as a definition.(6) Adherence was introduced as an alternative term (included as MeSH in 2008), and emphasises the involvement of patients in following a medication plan that has been agreed with prescribers.

Concordance is a more recent concept that focuses on patient and provider collaboration, and the degree to which a prescription represents a shared decision (discussion of therapeutic options, negotiation of regime, and discussion of adherence). In a concordant process the

beliefs and preferences of both the patient and provider are taken into consideration, whilst it is recognised that the patient's views are of prime importance.(7) Research has shown that patients who are satisfied with their medication regime are more likely to be adherent.(8) Once the decision about medication has been negotiated and agreed by patients and prescribers (concordance), it is important that they follow the planned regime (adherence), and therefore adherence is a focus of this review.

Poor adherence to treatment of chronic diseases has been described by WHO as a "worldwide problem of striking magnitude".(9) In developed countries, adherence in patients with chronic conditions is likely to be around 50%.(10) Poor adherence to treatment in chronic disease leads an increase in health care costs due to wastage and worse health outcomes.(11) The costs of non-adherence to anti-hypertensives in the United States has been estimated to be as much as $105 billion annually.(12)

Around 25% of patients initiated on hypertensive medication fail to fill their first prescription.(13) In the first year of anti-hypertensive treatment, patients on average have possession of medication for 50% of the time, and only 20% have sufficiently high adherence to achieve any benefit.(14) Adherence generally drops after the initiation of treatment, with 10% of hypertensive patients missing a dose on any given day, and it is likely that 50% of patients have stopped taking their medication completely within one year.

From a patient perspective, the factors affecting medication adherence are wide-ranging, and include patient-centred factors, therapy related factors, healthcare system factors and social and economic factors.(15) In hypertension, a recent study of half a million newly diagnosed patients found that treatment discontinuation was affected by type of treatment, co-treatments, clinical conditions and the demographic characteristics of the geographical area where patients live.(16)

Improving medication adherence is a key target for intervention in improving hypertension management, as it could have a significant impact on clinical outcomes.(9)

Medication non-adherence includes a number of interrelated patient actions such as (15):

- receiving a prescription but not filling it
- taking an incorrect dose
- taking medication at the wrong times
- increasing or decreasing the frequency of doses
- stopping the treatment too soon
- failure to follow doctor's instructions
- 'white-coat' compliance where patients are compliant to the medication regime around the time of appointments.
- 'drug holidays' where patients stop therapy for a while

For clarity, these factors have been condensed into definitions for medication adherence and persistence, and throughout the remainder of this chapter the definitions for medication adherence and persistence from Box 2.1 will be used.(17)

2.2.3 Objective and rationale for study design

A systematic review of studies investigating the effect of SMBP on adherence published in 2006 found that six of eleven included trials detected a statistically significant improvement in adherence to anti-hypertensive medication.(18) There is limited evidence from qualitative research, but it suggests that SMBP can influence compliance with diet and exercise regimes.(19, 20)

The primary objectives of this review were therefore to determine the effect of SMBP on medication adherence, medication persistence, and lifestyle factors in hypertensives, in order to better understand the mechanisms (mediators) through which SMBP may achieve better BP control.

When testing the efficacy of interventions (whether an intervention produces the expected result under ideal circumstances), randomised controlled trials (RCTs) are the gold standard. Systematic reviews are generally considered to provide the best evidence for any research question as they are based on the findings of multiple studies from a comprehensive search.

2.3 METHODS

2.3.1 Protocol and reporting

A protocol was developed and made available on the PROSPERO database prior to commencing the review, and is available in Appendix 1.1.(21) PRISMA (preferred reporting items for systematic reviews and meta-analyses) guidelines were used to report the results of the review (Appendix 1.2). Studies are ordered alphabetically in all tables and figures in this chapter.

2.3.2 Information sources and study selection

Electronic databases were searched in February 2014 (DARE, Cochrane Database of Systematic Reviews, MEDLINE, EMBASE, CINAHL, PsycINFO, Dissertation and Theses). Ongoing and completed studies without related publication were identified through searches of clinical trial databases (i.e. ClinicalTrials.gov, WHO trials portal, UKHTA, Current controlled trials).

There were no language or time restrictions to the search. The Medline search strategy was translated for use in the other databases (Appendix 1.3). Studies were also identified through citation searches of related reviews, and relevant trials, and authors were contacted for further information where necessary.

Randomised or quasi-randomised trials were eligible for inclusion if the intervention included self-measurement of BP; if usual care did not include self-measurement; if the participants were hypertensive and receiving care in ambulatory/outpatient settings; and if medication adherence and/or lifestyle factor outcomes were available. Two reviewers independently screened the reports for inclusion.

2.3.3 Data extraction and risk of bias assessment

Data were extracted on: recruitment and setting; baseline characteristics; intervention and control characteristics; and outcome measures. The data extraction form is available in Appendix 1.4. Raw unadjusted data were extracted where available for outcome measures, and where only adjusted results were given this is reported in the results.

Primary outcomes of interest were antihypertensive medication adherence and persistence, dietary outcomes (including alcohol consumption), physical activity and smoking. Medication adherence measures were divided into four groups to aid analysis: electronic monitoring, pill counts, pharmacy fill data, and self-reported measures. Secondary outcomes included BP, BP control and adherence to the SMBP component of interventions.

When extracting information on intervention characteristics, studies were classified according to whom the intervention was aimed at (patients and/or healthcare professionals (HCPs)), and any co-interventions beyond self-measurement of BP. Where patients' self-measured BP results were made available to their HCPs (either all BP results, or if SMBP above target) then the intervention was deemed to target both patients and HCPs. Co-interventions beyond SMBP were coded according to whether they: included education (verbal or print/online materials); utilised telemedicine; used self-measured BP to guide medication titration protocol; incorporated adherence reminders; or involved education aimed at physicians. These categories were coded as defined by the authors and agreed by both reviewers who extracted study data.

Data extraction and risk of bias assessment was carried out independently by two reviewers. Following guidance from the Cochrane Collaboration, studies were deemed to be at high, low or unclear risk of bias based on random sequence generation, allocation concealment, blinding of outcome assessment, selective reporting, attrition and other risks of bias.(22)

A funnel plot and Egger's test were used to investigate publication (or reporting) bias.(23)

2.3.4 Statistical analysis

Meta-analyses were performed using RevMan 5 using random-effects models for a comparison of SMBP versus usual care/control for medication adherence and BP outcomes.

The random-effects model assumes that parameters follow a distribution, as the studies vary in the populations addressed, interventions under investigation, and outcomes assessed.(24) The fixed-effects model is based on the assumption that all studies in the analysis are functionally identical, and that therefore a single parameter value is common to all studies. Due to expected heterogeneity between studies, as evidenced in previous reviews of SMBP (25, 26), random effects meta-analysis was chosen *a priori*.

The I^2 statistic was used to present statistical heterogeneity in meta-analyses, and was interpreted using the guidelines presented by the Cochrane Handbook(22):

- 0% to 40% - might not be important
- 30% to 60% - may represent moderate heterogeneity
- 50% to 90% - may represent substantial heterogeneity
- 75% to 100% - considerable heterogeneity

Statistical heterogeneity is due to variability in the intervention effects between studies and is a consequence of clinical and/or methodological heterogeneity. The Cochrane Handbook lists seven options for addressing statistical heterogeneity in meta-analyses:

- Check again that the data are correct
- Do not do a meta-analysis
- Explore heterogeneity
- Ignore heterogeneity
- Perform a random-effects meta-analysis

- Change the effect measure
- Exclude studies

As well as performing random-effects meta-analyses, heterogeneity was explored through sub-group analyses. As medication adherence was measured using different outcomes, standardised mean differences (SMD) were calculated in order to compare the effect of SMBP on adherence across studies. Cohen (1988) proposed guidelines for interpreting standardised mean difference effect sizes, stating that: 0.2 is a small effect, 0.5 is a medium effect, and 0.8 is a large effect.(27) Subgroup analysis was used to group studies by their measure of medication adherence. Where studies reported a number of adherence measures, the most objective measure (using direct observation or electronic measurement, i.e. not reliant on subjective assessment) was used in meta-analysis to avoid double counting. Subgroup analysis was also used to group studies according to whether the intervention included SMBP alone or SMBP plus co-intervention(s). Meta-regression explored the association between medication adherence and BP change.

For office systolic and diastolic BP at six months, weighted mean differences were calculated for overall change between intervention and control. Weighting depended on the standard deviation of the change in BP from baseline to final reading. Where data were only available on baseline and outcome standard deviation, the standard deviation for mean change was imputed according to the methods suggested in the Cochrane Handbook.(22) The correlation between baseline and final result was estimated from studies where all standard deviations were reported and then used to estimate the standard deviation for the mean change.

2.3.5 GRADE and summary of findings

The Grades of Recommendation, Assessment, Development and Evaluation Working Group (GRADE) began in 2000 and has developed an explicit and transparent approach to grading quality (or certainty) of evidence and strength of recommendations. The Cochrane Collaboration has adopted the GRADE system for evaluating the quality of evidence for outcomes reported in systematic reviews.

For the purposes of systematic reviews, GRADE defines quality of evidence as the "extent to which one can be confident that an estimate of effect or association is close to the quantity of specific interest".(28)

GRADE assesses the following:

- Methodological flaws within the component studies
- Consistency of results across different studies
- Generalisability of research results to the wider patient base
- How effective the treatments have shown to be

GRADE specifies four levels of quality (high, moderate, low, and very-low), with the highest level of quality reserved for evidence from RCTs. Quality score can be downgraded depending on the following factors:

- Limitations in the design and implementation of available studies suggesting high likelihood of bias.
- Indirectness of evidence (indirect population, intervention, control, outcomes)
- Unexplained heterogeneity or inconsistency of results
- Imprecision of results
- High probability of publication bias

The quality of evidence was assessed for outcomes where pooled effects were estimated. Two researchers independently applied GRADE criteria to the evidence and any discrepancies were resolved by discussion and consensus. The outcome of GRADE is reported in a summary of findings table following guidance from the Cochrane

Collaboration. The table presents the main findings of the review in a transparent and simple format, and includes information on quality of evidence, magnitude of effect, and sum of available data on the main outcomes.

2.4 RESULTS

2.4.1 Included studies

Twenty-eight trials with a total of 7,021 participants fulfilled the inclusion criteria (Figure 2.1).(29-56) Studies were carried out in 13 countries (12 in USA, four in Canada, two in Australia, two in Spain, and one each in Belgium, Brazil, Finland, Germany/Switzerland, Iran, the Netherlands, Nigeria, and the UK). Publication of the included studies spanned the period from 1976 to 2014. Half of the included studies were published in the five years preceding the review (2009-2014).

Of the included studies: medication adherence was assessed in twenty-five; dietary outcomes in eight; physical activity in six; smoking in three; and medication persistence in one study. The secondary outcome of BP was assessed in twenty-six studies.

Characteristics of the included studies are summarised in Table 2.1, and in full in Appendix 1.5. SMBP was the sole component of interventions in eleven studies (39%), with SMBP combined with co-interventions in seventeen (61%). Co-interventions were coded and grouped and are summarised in Table 2.1, and in more detail in Appendix 1.5. The most common co-intervention was education delivered either verbally (in eleven studies) or using either printed or on-line materials (in six studies).

Patients alone were the target of the intervention in eight studies (31, 36, 37, 39, 41, 42, 48, 54), whilst interventions targeted both patients and healthcare professionals in the remaining twenty. In the majority of cases where healthcare professionals were also targeted, intervention participants' GPs received self-measured BP results from patients, or were informed when patients exceeded target BP, and were able to act accordingly (29, 30, 34, 38, 43-47, 50, 53, 56). Three studies involved pharmacists implementing the intervention,

two involved nurses, and one involved dieticians. The theoretical basis for the development of the intervention was reported in only four studies.(35, 46, 49, 51)

Participants were initiated on new anti-hypertensive medications in four studies (32, 41, 53, 54), and medication titration protocols based on self-measured BP measurements were reported in five studies (32, 40, 51, 53, 56).

Protocols for self-measurement varied across studies, ranging from participants being asked to measure their BP twice daily every day(39), to four occasions per year (twice in morning on four consecutive days)(47). The SMBP protocol was not reported in five studies.(30, 32, 42, 48)

Follow-up ranged from two weeks to twelve months with a median of 6 months, and was deemed to be adequate (i.e. >80% of participants available for outcome assessment at follow-up) in 75% of studies.

Adherence to the SMBP intervention was reported in eleven of the studies, and this information is available in Appendix 1.6.(29, 33, 38, 40, 44-47, 49, 53, 55) Overall, SMBP interventions were carried out well by participants, however poor adherence may have been present, but not reported in some, if not all, of the remaining studies.

Figure 2.1 – PRISMA diagram

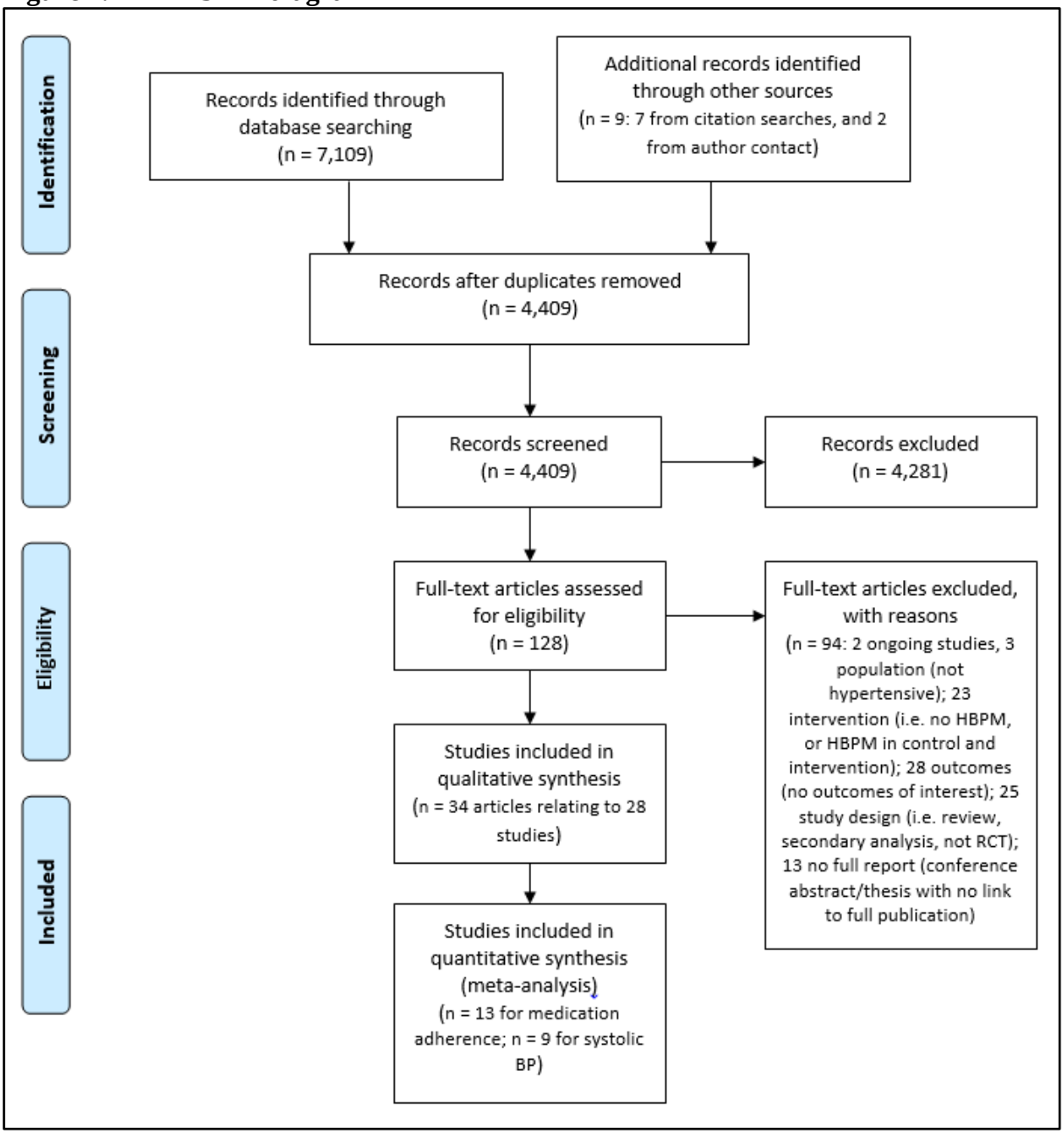


Table 2.1 – Characteristics of included studies

Study id, Country	Number of participants	Study arms included in review	Follow-up	SMBP protocol	Target (*)	Age	% Female	Outcomes (^)
Bailey (1999)(29) Australia	62	1. SMBP 2. Usual care	8 weeks (2 months)	Sitting twice daily (am and pm)	P+HCP	55	54	MA, BP, AI
Bove (2013)(30) USA	241	1. SMBP, telemedicine, and education (print/on-line materials) 2. Usual care	6 months	Unclear	P+HCP	60	65	MA, BP
De Souza (2012)(31) Brazil	57	1. SMBP, 2. Usual care	6 and 12 months	At least twice a week, at random times and quiet place	P	60	NR	MA, D, PA, BP
Dusing (2009)(32) Germany/Switzerland	206	1. SMBP, education (print/on-line materials), medication titration protocol, adherence reminders and physicians education 2. Control	34 weeks (9 months)	Unclear	P+HCP	51	46	MA/MP, BP
Fikri-Benbrahim (2013)(33) Spain	180	1. SMBP, education (verbal), and education (print/on-line materials) 2. Usual care	6 months	At least one day per week, on two occasions measure BP over 5 consecutive days	P+HCP	62	63	MA, BP, AI
Friedman (1996)(34) USA	299	1. SMBP and telemedicine 2. Usual care	6 months	Weekly	P+HCP	77	77	MA, BP

Study id, Country	Number of participants	Study arms included in review	Follow-up	SMBP protocol	Target (*)	Age	% Female	Outcomes (^)
Green (2014)(35) USA	101	1. SMBP and education (verbal) 2. Usual care	6 months	Three days per week	P+HCP	57	42	MA, D, PA, BP
Haynes (1976)(36) Canada	39	1. SMBP and education (verbal) 2. Control (no intervention)	6 months	Daily	P	NR	0	MA, BP
Hosseininasab (2014)(37) Iran	196	1. SMBP 2. Usual care	4, 12 , 24 weeks (1, 3, 6 months)	Daily	P	59	61	MA, BP
Johnson (1978)(38) Canada	136	1. SMBP 2. Control (no intervention)	6 months	Daily	P+HCP	53	40	MA, BP, AI
Kirscht (1981)(39) USA	417	1. SMBP 2. Control (no intervention)	2 weeks	Twice daily	P	78 % >50	NR	MA, D
Magid (2011)(40) USA	338	1. SMBP, telemedicine, education (verbal) and medication titration protocol 2. Usual care	6 months	3-4 times weekly	P+HCP	66	35	MA, BP, AI
Marquez-Contreras (2006)(41) Spain	200	1. SMBP 2. Usual care	6 months	Three days a week, twice am, twice pm	P	59	49	MA, BP

Study id, Country	Number of participants	Study arms included in review	Follow-up	SMBP protocol	Target (*)	Age	% Female	Outcomes (^)
McKenney (1992)(42) USA	70	1. SMBP 2. Control (no intervention)	12 weeks (3 months)	Unclear	P	75	59	MA, BP
McManus (2005)(43) UK	441	1. SMBP (in GP waiting room) 2. Usual care	6 and 12 months	Monthly	P+HCP	63	53	D, PA, BP
Mehos (2000)(44) USA	41	1. SMBP 2. Control (no intervention)	6 months	Daily in morning	P+HCP	42 % >50	70	MA, BP, AI
Midanik (1991)(45) USA	204	1. SMBP 2. Usual care	12 months	Twice weekly	P+HCP	47	53	D, PA, BP, AI
Migneault (2012)(46) USA	337	1. SMBP, telemedicine and education (verbal) 2. Control (education only)	8 and 12 months	Weekly	P+HCP	57	70	MA, D, PA, BP, AI
Niiranen (2014)(47) Finland	229	1. SMBP and education (verbal) 2. Control (no intervention)	12 months	Four times per year, twice in am on 4 consecutive days	P+HCP	38	55	D, PA, BP, AI
Ogbuokiri (1980)(48) Nigeria	29	1. SMBP 2. Control (no intervention)	5 months	Unclear	P	47	85	MA, BP

Study id, Country	Number of participants	Study arms included in review	Follow-up	SMBP protocol	Target (*)	Age	% Female	Outcomes (^)
Ogedegbe (2014)(49) USA	1,039	1. SMBP, education (verbal), education (print/on-line materials) and physician education 2. Usual care	6 and 12 months	Twice daily, three times per week	P+HCP	56	72	MA, BP, AI
Rinfret (2009)(50) Canada	223	1. SMBP, telemedicine and education (print/on-line materials) 2. Usual care	12 months	Weekly	P+HCP	56	46	MA, BP
Rudd (2004)(51) USA	150	1. SMBP, education (verbal), education (print/on-line materials) and medication titration protocol 2. Usual care	6 months	Twice daily	P+HCP	60	53	MA, BP
Stewart (2014)(52) Australia	395	1. SMBP, education (verbal) and adherence reminders 2. Usual care	6 months	Unclear	P+HCP	67	49	MA, BP
Van Onzenoort (2010)(53) Netherlands	430	1. SMBP and medication titration protocol 2. Control (office measures)	12 months	Monthly (before study visit), 7 consecutive days, three times am and pm	P+HCP	55	45	MA, BP, AI
Vrijens (1997)(54) Belgium	628	1. SMBP and education (verbal) 2. Control (no intervention)	6 weeks	Daily in am	P	NR	NR	MA
Wakefield (2012)(55) USA	302	1. SMBP, telemedicine, education (print/on-line materials) 2. Usual care	6 and 12 months	Daily	P+HCP	67	2	MA, BP, AI

Study id, Country	Number of participants	Study arms included in review	Follow-up	SMBP protocol	Target (*)	Age	% Female	Outcomes (^)
Zarnke (1997)(56) Canada	31	1. SMBP and medication titration protocol 2. Usual care	8 weeks (2 months)	Twice daily	P+HCP	55	65	MA, D, BP

(*) Target of intervention: P = patient only; P+HCP = patient and healthcare professional

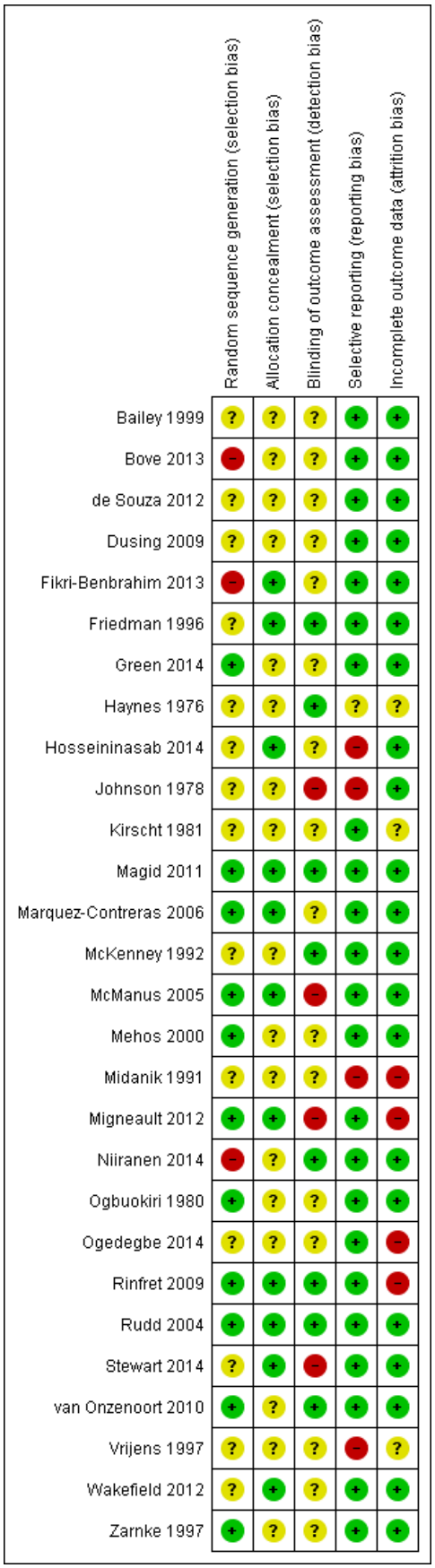
(^) Outcomes: MA = medication adherence; MP = medication persistence; PA = physical activity; D = diet; BP = blood pressure; AI = adherence to intervention

2.4.2 Risk of bias

Two studies were judged to be at low risk of bias across all domains (40, 51); twelve studies were judged to be at high risk of bias in at least one domain (30, 33, 37, 38, 43, 45-47, 49, 50, 52, 54). The remaining fourteen studies were at unclear risk of bias in at least one domain, most commonly due to allocation concealment. Risk of bias is across studies is presented in Figure 2.2, and a risk of bias summary is available in Appendix 1.7.

When assessing reports of studies that reported adherence outcomes, no evidence of publication bias was found. A funnel plot and the result of Egger's test are reported in Appendix 1.8.

Figure 2.2 – Risk of bias



2.4.3 Outcomes

2.4.3.1 Medication adherence and persistence

Adherence to antihypertensive medication was assessed by electronic monitoring in five studies (32, 41, 51, 53, 54), by pill count in eight (29, 33, 34, 36-38, 42, 53), using pharmacy fill data in six (39, 40, 44, 48, 50, 52), and by self-report in nine (30, 35, 39, 46, 49, 52, 55, 56). Three trials used two categories of measure (39, 52, 53). Full results of medication adherence are presented in Table 2.2.

Overall, SMBP interventions were associated with significantly better adherence to antihypertensive medications in eight of twenty-five studies (32%) (31, 33, 36, 37, 41, 42, 51, 53). The independent effect of SMBP on medication adherence (i.e. SMBP was the sole component of the intervention) was tested in nine studies (29, 31, 37-39, 41, 42, 44, 48), and was associated with significantly better adherence in four of those studies (44%) (31, 37, 41, 42). In contrast, when SMBP was part of a complex intervention, a significant effect on medication adherence was demonstrated in four of sixteen studies (25%) (33, 36, 50, 53).

When the results of all adherence measures are pooled, a small but significant overall effect in favour of the intervention is demonstrated (SMD 0.21, 95% CI 0.08, 0.34), with moderate heterogeneity (I^2=43%) (Figure 2.3). A test for subgroup differences did not demonstrate a significant effect of adherence measure on the overall effect size (Chi^2=5.47, df=3, p=0.14). The pooled effect size (ES) estimates increase with more objective measures of adherence, with the largest ES seen when adherence is measured using electronic monitoring. This is reflected in the proportion of studies showing a significant effect in medication adherence across measures (i.e. 60% for electronic monitoring, 50% for pill counts, 0% for pharmacy fill, 11% for self-report).

When assessed by electronic monitoring (i.e. medication event monitoring systems), SMBP was associated with significantly better adherence to antihypertensive medications in three of five studies (60%) (41, 51, 53). Medication adherence was generally high in these studies, for example proportion of days with correct dosing: >83% (Marquez-Contreras), >62% (Rudd), >77% (Dusing); >90% (van Onzenoort). The pooled results from two studies detected a significant effect in favour of the intervention (SMD 0.45, 95% CI 0.10 to 0.79), with moderate statistical heterogeneity (I^2=59%). This effect size (ES) represents a medium effect according to Cohen (1988)(27).

When pill counts were used to measure adherence, SMBP interventions were associated with significantly better adherence in four of eight studies (50%) (33, 36, 37, 53). Again adherence was generally high: proportion of available medication taken >97% (Hosseininasab), >88% (Bailey), >93% (McKenney); >85% (Fikri-Benbrahim), >87% (van Onzenoort). The pooled result of five studies detected a small significant ES in favour of the intervention (SMD 0.30, 95% CI 0.01 to 0.59), with moderate statistical heterogeneity (I^2=42%).

Of the six studies that used pharmacy fill data (i.e. medication possession ratio), none demonstrated a significant effect of SMBP interventions on medication adherence. A pooled estimate of two studies reflects this with no significant effect in favour of the intervention (SMD 0.12, 95% CI -0.05 to 0.29), with low statistical heterogeneity (I^2=0%).

SMBP interventions were associated with significantly better medication adherence in one of nine studies (11%) where self-reported measures were used.(31) A pooled estimate of four studies showed no significant effect in favour of the intervention (SMD 0.05, 95% CI -0.13 to 0.22), with low statistical heterogeneity (I^2=0%).

A test for subgroup differences explored the impact of co-interventions in addition to SMBP on medication adherence (Appendix 1.9). Four trials included in the meta-analysis investigated SMBP alone, and eight trials included co-interventions. No significant difference in medication adherence was found between trials where SMBP was used with or without co-interventions (Chi^2=1.19, df=1, p=0.28).

Medication persistence was assessed in one study.(32) No significant effect in favour of SMBP was found in the proportions not discontinuing their medication by the end of the trial (9 months). Similarly to the studies where medication adherence was measured, medication persistence was high (i.e. >83% of participants were still taking their medication at the end of the nine month study period).

Figure 2.3 – Medication adherence

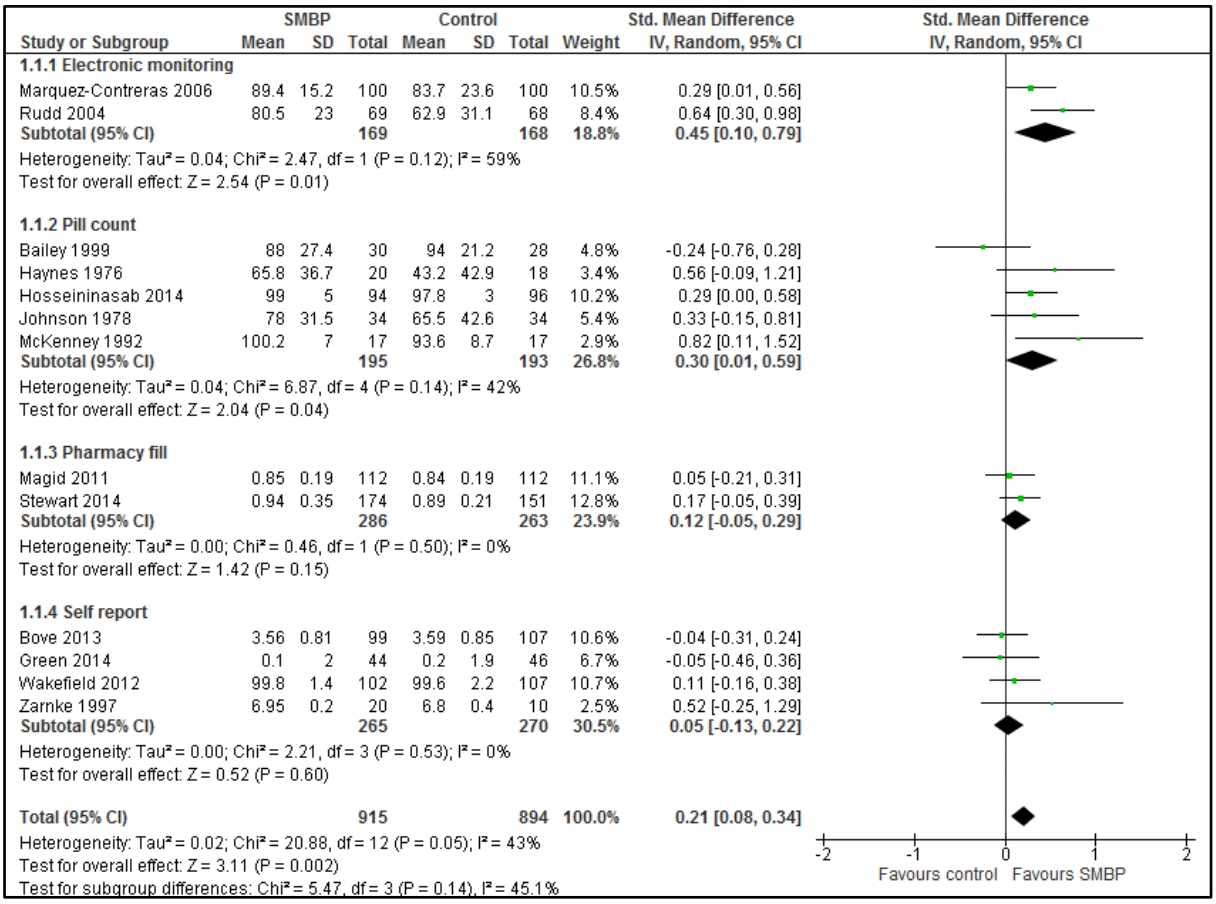


Table 2.2 – Effect of SMBP on medication adherence

Study ID	Description	Follow-up	Result		Between group difference?
			Intervention	Control	
Outcome Using Electronic monitoring					
Dusing (2009)(32)	MEMS cap monitors time and date of opening pill bottle: taking meds daily between 0700 and 1100 (i), taking meds daily with no time restriction (ii)	9 months	i: 57% ii: 86%	i: 54% ii: 77%	i: N (p-value not reported) ii: N (p-value not reported)
Marquez-Contreras (2006)(41)	MEMS cap monitors. Proportion of doses taken (i), proportion of correct days (ii), and correct time (iii), and proportion of patients who were adherent (taking 80-100% of meds) (iv)	6 months	i: 93.5% (sd15.7) ii: 89.4% (sd15.2) iii: 88.1% (sd21.6) iv: 92% (sd14.2)	i: 87.7% (sd23.6) ii: 83.7% (sd23.3) iii: 79.9 (sd28.2) iv: 74% (sd18.2)	i: Y (p=0.0001) ii: Y (p=0.0001) iii: Y (p=0.006) iv: Y (p=0.0007)
Rudd (2004)(51)	MEMs cap. Daily adherence defined as the number of days where patients took the correct dose.	6 months	80.5 (sd23.0)	62.9 (sd31.1)	Y (p=0.03)
Van Onzenoort (2010)(53)	MEMs caps used in a single centre sub study: proportion of days with correct dosing (i); and proportion adequately adherent [>85%] (ii).	12 months	i: 92.3% (IQR 86.9 to 94.4) ii: 81%	i: 90.9% (IQR 92.9 to 93.7) ii: 74%	i: Y (p=0.043) ii: N (p value not reported)
Vrijens (1997)(54)	MEMs caps. Average number of pills taken in the last week of the study (maximum of 7)	6 weeks	6.78	6.20	N (p-value not reported)
Outcome Using Pill count					
Bailey (1999)(29)	Proportion of available medication taken	2 months	88% (sd27.4)	94% (sd21.2)	N (p-value not reported)
Fikri-Benbrahim (2013)(33)	Proportion adherent (taking 80-110% of available medication)	6 months	96.5%	85.4%	Y (p=0.011)
Friedman (1996)(34)	Mean change from baseline in proportion of available medication taken	6 months	+2.4%	-0.4%	N (p=0.29)
Haynes (1976)(36)	Mean change from baseline in proportion of available medication taken	6 months	+21.3% (sd29.1)	-1.5% (sd33 1)	Y (p=0.025)
Hosseininasab (2014)(37)	Proportion of available medication taken	1, 3, 6 months	1m: 99.6% (sd3) 3m: 98.9% (sd5) 6m: 99.0% (sd5)	1m: 97.1% (sd9) 3m: 96.5% (sd7) 6m: 97.8% (sd3)	Y (p=0.01) Y (p=0.005) Y (p=0.04)

Study ID	Description	Follow-up	Result		Between group difference?
			Intervention	Control	
Johnson (1978)(38)	Mean change from baseline in adherence (i) and adherence at follow-up (ii) estimated by comparing pills on hand with pharmacy dispensing records	6 months	i: +11.8% (sd31.5) ii: 78.0 (sd31.5)	i: +1.0% (sd40.8) ii: 68.5 (sd42.6)	i: N (p value not reported) ii: N (p value not reported)
McKenney (1992)(42)	Overall study adherence	3 months	100.2% (sd7.0)	93.6% (sd8.7)	Y (p=0.02)
Van Onzenoort (2010)(53)	Overall study adherence	12 months	87.3%	88.1%	N (p=0.62)
Outcome Using Pharmacy fill					
Kirscht (1981)(39)	Pharmacy data was used to estimate the doses of medication prescribed compared to doses dispensed.	2 weeks	66.5%	66.5%	N (p value not)
Magid (2011)(40)	Medication possession ratio (MPR) total number of days supplied for each medication, divided by period for which the medication was prescribed	6 months	0.85 (sd0.19)	0.84 (sd0.19)	N (p=0.88)
Mehos (2000)(44)	Overall study compliance (no. tablets refilled/amount prescribed)	6 months	82%	89%	N (p=0.29)
Ogbuokiri (1980)(48)	Frequency of refill. Value arbitrarily chosen and defined pre study (refill within 1-10 days of refill date = 100%; within 2 weeks = 50%; within 4 weeks = 25%)	5 months	72.6%	59.26%	NA
Rinfret (2009)(50)	Continuous medication availability (CMA) [i] and continuous medication gaps (CMG) scores [ii], which estimate the proportion of time the subjects have or do not have medication available.	12 months	i: 0.95 (IQR 0.76 to 1.00) ii: 0.04 (IQR 0.00 to 0.19)	i: 0.91 (IQR 0.54 to 1.04) ii: 0.09 (IQR 0.00 to 0.38)	i: N (p=0.07) ii: N (p=0.12)
Stewart (2014)(52)	Follow-up mean and mean change from baseline in: MedsIndex score[100=perfect adherence] (i, ii); Medication Possession Ratio (iii, iv)	6 months	i: 84.75 (sd17.13) ii: +4.60 iii: 0.94 (sd0.35) iv: +0.13	i: 82.86 (sd19.42) ii: +2.44 iii: 0.89 (sd0.21) iv: +0.08	i: NR ii: N (p=0.228) iii: NR iv: N (p=0.496)
Outcome Using Self-report					
Bove (2013)(30)	Medication adherence self-efficacy scale (MASES). Four item scale, higher scores indicate greater level of adherence	6 months	3.56 (sd0.81)	3.59 (sd0.85)	N (p=0.86)
De Souza (2012)(31)	Proportion of patients who reported "regular use daily" of antihypertensive medication	6 and 12 months	6m: 94.7% 12m: 100%	6m: 83.3% 12m: 88.2%	6m: N (p=0.150) 12m: Y (p=0.031)
Green (2014)(35)	Mean change from baseline in Morisky 8 item score. Higher score indicates lower adherence	6 months	-0.1 (sd2.0)	-0.2 (sd1.9)	N (p=0.79)

Study ID	Description	Follow-up	Result		Between group difference?
			Intervention	Control	
Kirscht (1981)(39)	Patients were asked about pill taking behaviour and were ranked on an ordinal scale.	2 weeks	94.4%	94.3%	N (p value not reported)
Migneault (2012)(46)	Mean change from baseline in Morisky 7 score. Higher scores indicate better adherence.	8 months	+0.45	+0.26	N (p value not reported)
Ogedegbe (2014)(49)	Mean change in Morisky 4 item score. Higher score indicates poor adherence.	6 and 12 months	6m: -0.14 12m: -0.24	6m: -0.13 12m: -0.20	6m: N (p=0.87) 12m: N (p=0.71)
Stewart (2014)(52)	Follow-up mean and mean change from baseline in proportion adherent using Morisky 4 (i, ii); Morisky 4 score [0=good adherence] (iii, iv); TABS differential [>15=good adherence] (v, vi)	6 months	i: 73.5% ii: +13.5% iii: 0.36 (sd0.67) iv: -0.20 v: 11.10 (sd3.83) vi: +0.85	i: 63.6% ii: +6.4% iii: 0.44 (sd0.64) iv: -0.15 v: 11.59 (sd3.33) vi: +0.67	i: N (p=0.09) ii: N (p value not reported) iii: NR iv: N (p=0.310) v: NR vi: N (p=0.856)
Wakefield (2012)(55)	Patients were asked, "are you taking your medications as prescribed". Scores represent the proportion of medications for which responses agreed with the directions for use on the VA pharmacy medication profile	6 and 12 months	6m: 99.8 (sd1.4) 12m: 99.7% (sd1.4)	6m: 99.6 (sd2.2) 12m: 98.9% (sd6.0)	6m: N (p=0.79) 12m: N (p=0.20)
Zarnke (1997)(56)	Mean number of self-reported doses missed per week.	2 months	0.05 (sd0.2)	0.2 (sd0.4)	N (p value not reported)

2.4.3.2 Lifestyle factors

Diet, physical activity and smoking outcomes are presented in Table 2.3. Dietary outcomes were reported by eight studies (31, 35, 39, 43, 45-47, 56). Two studies investigated the effect of SMBP on the proportion of participants who reported food intake according to dietary guidelines, and reported no significant effect in favour of the intervention (31, 39). One study investigated the impact of SMBP on mean change from baseline in overall diet quality score and found a significant effect in favour of the intervention (+3.5 points on a 100 point composite scale, $p<0.03$ (46).

One study demonstrated the effect of a complex SMBP intervention on mean change from baseline in the average number of daily fruit and vegetables consumed, and found a significant effect in favour of the intervention, +2.3 daily servings, $p<0.01$ (35). SMBP was found to have no significant impact on coffee consumption (45).

Four studies reported alcohol consumption outcomes: three studies found no effect of interventions on mean change in daily alcohol consumption (45, 47, 56); and one study reported no effect on mean change in alcohol consumption according to guidelines (i.e. <21 units/week for men, and <14 units per week for women) (43).

Physical activity was an outcome in six studies (31, 35, 43, 45-47). In two studies SMBP had no effect on the proportion of participants exercising more than three times a week (31, 43). Two studies used the proportion engaging in regular exercise as an outcome, which again was not significantly affected by the intervention (35, 45). Finally, two studies investigated the impact of SMBP on the mean change in energy expenditure in MJ/day: in one study there was no significant effect (47), and in the other there was a significant increase in favour of the intervention, mean difference +80MJ/day, $p<0.05$ (46).

Three studies investigated the impact of SMBP interventions on smoking status, however no significant effect was found in favour of SMBP interventions (31, 43, 45).

Table 2.3 –Effect of SMBP on lifestyle factors

Study i.d.	Outcome measure	Follow-up	Results		Difference between groups?
			Intervention	Control	
Diet					
De Souza (2012) (31)	Proportion reporting food intake according to dietary guidelines	6 and 12 months	6m: 97.4% 12m: 97.3%	6m: 88.9% 12m: 100%	6m: N (p=0.21) 12m: N (p=0.68)
Green (2014) (35)	Mean change from baseline in average number of daily servings of fruit and vegetables	6 months	+2.3 (sd3.0)	+0.0 (sd1.9)	Y (p<0.01)
Kirscht (1981) (39)	Proportion adherent to dietary recommendations	2 weeks	75.2%	77.2%	N (p value not reported)
McManus (2005) (43)	Mean change from baseline in: proportion adding salt to food (i) and proportion drinking more than recommendations [men >21; women >14 units/week] (ii)	6 and 12 months	6m, i: -2% ii: -8% 12m, i: -4% ii: -6%	6m, i: -2% ii: -3% 12m, i: +3% ii: -2%	6m, i: N (p=0.82) ii: N (p=0.11) 12m, i: Y (p=0.03) ii: N (p=0.56)
Midanik (1991) (45)	Mean change in alcohol consumption [drinks/day] (i), and coffee consumption [drinks/day] (ii)	12 months	i: -0.2 (sd0.9) ii: -0.1 (sd1.4)	i: -0.2 (sd0.8) ii: -0.5 (sd1.4)	i: N (p=0.87) ii: N (p=0.05)
Migneault (2012) (46)	Mean change from baseline in overall diet quality score [higher score = healthier diet]	8 months	+2.8	-0.74	Y (p<0.05)
Niiranen (2014) (47)	Mean change from baseline in: alcohol intake [g/day] (i); total energy intake [MJ/day] (ii); total carbohydrate [%MJ/day] (iii); total protein [%MJ/day] (iv); total fat [%MJ/day] (v); total saturated fat [%MJ/day] (vi)	12 months	i: -0.1 (sd8.2) ii: -0.3 (sd1.8) iii: +1.5 (sd6.3) iv: +0.0 (sd1.8) v: -0.8 (sd6.1) vi: -0.7 (sd2.6)	i: +3.2 (sd16.5) ii: -0.1 (sd1.3) iii: +0.0 (sd6.7) iv: +0.7 (sd2.6) v: -0.2 (sd2.1) vi: -0.7 (sd2.6)	i: N (p=0.06) ii: N (p=0.37) iii: N (p=0.10) iv: N (p=0.12) v: N (p=0.41) vi: N (p=0.11)
Zarnke (1997) (56)	Mean change from baseline in alcohol intake (drinks per week)	2 months	-0.25 (sd1.59)	+0.10 (sd0.4)	N (p value not reported)

Study i.d.	Outcome measure	Follow-up	Results		Difference between groups?
			Intervention	Control	
Physical activity					
De Souza (2012) (31)	Proportion exercising more than three times weekly	6 and 12 months	6m: 67.6% 12m: 67.6%	6m: 61.1% 12m: 58.8%	6m: N (P=0.22) 12m: N (p=0.19)
Green (2014) (35)	Proportion at follow-up engaging in physical activity [often working up a sweat]	6 months	27.9% (sd44.1)	20.5% (sd40.2)	N (p=0.40)
McManus (2005) (43)	Mean change from baseline in proportion exercising more than three times weekly	6 and 12 months	6m:+9% 12m: +4%	6m: +13% 12m: +3%	6m: N (p=0.53) 12m: N (p=0.49)
Midanik (1991) (45)	Physical activity at follow up (*study reported no difference between groups, but reported no data)	12 months	Not reported	Not reported	N (p value not reported)
Migneault (2012) (46)	Mean change from baseline in: moderate or greater intensity activity time [min/week] (i); proportion exercising >150mins/week (ii); total energy expenditure [kcal/day] (iii)	8 months	i: -3.44 ii: -2% iii: +43.8	i: +2.77 ii: +5% iii: -36.2	i: N (p value not reported) ii: N (p value not reported) iii: Y (p<0.05)
Niiranen (2014) (47)	Mean change from baseline in leisure activity [MJ/day]	12 months	+0.00 (sd0.4)	+0.07 (sd0.3)	N (p=0.15)

2.4.3.3 Blood pressure

Medication adherence and BP outcomes were measured together in 23 studies: all but (39, 43, 45, 47, 54). In the eight trials where SMBP had a significant effect on medication adherence, office DBP improved in three (38%)(33, 41, 51). Similarly, office SBP significantly improved in favour of the intervention in three of the seven studies where adherence was significantly improved (43%).(33, 41, 51)

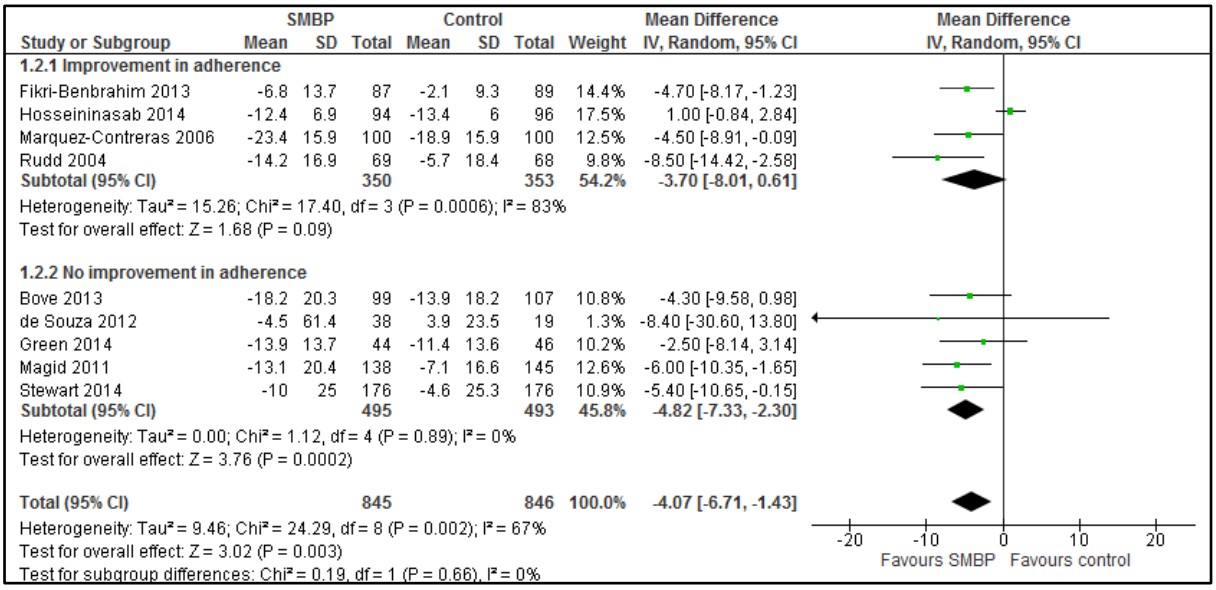
Interestingly office SBP significantly improved in three of fifteen studies (20%) where SMBP interventions had no reported effect on medication adherence as measured by pharmacy fill (40, 50, 52), as did office DBP in 2 of 14 studies (14%)(44, 50).

Figure 2.4 shows the results of pooled analysis at 6 months, which for DBP demonstrate a significant overall effect in favour of SMBP (weighted mean differences −2.02, 95% CI −2.93, −1.11; 11 studies), with low heterogeneity ($I^2 = 0\%$). A test for subgroup differences did not show a significant effect when studies were grouped according to whether medication adherence was improved or not ($\chi^2 = 0.11$, df = 1, p = 0.74). Results for SBP at 6 months were similar. Full BP results are available in Appendices 1.10-11.

Exploratory meta-regression demonstrated a trend for an association between increased medication adherence and BP change (SBP and DBP); however, the results were not statistically significant, potentially due to the lack of sufficient studies: nine studies reported diastolic BP and adherence outcomes at 6 months, and 6 systolic BP and adherence. Cochrane recommends that meta-regression should not usually be considered if there are fewer than ten studies in a meta-analysis. Results of meta-regression are presented in Figure 2.5.

Figure 2.4 – Effect of SMBP on BP at 6 months

Systolic BP



Diastolic BP

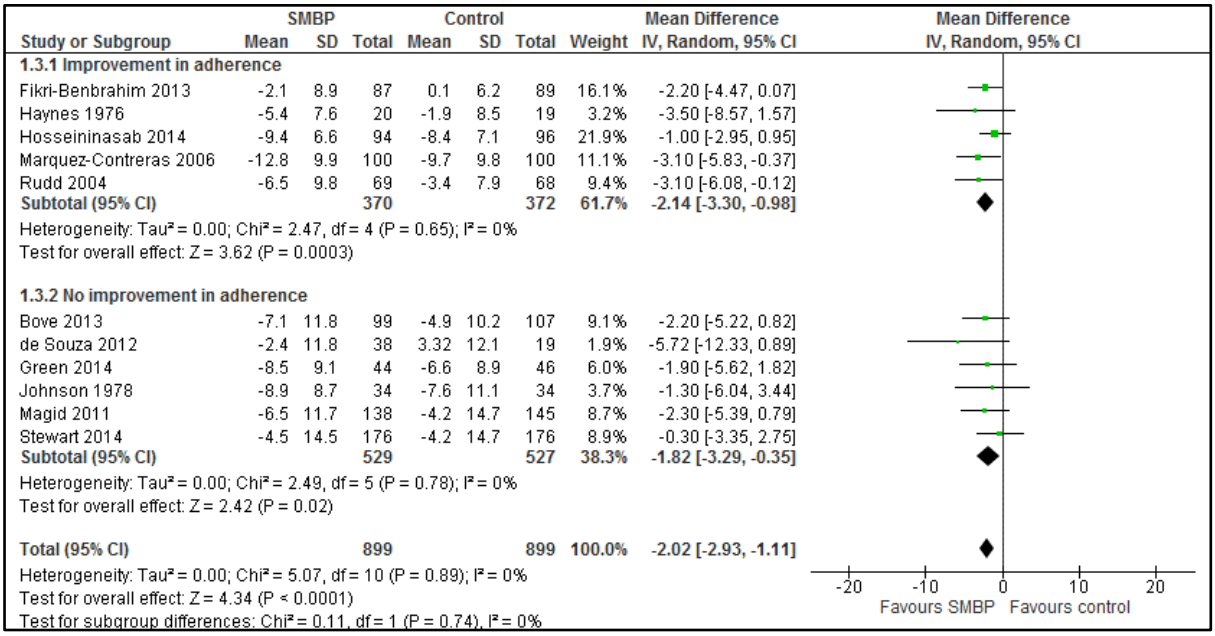
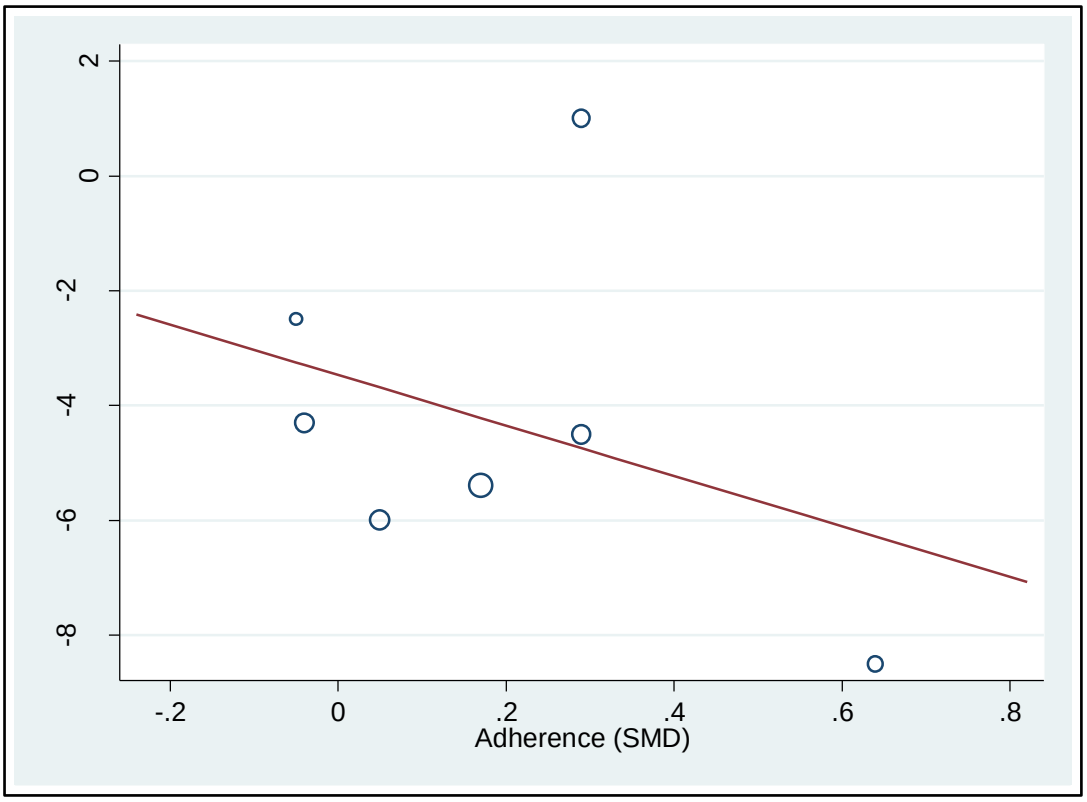
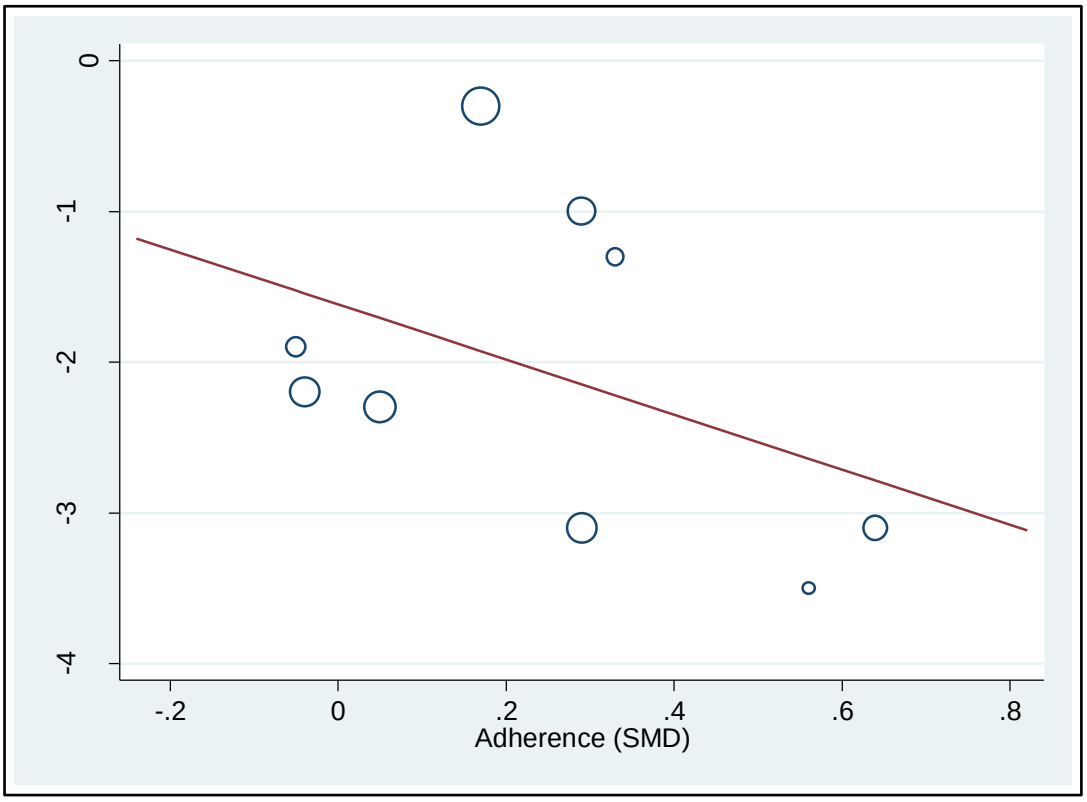


Figure 2.5 – Meta-regression for adherence and blood pressure (systolic and diastolic) at 6 months

Systolic BP



Diastolic BP



2.4.4 Summary of findings

Table 2.4 presents a summary of findings table for the review. The quality of evidence for medication adherence according to GRADE criteria is Low, as is the GRADE for systolic BP. The evidence for diastolic BP is of moderate quality. Grading was not conducted for diet or exercise as no summary effect was produced for these outcomes.

Table 2.4 Summary of findings

Outcomes	Usual care/ control	Self-monitoring group	Number of participants (studies)	Quality of the evidence (GRADE)
PRIMARY				
Medication adherence	The medication adherence score in the self-monitoring group was on average +0.21 SDs (0.08 to 0.34) higher than in the control/usual care group		1,809 (13)	○○⊕⊕ Low[A,B] (see notes below)
Diet	Meta-analysis not conducted for this outcome due to significant clinical heterogeneity (particularly type and timing of outcome assessment)			
Exercise	Meta-analysis not conducted for this outcome due to significant clinical heterogeneity (particularly type and timing of outcome assessment)			
SECONDARY				
Systolic BP at 6 months	The mean reduction in BP in the usual care groups ranged from 4.5mmHg to 23.4mmHg	The mean change in systolic BP in the self-monitoring groups was 4.1mmHg (1.4 to 6.7) greater	1,691 (9)	○○⊕⊕ Low[A,C]
	Absolute effect: BP lower in SMBP group, -4.1mmHg (-6.7 to -1.4)			
Diastolic BP at 6 months	The mean reduction in BP in the usual care groups ranged from 0.3mmHg to 5.7mmHg	The mean change in systolic BP in the self-monitoring groups was 2.0mmHg (1.1 to 2.9) greater	1,798 (11)	○⊕⊕⊕ Moderate[A]
	Absolute effect: BP lower in SMBP group, -2.0mmHg (-2.9 to -1.1)			

[A] Risk of bias: sequence generation, allocation concealment and blinding of outcome assessment the risk of bias was unclear in the majority of included trials.

[B] Imprecision: confidence interval for SMD estimate includes 0.2 (small effect)

[C] Inconsistency: I^2= 67% (substantial heterogeneity)

GRADE Working Group grades of evidence:

High quality: Further research is very unlikely to change our confidence in the estimate of effect

Moderate quality: Further research in likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

Very low quality: We are very uncertain about the estimate

2.5 DISCUSSION

The structure of the discussion follows recommendations made in the British Medical Journal by Docherty *et al* (1999).(57) The principal findings are stated followed by the strengths and weakness, comparison to other studies, implications for practice and future research and finally conclusions. This structure is used in all of the results chapters in this thesis.

2.5.1. Principal findings

SMBP had a small but significant positive effect on medication adherence, with the quality of evidence according to GRADE assessed as low (the true effect may differ significantly from the estimate). While the effect of SMBP on medication adherence may be small, this could have a significant impact at a population level; especially as only six in ten hypertensive patients are thought to be adherent.(58)

The impact of SMBP on lifestyle factors was inconclusive. Medication adherence and lifestyle change will be considered separately in the following sections.

As databases were searched in February 2014, an update was conducted in MEDLINE in November 2016 for the interim time period for trials of SMBP reporting medication adherence or lifestyle factor outcomes, and found no new studies.

2.5.1.1 Adherence

This is the first review to carry out a pooled analysis of the effect of SMBP on medication adherence, and showed a small but significant effect (fourteen RCTs, SMD = 0.21 (95%CI

0.08 to 0.34)). There are difficulties in interpreting standardised mean differences as they combine different estimates of effect. McGraw and Wong (1992) suggested a Common Language Effect Size (CLES) statistic: the probability that a score sampled at random from one distribution (i.e. SMBP) will be greater than a score sampled from another (i.e. no SMBP).(59) For medication adherence the CLES is 0.56 (probability that person from the experimental group will be higher than person from control if both chosen at random).

Importantly, studies using more objective measures of medication adherence showed a greater effect size in favour of intervention. The pooled estimate when electronic monitoring was used was almost double the overall estimate, and approaching ten times larger than the estimate from studies where the least objective self-reported measures were used. Objective measurement may remove the measurement noise associated with self-report, therefore making more precise estimates of adherence possible hence easier differentiation between low and high adherence.

SMBP interventions were associated with improvements in both systolic BP (nine RCTs, WMD = -4.1mmHg (95%CI -6.7 to -1.4)) and diastolic BP (eleven RCTs, WMD = -2.0mmHg (95%CI -2.9 to -1.1)). Exploratory meta-regression indicated a positive association between medication adherence and BP, however the results of this review do not provide evidence that medication adherence explains all of the observed BP reduction (as seen in sub-group analyses).

2.5.1.2 Lifestyle

There have to date been no other reviews of the effect of SMBP on other intermediate (mediator) outcomes such as lifestyle change. Overall, the quantity and quality of evidence

of the impact of SMBP on lifestyle factors was poor. Evidence for the effect of SMBP on diet and physical activity was available in only eight studies, and where significant effects in favour of the intervention were found, few were clinically significant.

2.5.2 Strengths and limitations

This review used a comprehensive search strategy and captured more than double the number of trials compared to an earlier study, with sufficient data to perform a meta-analysis for medication adherence allowing estimation of a pooled effect size.(26)

When conducting trials with adherence as the outcome, Haynes *et al* proposed a rule of thumb that when comparing a single intervention and control group, sixty participants per arm are required to detect a 25% difference in adherence.(60) In the previous review, four of eleven (36%) included studies met this criteria, while in this review this had increased to sixteen of twenty-five (64%), demonstrating that in the nine years since the previous review, not only has the quantity of the available evidence improved, but also the quality.

Participants in the included trials were generally adherent to medication at the outset and throughout trials. There is evidence that participation in a trial leads to higher adherence which returns to baseline levels following the trial.(61) Increases in adherence due to trial participation, and the potential that participants in trials may be more adherent than the general population, means that there is less scope to provide evidence of effectiveness of SMBP interventions on medication adherence in this type of patient. Designing future trials to explicitly target patients who have a history of non-adherence could allow the full potential benefits of SMBP to be evaluated.

Given the paucity of studies investigating the effect of SMBP on lifestyle factors it is difficult to know whether the results are representative, and that SMBP does not have an impact. Trials may have used poor methods of measurement that were unable to pick up real effects. Lifestyle factors are often secondary outcomes in trials and may not receive as much attention as the primary outcomes. Trials may lack sufficient power for secondary outcomes meaning that they lack the ability to detect an effect if one exists.

The theoretical basis for intervention development was only reported in 4 studies (14%). As SMBP interventions target behaviour change in patients and/or HCPs, conceptual models are needed to provide a framework for the development of interventions. As it stands, it is difficult to understand how many SMBP interventions have been developed, e.g., the justification for the frequency of SMBP and what patients/HCPs are expected to do with these readings.

This review focussed on patient behaviours, however it is clear that SMBP also targeted behaviour change in clinicians, and the attitudes of both towards SMBP is the focus of Chapter 3. The interventions tested were heterogeneous, with varying target population, SMBP protocol, medication titration protocol, and other co-interventions. Studies were often aimed at people with hypertension, but also required the input of HCPs to interpret the SMBP measurements and act accordingly. Using complex interventions and targeting both patients and HCPs together complicates the investigation of the independent effect of SMBP on patient behaviour.

2.5.3 Comparisons with existing literature

The Chronic Care Model (CCM) introduced in Chapter 1 highlights the importance of encouraging patients to become more knowledgeable about, and more involved in the management of their condition, and SMBP is one way of doing so. Self-monitoring can facilitate self-management through a process of problem identification and definition, implementation of change, and evaluation. With regard to implementing changes, this review found little evidence of SMBP impacting lifestyle change and a small positive impact on medication adherence. The CCM describes the need for tailored educational resources, priority setting, goal setting, identification of barriers, and problem solving; however in the studies included in this review it was often not clear whether these were provided along with a request to self-monitor BP. According to the CCM, self-monitoring is only one component of a multi-faceted approach that requires engaged patients are provided with appropriate support/services. It is therefore important to provide additional information and support along with a request to self-monitor, and the effect of SMBP on medication adherence and lifestyle factors be enhanced by doing so. The following two chapters both investigate in part resources available to support self-monitoring.

The effect of SMBP on medication adherence reported in this review is comparable to similar studies. SMBP has a greater effect on adherence than other behavioural/educational interventions.

A review investigating interventions to improve medication adherence in hypertensive patients with searches until 2015, and published in November 2015 found 36 studies (experimental and non-experimental) where SMBP was included and adherence measured. Studies that incorporated blood pressure self-monitoring into interventions had slightly

greater effect sizes than interventions lacking a self-monitoring component, but the difference was not significant (SMD 0.38 vs. 0.21, p=0.16).(62)

Evidence from a review of behavioural and educational interventions to improve adherence to anti-hypertensive medication carried out in 2004 showed a small but nonsignificant overall effect, SMD = 0.12 (95% CI −0.06 to 0.28).(63) A meta-analysis of behavioural interventions in any condition reported a small but significant effect, SMD = 0.08 (95% CI 0.04–0.12).(64)

The pooled estimate for office systolic BP at 6 months of -4.1mmHg was similar to previous estimates of -3.8 and -3.9; as was the pooled estimate for office diastolic BP at 6 months (-2.0mmHg, compared to -1.5 and -2.4).(1, 25)

2.5.4 Implications for practice and future research

The pooled analysis of SMBP on medication adherence is presented as a standardised mean difference (SMD), which is necessary to combine the results of studies that assess the same outcome using different measures. According to the guidelines provided by Cohen (1988) the effect of SMBP on medication adherence is 'small'.(27) However, small improvements in medication adherence could lead to significant impact at a population level, leading to better patient outcomes and lower health care expenditure. A review carried out in 2013 estimated that 59% of patients with hypertension had good adherence to medication, but that around 9% of cardiovascular events could be attributed to poor adherence.(58) In England, it has been estimated that increasing the proportion of adherent patients with hypertension to 70% (i.e. taking >80% of medications), would lead to 6,553 fewer cardiovascular events, and savings of up to €36billion over 10 years.(65)

Interventions that target improvement in medication adherence could have more impact on the health of the population than improvements in specific medical treatments.(9) A Cochrane review of interventions to improve adherence in patients with high BP in ambulatory settings found that reducing the number of doses was the most effective intervention, and that evidence for other strategies was lacking.(66)

Only one included study reported on medication persistence. Helping patients take their medication correctly on a day-to-day basis (adherence) is important, but in conditions that require long-term treatment, making sure patients persist in taking their treatments over time is of equal, if not greater importance. Meta-analysis has shown that the effect of antihypertensive treatment is apparent within a year and ongoing risk reduction is dependent on ongoing treatment.(67) Future trials of SMBP should also include medication persistence as an outcome, ideally beyond one year.

UK guidance for the management of hypertension recommends that lifestyle advice should be offered to all people undergoing treatment for hypertension, and before drug treatment commences.(68) SMBP could potentially act by helping hypertensives see the benefits of a healthier lifestyle, but more data are required before this can be substantiated. Future studies of the effect of SMBP on lifestyle factors need to be sufficiently powered.

Improvement in adherence did not explain all of the observed BP reduction. Further research is needed to clarify whether this is because the effect of SMBP is not mediated by medication adherence, or due to methodological issues such as the sensitivity of outcome measures and use of co-interventions targeting other behaviours.

Further work should specifically examine the effect of SMBP on physician behaviour. A review published in 2011, with searches to 2010, showed that SMBP led to more frequent antihypertensive medication reductions (RR 2.02 (95%CI 1.32 to 3.11)), and was associated

with less therapeutic inertia, defined as unchanged medication despite elevated BP (RR 0.82 (95%CI 0.68 to 0.99)).(18) Given the number of trials of SMBP published since 2011, it would be interesting to update this review.

2.5.5 Conclusions

SMBP leads to an increase in medication adherence, and this was best seen in those studies where objective measures were used, however the quality of evidence for medication adherence was low according to GRADE. To what extent medication adherence acts as a mediator of the effect of SMBP remains to be determined. The role of lifestyle factors is less clear, and it is feasible and indeed likely, that other mediators may affect the outcomes of SMBP such as clinician prescribing (i.e. overcoming inertia). Using SMBP to target medication adherence in everyday practice could potentially have a significant impact on patient outcomes.

Trials of SMBP interventions also need to be set up to test the impact of co-interventions; factorial trials would be useful for this as they allow the estimation of the effect of individual intervention components as well as any interactions, but can be difficult to set up.

How SMBP may help bring about BP benefits in hypertensive patients in real-world settings needs further investigation. A combination of qualitative methods and a cross sectional survey are reported in the following chapters (3, 4 and 5) to investigate patient and clinician attitudes to SMBP, and to what extent SMBP is used in everyday management of hypertension.

2.6 REFERENCES

1. 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):371-86.
2. Kraemer HC, Wilson GT, Fairburn CG, Agras WS. Mediators and moderators of treatment effects in randomized clinical trials. Arch Gen Psychiatry. 2002;59(10):877-83.
3. Marshall IJ, Wolfe CD, McKevitt C. Lay perspectives on hypertension and drug adherence: systematic review of qualitative research. BMJ. 2012;345:e3953.
4. Gascon JJ, Sanchez-Ortuno M, Llor B, Skidmore D, Saturno PJ, Treatment Compliance in Hypertension Study G. Why hypertensive patients do not comply with the treatment: results from a qualitative study. Fam Pract. 2004;21(2):125-30.
5. Vrijens B, De Geest S, Hughes DA, Przemyslaw K, Demonceau J, Ruppar T, et al. A new taxonomy for describing and defining adherence to medications. Br J Clin Pharmacol. 2012;73(5):691-705.
6. Aronson JK. Compliance, concordance, adherence. Br J Clin Pharmacol. 2007;63(4):383-4.
7. Royal Pharmaceutical Society of Great B. Partnership in medicine taking : a consultative document: taking medicines to best effect: Royal Pharmaceutical Society of Great Britain; 1996.
8. Barbosa CD, Balp MM, Kulich K, Germain N, Rofail D. A literature review to explore the link between treatment satisfaction and adherence, compliance, and persistence. Patient preference and adherence. 2012;6:39-48.
9. World Health Organization. Adherence to Long-term Therapies project., World Health Organization. Department of Noncommunicable Disease Management. Adherence to long-term therapies : evidence for action. Geneva: World Health Organization; 2003. xv, 198 p. p.
10. Brown MT, Bussell JK. Medication adherence: WHO cares? Mayo Clin Proc. 2011;86(4):304-14.
11. Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. Med Care. 2005;43(6):521-30.
12. Nasseh K, Glave Frazee S, Visaria J, Vlahiotis A, Tian Y. Cost of medication nonadherence associated with diabetes, hypertension, and dyslipidemia. American Journal of Pharmaceutical Benefits. 2012;4(2):e41-e7.
13. Fischer M, Stedman M, Lii J, Vogeli C, Shrank W, Brookhart MA, et al. Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions. Journal of General Internal Medicine. 2010;25(4):284-90.
14. Gwadry-Sridhar FH, Manias E, Lal L, Salas M, Hughes DA, Ratzki-Leewing A, et al. Impact of interventions on medication adherence and blood pressure control in patients with essential hypertension: A systematic review by the ISPOR medication adherence and persistence special interest group. Value in Health. 2013;16(5):863-71.
15. Jin J, Sklar GE, Min Sen Oh V, Chuen Li S. Factors affecting therapeutic compliance: A review from the patient's perspective. Therapeutics and clinical risk management. 2008;4(1):269-86.
16. Mancia G, Zambon A, Soranna D, Merlino L, Corrao G. Factors involved in the discontinuation of antihypertensive drug therapy: an analysis from real life data. J Hypertens. 2014;32(8):1708-15; discussion 16.
17. Cramer JA, Roy A, Burrell A, Fairchild CJ, Fuldeore MJ, Ollendorf DA, et al. Medication compliance and persistence: terminology and definitions. Value Health. 2008;11(1):44-7.
18. Agarwal R, Bills JE, Hecht TJW, 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.

19. Abdullah A, Othman S. The influence of self-owned home blood pressure monitoring (HBPM) on primary care patients with hypertension: a qualitative study. BMC Family Practice. 2011;12:143.
20. Saito I, Nomura M, Hirose H, Kawabe H. Use of home blood pressure monitoring and exercise, diet and medication compliance in Japan. Clinical & Experimental Hypertension. 2010;32(4):210-3.
21. Fletcher B, Hartmann-Boyce J, Roberts N, Hinton L, McManus RJ. Effect of home blood pressure monitoring on medication adherence, medication persistence and lifestyle factors in hypertensives: systematic review protocol. 2014.
22. Higgins J, Green S. Cochrane Handbook for Systematic Reviews of Interventions: The Cochrane, Collaboration; 2009.
23. Egger M, Davey Smith G, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. BMJ. 1997;315(7109):629-34.
24. Hedges LV, Vevea JL. Fixed- and random-effects models in meta-analysis. Psychol Methods. 1998;3(4):486-504.
25. Uhlig K, Patel K, Ip S, Kitsios GD, Balk EM. Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. Annals of Internal Medicine. 2013;159(3):185-94.
26. Ogedegbe G, Schoenthaler A. A systematic review of the effects of home blood pressure monitoring on medication adherence. Journal of Clinical Hypertension. 2006;8(3):174-80.
27. Cohen J, editor. Statistical Power Analysis for the Behavioral Sciences (second ed.): Lawrence Erlbaum Associates.; 1988.
28. Atkins D, Best D, Briss PA, Eccles M, Falck-Ytter Y, Flottorp S, et al. Grading quality of evidence and strength of recommendations. BMJ. 2004;328(7454):1490.
29. Bailey B, Carney SL, Gillies AAH, Smith AJ. Antihypertensive drug treatment: A comparison of usual care with self blood pressure measurement. Journal of Human Hypertension. 1999;13(2):147-50.
30. Bove AA, Homko CJ, Santamore WP, Kashem M, Kerper M, Elliott DJ. Managing hypertension in urban underserved subjects using telemedicine--a clinical trial. American Heart Journal. 2013;165(4):615-21.
31. deSouza WKSBd, Jardim PCBV, Brito LP, Araujo FA, Sousa ALL. Self measurement of blood pressure for control of blood pressure levels and adherence to treatment. Arquivos Brasileiros de Cardiologia. 2012;98(2):167-74.
32. Dusing R, Handrock R, Klebs S, Tousset E, Vrijens B. Impact of supportive measures on drug adherence in patients with essential hypertension treated with valsartan: the randomized, open-label, parallel group study VALIDATE. Journal of Hypertension. 2009;27(4):894-901.
33. Fikri-Benbrahim N, Faus MJ, Martinez-Martinez F, Sabater-Hernandez D. Impact of a community pharmacists' hypertension-care service on medication adherence. The AFenPA study. Research In Social & Administrative Pharmacy. 2013;9(6):797-805.
34. Friedman RH, Kazis LE, Jette A, Smith MB, Stollerman J, Torgerson J, et al. A telecommunications system for monitoring and counseling patients with hypertension. Impact on medication adherence and blood pressure control. American Journal of Hypertension. 1996;9(4 Pt 1):285-92.
35. Green BB, Anderson ML, Cook AJ, Catz S, Fishman PA, McClure JB, et al. e-Care for Heart Wellness: A Feasibility Trial to Decrease Blood Pressure and Cardiovascular Risk. American Journal of Preventive Medicine. 2014;46(4):368-77.
36. Haynes RB, Sackett DL, Gibson ES, Taylor DW, Hackett BC, Roberts RS, et al. Improvement of medication compliance in uncontrolled hypertension. Lancet [Internet]. 1976; 1(7972):[1265-8 pp.]. Available from: http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/229/CN-00017229/frame.html.

37. Hosseininasab M, Jahangard-Rafsanjani Z, Mohagheghi A, Sarayani A, Rashidian A, Javadi M, et al. Self-Monitoring of Blood Pressure for Improving Adherence to Antihypertensive Medicines and Blood Pressure Control: A Randomized Controlled Trial. American Journal of Hypertension. 2014.
38. Johnson AL, Taylor W, Sackett DL, Dunnett CD, Shimizu AG. Self-recording of blood pressure in the management of hypertension. Cmaj. 1978;119:1034-9.
39. Kirscht JP, Kirscht JL, Rosenstock IM. A test of interventions to increase adherence to hypertensive medical regimens. Health education quarterly [Internet]. 1981; 8(3):[261-72 pp.]. Available from: http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/277/CN-00027277/frame.html.
40. Magid DJ, Ho PM, Olson KL, Brand DW, Welch LK, Snow KE, et al. A multimodal blood pressure control intervention in 3 healthcare systems. American Journal of Managed Care. 2011;17(4):e96-103.
41. Marquez-Contreras E, Martell-Claros N, Gil-Guillen V, de la Figuera-Von Wichmann M, Casado-Martinez JJ, Martin-de Pablos JL, et al. Efficacy of a home blood pressure monitoring programme on therapeutic compliance in hypertension: the EAPACUM-HTA study. Journal of Hypertension. 2006;24(1):169-75.
42. McKenney JM, Munroe WP, Wright JT, Jr. Impact of an electronic medication compliance aid on long-term blood pressure control. Journal of Clinical Pharmacology. 1992;32(3):277-83.
43. McManus RJ, Mant J, Roalfe A, Oakes RA, Bryan S, Pattison HM, et al. Targets and self monitoring in hypertension: randomised controlled trial and cost effectiveness analysis. BMJ. 2005;331(7515):22.
44. Mehos BM, Saseen JJ, MacLaughlin EJ. Effect of pharmacist intervention and initiation of home blood pressure monitoring in patients with uncontrolled hypertension. Pharmacotherapy:The Journal of Human Pharmacology & Drug Therapy. 2000;20(11):1384-9.
45. Midanik LT, Resnick B, Hurley LB, Smith EJ, McCarthy M. Home blood pressure monitoring for mild hypertensives. Public Health Reports. 1991;106(1):85-9.
46. Migneault JP, Dedier JJ, Wright JA, Heeren T, Campbell MK, Morisky DE, et al. A culturally adapted telecommunication system to improve physical activity, diet quality, and medication adherence among hypertensive African-Americans: a randomized controlled trial. Annals of Behavioral Medicine. 2012;43(1):62-73.
47. Niiranen TJ, Leino K, Puukka P, Kantola I, Karanko H, Jula AM. Lack of impact of a comprehensive intervention on hypertension in the primary care setting. American Journal of Hypertension. 2014;27(3):489-96.
48. Ogbuokiri JE. Self-monitoring of blood pressures in hypertensive subjects and its effects on patient compliance. Drug Intell Clin Pharm. 1980;14(6):424-7.
49. Ogedegbe G, Tobin JN, Fernandez S, Cassells A, Diaz-Gloster M, Khalida C, et al. Counseling African Americans to Control Hypertension (CAATCH): Cluster Randomized Clinical Trial Main Effects. Circulation. 2014.
50. Rinfret S, Lussier M-T, Peirce A, Duhamel F, Cossette S, Lalonde L, et al. The Impact of a Multidisciplinary Information Technology–Supported Program on Blood Pressure Control in Primary Care. Circulation: Cardiovascular Quality and Outcomes. 2009;2(3):170-7.
51. Rudd P, Miller NH, Kaufman J, Kraemer HC, Bandura A, Greenwald G, et al. Nurse management for hypertension. A systems approach. American Journal of Hypertension. 2004;17(10):921-7.
52. Stewart K, Mc Namara KP, George J. Challenges in measuring medication adherence: experiences from a controlled trial. Int J Clin Pharm. 2014;36(1):15-9.
53. van Onzenoort HAW, Verberk WJ, Kroon AA, Kessels AGH, Nelemans PJ, van der Kuy P-HM, et al. Effect of self-measurement of blood pressure on adherence to treatment in patients with mild-to-moderate hypertension. Journal of Hypertension. 2010;28(3):622-7.

54. Vrijens B, Goetghebeur E. Comparing compliance patterns between randomized treatments. Control Clin Trials. 1997;18(3):187-203.
55. Wakefield BJ, Holman JE, Ray A, Scherubel M, Adams MR, Hills SL, et al. Outcomes of a home telehealth intervention for patients with diabetes and hypertension. Telemedicine Journal & E-Health. 2012;18(8):575-9.
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. Docherty M, Smith R. The case for structuring the discussion of scientific papers. BMJ. 1999;318(7193):1224-5.
58. Chowdhury R, Khan H, Heydon E, Shroufi A, Fahimi S, Moore C, et al. Adherence to cardiovascular therapy: a meta-analysis of prevalence and clinical consequences. European Heart Journal. 2013;34(38):2940-8.
59. Mcgraw KO, Wong SP. A Common Language Effect Size Statistic. Psychological Bulletin. 1992;111(2):361-5.
60. Haynes RB, McKibbon KA, Kanani R. Systematic review of randomised trials of interventions to assist patients to follow prescriptions for medications. Lancet. 1996;348(9024):383-6.
61. van Onzenoort HA, Menger FE, Neef C, Verberk WJ, Kroon AA, de Leeuw PW, et al. Participation in a clinical trial enhances adherence and persistence to treatment: a retrospective cohort study. Hypertension. 2011;58(4):573-8.
62. Conn VS, Ruppar TM, Chase JA, Enriquez M, Cooper PS. Interventions to Improve Medication Adherence in Hypertensive Patients: Systematic Review and Meta-analysis. Curr Hypertens Rep. 2015;17(12):94.
63. Takiya LN, Peterson AM, Finley RS. Meta-analysis of interventions for medication adherence to antihypertensives. The Annals of pharmacotherapy. 2004;38(10):1617-24.
64. Peterson AM, Takiya L, Finley R. Meta-analysis of trials of interventions to improve medication adherence. American Journal of Health-System Pharmacy. 2003;60(7):657-65.
65. Mennini FS, Marcellusi A, von der Schulenburg JM, Gray A, Levy P, Sciattella P, et al. Cost of poor adherence to anti-hypertensive therapy in five European countries. Eur J Health Econ. 2014;5:5.
66. Schroeder K, Fahey T, Ebrahim S. Interventions for improving adherence to treatment in patients with high blood pressure in ambulatory settings. Cochrane Database of Systematic Reviews. 2004;3:3.
67. Law MR, Morris JK, Wald NJ. Use of blood pressure lowering drugs in the prevention of cardiovascular disease: meta-analysis of 147 randomised trials in the context of expectations from prospective epidemiological studies. BMJ. 2009;338:b1665.
68. NICE. The Clinical Management of Primary Hypertension in Adults: Clinical Guideline 137. 2011.

CHAPTER THREE

PATIENT AND CLINICIAN ATTITUDES TO SELF-MONITORING BLOOD PRESSURE: SYSTEMATIC REVIEW AND THEMATIC SYNTHESIS

3.1 CHAPTER OVERVIEW

The following chapter presents the results of the second study, and the second systematic review within the thesis (Study 2 of Figure 1.1). This review investigated patient and clinician attitudes to SMBP.

The chapter begins with an introduction to the review, how it complements a review of effectiveness (Chapter 2), and the overall aims. The results are followed by a discussion of the research, strengths and limitations and suggestions for future research.

This review identified that SMBP targets behaviour change in patients and the clinicians managing their care, while also helping to facilitate the interaction between the two. This finding was then used as a topic of discussion in the patient interviews reported in Chapter 5.

3.2 BACKGROUND

3.2.1 Restatement of the impact of self-monitoring on patient and clinician behaviours

Evidence from randomised controlled trials (RCTs) shows that self-monitoring blood pressure (SMBP), either alone or as a co-intervention, is effective in achieving blood pressure (BP) reduction and better BP control in patients with hypertension.(1-3) The previous chapter (Chapter 2) reports the review and analysis that explored the mechanisms through which SMBP facilitated BP change, and found that SMBP led to a small but statistically significant increase in medication adherence, although it was unlikely that this explained all of the improvement in BP. It was also apparent that SMBP targets clinicians, helping to overcome clinical inertia, and this was discussed in section 2.5.2.

The review reported in this chapter investigates both patient and clinician attitudes to SMBP, in order to supplement the evidence from RCTs reported in chapter 2.

3.2.2 Beyond evidence of effectiveness from controlled trials

Chapter 2 reviewed evidence from randomised controlled trials (RCTs), and while RCTs are the gold standard for producing evidence of effectiveness, they often lack information that is vital to translating research into practice. The need for going beyond evidence of effectiveness was introduced in section 1.9. A common criticism of RCTs is that they lack external validity, due to: participants being unrepresentative of the wider population (demographics, stage of disease, comorbidities); intensive follow-up and assessment (can cause Hawthorne effect whereby individuals change their behaviour due to awareness of being observed), and differences between trial protocol and routine practice.(4, 5) Lack of external validity is the most frequent criticism of RCTs by clinicians, and is one explanation

for the widespread underuse in clinical practice of treatments that have been proven effective in trials and recommended in guidelines.(4)

A major contributor to the success of interventions is how acceptable they are to patients and clinicians, and this will be a focus of this chapter.

3.2.3 Need for evidence on patient and clinician acceptability

Recent clinical guidelines both in the UK and internationally have included recommendations for the use of SMBP in the diagnosis of hypertension and in monitoring BP control (i.e. UK NICE 2011, ESH/ESC Europe 2013).(6, 7) However, it is unclear to what extent the patient and clinician voice, particularly with regard to acceptability and use in "real-world settings" have been incorporated into these guidelines. When synthesising evidence to evaluate health technologies, data on effectiveness and cost-effectiveness are often prioritised and as such, reviews demonstrating the efficacy of SMBP have often ignored the needs, views and perceptions of patients and physicians.

There is currently now a focus in healthcare on patient centred care. In a report commissioned by the Royal College of General Practitioners in 2014 title "Patient Centred Care in the 21st Century", the concept of patient centricity is defined as:

> *"A new type of health system where empowered citizens are able to identify and manage health risk factors, receive individualised and holistic care and are demonstrably equal partners in managing their health"*

Recognising the importance of patient opinion and experience, trials now often include a qualitative component to elicit the views and preferences of patients. However, systematic reviews regularly have not included these data, leading to a loss of the patient and physician voice, and along with it the context within which interventions may or may not work. This

may be due to the focus on synthesising evidence of effectiveness attributed to the advent of Evidence Based Medicine, and demonstrated by the Cochrane movement that has "historically privileged the RCT design, thus excluding considering virtually all other types of study designs, both qualitative and quantitative".(8) Another reason may be the methodological difficulties inherent in combining qualitative and quantitative data. Methods for synthesising qualitative evidence and incorporating qualitative evidence in broader reviews have been developed, and are becoming more commonplace, with the first Cochrane review of qualitative studies published in 2013.(9-11)

This review complements recent reviews of the effectiveness of SMBP, by also presenting a synthesis of the available evidence on patient and clinician beliefs and preferences. Evidence is drawn from daily practice (i.e. 'real-world') settings, or linked to involvement in trials or intervention/program development. Exploring what works and what is acceptable to both patients and professionals is crucial to optimising SMBP interventions for use in real-world settings.

3.2.4 Objectives

The primary objectives of this review were to investigate:

- the motivation for patients to start self-monitoring
- how patients and clinicians use SMBP to promote behaviour change
- the perceived barriers and facilitators to SMBP use by patients and clinicians
- communication and interaction between the two parties.

3.3 METHODS

3.3.1 Protocol and reporting

A protocol was developed and registered on the PROSPERO database and is available in Appendix 2.1.(12) The ENTREQ (enhancing transparency in reporting the synthesis of qualitative research) framework was used to report the results of the review, and includes items grouped into five domains: introduction and methodology, literature search and selection, appraisal, and synthesis of findings (Appendix 2.2).(13) Studies are ordered alphabetically in all tables and figures in this chapter.

3.3.2 Information sources and study selection

Electronic databases (Medline, Embase, PsycINFO, Cinahl, Web of Science, SocAbs) were searched from inception to July 2014 to identify qualitative studies that examined the perspectives of patients with hypertension, or the healthcare professionals managing their care, on the use of SMBP. The search strategy was developed in Medline and translated for use in the other databases (Appendix 2.3). Forward and backward citation searches were carried out on any studies included following the electronic database searches.

Studies were eligible if they:

- included ambulatory patients with hypertension or the healthcare professionals managing their care
- were based in primary care, outpatient clinics or the community
- Investigated perspectives of self-monitoring of blood pressure
- reported the results of primary qualitative research (i.e. interviews, focus groups, ethnography)

Two reviewers independently screened the reports for inclusion looking first at title and abstracts (BF, JHB). Full text articles were obtained for studies that appeared to meet the inclusion criteria, or studies where a definite decision could not be made.

3.3.3 Quality assessment

There has been debate as to whether qualitative and quantitative studies should be assessed according to the same quality criteria.(14) According to Mays and Pope (2000):

> *"As in quantitative research, the basic strategy to ensure rigour, and thus quality, in qualitative research is systematic, self-conscious research design, data collection, interpretation, and communication."*

The Cochrane Collaboration currently states that:

> *"Opinion on the value of formal quality assessment is divided and there is insufficient evidence to inform a judgement on the rigour or added value of various approaches."*

Cochrane published their first qualitative evidence synthesis in 2013, and currently there are a further two completed reviews.(11, 15, 16) These reviews used the CASP (critical appraisal skills programme) checklist, which includes ten questions to "help make sense of qualitative research". The CASP checklists were designed as educational pedagogic tools, and CASP suggests that the tools are not used as a scoring system.(17) It was felt that CASP would not illuminate many differences between studies, this making discrimination difficult. For example the first three questions on the checklist (clear statement of aims; appropriate use of qualitative methodology; and appropriate research design) would be the same for all studies, as they would not have been included in the review otherwise.

A number of checklists are available, and for this review the Consolidated Criteria for Reporting Qualitative Health Research (COREQ) framework suggested by the EQUATOR

Network was chosen, and is available in Appendix 2.4.(18) The COREQ checklist has criteria relating to: research team and reflexivity; study design; and analysis and findings. Although COREQ was developed as a reporting guideline, it was chosen to be a guide to quality assessment for this review as it includes a number of important methodological areas where objective decisions can be made. COREQ has been used in other reviews as a quality assessment tool (i.e. Prorok 2013, Hole 2014).(19, 20) As the researchers conducting quality assessment were new to qualitative evidence synthesis the lack of subjective decisions was thought to be important in reaching consensus. Two Reviewers independently assessed each included report and disagreements were resolved through discussion.

3.3.4 Data extraction

Data extraction was first carried out using an adaptation of the JBI QARI form for interpretive research (Joanna Briggs Institute qualitative assessment and review instrument).(21) The form allowed broad themes to be identified from the studies, which were used to guide the first stage of analysis, and is available in Appendix 2.5.

All text was extracted from sections labelled as 'results' or 'findings' in the included reports and entered into QSR NVivo 10 software for analysis.

3.3.5 Synthesis

Systematic reviews of qualitative data should go further than simply describing the identified research to translating the findings into new theories to answer the research question. It has been argued that three criteria are the foundation of good qualitative reviews: interpretation

of subjective meaning; description of social context; and attention to lay knowledge.(22) This review aimed to be consistent with these methodological aims.

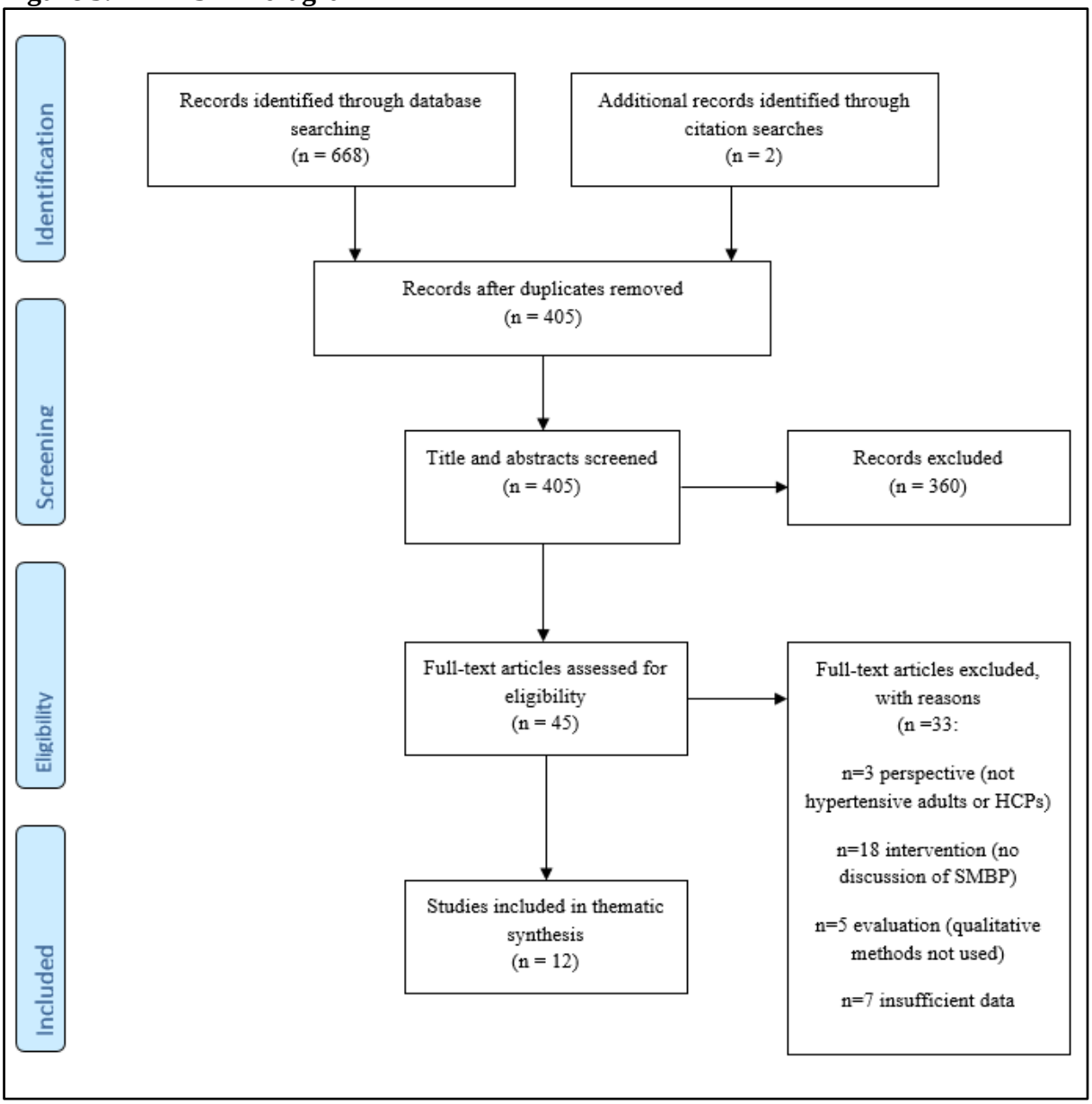
Thematic synthesis was chosen as it uses methods that are established for the analysis of primary data, and translates them for use in systematic reviews.(23) Line-by-line coding was carried out on relevant data by one researcher and agreed throughout by discussion with a second. Initial descriptive codes were grouped into related areas to construct descriptive themes. Abstracted analytical themes were then developed by one researcher (BF) and refined in collaboration with two DPhil supervisors (LH and RM). Coding was inductive, with theme development directed by the content of the data. Wherever possible quotes from the participants of included studies (primary data) have been presented to demonstrate the analytical themes; where participant quotes were not available author interpretations have been included. Quotes are presented followed by information about the individual (i.e. patient, clinician, author interpretation), and setting (i.e. study in 'daily practice' setting, linked to a trial, or part of intervention development).

3.4 RESULTS

3.4.1 Searches

Database searches yielded 668 articles, with two additional records from citation searches. Following removal of duplicates and title and abstract screening, 45 full text articles were assessed and 12 articles met the selection criteria (24-35). (PRISMA diagram, Figure 3.1)

Figure 3.1- PRISMA diagram



3.4.2 Study characteristics

The characteristics of included studies are presented in Table 3.1. Some studies included more than one population and/or more than one methodology.

Eleven studies involved patients (n=358), and five involved healthcare professionals (n=91). The earliest article was published in 2003 with the majority (8/12) published during the last five years. Seven studies took place in the UK, two in USA, and one each in Malaysia, Canada, and Sweden. Eight studies used interviews and five used focus groups.

Five studies were qualitative studies embedded within RCTs testing SMBP interventions; three were part of SMBP intervention/programme development; and the remaining four investigated SMBP use in "daily practice" settings.

Table 3.1 – Characteristics of included studies

Study	Country	Design	Participants	Objectives	Setting	RW/T/ID*
Abdullah (2011)(24)	Malaysia	Interviews (x6) and focus groups (x2)	**Patients** with hypertension who had self-initiated SMBP (n=24; 6 interview, 18 focus group)	To explore the experiences of purchasing and using SMBP at patients' own initiative	Urban primary care clinic	RW
Bengtsson (2014)(25)	Sweden	Focus groups (x5)	**Patients** with hypertension (n=15), and **healthcare professionals** (n=12: 4 nurses, 4 physicians and 4 pharmacists)	To explore and describe relevant aspects of hypertension and hypertension treatment, to be used in the development of an interactive mobile phone self-report system for hypertension self-management	Primary healthcare centre and internal medical outpatient clinic	ID
Bostock (2009)(26)	UK	Focus groups (x3)	**Patients** with hypertension (n=16), and **healthcare professionals** (n=25: 3 nurses and 6 GPs)	To establish any concerns patients and clinicians may have about mobile phone based BP monitoring before planning an RCT. To investigate how commonly patients and clinicians made use of home-monitoring results in managing their BP	Four general practices chosen to reflect range of socio-economic conditions.	ID
Halifax (2007)(27)	Canada	Focus groups (x6)	**Patients** with comorbid type II diabetes and hypertension (n=24) and **family practitioners** (n=18)	To determine the information needs of patients and clinicians for the design of a telemedicine system	Hypertension clinic, diabetes clinic or family medicine centre	ID

Study	Country	Design	Participants	Objectives	Setting	RW/T /ID*
Hanley (2013)(28)	UK	Interviews (x45)	**Patients** with hypertension (n=25), and **healthcare professionals** (n=20: 11 nurses and 9 doctors)	To explore the experiences of patients and professionals taking part in a RCT of remote BP telemonitoring supported by primary care. To identify factors facilitating or hindering the effectiveness of the intervention and those likely to influence its potential translation to routine practice.	Six socioeconomically diverse general practices	T
Jones (2012)(29)	UK	Interviews (x29)	**Patients** with hypertension (n=23) and **family members** (n=6)	Qualitative study embedded in RCT to explore patients' views of SMBP with self-titration of anti-hypertensive medication	Twenty four general practices	T
Jones (2013)(30)	UK	Interviews (x16)	**Healthcare professionals** (n=16: 13 GPs, 2 nurses and 1 healthcare assistant)	Qualitative study embedded in RCT to explore health professionals' views and experiences of patient self-management particularly with respect to future implementation into routine care.	Fourteen general practices	T
Lambert-Kerzener (2010)(31)	USA	Interviews (x146)	**Patients** with hypertension (n=146)	To explore patients' experiences with a multifaceted BP control intervention involving interactive voice response technology, home BP monitoring and pharmacist led BP management	Veterans affairs medical centre and municipal safety net hospital	T
Ovaisi (2011)(32)	UK	Interviews (x26)	**Patients** with hypertension who had suffered a stroke or TIA in past 9 months (n=26)	From the intervention arm of a community-based RCT of SMBP, to explore patients' experiences of self-monitoring with nurse-led support.	Hospital stroke clinic	T

Study	Country	Design	Participants	Objectives	Setting	RW/T/ID*
Rickerby (2003)(33)	UK	Interviews (x13)	**Patients** with hypertension (n=13)	To investigate the experiences of individuals who had carried out SMBP	Single GP practice	RW
Schmid (2009)(34)	USA	Focus groups (x6)	**Patients** with a stroke or TIA in the past 24 months (n=28)	To identify BP self-management strategies used by individuals who had suffered a stroke or TIA.	Veterans affairs medical centre	RW
Vasileiou (2013)(35)	UK	Interviews (x18)	**Patients** – users of SMBP (n=18)	To explore the reasoning behind the interpretation of home readings, and the way people interact with their doctor with reference to these values and the practice of SMBP	Community	RW

***Real-world (RW), linked to trial (T) or intervention/programme development (ID)**

3.4.3 Quality assessment

The comprehensiveness of reporting across studies is presented in Table 3.2. Reporting varied, with studies reporting between 13-25 of the 32 items in the COREQ checklist. The domain including research team and reflexivity was not generally well reported, with no item reported by more than half of the studies. The experience and training of the interviewer/facilitator, and their characteristics with regard to bias, assumptions and interest in the research topic were only reported by one study each.

The second domain regarding study design was better reported with the exception of: the presence of non-participants (one study); the presence of repeat interviews (zero studies); and the return of transcripts to participants for comment/correction (one study). The methodological orientation underpinning the study was only reported in two studies.

The final domain, analysis and findings, was generally well reported, with the exception of: the description of the coding tree (three studies), participants providing feedback on finding (one study), and the use of software for analysis (five studies).

Table 3.2 – Quality assessment (COREQ)

COREQ Domain/Item	Research team and reflexivity								Study design																Analysis and findings									Total (n=32)
	1. Interviewer/facilitator	2. Credentials	3. Occupation	4. Gender	5. Experience and training	6. Relationship established	7. Participant knowledge of the interviewer	8. Interviewer characteristics	9. Methodological orientation and theory	10. Sampling	11. Method of approach	12. Sample size	13. Non-participation	14. Setting of data collection	15. Presence of non-participants	16. Description of sample	17. Interview guide	18. Repeat interviews	19. Audio/visual recording	20. Field notes	21. Duration	22. Data saturation	23. Transcripts returned	24. Number of data coders	25. Description of the coding tree	26. Derivation of themes	27. Software	28. Participant checking	29. Quotations presented	30. Data and findings consistent	31. Clarity of major themes	32. Clarity of minor themes	
Abdullah 2011 (24)	Y	N	N	Y	N	N	N	N	Y	Y	Y	Y	N	N	N	Y	Y	N	Y	Y	Y	Y	N	Y	N	Y	Y	N	Y	Y	Y	Y	**19**
Bengtsson 2014 (25)	N	N	N	Y	N	N	N	N	N	Y	Y	Y	N	N	N	Y	Y	N	Y	N	Y	Y	N	N	Y	Y	Y	N	Y	Y	Y	Y	**16**
Bostock 2009 (26)	N	N	N	Y	N	N	N	N	N	Y	N	Y	N	Y	N	Y	N	N	Y	Y	Y	N	N	N	Y	N	N	N	Y	Y	Y	Y	**11**
Halifax 2007 (27)	N	Y	N	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	N	N	Y	N	Y	N	N	N	N	Y	N	N	N	N	Y	Y	**14**
Hanley 2013 (28)	Y	N	Y	Y	Y	N	N	Y	N	Y	Y	Y	Y	Y	N	Y	Y	N	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	**25**
Jones 2012 (29)	N	Y	Y	Y	N	N	N	N	N	Y	N	Y	Y	Y	N	Y	N	N	Y	Y	Y	Y	N	N	N	Y	N	N	Y	Y	Y	Y	**17**
Jones 2013 (30)	N	Y	Y	Y	N	N	N	N	N	Y	N	Y	Y	Y	N	Y	N	N	Y	Y	Y	Y	N	Y	N	Y	N	N	Y	Y	Y	Y	**18**
Lambert-Kerzener 2010 (31)	Y	Y	N	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N	Y	N	N	Y	N	Y	N	N	Y	N	Y	N	N	Y	Y	Y	Y	**17**
Ovaisi 2011 (32)	N	Y	Y	Y	N	N	N	N	N	Y	N	Y	Y	Y	N	Y	N	N	Y	Y	Y	N	N	Y	N	Y	Y	N	Y	Y	Y	Y	**18**
Rickerby 2003 (33)	Y	N	N	Y	N	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	N	Y	N	Y	N	Y	N	N	Y	Y	Y	Y	**19**
Schmid 2009 (34)	N	Y	N	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N	Y	N	N	Y	N	N	Y	N	Y	N	Y	N	N	Y	Y	Y	Y	**16**
Vasileiou 2013 (35)	Y	N	N	Y	N	N	N	N	N	Y	Y	Y	N	N	N	Y	Y	N	Y	N	N	Y	N	N	N	Y	Y	N	Y	Y	Y	Y	**15**
Total (n=12)	**5**	**6**	**4**	**12**	**1**	**0**	**0**	**1**	**2**	**12**	**8**	**12**	**8**	**9**	**1**	**12**	**5**	**0**	**12**	**6**	**9**	**8**	**1**	**7**	**3**	**11**	**5**	**1**	**11**	**11**	**12**	**12**	

3.4.4 Thematic synthesis

Initial coding produced 65 descriptive codes, which were grouped into three broad analytical themes. The development of a code structure is an iterative process, and there is substantial diversity in suggestions of how a code structure should be developed.(36) In a deductive approach, an organising framework for the analysis, based on the specific research objectives, is used to direct analysis. The three themes presented here were developed inductively, with themes driven by the data. An advantage of an inductive approach is that it limits researchers from "forcing a preconceived result".(37)

Coding across the twelve included studies is shown in Table 3.3. The first is pragmatic and describes how patients and clinicians use SMBP, how they interpret the results, to what patients attribute high/low/change in BP, and what actions are taken based on SMBP. The second theme describes the balance between SMBP being perceived as convenient and reassuring contrasted with the potential for causing anxiety and uncertainty. The final theme deals with patient empowerment, autonomy and self-efficacy, and how SMBP changes the traditional patient-clinician dynamic.

Table 3.3 – Coding across included studies

		Abdullah 2011	Bengtsson 2014	Bostock 2009	Halifax 2007	Hanley 2013	Jones 2012	Jones 2013	Lambert-Kerzener 2010	Ovaisi 2011	Rickerby 2003	Schmid 2009	Vasileiou 2013	Total
THEME 1 Interpretation, attribution and action	Pharmacological treatment	X	X	X	X	X	X	X	X	X	X	X		11
	Frequency of monitoring self	X		X	X	X	X		X	X	X	X	X	10
	Knowledge	X	X		X	X	X		X	X	X	X	X	10
	Target BP	X	X	X	X	X	X			X	X	X	X	10
	Interpreting SMBP	X	X	X	X		X	X	X		X		X	9
	Symptoms	X	X			X	X	X		X	X	X		8
	Attribution		X	X		X		X		X	X		X	7
	Variability of BP	X		X	X		X			X	X		X	7
	Lifestyle change	X		X		X			X		X		X	6
	Accuracy of SMBP	X			X	X		X					X	5
	Frequency of monitoring clinic	X			X	X	X							4
	Personalised norm		X										X	2
	Risk perception						X				X			2
	Confusion	X												1
	Consequences of high BP					X								1
	Frustration						X							1
	Normal BP												X	1
	Physical barrier to SM									X				1
THEME 2 Convenience and reassurance v anxiety and uncertainty	Anxiety			X	X	X		X		X	X		X	7
	Confidence	X					X		X	X	X		X	6
	Ease of use			X					X		X	X	X	5
	Uncertainty		X			X					X	X	X	5
	Reassurance	X					X	X		X				4
	Enjoyment							X	X		X			3
	Trust in technology				X					X	X			3
	Concern	X					X							2
	Convenience									X	X			2
	Comfortable						X							1
	Fear								X					1
	Improved mood									X				1
	Relaxed						X							1
	Relief									X				1
	Suspicious	X												1
	Time saving									X				1
	Unsure of benefit			X										1
THEME 3 Patient	Empowerment	X	X	X	X	X	X	X	X	X			X	10
	Self-efficacy	X	X		X	X	X		X	X	X	X	X	10

		Abdullah 2011	Bengtsson 2014	Bostock 2009	Halifax 2007	Hanley 2013	Jones 2012	Jones 2013	Lambert-Kerzener 2010	Ovaisi 2011	Rickerby 2003	Schmid 2009	Vasileiou 2013	Total
empowerment, autonomy and self-efficacy, and how SMBP changes the traditional patient-clinician dynamic	Recording and communicating results	X		X	X	X	X	X		X	X		X	9
	Communication with HCP		X	X		X			X	X	X		X	7
	Increased involvement in healthcare	X	X		X	X	X	X	X					7
	SMBP facilitates discussion with clinician	X		X		X	X		X	X			X	7
	GP supportive of SMBP		X	X	X			X		X			X	6
	Reduction in GP workload			X	X		X	X		X	X			6
	Clinician distrust of SMBP	X	X	X	X			X						5
	Doctor patient alliance		X	X	X	X				X				5
	Feeling of greater control		X	X			X			X				4
	Increased GP workload			X	X	X							X	4
	GP disinterested in SMBP			X						X			X	3
	Motivating					X		X	X					3
	Paternalism			X	X								X	3
	Questioning GP behaviour						X			X	X			3
	Autonomy			X						X				2
	Encouraging others to use SMBP	X					X							2
	Fewer visits to clinic			X	X									2
	Threat to traditional GP role					X							X	2
	Clinical inertia					X								1
	Clinician advice about SMBP							X						1
	Clinician awareness of patient SM				X									1
	Clinician reluctant to share BP data	X												1

		Abdullah 2011	Bengtsson 2014	Bostock 2009	Halifax 2007	Hanley 2013	Jones 2012	Jones 2013	Lambert-Kerzener 2010	Ovaisi 2011	Rickerby 2003	Schmid 2009	Vasileiou 2013	Total
	Clinician utilisation of SMBP							X						1
	False feeling of control						X							1
	GP last resort												X	1
	Increased family support	X												1
	Nervous						X							1
	Patient and clinician trust	X												1

3.4.4.1 Theme 1 - Interpretation, attribution and action

How patients interpreted their BP and acted upon self-measurement depended to a large extent on their understanding of high BP. While patients were aware of some of the potential risk factors for, and consequences of high BP, many did not know what their target BP should be.

> *"…people need to know [target BP] because you do get very uncomfortable whether… is this the danger level?"* Rickerby (2003) [patient, daily practice]

There was a belief among some patients that BP targets should be personalised to take their individual circumstances into account. Clinicians worked to guidelines, which were perceived to be inflexible in their definition of normal and target BP:

> *"Clearly, participants were trying to find functional ways to define acceptable ranges of BP values. The guideline values were an initial broad framework for judgements, but within this, the personalised norm was deployed as a more meaningful rule of thumb, especially for those users who had a relatively consistent history of elevated or reduced readings."* Vasileiou (2013) [author interpretation, daily practice]

> *"The healthcare professionals worked according to national guidelines, but did not use them as a tool to set individual goals. Subsequently, the patients had neither a goal to focus on not an understanding of the actual blood pressure value."* Bengtsson (2014) [author interpretation, intervention development]

There was a consensus between clinicians and patients that SMBP provided a more accurate picture of BP than casual clinic measurement due to the larger number of measurements, and it was this that led some patients to acquire their own monitor.

> *"I can't remember if they… if I was advised to go and buy a home monitoring machine, but I decided to do it anyway… I knew that my blood pressure would be checked every time, regularly at the surgery but certainly twice a year… but until that I would like more information than that."* Hanley (2013) [patient, intervention development]

However, the improved accuracy of SMBP was tempered by observation of the inherent variation in blood pressure. Patients and clinicians were aware that self-measured blood pressure tended to be lower than clinic measures, which led to a dilemma of which measurement was best to use for treatment. Variation between successive SMBP measurements was also noted, again with uncertainty as to which readings should be used.

> *"I could do it one minute and then five minutes later it would be completely different*." Rickerby (2003) [patient, daily practice]
>
> *"It's put us in a bit of a dilemma I think cos we're getting their blood pressures and then when they are doing them at home, they're low, it's difficult isn't it, to know what to do*." Jones (2013) [practice nurse, trial]

After using SMBP, patients questioned whether the usual practice of casual clinic measurement was sufficient to provide accurate information.

> "*Why we need the machine in the house? […] because our visit to the doctor is infrequent."* Abdullah (2011) [patient, daily practice]

Patients often found that high BP had little impact on their daily lives due to the lack of symptoms, and that SMBP gave them an insight into their condition by acting as a proxy for symptoms. SMBP enabled patients to begin to make associations between their BP,

symptoms and actions in their daily lives, and were then able to identify ways to self-manage.

> *"I mean I remember taking my blood pressure and it reading very high and I thought gosh I feel really great at the moment*." Rickerby (2003) [patient, daily practice]

> *"Perhaps because high blood pressure doesn't have proper symptoms. Many think…'oh, I'm fine'."* Bengtsson (2014) [HCP, intervention development]

Some clinicians were concerned that patients were not able to interpret SMBP correctly and might incorrectly attribute some symptoms to their BP.

> *"…and then you've got others; 'Oh, I feel a bit ill today, I'll better check my BP' … and I think that's the danger"* Hanley (2013) [HCP, trial]

Patients were able to use SMBP to monitor the effectiveness of their medication and changes to their lifestyle. SMBP had an impact on whether patients were adherent, whether they initiated or terminated treatment, and to what extent they tailored treatment. In the absence of symptoms, having SMBP as a symptom proxy helped demonstrate the effectiveness of treatment. Clinicians recognised the benefits of being able to use SMBP in conjunction with clinic measurements to make more rapid adjustments to patients' medication, thus overcoming clinical inertia.

> *"I think taking my BP regularly really made me show that I did need to take the medication and that was somewhat motivating… it did show that the medication was important."* Lambert-Kerzener (2010) [patient, trial]

As well as monitoring BP in relation to medication use, patients were able to use SMBP to attribute lifestyle factors to high BP, and then in many cases act in response. However, patients were concerned that they only received generalised advice about how lifestyle change could help, and would prefer the information to be tailored to hypertension in particular as well as more personalised or tailored advice.

> *"When it's high, then I know it's either my diet or I've not been exercising. So when it's high I'll take my walks. I'll do my aerobics and then cut down on meats, go vegetarian."* Abdullah (2011) [patient, daily practice]
>
> *"What I did do, and I've stuck to it, I've cut out salt. I was overweight a few years ago and I cut out butter, so now I don't have butter and I don't have salt. I just use general knowledge."* Hanley (2013) [patient, trial]
>
> "*Lifestyle advice was received from multiple sources and perceived to be general rather than being targeted at the reasons for them individually developing hypertension*." Hanley (2013) [author interpretation, trial]

One article raised the interesting perspective that patients and clinicians may have different expectations of treatment for hypertension:

> *"...patients who perceive symptoms they believe are due to high blood pressure should not expect to feel better from the treatment. Rather, the treatment should merely serve to prevent these patients from feeling worse."* Bengtsson (2014) [author interpretation, intervention development]

3.4.4.2 Theme 2 – convenience and reassurance v anxiety and uncertainty

SMBP was seen to be convenient and easy to use by patients, and the process was in some cases even said to be enjoyable. Patients were more relaxed out of the clinic environment, and liked the ability to be able to monitor as and when they wanted. Patients felt reassured by being able to check symptoms that were potentially attributable to elevated BP. Patients trusted the technology of automated BP monitors.

> *"And it always comes in handy; you feel a little bit dodgy, you can always take it to see what your blood pressure is."* Ovaisi (2011) [patient, trial]
>
> *"I am reassured and I feel quite happy with the fact that I know that my blood pressure is ok. I don't have to think 'oh God I haven't been to the doctor in 4 months, I wonder if my BP is alright' I know it is."* Jones (2012) [patient, trial]

While clinicians recognised that patients were generally positive about SMBP, they were concerned that some might be anxious about the process or results of self-monitoring,

potentially becoming neurotic. They also raised concerns about the ability of some patients to be able to manage the process of monitoring.

> *"I think they get a little bit neurotic about it. You know, they're checking it every day."* Jones (2013) [HCP, trial]
>
> *"… it may not be applicable to patients with poor technical skills or those who were easily 'over focused'."* Halifax (2007) [author interpretation, intervention development]

Some patients did discuss being anxious, and this was usually in relation to what to do when BP was high. While there is scope for patients to become anxious about high BP readings from self-monitoring, it was recognised that this anxiety can either inhibit or promote action; anxiety is only a bad thing if patients feel that they are unable to do anything about it.

> *"I would be quite worried if I took it all the time and it was high. I just think that I'm perfectly alright until I go to the surgery in four months' time. I don't worry about it. I don't think about it."* Bostock (2009) [patient, intervention development]

Little evidence was presented that showed patients feel burdened by the process of self-monitoring (i.e. following a monitoring protocol), which was a concern of a small number of clinicians.

Uncertainty for both patients and clinicians stemmed from how to interpret the results of SMBP, in particular coping with variability, as well as when and how to act upon the readings. For patients, the main concern was knowing at what point they needed to act, and to what degree: for example should they contact their GP or think about going to hospital.

> *"Where should it [BP] be? That way I'll know if me or the missus gotta give a call to an ambulance to come get me… because I don't know what it's supposed to be. I don't know if I should call."* Schmid (2009) [patient, daily practice]

It might be expected that providing clinicians with more accurate BP results would help reduce treatment uncertainty, but this does not seem to be the case. Even when clinicians were provided with clear protocols for treatment, as in trials where medication was titrated

based on SMBP, clinicians were still unsure how to manage borderline cases. In the daily practice settings clinicians were unsure how to incorporate SMBP into routine care, which may have been perceived as reticence by patients.

> *"The only problem I had with it in a way is these people that were coming up as uncontrolled who were one millimetre above the control level. And I just thought, oh come on, are you really going to add in another drug to bring this down?"* Hanley (2013) [HCP, trial]

> "*GPs were inconsistent in how they used patients' home readings. They reported patients sometimes brought home readings to consultations but not in an organised way and even when GPs asked to see the readings, they did not always incorporate these into decision making*." Jones (2013) [author interpretation, trial]

3.4.4.3 Theme 3 – patient empowerment, autonomy and self-efficacy, and how SMBP changes the traditional patient-clinician dynamic

Using SMBP increased patients' involvement in their own care, increased their knowledge about their condition, and empowered them to make changes to benefit/improve their BP. Empowering patients also changed the dynamic of the patient-clinician relationship. Some patients thought that clinicians could be protective of BP results from the clinic, perhaps because the clinicians did not think the patient could understand.

> *"But when we went for a check-up the doctor rarely tells us the actual BP reading. He did not tell us the readings he just said it's ok."* Abdullah (2011) [patient, daily practice]

In contrast SMBP was seen to facilitate discussion, creating a clinician-patient alliance with patients better able to understand and be involved in making decisions about treatment. SMBP provided clinicians with more concrete information rather than what could be sometimes ambiguous symptoms. Patients also thought that if they were self-monitoring they might be taken more seriously by their clinician.

> *"It's certainly given me more meaningful data to speak to the doctor rather than, 'Well, I think my BP has probably gone up'."* Hanley (2013) [patient, trial]
>
> *"I think the doctor will observe you're being a bit more serious than vaguely talking about this, that and the other."* Vasileiou (2013) [patient, daily practice]
>
> "*The knowledge and information (i.e. SMBP measurements) they brought to the visit facilitated a bidirectional conversation that supported their self-care as well as assisted their physicians*" Lambert-Kerzener (2010) [author interpretation, trial]

Whilst most clinicians were generally supportive of their patients' self-monitoring, some patients met with apparent disinterest from their clinician when they tried to communicate the results of self-monitoring, which was disempowering. The perceived disinterest may have been due to a lack of clear guidance for clinicians as to what to do with data from self-monitoring.

> *"I went back quite soon after the initial diagnosis just to confirm that everything was okay. I mentioned that I'd purchased this [SMBP], but that was it really. We didn't really speak about it any more than that."* Vasileiou (2013) [patient, daily practice]

SMBP combined with an increased knowledge of BP and hypertension resulted in patients demonstrating self-efficacy. Rather than being in a passive role relying on their GP to both measure their BP and dictate treatment, patients felt more in control of their own care.

> *"Well the strength is that I have better control. And then that in collaboration with others [nurse/physician] becomes a good foundation for judging how to plan the treatment."* Bengtsson (2014) [patient, intervention development]

Both patients and clinicians recognised that there was scope for SMBP to decrease the workload of GPs especially in trials where telemonitoring was used, or where medication was titrated based on SMBP by pharmacists, nurses or the patients themselves.

> *"It's quite nice to see if you can ship out some of the work to, or give the stuff back to the patients to do which if it makes them more involved and helps them understand is ultimately better."* Jones (2013) [HCP, trial]
>
> *"…maybe just saving time for more serious things and other people."* Rickerby (2003) [patient, daily practice]

3.5 DISCUSSION

3.5.1 Principal findings

This systematic review and thematic synthesis found three overarching themes in the worldwide qualitative literature concerning patient and provider perspectives on self-monitoring of hypertension: interpretation, attribution and action; convenience and reassurance versus anxiety and uncertainty; and patient empowerment, autonomy and self-efficacy, and how SMBP changes the traditional patient-clinician dynamic. The results complement systematic reviews of the efficacy of SMBP by providing information on ease of use and tolerability as well as day-to-day experiences of self-monitoring.

Both patients and clinicians reported being uncomfortable with interpretation of SMBP measurements, particularly in light of the variability (between home and clinic; reading to reading in the short and long-term). There was agreement that BP targets were not clear, and that guidelines currently do not allow enough flexibility for more personalised targets and norms.

SMBP empowered patients, and SMBP combined with an increased knowledge of BP resulted in greater self-efficacy. SMBP was described as providing a proxy for symptoms (in the usually symptomless setting of hypertension) allowing patients to link activities of daily life with changes in their BP. Patients were aware that certain lifestyle factors such as diet and exercise could affect their BP, and some even used SMBP to experiment with some of these factors.

Clinicians recognise the benefits of having a more accurate picture of patients' BP that is provided by self-monitoring, but are often concerned about how their patients may react to having to self-monitor.

3.5.2 Strengths and limitations

It has been argued by some that the synthesis of qualitative studies is impossible and/or meaningless, for example Thomas and Harnden (2007) stated:

> *"In bringing together qualitative research, reviewers are open to the charge that they decontextualize findings and wrongly assume that these are commensurable."*

However, it has also been contended that combing data from qualitative studies results in greater depth than interpreting the studies independently. Margarete Sandelowski (1997) argued:

> *"Metasyntheses are integrations that are more than the sum of parts, in that they offer novel interrelations of findings. These interpretations will not be found in any one research report, but rather are inferences derived from taking all of the reports in a sample as a whole."*

Given the breadth and complexity of qualitative data there is a need to summarise the results of primary studies to provide more accessible information:

> *"Users of reviews are interested in the answers that only qualitative research can provide, but are not able to handle the deluge of data that would result if they tried to locate and read all the relevant research themselves."*

When developing grounded theory, Glaser and Strauss (1971) were concerned that the findings of individual qualitative studies would remain "islands of knowledge" and would in isolation have limited impact.(38) Methods for the synthesis of qualitative studies emerged in response to the proliferation, but relative undervaluation and underutilisation of qualitative studies.(39) Noblit and Hare (1988) described two broad types of synthesis: aggregative (where focus is on summarising data) and interpretive (where intention is to develop concepts or theories).(40) Arguably, all systematic reviews should meet the criteria for being at least aggregative, by presenting all of the available area for a particular research question. However, to maximise the "utilisation value and power" of qualitative studies

some interpretation of the findings of individual studies is required. According to Dixon-Woods emphasised the need for interpretive reviews to generate concepts that have "maximum explanatory value".(8) The approach used in this review was interpretive, with new theory developed regarding how SMBP can be used to facilitate the interaction between patients and clinicians.

There is currently no consensus on appropriate guidance for qualitative synthesis. Thematic synthesis was chosen as it uses analytical methods from primary qualitative studies, applies them to secondary analysis, and allows the clear identification of prominent themes in a methodologically transparent fashion. A key feature of thematic synthesis (along with met-ethnograpy, meta-narrative and critical interpretive syntheses), is that it seeks to push beyond the simply describing and summarising primary data to a fresh interpretation of the phenomena under review.(9)

The synthesis covered SMBP use from a broad range of settings, including trials, development of interventions and daily practice, as well as from the perspectives of both patients and clinicians. All but two of the included studies were published within the five years prior to the searches. Only four of the studies represented "real-world" settings where patients and clinicians discussed using SMBP as part of their usual practice. It is possible that the participants of studies linked to trials or intervention development would have different perspectives than the wider population.

3.5.3 Comparison with the literature and implications for practice

With the growing enthusiasm for SMBP in everyday practice there is a need for further research into the use of SMBP in "real-world" settings, particularly why patients may initiate SMBP, and where it fits into their everyday lives. More guidance is needed as to how to

incorporate self-measured BP into routine practice. While current UK guidelines are clear about how to use SMBP in the diagnosis of hypertension (i.e. NICE 2011), guidance from the UK and internationally for its use in managing hypertension is less clear, reflecting the underlying evidence.(3)

SMBP allowed patients to link activities of daily life with changes in BP, which contrasts with Chapter 2 where little evidence was available to support a positive impact of SMBP on lifestyle factors. Chapter 2 also introduced the potential for SMBP to impact clinician behaviour, specifically by overcoming clinical inertia, however this was not reported as a major factor by the clinicians in the included studies.(41)

SMBP empowered patients, assisting them in managing their BP. Empowered, or 'activated' patients have been shown to less frequently attend their healthcare provider for management of their condition, thus potentially reducing burden on clinicians as well as costs.(42) Empowerment had an effect on the traditional patient-clinician relationship, with SMBP reported as facilitating discussion about hypertension and giving patients more understanding about their health state. Clinicians recognised the benefits of patient self-monitoring and self-management, but described concern that some patients may become anxious (or even neurotic), however there were no corroborating patient views to this effect.

SMBP combined with increased knowledge of BP was described as resulting in patients demonstrating increased self-efficacy. This supports the Chronic Care Model (CCM), which proposes a model of care where engaged informed individuals are provided with support and access to services. According to the CCM, successful self-management requires five important components: problem solving; decision making; resource utilisation (community resources); patient-provider relationship; and the ability for patients to take appropriate action.

The evidence from trials shows that adding educational support to SMBP is more effective than SMBP alone.(3) Interestingly educational interventions have not been proven to be effective in managing hypertension (43), suggesting that SMBP and education may have a synergistic effect (combined effect greater than sum of components). Understanding what information patients are given by their GP about how to use SMBP will be explored in Chapter 5, where the results of patient interviews are presented. It is likely that goal setting and problems solving are required.

Integrating SMBP into everyday practice remains an issue, with no clear current guidance for clinicians. SMBP provides a potential wealth of information, but how it is recorded by patients and then communicated to clinicians remains ad hoc. Current practice of UK GPs with regard to SMBP is the subject of Chapter 4. Telemonitoring is one method that has been shown to be successful in trials (in hypertension and other chronic conditions such as diabetes), however this has yet to be rolled out to scale.(44, 45) The CCM emphasises the need for optimisation of organisational and clinical processes to integrate information from patient self-monitoring, and that these processes should be co-designed with healthcare professionals and patients wherever practicable.

The results of this review suggest that uncertainty for patients and clinicians could be reduced by providing information specifically about how to interpret SMBP, what variation is acceptable, how to adjust for home-clinic difference, and for patients particularly what they should be concerned about and how to act (i.e. when to contact their clinician). Providing educational materials for patients along with self-monitoring may be crucial in optimising the potential health benefits. Future guidance for clinicians should include information on: targets for self-measured BP; how often patients need to self-monitor; how the information should be recorded by patients and communicated to clinicians in a format that can be readily used to guide treatment.

3.5.4 Conclusion

Further research should focus on the best protocol for SMBP for managing hypertension, as well as understanding the role SMBP can play in improving the patient-clinician consultation.

At its inception, the focus of the RCT review presented in Chapter 2 was on the role of SMBP in changing patient behaviour. While conducting that first systematic review it also became apparent that through overcoming clinical inertia, SMBP could have an impact on clinician behaviour. Perhaps the most interesting, and novel, finding of the qualitative review presented here is that SMBP can facilitate the interaction between patients and clinicians, therefore identifying a further target for research into SMBP interventions. This is an area that warrants closer attention in the future, using qualitative methods. A novel approach would be to use conversation analysis (CA): a sociolinguistic approach that has been used to study patient-clinician interactions in 'natural' settings, with the aim of understanding how SMBP influences discussion about BP and treatment.(46)

As SMBP appears to influence behaviour change in both patients and clinicians, it is important to understand where such an effect is greatest, as this would then provide a logical target for optimisation. Self-monitoring can empower patients and involve them more in their healthcare, as well as provide more accurate and timely information for clinicians, but the precise motivations for starting and continuing to self-monitor will vary from case to case. Targeting the interaction between patients and clinicians around self-monitoring might therefore be a fruitful avenue for future study. Research questions could include considering how SMBP can be used in consultation discussions, particularly in terms of clinician's acceptance and permission giving.

There is evidence that many patients may monitor their BP without informing their clinician, and while these patients may have some benefits from self-monitoring in isolation, they could be encouraged to bring the information into the clinical encounter.(47) Improved health communication has been shown to be associated with better health outcomes in chronic conditions, and is therefore a relevant topic for future interventions.(48)

3.6 REFERENCES

1. 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):371-86.
2. Stergiou GS, Bliziotis IA. Home blood pressure monitoring in the diagnosis and treatment of hypertension: a systematic review. American Journal of Hypertension. 2011;24(2):123-34.
3. Uhlig K, Patel K, Ip S, Kitsios GD, Balk EM. Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. Annals of Internal Medicine. 2013;159(3):185-94.
4. Rothwell PM. External validity of randomised controlled trials: "to whom do the results of this trial apply?". Lancet. 2005;365(9453):82-93.
5. Jones R, Jones RO, McCowan C, Montgomery AA, Fahey T. The external validity of published randomized controlled trials in primary care. BMC Fam Pract. 2009;10:5.
6. Mancia G, Fagard R, Narkiewicz K, Redon J, Zanchetti A, Bohm M, et al. 2013 ESH/ESC Guidelines for the management of arterial hypertension: the Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). J Hypertens. 2013;31(7):1281-357.
7. NICE. The Clinical Management of Primary Hypertension in Adults: Clinical Guideline 137. 2011.
8. Dixon-Woods M, Bonas S, Booth A, Jones DR, Miller T, Sutton AJ, et al. How can systematic reviews incorporate qualitative research? A critical perspective. Qualitative Research. 2006;6(1):27-44.
9. Barnett-Page E, Thomas J. Methods for the synthesis of qualitative research: a critical review. BMC Medical Research Methodology. 2009;9:59.
10. Petticrew M, Rehfuess E, Noyes J, Higgins JPT, Mayhew A, Pantoja T, et al. Synthesizing evidence on complex interventions: how meta-analytical, qualitative, and mixed-method approaches can contribute. Journal of Clinical Epidemiology. 2013;66(11):1230-43.
11. Glenton C, Colvin CJ, Carlsen B, Swartz A, Lewin S, Noyes J, et al. Barriers and facilitators to the implementation of lay health worker programmes to improve access to maternal and child health: qualitative evidence synthesis. Cochrane Database Syst Rev. 2013(10):CD010414.
12. How do patients and clinicians use home monitoring in the management of hypertension, and what are the barriers and facilitators to its use, both in trials and real-world settings: a systematic review and thematic synthesis [Internet]. 2014.
13. Tong A, Flemming K, McInnes E, Oliver S, Craig J. Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ. BMC Medical Research Methodology. 2012;12(1):181.
14. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. BMJ. 2000;320(7227):114-6.
15. Jordan J, Rose L, Dainty KN, Noyes J, Blackwood B. Factors that impact on the use of mechanical ventilation weaning protocols in critically ill adults and children: a qualitative evidence-synthesis. Cochrane Database Syst Rev. 2016;10:CD011812.
16. Ames HM, Glenton C, Lewin S. Parents' and informal caregivers' views and experiences of communication about routine childhood vaccination: a synthesis of qualitative evidence. Cochrane Database Syst Rev. 2017;2:CD011787.
17. Programme CAS. CASP Qualitative Research Checklist 2016.
18. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care. 2007;19(6):349-57.
19. Prorok JC, Horgan S, Seitz DP. Health care experiences of people with dementia and their caregivers: a meta-ethnographic analysis of qualitative studies. CMAJ. 2013;185(14):E669-80.

20. Hole E, Stubbs B, Roskell C, Soundy A. The patient's experience of the psychosocial process that influences identity following stroke rehabilitation: a metaethnography. TheScientificWorldJournal. 2014;2014:349151.
21. Institute JB. The Joanna Briggs Institute Reviewers' Manual: 2014 edition. Australia: The Joanna Briggs Institute; 2014.
22. Popay J, Rogers A, Williams G. Rationale and standards for the systematic review of qualitative literature in health services research. Qual Health Res. 1998;8(3):341-51.
23. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. BMC Medical Research Methodology. 2008;8(1):45.
24. Abdullah A, Othman S. The influence of self-owned home blood pressure monitoring (HBPM) on primary care patients with hypertension: a qualitative study. BMC Family Practice. 2011;12:143.
25. Bengtsson U, Kasperowski D, Ring L, Kjellgren K. Developing an interactive mobile phone self-report system for self-management of hypertension. Part 1: patient and professional perspectives. Blood Press. 2014;23(5):288-95.
26. Bostock Y, Hanley J, McGown D, Pinnock H, Padfield P, McKinstry B. The acceptability to patients and professionals of remote blood pressure monitoring using mobile phones. Primary Health Care Research & Development. 2009;10(4):299-308.
27. Halifax NV, Cafazzo JA, Irvine MJ, Hamill M, Rizo CA, McIssac WJ, et al. Telemanagement of hypertension: a qualitative assessment of patient and physician preferences. Canadian Journal of Cardiology. 2007;23(7):591-4.
28. Hanley J, Ure J, Pagliari C, Sheikh A, McKinstry B. Experiences of patients and professionals participating in the HITS home blood pressure telemonitoring trial: a qualitative study. BMJ Open. 2013;3(5).
29. Jones MI, Greenfield SM, Bray EP, Baral-Grant S, Hobbs FD, Holder R, et al. Patients' experiences of self-monitoring blood pressure and self-titration of medication: the TASMINH2 trial qualitative study. British Journal of General Practice. 2012;62(595):e135-42.
30. Jones MI, Greenfield SM, Bray EP, Hobbs FR, Holder R, Little P, et al. Patient self-monitoring of blood pressure and self-titration of medication in primary care: the TASMINH2 trial qualitative study of health professionals' experiences. British Journal of General Practice. 2013;63(611):e378-85.
31. Lambert-Kerzner A, Havranek EP, Plomondon ME, Albright K, Moore A, Gryniewicz K, et al. Patients' perspectives of a multifaceted intervention with a focus on technology: a qualitative analysis. Circulation Cardiovascular quality and outcomes [Internet]. 2010; 3(6):[668-74 pp.]. Available from: http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/943/CN-00788943/frame.html.
32. Ovaisi S, Ibison J, Leontowitsch M, Cloud G, Oakeshott P, Kerry S. Stroke patients' perceptions of home blood pressure monitoring: a qualitative study. British Journal of General Practice. 2011;61(590):e604-10.
33. Rickerby J, Woodward J. Patients' experiences and opinions of home blood pressure measurement. Journal of Human Hypertension. 2003;17(7):495-503.
34. Schmid AA, Damush TM, Plue L, Subramanian U, Bakas T, Williams LS. Current blood pressure self-management: a qualitative study. Rehabilitation Nursing Journal. 2009;34(6):223-9.
35. Vasileiou K, Barnett J, Young T. Interpreting and acting upon home blood pressure readings: a qualitative study. BMC Family Practice. 2013;14:97.
36. Bradley EH, Curry LA, Devers KJ. Qualitative data analysis for health services research: developing taxonomy, themes, and theory. Health Serv Res. 2007;42(4):1758-72.
37. Glaser BG. Basics of grounded theory analysis : emergence vs forcing. Mill Valley, Calif.: Sociology Press; 1992.
38. Glaser BG, Strauss, Strauss AL. Status passage. London: Routledge and Kegan Paul; 1971.
39. Sandelowski M, Barroso J. Handbook for synthesizing qualitative research. New York, NY: Springer Pub. Co.; 2007. xxv, 284 p. p.

40. Noblit GW, Hare RD. Meta-ethnography : synthesizing qualitative studies. Newbury Park, Calif. ; London: Sage; 1988.
41. Agarwal R, Bills JE, Hecht TJW, 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.
42. Donald M, Ware RS, Ozolins IZ, Begum N, Crowther R, Bain C. The role of patient activation in frequent attendance at primary care: A population-based study of people with chronic disease. Patient Education and Counseling. 2009;83(2):217-21.
43. Glynn LG, Murphy AW, Smith SM, Schroeder K, Fahey T. Interventions used to improve control of blood pressure in patients with hypertension. Cochrane Database of Systematic Reviews. 2010(3):CD005182.
44. McManus RJ, Mant J, Haque M, et al. Effect of self-monitoring and medication self-titration on systolic blood pressure in hypertensive patients at high risk of cardiovascular disease: The tasmin-sr randomized clinical trial. JAMA. 2014;312(8):799-808.
45. Pare G, Jaana M, Sicotte C. Systematic review of home telemonitoring for chronic diseases: the evidence base. Journal of the American Medical Informatics Association. 2007;14(3):269-77.
46. Drew P, Chatwin J, Collins S. Conversation analysis: a method for research into interactions between patients and health-care professionals. Health expectations : an international journal of public participation in health care and health policy. 2001;4(1):58-70.
47. Viera AJ, Cohen LW, Mitchell CM, Sloane PD. Use of home blood pressure monitoring by hypertensive patients in primary care: survey of a practice-based research network cohort. Journal of Clinical Hypertension. 2008;10(4):280-6.
48. Street Jr RL, Makoul G, Arora NK, Epstein RM. How does communication heal? Pathways linking clinician–patient communication to health outcomes. Patient Education and Counseling. 2009;74(3):295-301.

CHAPTER FOUR

UTILISATION OF SELF-MONITORING BLOOD PRESSURE RESULTS BY GENERAL PRACTITIONERS IN THE UNITED KINGDOM: AN INTERNET BASED SURVEY

4.1 CHAPTER OVERVIEW

This following chapter presents the third study within the thesis (Study 3 of Figure 1.1). An on-line survey of UK of 300 regionally representative general practitioners was carried out to assess use of SMBP in the diagnosis and management of hypertension. The results were compared with a similar survey completed immediately prior to changes to national guidelines in 2011. The study follows on from the previous chapter where review results found that clinicians were shown to be generally positive about SMBP, but had concerns about interpretation and patient anxiety. This survey investigated whether this generally positive attitude to SMBP translates into everyday practice. This chapter links to the following chapter which describes qualitative work where patients were interviewed about their experiences of SMBP to provide a picture of current practice.

The chapter begins with a recap of the benefits of out-of-office BP measurement, a summary of UK guidelines, and the study objectives. The results are followed by a discussion and implications for practice and future research.

4.2 BACKGROUND

4.2.1 Blood pressure measurement guidelines

How, where and when blood pressure is measured are key aspects in the diagnosis and management of hypertension.(1) In the United Kingdom (UK) and increasingly elsewhere, 24 hour ambulatory BP (ABPM) has replaced clinic measurement as the gold standard for diagnosis of hypertension.(2-4) As discussed in section 1.8, SMBP provides a further alternative to clinic measurement for a number of reasons: like ABPM it is a better predictor of cardiovascular risk than clinic measurements(5, 6); monitors are widely available and less expensive than ABPM(7); SMBP is generally more acceptable to patients(8-10), and SMBP provides information about day-to-day variability of BP whereas ABPM is usually only used over a single 24 hour period.(11)

In the United Kingdom (UK), the National Institute for Health and Care Excellence (NICE) updated their guidelines for the clinical management of hypertension in adults in 2011 to include recommendations for self-monitoring in response to the developing evidence base.(1) A survey was conducted immediately before their release in 2011 to assess knowledge and practice of SMBP in UK general practitioners (GPs).(12)

In the previous chapter, clinicians were shown to be generally supportive of SMBP, but some were uncomfortable with the interpretation of SMBP results in the absence of explicit guidance, and some had concerns about how their patients may react to being asked to monitor. These concerns could potentially translate into poor adoption in everyday practice. Successful implementation of SMBP into usual care relies to a certain degree on GPs' awareness and understanding of the relevant guidelines, although this is only part of the story. Blood pressure monitors for use by patients at home have been available for many years, and GPs would have had to develop approaches to deal with SMBP when no guidance

was available. Non-implementation of guidelines may be due to several factors, including: lack of awareness; lack of agreement; lack of belief that one can perform a behaviour; the inertia of previous practice; and lack of expectation that a given behaviour will lead to a particular consequence.(13) This study will assess current practice in the UK with regard to SMBP, and to what extent this is concordant with current national guidelines (summarised in the next section).

4.2.2 UK National Institute for Health and Care Excellence guidelines

The current guidelines recommend that out-of-office BP measurement should replace clinic measurement as the gold-standard for diagnosing hypertension.(1) For monitoring control to treatment SMBP is seen as an adjunct to clinic measurement, particularly in the case of white coat hypertension.

ABPM is recommended to confirm a diagnosis of hypertension, however if the patient is unable to tolerate ABPM, SMBP is suggested as "a suitable alternative". The current NICE guidelines set a threshold of 135/85mmHg for stage 1 hypertension and 150/95mmHg for stage 2 hypertension when using both ABPM and SMBP. The suggested protocol for diagnosis with SMBP is: for each BP recording, two consecutive measurements should be taken, at least 1 minute apart and with the person seated; and BP should be recorded twice daily, ideally in the morning and evening and; BP recording should continue for at least four days, ideally for seven days, dropping the first days readings and taking an average.(1, 14, 15)

Clinic BP measurement should be used to monitor the response to antihypertensive treatment with lifestyle modification or drugs. For people identified as having a white coat effect consider ABPM or SMBP as an adjunct to clinic measurements to monitor response to

treatment. SMBP targets for treatment are the same as the diagnostic criteria. No specific protocol for SMBP is given for monitoring response to treatment.

4.2.3 Objectives

The objective of the current survey was to reassess GPs use of SMBP in the diagnosis and management of hypertension in light of the change in guidance, specifically:

- What proportion of GPs use self-monitoring in the diagnosis and management of hypertension, and what are the characteristics of those who use self-monitoring compared to those that do not.
- What services are available in UK general practice to support SMBP.
- What SMBP measurement protocols do GPs recommend, and how do they interpret the results.
- Who do GPs believe may benefit most/least from self-monitoring.

4.3 METHODS

This was an internet based survey which largely replicated the methods used in the original survey in 2011 in order to allow comparison.(12)

4.3.1 Participants and recruitment

In order to provide a comparison with the previous survey, the same sampling frame was used. An invitation to participate in the survey was available to GPs on the doctors.net.uk (DNUK) web-site for six days from 26-31/05/2015. DNUK provides information services to around 212,000 UK registered doctors, of whom 60,000 are GPs.(16)

During the time of the survey, 8,125 GPs were active on the site. Responses were accepted until there were at least 300 completed questionnaires and responses had been received from GPs in each region of the UK in approximate proportion to the number in each region (using a sampling algorithm). The regions relate to UK Strategic Health Authority (SHA) regions, which although abolished in 2013 allowed for comparison with the 2011 results. Only doctors who identified themselves as GPs were able undertake the survey.

The survey was initially conducted in 11/2014, however unfortunately there was a problem with how the following question was coded:

> For which of the following reasons, if any, do you use SMBP? Please select all that apply.
>
> - For diagnosis of hypertension (1)
> - To exclude or confirm white coat hypertension (2)
> - To exclude or confirm masked hypertension (3)
> - To monitor control in treated patients (4)
> - As an aid to medication adherence (5)
> - As an aid to lifestyle change (6)
> - Other (please specify)
> - None of the above

The question was set up so that if participants selected (2) or (3), then (1) was automatically also selected, and the same was true if selecting (5) or (6) then (4) was automatically

selected. This meant that it was not possible to determine how many respondents selected 1 and 4 themselves, or for whom it was automatically selected. This question was intended to fulfil a primary objective of the survey: to determine the change in the proportion of GPs using SMBP in diagnosis and/or management. It was therefore decided to run the survey again with the automatic selection removed. All other questions remained the same.

The survey carried out in 2014 also included a comparison of recruitment: passive (i.e. open link on web-site available to all as utilised in final survey) and direct (representative sample of GPs were invited directly). The purpose was to investigate response rates, compare demographic characteristics and to determine whether different recruitment strategies introduce any bias. This was carried out in response to reviewer comments for the 2011 survey about the external validity of the results (personal communication Richard McManus).

4.3.2 Questionnaire

The questionnaire was designed to ascertain: the current use of SMBP in both diagnosing hypertension, and managing control in treated patients; protocols for use and communication of SMBP; interpretation of the results of SMBP; training and influences on practice with regard to SMBP; and participant demographics.

The questionnaire was based on the previous survey with a number of additions/changes in response to feedback from participants.(12) The previous survey combined questions about the use of SMBP in diagnosis and management, and a major change was to separate these topics to provide a more accurate picture.

The questionnaire was piloted among both academic and non-academic GPs and is available in Appendix 3.1.

4.3.3 Sample size

It was hypothesised that a greater proportion of GPs would report using SMBP in the diagnosis of hypertension as the new guidelines had specific recommendations for this. It was determined that a sample size of 300 GPs would detect a 10% difference compared to previous results (1-tailed, with 95% confidence and 90% power).

4.3.4 Data analysis

Descriptive statistics with confidence intervals around means are reported. The proportions of GPs who reported using SMBP to confirm a diagnosis of hypertension in 2011 and 2015 was compared using a z-test. BP thresholds were compared between 2011 and 2015 using a Wilcoxon signed rank test. Analyses were performed using Stata for Windows version 12.

Multivariable logistic regression was used to examine the association between physician and practice characteristics and the use of SMBP in the diagnosis of hypertension. Demographic variables hypothesised to be predictive of GP use of SMBP in diagnosis and management were chosen *a priori* for inclusion based on the clinical judgement of the authors: gender, age, GP role, year of qualification, country of training, years as a GP, UK region, practice setting, practice list size. Predictor variables were tested pairwise for correlation before entry into the model. P values <0.05 were considered statistically significant.

4.3.5 Ethical approval

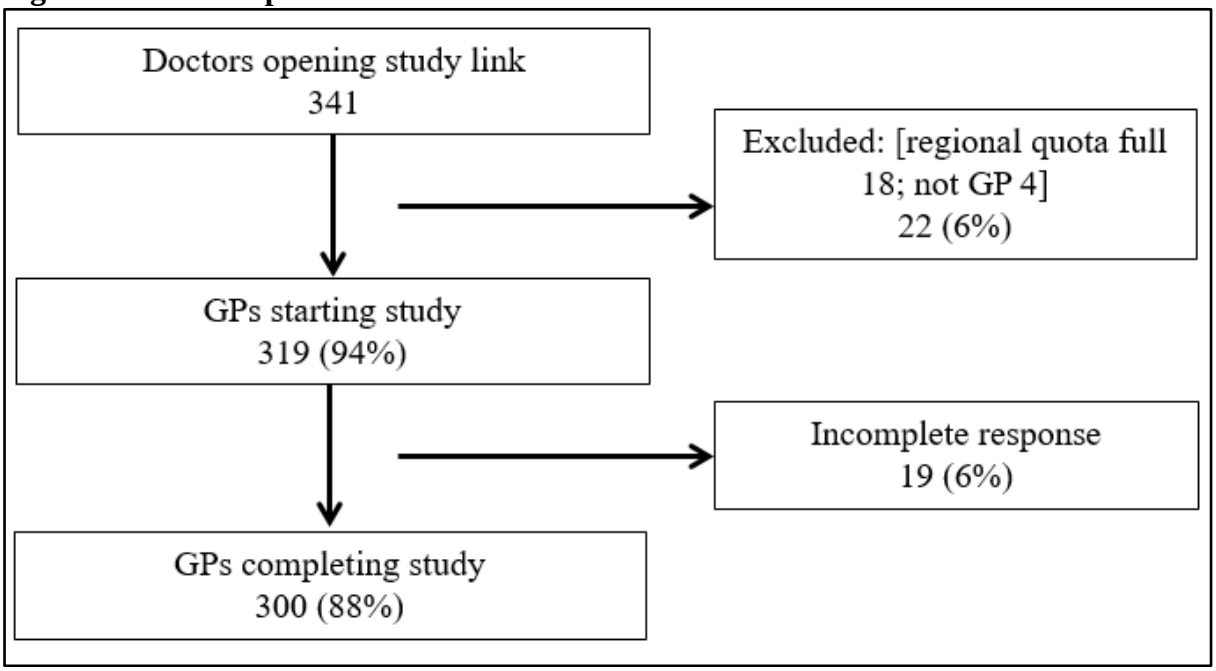
This study was approved by the Medical Sciences Inter Divisional Research Ethics Committee at the University of Oxford; reference number MSD-IDREC-C1-2014-120

4.4 RESULTS

4.4.1 Participants

In total, 341 doctors opened the study link and after exclusions for exceeding regional quotas and clinical role (i.e. excluding hospital doctor), 319 GPs started the survey of whom 300 (94%) completed all of the questions. Participant flow through the study is shown in Figure 4.1.

Figure 4.1 – Participant flow



The characteristics of the respondents are summarised in Table 4.1 along with data from the 2011 survey and NHS national workforce data up to 2014 where available.(17) In the linked methodological study, the response rate for individuals who were directly targeted was 83% (248/300) and 79% (237/300) completed the survey. Participant demographics were similar for passive and direct recruitment, and compared well with the participants in this survey. (Data in Appendix 3.2). The regional distribution of respondents matched national proportions.(17)

Only 6% of respondents (95%CI 4-9%) reported being involved in research in the past five years involving hypertensive treatment; 3% (95%CI 2-6) in research involving ambulatory monitors; and 4% (95%CI 2-6) were involved in research involving SMBP in the past five years.

All but one GP was involved in the management of hypertension (99% (95%CI 98-100)). The vast majority of GPs (97% (95%CI 95-99)) were aware of self-monitoring amongst their patients, which represents an increase from 90% (95%CI 87-92) in 2011. The denominator for the remainder of the results is those participants who were aware of patient self-monitoring, unless otherwise stated (n=291). GPs estimated that 38% (95%CI 35-41) of their patients self-monitored; an increase from 28% (95%CI 25-31) in 2011.

Table 4.1 – Participant characteristics

Characteristic	Detail	2015 survey (n=300)	2011 Survey where available (n=625)	2014 National data where available*
Practice role	Principal/partner	200 (**67%**)	357 (**57%**)	**65%**
	Salaried/locum	71 (**24%**)	190 (**30%**)	**24%**
	Registrar	28 (**9%**)	60 (**10%**)	**11%**
	Other	1 (**0%**)	18 (**3%**)	**1%**
Sex	Male	181 (**60%**)	370 (**59%**)	**48%**
	Female	119 (**40%**)	255 (**41%**)	**52%**
Age	<30	1 (**0%**)		**1%**
	30-39	114 (**38%**)		**28%**
	40-49	99 (**33%**)		**31%**
	50-59	65 (**22%**)		**30%**
	>60	21 (**7%**)		**9%**
Year of qualification	Median	1997	1995	
Country of training	United Kingdom	259 (**86%**)		**78%**
	Europe (excluding United Kingdom)	23 (**8%**)		**5%**
	Asia	11 (**4%**)		**13%**
	Africa	5 (**2%**)		**3%**
	Other	2 (**1%**)		**1%**
Practice list size	Median	8,500	7,800	
	Mean (s.d.)	8,590 (4,100)	9,154 (4,530)	7,171
Practice setting	Urban	128 (**43%**)		
	Suburban	78 (**26%**)		
	Semi-rural	63 (**21%**)		
	Rural	31 (**10%**)		
Region	East Midlands	20 (**7%**)	40 (**6%**)	**6%**
	East of England	26 (**9%**)	53 (**8%**)	**8%**
	London	36 (**12%**)	75 (**12%**)	**12%**
	North East	13 (**4%**)	28 (**4%**)	**4%**
	North West	35 (**12%**)	66 (**11%**)	**11%**
	South Central	20 (**7%**)	40 (**6%**)	**6%**
	South East Coast	19 (**6%**)	41 (**7%**)	**7%**
	South West	29 (**10%**)	58 (**9%**)	**10%**
	West Midlands	26 (**9%**)	51 (**8%**)	**9%**
	Yorkshire and Humber	25 (**8%**)	52 (**8%**)	**9%**
	Northern Ireland	8 (**3%**)	18 (**3%**)	**3%**
	Scotland	29 (**10%**)	74 (**12%**)	**10%**
	Wales	14 (**5%**)	29 (**5%**)	**5%**

*General and Personal Medical Services in England 2004-2014; Health and Social Care Information Centre

4.4.2 Services available for blood pressure monitoring

Table 4.2 summarises the services available to support BP measurement/monitoring. A large proportion of GPs offered ABPM (82% (95%CI 77-86)) and 65% (95%CI 59-70, n=189/291) saw SMBP as complementary to 24h ABPM, down from 81% (95%CI 78-84, n=453/557) in 2011. Not all GPs reported clinic measurement of BP (85% (95%CI 81-89)) or BP measurement by nurse allied health professional (86% (95%CI 81-89)).

In 2015 compared with 2011, GPs reported an increase in the availability of most services. However, fewer GPs reported that BP monitors were available for patient use in pharmacies in 2015 than in 2011: 32% (95%CI 27-38) v 43% (95%CI 39-47).

Table 4.2 – services available for blood pressure monitoring

Service	**2015 survey [n] % (95%CI)**	**2011 survey [n] % (95%CI)**
	N=291	**N=557**
Clinic measurement by general practitioner	[248] **85%** (81-89)	
Clinic measurement by nurse/allied healthcare professional	[250] **86%** (81-89)	
Ambulatory monitors for 24 hour measurement	[239] **82%** (77-86)	
Monitors to lend to patients	[134] **46%** (40-52)	[191] **34%** (30-38)
Patient training for self-monitoring	[114] **39%** (34-45)	[171] **31%** (27-35)
Monitor in waiting room	[103] **35%** (30-41)	[122] **22%** (19-25)
Monitors available for use in local pharmacies	[94] **32%** (27-38)	[239] **43%** (39-47)
Blood pressure taken by pharmacy staff	[148] **51%** (45-57)	
General practitioner training	[57] **20%** (15-25)	[52] **9%** (7-11)
Other	[4] **1%** (1-3)	
None of the above	[0] **0%**	

4.4.3 Reasons for self-monitoring

Reasons given by responding GPs for use of self-monitoring are reported in Table 4.3. The proportion of GPs using self-monitoring to diagnose hypertension was 58% (95%CI 52-64), compared with 37% (95%CI 33-41) in 2011, an absolute increase of 21% (95%CI 14-28,

p<0.001), or 57% relative increase. 87% (95%CI 83-90) and 54% (95%CI 48-59) of GPs used SMBP to exclude or confirm white-coat and masked hypertension.

Similar proportions of GPs reported using SMBP to monitor control in treated patients in 2015 as in 2011. Half of the GPs used SMBP as an aid to monitor medication adherence and lifestyle change.

Table 4.3 – Reasons for self-monitoring

	2015 (n=291) [n] % (95%CI)	**2011 (n=557) [n] % (95%CI)**
For diagnosis	[169] **58%** (52-64)*	[206] **37%** (33-41)*
To exclude or confirm white coat hypertension	[253] **87%** (83-90)	[465] **83%** (80-86)
To exclude or confirm masked hypertension	[156] **54%** (48-59)	
To monitor control	[245] **84%** (80-88)	[462] **83%** (80-86)
As an aid to medication adherence	[148] **51%** (45-57)	[260] **47%** (43-51)
As an aid to lifestyle change	[143] **49%** (43-55)	
Other	[14] **5%** (3-8)	[19] **3%** (2-5)
None of the above	[3] **1%** (0-3)	[4] **0%** (0-2)

*z test p<0.001

4.4.4 Groups that may or may not benefit from SMBP

Certain patient groups were identified that might particularly benefit from SMBP by 62% of participants (95%CI 56-67), with the most commonly reported group being those with white coat hypertension: 45% (95%CI 38-52). A further 52% (95%CI 47-58) recognised groups that would not benefit of which those with anxiety was the most common factor quoted (60% (95%CI 52-67)).

Table 4.4 – Patients who would or would not benefit from self-monitoring

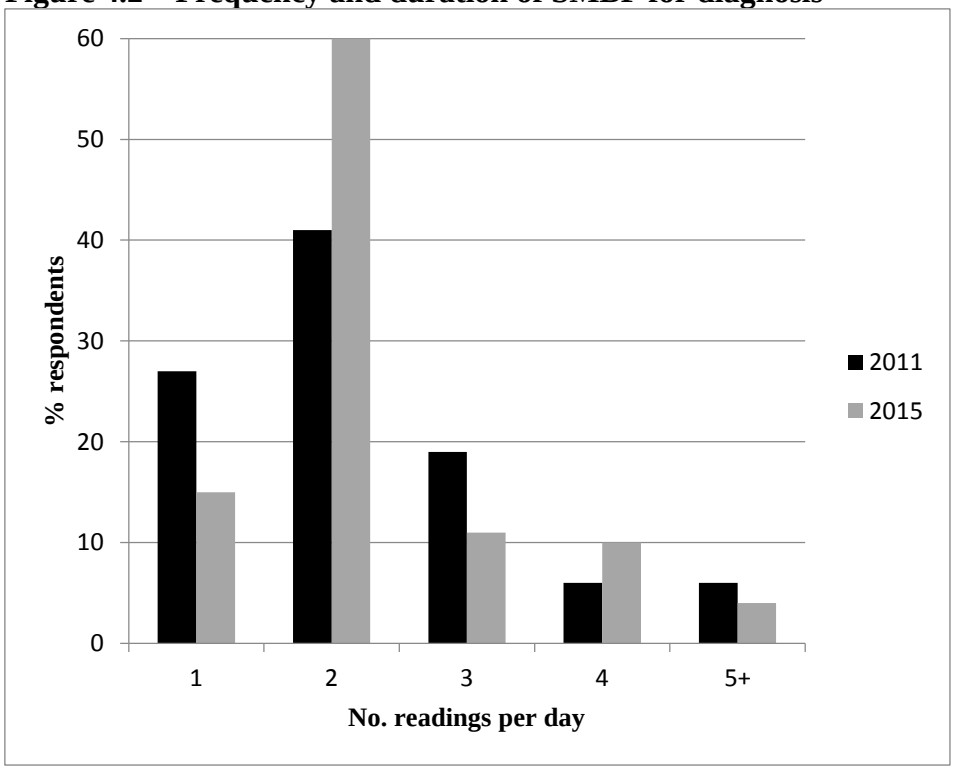
Response	**Would benefit from SMBP (n=179) [n] % (95%CI)**	**Would not benefit from SMBP (n=151) [n] % (95%CI)**
White coat/potential white coat hypertension	[80] **45%** (38-52)	
Difficulty attending surgery due to time or mobility issues	[33] **18%** (13-25)	
Anxious	[26] **15%** (10-20)	[90] **60%** (52-67)
Diabetes	[12] **7%** (4-11)	
Poor compliance with medication	[10] **6%** (3-10)	
Elderly	[8] **4%** (2-9)	[18] **12%** (8-18)
Cognitive impairment/dementia		[19] **13%** (8-19)
Neurotic/obsessive		[11] **7%** (4-13%)
Other	[54] **30%** (24-37)	[22] **15%** (10-21)

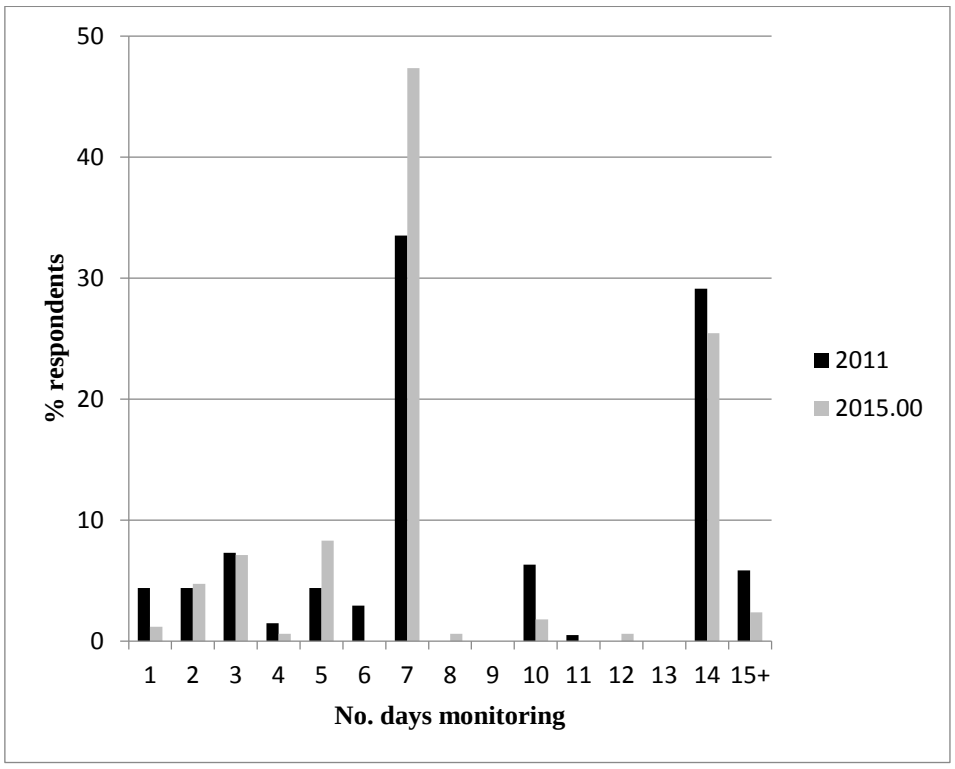
Note: multiple responses accepted

4.4.5 Diagnosis of hypertension

The protocols reported as being used for diagnosis with SMBP are presented in Figure 4.2. GPs most commonly reported recommending SMBP for diagnosis with readings twice a day (60% (95%CI 52-67)) for 7 days (47% (95%CI 40-55)). However 25% (95%CI 18-32) recommended more than twice per day and 31% (95%CI 24-38) for a period greater than one week.

Figure 4.2 – Frequency and duration of SMBP for diagnosis





The mean threshold for diagnosis using SMBP was 142mmHg systolic (95%CI 141-143) and 87mmHg diastolic (95%CI 87-88). This compares with a mean thresholds in 2011 of 146mmHg systolic (95%CI 145-147) and 90mmHg diastolic (95%CI 89-90) (t test $p<0.0001$ for the both systolic and diastolic comparison). 70% of GPs (95%CI 63-76) used a systolic threshold >135mmHg, and 54% (95%CI 46-61) had a diastolic threshold >85mmHg for diagnosis.

The majority of GPs (81% (95%CI 75-86)) reported different diagnostic thresholds for some groups of patients, most commonly diabetes (73% (95%CI 66-79)) and chronic kidney disease (40% (95%CI 33-47). Fewer reported different thresholds for patients with cardiovascular diseases (11% (95%CI 7-16) or because of advanced age (14% (95%CI 9-20).

4.4.6 Use of SMBP in managing control in treated patients with hypertension

Overall the median treatment target in 2015 was 140mmHg systolic (IQR 135-145) and 89mmHg diastolic (IQR 85-90) which had decreased from 150mmHg systolic (IQR 140-150) and 90mmHg diastolic (IQR 90-90) in 2011 (Mann-Whitney tests: systolic, $p<0.0001$; diastolic $p<0.0001$).

GPs differed as to how often they would request a set of measurements from patients: ranging from monthly (24%, 95%CI 20-30), to annually (6%, 95%CI 4-10). The most popular frequency of measurement was twice a year (34% (95%CI 28-40)).

4.4.7 Adjustment of self-monitored results

The proportion of GPs who reported that they would adjust SMBP readings rather than use them directly increased from 32% (95%CI 29-36) in 2011 to 41% (95%CI 36-47) in 2015. The mean adjustment reported was 8.3mmHg systolic (95%CI 7.5-9.1), and 5.6mmHg diastolic (96% CI 5.1-6.2). Median and mode adjustments were 10mmHg systolic and 5mmHg diastolic.

4.4.8 Type of monitor and calibration

The majority of GPs recommended that patients use an upper arm monitor (81% (95%CI 76-85)), with the remaining 19% (95%CI 15-24) not recommending any monitor in particular. 36% (95%CI 30-42) specifically warned against certain types of monitor, most commonly wrist or finger monitors (91% (95%CI 84-95)).

Checking the accuracy of their patients' monitors was suggested by 89% (95%CI 85-92) of GPs: most recommending annual checks (74% (95%CI 69-79)) by the practice nurse (57% (95%CI 50-63)). Only 10% (95%CI 7-15) of GPs were willing to check patients' monitors themselves.

4.4.9 Patient recording and communication of SMBP results

The majority of GPs recommended that their patients record their SMBP results in a written diary (86% (95%CI 81-89)) or using a computer spreadsheet (30% (95%CI 25-36)), and that they bring the results in person to consultation (69% (95%CI 64-74)) rather than communicate by phone (13% (95%CI 9-17)), text (1% (95%CI 0-3)) or email (6% (95%CI 4-10)).

4.4.10 Influence on practice with regard to hypertension

GPs were asked to rank what influenced their current practice with regard to diagnosing and monitoring hypertension (i.e. what would likely lead to change in practice), and the results are summarised in Table 4.5. The majority of GPs (56%) ranked national (i.e. NICE) guidelines as the most important for influencing practice followed by local guidelines and practice policy. Evidence from research was a primary influence for 6% of GPs.

Table 4.5 – Influences on practice

	Total (n=299)		
	Ranked first	**Ranked second**	**Ranked third**
Practice policy	33 (11%)	28 (9%)	47 (16%)
Local guidelines	41 (14%)	91 (30%)	51 (17%)
GP colleagues	12 (4%)	33 (11%)	56 (19%)
Cardiologists or other specialists	11 (4%)	32 (11%)	41 (14%)
Primary research	12 (4%)	15 (5%)	14 (5%)
Secondary research	5 (2%)	20 (7%)	19 (6%)
National guidance	168 (56%)	43 (14%)	37 (12%)
International guidance	7 (2%)	24 (8%)	15 (5%)
Patient request	5 (2%)	11 (4%)	16 (5%)
Other	3 (0%)	0 (0%)	1 (0%)
None	2 (1%)		

4.4.11 Regression analysis

Regression analysis results are presented in Tables 4.6 and 4.7. Neither bivariate nor logistic regression analysis showed that any of the following variables in the model were significant predictors of GPs' use of SMBP to diagnose hypertension: gender, GP role, year of qualification, country of training, UK region, practice location, and practice list size. Backwards selection did not result in a model with any significant predictors.

For management of hypertension the odds of a GP in Scotland using SMBP were 64% less than GPs in the South of England (95%CI 13 to 87). None of the other variables in the model were significant predictors of SMBP use in hypertension management.

Table 4.6 – Regression analysis: effects of GP demographics on use of SMBP to diagnose hypertension

	Odds Ratio (OR)	**95% Confidence Interval**		**P-value**
		Upper	**Lower**	
Year of qualification				
1989 and before	Reference category			
1990 to 1999	1.10	0.58	2.11	0.77
2000 and after	1.10	0.59	2.04	0.76
Gender				
Male	Reference category			
Female	0.78	0.47	1.29	0.33
GP role				
GP Principal	Reference category			
Other GP (salaried GP, GP registrar, locum GP, academic GP)	0.93	0.54	1.60	0.79
Location of training				
UK	Reference category			
Asia	0.66	0.26	1.67	0.38
Europe	7.14	0.86	59.3	0.07
Africa	0.74	0.10	5.63	0.78
Practice list size				
<5,000	Reference category			
5,001-7,500	1.31	0.61	2.81	0.60
7,501-10,000	1.01	0.49	2.09	0.97
>10,001	0.96	0.48	1.94	0.92
Region				
North England	Reference category			
South England	0.66	0.38	1.13	0.13
Wales	0.70	0.30	1.65	0.42
Scotland	1.76	0.52	6.01	0.37
Northern Ireland	3.51	0.40	31.11	0.26
Practice location				
Rural/semi-rural	Reference category			
Urban/suburban	1.06	0.65	1.74	0.80

Table 4.7 – Regression analysis: effects of GP demographics on use of SMBP in the management of hypertension

	Odds Ratio (OR)	95% Confidence Interval		P-value
		Upper	Lower	
Year of qualification				
1989 and before	Reference category			
1990 to 1999	0.77	0.34	1.75	0.53
2000 and after	0.97	0.43	2.18	0.94
Gender				
Male	Reference category			
Female	1.18	0.62	2.26	0.62
GP role				
GP Principal	Reference category			
Other GP (salaried GP, GP registrar, locum GP, academic GP)	0.53	0.28	1.00	0.05
Location of training				
UK	Reference category			
Asia	0.79	0.25	2.48	0.69
Africa	0.37	0.07	2.11	0.27
Practice list size				
<5,000	Reference category			
5,001-7,500	1.68	0.64	4.44	0.30
7,501-10,000	1.40	0.57	3.43	0.47
>10,001	1.20	0.52	2.78	0.67
Region				
South England	Reference category			
North England	0.65	0.30	1.41	0.28
Wales	0.86	0.18	4.09	0.85
Scotland	0.34	0.13	0.87	0.02
Northern Ireland	0.36	0.07	1.95	0.24
Practice location				
Rural/semi-rural	Reference category			
Urban/suburban	1.52	0.80	2.89	0.20

4.5 DISCUSSION

4.5.1 Principal findings

While care should be taken in generalising the results of the findings of this survey, the results suggest that the majority of GPs now use self-monitoring of blood pressure in the diagnosis of hypertension, an increase of more than 50% since the implementation of the updated NICE hypertension guideline in 2011. In contrast, the proportions of GPs using self-monitoring in general and for ongoing management have stayed stable and at a high level. The GPs responding to the survey may have had different characteristics to the general population, particularly in that those responding may have had an interest in SMBP, potentially leading to an overestimation of SMBP use. Further discussion of the sample and how it compares to the general population and previous surveys is presented in section 4.5.2.

There remains significant variation in diagnostic threshold and protocol for measurement. Over half of GPs reported a threshold higher than the NICE threshold for diagnosis with SMBP (135/85mmHg). However the proportion of GPs using higher thresholds for diagnosis has decreased since 2011.

The majority of GPs reported using SMBP to monitor BP control in treated patients, despite a relative paucity of evidence.(18) As with diagnostic thresholds, GPs generally reported a higher target for treatment than recommended by guidelines but again this had improved since 2011.

GPs generally recommended that their patients record SMBP results in a written diary and bring them to consultation. Few GPs wanted their patients to communicate their results by phone, text or email.

On the whole, the findings did not identify any GP predictors of SMBP use in either diagnosis or management of hypertension, and this could be because:

- No GP characteristics predict SMBP use – there is no variation in SMBP use across the categories included in the analysis.

- The study was not sufficiently powered – the study did not have a sufficient sample size to detect an effect assuming the effect exists. All other things being equal effects are harder to detect in smaller samples.

The findings suggested that GPs trained in Europe were more likely than those trained in England to use SMBP in the diagnosis of hypertension, and the result approached statistical significance (OR=7.14 (0.86 to 59.3), p=0.07). If this finding were verified it would support the findings of other cross sectional surveys that report higher utilisation of SMBP in Europe.(19, 20)

The results did suggest that GPs in Scotland may be less likely to use SMBP in the ongoing management of hypertension than those in the south of England (OR=0.34 (0.13 to 0.87), p=0.02), although no difference was seen in the use of SMBP for diagnosis. This result could either suggest a true difference in practice or a false positive finding as a result of multiple statistical tests. When the number of statistical tests increases, so does the chance of false positive results (i.e. for every 100 statistical tests, assuming for all of them the null hypothesis is true, five would be expected to be significant at the $p<0.05$ level due to chance).

The difference in SMBP use in Scotland could reflect a difference in practice guidelines. The Scottish Intercollegiate Guidelines Network (SIGN) develops evidence based clinical practice guidelines for the NHS in Scotland. The most recent SIGN guidelines for the prevention of cardiovascular disease were released in 2007 and did not include recommendations for the use of SMBP.(21) Further research is required to investigate the different use of SMBP in Scotland and England.

4.5.2 Strengths and limitations

This is the first study to compare self-monitoring practice in UK GPs with data both before and after changes to national guidelines. Both surveys used the same methodology for sampling, as well as largely the same questions. Where additional questions and options were added, they aimed to strengthen and fill gaps identified through feedback from the previous survey. A regionally representative sample of UK GPs were recruited, and respondents were similar to national data across a range of demographics, with the greater proportion of males GPs in the survey the only significant difference. The average practice list size reported by GPs was slightly higher than the national average (8,590 v 7,171), however this may well be due to this being a comparison of self-reported data with general practice census data. Larger practices may have more resource for home and ambulatory monitoring but small differences in list size such as this are unlikely to have an effect on the results.

Recruitment of the sample was passive by placing an advert on-line rather than directly contacting GPs. It is therefore impossible to know how many of the GPs active on the web-site saw the advert; however a high proportion of those who clicked on the link completed the questionnaire. This method was used to allow comparison with the 2011 data. The survey in 2014 that contained a methodological study using the same questionnaire with direct targeting via the same website found comparable demographics with similar responses to the questionnaire used to those recruited passively suggesting that passive recruitment did not introduce significant bias.

The decision to complete the survey may have been influenced by the extent to which the respondent was interested in the topic. This is unlikely to have affected the validity of the

comparison between 2011 and 2015, but may have led to over-estimation of the proportion of GPs that use SMBP.

4.5.3 Comparison with literature and implications for practice

The increase in use of self-monitoring in diagnosis might be expected to reduce unnecessary treatment of white coat hypertension but interestingly, over 80% of GPs also reported access to ambulatory monitoring. This suggests a mixed picture with a combination of self- and ambulatory monitoring being used. Not all GPs reported offering clinic BP measurement (by GPs or allied health professionals), which may represent a shift to sole use of out-of-office measurement in some practices, although this warrants further investigation.

GPs estimated that just over a third of their patients with hypertension currently self-monitor BP, which was slightly higher than the results of a cross-sectional survey in the UK in 2011.(22) Despite this, the estimated proportion self-monitoring still fell behind results from other countries where the figure is over 70%.(19, 23, 24) It might be the case that patients are using SMBP without talking to their GP about it.

The Chronic Care Model (CCM) emphasises the importance of providing services to support engaged patients who self-monitor, and the results of this survey show that there has been an almost universal increase in the services delivered by GPs to support SMBP since 2011. This suggests an increased enthusiasm for SMBP, however only a minority offered training to patients in self-monitoring (currently 39%). Modern monitors are relatively easy to use but minimal training – especially in cuff position – might be expected to improve accuracy of measurement. This need not be a GP led service and could equally well be delivered by pharmacists or district nurses, or well-designed information sheets. The British Hypertension Society has produced a series of free evidence based SMBP resources for both

patients and clinicians including: SMBP protocol; poster with clinic and SMBP targets; "how-to" instructions for patients; a BP diary for patients; and GP guide for implementing SMBP.(25) Mobilising community resources to support patients who self-monitor is an important component of the CCM. The model acknowledges the importance of links with the community for peer support, care coordination, education and community based interventions. GP awareness of and advocacy for community resources was not assessed in this survey, and would be an interesting target for future research. Availability of community resources is investigated in patient interviews in Chapter 5.

As discussed in Chapters 1 and 3, the CCM also describes the need for improved information systems, information sharing and communication between healthcare professionals and patients. Currently communication of the results of SMBP is limited to in-person during consultation, which may be a missed opportunity or simply reflect the realities of contemporary practice in the NHS: a number of trials have demonstrated the potential benefits of communicating by text or telemonitoring, and that this is well liked by patients and clinicians.(18) Blood pressure telemonitoring has been shown to be cost effective, with the costs of equipment and technology offset by lower medical costs.(26) Patients have also been shown to have a generally positive attitude towards telemonitoring, and a high level of compliance with telemonitoring programs and data transfer.(27) Remote communication of results – not routinely available in the NHS - would be of particular benefit to those patients who have difficulty getting to the clinic for appointments, groups GPs identified as potentially benefitting most from SMBP in this survey. Patient preferences for some of these care options will be explored further in Chapter 6

GPs reported using higher thresholds for diagnosis and management, but given that self-monitored blood pressure is usually lower than clinic blood pressure, this may result in under treatment and worse outcomes.(28) Potential explanations for the discrepancy between

guidelines and practice include: not being aware of the different threshold; using self-imposed higher target to avoid over diagnosis; or having different individual practice policies. Discordance between guidance and practice is a common occurrence and perhaps reflects too simplistic a model for how clinicians use information (29):

> *"The standard model of how medical knowledge influences physicians' behaviour is based on the assumption that information that is synthesised and disseminated by respected national authorities consistently leads to changes in physicians' clinical behaviour."*

However, the majority of GPs in this survey indicated that NICE guidelines were the most important influence on practice. This survey has highlighted areas where GPs practice varies, which could represent uncertainty in the current guidelines, and these areas of uncertainty should be addressed in updated guidance.

4.5.4 Conclusions

Since guidelines changed in 2011, GPs appear more aware of the benefits of self-monitoring, as well as the practicalities of incorporating SMBP into routine care. However there remains room for improvement in: implementing appropriate thresholds for diagnosis with SMBP; encouragement and training of SMBP for patients; and incorporating new ways of communicating the results of SMBP. This reflects practice outside the UK: for example, a survey in Canada found that primary care physicians preferred office or ambulatory readings to SMBP to make diagnostic and therapeutic decisions, and inferred that this was due to lack of standard measurement protocols, proper training on measurement technique and specific information on handling and interpreting results.

According to Heneghan *et al*, "if uptake of a recommendation is low, an analysis of the concerns and barriers is appropriate".(29) This survey has shown that uptake of

recommendations has increased in terms of the proportion of GPs using SMBP, but there continues to be an issue with interpretation. Current guidelines may fail to account for the concerns, information needs and logistical problems that GPs need to consider as they apply recommendations in routine care, and these issues should be investigated in future research to reduce barriers to SMBP use.

Guidance for clinicians and patients could be standardised in order to provide useful information to guide practice, while not being over-burdensome to either group. Efforts have been made to achieve this goal, for example the British Hypertension Society resources mentioned earlier.

GPs in this survey were concerned that SMBP would be unsuitable for anxious or neurotic patients, which is in agreement with the findings of the review in Chapter 3. This finding will be explored from the patient perspective in the following chapter.

4.6 REFERENCES

1. NICE. The Clinical Management of Primary Hypertension in Adults: Clinical Guideline 137. 2011.
2. Daskalopoulou SS, Rabi DM, Zarnke KB, Dasgupta K, Nerenberg K, Cloutier L, et al. The 2015 Canadian Hypertension Education Program recommendations for blood pressure measurement, diagnosis, assessment of risk, prevention, and treatment of hypertension. The Canadian journal of cardiology. 2015;31(5):549-68.
3. Chapter 2. Measurement and clinical evaluation of blood pressure. Hypertens Res. 2009;32(1):11-23.
4. Siu AL, Force USPST. Screening for High Blood Pressure in Adults: U.S. Preventive Services Task Force Recommendation Statement. Ann Intern Med. 2015;163(10):778-86.
5. Ohkubo T, Imai Y, Tsuji I, Nagai K, Kato J, Kikuchi N, et al. Home blood pressure measurement has a stronger predictive power for mortality than does screening blood pressure measurement: a population-based observation in Ohasama, Japan. Journal of Hypertension. 1998;16(7):971-5.
6. Niiranen TJ, Hanninen MR, Johansson J, Reunanen A, Jula AM. Home-measured blood pressure is a stronger predictor of cardiovascular risk than office blood pressure: the Finn-Home study. Hypertension. 2010;55(6):1346-51.
7. Boubouchairopoulou N, Karpettas N, Athanasakis K, Kollias A, Protogerou AD, Achimastos A, et al. Cost estimation of hypertension management based on home blood pressure monitoring alone or combined office and ambulatory blood pressure measurements. Journal of the American Society of Hypertension : JASH. 2014;8(10):732-8.
8. Nasothimiou EG, Karpettas N, Dafni MG, Stergiou GS. Patients' preference for ambulatory versus home blood pressure monitoring. J Hum Hypertens. 2014;28(4):224-9.
9. Jones MI, Greenfield SM, Bray EP, Baral-Grant S, Hobbs FD, Holder R, et al. Patients' experiences of self-monitoring blood pressure and self-titration of medication: the TASMINH2 trial qualitative study. British Journal of General Practice. 2012;62(595):e135-42.
10. Wood S, Greenfield SM, Haque MS, Martin U, Gill PS, Mant J, et al. Influence of ethnicity on acceptability of method of blood pressure monitoring: a cross-sectional study in primary care. The British journal of general practice : the journal of the Royal College of General Practitioners. 2016.
11. Juhanoja EP, Puukka PJ, Johansson JK, Niiranen TJ, Jula AM. The impact of the day of the week on home blood pressure: the Finn-Home study. Blood Press Monit. 2015.
12. McManus RJ, Wood S, Bray EP, Glasziou P, Hayen A, Heneghan C, et al. Self-monitoring in hypertension: a web-based survey of primary care physicians. J Hum Hypertens. 2014;28(2):123-7.
13. Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud PA, et al. Why don't physicians follow clinical practice guidelines? A framework for improvement. JAMA. 1999;282(15):1458-65.
14. Mancia G, Fagard R, Narkiewicz K, Redon J, Zanchetti A, Bohm M, et al. 2013 ESH/ESC Guidelines for the management of arterial hypertension: the Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). J Hypertens. 2013;31(7):1281-357.
15. Weber MA, Schiffrin EL, White WB, Mann S, Lindholm LH, Kenerson JG, et al. Clinical practice guidelines for the management of hypertension in the community: a statement by the American Society of Hypertension and the International Society of Hypertension. J Clin Hypertens (Greenwich). 2014;16(1):14-26.
16. www.doctors.net.uk. 2015 [cited 2015].
17. Workforce and Facilities Team HaSCIC. General and Personal Medical Services, England 2004-14. In: Centre HaSCI, editor. 2015.

18. Uhlig K, Patel K, Ip S, Kitsios GD, Balk EM. Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. Annals of Internal Medicine. 2013;159(3):185-94.
19. Cuspidi C, Meani S, Lonati L, Fusi V, Magnaghi G, Garavelli G, et al. Prevalence of home blood pressure measurement among selected hypertensive patients: results of a multicenter survey from six hospital outpatient hypertension clinics in Italy. Blood Pressure. 2005;14(4):251-6.
20. Krecke HJ, Lutkes P, Maiwald M. Patient assessment of self-measurement of blood pressure: results of a telephone survey in Germany. J Hypertens. 1996;14(3):323-6.
21. Network SIG. Risk estimation and the prevention of cardiovascular disease. 2007.
22. Baral-Grant S, Haque MS, Nouwen A, Greenfield SM, McManus RJ. Self-Monitoring of Blood Pressure in Hypertension: A UK Primary Care Survey. International Journal of Hypertension. 2012;2012:582068.
23. Viera AJ, Cohen LW, Mitchell CM, Sloane PD. How and why do patients use home blood pressure monitors? Blood Pressure Monitoring. 2008;13(3):133-7.
24. Breaux-Shropshire TL, Brown KC, Pryor ER, Maples EH. Prevalence of blood pressure self-monitoring, medication adherence, self-efficacy, stage of change, and blood pressure control among municipal workers with hypertension. Workplace Health & Safety. 2012;60(6):265-71.
25. Society BH. Home Blood Pressure Monitoring 2014 [updated 09/2014; cited 2016]. Available from: http://bhsoc.org/resources/hbpm/.
26. Omboni S, Gazzola T, Carabelli G, Parati G. Clinical usefulness and cost effectiveness of home blood pressure telemonitoring: meta-analysis of randomized controlled studies. Journal of Hypertension. 2013;31(3):455-67; discussion 67-8.
27. Pare G, Jaana M, Sicotte C. Systematic review of home telemonitoring for chronic diseases: the evidence base. Journal of the American Medical Informatics Association. 2007;14(3):269-77.
28. Staessen JA, Den Hond E, Celis H, Fagard R, Keary L, Vandenhoven G, et al. Antihypertensive Treatment Based on Blood Pressure Measurement at Home or in the Physician's Office: A Randomized Controlled Trial. Journal of the American Medical Association. 2004;291(8):955-64.
29. Heneghan C, Perera R, Mant D, Glasziou P. Hypertension guideline recommendations in general practice: awareness, agreement, adoption, and adherence. The British journal of general practice : the journal of the Royal College of General Practitioners. 2007;57(545):948-52.

CHAPTER FIVE

PATIENT EXPERIENCES OF SELF-MONITORING BLOOD PRESSURE: SEMI-STRUCTURED INTERVIEWS

5.1 CHAPTER OVERVIEW

The following chapter presents the fourth of five studies within this thesis (Study 4 of Figure 1.1). In this qualitative study semi-structured interviews with patients with hypertension were conducted in order to explore their experiences of SMBP, how it fits into their daily lives, and to what extent SMBP was used in the clinical encounter. The findings from the thematic synthesis conducted in Chapter 3 were used to develop the basis for the topic guide used in the interviews, as well as to inform the initial coding strategy. The data were analysed using a framework approach.

The chapter begins with an introduction to the study, the methodology and rationale for the approach, with subsequent reporting of results. Finally, the findings are discussed in relation to the literature, and how the results were used to inform a discrete choice experiment; the results of which are described in the next Chapter.

5.2 BACKGROUND

5.2.1 Need for new models of care for hypertension

The prevalence of chronic conditions, including hypertension, is increasing globally due to an ageing population and increased exposure to risk factors resulting from environmental and social change.(1) Hypertension already constitutes a significant component of GP workload in the UK, and this is likely to increase unless improvements are made in prevention and treatment. (2)

Much health care in the UK today is structured around acute episodes, rather than providing continued care for patients with chronic and often multi-morbid conditions. Managing chronic conditions requires a long-term and complex response, coordinated by multidisciplinary teams of health care professionals, and often extends beyond provision of medication and equipment into social care and self-care.(3) In a report about care planning for long-term conditions the Royal College of General Practitioners (RCGP) describe the need for a shift towards "managing and planning 'whole person' patient care in the community".(4)

Similarly, when describing better services for people with long-term conditions, the King's Fund defined optimum care as involving: engaged and motivated patients; the clinicians managing their care being willing and able to involve their patients in shared decision making; as well as an infrastructure to support both patients and clinicians.(5) In written evidence to the Health Select Committee Inquiry on Management of Long-Term Conditions in 2013, the RCGP stated that maximising self-care and promoting shared decision making requires cultural change to "redesign services in a way that encourages shared ownership and responsibility for ensuring that those with long-term conditions are supported to manage and plan their own care".(6)

It is clear that new approaches for managing chronic conditions are needed: one example of this is the Chronic Care Model (CCM) (see 1.7) which was developed in the USA in the 1990s, and promotes the idea that improvements in care require a combination of patient, provider and system level interventions.(7) Implementation of the CCM has been shown to be effective in a wide range of settings. A recent review found that in 77 studies testing the effectiveness of components of the CCM, all but two reported improvements in healthcare practice and outcomes.(8) Given the proven efficacy and widespread use of the CCM approach, it was deemed an appropriate framework by which to evaluate the potential contribution of SMBP to holistic care in the management of hypertension. The CCM sets out six interrelated components for a holistic approach to managing chronic conditions(9):

- Health care organisation – create organisations that provide high quality care, with a commitment to the CCM, and support for multi-disciplinary care teams.
- Community resources and policies – mobilisation of community resources such as exercise, self-help and education programs to meet patient needs.
- Self-management support – empowerment of patients through self-monitoring, goal setting, and identification of barriers/challenges.
- Delivery system design – regular planned visits incorporating patient goals, and employing the skills of different care providers.
- Decision support – promoting care consistent with both the best scientific evidence and patient preferences.
- Clinical information systems – organisation of patient data to facilitate effective and efficient care, and incorporate the results of patient self-measurement.

This study sought to seek evidence of components of the CCM in relation to SMBP and hypertension management. SMBP has been identified as an intervention that has promise in improving hypertension management in primary care. However, previous chapters have identified questions that need to be addressed relating to how SMBP facilitates change and what support is available for patients who self-monitor:

1. SMBP has been shown to be effective in reducing BP in patients with hypertension, however, uncertainty remains about *how* SMBP helps facilitate BP reduction. Much of the evidence for the effectiveness of SMBP comes from clinical trials, which do

not necessarily represent everyday practice.(10, 11) Results from the systematic review in Chapter 2 provided evidence that SMBP was associated with improved medication adherence, but evidence for its impact on lifestyle change was equivocal. SMBP has also been shown to affect behaviour change in GPs, by overcoming clinical inertia.(12) Nevertheless, further understanding of whether SMBP targets patients, clinicians, or both would allow for more focussed information/education about SMBP.

2. The systematic review reported in Chapter 3 provided evidence that for patients with hypertension, measuring their own BP at home resulted in empowerment, increased self-efficacy, and facilitated the interaction between patients and clinicians during consultation. However, of eleven included studies only four represented real-world SMBP use (i.e. not linked to trials or intervention development), and only two of those were in the UK.(13, 14) Given an increase in the numbers of patients with hypertension who own and use BP monitors, and the inclusion of SMBP in UK NICE hypertension guidance in 2011, further exploration of patient experiences and perceptions is timely.
3. The survey in Chapter 4 showed that clinicians are increasingly incorporating SMBP into everyday practice for managing patients with hypertension, with 80% using SMBP to monitor control in treated patients. While the GPs surveyed were generally supportive of SMBP, it is important to investigate whether support and infrastructure as described in the CCM are available to support engaged, motivated patients and clinicians.

This study builds upon the findings presented in previous chapters by investigating how patients in a "real-world" setting utilise SMBP in the management of hypertension, and explored what support is in place to facilitate its use.

5.2.2 Objectives

The objectives of the qualitative study presented here were to explore the following topics using semi-structured interviews and a framework analysis:

- How and where does self-monitoring fit into patients' everyday activities?
- Does SMBP influence medication taking or changes to diet or exercise?
- How do patients keep track of their SMBP measurements, and how do they interpret them?
- What are patients' experiences of discussion of SMBP with their GP?
- Do patients have any concerns about SMBP?
- What information sources are important in decision making with regard to SMBP?
- What components of the Chronic Care Model are in place to support SMBP?

5.3 METHODS

5.3.1 Participants and recruitment

English-speaking adults with a clinical diagnosis of hypertension and experience of self-monitoring were recruited from two general practices in Oxfordshire: one in a city centre location (27 Beaumont Street, Oxford), and the other in a semi-rural setting (Broadshires Health Centre, Carterton). Potential participants were identified by their GP, and were either invited to take part in person during consultation, or by letter. Individuals were asked to contact the researcher directly if they wished to take part.

5.3.2 Interviews

Interviews were conducted either in participant's homes, or in the Nuffield Department of Primary Care at the University of Oxford, according to the preference of the interviewee. Interviews were audio-recorded using a digital voice recorder and subsequently transcribed verbatim. Prior to the interviews taking place the researcher described the study and provided the opportunity for participants to ask any questions before informed consent was obtained. A brief questionnaire was used at the end of the interview to collect demographic information on: age, gender, ethnicity, relationship status, education, employment history, postcode, time since diagnosis with hypertension, and the number of medications for hypertension and other conditions.

Interviews were semi-structured, following a topic guide. The topic guide was developed by BF in consultation with his supervisors based on the main research objectives identified in earlier chapters. The guide ensured that similar data were collected from each interviewee, and would contribute to the components of the analysis framework (see 6.3.3).

Open-ended questions were used in an attempt to allow participants to take the lead and shape their own narrative, and began with "how", "what" and "tell me about". While the same broad set of issues was covered in each interview, questioning remained flexible to allow probing of any topics raised spontaneously by the interviewees. Interviews began with general discussion of patients' lifestyle and health/wellbeing, before focusing on hypertension and the role of SMBP.

The interview topic guide is available in Appendix 4.1. The topic guide and interview strategy were adapted as the interviews progressed to reflect emerging themes, and to probe for specific information. This iterative process led to two main additions to the topic guide over the course of the study: to focus on the understanding of the risks of hypertension (and this in turn led to the inclusion of risk as an attribute in the discrete choice experiment that is the final study reported in Chapter 7); and also to describe the overall research aims and hypotheses at the end of each interview as a prompt for further discussion.

5.3.3 Data analysis

Descriptive statistics were used to summarise demographic data.

Coding of the interviews was conducted using NVivo11.

Interviews were analysed using the framework approach, a methodological approach developed in the 1980s by the National Centre for Social Research to manage and analyse data in applied policy research.(15) Framework analysis has gained popularity in health research as it can be used to manage qualitative data and undertake analysis systematically, and maintains an "effective and transparent audit trail, which enhances the rigour of the analytical process and the credibility of the findings".(16, 17)

There are a number of approaches to qualitative data analysis (i.e. Grounded Theory, phenomenology, discourse analysis, etc), and these are associated with specific disciplines and underpinned by philosophical ideas that shape the analytic process.(18) Framework analysis is not aligned with any particular epistemological, philosophical, or theoretical approach, rather it is a flexible tool that can be adapted for use with many qualitative approaches that aim to generate themes.(19) Unlike some purely inductive approaches, framework analysis can be shaped by existing ideas and is less focussed on producing new theory. The theoretical underpinning for the study was closest to subtle realism which assumes that there is an objective reality and that this is an ideal that researchers should try and achieve.(20) However, the researcher's ability to know reality is imperfect and involves subjective observations and perceptions.

Framework analysis can be adapted for use in inductive or deductive analysis, or a combination of the two as is the approach used in this study.(18) Deductive analysis works from the more general to the specific using evidence *in support* of a conclusion, while inductive looks for patterns and associations derived from observations, using evidence as the *genesis* of a conclusion.(16)

Ritchie and Spencer outlined four types of research question that they believed could be addressed using the framework approach(15):

- Contextual: identifying the form and nature of what exists
- Diagnostic: examining the reasons for, or causes of what exists
- Evaluative: appraising the effectiveness of what exists
- Strategic: identifying new theories, policies, plans or actions

The research questions for this study fall within the contextual category by exploring the experiences of self-monitoring in patients with hypertension; as well as evaluative with how useful SMBP is for patients.

Data analysis followed the five main stages of the framework method, and the following were undertaken (18):

1. Familiarisation (immersion in the data) – during this phase the researcher listened to recordings and read through interview transcripts, and listed key ideas and recurrent themes.
2. Identifying a thematic framework – the framework was created using a priori topics, emergent issues raised by the respondents themselves, and analytical themes. *A priori* topics represented the original research aims that were included in the interview topic guide, which themselves were informed by the systematic review of previous qualitative studies.(21) Analytic coding explored support for the components for the Chronic Care Model, specifically: community resources, delivery system design, and self-management support.
3. Indexing – this was the process where the framework was applied to the data, and where the raw data was assigned to the theme or category it relates to. All data were first grouped into general themes, and then into sub-themes once all interviews had been initially coded. Themes were added and the overall structure adjusted as necessary to reflect emerging themes. The end product of this stage was a detailed index of the data labelled into "manageable chunks for subsequent retrieval and exploration".(22)
4. Charting – data were summarised and then synthesised within the framework; and this involved ordering and reducing the data, as well as abstraction and synthesis.

Mapping and interpretation – going beyond aggregation of data, the evidence was synthesised, and an overview of the data within the framework was produced.

5.3.4 Interviewer/researcher characteristics and reflexivity

> *"Given that the researcher is intimately involved in both the process and product of the research enterprise, it is necessary for the reader to evaluate the extent to which an author identifies and explicates their involvement and its potential or actual effect upon the findings."* Horsburgh 2007 (23)

Reflexivity can be defined as self-appraisal in research and relates to the researcher reflecting on their "situatedness" within their research and the effect that this may have on: the setting and people being studied, questions asked, data collected and interpretation. Berger (2013) suggests three areas where the position of the researcher can impact on the research process, and these are used to frame discussion (24):

- Access to the field – respondents may be more willing to share their experiences with a researcher whom they think is sympathetic or shares their viewpoint.
- Nature of the researcher-researched relationship.
- Worldview and background of the researcher affects how he/she uses language, poses questions, and choses lens for filtering the information gathered from participants.

All interviews were conducted by one researcher, a DPhil student with a background in basic sciences, and an interest in research methodology. He was the only researcher to meet and interview participants. Prior to the interviews the researcher had a sense of some of the key issues in the topic identified in the systematic review (Chapter 4), and as such these topics formed the basis of the interview guide and analytic framework. Previous research, as summarised in Chapters 2 and 3, had shown SMBP in a positive light, however the

researcher was careful to listen during interviews and for any negative experiences discussed by participants.

Where possible, interviews were conducted in participants' own homes, where they were comfortable, and it was hoped that this would mitigate any power differential felt by the interviewees. The interviewer informed participants that he was not a clinician, and how any information shared would be used (i.e. not shared with their GP).

Open ended questions were used in an attempt to elicit the experiences of participants without asking leading questions. At the end of the interview the researcher explained his research to date on SMBP, and this often facilitated further discussion.

While the researcher does not have hypertension, he did have some experience of self-monitoring. When he began research into SMBP he tried out 24 hour ABPM as well as one week of self-monitoring according to NICE guidelines, so had some limited experience, at least of the practicalities of self-monitoring.

To provide balance, and a range of perspectives, three other researchers were involved with developing the framework and coding/analysis of the data. The framework was initially developed in collaboration with Lisa Hinton (DPhil supervisor, and senior qualitative researcher), Richard McManus (DPhil supervisor, professor of primary care and general practitioner), and Charlotte Albury (a DPhil student with an interest in narrative and conversation analysis). CA also assisted with initial coding of interviews and in refining the coding strategy.

5.3.5 Reporting

Results are reported according to the Standards for Reporting Qualitative Research (SRQR), as recommended by the Equator Network (Appendix 4.2).(25)

The Results section covers the application of the framework to the data (indexing and charting), with mapping and interpretation reported in the Discussion and Conclusions.

5.3.6 Ethics

Ethical approval was obtained from Health and Social Care Research Ethics Committee A, reference 15/NI/0199 on 15th September 2015.

5.4 RESULTS

5.4.1 Characteristics of sample

Eleven participants agreed to take part in the study and were interviewed between November 2015 and March 2016. All individuals who were invited to be interviewed by their GP agreed to participate. Participant demographics are summarised in Table 5.1., and characteristics of individual participants is reported in Table 5.2. Two interviews were conducted at the University of Oxford with the remainder in participants' homes. Interviews ranged from 19-60 minutes in duration, with a mean of 28 minutes. There was no apparent difference in the length of interviews conducted either at university or in participants' homes.

The majority of participants were female, had a diagnosis of hypertension for more than five years, and all described themselves as white British. Interviewees lived in areas that were in the least deprived two quintiles of the index of deprivation, and were generally well educated.

Table 5.1 – Participant demographics

	Participants (n=11)
Practice	
Broadshires	8 (73%)
27 Beaumont street	3 (27%)
Female	7 (64%)
Age	72.7 (range 50-86)
Time since diagnosis with hypertension	
<1 year	2 (18%)
1-5 years	1 (9%)
>5 years	8 (73%)
Number of hypertension medications	1.6 (range 1-2)
Number of medications for other conditions	2.1 (range 0-5)
Ethnicity	
White British	11 (100%)
Employment	
Full time employment	1 (9%)
Retired	10 (91%)
Relationship status	
Married	7 (64%)
Widow/widower	3 (27%)
Divorced	1 (9%)
Highest level of education	
Left school at 16	2 (18%)
College	3 (27%)
Vocational qualification	1 (9%)
University	5 (45%)
Index of deprivation for postcode	
1st quintile (least deprived)	3 (27%)
2nd quintile	8 (73%)

Table 5.2 – Interviewee characteristics

Practice	Participant	Time since diagnosis	Brief description	Interview length (minutes)	Location of interview	Diagnosis of hypertension
Beaumont Street, Oxford	OM1	9 years	University lecturer (physiology). Interest in quantified self. Lives with wife.	60	University	Found out when volunteering for research study, and referred to GP
	OW1	>10 years	Originally from Poland. Retired library worker. Has private healthcare. Lives with husband.	23	At home in kitchen	High BP during annual BUPA check-up
	OW2	>20 years	Retired UN worker. Originally from Italy. Widower.	23	At home in living room	At GP check-up
Broadshires, Carterton	BM1	<1 year	Retired engineer with keen interest in science and health. Keen to explore lifestyle change to reduce BP Lives with wife.	31	At home in dining room	At GP check-up
	BM2	25 years	Retired air force technician. Has owned wrist monitor for 15 years. Believes BP levels are arbitrary. Lives with wife.	19	At home in presence of wife who was interviewed afterwards (BW1)	At GP check-up
	BM3	>20 years	Worked as chemist in glass manufacture. Interested in taking part in health research. Self-monitors, but does not talk about it with GP	36	At GP in vacant office	At induction for gym membership

Practice	Participant	Time since diagnosis	Brief description	Interview length (minutes)	Location of interview	Diagnosis of hypertension
Broadshires, Carterton	BW1	10 years	Retired nurse. Has history of poor health and co-morbidities. Lives with wife.	21	At home in presence of husband (BM1)	At visit to donate blood, referred to GP
	BW2	35 years	Retired comptometrist. Moved around a lot with husband in air force. Interested in keeping up to date with technology. Lives with husband.	32	At home in kitchen	At GP check-up
	BW3	>20 years	Retired housewife. Widower and lives alone. Poor mobility so GP asks her to phone in with SMBP results rather than visiting	23	At home in kitchen	At GP check-up
	BW4	3 years	Retired civil servant. Widower and lives alone. Keen interest in gardening and walking.	21	At university	At GP check-up
	BW5	1 year	Retired GP. Divorced and lives alone. SMBP at request of her own doctor.	22	At home in living room.	Self-diagnosed.

5.4.2 Framework analysis

Quotes are presented in italics to support analysis, and represent verbatim transcription along with an interviewee identifier: for example, CM1 refers to a male interviewee from Broadshires Health Centre (Carterton), OW2, refers to a female from 27 Beaumont Street Practice (Oxford).

An overview of the framework is presented in Figure 6.1. Seven broad themes were created: three analytical codes exploring components of the Chronic Care Model directly relevant to patients (community resources, delivery system design, self-management support), and four describing individual context and experiences of SMBP (context, personal practice, knowledge and interpretation, emotional impact). Table 5.3 presents full coding across participants.

Figure 5.1 Analysis framework

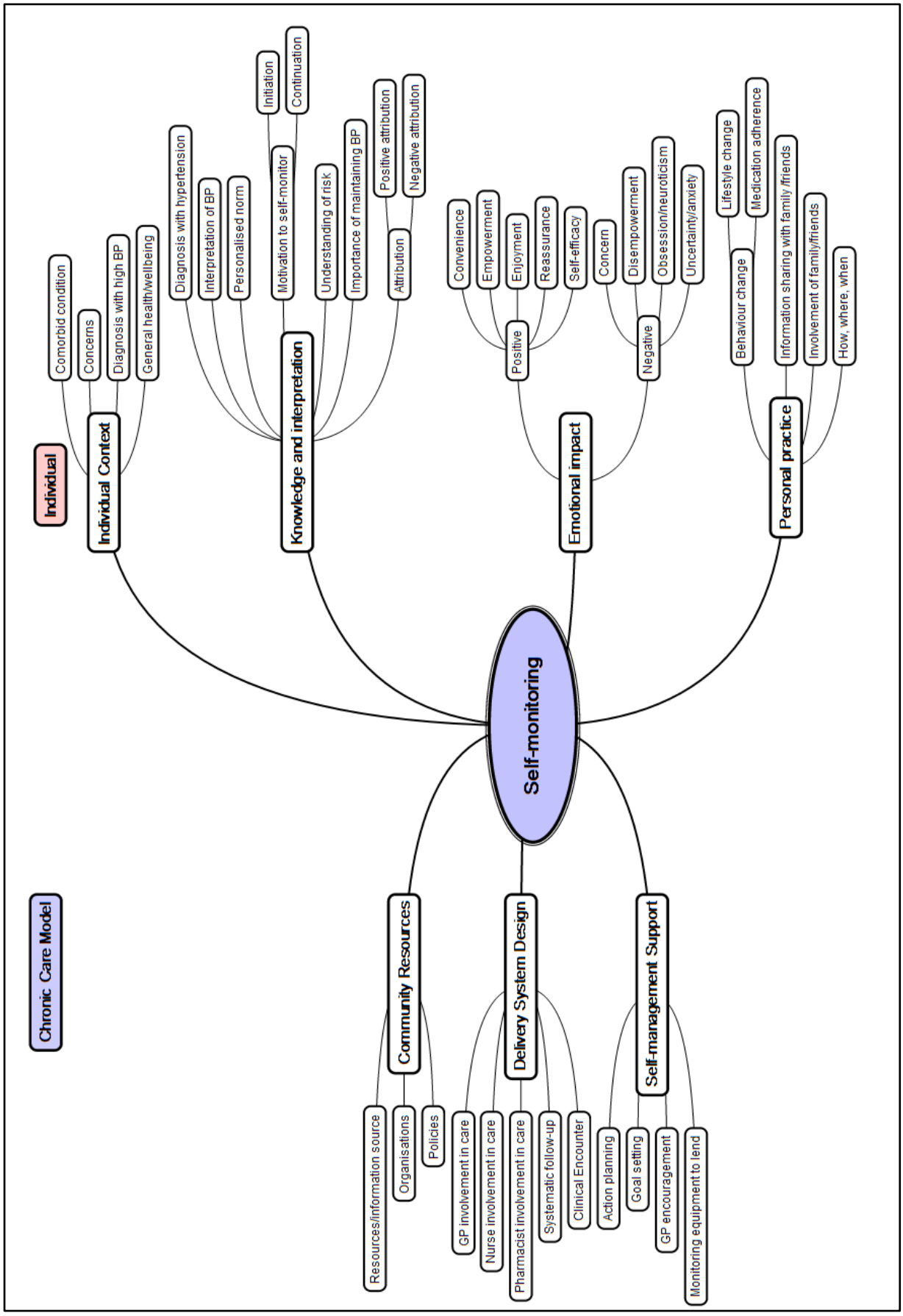


Table 5.3 Coding across participants

			Participants										
			OM1	**OW1**	**OW2**	**BM1**	**BM2**	**BM3**	**BW1**	**BW2**	**BW3**	**BW4**	**BW5**
Chronic care model	**Community resources**	Resources/information source						X					
		Organisations	X					X	X				
		Policies									X		
	Delivery system design	GP involvement in care		X	X	X	X		X	X	X	X	X
		Nurse involvement in care				X				X		X	
		Pharmacist involvement in care				X							
		Systematic follow-up				X	X	X					
		Clinical encounter				X							
	Self-management support	Action planning								X	X		
		Goal setting											
		GP encouragement				X				X			
		Monitoring equipment to lend				X				X			X
Individual	**Individual context**	Comorbid condition		X	X	X	X	X	X		X	X	X
		Concerns	X		X		X	X		X		X	
		Diagnosis with high BP	X	X	X	X	X	X	X	X	X	X	X
		General health/wellbeing	X	X	X	X	X	X	X	X	X	X	X
	Knowledge and interpretation	Interpretation of BP	X	X	X	X	X	X		X	X	X	
		Personalised norms	X			X				X	X		
		Motivation to self-monitor	X	X	X		X		X	X			
		Importance of maintaining BP	X	X	X	X	X	X	X	X	X	X	X
		Attribution	X	X	X	X	X	X	X	X		X	
	Emotional impact	Convenience		X	X		X				X		X
		Empowerment	X	X	X	X		X					
		Enjoyment		X		X					X		
		Reassurance								X		X	
		Self-efficacy	X			X		X				X	
		Concern						X				X	
		Disempowerment		X			X	X			X		X
		Obsession/neuroticism										X	X
		Uncertainty/anxiety		X	X				X			X	
	Personal practice	Lifestyle change	X	X		X						X	X
		Medication adherence					X	X					X
		Information sharing with family/friends	X			X	X	X		X			
		How, where, when	X	X	X	X	X	X	X	X	X	X	X

5.4.2.1 Individual context

This theme was used to capture any contextual factors that influenced how patients use or experience SMBP, and as such was used as a background to probe other themes for similarities/differences. Patients described their general wellbeing and any health concerns, and more specific topics such as their diagnosis with hypertension.

Interestingly, a number of patients reported that they initially discovered that they had high BP outside of the clinic environment, through opportunistic testing.

> *"I wanted to join the gym […] and they have a test, take your blood pressure before they allow you in the gym, and it was off the scale."* (CM3)
>
> *"When I went to the blood centre in the West End, they always used to take your blood pressure before you gave blood and mine was two hundred and twenty over a hundred and ten and they refused to take it and suggested I went to see my doctor."* (CM2)

5.4.2.2 Personal practice

Participants described the practicalities of SMBP, the equipment used, and the process of self-monitoring (how, where, and when), as well as what individuals did with the results of SMBP.

The motivation to initiate monitoring for many of the interviewees was in response to a request from their GP, often to confirm the diagnosis of hypertension, or to monitor changes related to treatment. For these patients, often the only other reason for measuring their BP was to provide reassurance when they felt unwell, and this process of attribution is described below (in 5.4.2.3):

> *"But as I say, I don't do it because it's there. We don't take our blood pressure unless we're requested to or we don't feel too good."* (CW2)

"And I don't measure my blood pressure […] I just do it when I go to Dr X." (OW2)

"…if I got a monitor and then, just when I was going to come and see them for a review, I would do a week." (CW4)

"I don't see much point taking it for myself, because it won't alter what I do." (CW5)

None of the interviewees said they used SMBP as a way of tracking changes linked to medication adherence, diet or exercise. Some participants were aware that being more active or reducing salt in diet could help lower BP, but this was not linked to the practice of self-monitoring in an interactive way. Self-monitoring was used reactively, rather than as part of a plan to track improvements to behaviour change.

"It was just a whim. I wasn't that I felt, oh my blood pressure's, I'm having problems, let me take it. It was just, if it was in the room and it was there." (CM3)

*"If I've been a bit naughty, […] eaten too much, weight going up, something like that, I might think, oh, I'll take it [*BP measurement*] for a couple of days and see what I am doing to myself."* (CW4)

All of the participants owned their own BP monitor, frequently choosing a monitor based on the recommendation of their GP, or finding a monitor that looked like their GP's. The cost of the equipment was not seen as prohibitive, and not a concern when choosing monitors. Two participants reported using wrist monitors, and one told how his GP did not recommend these types of monitor.

"But the doctor said, "Well, they're at bit hit and miss. Good comparator, but a bit hit and miss." So I've gone and, and [er] had the same as the practitioner." (CM1)

Participants were asked where they usually kept their monitor, and the reason for this decision: whether this was somewhere that would remind them to monitor; or perhaps placing the monitor in a place to act as a prompt for some other action, such as remembering to take their medication. Interviewees mostly kept their monitor in a convenient place, usually the kitchen or living room, places where they were able to sit down and relax.

Monitoring was often a public and shared experience. Interviewees said that they often measured their BP at the same time as their partner, assisting each other in the process. Monitoring was also something that was shared with visiting friends and family: one participant said they were running "clinics". Monitors were rarely stored away between measurements and were left out on display.

> *"I left it [*BP monitor*] on the kitchen table and every time I passed it I took a blood pressure."* (CW5)
>
> *"Well, I tend to measure myself sitting down, lying down. Not lying down, sitting up in bed, that sort of thing."* (OW2)
>
> *"[chuckles] Since I've had the equipment, when people visit and they know, I do […] this little sort of clinic, and I do the test on anybody that wants me to."* (CM1)

For those participants who reported monitoring at the request of their GP, they followed the protocol suggested by NICE: twice daily, in the morning and evening for 5-7 days, however some were more precise about their timings than others.

> *"We always do it, we're pretty precise where we do it. We do it before we take medicine in the morning. So at breakfast […] and again in the evening."* (CM2)
>
> *"I'm usually sitting where you are now* [table in conservatory]. *I'm not consistent that I do it on the hour each day, it can vary. But I usually put it on the table, do it and then take the reading, relieve the pressure wait a couple of minutes and do it again."* (CM1)
>
> *"I mean I'm not doing it every day or anything. It doesn't control my life. It's just really, just occasionally, maybe once a month for a couple of days but always to do it if they're going to do a review."* (CW4)

Some reported 'testing-to-target'; that is when they repeated measurements until they achieved a reading that they were happy with. This happened with individuals who thought of themselves as fit and healthy, and who monitored more frequently.

> *"So I'll take one reading and it would be higher than I would like, so I'd take another one to try [laughs] and find a low reading, but it actually jumped around a bit."* (CM3)

Communication of SMBP results was predominantly in-person during consultation, although one participant with mobility issues described how her GP told her she could telephone with the results of her self-monitoring to avoid unnecessary trip to the surgery. A number of participants used log sheets to record their SMBP. One of the GP practices provided printed logs for their patients to fill in and take along to appointments with their GP which patients found convenient. While some mentioned using the digital memory of their monitor, or computer software to record their measurements, these were exceptions rather than the rule.

> *"I don't put it in* [the monitor] *memory, I don't do anything that sophisticated. I just record it and write my sheets up."* (CM1)
>
> *"Oh, the, the nurse gave me a sheet [er] where I could monitor it. We took a copy […] I would then fill it in and I handed, used to hand that sheet to them."* (CW2)

SMBP gave patients solid information to take to consultations, and gave patients confidence to state how they thought their treatment was working without equivocation, and even challenge the doctor.

> *"I will go armed with my test results, and I should be able to report back that there's no reaction to these tablets."* (CM1)
>
> *"If it's high the doctor will say to me, 'That's high.' And I say, 'Well I took it yesterday, or this morning, you've got it written down there, you can see what it was like."* (CM2)

There was also recognition that SMBP had the potential to make consultations more efficient, by avoiding the need for clinic measurement, as well as providing concise, readily interpretable information.

> *"These days when you're booked in, you're not there for a half hour chat, you're there for ten minutes, and you can't sort of go on and on, you have to be very concise. That's why I take my forms, say my piece, present the documents and then wait and see what the doctor's reaction is."* (CM1)

5.4.2.3 Knowledge and interpretation

This theme describes how participants understand and interpret BP and self-monitoring. Interviewees recognised that the results of SMBP represent a better overall picture of their underlying BP than clinic measurement alone. Many discussed how they reacted to the 'white-coat' and that the stress of the clinic environment was likely to result in higher BP readings. One participant was so distrustful of clinic measurement he started self-monitoring to try and make the case that he did not need medication.

> *"I think it was my own approach that started me measuring it regularly, partly because of the attitude of not wanting medication. I think I was trying to monitor myself out of medication."* (CM3)

Self-monitoring was thought to save time during consultation by removing the need for GPs to measure BP, and this also meant that a GP's time was not being 'wasted'.

> *"I always thought that I was probably looking at a white coat and it's going really high. And thought about it and thought I only get ten minutes really with my GP, and I thought it was fairer if I discussed with them, if I got a monitor and then, just when I was going to come and see them for a review, I would do a week."* (CW4)

When interpreting the results of self-monitoring, patients often found it hard to define what having high BP meant. Individuals recognised that early diagnosis was key, as this could lead to better treatment results, and that SMBP could play a key role in this. Patients were concerned about the risks associated with having high BP, and this is discussed further below (in 5.4.2.4).

> *"They say that blood pressure, you don't know whether you've got it high or low, it's not something that you can itemise, identify."* (OW2)

> *"I presume, the longer you have high blood pressure, the more damage you are likely to be doing to your body. So the sooner it's found the better."* (CM3)

Blood pressure variability was difficult to deal with for some, and as stated previously, led to some participants testing to target. There was awareness that BP varied between readings,

but individuals had difficulty knowing whether the variation was natural or could be attributed to something, such stress or due to inaccuracies in measurement.

> *"I can't imagine that the blood pressure should vary. So if I'm getting a different measurement then it must be the machine. But then when I came into the surgery […] that wasn't particularly consistent. So I kind of held my hands up at that stage and I thought I'll just accept that there's variation."* (CM3)

A key concept arising from the interviews was attribution where SMBP allowed patients to link BP to aspects of their daily life: either attributing high BP to situational factors such as stress or stressful events, or measuring BP in response to feeling unwell (i.e. reassurance that feeling unwell not attributed to high BP). Participants were aware that certain lifestyle factors were associated with high BP.

> *"I've just been a bit naughty with my weight, and you know, perhaps diet, and I think that might have contributed really"* (CW4)
>
> *"Tuesday morning, when it was very high, I'd had a spat with my wife. We'd had an argument about something."* (CM2)
>
> *"… I was probably a bit worried about going for the injection. For me I don't think that's applied because I'm very laid back about it."* (CM1)
>
> *"I blame the cricket, or something like that [laughs], because the cricket was on the television and took my focus away…"* (CM3)

Another key concept in this theme was the understanding of the risks of high BP. Participants were most worried about the increased risk of stroke, but when questioned could not provide an estimate of what their risk might be. Some saw the risk of stroke as black and white, and if BP remained uncontrolled then a stroke would be the outcome.

> *"It's an increased risk, it's not an absolute event, it's a probability."* (OM1)
>
> *"You really have got to look after your blood pressure, because if not, you'll end up having a stroke."* (OW1)
>
> *"And [the GP] said, "Well, yes but it often doesn't work like that, you finish up so that you're still here but you're not in a very good state." So that, the message has got through to me loud and clear."* (CM1)

> *"I think the worst thing that could happen to me would be to have a devastating heart attack and not die."* (CW5)

This theme is linked to the potential negative impact of SMBP which is discussed in the next section.

5.4.2.4 Emotional impact

SMBP had positive and negative impacts on the interviewees. Some felt more involved in their care when they provided SMBP readings to their GP. Linked to previous themes, patients enjoyed having something concrete to discuss with their GP, and it made them feel more believable/credible. Some enjoyed the process of self-monitoring, particularly those with a scientific or technical background.

> *"My original background is in engineering, it's right up my street really, testing and so forth. Recording information, presenting things on graphs. So when the practice suggested to take their equipment and do it at home… [hands rubbing]"* (CM1)

Several participants found the feedback from SMBP reassuring as it allowed them to see that their BP was controlled. Others liked that they were being trusted by their GP to provide BP measurements that could be used to guide care.

> *"So the GP just said, you know, "I rely on your honesty [um] and just do it twice in the morning and twice in in the afternoon and come back with the results."* (OW1)

> *"I, oh, how shall I say? I, I do ignore it, I try and ignore it and I do ignore it. I do ignore it because I'm doing something about it. I measured, it's stabilised, not as low as perhaps we would like, but it's stabilised now."* (CM1)

Participants did not really discuss any concerns with the physical process of self-monitoring. Where anxiety was reported it was related to having to remember to self-monitor, or with the results of SMBP. SMBP could be seen as empowering patients by giving them a tool to understand their condition better and increasing their knowledge as described earlier.

However, SMBP was disempowering for a number of participants, particularly when patients found their BP to be high and did not think they could do anything to change the situation. When this was the case they measured less frequently.

> *"It's the monitoring and finding that it's not normal, that's the stress."* (CM3)
>
> *"I used to do it quite regular, but then when it started going up, I started worrying about it so then I stopped doing it."* (CW2)

SMBP caused some people to think about hypertension more often than they would like, and some would prefer not knowing what their BP was doing from one consultation to the next.

> *"I don't measure my blood pressure often. I think it will just make me nervous if it's high and it's changing all the time anyhow, so I just do it when I go to Dr X."* (OW2)
>
> *"It's perceptual. It's the same worry you have about terrorism, there's not a lot you can do to stop it."* (OM1)
>
> *"If I wasn't monitoring it I wouldn't have an idea, I would just get on with life. Monitoring it had made me not worry about it, but now it's just another concern that there is maybe something that will pop."* (CM3)

One participant who was a retired health professional commented being concerned about patients becoming obsessed. However only one interviewee expressed any concerns in that regard, linking tracking and recording data as having the potential to lead to obsessive behaviour.

> *"I told people to ease off [*regular self-monitoring*] and stop getting so worked up about it. Live life and forget about it."* (CW5, retired HCP)
>
> *"if you take data, you really ought to transcribe it, you want to keep a record of it. And then there's the root there to obsession."* (OM1)

5.4.2.5 Community resources

There was evidence for some participants having their BP measured outside the direct health care environment, for example in a gym, during a health check at work, or at the supermarket. However, the motivation in those contexts was not necessarily to support self-management or primary care. While opportunistic BP measurement services may signpost general practice for those with high BP, their primary intention was likely marketing BP measurement devices (supermarket) or assessing risk for insurance reasons (gym).

Participants were asked about community support programs and education initiatives, however, none reported being aware of any locally.

5.4.2.6 Delivery system design

Patients reported that their GP was actively supportive of SMBP, usually to monitor the response to treatment, and that SMBP played an important part in the clinical encounter. Pharmacists were also involved, at least at one of the practices, and would call to talk to patients about their BP, again usually in the context of medication change. Patients liked this linked up care.

> *"And the surgery ring me up on a regular basis. Not the surgery, the pharmacist that is attached to the practice, they ring me up and ask for a reaction, and so I'm pleased, they're pleased, I think everybody's pleased."* (CM1)

5.4.2.7 Self-management support

According to the chronic care model, self-management support includes: action planning, goal setting, GP encouragement, and monitoring equipment to lend. While GPs were

supportive of their patients self-monitoring, and some patients reported being lent a BP monitor, few patients had agreed BP goals or action plans.

5.5 DISCUSSION

5.5.1 Principal findings

5.5.1.1 Motivation to self-monitor BP

Participants reported two main reasons for initiating self-monitoring: either at the request of their GP, or out of a desire to track their BP following a diagnosis of hypertension. There was little evidence that participants changed their behaviour beyond initiating self-monitoring (i.e. medication adherence, diet, exercise). Patients were knowledgeable about factors related to hypertension, but seemed neither willing nor able to make changes to their lifestyle in order to try and improve their BP.

Patients were comfortable integrating SMBP into their everyday lives. Rather than being a private and hidden experience, as might be the case with other medical procedures, self-monitoring was often carried out with family or friends in living rooms and kitchens.

GP encouragement, goal setting and action planning are important components of self-management support according to the CCM.(9) While participants did talk about encouragement and support for their self-monitoring from their GP, goal setting and action planning were uncommon.

Participants were happy to carry out a period of monitoring at the request of their GP, and this was normally in preparation for a routine check-up, or was requested after medication changes or up-titration. Patients much preferred this method to traditional clinic measurement for a number of reasons: they recognised that SMBP provided a better overall picture of 'true' BP; they felt stressed having BP measured in clinic and related this to white-coat effect; they thought cutting clinic measurements led to a more efficient use of their time

with their GP; and they felt trusted by their GPs, and more involved in their care when asked to self-monitor.

Of concern was the potential for some patients to "test to target", which might make the results presented to clinicians less reliable, and highlights how some patients do not appreciate that BP varies.

5.5.1.2 Empowerment and disempowerment

There was evidence of both empowerment and disempowerment linked to SMBP. Empowerment came from patients feeling more involved in decisions about their care, being 'armed' with information for discussion, and even to challenge their GP. Interviewees were empowered when their BP was well controlled, and they used SMBP to monitor this (positive feedback). SMBP also gave patients reassurance that symptoms which they experienced when feeling unwell were not related to high BP.

Participants felt disempowered, or powerless, when their BP was high and they did not think they could do anything about it. When this was the case, patients reported that they would rather not know what their BP was, as it caused them to think more about their BP than they would like.

5.5.1.3 Support for patients who self-monitor

The two GP practices from which interviewees were recruited were supportive of SMBP, and there was some evidence of the involvement of community pharmacy. However, there was little evidence in interviews of the community resources or delivery system design

components of the CCM. Community support is an area where improvement could potential prove effective.

5.5.2 Strengths and limitations

The sample recruited for this study was small, but a similar size to those of two previous studies in the UK. The results reported here add to these previous studies, and focus more on how SMBP is used in interactions between patients and clinicians, and how SMBP fits into their everyday lives.

For pragmatic reasons participants were recruited opportunistically, rather than purposively for a maximum variation sample. However a diverse range of experiences were nevertheless obtained. Ideally, further investigation would include younger participants, diverse ethnic groups and individuals who self-monitor but do not communicate this to their GP. People of South Asian, African Caribbean, and Irish ethnicity are known to have worse cardiovascular outcomes than White British, and have differing experiences of out-of-office BP measurement. Therefore recruiting from these groups would be of particular interest.(26, 27) It is estimated that 30% of UK patients with hypertension own and use SMBP, however it is likely not all of those who use SMBP discuss this with their GP.(28) Investigation of how these individuals utilise SMBP is important. Efforts were made using adverts placed on social media and on research participation databases (i.e. PAIR Thames Valley) to specifically recruit from these groups, but were unfortunately unsuccessful.

The use of a Framework methodology allowed in-depth exploration of patient experiences of SMBP, and used inductive and deductive analysis. Inductive reasoning was used to search for patterns in why patients chose to self-monitor and how SMBP was integrated into

their everyday lives. Deduction was used to investigate what support was available for SMBP, and how SMBP was used to guide care, in support of components of the Chronic Care Model. Framework analysis enhances rigor by providing a clear audit trail from raw data to final themes, and the decisions made for coding.

5.5.3 Reflections on sample and data saturation

Samples in qualitative research are generally much smaller than in quantitative research, and are often based on the idea of data saturation, the point of diminishing return when more data does not necessarily lead to more information. Sampling approaches used in qualitative research fall into three broad categories (29):

- Convenience – involves the selection of the most accessible subjects. The benefits of this approach are that it is the least costly in terms of time and money, however the downside may be that it can result in poor quality data, and can lack intellectual credibility.
- Judgement – involves the researcher selecting the most productive sample to answer the research question. Can be based on a framework of variables that might influence an individual's experience and perspective, and is based on researcher's own knowledge, available literature and the study itself.
- Theoretical – iterative approach where samples are theory driven, with individuals selected to elaborate and examine theories emerging from the data (Grounded Theory approach)

Ritchie et al (2003) outlined seven factors that might affect the potential sample size of a sample (16):

- Heterogeneity of the population
- Number of selection criteria
- Extent to which nesting of criteria is needed
- Groups of special interest that require intensive study
- Multiple samples within one study
- Types of data collection methods used
- Budget and resources available

Whatever the sampling approach used, the concept of data saturation is often proposed as a means to determine how many interviews are sufficient. Data saturation in qualitative analysis is rooted in Grounded Theory research that was pioneered by Glaser and Strauss.(30) In Grounded Theory researchers develop theory through the collection and analysis of data, rather than simply presenting major themes, or first forming a theory and then testing it. Sampling is based on emergent theory and continues until the point at which no new or relevant insights emerge from the data.

It has been argued that data saturation is inappropriate when used outside Grounded Theory research, at least in the extent to which it should be an explicit aim. O'Reilly (2012) argued that data saturation should not be a generic requirement applied to all forms of qualitative inquiry, and that saturation as a quality criterion is irrelevant.(31) Whereas the criterion of data saturation may be applicable to inductive research where particular areas of interest are pursued as the study progresses, deductive research is not guided by categories that may emerge from the data when collecting it.

Strauss and Corbin (1998) suggested that "saturation should be more concerned with reaching the point where it becomes counter-productive and that the 'new' that is discovered does not necessarily add anything to the overall story, model, theory or framework".(32) They also argued that saturation is a matter of degree, as there is always the potential for "the new to emerge".

There is no agreed number or formula for achieving data saturation with many authors proposing different figures and methodologies. The current definition of data saturation is more concerned with the size, number or adequacy of the sample rather than how deeply data was gathered from each of the sample. There is also debate that in reality, data can never be saturated because there is always something new to be interpreted albeit under

different perspectives. Morse (1995) describes how researchers often claim to have achieved saturation, but are not necessarily able to prove it.(33) This is supported by Bowen (2008) who discusses how saturation may be claimed in a number of qualitative research reports without any description of what it means or how it was achieved.(34)

In the study reported in this chapter, the intention was to use a sampling approach that incorporated elements of convenience and judgement sampling. The participants were all recruited from two local practices. These practices were chosen as they employed GPs who were interested in the research and were willing to recruit. Attempts were made through to broaden the sample, however to no avail. With more time and available resources it may have been possible to recruit further, to include younger participants, those from ethnic minorities and individuals who use SMBP without discussing the outcome with their GP, as discussed in the previous section. The outcome is that the sample can only be described as a convenience sample. With regard to data saturation, interviews were conducted until no new and meaningful information was collected. However, due to the challenges with recruiting a diverse sample, this has the impact of restricting the findings and conclusions to the local context.

5.5.4 Comparison to literature and implications for practice and future research

5.5.4.1 Previous studies on SMBP in UK

This was only the third study in the UK to explore SMBP in everyday practice; the previous two were carried out before or around the time of the most recent changes to NICE hypertension guidelines in 2011. In 2003, Rickerby and Woodward interviewed thirteen individuals from one general practice in the UK to investigate experiences of SMBP, with a

focus on the acceptability of monitoring itself.(13) They found that patients were willing to carry out self-measurement and were pleased to have been asked to be more involved in their management. Vasileiou *et al* conducted interviews with eighteen users of SMBP in early 2012 which explored the interpretation of SMBP readings, and the way people communicate readings with their GP.(14) This study concluded that doctors should help patients resolve the uncertainties around the interpretation of home readings, and ensure "rules of thumb are appropriate". Data from the eleven interviews presented here broadly agrees with the findings from these two studies, and contributes findings as to how SMBP fits into the everyday lives of patients with hypertension.

5.5.4.2 Using SMBP to track changes

The findings from these interviews contradict the findings from Chapter 3 which found that patients made changes to their lifestyle and medication, and used SMBP to track improvements.(21) Interviewees lacked the specific skills to make positive changes. New strategies that encourage behaviour change involving a collaborative process whereby patients choose a goal, and negotiate a specific action plan with their clinician have shown promise, but do require an investment in time from both parties.(35, 36) While this approach may not be realistic within the average GP consultation (ten minutes in the UK), there is a role for other healthcare professionals (i.e. nurses or pharmacists) to be involved. The patients in this study were generally engaged, and wanted to improve their BP, and providing them with specific, personalised information about how to enact change, and planning accordingly may have been beneficial.

SMBP has been linked to overcoming clinical inertia in trials (12), and by using SMBP to keep track of BP in their patients. GPs of patients in this study may have been able to react

to their patients' condition quicker than if they had been using clinic monitoring. However, given the evidence that some patients may "test to target" (i.e. repeat measurements until readings are satisfactory), patients should be reminded that obtaining an accurate overall picture of BP is important, and that the occasional high or low reading should not be of great concern.

5.5.4.3 Responding to disempowerment

The results from the review in Chapter 3 showed that SMBP was linked to empowerment and increased self-efficacy for patients with hypertension. However, this interview study provides contradictory findings with disempowerment emerging as an important theme. These patients may require tools to make positive changes, such as goal setting and action planning as mentioned previously, or even to be given more control over their own treatment. For example, recent trials of self-management, where patients are able to titrate their own medication in accordance with a pre-arranged protocol, have been shown to be clinically effective and acceptable to patients.(37, 38) For engaged patients, such as those in this study, it may be possible to reduce disempowerment by helping patients to help themselves. Patients need the confidence and knowledge to know what they can do safely and effectively for themselves, and when to seek professional help.(39)

5.5.4.4 Concerned clinicians

Clinicians have raised concerns that SMBP causes anxiety or neuroticism.(40) In Chapter 4, 60% of GPs expressed concern that SMBP would not be beneficial to those who were already anxious. One of the interviewees in this study was a retired GP, and reported similar

worry that patients would be burdened by monitoring, although they were themselves not made anxious by SMBP.

From the perspective of the patients interviewed for this study however, anxiety was linked to not having control over BP, rather than the process of monitoring itself, which some even described as enjoyable. Clinicians have legitimate concerns about their patients, however the evidence suggests that the anxiety is linked to their patients' health rather than the practicalities of SMBP.

5.5.5 Conclusion

SMBP was often taken by patients at the request of their GP, but otherwise patients did not monitor regularly. Patients were empowered when they felt in control of their BP, however, they felt anxious and unable to enact positive change when their BP was high. Community support for SMBP was lacking, as was specific information for patients to utilise SMBP to improve BP control.

Future research should aim to recruit a broader sample of participants, and investigate further the theme of disempowerment, which was a novel finding in this study.

Individuals in this study provided their experiences of SMBP specifically as this was the focus of the study, however SMBP is only one approach to improving the management of hypertension. Other approaches include: community pharmacy management, telecare, and patient self-management. Understanding patient preferences given the range of models, and therefore placing SMBP in a broader context will be the focus of the final study reported in Chapter 7.

5.6 REFERENCES

1. World Health Organization. Global status report on noncommunicable diseases 2014. Geneva: World Health Organization; 2014. 280 p. p.
2. Scotland NNS. Practice Team Information (PTI) Annual Update (2012/2013). National Statistics Publication for Scotland; 2013.
3. Busse R, European Observatory on Health Systems and Policies., World Health Organization. Regional Office for Europe. Tackling chronic disease in Europe : strategies, interventions and challenges. Geneva: WHO : UK distributor: Stationery Office; 2010. xii, 111 p. p.
4. RCGP. Care Planning: improving the lives of people with long-term conditions. 2012.
5. Coulter A, Roberts S, Dixon A, King Edward's Hospital Fund for London. Delivering better services for people with long-term conditions : building the house of care. London: The King's Fund; 2013. 27 pages p.
6. RCGP. RCGP written evidence. Health Select Committee on Management of Long-Term Conditions. 2013.
7. Wagner EH. Chronic disease management: what will it take to improve care for chronic illness? Eff Clin Pract. 1998;1(1):2-4.
8. Davy C, Bleasel J, Liu H, Tchan M, Ponniah S, Brown A. Effectiveness of chronic care models: opportunities for improving healthcare practice and health outcomes: a systematic review. BMC Health Serv Res. 2015;15:194.
9. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. JAMA. 2002;288(14):1775-9.
10. Rothwell PM. Factors that can affect the external validity of randomised controlled trials. PLoS Clin Trials. 2006;1(1):e9.
11. Jones R, Jones RO, McCowan C, Montgomery AA, Fahey T. The external validity of published randomized controlled trials in primary care. BMC Fam Pract. 2009;10:5.
12. Agarwal R, Bills JE, Hecht TJW, 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.
13. Rickerby J, Woodward J. Patients' experiences and opinions of home blood pressure measurement. Journal of Human Hypertension. 2003;17(7):495-503.
14. Vasileiou K, Barnett J, Young T. Interpreting and acting upon home blood pressure readings: a qualitative study. BMC Family Practice. 2013;14:97.
15. Bryman A, Burgess RG. Analyzing qualitative data. London: Routledge; 1994. xiii , 232 p. p.
16. Ritchie J, Lewis J. Qualitative research practice : a guide for social science students and researchers. Thousand Oaks, Calif. ; London: Sage; 2003. xv, 336 p. p.
17. Smith J, Firth J. Qualitative data analysis: the framework approach. Nurse Res. 2011;18(2):52-62.
18. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol. 2013;13:117.
19. Crotty M. The foundations of social research : meaning and perspective in the research process. London ; Thousand Oaks, Calif.: Sage Publications; 1998.
20. Hammersley M. What's wrong with ethnography? : methodological explorations. London: Routledge; 1992.
21. Fletcher BR, Hinton L, Hartmann-Boyce J, Roberts NW, Bobrovitz N, McManus RJ. Self-monitoring blood pressure in hypertension, patient and provider perspectives: A systematic review and thematic synthesis. Patient Educ Couns. 2016;99(2):210-9.
22. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. BMJ. 2000;320(7227):114-6.
23. Horsburgh D. Evaluation of qualitative research. J Clin Nurs. 2003;12(2):307-12.

24. Berger R. Now I see it, now I don't: researcher's position and reflexivity in qualitative research. Qualitative Research. 2015;15(2):219-34.
25. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-51.
26. Khattar RS, Swales JD, Senior R, Lahiri A. Racial variation in cardiovascular morbidity and mortality in essential hypertension. Heart. 2000;83(3):267-71.
27. Wood S, Greenfield SM, Haque MS, Martin U, Gill PS, Mant J, et al. Influence of ethnicity on acceptability of method of blood pressure monitoring: a cross-sectional study in primary care. The British journal of general practice : the journal of the Royal College of General Practitioners. 2016.
28. Baral-Grant S, Haque MS, Nouwen A, Greenfield SM, McManus RJ. Self-Monitoring of Blood Pressure in Hypertension: A UK Primary Care Survey. International Journal of Hypertension. 2012;2012:582068.
29. Marshall MN. Sampling for qualitative research. Fam Pract. 1996;13(6):522-5.
30. Glaser BG. The discovery of grounded theory : strategies for qualitative research. New York: Aldine de Gruyter; 1967.
31. O'Reilly M, Parker N. Unsatisfactory saturation: a critical exploration of the notion of saturated sample sizes in qualitative research. Qualitative Research. 2012;13(2):190-7.
32. Corbin JMa, Strauss ALa. Basics of qualitative research : techniques and procedures for developing grounded theory. Fourth edition. ed.
33. Morse JM. The Significance of Saturation. Qualitative Health Research. 1995;5(2):147-9.
34. Bowen GA. Naturalistic inquiry and the saturation concept: a research note. Qualitative Research. 2008;8(1):137-52.
35. MacGregor K, Handley M, Wong S, Sharifi C, Gjeltema K, Schillinger D, et al. Behavior-change action plans in primary care: a feasibility study of clinicians. J Am Board Fam Med. 2006;19(3):215-23.
36. Handley M, MacGregor K, Schillinger D, Sharifi C, Wong S, Bodenheimer T. Using action plans to help primary care patients adopt healthy behaviors: a descriptive study. J Am Board Fam Med. 2006;19(3):224-31.
37. Jones MI, Greenfield SM, Bray EP, Baral-Grant S, Hobbs FD, Holder R, et al. Patients' experiences of self-monitoring blood pressure and self-titration of medication: the TASMINH2 trial qualitative study. British Journal of General Practice. 2012;62(595):e135-42.
38. McManus RJ, Mant J, Bray EP, Holder R, Jones MI, Greenfield S, et al. Telemonitoring and self-management in the control of hypertension (TASMINH2): a randomised controlled trial. Lancet. 2010;376(9736):163-72.
39. Great Britain. Department of Health. Raising the profile of long term conditions care : a compendium of information. London: Dept. of Health; 2008. 50 p. p.
40. Jones MI, Greenfield SM, Bray EP, Hobbs FR, Holder R, Little P, et al. Patient self-monitoring of blood pressure and self-titration of medication in primary care: the TASMINH2 trial qualitative study of health professionals' experiences. British Journal of General Practice. 2013;63(611):e378-85.

CHAPTER SIX

PATIENT PREFERENCES FOR HYPERTENSION MANAGEMENT IN THE UK: A STATED-PREFERENCE DISCRETE CHOICE EXPERIMENT

6.1 CHAPTER OVERVIEW

The following chapter presents the fifth and final study within the thesis. An on-line questionnaire including sixteen discrete choice questions was completed by 167 patients with hypertension, to better understand how patients choose between different packages of care, and what trade-offs they may make between potential attributes associated to each package. The design of the discrete choice was informed in part using the findings of the patient interviews reported in Chapter 5. This chapter explores patient preferences for different packages of hypertension management in order to better understand the relative importance patients place on SMBP compared to other models of care. Data were analysed using different econometric methods for choice data, and the model with best fit is presented.

The chapter begins with an introduction to the study including a brief description of the theoretical framework employed, followed by experimental design, and objectives. Following the results, the findings are discussed in relation to the literature.

6.2 BACKGROUND

6.2.1 Models of care for hypertension

If choices between treatment options in health were based solely on clinical outcomes, then health care decision making would be relatively simple. There are however many aspects that affect health decisions beyond outcomes: cost, convenience, availability, ease of use, potential risks or side effects, etc. While patients may not be best placed to determine the best form of medical intervention for their medical condition, there are a number of other attributes, especially those related to quality of delivery that are susceptible to the judgements of patients.(1) With a variety of potentially effective hypertension management options, it is important to determine how patients value different models of care, and the relative importance of factors in the decision making process. The Chronic Care Model (CCM) introduced in Chapter 1 and discussed in previous results chapters, is a model that focuses on patient centricity, supporting self-management behaviours and improving care pathways with better integration of healthcare professional teams.(2) The delivery system design component of the CCM, which relates to organising regular planned visits incorporating patient goals and employing the skills of different providers, and/or supporting self-management is a focus of this study. Examining patient preferences for who measures BP, where this occurs (i.e. using out-of-office measurement of BP rather than clinic measurements), and who leads treatment changes (i.e. drug titration plan carried out by nurses, pharmacists or patients) is important to optimising the management of hypertension.

Discrete choice methodology (DCM), is a technique for eliciting preferences that provides information about the way individuals value different attributes of health, as well as the potential demand for different programs/services where there is no apparent market.(3) A discrete choice experiment (DCE) was used to build upon the evidence from Chapters 2, 3

and 5, that showed involving patients more in their care via SMBP is clinically effective, increases self-efficacy and empowerment.

As little evidence is currently available about how patients may make decisions about different models of care for hypertension management an exploratory study was proposed. There are a number of definitions for pilot and feasibility studies, however all are used to describe preparation for a larger study.(4) In the case of this study the aim was on providing information to inform and improve the quality of a future substantive stated-preference DCE study.

Designing a discrete choice experiment is a complex process, with a number of key decisions along the way, from how the experiment is designed, what information to include and how to analyse and interpret data.

6.2.2 Discrete choice methodology

6.2.2.1 History

Discrete choice methodology was developed in mathematical psychology, and subsequently became popular in marketing research and environmental and transportation economics.(5) DCEs have become increasingly common in health research with 293 examples published between 2001-2012 compared with only 34 in the 1990s.(6) DCEs go beyond traditional qualitative assessments and traditional ranking and rating methods, to provide information on decision making, strength of preferences and trade-offs between different options. DCEs can be seen as a true mixed-method as although they provide quantitative data, they are based on qualitative methods to determine what attributes are included in the experimental design.

6.2.2.2 Economic utility, satisfaction and random utility theory

Utility is a ubiquitous concept in economics that defines the degree of satisfaction provided by a good or service. In health economics health utilities are cardinal values that reflect an individual's preference for different health outcomes: utilities are typically combined with survival estimates to generate quality adjusted life years (QALYs) for use in cost-utility analyses of health care interventions. In this study the more general economic term of utility will be used.

If total utility was measureable, it would represent the number of units of utility that a consumer gained from a given quantity of a good/service in a set time period: the higher the total utility, the higher the level of satisfaction. According to Lancaster's Theory of Consumer Demand, "the good (or service), *per se*, does not give utility to the consumer; it possesses characteristics, and these characteristics give rise to utility".(7) This idea forms the basis for the DCE approach, as goods/services are described by their components, allowing us to understand the relative importance and trade-offs between those components.

Economists believe that individuals largely behave in a rational manner and seek to maximise utility: for example, all else being equal, when choosing between two or more products an individual should choose the one that provides the greatest overall utility (or satisfaction). It is however impossible to exactly measure utility as it is not possible to measure all characteristics of a service, individual characteristics and the situation in which choice is made. Random utility theory (RUT) states that utility is a latent construct that cannot be observed directly, and assumes that latent utility can be partitioned into two components: a systematic and a random, unexplainable component, and this plays an important role in modelling DCEs, and will be discussed later.(8)

6.2.2.3 Revealed versus stated preference and external validity of DCEs

There are two possible options for understanding choice behaviour through quantifying individual's preferences for goods or services: revealed and stated preference methods. Stated preference methods, including DCEs, ask participants to choose between hypothetical scenarios describing a good/service using a set of attributes. One of the main benefits of stated preference methods is that they allow the investigation of products or services that are not yet available (non-market).

Revealed preferences assume that consumer preferences can be revealed by observing behaviour, and therefore have the advantage of being based on real-world choices, and avoid the potential problems associated with hypothetical scenarios such as strategic responses (empirical evidence suggest that the repeated choice task format induces strategic behaviours).(9) However, revealed preference methodologies face many of the same biases as other more common observational methods, including selection bias and confounding. Another downside of revealed preference methods are that they cannot include non-market choices, which is the case for new models of care for hypertension.

6.2.2.4 Why choose discrete choice as a method?

The default for the management of hypertension in the UK is GP led care, with patients visiting their GP every 6-12 months for BP measurement and medication assessment.(10) Previous chapters have demonstrated the role that SMBP can play in improving hypertension control, as well as showing the ever increasing extent to which GPs incorporate it into everyday practice. A DCE affords the opportunity to present individuals with choices in a real-world context (i.e. multi-dimensional) in order to investigate their preferences for the management of hypertension beyond the traditional approach.

Discrete choice experiments (DCEs) measure the relative importance that individuals place on different aspects of a service, and the extent to which they make trade-offs between those aspects (i.e. how much of one aspect of a service they are willing to forfeit for another).

6.2.2.5 Example of a DCE question and glossary of terms

Discrete choice experiments are based on the premise that:

- Services can be described by their characteristics, and
- The extent to which individuals value services depends on the nature and level of these characteristics (11)

The method involves presenting individuals with a number of scenarios to choose between that are described in terms of characteristics and associated levels. An example DCE question in the area of a hypothetical diagnostic test in primary care is presented in Table 6.1.

Table 6.1 – Example of a discrete choice question

	Test A	**Test B**
Level of information	COMPREHENSIVE	SIMPLE
No. days to wait for result	16	6
Cost to you	20	100
Which would you choose (tick)	**Test A** □	**Test B** □
	Neither □	

This represents one question, a **choice** between two tests. Where more than one option is presented this is known as the **choice set**. The **attributes** are listed on the left hand side (level of information, days to wait for result, cost). **Levels** for each attribute are provided

for each test. Participants are asked to indicate whether they **prefer** Test A, Test B, or neither.

6.2.3 Objectives

The objective of this chapter was to conduct a pilot study to explore patient preferences for hypertension models of care in the UK with a focus on:

- Recruitment rate, completion rate and acceptability of questionnaire design
- The relative importance of various factors that influence the decision making process in the management of hypertension
- Trade-offs between those factors
- Estimating the probability of take-up of defined packages of care
- Calculating the monetary values of attributes and levels

Understanding these factors may contribute to further research into tailored approaches to hypertension management that meet patients' needs and preferences, improve clinical outcomes, and reduce burden on the health care system.

6.3 METHODS

6.3.1 Stages to a discrete choice experiment

Lancsar and Louviere (2008) conceptualised a 14 point checklist to consider in undertaking a DCE: attribute selection; level selection; experimental design; questionnaire design; piloting; population perspective; sample and sample size; data collection; coding of data; econometric analysis; validity; interpretation; and welfare analysis.(12) Ryan (2008) condensed this into five stages: selection of attributes and level setting; experimental design and construction of choice sets; measurements; estimation procedure; and tests of validity of responses.(13) The methods reported here follow a combination of components from both of these checklists.

6.3.2 Selection of attributes and level setting

Attributes selected for a DCE should be realistic, actionable by policy and tradeable.(14) Attributes were identified and refined from a combination of published literature, qualitative methods and expert opinion, and the rationale for each attribute is described in detail in 6.3.2.1-4. Choosing attributes and levels has been described to be as much an art as science; capturing as much relevant information from expert opinion and qualitative work and combining them together in scenarios that individuals could face in real-world settings.(1)

The decision about the number of attributes to include in a DCE involves making a trade-off between including sufficient important attributes whilst minimising the difficulty of the tasks and cognitive burden. When participants are presented with choice sets that are too complex (i.e. too many attributes per choice set, or too many choices) participants may choose randomly between scenarios, or make decisions based on only a few of the presented

attributes in each scenario. Presenting too many options to participants also runs the risk that participants become fatigued, and it is plausible that their choices will exhibit higher variability.(15) A systematic review of DCEs in health care showed that the most common number of attributes was six.(6)

Four attributes were chosen for inclusion based on the results of previous qualitative research (Chapters 4 and 6) and to align with the objectives of the research. Each attribute was assigned four levels (i.e. equal across attributes) for two reasons: attributes with more levels can be perceived to be more important; and attribute level balance is easier to satisfy in the final design. Attribute level balance is where each attribute level appears an equal number of times for each attribute over the design and is important factor in experimental design (discussed in section 6.3.3). Attributes needed also to be independent, i.e. have no overlap or correlation with the others (inter-attribute correlation), as this could prevent the estimation of each attribute on the dependent (choice) variable.

The attributes and levels chosen along with the rationale for inclusion are as follows:

6.3.2.1 Attribute One – model of care

As stated in a report from the Royal College of General Practitioners about future models of care in the NHS, "The patient experience in 2022 is likely to include improved resilience and self-sufficiency to manage one's own health and illness, with appropriate support from a range of community resources".(16) Traditionally hypertension care has been managed by patients visiting their GP for BP measurement, with the GP making treatment decisions using those measurements. However, with evidence supporting the effectiveness and potential cost savings of the new models of care, research is needed to investigate which

modes of care patients may prefer, as well as any perceived trade-offs between different models.

In the past decade or so, out-of-office BP measurement has been shown to be effective in managing BP control, whether the measurement be in the pharmacy or in patients' own homes.(17-19) Out-of-office measurement is a better predictor of cardiovascular risk, is associated with better medication adherence, provides a better overall picture of BP and can help to overcome clinical inertia.(20-22)

Telehealth is defined by the UK Department of Health as a "service that uses equipment to monitor people's health in their own home […] readings that indicate changes outside the normal parameters, which may indicate deterioration in health are then flagged for action". This model of care is perhaps the closest to the traditional method, but provides the clinician with a more accurate picture of their patients' BP control. Telemonitoring has been shown to be effective and acceptable to patients and clinicians.(23)

Medication titration (increasing/decreasing medication or changing medication type) can also be carried out with away from the clinic, usually according to a plan prearranged with the patients' GP. Medication titration can be carried out effectively by nurses(24), pharmacists(18) and patients themselves(25).

Varying who measures BP (patient, nurse, pharmacist, GP), and who is responsible for making medication changes (patient, nurse, pharmacist, GP) resulted in 16 possible combinations. For this experiment it was decided to pick the default option (GP measurement and management) as well as three options that are realistic, actionable by policy, and have already been shown to be effective and acceptable interventions.

The four levels for the model of care attribute were (as described to participants):

- **GP led –** you schedule an appointment during normal clinic hours at your local general practice. Your BP is measured, and any necessary changes to your medication, are made by your GP.

- **Pharmacist led –** you attend a walk-in service (no appointment required) at your local pharmacy. Your BP is measured by the pharmacist, and medication changes are made by the pharmacist in accordance with plan made by you and your GP.

- **Telehealth –** you measure your BP at home using an automated BP device which automatically transmits the results to your GP. Your GP will review the measurements you made to make any necessary changes to your medication. You will not have to schedule any clinic appointments for your BP as long as it remains controlled.

- **Self-management –** you measure your BP at home using an automated BP device. You are responsible for making any necessary medication changes, according to a protocol agreed beforehand with your GP.

6.3.2.2 Attribute Two – frequency of measurement

For necessary medical interventions to occur in a timely manner, patients with hypertension, need to be monitored frequently. However, there is a trade-off in measuring BP between having sufficient information to guide treatment, while not overburdening the patient with repeated measurements. While there is limited information on encounter frequency linked to BP outcomes in hypertensive patients; the available evidence supports faster decrease in BP in those who are followed-up more frequently.(26, 27)

Currently, it is recommended by NICE that patients with hypertension with well controlled BP are offered an annual review of their care, and therefore may only have their BP measured for that occasion.(10) However, 30% of hypertensive patients currently visit their GP at least three times per year, with one in ten making more than 5 visits.(28) Patients may find it more convenient to measure their BP less frequently, especially if the measurement involves a trip to the GP or pharmacy. Conversely it is possible that patients like to be

followed up more frequently to provide reassurance that their treatment is having the desired effect.

The four levels for the frequency of measurement attribute were:

- **Every month**
- **Every three months**
- **Every six months**
- **Every twelve months**

6.3.2.3 Attribute Three – risk

Epidemiological evidence suggests that the risk of cardiovascular disease rises with increasing BP starting at around 115/75mmHg.(29) A large number of clinical trials have shown that lowering BP reduces risk of stroke by 35-40%, myocardial infarction (MI) by 20-25%, and heart failure by up to 50%.(30)

The interviews with patients in chapter 5 showed that increased risk of stroke associated with high BP is of particular concern. Communicating risk is a complex issue, for example whether to communicate absolute or relative risks, and whether to frame advice using positive or negative language (i.e. treatment will lead to reduced risk, versus, if no treatment is given risk is increased).(31) Patients can see treatment as binary with success or failure, rather than a reduction of risk. There is evidence that patients prefer use of relative risk over absolute risk, natural frequencies or number needed to treat.(32)

Different modes of care, with different frequencies of feedback on the results of treatment, and less frequent contact with healthcare providers, have the potential to result in different

reductions in CVD risk (i.e. due to different patterns of medication adherence and medication prescribing). It is important to see to what extent patients are willing to trade-off differing levels of risk.

Ideally risk would be calculated on an individual basis (i.e. older, higher BP, Black/South Asian at increased risk), and appropriate risk reduction tailored to each person. It was however necessary to present the same data to all participants. The levels of risk included represent realistic reductions in five year cardiovascular risk given appropriate treatment.

The four levels for the cardiovascular risk category were:

- **By using this service you will be 5% less likely to have a stroke or heart attack in the next 5 years**
- **By using this service you will be 10% less likely to have a stroke or heart attack in the next 5 years**
- **By using this service you will be 15% less likely to have a stroke or heart attack in the next 5 years**
- **By using this service you will be 25% less likely to have a stroke or heart attack in the next 5 years**

6.3.2.4 Attribute Four – cost

It is estimated that diseases caused by hypertension cost the NHS £2 billion every year (Public Health England). Cost is an important attribute in DCEs as the cost coefficient can be used to calculate the marginal willingness to pay for the other attributes included in the experiment (i.e. patient's willingness to pay for different models of care).

As NHS patients do not pay at the point of care, this can make the communication of costs in a DCE difficult. For this experiment two options were explored: framing cost as a cost

to the NHS, or asking participants to think about the direct value to themselves within a personal care budget (local authority). As personal care budgets are yet to be widely introduced it was decided that the former option would be used.

The cost levels included are based on the costs of health care providers' time, as reported in the Unit Costs of Health and Social Care.(33) The ordering of attributes has been shown to influence estimates, so it has been suggested that the cost attribute should be placed at the bottom of the choice set following a precautionary principle.(34)

The four levels for the cost category were:

- **£50 per year**
- **£100 per year**
- **£250 per year**
- **£500 per year**

6.3.3 Experimental design

According to Hensher (2015) "experimental design has at its core two common objectives: (i) the ability to detect independently the effects of multiple variables on some observable outcome, and (ii) the improvement of the statistical efficiency of the experiment".(35)

The experimental design of a DCE relates to the combination of attributes and levels used to construct the alternatives presented in the choice set. The choice set relates to the number of individual choices presented to the participants.

Identification is a key concept in understanding the design goals of DCEs, and relates to which effects can be independently estimated from the experimental design:

- Main effects – the direct effect of each independent variable (attributes) on the dependent variable (choice variable).

- Interaction effects – occur when the combined effect of two or more attributes is different from the sum of their two main effect utilities.

A full factorial design includes all of the possible combinations of the levels of attributes and would allow the estimation of main effects and all interaction effects independent of each other. However, full factorial designs are often too large to be examined by respondents. For example, given four factors with four levels, the full factorial array for one set of choices would be 4^4 (256), and in a pairwise DCE where one alternative is compared to another the total number of possible pairs would be 32,640 pairs of alternatives (256*255/2). It is common practice in fractional factorial plans in DCEs to include only main effects, as it is thought that they explain most of the variation in preferences (approximately 80% of variance).(36)

It was therefore necessary to design an experiment that resulted in a much smaller number of choice sets, and according to Street (2007) there were four characteristics to think about when designing an optimal choice experiment (37):

- Level balance – all levels of each attribute occur with equal frequency over all options of choice sets.

- Orthogonality – a property that requires strictly independent variation of levels across attributes, in which each level appears an equal number of times in combination with all other attribute levels.

- Minimal overlap – the probability that an attribute repeats itself in each choice set should be as small as possible.

- Utility balance – options within a choice should be equally attractive to subjects.

There are two main classes of procedure to systematically select choice sets: orthogonal and efficient design. Efficient designs use software to compute the choice sets with the highest

statistical efficiency, but require prior information about the direction and size of the effects of each attribute on the dependent choice variable. As this was a pilot study such information was not available.

Optimal orthogonal designs do not require any prior information; they begin with an orthogonal design derived from the full factorial array, and then the alternatives are created by applying a design calculator.

The process for this experiment entailed identifying an orthogonal main effects plan (available from Hahn and Shapiro 1966 and SPSS statistical software), and the alternatives were created by using a shifted design generator (1313 shifted design). The design process resulted in 16 binary choice sets, with 94.5% D-efficiency, and allows for the identification of all main effects [main effects are uncorrelated] (Appendix 5.1).

The final position of each option within each choice (i.e. A v B; B v A), and the position of each choice (1-16) were assigned randomly. The process is shown in Appendix 5.2.

6.3.4 Simulation

Simulation was conducted to understand whether the parameters of the models were estimable for different sample sizes. Once complete, the experimental design was tested with simulated participant responses (n=100, 250 and 500). For each number of simulated participants three sets of data were created:

- Random – where each choice for each participant was randomly chosen (coded as 0 for choice A, and 1 for choice B), therefore for each question there were a random allocation of 0s and 1s. This option represented a situation where none of the attributes had any effect on choice, therefore the model should have provided no significant β coefficients.

- 50/50 – where for each of the sixteen choice questions the proportion of choices for A v B was exactly 50%. In this option all of the β coefficients should have equalled zero for each of the attribute levels.

- 95% GP – this option was based on the 50/50, but where GP was an option in a choice set 95% of the time the GP option was chosen (i.e. questions 1, 2, 4, 7, 10, 12, 13, 15). In this option the β coefficient for GP should be positive and significant, while all of the other predictor variables should remain close to 0.

The results of the simulations are presented in Appendix 5.3, and proved the experimental design was robust with sample size ranging from 100 to 500.

6.3.5 Survey instrument development

An on-line questionnaire was developed using LimeSurvey, an open source software survey tool (www.limesurvey.org). The questionnaire contained the following sections:

- Study information: the aims of the study, inclusion criteria for participation, what participation would involve, estimated time to complete.

- Screening questions based on inclusion criteria (age >18, hypertension, consent to participate).

- Description of attributes and levels, followed by an example choice question.

- Choice questions: sixteen choice situations as described in experimental design.

- Feedback about choices: three questions about understanding and completion of choice tasks.

- Demographic questions.

- Feedback: opportunity to provide any information about choices in hypertension management that participants felt were not covered in the choice scenarios presented.

The questionnaire was piloted among members of staff and students in the Nuffield Department of Primary Care Health Sciences, to test the format and ordering of the questionnaire, and the wording of questions, as well as to provide an estimate of the time to complete.

6.3.6 Sample size and sample

A database of patients who registered an interest in taking part in research was used to recruit participants: Research for the Future is a NHS supported campaign to encourage people to take part in health research opportunities and is made up of Help BEAT Diabetes, Help BEAT Respiratory Disease, and Help BEAT Heart Disease. A previous survey investigating BP measurement in GP practices had recruited from this population and received a good response from individuals with hypertension. Adults with a self-reported diagnosis of hypertension were invited to take part by email.

There is currently no definitive method of calculating sample sizes for DCEs, and this is a developing field.(38) Permain *et al* suggested that sample sizes over 100 are able to provide a basis for modelling choice data, while Lancsar and Louviere proposed 20 observations per choice set are sufficient to estimate reliable model.(12, 38) Johnson and Orme proposed the following "rule of thumb" sample size calculation for DCEs (39):

$$nta/c \geq 500$$

(Equation 6.1)

Where n is the number of respondents, t is the number of tasks, a is the number of alternatives per task, and when considering main effects c is equal to the largest number of levels of any two attributes. 500 relates to the number of times each main effect is

represented across the design, and Orme *et al* have argued that this should be a minimum threshold, and that it would be better to have 1,000. As shown in Equation 6.2, a sample of 100 would fall between these two recommendations, and also meet the criteria by Permain *et al* and Lancsar and Louviere, and was thus deemed a suitable target for this experiment.

[100 participants (*n*) X 16 tasks (*t*) x 2 choices per task (*a*)] / 4 levels per attribute (*c*) = 800

(**Equation 6.2**)

6.3.7 Data analysis

All data analyses was carried out using Stata version 12 (StataCorp. Stata Statistical Software. 2013: College Station, TX: StataCorp LP).

6.3.7.1 Demographic data

Demographic details were summarised using descriptive statistics.

6.3.7.2 Coding of choice data

Categorical variables were coded using both dummy and effects coding, and the effect on the overall model fit was compared. As an example, Table 6.2 show how the 'Frequency of Monitoring' attribute was coded using both coding options. Dummy coding creates n-1 variables for a categorical variable with n levels, and uses 1s to represent membership and 0s to represent non membership. Effects coding again creates n-1 variables, and uses 1s and 0s in the same way as dummy coding, but introduces -1s to denote the reference category.

Many discrete choice researchers recommend the use of effects coding as it simplifies subsequent calculations of choice probabilities because it provides a parameter estimate for every attribute level by defining zero as the mean effect rather than the combined utility of all the omitted categories as with dummy coding.(40)

Table 6.2 – Example of dummy v effects coding

	Dummy 1	Dummy 2	Dummy 3	Effects 1	Effects 2	Effects 3
Monthly (reference)	0	0	0	-1	-1	-1
Every three months	1	0	0	1	0	0
Every six months	0	1	0	0	1	0
Yearly	0	0	1	0	0	1

The cost and risk attributes were coded as categorical variables, and as continuous variables. Continuous coding allowed for the calculation of willingness to pay (WTP) and willingness to trade risk reduction, described in 6.3.7.4.

6.3.7.3 Model selection

As shown in Equation 6.3, responses from choices were modelled within a random utility theory (RUT) framework whereby the latent utility of an alternative i in a choice set C_n is made up of two separate parts: (i) a systematic component specified as a function of the attributes of the alternatives V_{ij}; and (ii) a random (unexplainable) component representing unmeasured variation in responses $\mathcal{E}_{ij}$. It is assumed, according to utility maximisation, that individual i will choose alternative j if the alternative maximises their utility among all alternatives in the choice set.(36)

$$U_{ij} = V_{ij} + \mathcal{E}_{ij}$$

(**Equation 6.3**)

If choices are binary (i.e. include two forced options, A v B), binary logit or binary probit models are appropriate. Traditionally the conditional multinomial logit (CL) model was used to estimate choice models, which has three assumptions:

- Independence of irrelevant alternatives (IIA) (i.e. the ratio of probabilities for any two alternatives is assumed to be independent of the attribute levels in a third alternative)
- Error terms are independent and identically distributed across observations
- No preference heterogeneity (i.e. homogenous preferences across respondents)

According to De Bekker-Grob, "such assumptions may be restrictive in describing human behaviour questioning the validity of policy conclusion". New models were developed to account for the behaviour of respondents in DCEs.(41) Preference heterogeneity, whereby some individuals care more about particular attributes than others, is accounted for in the mixed logit (MIXL) model.(42) It has been argued that in most choice contexts much of the preference heterogeneity is better described as scale heterogeneity, or that choice behaviour is more random for some decision makers than others, which led to the development of the scale heterogeneity multinomial logit model (S-MNL), as well as the generalised multinomial logit model (G-MNL) which nests MIXL and S-MNL.(43)

For this experiment all four models (i.e. CL, MIXL, S-MNL and G-MNL) were estimated, with model fit compared using log-likelihood (LL) and Akaike's Information Criteria (AIC). AIC was developed in 1973 to compare the relative quality of statistical models for a given set of data.(44) Comparison of log-likelihoods is another method that is often used to compare different models. For both AIC and LL, the closer to zero the better the model fit.

The following equation was estimated using four models, where utility (represented by U) is characterised by different combinations of attribute levels. Subscript i denotes the

individual and *j* the alternatives in a choice set. This equation was estimated for all participants who completed all sixteen choice sets:

$$U_{ij} = \beta_1 GP_j + \beta_2 Pharmacist_j + \beta_3 Telehealth_j + \beta_4 Selfcare_j + \beta_5 Monthly_j + \beta_6 Threemonthly_j + \beta_7 SixMonthly_j + \beta_8 Yearly_j + \beta_9 Reduction5\%_j + \beta_{10} Reduction10\%_j + \beta_{11} Reduction15\%_j + \beta_{12} Reduction25\%_j + \beta_{13} Cost_j$$

(**Equation 6.4**)

6.3.7.4 Interpretation of data

The coefficients (βs) generated were used in the following ways:

- To determine: whether attributes were important (statistically significant as shown by the significance level of the β); the direction of importance (shown by sign of the estimated β); and relative importance (size of the estimated parameter). Coefficients were considered statistically significant at the 5% level. The direction of the coefficient signs also provided a check on the theoretical/internal validity of the DCE model – that is whether the coefficients moved as economic theory, or *a priori* expectation would predict.

- The negative ratio of any two βs represents the trade-offs made between the two attributes, and is called the marginal rate of substitution. When the β for cost was used as the denominator, the negative ratio provided an estimate of the willingness to pay for a particular characteristic. For example: $-(\beta_1 GP/\beta_{13} Cost)$ indicated the willingness to pay for the GP model.

- Combining βs allowed for the calculation of predicted probability of uptake for different models of care. First the indirect utility of each combination of attribute levels was calculated, and then the exponential function used to calculate the probability of uptake of any combination of models.

6.3.8 Ethical approval

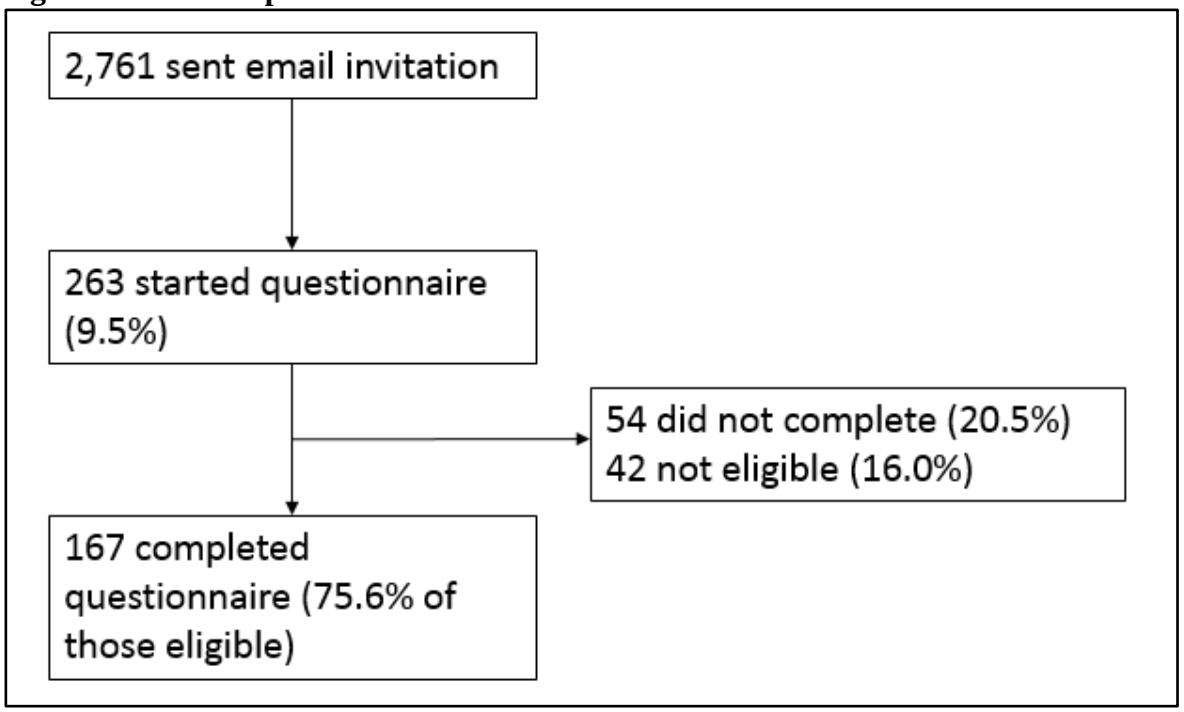
Ethical approval was granted by the University of Oxford Medical Sciences Inter-Divisional Research Ethics Committee, ref: R5623/RE001.

6.4 RESULTS

6.4.1 Participants

Participant flow is presented in Figure 6.1. An invitation to take part was emailed to 2,761 individuals. Over three weeks between 03-20/06/2016, 263 people opened the link to the survey, representing 10% of those approached. Of those starting the survey 16% were ineligible (i.e. <18, non-hypertensive, no consent), and of those eligible to take part 167 completed the survey (76%). Fifty four (21%) people completed at least one choice question, but did not finish the questionnaire, and were excluded from analysis.

Figure 6.1 – Participant flow



Participant demographics are presented in Table 6.3. All but five of the respondents described themselves as white (97%), over half were retired (61%), and half reported university as their highest level of education (49%). According to the Index of Multiple Deprivation score, participants lived in areas evenly spread across quintiles. The majority

(82%) reported that it was more than 5 years since diagnosis with hypertension. Slightly over half measured their own BP at home (52%).

Table 6.3 – Participant demographics

		Participants, n=167
Age (mean, s.d.)		61.41 (9.9)
Age (range)		25-84
Years since diagnosis with hypertension (n, %)	Less than 1 years	10, 6.3%
	Between 1 and 5 years	20, 12.3%
	More than 5 years	133, 81.6%
Measure own BP at home (n, %)		86, 51.5%
No. medications for hypertension (mean, s.d.)		1.76 (1.06)
No. medications for other conditions (mean, s.d.)		4.79 (3.06)
Ethnicity (n, %)	White	160, 97.0%
	Mixed/multiple ethnic groups	1, 0.6%
	Asian/Asian British	3, 1.8%
	Black/African/Caribbean/Black British	1, 0.6%
	Other/rather not say	0, 0%
Index of Multiple Deprivation score (mean, s.d.)		19.6 (17.1)
Deprivation from postcode, quintiles 1-5 (1 least deprived) (n, %)	1	44, 30.1%
	2	34, 23.3%
	3	18, 12.3%
	4	24, 16.4%
	5	26, 17.8%
Highest level of education (n, %)	GCSE/O level or equivalent (left school at 16)	39, 23.9%
	A level or equivalent (left school at 18)	17, 10.7%
	Vocational (NVQ)	18, 11.0%
	University	79, 48.5%
	Other/rather not say	9, 5.5%
Employment (n, %)	Full time employment	36, 22.2%
	Part time employment	21, 12.9%
	Homemaker looking after family	3, 1.9%
	Student in full-time education	0, 0%
	Retired	99, 61.1%
	Unemployed	3, 1.9%

6.4.2 Completion of questions

Table 6.4 summarises participants' views of the ease completion of the questions. The majority of participants agreed that questions were easy to understand (79.5%), that the

differences between choices was clear (81.3%), and that it was easy to make a choice for each option (67.5%).

Table 6.4 – Completion of discrete choice questions

	Strongly disagree	**Disagree**	**Neither agree or disagree**	**Agree**	**Strongly agree**
The questions were easy to understand	1 [0.6%]	10, [6.0%]	23, [13.9%]	78, [47.0%]	54, [32.5%]
The difference between the choices on each question was clear	1, [0.6%]	7, [4.2%]	23, [13.9%]	84, [50.6%]	51, [30.7%]
It was easy to make a choice on each question	2, [1.2%]	21, [12.7%]	31, [18.7%]	85, [51.2%	27, [16.3%]

6.4.3 Model estimation

Four models (CL, MIXL, S-MNL and G-MNL) were tested using either dummy or effects coding, and with either risk and or cost coded as a continuous variable. Full results are presented in Appendix 5.4. The model with the best fit according to both log-likelihood and Akaike's Information Criteria was the G-MNL with effects coded variables and cost as a continuous variable, and the results are shown in Table 6.5. All of the following results are based on this model unless otherwise specified.

Table 6.5 – Results of Generalised Multinomial Logit (G-MNL) regression analysis

Variable		Regression coefficient (β) (95% CI)	p-value
Model of care	**GP**	-0.483 (-0.058 to 1.023)	0.080
	Pharmacist	0.565 (0.091 to 1.039)	0.020
	Telehealth	-0.033 (-0.408 to 0.343)	0.865
	Self-management	-0.050 (-0.429 to 0.330)	0.798
Frequency of BP measurement	**Monthly**	0.437 (0.045 to 0.829)	0.029
	Three monthly	0.776 (0.070 to 1.481)	0.031
	Six monthly	-0.090 (-0.460 to 0.279)	0.632
	Yearly	-1.122 (-1.743 to -0.401)	0.002
Reduction in 5 year risk of cardiovascular events	**5%**	-2.606 (-4.049 to -1.163)	<0.001
	10%	-0.261 (-0.562 to 0.040)	0.089
	15%	0.462 (0.131 to 0.792)	0.006
	25%	2.406 (0.984 to 3.827)	0.001
Cost	**£**	-0.004 (-0.007 to -0.002)	0.001
Log likelihood		-1355.52	
Akaike's Information criteria		2755.03	
Number of observations		5344	
Number of individuals		167	

6.4.4 Importance of attributes

All attributes had at least one significant difference between levels indicating that all played an important part in decision making. The coefficient for cost was negative and significant (-0.004, p=0.001) indicating that responders preferred scenarios that cost less.

The coefficient for pharmacy management was positive and significant (0.565, p=0.020), showing that participants preferred this over the other options. Responders preferred not to

visit the GP, or use telehealth or self-management, although these did not have significant coefficients.

Significant positive coefficients for monthly (0.437, p=0.029) and three monthly (0.776, p=0.031) monitoring of BP, together with a negative significant coefficient for yearly measurement (-1.122, p=0.002), demonstrate that patients prefer more frequent monitoring.

Reduction in cardiovascular risk was a significant driver of preferences, with respondents' greatest preference for 25% reduction (2.406, p=0.006), followed by 15% (0.462, p=0.006). There was a significant negative preference for the lowest risk reduction of 5% (-2.606, p<0.001). The largest coefficients were present in the risk reduction attribute, indicating that this was the main driver of risk.

6.4.5 Marginal rates of substitution

Trade-offs between attributes were calculated in terms of cost and CVD risk, to determine how much participants were willing to pay (WTP), and willing to trade risk of CVD outcomes. Results are presented in Table 6.6. Willingness to risk estimates were based on a G-MNL model with effects coding for model, frequency and cost, and risk as a continuous variable (Appendix 5.5).

Table 6.6 – Willingness to pay, and willingness to trade risk

		Willingness to pay (£)	Willingness to 'risk' (% reduction in 5 year CVD risk)
Model of care	GP	-£109.01 (-£230.34 to £13.01)	-1.59 (-4.07 to -0.80)
	Pharmacist	£127.19 (£66.57 to £187.81)	2.25 (0.71 to 3.80)
	Telehealth	-£7.36 (£-94.26 to £79.55)	-0.05 (-1.40 to 1.31)
	Self-management	-£11.16 (-£93.48 to £71.16)	-0.62 (-2.03 to 0.79)
Frequency	Monthly	£98.66 (£10.22 to £186.48)	3.32 (1.54 to 5.09)
	Three monthly	£174.58 (£94.01 to £255.14)	2.16 (1.04 to 3.27)
	Six monthly	-£20.34 (-£98.99 to £58.31)	-0.96 (-1.96 to 0.05)
	Yearly	-£252.58 (-£330.77 to -£174.40)	-4.52 (-5.62 to -3.41)
Reduction in five year CVD risk	5%	-£588.38 (-£911.30 to -£261.78)	
	10%	-£58.80 (-£110.74 to £6.86)	
	15%	£103.90 (£34.62 to £173.17)	
	25%	£541.44 (£405.52 to £677.37)	
Cost	£50		3.44 (1.49 to 5.39)
	£100		5.89 (4.79 to 6.99)
	£250		-1.68 (-2.83 to -0.54)
	£500		-7.65 (-9.09 to -6.20)

All else being equal, participants were willing to pay £127 (95%CI £66.57 to 187.81) for pharmacist management. Participants were willing to pay £98.66 (£10.22 to £186.48) for monthly BP measurement, and £174.58 (£94.01 to £255.14) for three-monthly. The marginal willingness to pay (MWTP) for three-monthly over yearly measurement is

£427.16. Respondents' WTP for 25% reduction in 5 year CVD risk was £541.44 (£405.52 to £677.37), with the MWTP over 5% reduction in 5 year risk of £1,129.82.

Participants were willing to trade 2.25% (0.71% to 3.80%) 5 year CVD risk for pharmacist management, and the marginal willingness to trade over GP management was 3.84%. For frequency of BP measurement, respondents were willing to trade 3.32% (1.54% to 5.09%) CVD risk reduction for monthly, and 2.16% (1.04 to 3.27) for three-monthly. The marginal willingness to trade risk for monthly versus yearly measurement was 7.84%.

6.4.6 Predicted uptake rates

Table 6.7 presents the predicted probability of uptake estimated from the G-MNL model. Predicted uptake rates were calculated based on a hypothetical scenario where all models of hypertension care available, as well as all four options for frequency of BP measurement, with cost and risk constant. The most preferred scenarios with the highest probability of uptake were pharmacist management every three months, followed by pharmacist management monthly. All else being equal, the probability that participants would choose monthly pharmacist management from all combinations was 17.8%. The least preferred scenario was GP led care and BP measurement once per year (1.0% uptake).

Table 6.7 - Predicted uptake of attribute combinations (model and frequency of measurement)

Rank	Model	Frequency of BP measurement	Probability of uptake (%)
1	Pharmacist	Three monthly	17.8
2	Pharmacist	Monthly	12.7
3	Telecare	Three monthly	9.8
4	Self-management	Three monthly	9.6
5	Pharmacist	Six monthly	7.5
6	Telecare	Monthly	7.0
7	Self-management	Monthly	6.9
8	GP	Three monthly	6.5
9	GP	Monthly	4.7
10	Telecare	Six monthly	4.1
11	Self-management	Six monthly	4.1
12	GP	Six monthly	2.8
13	Pharmacist	Yearly	2.7
14	Telecare	Yearly	4.5
15	Self-management	Yearly	1.4
16	GP	Yearly	1.0

6.5 DISCUSSION

6.5.1 Principal findings

6.5.1.1 Piloting

This is the first study investigating patient preferences for hypertension management using a discrete choice experiment. Overall response rate was relatively low (9.5%), and respondents were predominantly white and well educated. Participants were registered on research databases for diabetes, heart disease or respiratory disease and it was not known how many of those registered on the database had a diagnosis of hypertension, nor was any other demographic information available from the database providers. Calculation of true response rates (i.e. proportion of eligible participants who took part) and the representativeness of the sample was therefore impossible. Evidence suggests that it is difficult to recruit minority groups into research in general, and this would need to be addressed in future DCEs in this area.(45)

The response rate may have been low for a number of reasons:

- Large proportion of invitees may not have had hypertension (overall response rate not represent good response rate among individuals with hypertension)
- Individuals may not have opened the invitation email
- Individuals may not have been interested in the research topic
- Individuals may have had concerns about taking part in the survey

Extensive evidence shows that internet based surveys have lower response rates to postal surveys, and for any follow-up study this could be an avenue to explore.(46) A recent meta-analysis of response rates to postal DCEs found the mean response rate to be 50%.(47) Participants were not sent follow-up reminders which have been shown to improve response rates, and could be included in any future studies.(48)

Three quarters of those who opened the link to the questionnaire completed all of the questions, and reported that they found the questions easy to understand and complete. Both cost and risk had negative coefficients in the study, with participants preferring lower costs and risk of CVD events, which is further evidence of understanding and completion of choice tasks (theoretical validity).

A sample size calculation for a future study was conducted based on the results of the pilot using the methods described by de Bekker-Grob *et al* and are presented in Appendix 5.6.(38) With a significance level (α) of 0.05, and statistical power ($1-\beta$) of 0.8, the minimum sample size to estimate all coefficients would be 25,645. This large sample size is mainly due to the small coefficients and considerable variance for telehealth, and the experimental design used (orthogonal). A future study would utilise the estimates for the coefficients from this pilot study, and use efficient design (d-optimal) to reduce this figure significantly, likely into the hundreds. Efficient designs rely on expensive specialist software however, and were beyond the capacity of this project.

6.5.1.2 Preferences

Risk reduction was a significant driver of choice, and patients were willing to pay £1,129.82 for 25% reduction in 5 year risk compared to 5% (highest v lowest attribute level), known as the marginal willingness to pay. All attributes contained levels with significant coefficients, showing that they were all important in decision making, and would therefore all need to be included in any future DCEs in hypertension. Participants were willing to trade some risk reduction for other attributes, as shown by the marginal rates of substitution in Table 6.5. For example, participants were willing to accept 2.5% increase in their 5 year CVD risk to have pharmacist management of hypertension.

Participants preferred pharmacist management over the other options, and perhaps surprisingly GP management was least preferred. The reasons for this choice needs further exploration: it might be the case that participants saw pharmacy as the more convenient option, as they could choose to attend without an appointment. Results from earlier chapters, along with published research, have shown that patients are keen to have more flexible options for the management of hypertension.(49) The strong preferences for GP and pharmacist management may have been influenced by patients' prior experiences. Although participants would not have had hypertension managed in the pharmacy, they would be likely have experience of visiting the pharmacy for other reasons. Self-management and telehealth were probably less known to participants, and therefore they would perhaps not have bad strong feelings either way. There is evidence of experience affecting preference from a trial where patients were randomised to a telemonitoring and self-management intervention group or to usual care: in the usual care group participants preferred GP management and in the intervention patients preferred self-management.(50)

Both telehealth and self-management were preferred over GP care, however this result was not statistically significant. Further research is needed to further break down the components of each model of care to determine what is driving decision making, and should be the focus of a future DCE. A better understanding of the important components would allow the design of hypertension management options to maximise utility (satisfaction).

Respondents preferred more frequent monitoring than the current NICE guidelines which suggest yearly measurement for patients with controlled BP. Patients had positive preferences for monthly and three monthly, with the latter being the optimum.

6.5.1.3 Preference heterogeneity

The Generalised Multinomial Logit model (G-MNL) which nests the Mixed Logit (MIXL) and Scale Heterogeneity Multinomial logit (S-MNL) provided the best fit for the choice data in this study. G-MNL was developed to counteract violations to the conditional logit model, three of which were described in section 6.3.7.3.(41)

As the G-MNL model provided the best fit, it suggests that preference and scale heterogeneity were present in the choice data. This shows that individuals did not make homogenous choices across individuals, and that choice behaviour was more random for some individuals than others. This variation in choice behaviour could be explained by a number of factors including "the way a choice is posed, the social context of the decision, the emotional state of the decision maker, and a host of other environmental factors".(51) This is an interesting finding that would benefit from further study. One way to do this would be to ask participants to "talk aloud" while completing DCE questions in order to understand how they are making choices, and see how this compares across participants, and for each individual.

6.5.2 Strengths and limitations

Increased choice in primary care services encourages individuals to make choices and trade-offs between one type of care and another.(52) It is however not clear how the public responds to increased choice, and this study provides evidence for decision making in hypertension. The results will inform development of interventions tailored to patient preference, and encourage efficient use of healthcare resources.

This was an experimental study and participant choices may not represent how individuals behave in 'real-world' situations. As three of the models of care were not available routinely to patients in the UK an experimental approach was the only way of determining how patients may make choices about the management of hypertension. As mentioned previously, the direction of effects for risk (choosing greater risk reduction) and cost (choosing lower cost), combined with the fact that all four attributes were important in decision making, provide evidence that participants engaged with the choice tasks and that the choices were appropriate. To validate the findings requires observation of actual choices, and until all of the options included here are routinely available, this will be difficult.

The external validity of DCEs (i.e. comparing DCE results with revealed preference method) is an under-researched area in health, in part due to the scarcity of revealed preference data, however three studies that have explored the external validity of DCEs have shown promising results.(53-56) The external validity of the results of this study are questionable given the demographics of those who took part, however as this was a pilot study the results still provide valuable information about how patients may make decisions about the models of care that may potentially available, particularly the relative importance of different attributes if not the absolute importance.

6.5.3 Conclusions and future research

This study has shown that patients with hypertension recruited to a discrete study found discrete choice questions easy to understand, which was reflected in a good completion rate. Calculating a true response rate was difficult, however the response rate could be used as the lower limit when planning recruitment for future experiments. Of those that opened the

survey, the vast majority completed all of the questions. Conducting a larger discrete choice experiment in a representative UK sample is therefore feasible.

Reduction of CVD risk was a significant component of choice. Models of care outside the clinic environment were preferred to the standard GP management option, and the reasons for this require further investigation in order to provide the package of care that is provides the greatest utility, and therefore high levels of uptake/adherence.

6.6 REFERENCES

1. Ryan M, Office of Health Economics (London England). Using consumer preferences in health care decision making : the application of conjoint analysis. London: Office of Health Economics; 1996. 35 p. p.
2. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. JAMA. 2002;288(14):1775-9.
3. Hall J, Viney R, Haas M, Louviere J. Using stated preference discrete choice modeling to evaluate health care programs. J Bus Res. 2004;57(9):1026-32.
4. Whitehead AL, Sully BG, Campbell MJ. Pilot and feasibility studies: is there a difference from each other and from a randomised controlled trial? Contemp Clin Trials. 2014;38(1):130-3.
5. Louviere JJ, Woodworth G. Design and Analysis of Simulated Consumer Choice or Allocation Experiments - an Approach Based on Aggregate Data. J Marketing Res. 1983;20(4):350-67.
6. Clark MD, Determann D, Petrou S, Moro D, de Bekker-Grob EW. Discrete choice experiments in health economics: a review of the literature. Pharmacoeconomics. 2014;32(9):883-902.
7. Lancaster KJ. New Approach to Consumer Theory. J Polit Econ. 1966;74(2):132-57.
8. Manski CF. The structure of random utility models. Theory and Decision. 1977;8(3):229-54.
9. Scheufele G, Bennett J. Response Strategies and Learning in Discrete Choice Experiments. Environ Resour Econ. 2012;52(3):435-53.
10. NICE. The Clinical Management of Primary Hypertension in Adults: Clinical Guideline 137. 2011.
11. Ryan M, Scott DA, Reeves C, Bate A, van Teijlingen ER, Russell EM, et al. Eliciting public preferences for healthcare: a systematic review of techniques. Health Technol Assess. 2001;5(5):1-186.
12. Lancsar E, Louviere J. Conducting discrete choice experiments to inform healthcare decision making: a user's guide. Pharmacoeconomics. 2008;26(8):661-77.
13. Ryan M, Gerard K, Amaya-Amaya M. Using Discrete Choice Experiments to Value Health and Health Care Preface. Econ Non-Mark Good. 2008;11:Xiii-Xiv.
14. Ryan M, Gerard K. Using discrete choice experiments to value health care programmes: current practice and future research reflections. Applied health economics and health policy. 2003;2(1):55-64.
15. Campbell D, Boeri M, Doherty E, Hutchinson WG. Learning, fatigue and preference formation in discrete choice experiments. J Econ Behav Organ. 2015;119:345-63.
16. Practitioners RCoG. The 2022 GP: a vision for general practice in the future NHS. London: RCGP; 2013.
17. Uhlig K, Patel K, Ip S, Kitsios GD, Balk EM. Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. Annals of Internal Medicine. 2013;159(3):185-94.
18. Cheema E, Sutcliffe P, Singer DR. The impact of interventions by pharmacists in community pharmacies on control of hypertension: a systematic review and meta-analysis of randomized controlled trials. Br J Clin Pharmacol. 2014;78(6):1238-47.
19. Santschi V, Chiolero A, Colosimo AL, Platt RW, Taffe P, Burnier M, et al. Improving blood pressure control through pharmacist interventions: a meta-analysis of randomized controlled trials. Journal of the American Heart Association. 2014;3(2):e000718.
20. Niiranen TJ, Hanninen MR, Johansson J, Reunanen A, Jula AM. Home-measured blood pressure is a stronger predictor of cardiovascular risk than office blood pressure: the Finn-Home study. Hypertension. 2010;55(6):1346-51.

21. Fletcher BR, Hartmann-Boyce J, Hinton L, McManus RJ. The Effect of Self-Monitoring of Blood Pressure on Medication Adherence and Lifestyle Factors: A Systematic Review and Meta-Analysis. American Journal of Hypertension. 2015.
22. Agarwal R, Bills JE, Hecht TJW, 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.
23. Parati G, Omboni S. Role of home blood pressure telemonitoring in hypertension management: an update. Blood Pressure Monitoring. 2010;15(6):285-95.
24. Clark CE, Smith LFP, Taylor RS, Campbell JL. Nurse led interventions to improve control of blood pressure in people with hypertension: Systematic review and meta-analysis. BMJ (Online). 2010;341(7771):491.
25. McManus RJ, Mant J, Haque M, et al. Effect of self-monitoring and medication self-titration on systolic blood pressure in hypertensive patients at high risk of cardiovascular disease: The tasmin-sr randomized clinical trial. JAMA. 2014;312(8):799-808.
26. Guthmann R, Davis N, Brown M, Elizondo J. Visit frequency and hypertension. J Clin Hypertens (Greenwich). 2005;7(6):327-32.
27. Turchin A, Goldberg SI, Shubina M, Einbinder JS, Conlin PR. Encounter frequency and blood pressure in hypertensive patients with diabetes mellitus. Hypertension. 2010;56(1):68-74.
28. Scotland NNS. Practice Team Information (PTI) Annual Update (2012/2013). National Statistics Publication for Scotland; 2013.
29. Prospective Studies C. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. The Lancet. 2002;360(9349):1903-13.
30. Turnbull F. Effects of different blood-pressure-lowering regimens on major cardiovascular events: results of prospectively-designed overviews of randomised trials. Lancet. 2003;362(9395):1527-35.
31. Gallagher KM, Updegraff JA. Health Message Framing Effects on Attitudes, Intentions, and Behavior: A Meta-analytic Review. Annals of Behavioral Medicine. 2012;43(1):101-16.
32. Goodyear-Smith F, Kenealy T, Wells S, Arroll B, Horsburgh M. Patients' preferences for ways to communicate benefits of cardiovascular medication. Ann Fam Med. 2011;9(2):121-7.
33. Curtis L, Burns A. Unit costs of health and social care 2015. Canterbury: Personal Social Services Research Unit; 2015.
34. Kjaer T, Bech M, Gyrd-Hansen D, Hart-Hansen K. Ordering effect and price sensitivity in discrete choice experiments: need we worry? Health Econ. 2006;15(11):1217-28.
35. Hensher DA, Rose JM, Greene WH. Applied choice analysis. Second edition. ed. Cambridge: Cambridge University Press; 2015. xxx, 1188 pages p.
36. de Bekker-Grob EW, Ryan M, Gerard K. Discrete choice experiments in health economics: a review of the literature. Health Econ. 2012;21(2):145-72.
37. Street DJ, Burgess L. The construction of optimal stated choice experiments : theory and methods. Hoboken, N.J.: John Wiley; 2007. xix, 312 p. p.
38. de Bekker-Grob EW, Donkers B, Jonker MF, Stolk EA. Sample Size Requirements for Discrete-Choice Experiments in Healthcare: a Practical Guide. Patient. 2015;8(5):373-84.
39. Johnson FR, Lancsar E, Marshall D, Kilambi V, Muhlbacher A, Regier DA, et al. Constructing Experimental Designs for Discrete-Choice Experiments: Report of the ISPOR Conjoint Analysis Experimental Design Good Research Practices Task Force. Value in Health. 2013;16(1):3-13.
40. Muhlbacher A, Johnson FR. Choice Experiments to Quantify Preferences for Health and Healthcare: State of the Practice. Applied health economics and health policy. 2016;14(3):253-66.
41. Cu YY, Hole AR, Knox S. Fitting the generalized multinomial logit model in Stata. Stata J. 2013;13(2):382-97.

42. McFadden D, Train K. Mixed MNL models for discrete response. J Appl Econom. 2000;15(5):447-70.
43. Fiebig DG, Keane MP, Louviere J, Wasi N. The Generalized Multinomial Logit Model: Accounting for Scale and Coefficient Heterogeneity. Market Sci. 2010;29(3):393-421.
44. Akaike H. New Look at Statistical-Model Identification. Ieee T Automat Contr. 1974;Ac19(6):716-23.
45. Redwood S, Gill PS. Under-representation of minority ethnic groups in research--call for action. The British journal of general practice : the journal of the Royal College of General Practitioners. 2013;63(612):342-3.
46. Hoonakker P, Carayon P. Questionnaire Survey Nonresponse: A Comparison of Postal Mail and Internet Surveys. International Journal of Human-Computer Interaction. 2009;25(5):348-73.
47. Watson V, Becker F, de Bekker-Grob E. Discrete Choice Experiment Response Rates: A Meta-analysis. Health Econ. 2016.
48. Fan WM, Yan Z. Factors affecting response rates of the web survey: A systematic review. Comput Hum Behav. 2010;26(2):132-9.
49. Morecroft C, Cantrill J, Tully MP. Individual patient's preferences for hypertension management: a Q-methodological approach. Patient Education & Counseling. 2006;61(3):354-62.
50. McManus RJ, Mant J, Bray EP, Holder R, Jones MI, Greenfield S, et al. Telemonitoring and self-management in the control of hypertension (TASMINH2): a randomised controlled trial. Lancet. 2010;376(9736):163-72.
51. Levin J, Milgrom P. Introduction to choice theory. In: Stanford, editor. http://web.stanford.edu/~jdlevin/Econ%20202/Choice%20Theory.pdf 2004.
52. McAteer A, Yi D, Watson V, Norwood P, Ryan M, Hannaford PC, et al. Exploring preferences for symptom management in primary care: a discrete choice experiment using a questionnaire survey. The British journal of general practice : the journal of the Royal College of General Practitioners. 2015;65(636):e478-88.
53. Mark TL, Swait J. Using stated preference and revealed preference modeling to evaluate prescribing decisions. Health Econ. 2004;13(6):563-73.
54. Ryan M, Watson V. Comparing welfare estimates from payment card contingent valuation and discrete choice experiments. Health Econ. 2009;18(4):389-401.
55. Kesternich I, Heiss F, McFadden D, Winter J. Suit the action to the word, the word to the action: Hypothetical choices and real decisions in Medicare Part D. J Health Econ. 2013;32(6):1313-24.
56. Lancsar E, Swait J. Reconceptualising the external validity of discrete choice experiments. Pharmacoeconomics. 2014;32(10):951-65.

CHAPTER SEVEN

DISCUSSION AND CONCLUSIONS

7.1 CHAPTER OVERVIEW

The final thesis chapter presents discussion and conclusions. The chapter begins with the rationale for the approach used in this thesis, with a summary of the evidence that was available for SMBP in 2013, and discussion of the methodological approach used.

The findings of the five studies in this thesis are summarised and then discussed in relation to one another, before the implications for practice and suggestions for future research. Finally the conclusions of the thesis are presented.

7.2 RATIONALE FOR RESEARCH

7.2.1 Why self-monitoring blood pressure?

Hypertension is the single biggest contributor to global burden of disease and global mortality.(1) The number of people affected by hypertension is expected to rise in all regions in the world by 2025.(2) Section 1.3 introduced the 'rule of halves' to describe how large proportions of individuals with hypertension remain undiagnosed, and how often treated patients remain uncontrolled.

This thesis has focussed on the role of SMBP in improving BP control in those patients who have already been diagnosed with hypertension and are on treatment. The most recently available data from the Health Survey for England (2014) estimated that only 63% of those patients on treatment had controlled BP (BP <140/90mmHg).(3) In 2016, Neil Poulter, president of the International Society of Hypertension, stated (4):

> *"When only one-third of patients* [globally] *being treated are being controlled, that's nonsense. We must do better."*

Poulter also discussed the "huge gains" that can be made simply by implementing what we already know about the determinants of hypertension and the range of effective treatments. There is a significant body of evidence for treatments/interventions that work, however translating those findings into 'real-world' settings has proved problematic.(5)

SMBP is an attractive intervention for improving the management of hypertension due to its potential to be used across all hypertensive patients regardless of age, stage, baseline cardiovascular risk, treatment type, treatment target, etc. If SMBP could contribute to even small benefits in a large proportion of individuals with hypertension, these changes could potentially have a significant impact at a population level.

When research for this thesis began in late 2013 there was already a wealth of information regarding the effectiveness of SMBP in the management of hypertension (introduced in section 1.8): for example in 2013 a systematic review and meta-analysis was published that contained 52 prospective comparative studies of SMBP versus usual care.(6)

The most recent NICE (2011) guidelines for hypertension made six recommendations for further research to improve future guidance and patient care.(7) The first recommendation was to answer:

> *"In adults with primary hypertension, does the use of out-of-office measurement improve response to treatment?"*

It was noted that there were very few data regarding the utility of SMBP as a means of monitoring BP control or as an indicator of clinical outcome in treated hypertension. Similarly the European Society for Hypertension/European Society for Cardiology (ESH/ESC) guidelines for the management of hypertension recognised the following gap in evidence (8):

> *"Do treatment strategies based on control of out-of-office BP provide an advantage (reduced clinical morbidity and mortality, fewer drugs, fewer side-effects) over strategies based on conventional (office) BP control?"*

Given the quantity of evidence available from clinical trials, the question remained as to why this was not sufficient to impact guidelines, and what further information might be required. The aims of this thesis, as stated in Chapter 1, were to investigate the role of SMBP in the management of hypertension to better understand: patient and clinician attitudes to SMBP; what behaviour change SMBP targets in patients to bring about better BP outcomes; to what extent SMBP is utilised as part of routine hypertension management in the UK; and to understand patient preferences for hypertension management in light of other effective models of care. These aims aligned with those of NICE and ESH/ESH, including a

combination of synthesising previous research and conducting novel research, to fill gaps in the evidence base.

The next section presents the evidence for SMBP that was available when this research began in 2013, followed by discussion of why the evidence from trials did not provide sufficient evidence to inform guidelines, and why the results of RCTs can have limited generalisability.

7.2.2 What evidence was available in 2013?

A common maxim in process improvement is:

> *"That which is measured improves. That which is measured and reported improves exponentially."*

Evidence from trials of SMBP broadly agree with this statement: patients who self-monitor have lower BP than those who do not, and when the results of SMBP are reported to patients' clinicians the benefits are magnified.(6) However this is only part of the story, as there remains uncertainty as to the best way to utilise SMBP.

One of the main reasons for uncertainty for decision makers was the high level of heterogeneity in the results of trials: for example in one meta-analysis the effect of SMBP on office systolic BP ranged from -25.6mmHg (-41.8 to -9.4) to +5.0mmHg (-6.1 to +16.1), (I^2 = 71.9%, $p<0.001$).(9) This heterogeneity made it difficult for policy makers to set guidelines for practice and for clinicians wanting to make decisions about whether to recommend SMBP to patients.

Heterogeneity in trial results is linked to a number of factors including:

- Clinical heterogeneity – variability in the participants, the types or timing of outcome measurements, and intervention characteristics.
- Methodological heterogeneity – variability in the trial design and quality
- Statistical heterogeneity – variability in summary treatment effects between trials

In the largest review of SMBP to date, heterogeneity was reported at all of these levels, and potential reasons were noted in the limitations (6):

> *"Despite the ostensible similarity in research questions across studies, there was a large degree of variability in SMBP monitoring protocols, transmission of and response to BP data, and types of additional support. Additional support varied in the primary intents, ancillary equipment, educational materials and encounters, qualification and effort of personnel, and algorithms for medication adjustments."*

As noted in section 1.9, development of SMBP has not followed the traditional linear trajectory of testing of simple medical interventions, where mechanism of action, method of delivery etc. are evaluated before "real-world" trials. Also, unlike novel pharmacological treatments, SMBP was already widely available to patients before understanding fully how it works best; with the proportion of hypertensive patients using SMBP steadily rising (31% of hypertensives in UK in 2011).(10) This afforded the opportunity for investigation of how patients and clinicians manage data from SMBP as part of everyday practice, with the lessons learned complementing those of RCTs to provide evidence to support future guidance.

7.2.3 Why trial results are not sufficient for evaluation of SMBP

Taken at face-value an evaluation of the use of SMBP in the management of hypertension should be reasonably straightforward, based primarily on evidence of effectiveness, along with assessment of efficacy, cost-effectiveness and acceptability to both patients and healthcare professionals.

Evidence from controlled trials, as synthesised in systematic reviews and individual patient data meta analyses (IPD –where individual level data from a number of studies is combined), can tell us a great deal about whether an intervention works and for whom, but trials often poorly represent everyday practice and populations.(11, 12) When designing RCTs, the focus is often on internal validity, ensuring the design and conduct minimise bias. However to be clinically relevant, trials must also be externally valid, or "reasonably likely to be replicated when applied to a definable group of patients in a particular clinical setting".(13) A study in the UK investigating how centres were selected for participation in multi-centre RCTs, found that site diversity or representativeness was an explicit factor in only 31% of cases.(14) It is also the case that participants in trials are rarely selected to provide external validity, and often poorly represent those faced by clinicians in everyday practice.(15) If participants and centres are not selected with external validity in mind, this leads to difficulties in applying the results of research. The need for purchasers and providers of health care to use evidence from trials in policy decisions has, in the past decade or so, increased the focus on pragmatic trials where participants more closely resemble those seen in routine care.(16)

Section 1.9 introduced the need and rationale for moving beyond solely evidence of effectiveness in the evaluation of SMBP. The next section contains discussion of the complex nature of SMBP along with methods for evaluating complex interventions, before describing how this influenced the studies included in this thesis.

7.2.4 Evaluating complex interventions and the role of Realism

It was apparent early on in this research that SMBP was not a simple intervention, and comparison of outcomes in patients who self-monitor versus those that do not only tells part of the story. The Medical Research Council (MRC) developed guidelines for the development and evaluation of complex interventions in 2000 with an update in 2008. In these guidelines complex interventions were described as those that contain several interacting components, and factors that complex interventions have in common were listed (17):

1. Number of, and interactions between, components within the experimental and control interventions
2. Number and difficulty of behaviours required by those delivering or receiving the intervention
3. Number of groups or organisational levels targeted by the intervention
4. Number and variability of outcomes
5. Degree of flexibility or tailoring of the intervention permitted

For SMBP key areas for clarification lay in the second and third points above: SMBP can potentially target a number of different behaviours in both patients and clinicians. Broadly SMBP can impact change at three different levels:

A. Providing better, more accurate information for healthcare professionals to guide practice.

B. Helping patients choose more healthy behaviours

C. "Fundamental transformation of the patient care-giver relationship into a collaborative partnership"(18)

Understanding the impact that SMBP has on each of these areas is important to optimising its use as part of everyday care. At the beginning of this thesis the focus was on patient behaviour change in response to the results of self-monitoring, however the focus soon shifted to recognise the second two points.

According to the MRC guidelines, complex interventions present a number of problems for evaluators relating to the difficulty standardising the design and delivery of interventions, their sensitivity to features of local context, and the complexity of causal chains linking intervention with outcome.

With the evidence that SMBP can have positive outcomes it was important to understand how to use this evidence to translate into practice. This required an approach that was sensitive to the complexity of SMBP, but allowed overall conclusions to be made. The MRC provided the following two key questions for evaluation:

> *"A key question […] is about practical effectiveness – whether the intervention works in everyday practice – in which case it is important to understand the whole range of effects, how they vary among recipients of the intervention, between sites, over time, etc., and the causes of that variation."*

> *"A second key question […] is how the intervention works, in other words, what are the active ingredients within the intervention and how are they exerting their effect? Only by addressing this kind of question can we build a cumulative understanding of causal mechanisms, design more effective interventions and apply them appropriately across group and setting."*

The importance of understanding context and providing mechanistic evidence is also at the heart of Realist evaluation as described by Pawson and Tilley. The Realist approach can be summarised in the following statement (19, 20):

> *"Finding out what works for whom, in what circumstances and in what respects and how."*

Realist evaluation (or Realistic evaluation) presents a model of theory driven evaluation that aims to find what outcomes are impacted by interventions and also how they are produced, and what is significant about the varying conditions in which the interventions take place. Realist evaluation stresses four key linked concepts for explaining and understanding

programmes: mechanism, context, outcome pattern, and "context-mechanism-outcome pattern configuration".(20)

Both the MRC guideline and the Realist approach provide frameworks by which to evaluate complex interventions or programmes. The approach used in this thesis was influenced by both, but was not confined to either. The aim was to fill in gaps in evidence to provide a greater understanding of how SMBP may work, how it is currently being used, and how it could best be integrated into everyday practice. My focus was on the use of SMBP in the UK, however evidence from further afield was included in the evidence synthesis studies. A number of research methods were chosen to answer specific research questions to fill gaps in the evidence base for SMBP including: systematic reviews, qualitative interviews and online surveys.

The following sections (7.3.1-3) discuss the findings from the research studies in relation to one another, and the extant literature, followed by a restatement of the principal findings in 7.3.4. The implications of the findings for clinical practice and future research are then presented in sections 7.4 and 7.5.

7.3 FINDINGS IN RELATION TO THE LITERATURE

A table summarising the findings of each chapter is shown in Appendix 6.1.

7.3.1 How does SMBP work?

> *"Self-monitoring can be seen in two ways: a technique or tool that helps patients choose healthy behaviours, and a fundamental transformation of the patient-caregiver relationship into a collaborative partnership."* (21)

Understanding how SMBP 'works' is key to optimising its use in everyday practice. Evidence from the review of qualitative studies in Chapter 3 showed that SMBP influenced behaviour change in both patients and clinicians, both independently and collaboratively. Twelve studies were included in thematic synthesis, and three broad analytical themes were presented (use and interpretation of SMBP; balance between SMBP being convenient/reassuring contrasted with the potential to cause anxiety/uncertainty; patient empowerment, autonomy and efficacy and impact of SMBP on patient-clinician alliance). Patients used SMBP to track changes in response to medication taking and lifestyle change, and SMBP provided more accurate and timely information for clinicians on which to base treatment decisions. SMBP was also shown to facilitate the interaction between patients and clinicians.

The systematic review of RCTs reported in Chapter 2 attempted to determine to what extent SMBP brought about different patient behaviour changes. The review incorporated the results of twenty-eight RCTs: twenty-five reported medication adherence and eight reported lifestyle change outcomes. In a random-effects meta-analysis SMBP was associated with a small but significant increase in medication adherence (SMD=0.21 (0.08 to 0.34)), however the quality of evidence according to GRADE was assessed as low, meaning that the true effect may differ significantly from the estimate. That SMBP can lead to better medication

adherence is an important finding given the large number of patients with hypertension who do not take their medication correctly, or who do not take their medication at all (introduced in section 2.2.2). Any intervention that has the potential to improve adherence could have a significant effect at a population level. According to the WHO (22):

> *"Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvements in specific medical treatments."*

There was a paucity of evidence for the effect of SMBP on lifestyle change, and while this could be explained by a number of methodological issues such as poor measurement of outcomes, publication bias, etc., it is likely given the quantity of studies investigating SMBP that if there is an effect, it is likely to be small. It could equally be the case that there is limited evidence in support of an effect of SMBP on lifestyle factors because there is no effect, however due to the potential importance of lifestyle change, this still warrants further study. In order for patients to be able to make positive lifestyle change relies on them having specific information/advice, and this is discussed further in 7.3.3.

The final piece of the puzzle for how SMBP works is evidence for its effect on clinician behaviour. A systematic review published in 2011 showed that SMBP was associated with more frequent anti-hypertensive medication reductions, and with less therapeutic inertia defined as unchanged medication despite elevated BP.(23)

With a better knowledge of how SMBP works, it was important to then investigate whether these factors are translated into everyday practice, and this is discussed in the following section.

7.3.2 Implementation of SMBP

> *"Embedded in the everyday practices of patients, self-measurement devices sometimes become the means for the development of autonomous self-care practices even if this redefines their interdependency with some healthcare professionals; at other times they instead lead to the development of unsafe and frantic practices that complicate rather than ease the collective management of disease."* (24)

Patients need to be knowledgeable and engaged in order to be able to bring about positive change.(25) In Chapter 5, eleven patients from two practices in Oxfordshire were interviewed about their experiences of SMBP. The focus was on how SMBP use fitted into everyday life, and to what extent SMBP was used to facilitate discussion with patient's GPs. Interviews were analysed using framework analysis, which included codes exploring components of the CCM, as well as codes describing individual context and experiences.

Patients in the qualitative review (Chapter 3) were predominantly positive about using SMBP, with clinicians more reserved due to concerns about the potential for patients to become anxious. In contrast, those patients interviewed in Chapter 5 were happy to use SMBP to provide information for clinical decisions, but felt unprepared to make positive changes to their lifestyle, at odds with the first statement in quote at the beginning of this section. This discrepancy may be explained by the different settings: those in the review were often involved in trials of SMBP, and may have been given specific advice about how to use SMBP to track changes to lifestyle. Patients interviewed in Chapter 5 were using SMBP in the 'real-world', and did not report being given specific advice about how they could enact change. These findings agree with the results from trials that show that SMBP works best with additional support. An analysis of individual patient data (unpublished) from trials of SMBP (up to 10,000 patients) has been undertaken to better understand the between trial heterogeneity, as well as the identification of the characteristics of both the intervention and individuals most likely to benefit from SMBP [personal communication J

Sheppard and K Tucker 2016]. This study was powered to compare the effectiveness of SMBP in different subgroups which has not previously been possible.(26) The study has shown that SMBP alone has no effect on BP at 12 months (-1.0 mmHg (95%CI -3.3 to 1.2)), but was effective when combined with additional support (-6.1mmHg (95%CI -9.0 to -3.2)).

A distinction should perhaps be made between self-measuring and self-monitoring BP and for the purposes of this thesis this is important: patients interviewed in Chapter 5 were happy to self-measure their BP for the purpose of providing the results to their GP; while self-monitoring can be considered to imply a more active involvement in interpreting results and then acting on them through changes in health behaviours, such as medication adherence for instance, or through interaction with GP/pharmacist. This latter form of intervention was not necessarily welcomed by patients in Chapter 5. However, this does open the possibility of a model comprising asking patients to self-measure solely to provide results for their next clinic visit as the first stage to involving patients more in their care, and when/if they become comfortable with measurement and interpreting results, they could then be encouraged to become more autonomous by self-monitoring BP in relation to specific lifestyle and/or medication change advice from their GP.

Interventions where patients have been asked to self-measure BP, with interpretation and treatment decision the responsibility of others, as is the case with telemonitoring, have proven to be effective and well-liked by patients.(27) Patients have been shown to be compliant with telemonitoring regardless of age or socioeconomic status.(28) Offering patients the choice of new models of care is discussed further in 7.3.4.

Self-management is likely to be reviewed as a possible intervention by the new update of NICE guidelines in 2016-17. The success of SMBP as part of self-management is likely to be dependent on the quality of information available to patients to help them make those

changes. Understanding patient circumstance and priorities in order to provide tailored advice as part of shared decision making has been shown to lead to improved patient outcomes.(29) A study that investigated why hypertensive patients were not adherent with treatment showed that lack of tailored information was key.(30) The following quotes from two patients demonstrate what kind of information they wanted, and this could explain why patients in the Chapter 5 did not feel able to act on the results of SMBP:

> *"They give you advice: stop smoking and take some physical exercise, but they don't tell you, say, how to go walking or if you can ride a bicycle or not."*

> *"They've told me hundreds of times that I have to lose weight and I just don't know how because they never explain how to do it."*

A barrier to GPs recommending SMBP to patients could be their concern that patients become anxious or even neurotic if asked to self-monitor BP, and this was noted in both chapter 3 and 4 (qualitative review and survey). GPs should be encouraged that the evidence suggests that patients are happy to, and often enjoy self-monitoring, especially when their BP is well controlled. Patients were only seen to be anxious when their BP was high due to fears of an increased risk of stroke, rather than anxiety towards monitoring itself. Although there was evidence of anxiety about the results of SMBP, patients included in the studies in this thesis did not "develop unsafe and frantic practices" described in the quote at the beginning of this section.

Chapter 4 presents the results of a cross-sectional survey of UK GPs investigating current practice with regard to SMBP. Questionnaires were completed by 300 GPs (94% of those who started). The survey found that 58% of GPs used SMBP in the diagnosis of hypertension, and 84% in the ongoing management of patients with hypertension. GPs reported varying protocols and treatment targets for SMBP, perhaps reflecting the heterogeneity in the results of trials, and the lack of specific guidance. Patients in Chapter

5 reported that they were requested to measure their BP twice daily for the week before their next appointment following the protocol suggested by NICE for diagnosis, and this was consistent with what GPs reported in the survey. This seems a sensible idea if the intention is to obtain results for treatment decisions. If SMBP is to be used by patients autonomously as part of self-management then they would need to monitor more frequently. It would however be important to find the right balance between monitoring sufficiently frequently to provide useable information, while at the same time not so intensively as to be intrusive or to cause anxiety. A recent qualitative study has shown that patients liked to follow structured schedules while allowing sufficient flexibility for individual routine, and preferred shorter schedules (three day) to longer (7 days).(31) The same study concluded that:

> *"Given there is no clear consensus on the optimal approach to home monitoring, it appears that this then makes it harder for HCPs to educate their patients."*

In summary, optimising SMBP use in everyday care requires GPs and patients to acknowledge the specific intentions for monitoring: either for GPs to inform treatment decisions, or to promote self-care. Protocols for measurement should be flexible to the needs of patients and clinicians. GPs should be aware that if they promote SMBP and lifestyle change, then this should be followed up with tailored advice, targets and action plans.

Implementation of SMBP in light of the evidence from this thesis are presented in 7.4, along with areas where additional support is needed. The impact of patient choice on the method of hypertension management is discussed in the following section.

7.3.3 Patient choice for hypertension management

Providing patients with greater choice in how their hypertension is managed could potentially lead to improvements in patient satisfaction and outcomes. Beyond current usual care for hypertension (BP measured and treatment decision made by GP with visits every 6/12 months), self-management, nurse management, pharmacist management have all been proven to be effective (introduced in 6.3.2.1).

Chapter 6 presented data from a discrete choice experiment where patients were asked to choose between different management scenarios. The experiment was completed by 167 participants. The choices presented included trade-offs in terms of frequency of BP measurement, reduction in risk as a result of treatment, model of care and cost. This kind of choice scenario is thought to closely resemble 'real-world' decisions. Participants were willing to consider new management options, and most preferred pharmacist management, perhaps representing their greater convenience. GP management which is the norm in the UK was the least preferred option. Further investigation will hopefully illuminate exactly what it is about GP management that patients least preferred, and why pharmacy was most popular.

Pharmacist management for hypertension in the UK could be a fruitful avenue for future service provision, given the proven effectiveness in RCTs and that patients prefer this option. General practice is increasingly under pressure from increased work-load and financial constraints, and perhaps for this reason is facing a GP recruitment crisis.(32) NHS England recently commissioned a three year pilot integrating clinical pharmacists into general practice teams. Clinical pharmacists will provide management for long-term conditions, advice for those on multiple medications and better access to health checks.

> *"There should be greater involvement of clinical pharmacists, including prescribing pharmacists, in the management of people on long-term medication. This role is best carried out in the GP practice in order to allow full access to the patient record and to maximise interaction between the pharmacist and other clinical staff in the practice."*(33)

Provision of a range of treatment options and allowing patients to choose may raise issues for continuity of care. Enhancing communication between healthcare providers and improving information systems are both key to the Chronic Care Model, and as such would need to be addressed before offering broader services to patients.

Patient choices in the discrete choice experiment appeared to be driven to a large extent by reducing the risk of stroke or heart attack, with patients preferring scenarios with better risk outcome. Those interviewed in Chapter 5 were asked about their interpretation of risk in relation to BP, and many overestimated the risks. Patients perceived risk as a binary, where controlled BP eliminated risk, and uncontrolled BP likely to result in a stroke/heart attack, rather than thinking about overall CVD risk as a continuum based on a number of risk factors including BP. Improving communication, and patient understanding of risk may be crucial when providing new management options, as patients will want to be confident that the options do not have significant trade-offs in risk.

7.4 STRENGTHS AND LIMITATIONS

The strengths and limitations of each method used in this thesis have been discussed in their respective chapters. In this section the strengths and limitations of the overall approach are discussed.

The use of a different research methods from different paradigms presented a number of challenges, however these were mitigated by the opportunity to synthesise a range of evidence for SMBP use in different contexts, and from the perspective of both patients and clinicians. As such the findings of the individual studies have a synergistic effect when combined.

A pragmatic mixed methods approach was used in this thesis. Pragmatism has been described as having no loyalty to a particular system or philosophy, and therefore can borrow from a range of others. As Morgan (2007) stated:

> *"A more pragmatic approach examining what people can do with the knowledge they produce and not on abstract arguments about the possibility or impossibility of generalisability should be favoured."*

It has been proposed that mixed methods research is one of the three major paradigms (qualitative, quantitative and mixed methods).(34) There are various definitions for mixed methods research, however for the purpose of this thesis the definition proposed by Caracelli provides the best fit (34):

> *"A mixed method study is one that planfully juxtaposes or combines methods of different types (qualitative and quantitative) to provide a more elaborated understanding of the phenomenon of interest (including its context) and, as well, to gain greater confidence in the conclusions generated by the evaluation study."*

The aim of mixed method research is not to replace either qualitative or quantitative approaches, but to draw from the strengths and minimise the weaknesses of both across research studies. Onwuegbuzie (2006) commented (35):

> *"Because of its logical and intuitive appeal, providing a bridge between the qualitative and quantitative paradigms, an increasing number of researchers are utilising mixed methods research to undertake their studies."*

The aim was to complement the evidence already available in RCTs, providing evidence from everyday settings, with patients and clinicians who were already using SMBP. It was hoped that this approach would provide information to aid translation of the success of SMBP from trials into 'real-world' settings. Knowing that an intervention works in RCTs does not necessarily help patients or clinicians know whether it would work for them. This thesis has shown that patients and clinicians are generally enthusiastic about SMBP, and some specific recommendations have been made to improve implementation.

Particular focus was placed on evaluating SMBP from both patient and clinician perspectives as both parties are vital to successful implementation. Research should wherever possible focus on the priorities of patients and clinicians rather than those of the researcher. As such the research questions were aligned with decisions that patients, clinicians and policy makers face. The approach used was iterative, and each study built upon the results of those before in, with the focus on gaps in the evidence or areas of uncertainty. A novel method was used in the final results chapter to investigate how patients make choices between packages of care, and there is scope to use this in future to highlight those factors that are important to patients and likely to impact whether they would choose an intervention/service or not.

The approach was iterative, with each study building upon the results of those before. In hindsight it would have been beneficial to have conducted the qualitative review before the

quantitative review, as the role of SMBP in overcoming clinical inertia could have been explored in parallel. Tying together the results of multiple methods can be a challenge, and this thesis was informed by, but not limited to, methods proposed by MRC complex interventions framework and the Realist approach.

Difficulties can arise when in combining the results of mixed methods research, as the data produced by different methods are not commensurate. Different study designs respond to different questions, and therefore have different impact (i.e. generalisability of intervention effect or in-depth description of patient experience). As Sandelowski noted (36):

> *"Purists view qualitative and quantitative research as two wholly different species of inquiry, the chasm between qualitative and quantitative modes of inquiry is deep enough to make it difficult or even impossible to cross it without endangering the imperatives and integrity of one or both domains of inquiry."*

In order to aid the interpretation and evaluation of research evidence, hierarchies have been developed to rank research findings according to their validity.(37, 38) However, most have focused on the evaluation of the effectiveness of interventions. When evaluations of healthcare address appropriateness or feasibility, these hierarchies are inadequate.(39) Hierarchies of evidence have also been proposed for qualitative evidence, such as that proposed by Daly (2007) based on the "capacity to provide evidence for practice or policy."(37) Whether quantitative or qualitative methods are used, it has been argued that study design alone is insufficient as a surrogate for risk of bias, and other factors should be used in decision making. For example, the approach proposed by the GRADE working group (used in Chapter 2) developed a framework where decisions about the certainty of evidence is based on limitations of study design as well as indirectness of evidence and imprecision of results.

Throughout this thesis the intention has been to provide evidence for decision makers, be it policy makers, healthcare professionals or patients. Research methods were chosen that were the best for the specific research questions, and while each has its own strengths and limitations, all contribute important information to the thesis. As such, rather than challenging one another, the results are complementary.

7.5 PERSONAL REFLECTIONS ON METHODOLOGICAL APPROACH

Conducting research for a DPhil thesis presented a number of challenges and opportunities. There is a tension between choosing the research methods that best fit the research questions, at the same time recognising the unique opportunity to gain experience in a variety of novel methods while receiving supervision from experts in their field.

The two most rewarding components of this thesis were also, for different reasons, the most challenging. There were difficulties in recruiting a broad range of participants to the interview study (Chapter 5), which limited the scope of the findings. While attempts were made using different strategies, the sample was relatively homogenous, both in terms of demographics and experiences of SMBP. With more time and finances, it may have been possible to recruit a better sample

From a personal perspective the sample did not diminish the skills that I acquired through interviewing participants. I particularly enjoyed gaining more experience and developing my interview techniques throughout the study, and the later interviews as a result were better than those conducted early on. The participants were engaged with the topic of SMBP, and it was a pleasure to meet them. Health research can often be conducted away from those

whom it is hoped will benefit from the research, so it was insightful to talk to patients who self-monitor, and this provided greater confidence in the findings of the thesis.

The DCE also presented challenges: as it was based on the evidence collected in the earlier stages of the DPhil it could not be developed until the final year. The limited time meant that DCE was designed as a feasibility study, and as with the interviews this limited the scope of the findings. Learning a new, and relatively niche methodology, from scratch was difficult at times, particularly the econometrics, however this is the chapter of which I am most proud.

7.6 IMPLICATIONS FOR PRACTICE

This thesis has highlighted a number of areas where suggestions for clinical practice as well as recommendations for future research, and the priorities are presented here:

- In UK general practice the communication of results of SMBP is currently limited to in-person during consultation. These results could be transmitted to patients' GPs via text, email or by phoning in. For controlled patients who are happy to use SMBP this could have the potential to reduce the need for face-to-face consultation. There is also the need to improve clinical information systems to better integrate the results of SMBP.

- Both parties, clinicians and patients, need to recognise the distinction between self-measurement of BP for clinical decision making or as part of self-management. If the former, clinicians can discuss plans for measurement protocols with their patients, recognising the need for individual flexibility. If the latter, specific information tailored to the individual patient is needed.

- Patients need to be informed/educated how to use SMBP, and how to make specific changes to their lifestyle to impact change. There are a number of potential options for this: easy-to-use decision tools, mobile tracking apps, participation in hypertension patient associations.

- Commissioners should consider providing new models of care for hypertension in light of their effectiveness and that patients welcome choice.

7.7 SUGGESTIONS FOR FUTURE RESEARCH

- There is a need to move beyond trials comparing SMBP versus usual care, and to reach consensus as to the best protocols for BP measurement. There is little added value from testing a unique package of measurement protocol plus additional support. Better standardization is needed regarding how patients use SMBP and the types of additional support that are employed. To reduce heterogeneity researchers should consider which already investigated method of SMBP and additional support they believe is most promising and implement that in their population of interest.

- Research should explore the information needs of patients who wish to use SMBP as part of self-management. What specific information patients need to be motivated (empowered) to make change for the better (self-efficacy) warrants investigation. Also investigation in how patients want the information to be provided: face-to-face, paper decision aids, on-line information.

- Patients were shown to prefer pharmacist management to GP management. Further investigation is required to understand why this was the case. Similar methodology should also be used to understand which models of care clinicians prefer.

- In this thesis attempts were made to contact patients who self-monitor without informing their GP. This is likely to be a large number of patients and it is of interest to find out what these patients currently do with the results of SMBP. If there are barriers to talking to their GP about SMBP, it would be useful to know if they would consider the other models for care discussed in this thesis.

7.8 CONCLUSION

This thesis has added to the evidence base for SMBP, through contributing evidence to support data from controlled trials, assessing current practice in the UK from clinician and patient perspectives, and investigating patient decision making regarding hypertension management.

Self-monitoring is associated with better medication adherence, which could have significant impact at a population level given the high proportion of non-adherent hypertensive patients.

Use of SMBP should be seen as a continuum from being used solely to inform clinical decisions, through facilitating interaction between patients and clinicians, to empowering patients to be autonomous and increasing their self-efficacy.

SMBP is most effective when patients have the knowledge and skills to make improvements in their lifestyle, and this has been shown in clinical trials and through qualitative investigation.

Clinicians recognise the potential benefits of SMBP, but are concerned that patients may become burdened. Clinicians should feel encouraged that patients are supportive of self-monitoring, but they must ensure that patients who wish to self-manage are equipped with

the skills to do so. Lack of facility to make positive change may lead some patients to feeling disempowered and clinicians need to be cognisant of this fact.

7.9 REFERENCES

1. Lim SS, Vos T, Flaxman AD, Danaei G, Shibuya K, Adair-Rohani H, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet. 2012;380(9859):2224-60.
2. Kearney PM, Whelton M, Reynolds K, Muntner P, Whelton PK, He J. Global burden of hypertension: analysis of worldwide data. Lancet. 2005;365(9455):217-23.
3. Centre HaSCI. Health Survey for England, 2014: Trend tables 2015 [cited 2016]. Available from: http://content.digital.nhs.uk/.
4. Watts G. Neil Poulter: upping the pressure on hypertension. Lancet. 2016.
5. Glasgow RE, Lichtenstein E, Marcus AC. Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. Am J Public Health. 2003;93(8):1261-7.
6. Uhlig K, Patel K, Ip S, Kitsios GD, Balk EM. Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. Annals of Internal Medicine. 2013;159(3):185-94.
7. NICE. The Clinical Management of Primary Hypertension in Adults: Clinical Guideline 137. 2011.
8. Mancia G, Fagard R, Narkiewicz K, Redon J, Zanchetti A, Bohm M, et al. 2013 ESH/ESC Guidelines for the management of arterial hypertension: the Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). J Hypertens. 2013;31(7):1281-357.
9. 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):371-86.
10. Baral-Grant S, Haque MS, Nouwen A, Greenfield SM, McManus RJ. Self-Monitoring of Blood Pressure in Hypertension: A UK Primary Care Survey. International Journal of Hypertension. 2012;2012:582068.
11. Mant J, McManus RJ, Hare R. Applicability to primary care of national clinical guidelines on blood pressure lowering for people with stroke: cross sectional study. BMJ. 2006;332(7542):635-7.
12. Kennedy-Martin T, Curtis S, Faries D, Robinson S, Johnston J. A literature review on the representativeness of randomized controlled trial samples and implications for the external validity of trial results. Trials. 2015;16:495.
13. Rothwell PM. External validity of randomised controlled trials: "to whom do the results of this trial apply?". Lancet. 2005;365(9453):82-93.
14. Gheorghe A, Roberts TE, Ives JC, Fletcher BR, Calvert M. Centre selection for clinical trials and the generalisability of results: a mixed methods study. PLoS One. 2013;8(2):e56560.
15. Jones R, Jones RO, McCowan C, Montgomery AA, Fahey T. The external validity of published randomized controlled trials in primary care. BMC Fam Pract. 2009;10:5.
16. Eldridge S. Pragmatic trials in primary health care: what, when and how? Fam Pract. 2010;27(6):591-2.
17. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.
18. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. JAMA. 2002;288(14):1775-9.
19. Pawson R. Evidence-based policy : a realist perspective. London: Sage; 2006. xi, 196 p. p.
20. Pawson R, Tilley N. Realistic evaluation. London: Sage; 1997. xvii, 235 p. p.

21. Bodenheimer T. Helping patients improve their health-related behaviors: what system changes do we need? Dis Manag. 2005;8(5):319-30.
22. World Health Organization. Adherence to Long-term Therapies project., World Health Organization. Department of Noncommunicable Disease Management. Adherence to long-term therapies : evidence for action. Geneva: World Health Organization; 2003. xv, 198 p. p.
23. Agarwal R, Bills JE, Hecht TJW, 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.
24. Storni C. Multiple Forms of Appropriation in Self-Monitoring Technology: Reflections on the Role of Evaluation in Future Self-Care. International Journal of Human-Computer Interaction. 2010;26(5):537-61.
25. Hibbard JH, Greene J. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. Health Aff (Millwood). 2013;32(2):207-14.
26. Tucker KL, Sheppard JP, Stevens R, Bosworth HB, Bove A, Bray EP, et al. Individual patient data meta-analysis of self-monitoring of blood pressure (BP-SMART): a protocol. BMJ Open. 2015;5(9):e008532.
27. Zullig LL, Melnyk SD, Goldstein K, Shaw RJ, Bosworth HB. The role of home blood pressure telemonitoring in managing hypertensive populations. Curr Hypertens Rep. 2013;15(4):346-55.
28. Pare G, Jaana M, Sicotte C. Systematic review of home telemonitoring for chronic diseases: the evidence base. Journal of the American Medical Informatics Association. 2007;14(3):269-77.
29. Joosten EA, DeFuentes-Merillas L, de Weert GH, Sensky T, van der Staak CP, de Jong CA. Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. Psychother Psychosom. 2008;77(4):219-26.
30. Gascon JJ, Sanchez-Ortuno M, Llor B, Skidmore D, Saturno PJ, Treatment Compliance in Hypertension Study G. Why hypertensive patients do not comply with the treatment: results from a qualitative study. Fam Pract. 2004;21(2):125-30.
31. Grant S, Hodgkinson JA, Milner SL, Martin U, Tompson A, Hobbs FR, et al. Patients' and clinicians' views on the optimum schedules for self-monitoring of blood pressure: a qualitative focus group and interview study. The British journal of general practice : the journal of the Royal College of General Practitioners. 2016;66(652):e819-e30.
32. Baird B, Charles A, Honeyman M, Maguire D, Das P. Understanding pressures in general practice. London: King's Fund; 2016. 97 pages p.
33. Commission PCW. The future of primary care: creating teams for tomorrow. 2015.
34. Johnson RB, Onwuegbuzie AJ, Turner LA. Toward a definition of mixed methods research. Journal of Mixed Methods Research. 2007;1(2):112-33.
35. Onwuegbuzie AJ, Leech NL. Linking research questions to mixed methods data analysis procedures. The Qualitative Report. 2006;11(3):474-98.
36. Sandelowski M, Voils CI, Barroso J. Defining and Designing Mixed Research Synthesis Studies. Res Sch. 2006;13(1):29.
37. Daly J, Willis K, Small R, Green J, Welch N, Kealy M, et al. A hierarchy of evidence for assessing qualitative health research. J Clin Epidemiol. 2007;60(1):43-9.

PUBLICATIONS RESULTING FROM THESIS

Chapter 2

ORIGINAL ARTICLE

The Effect of Self-Monitoring of Blood Pressure on Medication Adherence and Lifestyle Factors: A Systematic Review and Meta-Analysis

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BACKGROUND
Self-monitoring of blood pressure (SMBP) can contribute to reduced blood pressure in people with hypertension. Potential mediators include increased medication, improved adherence, and changes in lifestyle factors including dietary change and increased physical activity. The objective of this review was to determine the effect of SMBP on medication adherence, medication persistence, and lifestyle factors in people with hypertension.

METHODS
Electronic bibliographic databases were searched through February 2014 to identify randomized controlled trials that compared SMBP to control/usual care in ambulatory hypertensive patients and reported medication or nonpharmacologic treatment adherence measures.

RESULTS
Twenty-eight trials with 7,021 participants fulfilled the inclusion criteria. Medication adherence was assessed in 25 trials (89%), dietary outcomes in 8 (29%), physical activity in 6 (21%), and medication persistence in 1 (4%). Blood pressure was assessed in 26 studies (93%). Follow-up ranged from 2 weeks to 12 months. Pooled results of 13 studies demonstrated a small but significant overall effect on medication adherence in favor of SMBP interventions (standardized mean difference 0.21, 95% CI 0.08, 0.34), with moderate heterogeneity ($I^2 = 43\%$). Standardized mean difference was used to express the size of intervention effect in each study relative to the variability observed, and was used to combine the results of studies where different measures of medication adherence were used. Where SMBP interventions had a significant effect on lifestyle factor change, the effect was unlikely to be clinically significant. Pooled results of 11 studies demonstrate a significant overall effect on diastolic blood pressure in favor of SMBP (weighted mean difference −2.02, 95% CI −2.93, −1.11), with low heterogeneity ($I^2 = 0\%$). A test for subgroup differences showed no difference when studies were grouped according to whether medication adherence was significantly improved or not.

CONCLUSIONS
SMBP may contribute to improvements in medication adherence in hypertensives. However, evidence for the effect of SMBP on lifestyle change and medication persistence is scarce, of poor quality, and suggests little clinically relevant benefit.

Keywords: adherence; blood pressure; hypertension; meta-analysis; non-pharmacologic; self-monitoring.

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Self-monitoring of blood pressure (SMBP) leads to reduced blood pressure (BP) in people with hypertension, but how this change occurs is not well understood.[1–3] Potential explanations include pharmacological (increased medication, better adherence) or nonpharmacological (diet, alcohol, exercise, weight loss) mediators. Understanding which mediating factors are important could allow optimization of future interventions.

Around 25% of patients initiated on hypertensive medication fail to fill their first prescription.[4] In the first year of antihypertensive treatment, patients on average have possession of medication for 50% of the time, and only 20% have sufficiently high adherence to achieve any benefit.[5] Improving adherence is therefore a key target for behavioral interventions. Lifestyle change is another target as it has been estimated that diet and weight loss can be at least as effective as single drug therapy at reducing BP.[6]

A systematic review published in 2006 found that 6 of 11 included trials detected a statistically significant improvement in adherence to antihypertensive medication from SMBP.[7] Limited evidence from qualitative research suggests that SMBP can influence compliance with diet and exercise regimes.[8,9]

The primary objectives of this review were to synthesize the literature to determine the effect of SMBP on medication adherence, medication persistence, and lifestyle factors in people with hypertension.

METHODS

Information sources and study selection

Electronic databases (DARE, Cochrane Database of Systematic Reviews, MEDLINE, EMBASE, CINAHL,

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PsycINFO, Proquest Dissertation, and Theses) were searched from inception to February 2014 to identify randomized trials of interventions including SMBP compared with control groups without SMBP. Ongoing and completed studies without related publication were identified through searches of clinical trial databases (i.e., ClinicalTrials.gov, WHO trials portal, UKHTA, and Current controlled trials).

The search strategy was developed in Medline and translated for use in the other databases (Supplementary Appendix S1). No language or time restrictions were applied. Studies were also identified through citation searches of related reviews and relevant trials, and authors were contacted for further information wherever necessary.[10]

Randomized and quasi-randomized trials were eligible for inclusion if the participants had hypertension, were receiving care in ambulatory/outpatient settings, and if medication adherence and/or lifestyle factor outcomes were available. Two reviewers independently screened the reports for inclusion (B.F., J.H.B.). A protocol was developed and made available on the PROSPERO database prior to commencing the review.[11]

Data extraction and risk of bias assessment

Data were extracted on setting, demographics, intervention and control characteristics, and outcome measures. Raw unadjusted data were extracted wherever available.

Primary outcomes of interest were antihypertensive medication adherence and persistence, dietary outcomes, alcohol consumption, and physical activity. Medication adherence measures were divided into 4 groups to aid analysis: electronic monitoring, pill counts, pharmacy fill data, and self-reported measures. Secondary outcomes included BP, BP control, and adherence to the SMBP component of interventions.

Studies were classified according to whom the intervention was aimed at (patients and/or healthcare professionals (HCPs)), and any cointerventions beyond SMBP.

Data extraction and risk of bias assessment were carried out independently by 2 reviewers (B.F., J.H.B.). Following guidance from the Cochrane Collaboration, studies were deemed to be at high, low, or unclear risk of bias based the following factors: random sequence generation, allocation concealment, blinding of outcome assessment, selective reporting, and attrition.[12] Risk of bias across studies was assessed using a Funnel plot and Egger's test.

Statistical analysis

Meta-analyses were performed with RevMan 5 using random-effect models for a comparison of SMBP vs. usual care/control for medication adherence and BP outcomes. Meta-analysis was not undertaken for lifestyle factor outcomes due to insufficient data. As medication adherence was measured in different ways, standardized mean differences (SMD) were calculated in order to compare adherence across studies. Subgroup analyses were used to group studies that measured medication adherence by type of measurement. Where studies reported a number of adherence measures, the most objective measure was used. Meta-regression explored the association between BP change and medication adherence.

For office systolic blood pressure (SBP) and diastolic blood pressure (DBP), weighted mean differences were calculated for overall change between intervention and control.[12] Weighting depended on the SD of the change in BP from baseline to final reading. Where no such data were available, the SD for mean change was imputed.[12]

The I^2 statistic was used to present statistical heterogeneity for all meta-analyses.

RESULTS

Included studies

Twenty-eight trials with a total of 7,021 participants fulfilled the inclusion criteria (Figure 1).[13–40] Medication adherence was assessed in 25 trials (89%) dietary outcomes in 8 (29%), physical activity in 6 (21%), and medication persistence in 1 (4%). BP was also assessed in 26 (93%) studies.

Characteristics of included studies are summarized in Table 1. SMBP was the sole component of interventions in 11 studies (39%) and combined with cointerventions in 17 (61%). Cointerventions were coded and grouped using *a priori* categories and are summarized in Table 1, and in more detail in the Supplementary Appendix S2. The most common cointervention was education delivered either verbally (in 11 studies) or using either printed or online materials (in 6 studies).

SMBP interventions may target behavior change in patients (i.e., improving treatment adherence, self-titration of medication, etc.). Equally, SMBP interventions can target behavior change in HCPs (i.e., medication prescribing, overcoming clinical inertia). Patients alone were the target of the intervention in 8 studies, while interventions targeted both patients and HCPs in the remaining 20. In the majority of cases where both patients and clinicians were targeted, intervention participants' general practitioners (GPs, family physicians) received self-measured BP results from participants, or were informed when patients exceeded target BP, and were able to act accordingly.[13,14,18,22,27–31,34,37,40] Three studies involved pharmacists implementing the intervention, 2 involved nurses, and 1 involved dieticians. The theoretical basis for the development of the intervention was reported in only 4 studies.[19,30,33,35]

Participants were initiated on new antihypertensive medications in 4 studies,[16,25,37,38] and medication titration protocols based on self-measured BP were reported in 5.[16,24,35,37,40]

Protocols for self-monitoring varied across studies, ranging from participants being asked to measure their BP twice daily every day,[23] to monthly.[27] The SMBP protocol was not reported in 5 studies.[14,16,26,32,36]

Follow-up ranged from 2 weeks to 12 months with a median of 6 months, and was deemed to be adequate (i.e., >80% of participants available for outcome assessment at follow-up) in 75% of studies.

Risk of bias

Two studies were judged to be at low risk of bias;[24,35] 12 studies were judged to be at high risk of bias in at least

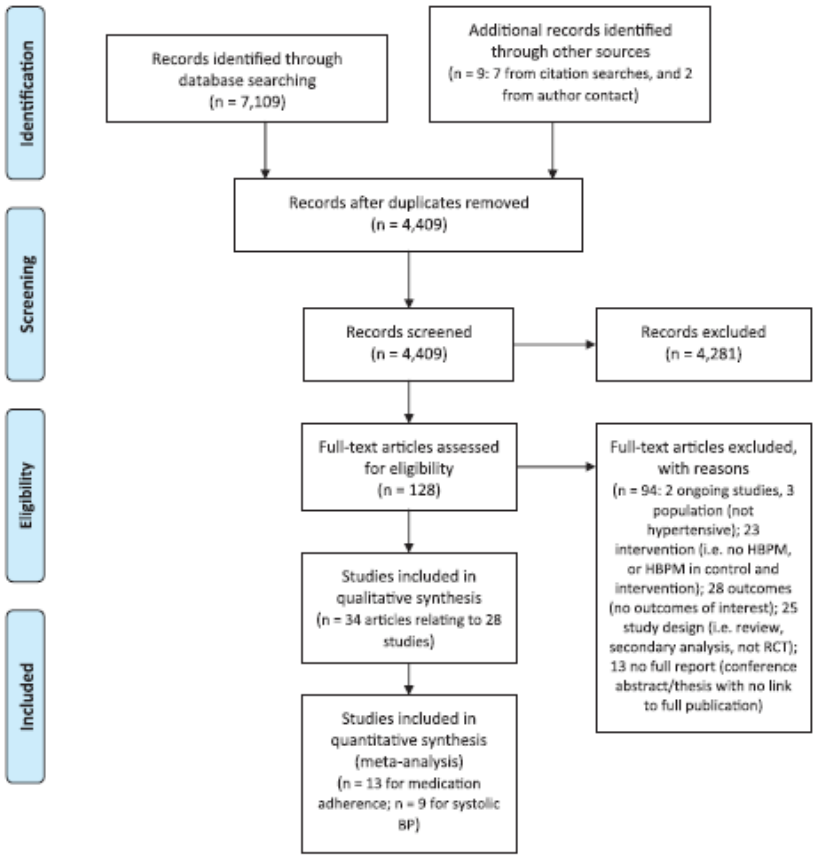

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.

1 domain.[14,17,21,22,27,29–31,33,34,36,38] Results were unclear for the remaining 14 studies, most commonly due to lack of detail regarding allocation concealment. Risk of bias for each domain in each included study is presented in Figure 2.

Adherence and persistence to antihypertensive medication

Adherence to antihypertensive medication was assessed by electronic monitoring in 5 studies, by pill count in 8, using pharmacy fill data in 6, and by self-report in 9. Three trials used 2 categories of measure.[23,36,37] Full results of medication adherence are presented in Table 2.

Pooled analysis of all adherence measures demonstrated a small but significant overall effect in favor of SMBP (SMD 0.21, 95% CI 0.08, 0.34; 13 studies), with moderate heterogeneity ($I^2 = 43\%$) (Figure 3). A test for subgroup differences did not suggest a significant association between adherence measures and overall effect size ($\chi 2 = 5.47$, df = 3, $P = 0.14$). We carried out a sensitivity analysis removing self-reported measures from the meta-analysis, and this had a small impact on the overall effect: SMD 0.27 (95% CI 0.11–0.34), compared to 0.21 (95% CI 0.08–0.44); with a small increase in heterogeneity: I^2 46% compared to 43%.

When assessed by electronic monitoring (i.e., medication event monitoring systems), the pooled result of 2 studies detected a significant effect in favor of the intervention (SMD 0.45, 95% CI 0.10–0.79), with moderate statistical heterogeneity ($I^2 = 59\%$). The pooled result of 5 studies where adherence was assessed by pill counts showed a small significant effect size in favor of the intervention (SMD 0.30, 95% CI 0.01–0.59), with moderate statistical heterogeneity ($I^2 = 42\%$).

Assessment of adherence using pharmacy fill data (2 studies) and self-report (4 studies) showed no significant effect in favor of the intervention (SMD 0.12, 95% CI −0.05 to 0.29 and SMD 0.05, 95% CI −0.13 to 0.22, respectively), with low statistical heterogeneity in both cases ($I^2 = 0\%$). Medication persistence was assessed in 1 study.[16] No significant effect in favor of SMBP was found in the proportions not discontinuing their medication by the end of the trial (9 months).

Rates of adherence in the included randomized controlled trials tended to be high, e.g., >97%,[21] >93%,[26] 90%,[37] and >88%[13].

Lifestyle factors: diet and physical activity

Diet and physical activity outcomes are presented in Table 3.

Table 1. Characteristics of included studies

Study id, Country	Number of participants	Study arms included in review	Follow-up	SMBP protocol	Target[a]	Age	% Female	Outcomes[b]
Bailey,[13] Australia	62	(i) SMBP (ii) Usual care	8 weeks (2 months)	Sitting twice daily (AM and PM)	P + HCP	55	54	MA, BP, AI
Bove,[14] USA	241	(i) SMBP, telemedicine, and education (print/online materials) (ii) Usual care	6 months	Unclear	P + HCP	60	65	MA, BP
De Souza,[15] Brazil	57	(i) SMBP (ii) Usual care	6 and 12 months	At least twice a week, at random times and quiet place	P	60	NR	MA, D, PA, BP
Düsing,[16] Germany/Switzerland	206	(i) SMBP, education (print/online materials), medication titration protocol, adherence reminders, and physicians education (ii) Control	34 weeks (9 months)	Unclear	P + HCP	51	46	MA/MP, BP
Fikri-Benbrahim, [17] Spain	180	(i) SMBP, education (verbal), and education (print/online materials) (ii) Usual care	6 months	At least 1 day per week, on 2 occasions measure BP over 5 consecutive days	P + HCP	62	63	MA, BP, AI
Friedman,[18] USA	299	(i) SMBP and telemedicine (ii) Usual care	6 months	Weekly	P + HCP	77	77	MA, BP
Green,[19] USA	101	(i) SMBP and education (verbal) (ii) Usual care	6 months	3 days per week	P + HCP	57	42	MA, D, PA, BP
Haynes,[20] Canada	39	(i) SMBP and education (verbal) (ii) Control (no intervention)	6 months	Daily	P	NR	0	MA, BP
Hosseininasab,[21] Iran	196	(i) SMBP (ii) Usual care	4, 12, 24 weeks (1, 3, 6 months)	Daily	P	59	61	MA, BP
Johnson,[22] Canada	136	(i) SMBP (ii) Control (no intervention)	6 months	Daily	P + HCP	53	40	MA, BP, AI
Kirscht,[23] USA	417	(i) SMBP (ii) Control (no intervention)	2 weeks	Twice daily	P	78% > 50	NR	MA, D
Magid,[24] USA	338	(i) SMBP, telemedicine, education (verbal), and medication titration protocol (ii) Usual care	6 months	3–4 times weekly	P + HCP	66	35	MA, BP, AI
Marquez-Contreras,[25] Spain	200	(i) SMBP (ii) Usual care	6 months	3 days a week, twice AM, twice PM	P	59	49	MA, BP
McKenney,[26] USA	70	(i) SMBP (ii) Control (no intervention)	12 weeks (3 months)	Unclear	P	75	59	MA, BP
McManus,[27] UK	441	(i) SMBP (ii) Usual care	6 and 12 months	Monthly	P + HCP	63	53	D, PA, BP
Mehos,[28] USA	41	(i) SMBP (ii) Control (no intervention)	6 months	Daily in morning	P+HCP	42% > 50	70	MA, BP, AI
Midanik,[29] USA	204	(i) SMBP (ii) Usual care	12 months	Twice weekly	P+HCP	47	53	D, PA, BP, AI
Migneault,[30] USA	337	(i) SMBP, telemedicine and education (verbal) (ii) Control (education only)	8 and 12 months	Weekly	P+HCP	57	70	MA, D, PA, BP, AI

(Continued)

Table 1. Continued

Study id, Country	Number of participants	Study arms included in review	Follow-up	SMBP protocol	Target[a]	Age	% Female	Outcomes[b]
Niiranen,[31] Finland	229	(i) SMBP and education (verbal) (ii) Control (no intervention)	12 months	Four times per year, twice in AM on 4 consecutive days	P+HCP	38	55	D, PA, BP, AI
Ogbuokiri,[32] Nigeria	29	(i) SMBP (ii) Control (no intervention)	5 months	Unclear	P	47	85	MA, BP
Ogedegbe,[33] USA	1,039	(i) SMBP, education (verbal), education (print/online materials) and physician education (ii) Usual care	6 and 12 months	Twice daily, 3 times per week	P + HCP	56	72	MA, BP, AI
Rinfret,[34] Canada	223	(i) SMBP, telemedicine and education (print/online materials) (ii) Usual care	12 months	Weekly	P+HCP	56	46	MA, BP
Rudd,[35] USA	150	(i) SMBP, education (verbal), education (print/online materials) and medication titration protocol (ii) Usual care	6 months	Twice daily	P + HCP	60	53	MA, BP
Stewart,[36] Australia	395	(i) SMBP, education (verbal) and adherence reminders (ii) Usual care	6 months	Unclear	P + HCP	67	49	MA, BP
Van Onzenoort,[37] Netherland	430	(i) SMBP and medication titration protocol (ii) Control (office measures)	12 months	Monthly (before study visit), 7 consecutive days, 3 times AM and PM	P + HCP	55	45	MA, BP, AI
Vrijens,[38] Belgium	628	(i) SMBP and education (verbal) (ii) Control (no intervention)	6 weeks	Daily in AM	P	NR	NR	MA
Wakefield,[39] USA	302	(i) SMBP, telemedicine, education (print/online materials) (ii) Usual care	6 and 12 months	Daily	P + HCP	67	2	MA, BP, AI
Zamke,[40] Canada	31	(i) SMBP and medication titration protocol (ii) Usual care	8 weeks (2 months)	Twice daily	P + HCP	55	65	MA, D, BP

Abbreviation: SMBP, self-monitoring of blood pressure.
[a]Target of intervention: P = patient only; P + HCP = patient and healthcare professional.
[b]Outcomes: MA = medication adherence; MP = medication persistence; PA = physical activity; D = diet; BP = blood pressure; AI = adherence to intervention

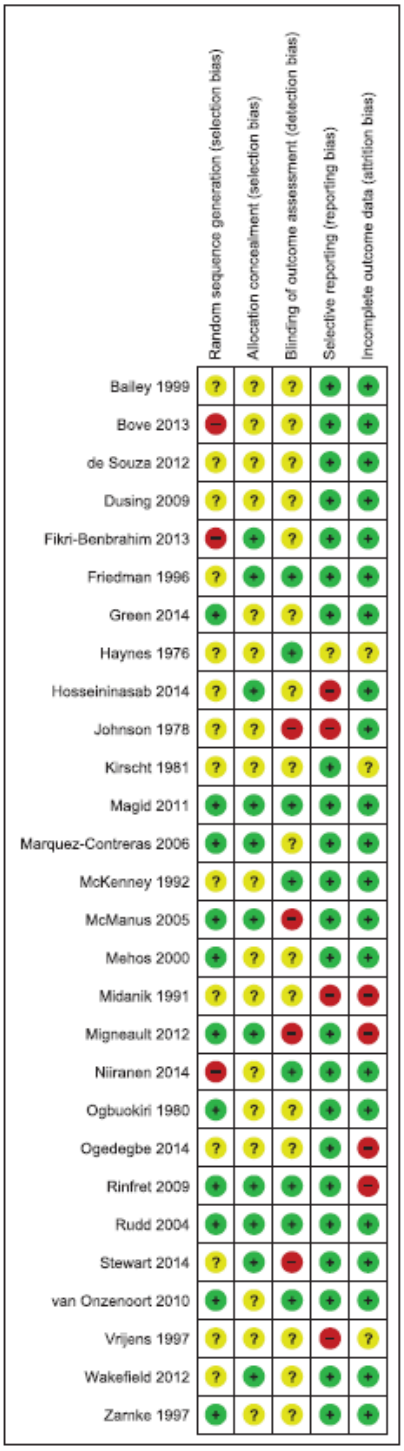

Figure 2. Risk of bias summary.

Dietary outcomes were reported by 8 studies: diet quality (3 studies), fruit and vegetables consumption (2 studies), coffee (1 study), and alcohol consumption (4 studies). One study reported a significant improvement in overall diet quality,[30] and another significant improvement in the average number of fruit and vegetables consumed[19]; the remaining results showed no effect.

Physical activity was measured in 6 studies; 1 of these showed an increase in mean energy expenditure,[30] but the other 5 were negative.[15,19,27,29,31]

Blood pressure

Medication adherence and BP outcomes were measured together in 23 studies (all but[23,27,29,31,38]). In the 8 trials where SMBP had a significant effect on medication adherence, office DBP improved in 3 (38%).[17,25,35] Similarly, office SBP significantly improved in favor of the intervention in 3 of the 7 studies where adherence was significantly improved (43%).[17,25,35]

Interestingly office SBP significantly improved in 3 of 15 studies (20%) where SMBP interventions had no report effect on medication adherence,[24,34,36] as did office DBP in 2 of 14 studies (14%).[28,34]

Figure 4 shows the results of pooled analysis of DBP at 6 months, which demonstrate a significant overall effect in favor of SMBP (weighted mean differences −2.02, 95% CI −2.93, −1.11; 11 studies), with low heterogeneity (I^2 = 0%). A test for subgroup differences did not show a significant effect when studies were grouped according to whether medication adherence was improved or not ($\chi 2$ = 0.11, df = 1, P = 0.74). Results for SBP at 6 months were similar. Full BP results are available in the Supplementary Appendices S3, S4 and S5.

Exploratory meta-regression demonstrated a trend for an association between increased medication adherence and BP change (SBP and DBP); however, the results were not statistically significant, potentially due to the lack of sufficient studies.

DISCUSSION

Main results and clinical implications

This review to our knowledge is the first to carry out a pooled analysis of the effect of SMBP interventions on medication adherence, and has shown a small but significant effect (SMD = 0.21 (95%CI 0.08–0.34)).[41]

A recent review estimated that 59% of people with hypertension had good adherence to medication, and that around 9% of cardiovascular events could be attributed to poor adherence to medication.[42] Another study estimated the reduction in healthcare costs potentially associated with increasing medication adherence in hypertension in 5 European countries.[43] In England, it was estimated that an increase in the proportion of patients adherent to treatment to 70% (i.e., 70% taking >80% of their medication), would lead to 6,553 fewer cardiovascular events, and savings of up to €36 billion over 10 years.[43] The costs of nonadherence to

Table 2 Effect of SMBP on medication adherence

Study ID	Description	Follow-up	Result		Between group difference?
			Intervention	Control	
Outcome using electronic monitoring					
Düsing[16]	MEMS cap monitors time and date of opening pill bottle: (i) taking meds daily between 07:00 and 11:00, (ii) taking meds daily with no time restriction	9 months	(i) 57% (ii) 86%	(i) 54% (ii) 77%	(i) *N* (*P* value not reported) (ii) *N* (*P* value not reported)
Marquez-Contreras[25]	MEMS cap monitors. (i) Proportion of doses taken, (ii) proportion of correct days, (iii) correct time, and (iv) proportion of patients who were adherent (taking 80–100% of meds)	6 months	(i) 93.5% (SD 15.7) (ii) 89.4% (SD 15.2) (iii) 88.1% (SD 21.6) (iv) 92% (SD 14.2)	(i) 87.7% (SD 23.6) (ii) 83.7% (SD 23.3) (iii) 79.9 (SD 28.2) (iv) 74% (SD 18.2)	(i) *Y* (*P* = 0.0001) (ii) *Y* (*P* = 0.0001) (iii) *Y* (*P* = 0.006) (iv) *Y* (*P* = 0.0007)
Rudd[36]	MEMs cap. Daily adherence is defined as the number of days where patients took the correct dose	6 months	80.5 (SD 23.0)	62.9 (SD 31.1)	*Y* (*P* = 0.03)
Van Onzenoort[37]	MEMs caps used in a single centre sub study: (i) proportion of days with correct dosing and (ii) proportion adequately adherent (>85%)	12 months	(i) 92.3% (IQR 86.9–94.4) (ii) 81%	(i) 90.9% (IQR 92.9–93.7) (ii) 74%	(i) *Y* (*P* = 0.043) (ii) *N* (*P* value not reported)
Vrijens[38]	MEMs caps. Average number of pills taken in the last week of the study (maximum of 7)	6 weeks	6.78	6.20	*N* (*P* value not reported)
Outcome using pill count					
Bailey[13]	Proportion of available medication taken	2 months	88% (SD 27.4)	94% (SD 21.2)	*N* (*P* value not reported)
Fikri-Benbrahim[17]	Proportion adherent (taking 80–110% of available medication)	6 months	96.5%	85.4%	*Y* (*P* = 0.011)
Friedman[18]	Mean change from baseline in proportion of available medication taken	6 months	+2.4%	−0.4%	*N* (*P* = 0.29)
Haynes[20]	Mean change from baseline in proportion of available medication taken	6 months	+21.3% (SD 29.1)	−1.5% (SD 33 1)	*Y* (*P* = 0.025)
Hosseininasab[21]	Proportion of available medication taken	1, 3, 6 months	1 month: 99.6% (SD 3) 3 months: 98.9% (SD 5) 6 months: 99.0% (SD 5)	1 month: 97.1% (SD 9) 3 months: 96.5% (SD 7) 6 months: 97.8% (SD 3)	*Y* (*P* = 0.01) *Y* (*P* = 0.005) *Y* (*P* = 0.04)
Johnson[22]	(i) Mean change from baseline in adherence and adherence at follow-up, (ii) estimated by comparing pills on hand with pharmacy dispensing records	6 months	(i) +11.8% (SD 31.5) (ii) 78.0 (SD 31.5)	(i) +1.0% (SD 40.8) (ii) 68.5 (SD 42.6)	(i) *N* (*P* value not reported) (ii) *N* (*P* value not reported)
McKenney[26]	Overall study adherence	3 months	100.2% (SD 7.0)	93.6% (SD 8.7)	*Y* (*P* = 0.02)
Van Onzenoort[37]	Overall study adherence	12 months	87.3%	88.1%	*N* (*P* = 0.62)
Outcome using pharmacy fill					
Kirscht[23]	Pharmacy data was used to estimate the doses of medication prescribed compared to doses dispensed	2 weeks	66.5%	66.5%	*N* (*P* value not)
Magid[24]	Medication possession ratio (MPR) total number of days supplied for each medication, divided by period for which the medication was prescribed	6 months	0.85 (SD 0.19)	0.84 (SD 0.19)	*N* (*P* = 0.88)

(Continued)

Table 2. Continued

Study ID	Description	Follow-up	Result		Between group difference?
			Intervention	Control	
Mehos[28]	Overall study compliance (no. tablets refilled/ amount prescribed)	6 months	82%	89%	*N* (*P* = 0.29)
Ogbuokiri[32]	Frequency of refill. Value arbitrarily chosen and defined prestudy (refill within 1–10 days of refill date = 100%; within 2 weeks = 50%; within 4 weeks = 25%)	5 months	72.6%	59.26%	NA
Rinfret[34]	(i) Continuous medication availability (CMA) and (ii) continuous medication gaps (CMG) scores, which estimate the proportion of time the subjects have or do not have medication available	12 months	(i) 0.95 (IQR 0.76 to 1.00) (ii) 0.04 (IQR 0.00–0.19)	(i) 0.91 (IQR 0.54–1.04) (ii) 0.09 (IQR 0.00–0.38)	(i) *N* (*P* = 0.07) (ii) *N* (*P* = 0.12)
Stewart[36]	Follow-up mean and mean change from baseline in: (i, ii) MedsIndex score (100 = perfect adherence); (iii, iv) Medication Possession Ratio	6 months	(i) 84.75 (SD 17.13) (ii) +4.60 (iii) 0.94 (SD 0.35) (iv) +0.13	(i) 82.86 (SD 19.42) (ii) +2.44 (iii)0.89 (SD 0.21) (iv) +0.08	(i) NR (ii) *N* (*P* = 0.228) (iii) NR (iv) *N* (*P* = 0.496)
Outcome using self-report					
Bove[13]	Medication adherence self-efficacy scale (MASES). Four-item scale, higher scores indicate greater level of adherence	6 months	3.56 (SD 0.81)	3.59 (SD 0.85)	*N* (*P* = 0.86)
De Souza[15]	Proportion of patients who reported "regular use daily" of antihypertensive medication	6 and 12 months	6 months: 94.7% 12 months: 100%	6 months: 83.3% 12 months: 88.2%	6 months: *N* (*P* = 0.150) 12 months: *Y* (*P* = 0.031)
Green[19]	Mean change from baseline in Morisky 8-item score. Higher score indicates lower adherence	6 months	−0.1 (SD 2.0)	−0.2 (SD 1.9)	*N* (*P* = 0.79)
Kirscht[23]	Patients were asked about pill taking behaviour and were ranked on an ordinal scale	2 weeks	94.4%	94.3%	*N* (*P* value not reported)
Migneault[30]	Mean change from baseline in Morisky 7 score. Higher scores indicate better adherence	8 months	+0.45	+0.26	*N* (*P* value not reported)
Ogedegbe[33]	Mean change in Morisky 4-item score. Higher score indicates poor adherence	6 and 12 months	6 months: −0.14 12 months: −0.24	6 months: −0.13 12 months: −0.20	6 months: *N* (*P* = 0.87) 12 months: *N* (*P* = 0.71)
Stewart[36]	(i, ii) Follow-up mean and mean change from baseline in proportion adherent using Morisky 4; (iii, iv) Morisky 4 score (0 = good adherence); (v, vi) TABS differential (>15 = good adherence)	6 months	(i) 73.5% (ii) +13.5% (iii) 0.36 (SD 0.67) (iv) −0.20 (v) 11.10 (SD 3.83) (vi) +0.85	(i) 63.6% (ii) +6.4% (iii) 0.44 (SD 0.64) (iv) −0.15 (v) 11.59 (SD 3.33) (vi) +0.67	(i) *N* (*P* = 0.09) (ii) *N* (*P* value not reported) (iii) NR (iv) *N* (*P* = 0.310) (v) NR (vi) *N* (*P* = 0.856)
Wakefield[39]	Patients were asked, "are you taking your medications as prescribed". Scores represent the proportion of medications for which responses agreed with the directions for use on the VA pharmacy medication profile	6 and 12 months	6 months: 99.8 (SD 1.4) 12 months: 99.7% (SD 1.4)	6 months: 99.6 (SD 2.2) 12 months: 98.9% (SD 6.0)	6 months: *N* (*P* = 0.79) 12 months: *N* (*P* = 0.20)
Zamke[40]	Mean number of self-reported doses missed per week	2 months	0.05 (SD 0.2)	0.2 (SD 0.4)	*N* (*P* value not reported)

Abbreviation: SMBP, self-monitoring of blood pressure; MEMS, medication event monitoring system; IQR, interquartile range; NR, not reported; VA, Veterans Affairs.

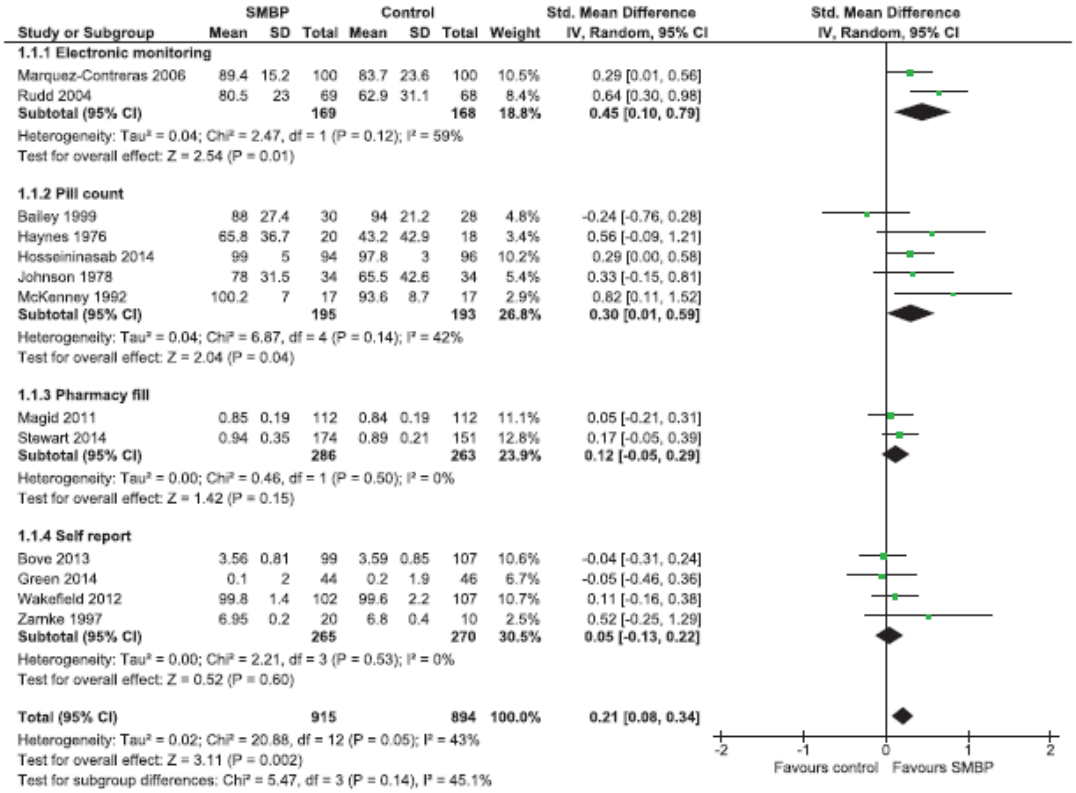

Figure 3. Self-monitoring of blood pressure interventions vs. controls for antihypertensive medication adherence.

antihypertensives in the United States has been estimated to be as much as $105 billion annually.[44]

Only one study in the review included evidence on medication persistence. Helping patients take their medication correctly on a day-to-day basis is important (adherence), but in conditions that require long-term treatment such as hypertension, making sure patients keep taking the medication over time (persistence) is of equal if not greater importance. Meta-analysis shows that the effect of antihypertensive treatment is apparent within a year and ongoing risk reduction is dependent on ongoing treatment.[45]

Importantly, studies using more objective measures of medication adherence showed a greater effect size in favor of intervention. The pooled estimate when electronic monitoring was used was almost double the overall estimate, and approaching 10 times larger than the estimate from studies where the least objective self-reported measures were used. Objective measurement may remove the measurement noise associated with self-report, therefore making more precise estimates of adherence possible hence easier differentiation between low and high adherence.

While SMBP has been shown to improve medication adherence, the results of this review do not provide evidence that this explains all of the observed BP reduction. Further research is needed to clarify whether this is because the effect of SMBP is not mediated by medication adherence, or due to methodological issues such as the sensitivity of outcome measures and use of cointerventions targeting other behaviors.

There is insufficient evidence from randomized controlled trials testing the effect of SMBP on lifestyle factors to be able to draw any conclusions about the extent to which they may mediate the effect of SMBP.

Comparison to the literature

The effect of SMBP on medication adherence shown in this review compares favorably with other interventions aimed at improving adherence. Evidence from a review of interventions to improve medication adherence in hypertensives carried out in 2004 showed a small and nonsignificant overall effect, SMD = 0.12 (95% CI −0.06 to 0.28).[46] A meta-analysis of trials to improve medication adherence in any condition reported a small but significant effect, SMD = 0.08 (95% CI 0.04–0.12).[47]

Strengths and weaknesses

This review used a comprehensive search strategy and captured more than double the number of studies compared to previously.[7] Sufficient data were available to perform meta-analysis for medication adherence allowing estimation of the effect size.

Table 3 Effect of SMBP on lifestyle factor outcomes

Study i.d.	Outcome measure	Follow-up	Results		Difference between groups?
			Intervention	Control	
Medication persistence					
Düsing[16]	Proportion not discontinuing medication by end of trial	9 months	95.9%	88.3%	*N* (*P* value not reported)
Diet					
De Souza[15]	Proportion reporting food intake according to dietary guidelines	6 and 12 months	6 months: 97.4% 12 months: 97.3%	6 months: 88.9% 12 months: 100%	6 months: *N* (*P* = 0.21) 12 months: *N* (*P* = 0.68)
Green[19]	Mean change from baseline in average number of daily servings of fruit and vegetables	6 months	+2.3 (SD 3.0)	+0.0 (SD 1.9)	*Y* (*P* < 0.01)
Kirscht[23]	Proportion adherent to dietary recommendations	2 weeks	75.2%	77.2%	*N* (*P* value not reported)
McManus[27]	Mean change from baseline in: (i) proportion adding salt to food and (ii) proportion drinking more than recommendations (men >21; women >14 units/week)	6 and 12 months	6 months: (i) −2%, (ii) −8% 12 months: (i) −4%, (ii) −6%	6 months: (i) −2%, (ii) −3% 12 months: (i) +3%, (ii) −2%	6 months: (i) *N* (*P* = 0.82), (ii) *N* (*P* = 0.11) 12 months: (i) *Y* (*P* = 0.03), (ii) *N* (*P* = 0.56)
Midanik[29]	(i) Mean change in alcohol consumption (drinks per day) and (ii) coffee consumption (drinks per day)	12 months	(i) −0.2 (SD 0.9) (ii) −0.1 (SD 1.4)	(i) −0.2 (SD 0.8) (ii) −0.5 (SD 1.4)	(i) *N* (*P* = 0.87) (ii): *N* (*P* = 0.05)
Migneault[30]	Mean change from baseline in overall diet quality score (higher score = healthier diet)	8 months	+2.8	−0.74	*Y* (*P* < 0.05)
Niiranen[31]	(i) Mean change from baseline in: alcohol intake (g/day); (ii) total energy intake (MJ/day); (iii) total carbohydrate (%MJ/day); (iv) total protein (%MJ/day); (v) total fat (%MJ/day); (vi) total saturated fat (%MJ/day)	12 months	(i) −0.1 (SD 8.2) (ii) −0.3 (SD 1.8) (iii) +1.5 (SD 6.3) (iv) +0.0 (SD 1.8) (v) −0.8 (SD 6.1) (vi) −0.7 (SD 2.6)	(i) +3.2 (SD 16.5) (ii) −0.1 (SD 1.3) (iii) +0.0 (SD 6.7) (iv) +0.7 (SD 2.6) (v) −0.2 (SD 2.1) (vi) −0.7 (SD 2.6)	(i) *N* (*P* = 0.06) (ii) *N* (*P* = 0.37) (iii) *N* (*P* = 0.10) (iv) *N* (*P* = 0.12) (v) *N* (*P* = 0.41) (vi) *N* (*P* = 0.11)
Zamke[40]	Mean change from baseline in alcohol intake (drinks per week)	2 months	−0.25 (SD 1.59)	+0.10 (SD 0.4)	*N* (*P* value not reported)
Physical activity					
De Souza[15]	Proportion exercising more than 3 times weekly	6 and 12 months	6 months: 67.6% 12 months: 67.6%	6 months: 61.1% 12 months: 58.8%	6 months: *N* (*P* = 0.22) 12 months: *N* (*P* = 0.19)
Green[19]	Proportion at follow-up engaging in physical activity (often working up a sweat)	6 months	27.9% (SD 44.1)	20.5% (SD 40.2)	*N* (*P* = 0.40)
McManus[27]	Mean change from baseline in proportion exercising more than 3 times weekly	6 and 12 months	6 months: +9% 12 months: +4%	6 months: +13% 12 months: +3%	6 months: *N* (*P* = 0.53) 12 months: *N* (*P* = 0.49)
Midanik[29]	Physical activity at follow-up (*study reported no difference between groups, but reported no data)	12 months	Not reported	Not reported	*N* (*P* value not reported)
Migneault[30]	(i) Mean change from baseline in: moderate or greater intensity activity time (min/week), (ii) proportion exercising >150 min/week, and (iii) total energy expenditure (kcal/day)	8 months	(i) −3.44, (ii) −2%, (iii) +43.8	(i) +2.77, (ii) +5%, (iii) -36.2	(i) *N* (*P* value not reported), (ii) *N* (*P* value not reported) (iii) *Y* (*P* < 0.05)
Niiranen[31]	Mean change from baseline in leisure activity (MJ/day)	12 months	+0.00 (SD 0.4)	+0.07 (SD 0.3)	*N* (*P* = 0.15)

Abbreviation: SMBP, self-monitoring of blood pressure.

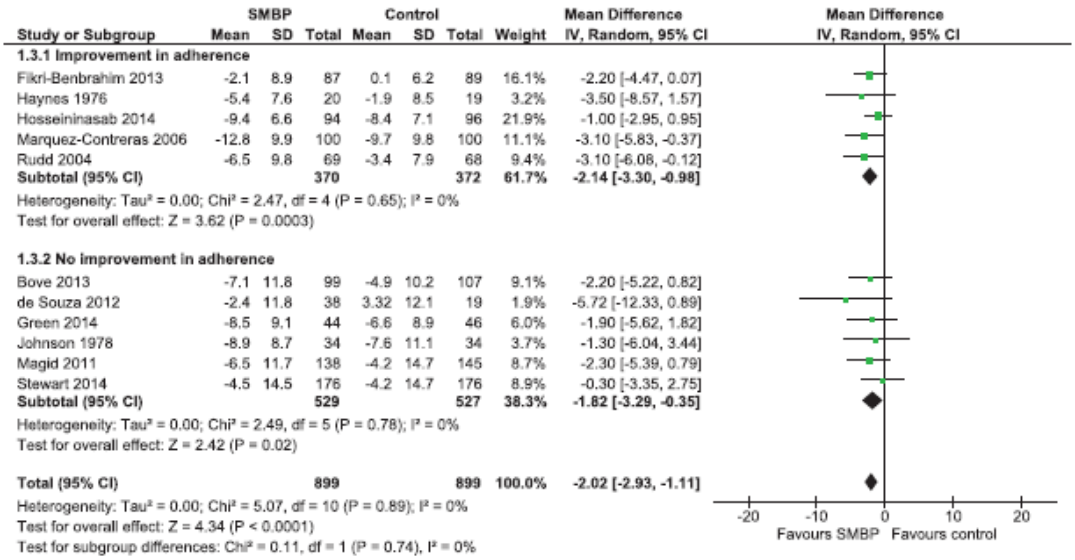

Figure 4. Self-monitoring of blood pressure interventions vs. controls for office diastolic blood pressure at 6 months.

Overall, the quantity and quality of evidence of the impact of SMBP on lifestyle factors was poor. Evidence for the effect of SMBP on diet and physical activity was available in only 9 studies, and where significant effects in favor of the intervention were found, few were clinically significant. UK guidance for the management of hypertension recommends that lifestyle advice should be offered to all people undergoing treatment for hypertension. SMBP could potentially act by helping hypertensives see the benefits of a healthier lifestyle, but more data are required before this can be substantiated.

The interventions tested were heterogeneous, with varying target population, SMBP protocol, medication titration protocol, and other cointerventions. Studies were often aimed at people with hypertension, but also required the input of HCPs to interpret the SMBP measurements and act accordingly. Using complex interventions and targeting both patients and HCPs together complicate the investigation of the independent effect of SMBP on patient behavior. Further work should specifically examine the effect of SMBP on physician behavior, e.g., prescribing, and the extent to which this could be a mediator.

The theoretical basis for intervention development only reported in 4 studies (14%). As SMBP interventions target behavior change in patients and/or HCPs, conceptual models are needed to provide a framework for the development of interventions. As it stands, it is difficult to understand how many SMBP interventions have been developed, e.g., the justification for the frequency of SMBP and what patients/HCPs are expected to do with these readings.

CONCLUSIONS

SMBP leads to an increase in medication adherence, and best seen in those studies where objective measures are used. However, to what extent medication adherence acts as a mediator of the effect of SMBP remains to be determined. The role of lifestyle factors is less clear, and it is feasible and indeed likely, that other mediators may affect the outcomes of SMBP such as physician prescribing.

Furthermore, future trials should ideally use methods that allow for the potential incremental effects of cointerventions to be determined (e.g., using a multifactorial design). More transparency is needed in reporting the basis of the intervention development. SMBP improves adherence to medication as well as lowering BP, however a better understanding of the mediators of these effects is needed, in order to optimize SMBP interventions for translation to the "real-world".

SUPPLEMENTARY MATERIAL

Supplementary materials are available at *American Journal of Hypertension* (http://ajh.oxfordjournals.org).

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DISCLOSURE

B.R.F., J.H.B.., and L.H. declare no conflicts of interest.

REFERENCES

1. 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; 42:371–386.

2. Stergiou GS, Bliziotis IA. Home blood pressure monitoring in the diagnosis and treatment of hypertension: a systematic review. *Am J Hypertens* 2011; 24:123–134.
3. Uhlig K, Patel K, Ip S, Kitsios GD, Balk EM. Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. *Ann Intern Med* 2013; 159:185–194.
4. Fischer M, Stedman M, Lii J, Vogeli C, Shrank W, Brookhart MA, Weissman J. Primary medication non-adherence: analysis of 195,930 electronic prescriptions. *J Gen Intern Med* 2010; 25:284–290.
5. Gwadry-Sridhar FH, Manias E, Lal L, Salas M, Hughes DA, Ratzki-Leewing A, Grubisic M. Impact of interventions on medication adherence and blood pressure control in patients with essential hypertension: a systematic review by the ISPOR medication adherence and persistence special interest group. *Value Health* 2013; 16:863–871.
6. Hedayati SS, Elsayed EF, Reilly RF. Non-pharmacological aspects of blood pressure management: what are the data? *Kidney Int* 2011; 79:1061–1070.
7. Ogedegbe G, Schoenthaler A. A systematic review of the effects of home blood pressure monitoring on medication adherence. *J Clin Hypertens* 2006; 8:174–180.
8. Abdullah A, Othman S. The influence of self-owned home blood pressure monitoring (HBPM) on primary care patients with hypertension: a qualitative study. *BMC Fam Pract* 2011; 12:143.
9. Saito I, Nomura M, Hirose H, Kawabe H. Use of home blood pressure monitoring and exercise, diet and medication compliance in Japan. *Clin Exp Hypertens* 2010; 32:210–213.
10. McManus RJ, Wilson S, Delaney BC, Fitzmaurice DA, Hyde CJ, Tobias RS, Jowett S, Hobbs FD. Review of the usefulness of contacting other experts when conducting a literature search for systematic reviews. *BMJ* 1998; 317:1562–1563.
11. Fletcher B, Hartmann-Boyce J, Roberts N, Hinton L, McManus RJ. *Effect of home blood pressure monitoring on medication adherence, medication persistence and lifestyle factors in hypertensives: systematic review protocol*, http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014007567, 2014.
12. Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions [Version 5.0.2] The Cochrane Collaboration. www.cochrane-handbook.org, 2009.
13. 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; 13:147–150.
14. Bove AA, Homko CJ, Santamore WP, Kashem M, Kerper M, Elliott DJ. Managing hypertension in urban underserved subjects using telemedicine–a clinical trial. *Am Heart J* 2013; 165:615–621.
15. De Souza WKSB, Jardim PCBV, Brito LP, Araujo FA, Sousa ALL. Self measurement of blood pressure for control of blood pressure levels and adherence to treatment. *Arquivos Brasileiros de Cardiologia* 2012; 98:167–174.
16. Düsing R, Handrock R, Klebs S, Tousset E, Vrijens B. Impact of supportive measures on drug adherence in patients with essential hypertension treated with valsartan: the randomized, open-label, parallel group study VALIDATE. *J Hypertens* 2009; 27:894–901.
17. Fikri-Benbrahim N, Faus MJ, Martínez-Martínez F, Sabater-Hernández D. Impact of a community pharmacists' hypertension-care service on medication adherence. The AFenPA study. *Res Social Adm Pharm* 2013; 9:797–805.
18. Friedman RH, Kazis LE, Jette A, Smith MB, Stollerman J, Torgerson J, Carey K. A telecommunications system for monitoring and counseling patients with hypertension. Impact on medication adherence and blood pressure control. *Am J Hypertens* 1996; 9:285–292.
19. Green BB, Anderson ML, Cook AJ, Catz S, Fishman PA, McClure JB, Reid RJ. e-Care for heart wellness: a feasibility trial to decrease blood pressure and cardiovascular risk. *Am J Prev Med* 2014; 46:368–377.
20. Haynes RB, Sackett DL, Gibson ES, Taylor DW, Hackett BC, Roberts RS, Johnson AL. Improvement of medication compliance in uncontrolled hypertension. http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/229/CN-00017229/frame.html 1976.
21. Hosseininasab M, Jahangard-Rafsanjani Z, Mohagheghi A, Sarayani A, Rashidian A, Javadi M, Ahmadvand A, Hadjibabaie M, Gholami K. Self-monitoring of blood pressure for improving adherence to antihypertensive medicines and blood pressure control: a randomized controlled trial. *Am J Hypertens* 2014; 27:1339–1345.
22. Johnson AL, Taylor DW, Sackett DL, Dunnett CD, Shimizu AG. Self-recording of blood pressure in the management of hypertension. *Can Med Assoc J* 1978; 119:1034–1039.
23. Kirscht JP, Kirscht JL, Rosenstock IM. A test of interventions to increase adherence to hypertensive medical regimens. http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/277/CN-00027277/frame.html 1981.
24. Magid DJ, Ho PM, Olson KL, Brand DW, Welch LK, Snow KE, Lambert-Kerzner AC, Plomondon ME, Havranek EP. A multimodal blood pressure control intervention in 3 healthcare systems. *Am J Manag Care* 2011; 17:e96–103.
25. Márquez-Contreras E, Martell-Claros N, Gil-Guillén V, de la Figuera-Von Wichmann M, Casado-Martínez JJ, Martín-de Pablos JL, Figueras M, Galera J, Serra A; Compliance Group of the Spanish Society of Hypertension (SEE). Efficacy of a home blood pressure monitoring programme on therapeutic compliance in hypertension: the EAPACUM-HTA study. *J Hypertens* 2006; 24:169–175.
26. McKenney JM, Munroe WP, Wright JT Jr. Impact of an electronic medication compliance aid on long-term blood pressure control. *J Clin Pharmacol* 1992; 32:277–283.
27. McManus RJ, Mant J, Roalfe A, Oakes RA, Bryan S, Pattison HM, Hobbs FD. Targets and self monitoring in hypertension: randomised controlled trial and cost effectiveness analysis. *BMJ* 2005; 331:22.
28. Mehos BM, Saseen JJ, MacLaughlin EJ. Effect of pharmacist intervention and initiation of home blood pressure monitoring in patients with uncontrolled hypertension. *Pharmacotherapy* 2000; 20:1384–1389.
29. Midanik LT, Resnick B, Hurley LB, Smith EJ, McCarthy M. Home blood pressure monitoring for mild hypertensives. *Public Health Rep* 1991; 106:85–89.
30. Migneault JP, Dedier JJ, Wright JA, Heeren T, Campbell MK, Morisky DE, Rudd P, Friedman RH. A culturally adapted telecommunication system to improve physical activity, diet quality, and medication adherence among hypertensive African-Americans: a randomized controlled trial. *Ann Behav Med* 2012; 43:62–73.
31. Niiranen TJ, Leino K, Puukka P, Kantola I, Karanko H, Jula AM. Lack of impact of a comprehensive intervention on hypertension in the primary care setting. *Am J Hypertens* 2014; 27:489–496.
32. Ogbuokiri JE. Self-monitoring of blood pressures in hypertensive subjects and its effects on patient compliance. *Drug Intell Clin Pharm* 1980; 14:424–427.
33. Ogedegbe G, Tobin JN, Fernandez S, Cassells A, Diaz-Gloster M, Khalida C, Pickering T, Schwartz J. Counseling African Americans to Control Hypertension: cluster-randomized clinical trial main effects. *Circulation* 2014; 129:2044–2051.
34. Rinfret S, Lussier MT, Peirce A, Duhamel F, Cossette S, Lalonde L, Tremblay C, Guertin MC, LeLorier J, Turgeon J, Hamet P; LOYAL Study Investigators. The impact of a multidisciplinary information technology-supported program on blood pressure control in primary care. *Circ Cardiovasc Qual Outcomes* 2009; 2:170–177.
35. Rudd P, Miller NH, Kaufman J, Kraemer HC, Bandura A, Greenwald G, Debusk RF. Nurse management for hypertension. A systems approach. *Am J Hypertens* 2004; 17:921–927.
36. Stewart K, Mc Namara KP, George J. Challenges in measuring medication adherence: experiences from a controlled trial. *Int J Clin Pharm* 2014; 36:15–19.
37. van Onzenoort HA, Verberk WJ, Kroon AA, Kessels AG, Nelemans PJ, van der Kuy PH, Neef C, de Leeuw PW. Effect of self-measurement of blood pressure on adherence to treatment in patients with mild-to-moderate hypertension. *J Hypertens* 2010; 28:622–627.
38. Vrijens B, Goetghebeur E. Comparing compliance patterns between randomized treatments. *Control Clin Trials* 1997; 18:187–203.
39. Wakefield BJ, Holman JE, Ray A, Scherubel M, Adams MR, Hills SL, Rosenthal GE. Outcomes of a home telehealth intervention for patients with diabetes and hypertension. *Telemed J E Health* 2012; 18:575–579.
40. 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; 10:58–67.
41. Cohen J (ed). *Statistical Power Analysis for the Behavioral Sciences*, 2nd edn. Hillsdale, NJ: Lawrence Erlbaum Associates, 1988.
42. Chowdhury R, Khan H, Heydon E, Shroufi A, Fahimi S, Moore C, Stricker B, Mendis S, Hofman A, Mant J, Franco OH. Adherence to cardiovascular therapy: a meta-analysis of prevalence and clinical consequences. *Eur Heart J* 2013; 34:2940–2948.
43. Mennini FS, Marcellusi A, von der Schulenburg JM, Gray A, Levy P, Sciattella P, Soro M, Staffiero G, Zeidler J, Maggioni A, Schmieder RE.

Cost of poor adherence to anti-hypertensive therapy in five European countries. *Eur J Health Econ* 2014; 5:5.
44. Nasseh K, Glave Frazee S, Visaria J, Vlahiotis A, Tian Y. Cost of medication nonadherence associated with diabetes, hypertension, and dyslipidemia. *Am J Pharm Benefits* 2012; 4:e41–e47.
45. Law MR, Morris JK, Wald NJ. Use of blood pressure lowering drugs in the prevention of cardiovascular disease: meta-analysis of 147 randomised trials in the context of expectations from prospective epidemiological studies. *BMJ* 2009; 338:b1665.
46. Takiya LN, Peterson AM, Finley RS. Meta-analysis of interventions for medication adherence to antihypertensives. *Ann Pharmacother* 2004; 38:1617–1624.
47. Peterson AM, Takiya L, Finley R. Meta-analysis of trials of interventions to improve medication adherence. *Am J Health Syst Pharm* 2003; 60:657–665.

Chapter 3

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Review article

Self-monitoring blood pressure in hypertension, patient and provider perspectives: A systematic review and thematic synthesis

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ABSTRACT

Objective: To systematically review the qualitative evidence for patient and clinician perspectives on self-measurement of blood pressure (SMBP) in the management of hypertension focussing on: how SMBP was discussed in consultations; the motivation for patients to start self-monitoring; how both patients and clinicians used SMBP to promote behaviour change; perceived barriers and facilitators to SMBP use by patients and clinicians.
Methods: Medline, Embase, PsycINFO, Cinahl, Web of Science, SocAbs were searched for empirical qualitative studies that met the review objectives. Reporting of included studies was assessed using the COREQ framework. All relevant data from results/findings sections of included reports were extracted, coded inductively using thematic analysis, and overarching themes across studies were abstracted.
Results: Twelve studies were included in the synthesis involving 358 patients and 91 clinicians. Three major themes are presented: interpretation, attribution and action; convenience and reassurance v anxiety and uncertainty; and patient autonomy and empowerment improve patient-clinician alliance.
Conclusions: SMBP was successful facilitating the interaction in consultations about hypertension, bridging a potential gap in the traditional patient-clinician relationship.
Practice implications: Uncertainty could be reduced by providing information specifically about how to interpret SMBP, what variation is acceptable, adjustment for home-clinic difference, and for patients what they should be concerned about and how to act.
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1. Introduction

Evidence from randomised controlled trials (RCTs) shows that self-monitoring blood pressure (SMBP), either alone or as part of a complex intervention, is effective in achieving blood pressure (BP) reduction and better BP control in patients with hypertension [1–3]. In trials patients who self-monitor compared to usual care, on average have lower BP at 6 months (−3.9 mmHg systolic [$p \leq 0.001$], −2.4 mmHg diastolic [$p \leq 0.001$]), and this effect is increased when SMBP is used with additional support such as provision of educational materials, electronic transmission of BP data, telecounseling, etc. [3]. While SMBP has been shown to be effective at improving BP over periods of 6–18 months, there is currently little information as to whether it has any impact on longer-term outcomes such as cardiovascular outcomes or death, although modelling the impact of the blood pressure effects is likely to be cost effective intervention in the longer term [4].

For SMBP to achieve an effect on BP, it is likely that regular monitoring initiates or supports behaviour change in patients, the healthcare professionals managing their condition, or both. Potential mechanisms through which SMBP may be successful include improvements in medication adherence and lifestyle factors in patients, and helping overcome clinical inertia in clinicians [5]. Evidence from RCTs shows an association between SMBP use and medication adherence, however the evidence for lifestyle change remains equivocal [6].

Recent clinical guidelines have included recommendations for the use of SMBP in the diagnosis of hypertension and in monitoring BP control (i.e. UK NICE 2011, ESH/ESC Europe 2013). However, it is unclear to what extent the patient and clinician voice, particularly with regard to acceptability and use in "real-world settings" have been incorporated. When evaluating health technologies, data on effectiveness and cost-effectiveness are often prioritised and as such, reviews demonstrating the efficacy of SMBP have often ignored the needs, views and perceptions of patients and physicians. With a current focus in healthcare on patient-centred care, trials now often include a qualitative component to elicit the views and preferences of patients, and sometimes clinicians. However, systematic reviews regularly do not include these data, leading to a loss of the patient and physician voice, and along with it the context within which interventions may or may not work. Methods for synthesising qualitative evidence and incorporating qualitative evidence in broader reviews have been developed, and are becoming more commonplace [7,8]. This review complements recent reviews of the effectiveness of SMBP, by also presenting a synthesis of the available evidence on patient and clinician beliefs and preferences. Evidence is drawn from daily practice (i.e. 'real-world') settings, or linked to involvement in trials or intervention/program development.

Exploring what works and what is acceptable to both patients and professionals is crucial to optimising SMBP interventions for use in real-world settings. The objectives of this review were to investigate: the motivation for patients to start self-monitoring; how patients and clinicians use SMBP to promote behaviour change; the perceived barriers and facilitators to SMBP use by patients and clinicians; as well as communication and interaction between the two parties.

2. Methods

The methods are described in detail in the protocol that was developed and registered on the PROSPERO database [9]. The ENTREQ (enhancing transparency in reporting the synthesis of qualitative research) framework was used to report the results of the review, and includes items grouped into five domains: introduction and methodology, literature search and selection, appraisal, and synthesis of findings (Appendix 1) [10].

2.1. Information sources and study selection

Electronic databases (Medline, Embase, PsycINFO, Cinahl, Web of Science, SocAbs) were searched from inception to July 2014 to identify qualitative studies that examined the perspectives of patients with hypertension, or the healthcare professionals managing their care, on the use of SMBP. The search strategy was developed in Medline and translated for use in the other databases (Appendix 2). Forward and backward citation searches were carried out on any studies included following the electronic database searches.

Studies were eligible if they:

- Included ambulatory patients with hypertension or the healthcare professionals managing their care;
- Were based in primary care, outpatient clinics or the community;
- Investigated perspectives of self-monitoring of blood pressure and
- Reported the results of primary qualitative research (i.e. interviews, focus groups, ethnography).

Two reviewers independently screened the reports for inclusion looking first at title and abstracts (BF, JHB). Full text articles were obtained for studies that appeared to meet the inclusion criteria, or studies where a definite decision could not be made.

2.2. Quality assessment

Two Reviewers independently assessed each included report using the Consolidated Criteria for Reporting Qualitative Health Research (COREQ) framework (BF/NB), which has criteria relating to: research team and reflexivity; study design; and analysis and findings [11].

2.3. Data extraction

Data extraction was first carried out using an adaptation of the JBI QARI form for interpretive research (Joanna Briggs Institute qualitative assessment and review instrument) [12]. The form allowed broad themes to be identified from the studies, which were used to guide the first stage of analysis.

All text was extracted from sections labelled as 'results' or 'findings' in the included reports and entered into QSR NVivo 10 software for qualitative thematic analysis.

2.4. Synthesis

Systematic reviews of qualitative data should go further than simply describing the identified research to translating the findings into new theories to answer the research question. It has been argued that three criteria are the foundation of good qualitative reviews: interpretation of subjective meaning; description of social context; and attention to lay knowledge [13]. This review is consistent with these methodological aims.

Thematic synthesis was chosen as it uses methods that are established for the analysis of primary data, and translates them for use in systematic reviews [14]. Line-by-line coding was carried out on relevant data by one researcher (BF) and agreed throughout by discussion with a second (LH). Initial descriptive codes were grouped into related areas to construct descriptive themes. Abstracted analytical themes were then developed by BF and refined in collaboration with LH and RM. Coding was inductive, with theme development directed by the content of the data. Wherever possible quotes from the participants of included studies (primary data) have been presented to demonstrate the analytical themes; where participant quotes were not available author interpretations have been included. Quotes are presented followed by information about the individual (i.e. patient, clinician, author interpretation), and setting (i.e. study in 'daily practice' setting, linked to a trial, or part of intervention development).

3. Results

3.1. Searches

Database searches yielded 668 articles, with two additional records from citation searches. Following removal of duplicates and title and abstract screening, 45 full text articles were assessed and 12 articles met the selection criteria [15–26]. (PRISMA diagram, Fig. 1)

3.2. Study characteristics

The characteristics of included studies are presented in Table 1. Some studies included more than one population and/or more than one methodology.

Eleven studies involved patients ($n = 358$), and five involved healthcare professionals ($n = 91$). The earliest article was published in 2003 with the majority (8/12) published during the last five years. Seven studies took place in the UK, two in USA, and one each in Malaysia, Canada, and Sweden. Eight studies used interviews and five used focus groups.

Five studies were qualitative studies embedded within RCTs testing SMBP interventions; three were part of SMBP intervention/programme development; and the remaining four investigated SMBP use in "daily practice" settings.

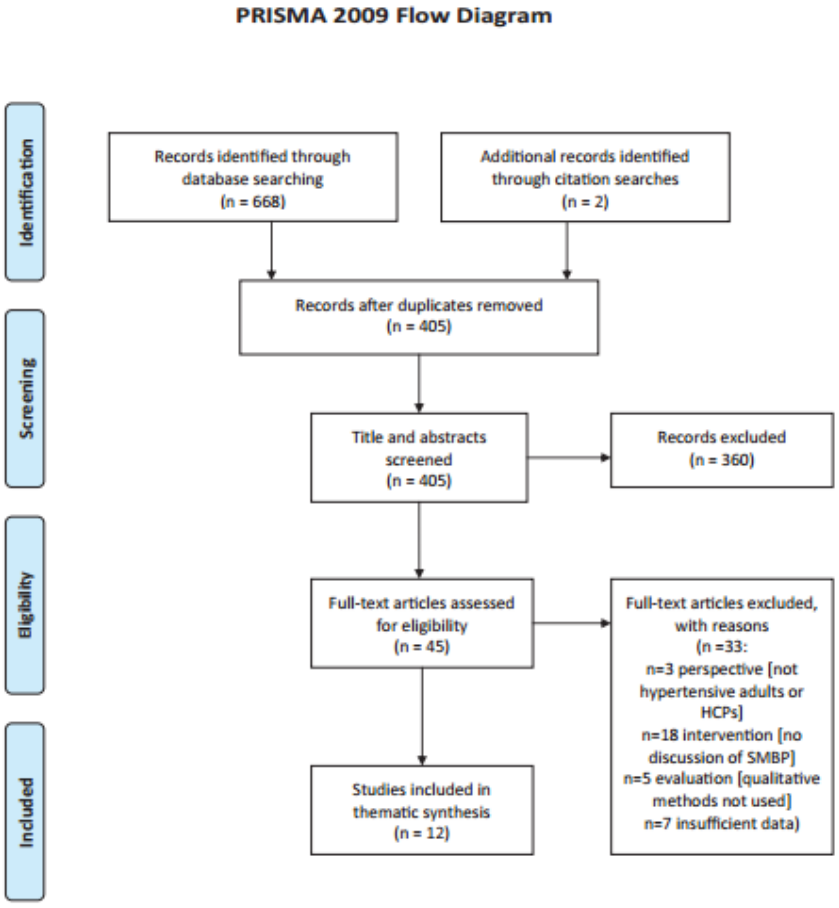

Fig. 1. PRISMA 2009 flow diagram.

Table 1
Characteristics of included studies.

Study	Country	Design	Participants	Objectives	Setting	RW/T/ID
Abdullah and Othman [15]	Malaysia	Focus groups (×2)	Patients with hypertension who had self-initiated SMBP (n = 24; 6 interview, 18 focus group)	To explore the experiences of purchasing and using SMBP at patients' own initiative	Urban primary care clinic	RW
Bengtsson et al. [16]	Sweden	Focus groups (×5)	Patients with hypertension (n = 15), and healthcare professionals (n = 12: 4 nurses, 4 physicians and 4 pharmacists)	To explore and describe relevant aspects of hypertension and hypertension treatment, to be used in the development of an interactive mobile phone self-report system for hypertension self-management	Primary healthcare centre and internal medical outpatient clinic	ID
Bostock et al. [17]	UK	Focus groups (×3)	Patients with hypertension (n = 16), and healthcare professionals (n = 25: 3 nurses and 6 GPs)	To establish any concerns patients and clinicians may have about mobile phone based BP monitoring before planning an RCT. To investigate how commonly patients and clinicians made use of home-monitoring results in managing their BP	Four general practices chosen to reflect range of socio-economic conditions.	ID
Halifax et al. [18]	Canada	Interviews (×6)	Patients with comorbid type II diabetes and hypertension (n = 24) and family practitioners (n = 18)	To determine the information needs of patients and clinicians for the design of a telemedicine system	Hypertension clinic, diabetes clinic or family medicine centre	ID
Hanley et al. [19]	UK	Interviews (×45)	Patients with hypertension (n = 25), and healthcare professionals (n = 20: 11 nurses and 9 doctors)	To explore the experiences of patients and professionals taking part in a RCT of remote BP telemonitoring supported by primary care. To identify factors facilitating or hindering the effectiveness of the intervention and those likely to influence its potential translation to routine practice.	Six socioeconomically diverse general practices	T
Jones et al. [20]	UK	Interviews (×29)	Patients with hypertension (n = 23) and family members (n = 6)	Qualitative study embedded in RCT to explore patients' views of SMBP with self-titration of anti-hypertensive medication	Twenty four general practices	T
Jones et al. [21]	UK	Interviews (×16)	Healthcare professionals (n = 16: 13 GPs, 2 nurses and 1 healthcare assistant)	Qualitative study embedded in RCT to explore health professionals' views and experiences of patient self-management particularly with respect to future implementation into routine care.	Fourteen general practices	T
Lambert-Kerzener et al. [22]	USA	Interviews (×146)	Patients with hypertension (n = 146)	To explore patients' experiences with a multifaceted BP control intervention involving interactive voice response technology, home BP monitoring and pharmacist led BP management	Veterans affairs medical centre and municipal safety net hospital	T
Ovaisi et al. [23]	UK	Interviews (×26)	Patients with hypertension who had suffered a stroke or TIA in past 9 months (n = 26)	From the intervention arm of a community-based RCT of SMBP, to explore patients' experiences of self-monitoring with nurse-led support.	Hospital stroke clinic	T
Rickerby and Woodward [24]	UK	Interviews (×13)	Patients with hypertension (n = 13)	To investigate the experiences of individuals who had carried out SMBP	Single GP practice	RW
Schmid et al. [25]	USA	Focus groups (×6)	Patients with a stroke or TIA in the past 24 months (n = 28)	To identify BP self-management strategies used by individuals who had suffered a stroke or TIA.	Veterans affairs medical centre	RW
Vasileiou et al. [26]	UK	Interviews (×18)	Patients—users of SMBP (n = 18)	To explore the reasoning behind the interpretation of home readings, and the way people interact with their doctor with reference to these values and the practice of SMBP	Community	RW

*Real-world (RW), linked to trial (T) or intervention/programme development (ID).

3.3. Quality assessment

The comprehensiveness of reporting across studies is presented in Table 2. Reporting varied, with studies reporting between 13 and 25 of the 32 items in the COREQ checklist. The domain including research team and reflexivity was not generally well reported, with no item reported by more than half of the studies. The experience and training of the interviewer/facilitator, and their characteristics with regard to bias, assumptions and interest in the research topic were only reported by one study each.

The second domain regarding study design was better reported with the exception of: the presence of non-participants (1 study); the presence of repeat interviews (0 studies); and the return of transcripts to participants for comment/correction (1 study). The methodological orientation underpinning the study was only reported in 2 studies.

The final domain, analysis and findings, was generally well reported, with the exception of: the description of the coding tree (3 studies), participants providing feedback on finding (1 study), and the use of software for analysis (5 studies).

3.4. Thematic synthesis

Initial coding produced 65 descriptive codes which were grouped into three broad analytical themes. The first is pragmatic and describes how patients and clinicians use SMBP, how they interpret the results, to what patients attribute high/low/change in BP, and what actions are taken based on SMBP. The second theme describes the balance between SMBP being perceived as convenient and reassuring contrasted with the potential for causing anxiety and uncertainty. The final theme deals with patient empowerment, autonomy and self-efficacy, and how SMBP changes the traditional patient-clinician dynamic.

3.4.1. Theme 1—interpretation, attribution and action

How patients interpreted their BP and acted upon self-measurement depended to a large extent on their understanding of high BP. While patients were aware of some of the potential risks factors for, and consequences of high BP, many did not know what their target BP should be.

Table 2
Quality assessment using the COREQ checklist.

COREQ Domain/ Item	Research team and reflexivity								Study design								
	1. Interviewer/ facilitator	2. Credentials	3. Occupation	4. Gender	5. Experience and training	6. Relationship established	7. Participant knowledge of the interviewer	8. Interviewer characteristics	9. Methodological orientation and theory	10. Sampling	11. Method of approach	12. Sample size	13. Non-participation	14. Setting of data collection	15. Presence of non-participants	16. Description of sample	17. Interview guide
Abdullah and Othman [15]	Y	N	N	Y	N	N	N	N	Y	Y	Y	Y	N	N	N	Y	Y
Bengtsson et al. [16]	N	N	N	Y	N	N	N	N	N	Y	Y	Y	N	N	N	Y	Y
Bostock et al. [17]	N	N	N	Y	N	N	N	N	N	Y	N	Y	N	Y	N	Y	N
Halifax et al. [18]	N	Y	N	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	N
Hanley et al. [19]	Y	N	Y	Y	Y	N	N	Y	N	Y	Y	Y	Y	Y	N	Y	Y
Jones et al. [20]	N	Y	Y	Y	N	N	N	N	N	Y	N	Y	Y	Y	N	Y	N
Jones et al. [21]	N	Y	Y	Y	N	N	N	N	N	Y	N	Y	Y	Y	N	Y	N
Lambert-Kerzener et al. [22]	Y	Y	N	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N	Y	N
Ovaisi et al. [23]	N	Y	Y	Y	N	N	N	N	N	Y	N	Y	Y	Y	N	Y	N
Rickerby and							Woodward [24]	Y	N	N	Y	N	N	N	N	Y	Y
Y	Y	Y	Y	N	Y	Y											
Schmidet al. [25]	N	Y	N	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N	Y	N
Vasileiou et al. [26]	Y	N	N	Y	N	N	N	N	N	Y	Y	Y	N	N	N	Y	Y
Total (n = 12)	5	6	4	12	1	0	0	1	2	12	8	12	8	9	1	12	5

COREQ Domain/ Item	Study design						Analysis and findings									Total (n = 32)
	18. Repeat interviews	19. Audio/ visual recording	20. Field notes	21. Duration	22. Data saturation	23. Transcripts returned	24. Number of data coders	25. Description of the coding tree	26. Derivation of themes	27. Software	28. Participant checking	29. Quotations presented	30. Data and findings consistent	31. Clarity of major themes	32. Clarity of minor themes	
Abdullah et al. [15]	N	Y	Y	Y	Y	N	Y	N	Y	Y	N	Y	Y	Y	Y	19
Bengtsson et al. [16]	N	Y	N	Y	Y	N	N	Y	Y	Y	N	Y	Y	Y	Y	16
Bostock et al. [17]	N	Y	Y	Y	N	N	N	Y	N	N	N	Y	Y	Y	Y	11
Halifax et al. [18]	N	Y	N	Y	N	N	N	N	Y	N	N	N	N	Y	Y	14
Hanley et al. [19]	N	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	25
Jones et al. [20]	N	Y	Y	Y	Y	N	N	N	Y	N	N	Y	Y	Y	Y	17
Jones et al. [21]	N	Y	Y	Y	Y	N	Y	N	Y	N	N	Y	Y	Y	Y	18
	N	Y	N	Y	N	N	Y	N	Y	N	N	Y	Y	Y	Y	17

Lambert-Kerzner et al. [22]																							18	
Owais et al. [23]	N	Y	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	Y	19	
Rickerby and Woodward [24]	N	Y	Y	Y	N	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	Y		
Schmid et al. [25]	N	Y	N	N	N	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	Y	16	
Vasileiou et al. [26]	N	Y	N	N	N	N	Y	N	N	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	Y	15	
Total (n = 12)	0	12	6	9	8	1	7	3	11	5	1	11	11	12	12									

" . . . people need to know [target BP] because you do get very uncomfortable whether . . . is this the danger level?" Rickerby (2003) [patient, daily practice]

There was a belief among some patients that BP targets should be personalised to take their individual circumstances into account. Clinicians worked to guidelines, which were perceived to be inflexible in their definition of normal and target BP:

"Clearly, participants were trying to find functional ways to define acceptable ranges of BP values. The guideline values were and initial broad framework for judgements, but within this, the personalised norm was deployed as a more meaningful rule of thumb, especially for those users who had a relatively consistent history of elevated or reduced readings." Vasileiou (2013) [author interpretation, daily practice]

"The healthcare professionals worked according to national guidelines, but did not use them as a tool to set individual goals. Subsequently, the patients had neither a goal to focus on not an understanding of the actual blood pressure value." Bengtsson (2014) [author interpretation, intervention development]

There was a consensus between clinicians and patients that SMBP provided a more accurate picture of BP than casual clinic measurement due to the larger number of measurements, and it was this that led some patients to acquire their own monitor.

"I can't remember if they . . . if I was advised to go and buy a home monitoring machine, but I decided to do it anyway . . . I knew that my blood pressure would be checked every time, regularly at the surgery but certainly twice a year . . . but until that I would like more information than that." Hanley (2013) [patient, intervention development]

However, the improved accuracy of SMBP was tempered by observation of the inherent variation in blood pressure. Patients and clinicians were aware that self-measured blood pressure tended to be lower than clinic measures, which led to a dilemma of which measurement was best to use for treatment. Variation between successive SMBP measurements was also noted, again with uncertainty as to which readings should be used.

"I could do it one minute and then five minutes later it would be completely different." Rickerby (2003) [patient, daily practice]

"It's put us in a bit of a dilemma I think cos we're getting their blood pressures and then when they are doing them at home, they're low, it's difficult isn't it, to know what to do." Jones (2013) [practice nurse, trial]

After using SMBP, patients questioned whether the usual practice of casual clinic measurement was sufficient to provide accurate information.

" Why we need the machine in the house? [. . .] because our visit to the doctor is infrequent." Abdullah (2011) [patient, daily practice]

Patients often found that high BP had little impact on their daily lives due to the lack of symptoms, and that SMBP gave them an insight into their condition by acting as a proxy for symptoms. SMBP enabled patients to begin to make associations between their BP, symptoms and actions in their daily lives, and were then able to identify ways to self-manage.

"I mean I remember taking my blood pressure and it reading very high and I thought gosh I feel really great at the moment." Rickerby (2003) [patient, daily practice]

"Perhaps because high blood pressure doesn't have proper symptoms. Many think . . . 'oh, I'm fine'." Bengtsson (2014) [HCP, intervention development]

Some clinicians were concerned that patients were not able to interpret SMBP correctly and might incorrectly attribute some symptoms to their BP.

" . . . and then you've got others; 'Oh, I feel a bit ill today, I'll better check my BP' . . . and I think that's the danger" Hanley (2013) [HCP, trial]

Patients were able to use SMBP to monitor the effectiveness of their medication and changes to their lifestyle. SMBP had an impact on whether patients were adherent, whether they initiated or terminated treatment, and to what extent they tailored treatment. In the absence of symptoms, having SMBP as a symptom proxy helped demonstrate the effectiveness of treatment. Clinicians recognised the benefits of being able to use SMBP in conjunction with clinic measurements to make more rapid adjustments to patients' medication, thus overcoming clinical inertia.

"I think taking my BP regularly really made me show that I did need to take the medication and that was somewhat motivating . . . it did show that the medication was important." Lambert-Kerzener (2010) [patient, trial]

As well as monitoring BP in relation to medication use, patients were able to use SMBP to attribute lifestyle factors to high BP, and then in many cases act in response. However, patients were concerned that they only received generalised advice about how lifestyle change could help, and would prefer the information to be tailored to hypertension in particular as well as more personalised or tailored advice.

"When it's high, then I know it's either my diet or I've not been exercising. So when it's high I'll take my walks. I'll do my aerobics and then cut down on meats, go vegetarian." Abdullah (2011) [patient, daily practice]

"What I did do, and I've stuck to it, I've cut out salt. I was overweight a few years ago and I cut out butter, so now I don't have butter and I don't have salt. I just use general knowledge." Hanley (2013) [patient, trial]

"Lifestyle advice was received from multiple sources and perceived to be general rather than being targeted at the reasons for them individually developing hypertension." Hanley (2013) [author interpretation, trial]

One article raised the interesting perspective that patients and clinicians may have different expectations of treatment for hypertension:

" . . . patients who perceive symptoms they believe are due to high blood pressure should not expect to feel better from the treatment. Rather, the treatment should merely serve to prevent these patients from feeling worse." Bengtsson (2014) [author interpretation, intervention development]

3.4.2. Theme 2—convenience and reassurance v anxiety and uncertainty

SMBP was seen to be convenient and easy to use by patients, and the process was in some cases even said to be enjoyable. Patients were more relaxed out of the clinic environment, and liked the ability to be able to monitor as and when they wanted. Patients felt reassured by being able to check symptoms that were potentially attributable to elevated BP. Patients trusted the technology of automated BP monitors.

"And it always comes in handy; you feel a little bit dodgy, you can always take it to see what your blood pressure is." Ovaisi (2011) [patient, trial]

"I am reassured and I feel quite happy with the fact that I know that my blood pressure is ok. I don't have to think 'oh God I haven't been to the doctor in 4 months, I wonder if my BP is alright' I know it is." Jones (2012) [patient, trial]

While clinicians recognised that patients were generally positive about SMBP, they were concerned that some might be anxious about the process or results of self-monitoring, potentially becoming neurotic. They also raised concerns about the ability of some patients to be able to manage the process of monitoring.

"I think they get a little bit neurotic about it. You know, they're checking it every day." Jones (2013) [HCP, trial]

" . . . it may not be applicable to patients with poor technical skills or those who were easily 'over focused'." Halifax (2007) [author interpretation, intervention development]

Some patients did discuss being anxious, and this was usually in relation to what to do when BP was high. While there is scope for patients to become anxious about high BP readings from self-monitoring, it was recognised that this anxiety can either inhibit or promote action; anxiety is only a bad thing if patients feel that they are unable to do anything about it.

"I would be quite worried if I took it all the time and it was high. I just think that I'm perfectly alright until I go to the surgery in four months' time. I don't worry about it. I don't think about it." Bostock (2009) [patient, intervention development]

Little evidence was presented that showed patients feeling burdened by the process of self-monitoring (i.e. according to a rigorous protocol), which was a concern of a small number of clinicians.

Uncertainty for both patients and clinicians stemmed from how to interpret the results of SMBP, in particular coping with variability, as well as when and how to act upon the readings. For patients, the main concern was knowing at what point they needed to act.

"Where should it [BP] be? That way I'll know if me or the missus gotta give a call to an ambulance to come get me . . . because I don't know what it's supposed to be. I don't know if I should call." Schmid (2009) [patient, daily practice]

It might be expected that providing clinicians with more accurate BP results would help reduce treatment uncertainty, but this does not seem to be the case. Even when clinicians were provided with clear protocols for treatment, as in trials where medication was titrated based on SMBP, clinicians were still unsure how to manage borderline cases. In the daily practice settings clinicians were unsure how to incorporate SMBP into routine care, which may have been perceived as reticence by patients.

"The only problem I had with it in a way is these people that were coming up as uncontrolled who were one millimetre above the control level. And I just thought, oh come on, are you really going to add in another drug to bring this down?" Hanley (2013) [HCP, trial]

"GPs were inconsistent in how they used patients' home readings. They reported patients sometimes brought home readings to consultations but not in an organised way and even when GPs asked to see the readings, they did not always incorporate these into decision making." Jones (2013) [author interpretation, trial]

3.4.3. Theme 3—patient empowerment, autonomy and self-efficacy, and how SMBP changes the traditional patient-clinician dynamic

Using SMBP increased patients' involvement in their own care, increased their knowledge about their condition, and empowered them to make changes to benefit/improve their BP. Empowering patients also changed the dynamic of the patient-clinician relationship. Some patients thought that clinicians could be protective of BP results from the clinic, perhaps because the clinicians did not think the patient could understand.

"But when we went for a check-up the doctor rarely tells us the actual BP reading. He did not tell us the readings he just said it's ok." Abdullah (2011) [patient, daily practice]

In contrast SMBP was seen to facilitate discussion, creating a clinician-patient alliance with patients better able to understand and be involved in making decisions about treatment. SMBP provided clinicians with more concrete information rather than what could be sometimes ambiguous symptoms. Patients also thought that if they were self-monitoring they might be taken more seriously by their clinician.

"It's certainly given me more meaningful data to speak to the doctor rather than, 'Well, I think my BP has probably gone up'." Hanley (2013) [patient, trial]

"I think the doctor will observe you're being a bit more serious than vaguely talking about this, that and the other." Vasileiou (2013) [patient, daily practice]

" The knowledge and information (i.e. SMBP measurements) they brought to the visit facilitated a bidirectional conversation that supported their self-care as well as assisted their physicians " Lambert-Kerzener (2010) [author interpretation, trial]

Whilst most clinicians were generally supportive of their patients self-monitoring, some patients met with apparent disinterest from their clinician when they tried to communicate the results of self-monitoring, which was disempowering. The perceived disinterest may have been due to a lack of clear guidance for clinicians as to what to do with data from self-monitoring.

"I went back quite soon after the initial diagnosis just to confirm that everything was okay. I mentioned that I'd purchased this [SMBP], but that was it really. We didn't really speak about it any more than that." Vasileiou (2013) [patient, daily practice]

SMBP combined with an increased knowledge of BP and hypertension resulted in patients demonstrating self-efficacy. Rather than being in a passive role relying on their GP to both measure their BP and dictate treatment, patients felt more in control of their own care.

"Well the strength is that I have better control. And then that in collaboration with others [nurse/physician] becomes a good foundation for judging how to plan the treatment." Bengtsson (2014) [patient, intervention development]

Both patients and clinicians recognised that there was scope for SMBP to decrease the workload of GPs especially in trials where telemonitoring was used, or where medication was titrated based on SMBP by pharmacists, nurses or the patients themselves.

"It's quite nice to see if you can ship out some of the work to, or give the stuff back to the patients to do which if it makes them more involved and helps them understand is ultimately better." Jones (2013) [HCP, trial]

" . . . maybe just saving time for more serious things and other people." Rickerby (2003) [patient, daily practice]

4. Discussion and conclusion

4.1. Discussion

This systematic review and thematic synthesis found three overarching themes in the world-wide qualitative literature concerning patient and provider perspectives on self-monitoring of hypertension: interpretation, attribution and action; convenience and reassurance versus anxiety and uncertainty; and patient empowerment, autonomy and self-efficacy, and how SMBP changes the traditional patient-clinician dynamic.

The synthesis covered SMBP use from a broad range of settings, including trials, development of interventions and daily practice, as well as from the perspectives of both patients and clinicians. Only four of the studies represented "real-world" settings where patients and clinicians discussed using SMBP as part of their usual practice [15,24–26]. It is possible that the participants of studies linked to trials or intervention development would have different perspectives than the wider population. With the growing enthusiasm for SMBP in everyday practice there is a need for further research into the use of SMBP in "real-world" settings, particularly why patients may initiate SMBP, and where it fits into their everyday lives. The results complement systematic reviews of the efficacy of SMBP by providing information on ease of use and tolerability as well as day to day experiences of self-monitoring.

Thematic synthesis was chosen as it uses analytical methods from primary qualitative studies, applies them to secondary analysis, and allows the clear identification of prominent themes in a methodologically transparent fashion. As with all qualitative research, the analysis was dependent on self-awareness of the potential impact of prior knowledge and experience (reflexivity). The systematic review was conducted by a research team with a broad range of clinical, qualitative, methodological and health services research experience; and all were involved in the development and interpretation of analytical themes.

Both patients and clinicians reported being uncomfortable with interpretation of SMBP measurements, particularly in light of the variability (between home and clinic; reading to reading in the short and long-term). There was agreement that BP targets were not clear, and that guidelines currently do not allow enough flexibility for more personalised targets and norms. While current UK guidelines are clear about how to use SMBP in the diagnosis of hypertension (i.e. NICE 2011), guidance from the UK and internationally for its use in managing hypertension is less clear, reflecting the underlying evidence [3].

SMBP was described as providing a proxy for symptoms (in the usually symptomless setting of hypertension) allowing patients to link activities of daily life with changes in their BP. Patients were aware that certain lifestyle factors such as diet and exercise could affect their BP, and some even used SMBP to experiment with some of these factors. A recent systematic review found that in RCTs, SMBP is associated with improved adherence, but the evidence for associated lifestyle change was equivocal [6]. Another systematic review of RCTs showed that SMBP was associated with less therapeutic inertia (where medication remains unchanged despite elevated BP), however this was not reported as a major factor by the clinicians in the current review [5].

SMBP was described (by both patients and clinicians) as empowering patients, assisting them in managing their BP. Empowered, or 'activated' patients have been shown to be less likely to frequently attend their healthcare provider for management of their condition, thus potentially reducing burden on clinicians as well as costs [27]. This empowerment had an effect on the traditional patient-clinician relationship, with SMBP reported as facilitating discussion about hypertension and giving patients more understanding. Clinicians recognised the benefits of patient self-monitoring and self-management, but described concern that some patients may become anxious (or even neurotic), despite a lack of corroborating patient views.

SMBP combined with increased knowledge of BP was described as resulting in patients demonstrating increased self-efficacy. This supports the evidence from trials that show that adding educational support to SMBP is more effective than SMBP alone [3]. Interestingly educational interventions have not been proven to be effective in managing hypertension [28], suggesting that SMBP and education may have a synergistic effect. Future research could further investigate the interaction between patient education and SMBP.

As SMBP appears to influence behaviour change in both patients and clinicians, it is important to understand where such an effect is greatest, as this would then provide a logical target for

optimisation. Self-monitoring can empower patients and involve them more in their healthcare, as well as provide more accurate and timely information for clinicians, but the precise motivations for starting it will vary from case to case. Targeting the interaction between patients and clinicians around self-monitoring might therefore be a fruitful avenue for future research. This could include considering how SMBP can be used in consultation discussions, particularly in terms of clinician's acceptance and permission giving. There is evidence that many patients may monitor their BP without informing their clinician, and while these patients may have some benefits from self-monitoring in isolation, they should be encouraged to bring the information into the clinical encounter [29]. Improved health communication has been shown to be associated with better health outcomes in chronic conditions, and is therefore a relevant topic for future interventions [30].

Integrating SMBP into everyday practice remains an issue, with no clear current guidance for clinicians. SMBP provides a potential wealth of information, but how it is recorded by patients and then communicated to clinicians remains ad hoc. Telemonitoring is one method that has been shown to be successful in trials, however this has yet to be rolled out to scale [31].

4.2. Conclusion

Whilst patients are often aware of the risks of high BP, they can find BP readings and targets confusing. SMBP, often in conjunction with education about BP and hypertension, gives patients a better understanding of their health state, and a proxy for symptoms in order to be able to act. SMBP empowers patients and facilitates discussion with clinicians.

Clinicians recognise the benefits of having a more accurate picture of patients' BP that is provided by self-monitoring, but are often concerned about how their patients may react to having to self-monitor. More guidance is needed as to how to incorporate self-measured BP into routine practice.

Further research should focus on the best protocol for SMBP for managing hypertension, as well as understanding the role SMBP can play in improving the patient-clinician consultation.

4.3. Practice implication

The results of this review suggest that uncertainty for patients and clinicians could be reduced by providing information specifically about how to interpret SMBP, what variation is acceptable, how to adjust for home-clinic difference, and for patients particularly what they should be concerned about and how to act (i.e. when to contact their clinician). Providing educational materials for patients along with self-monitoring may be crucial in optimising the potential health benefits. Future guidance for clinicians should include information on: targets for self-measured BP; how often patients need to self-monitor; how the information should be recorded by patients and communicated to clinicians in a format that can be readily used to guide treatment.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.pec.2015.08.026.

References

[1] E.P. Bray, R. Holder, J. Mant, R.J. McManus, Does self-monitoring reduce blood pressure? Meta-analysis with meta-regression of randomized controlled trials, Ann. Med. 42 (2010) 371–386.
[2] G.S. Stergiou, I.A. Bliziotis, Home blood pressure monitoring in the diagnosis and treatment of hypertension: a systematic review, Am. J. Hypertens. 24 (2011) 123–134.
[3] K. Uhlig, K. Patel, S. Ip, G.D. Kitsios, E.M. Balk, Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis, Ann. Intern. Med. 159 (2013) 185–194.
[4] B. Kaambwa, S. Bryan, S. Jowett, J. Mant, E.P. Bray, F.D. Hobbs, et al., Telemonitoring and self-management in the control of hypertension (TASMINH2): a cost-effectiveness analysis, Eur. J. Prev. Cardiol. 21 (2014) 1517–1530.
[5] R. Agarwal, J.E. Bills, T.J.W. Hecht, R.P. Light, Role of home blood pressure monitoring in overcoming therapeutic inertia and improving hypertension control: a systematic review and meta-analysis, Hypertension 57 (2011) 29–38.
[6] B.R. Fletcher, J. Hartmann-Boyce, L. Hinton, R.J. McManus, The effect of self-monitoring of blood pressure on medication adherence and lifestyle factors: a systematic review and meta-analysis, Am. J. Hypertens. (2015) .
[7] E. Barnett-Page, J. Thomas, Methods for the synthesis of qualitative research: a critical review, BMC Med. Res. Methodol. 9 (2009) 59.
[8] M. Petticrew, E. Rehfuess, J. Noyes, J.P.T. Higgins, A. Mayhew, T. Pantoja, et al., Synthesizing evidence on complex interventions: how meta-analytical, qualitative, and mixed-method approaches can contribute, J. Clin. Epidemiol. 66 (2013) 1230–1243.
[9] B.R. Fletcher, J. Hartmann-Boyce, N.W. Roberts, L. Hinton, R.J. McManus, How do patients and clinicians use home monitoring in the management of hypertension, and what are the barriers and facilitators to its use, both in trials and real-world settings: a systematic review and thematic synthesis, PROSPERO (2014) .
[10] A. Tong, K. Flemming, E. McInnes, S. Oliver, J. Craig, Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ, BMC Med. Res. Methodol. 12 (2012) 181.
[11] A. Tong, P. Sainsbury, J. Craig, Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups, Int. J. Qual. Health Care 19 (2007) 349–357.
[12] J.B. Institute, The Joanna Briggs Institute Reviewers' Manual: 2014 Edition, The Joanna Briggs Institute, Australia, 2014.
[13] J. Popay, A. Rogers, G. Williams, Rationale and standards for the systematic review of qualitative literature in health services research, Qual. Health Res. 8 (1998) 341–351.
[14] J. Thomas, A. Harden, Methods for the thematic synthesis of qualitative research in systematic reviews, BMC Med. Res. Methodol. 8 (2008) 45.
[15] A. Abdullah, S. Othman, The influence of self-owned home blood pressure monitoring (HBPM) on primary care patients with hypertension: a qualitative study, BMC Fam. Pract. 12 (2011) 143.
[16] U. Bengtsson, D. Kasperowski, L. Ring, K. Kjellgren, Developing an interactive mobile phone self-report system for self-management of hypertension. Part 1: patient and professional perspectives, Blood Press. 23 (2014) 288–295.
[17] Y. Bostock, J. Hanley, D. McGown, H. Pinnock, P. Padfield, B. McKinstry, The acceptability to patients and professionals of remote blood pressure monitoring using mobile phones, Prim. Health Care Res. Dev. 10 (2009) 299–308.
[18] N.V. Halifax, J.A. Cafazzo, M.J. Irvine, M. Hamill, C.A. Rizo, W.J. McIssac, et al., Telemanagement of hypertension: a qualitative assessment of patient and physician preferences, Can. J. Cardiol. 23 (2007) 591–594.
[19] J. Hanley, J. Ure, C. Pagliari, A. Sheikh, B. McKinstry, Experiences of patients and professionals participating in the HITS home blood pressure telemonitoring trial: a qualitative study, BMJ Open 3 (2013) .
[20] M.J. Jones, S.M. Greenfield, E.P. Bray, S. Baral-Grant, F.D. Hobbs, R. Holder, et al., Patients' experiences of self-monitoring blood pressure and self-titration of medication: the TASMINH2 trial qualitative study, Br. J. Gen. Pract. 62 (2012) e135–42.
[21] M.J. Jones, S.M. Greenfield, E.P. Bray, F.R. Hobbs, R. Holder, P. Little, et al., Patient self-monitoring of blood pressure and self-titration of medication in primary care: the TASMINH2 trial qualitative study of health professionals' experiences, Br. J. Gen. Pract. 63 (2013) e378–85.
[22] A. Lambert-Kerzner, E.P. Havranek, M.E. Plomondon, K. Albright, A. Moore, K. Gryniewicz, et al., Patients' perspectives of a multifaceted intervention with a focus on technology: a qualitative analysis, Circ. Cardiovasc. Qual. Outcomes (2010) 668–674.
[23] S. Ovaisi, J. Ibison, M. Leontowitsch, G. Cloud, P. Oakeshott, S. Kerry, Stroke patients' perceptions of home blood pressure monitoring: a qualitative study, Br. J. Gen. Pract. 61 (2011) e604–e610.
[24] J. Rickerby, J. Woodward, Patients' experiences and opinions of home blood pressure measurement, J. Hum. Hypertens. 17 (2003) 495–503.
[25] A.A. Schmid, T.M. Damush, L. Plue, U. Subramanian, T. Bakas, L.S. Williams, Current blood pressure self-management: a qualitative study, Rehabil. Nurs. J. 34 (2009) 223–229.
[26] K. Vasileiou, J. Barnett, T. Young, Interpreting and acting upon home blood pressure readings: a qualitative study, BMC Fam. Pract. 14 (2013) 97.

[27] M. Donald, R.S. Ware, I.Z. Ozolins, N. Begum, R. Crowther, C. Bain, The role of patient activation in frequent attendance at primary care: a population-based study of people with chronic disease, Patient Educ. Couns. 83 (2009) 217–221.
[28] L.G. Glynn, A.W. Murphy, S.M. Smith, K. Schroeder, T. Fahey, Interventions used to improve control of blood pressure in patients with hypertension, Cochrane Database Syst. Rev. (2010) CD005182.
[29] A.J. Viera, L.W. Cohen, C.M. Mitchell, P.D. Sloane, Use of home blood pressure monitoring by hypertensive patients in primary care: survey of a practice-based research network cohort, J. Clin. Hypertens. 10 (2008) 280–286.
[30] R.L. Street Jr., G. Makoul, N.K. Arora, R.M. Epstein, How does communication heal? Pathways linking clinician–patient communication to health outcomes, Patient Educ. Couns. 74 (2009) 295–301.
[31] R.J. McManus, J. Mant, M. Haque, et al., Effect of self-monitoring and medication self-titration on systolic blood pressure in hypertensive patients at high risk of cardiovascular disease: The tasmin-sr randomized clinical trial, JAMA 312 (2014) 799–808.

Chapter 4

Research

Benjamin R Fletcher, Lisa Hinton, Emma P Bray, Andrew Hayen, FD Richard Hobbs, Jonathan Mant, John F Potter and Richard J McManus

Self-monitoring blood pressure in patients with hypertension:

an internet-based survey of UK GPs

Abstract

Background
Previous research suggests that most GPs in the UK use self-monitoring of blood pressure (SMBP) to monitor the control of hypertension rather than for diagnosis. This study sought to assess current practice in the use of self-monitoring and any changes in practice following more recent guideline recommendations.

Aim
To survey the views and practice of UK GPs in 2015 with regard to SMBP and compare them with a previous survey carried out in 2011.

Design and setting
Web-based survey of a regionally representative sample of 300 UK GPs.

Method
GPs completed an online questionnaire concerning the use of SMBP in the management of hypertension. Analyses comprised descriptive statistics, tests for between-group differences (*z*; Wilcoxon signed-rank, and χ^2 tests), and multivariate logistic regression.

Results
Results were available for 300 GPs (94% of those who started the survey). GPs reported using self-monitoring to diagnose hypertension (169/291; 58%; 95% confidence interval (CI) = 52 to 64) and to monitor control (245/291; 84%; 95% CI = 80 to 88), the former having significantly increased since 2011 (from 37%; 95% CI = 33 to 41; $P<0.001$) with no change in monitoring for control. More than half of GPs used higher systolic thresholds for diagnosis (118/169; 70%; 95% CI = 63 to 77) and treatment (168/225; 75%; 95% CI = 69 to 80) than recommended in guidelines, and under half (120/289; 42%; 95% CI = 36 to 47) adjusted the SMBP results to guide treatment decisions.

Conclusion
Since new UK national guidance in 2011, GPs are more likely to use SMBP to diagnose hypertension. However, significant proportions of GPs continue to use non-standard diagnostic and monitoring thresholds. The use of out-of-office methods to improve the accuracy of diagnosis is unlikely to be beneficial if suboptimal thresholds are used.

Keywords
blood pressure monitoring, self; general practice; hypertension.

INTRODUCTION

How, where, and when blood pressure (BP) is measured are key aspects in the diagnosis and management of hypertension.[1] In the UK and increasingly elsewhere, 24-hour ambulatory BP monitoring (ABPM) has replaced clinic measurement as the gold standard for the diagnosis of hypertension.[2–4]

Patient self-monitoring of BP (SMBP) provides an alternative to clinic measurement: it is a better predictor of cardiovascular risk than clinic measurements;[5,6] monitors are widely available and less expensive than ABPM.[7] SMBP is generally more acceptable to patients[8,9] and provides information about day-to-day variability of BP, whereas ABPM is generally only used over a single 24-hour period.[10] Self-monitoring involves patients in the management of their own health and has been shown to lead to small but significant improvements in BP, which is potentially important given the ongoing suboptimal BP in the community.[11,12] SMBP has been shown to support medication adherence in patients and aid in overcoming clinical inertia in the doctors managing their care.[13,14]

In the UK, the National Institute for Health and Care Excellence (NICE) updated its guidelines for the clinical management of hypertension in adults in 2011 to include recommendations for self-monitoring in response to the developing evidence base.[1] A survey was conducted immediately before their release in 2011 to assess the knowledge and practice of SMBP in UK GPs.[15] The aim of the current survey was to reassess GPs' use of SMBP in the diagnosis and management of hypertension in light of the change in guidance.

METHOD

Participants and recruitment

An invitation to participate in the survey was made available to GPs on the website Doctors.net.uk for 6 days from 26 to 31 May 2015. Doctors.net.uk provides information services to 212 000 UK registered doctors, of whom 60 000 are GPs; 8125 GPs were active on the site at the time of the survey. Responses were accepted until there were at least 300 completed questionnaires and responses had been received from GPs in each region of the UK in approximate proportion to the number in each region, achieved using a sampling algorithm. Only doctors who identified themselves as GPs could undertake the survey. This is the same methodology used in the original survey in 2011.[15]

As part of a linked methodological study carried out in November 2014, in addition to the responses reported here, the same questionnaire was tested through passive recruitment (that is, an open link on the website available to all as used in this study) and direct recruitment (a representative

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How this fits in

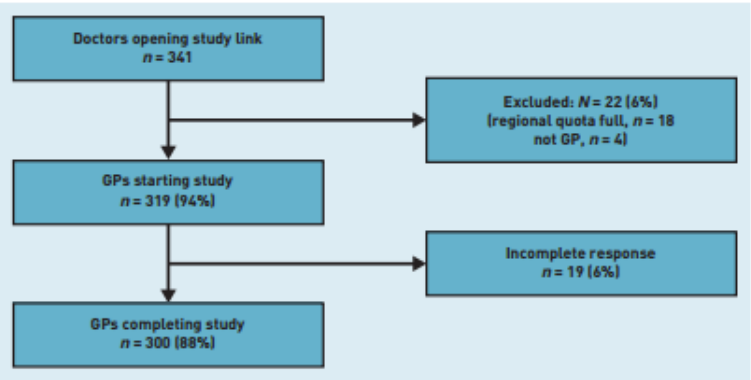
Self-monitoring of blood pressure (SMBP) has shown promise in improving the diagnosis and ongoing management of hypertension, and the UK guidelines were updated in 2011 to reflect this. This study shows that, compared with immediately after the guidelines update, GPs are now more likely to use SMBP to diagnose hypertension; however, significant proportions continue to use non-standard diagnostic and monitoring thresholds. GPs who were surveyed were aware of the benefits of self-monitoring and the practicalities of incorporating SMBP into routine care. There remains room for improvement in implementing appropriate thresholds for diagnosis with SMBP; encouraging and training patients in the use of SMBP; and incorporating new ways of communicating the results of SMBP.

sample of GPs was invited directly). The purpose was to investigate response rates, compare demographic characteristics, and determine whether different recruitment strategies would introduce any bias.

Questionnaire

The questionnaire was designed to ascertain the current use of SMBP to diagnose hypertension and manage control in treated patients; identify the protocols for the use and communication of SMBP; interpret the results of SMBP; identify training and influences on practice with regard to SMBP; and gather participant demographics. The questionnaire replicated a number of questions from a survey carried out in 2011 to allow comparison.[15] It was piloted among academic and non-academic GPs, and further information is available from the authors.

Figure 1. Participant flow chart.



Sample size

It was hypothesised that a greater proportion of GPs would report using SMBP to diagnose hypertension, and that a sample of 300 GPs would detect a 10% difference compared with previous results (one-tailed, 95% confidence interval (CI), 90% power).

Data analysis

Descriptive statistics with CIs around the means are reported. The proportions of GPs who reported using SMBP to confirm a diagnosis of hypertension in 2011 and 2015 were compared using a *z*-test. BP thresholds were compared between 2011 and 2015 using a Wilcoxon signed-rank test. Analyses were performed using Stata for Windows version 12.

Multivariate logistic regression was used to examine the association between physician and practice characteristics and the use of SMBP to diagnose hypertension. Demographic variables hypothesised to be predictive of GP use of SMBP in diagnosis were chosen a priori for inclusion based on the clinical judgement of the authors. These were: sex, age, GP role, year of qualification, country of training, years as a GP, UK region, practice setting, and practice list size. Predictor variables were tested pairwise for correlation before entry into the model.

RESULTS

Participants

A total of 341 doctors opened the study link; after exclusions for exceeding regional quotas and clinical role (that is, hospital doctor), 319 GPs started the survey, of whom 300 (94%) completed all of the questions. Participant flow through the study is shown in Figure 1.

The characteristics of the responders are summarised in Table 1 along with data from the 2011 survey and NHS national workforce data up to 2014 where available.[16] In the linked methodological study, the response rate for individuals who were directly targeted was 83% (248/300) and 79% (237/300) completed the survey. Participant demographics were similar for passive and direct recruitment, and compared well with the participants in this survey (data available from the authors.) The regional distribution of responders matched national proportions.[16]

Only 6% of responders (95% CI = 4 to 9) reported being involved in research involving hypertensive treatment in the past 5 years; 3% (95% CI = 2 to 6) in research involving ambulatory monitors; and 4% (95% CI = 2 to 6) in research involving SMBP in the past 5 years.

Table 1. Characteristics of responders

Characteristic	2015 survey (*N* = 300), *n* (%)	2011 survey[a] (*N* = 625), *n* (%)	2014 national workforce data,[a] %
Practice role			
Principal/partner	200 (67)	357 (57)	65
Salaried/locum	71 (24)	190 (30)	24
Registrar	28 (9)	60 (10)	11
Other	1 (0)	18 (3)	1
Sex			
Male	181 (60)	370 (59)	48
Female	119 (40)	255 (41)	52
Age group, years			
<30	1 (0)	–	1
30–39	114 (38)	–	28
40–49	99 (33)	–	31
50–59	65 (22)	–	30
>60	21 (7)	–	9
Year of qualification			
Median	1997	1995	–
Country of training			
UK	259 (86)	–	78
Europe (excluding UK)	23 (8)	–	5
Asia	11 (4)	–	13
Africa	5 (2)	–	3
Other	2 (1)	–	1
Practice list size			
Median	8500	7800	–
Mean (SD)	8590 (4100)	9154 (4530)	7171
Practice setting			
Urban	128 (43)	–	–
Suburban	78 (26)	–	–
Semi-rural	63 (21)	–	–
Rural	31 (10)	–	–
Region			
East Midlands	20 (7)	40 (6)	6
East of England	26 (9)	53 (8)	8
London	36 (12)	75 (12)	12
North East	13 (4)	28 (4)	4
North West	35 (12)	66 (11)	11
South Central	20 (7)	40 (6)	6
South East Coast	19 (6)	41 (7)	7
South West	29 (10)	58 (9)	10
West Midlands	26 (9)	51 (8)	9
Yorkshire and the Humber	25 (8)	52 (8)	9
Northern Ireland	8 (3)	18 (3)	3
Scotland	29 (10)	74 (12)	10
Wales	14 (5)	29 (5)	5

[a]*Where data were available.* [N] *SD = standard deviation.*

All but one GP were involved in the management of hypertension (99%; 95% CI = 98 to 100). The vast majority of GPs (97%; 95% CI = 95 to 99) were aware of self-monitoring among their patients, which represents an increase from 90% (95% CI = 87 to 92) in 2011. The denominator for the remainder of the results is those participants who were aware of patient self-monitoring, unless otherwise stated (*n* = 291). GPs estimated that 38% (95% CI = 35 to 41) of their patients self-monitored, an increase from 28% (95% CI = 25 to 31) in 2011.

Services available for BP monitoring

Table 2 summarises the services available to support BP measurement/monitoring.

A large proportion of GPs offered ABPM (82%; 95% CI = 77 to 86) and 65% (95% CI = 59 to 70; *n* = 189/291) saw SMBP as complementary to 24-hour ABPM, down from 81% (95% CI = 78 to 84; *n* = 453/557) in 2011.

In 2015 compared with 2011, GPs reported an increase in the availability of most services. However, fewer GPs reported that BP monitors were available for patient use in pharmacies in 2015 than in 2011: 32% (95% CI = 27 to 38) versus 43% (95% CI = 39 to 47).

Reasons for self-monitoring

The reasons given by responding GPs for the use of self-monitoring are reported in Table 3.

The proportion of GPs using self-monitoring to diagnose hypertension was 58% (95% CI = 52 to 64), compared with 37% (95% CI = 33 to 41) in 2011, an absolute increase of 21% (95% CI = 14 to 28; *P*<0.001), or a 57% relative increase; 87% (95% CI = 83 to 90) and 54% (95% CI = 48 to 59) of GPs used SMBP to exclude or confirm white coat and masked hypertension.

Similar proportions of GPs reported using SMBP to monitor control in treated patients in 2015 as in 2011. Half of the GPs used SMBP as an aid to monitor medication adherence and the effects of lifestyle changes (51% (95% CI = 45 to 57) and 49% (95% CI = 43 to 55), respectively).

Certain patient groups that might particularly benefit from SMBP were identified by 62% of participants (95% CI = 56 to 67), with the most commonly reported group being those with white coat hypertension 45% (95% CI = 38 to 52) (Table 4). A further 52% (95% CI = 47 to 58) recognised groups that would not benefit; patients with anxiety was the most common factor quoted (60%; 95% CI = 52 to 67).

Diagnosis of hypertension

The current NICE guidelines set a threshold of 135/85 mmHg for stage 1 hypertension and 150/95 mmHg for stage 2 hypertension when using SMBP. The suggested protocol to diagnose SMBP is: for each BP recording, two consecutive measurements should be taken, at least 1 minute apart and with the person seated; BP should be recorded twice

Table 2. Services available for blood pressure monitoring

Service	2015 survey (*N* = 291), (*n*) % [95% CI]	2011 survey (*N* = 557), (*n*) % [95% CI]
Clinic measurement by GP	[248] 85 [81 to 89]	–
Clinic measurement by nurse/allied healthcare professional	[250] 86 [81 to 89]	–
Ambulatory monitors for 24-hour measurement	[239] 82 [77 to 86]	–
Monitors to lend to patients	[134] 46 [40 to 52]	[191] 34 [30 to 38]
Patient training for self-monitoring	[114] 39 [34 to 45]	[171] 31 [27 to 35]
Monitor in waiting room	[103] 35 [30 to 41]	[122] 22 [19 to 25]
Monitors available for use in local pharmacies	[94] 32 [27 to 38]	[239] 43 [39 to 47]
Blood pressure taken by pharmacy staff	[148] 51 [45 to 57]	–
GP training	[57] 20 [15 to 25]	[52] 9 [7 to 11]
Other	[4] 1 [1 to 3]	–
None of the above	[0] 0	–

Table 3. Reasons for self-monitoring blood pressure

Reason given by GP	2015 (*N* = 291), (*n*) % [95% CI]	2011 (*N* = 557), (*n*) % [95% CI]
For diagnosis	[169] 58 [52 to 64][a]	[206] 37 [33 to 41][a]
To exclude or confirm white coat hypertension	[253] 87 [83 to 90]	[465] 83 [80 to 86]
To exclude or confirm masked hypertension	[156] 54 [48 to 59]	[b]
To monitor control	[245] 84 [80 to 88]	[462] 83 [80 to 86]
As an aid to medication adherence	[148] 51 [45 to 57]	[260] 47 [43 to 51]
As an aid to lifestyle changes	[143] 49 [43 to 55]	[b]
Other	[14] 5 [3 to 8]	[19] 3 [2 to 5]
None of the above	[3] 1 [0 to 3]	[4] 0 [0 to 2]

[a]z-test, P<0.001. [b]Option not included in 2011 survey.

Table 4. Patients who would or would not benefit from self-monitoring blood pressure

Response[a]	Would benefit from SMBP (*N* = 179), (*n*) % [95% CI]	Would not benefit from SMBP (*N* = 151), (*n*) % [95% CI]
White coat/potential white coat hypertension	[80] 45 [38 to 52]	–
Difficulty attending surgery because of time or mobility issues	[33] 18 [13 to 25]	–
Anxious	[26] 15 [10 to 20]	[90] 60 [52 to 67]
Diabetes	[12] 7 [4 to 11]	–
Poor compliance with medication	[10] 6 [3 to 10]	–
Older patient	[8] 4 [2 to 9]	[18] 12 [8 to 18]
Cognitive impairment/dementia	–	[19] 13 [8 to 19]
Neurotic/obsessive	–	[11] 7 [4 to 13]
Other	[54] 30 [24 to 37]	[22] 15 [10 to 21]

[a]Multiple responses accepted. SMBP = self-monitored blood pressure.

daily, ideally in the morning and evening; and BP recording should continue for at least 4 days, ideally for 7 days.[1]

Figures 2 and 3 show the frequency and duration of SMBP for the diagnosis of hypertension. GPs most commonly reported recommending SMBP to diagnose hypertension, with readings twice a day (60%; 95% CI = 52 to 67) for 7 days (50%; 95% CI = 40 to 55).

The mean threshold for diagnosis using SMBP was 141.7 mmHg systolic (95% CI = 140.9 to 142.6) and 87.2 mmHg diastolic (95% CI = 86.6 to 87.7). This compares with mean thresholds in 2011 of 145.9 mmHg systolic (95% CI = 45.2 to 146.6) and 89.5 mmHg diastolic (95% CI = 89.0 to 90.0; *t*-test $P<0.001$ for both systolic and diastolic comparisons). Seventy per cent of GPs (95% CI = 63 to 76) used a systolic threshold ≥136 mmHg, and 54% (95% CI = 46 to 61) used a diastolic threshold >85 mmHg for diagnosis.

The majority of GPs (81%; 95% CI = 75 to 86) reported different diagnostic thresholds for some groups of patients, most commonly patients with diabetes (73%; 95% CI = 66 to 79) and chronic kidney disease (40%; 95% CI = 33 to 47). Fewer reported different thresholds for patients with cardiovascular disease (11%; 95% CI = 7 to 16) or because of advanced age (14%; 95% CI = 9 to 20).

Use of SMBP in managing control in treated patients with hypertension

Overall, the median treatment target in 2015 was 140 mmHg systolic (interquartile range (IQR) 135–145) and 89 mmHg diastolic (IQR 85–90), which had decreased from 150 mmHg systolic (IQR 140–150) and 90 mmHg diastolic (IQR 90–90) in 2011 (Mann–Whitney *U* tests: systolic $P<0.0001$ and diastolic $P<0.001$).

GPs differed in how often they would request a set of measurements from patients, ranging from 24% monthly (95% CI = 20 to 30) to 6% annually (95% CI = 4 to 10). The most popular frequency of measurement was twice a year (34%; 95% CI = 28 to 40).

Adjustment of self-monitored results

The proportion of GPs who reported that they would adjust SMBP readings rather than use them directly increased from 32% (95% CI = 29 to 36) in 2011 to 42% (95% CI = 36 to 47) in 2015. The mean adjustments reported were 8.3 mmHg systolic (95% CI = 7.5 to 9.1) and 5.6 mmHg diastolic (96% CI = 5.1 to 6.2).

Type of monitor and calibration

The majority of GPs recommended that patients use an upper-arm monitor (81%; 95% CI = 76 to 85), with the remaining 19% (95% CI = 15 to 24) not recommending any

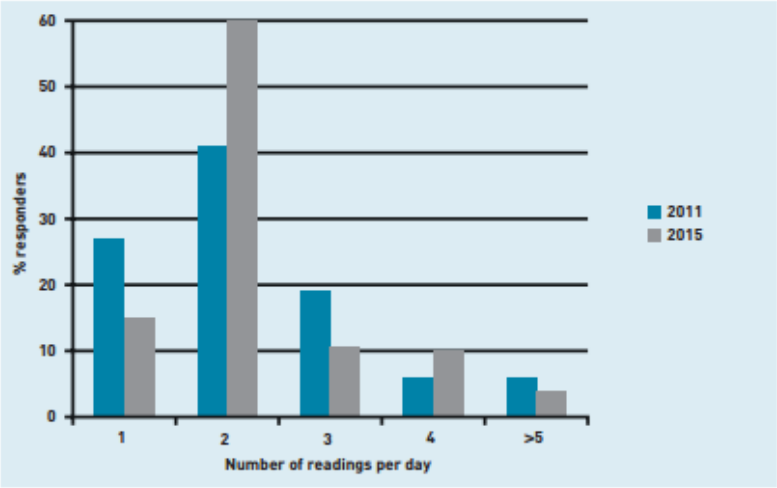


Figure 2. Frequency of self-monitoring.

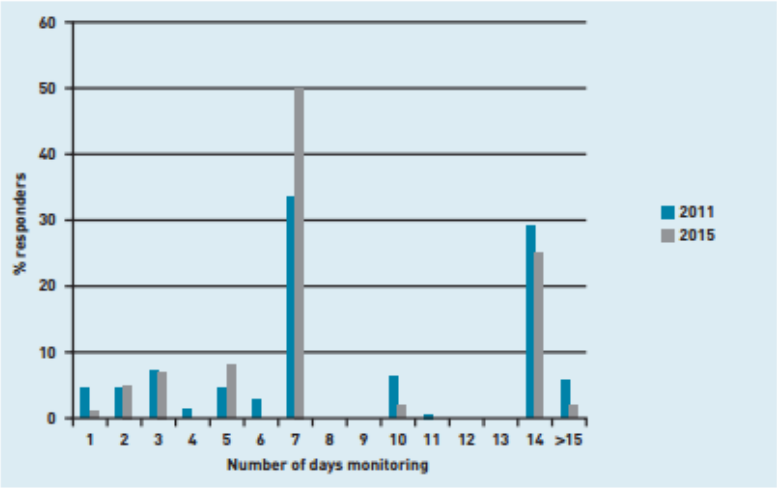
monitor in particular. Thirty-six per cent (95% CI = 30 to 42) specifically warned against certain types of monitor, most commonly wrist or finger monitors (91%; 95% CI = 84 to 95).

Checking the accuracy of their patients' monitors was suggested by 89% (95% CI = 85 to 92) of GPs. Most recommended annual checks (74%; 95% CI = 69 to 79) by practice nurses (57%; 95% CI = 50 to 63). Only 10% (95% CI = 7 to 15) of GPs were willing to check patients' monitors themselves.

Patient recording and communication of SMBP results

The majority of GPs recommended that their patients record their SMBP results in a handwritten diary (86%; 95% CI = 81 to 89) or using a computer spreadsheet (30%; 95% CI = 25 to 36), and that they bring the results in person to consultation (69%; 95% CI = 64 to 74) rather than communicate them by phone (13%; 95% CI = 9 to 17), text (1%; 95% CI = 0 to 3), or e-mail (6%; 95% CI = 4 to 10).

Figure 3. Duration of self-monitoring.



Regression analysis

Logistic regression analysis showed that none of the following variables in the model was a significant predictor of GPs' use of SMBP to diagnose hypertension: sex, GP role, year of qualification, country of training, UK region, practice location, and practice list size. (Full results are available from the authors.) Backwards selection did not result in a model with any significant predictors.

DISCUSSION

Summary

This survey has shown that the majority of GPs now use SMBP to diagnose hypertension, an increase of more than 50% since the implementation of the NICE hypertension guidelines in 2011. In contrast, the proportions of GPs using self-monitoring in general and for ongoing management have stayed stable and at a high level. The increase in use of self-monitoring to diagnose hypertension might be expected to reduce unnecessary treatment of white coat hypertension; interestingly, over 80% of GPs also reported access to ambulatory monitoring. This suggests a mixed picture with a combination of self- and ambulatory monitoring being used. To our knowledge these data are unique.

Significant variation in diagnostic thresholds and protocols for measurement remains. Over half of GPs reported a threshold higher than the NICE threshold for diagnosis with SMBP (135/85 mmHg). This proportion was less than in 2011, but, given that SMBP is usually lower than clinic BP, this may result in undertreatment and worse outcomes.[17] Potential explanations for the discrepancy between guidelines and practice include: not being aware of the different thresholds; using a self-imposed higher target to avoid overdiagnosis; or having different individual practice policies.

The majority of GPs reported using SMBP to monitor BP control in treated patients, despite a relative paucity of evidence.[12] As with diagnostic thresholds, GPs generally reported a higher target for treatment than recommended by the guidelines, but again this had improved since 2011.

There has been an almost universal increase in the services delivered by GPs to support SMBP since 2011, suggesting increasing enthusiasm for SMBP, but only a

minority offer training in self-monitoring to patients (currently 39%). Modern monitors are relatively easy to use but minimal training, especially in cuff positioning, might be expected to improve accuracy of measurement. This need not be a GP-led service and could be delivered equally well by pharmacists or district nurses.

GPs generally recommended that their patients record SMBP results in a handwritten diary and bring them to consultation. Few GPs wanted their patients to communicate their results by phone, text, or e-mail; this may be a missed opportunity or simply reflect the realities of contemporary practice in the NHS. A number of trials have demonstrated the potential benefits of communicating by text or telemonitoring, and that this is well liked by patients and clinicians.[12] BP telemonitoring is cost-effective, with the costs of equipment and technology offset by lower medical costs.[18] Patients also have a generally positive attitude towards telemonitoring, and a high level of compliance with telemonitoring programmes and data transfer.[19] Remote communication of results (not routinely available on the NHS) would be of particular benefit to those patients who have difficulty getting to the clinic for appointments, the group GPs identified as potentially benefiting most from SMBP in this survey.

Strengths and limitations

This is the first study to compare self-monitoring practice in UK GPs with data both before and after changes to national guidelines. Both surveys used the same sampling methodology, as well as the same questions. Additional questions and options were added to strengthen and fill gaps identified through feedback from the previous survey. A regionally representative sample of UK GPs was recruited, and responders were similar to national data across a range of demographics, with the greater proportion of GPs being male in the survey as the only significant difference. The average practice list size reported by GPs was slightly higher than the national average (8590 versus 7171); however, this may well be because this is a comparison of self-reported data with general practice census data. Larger practices may have more resources for home and ambulatory monitoring, but small differences such as this are unlikely to have an effect on the results.

Recruitment of the sample was passive by placing an advert online rather than directly contacting GPs. It is therefore impossible to know how many of the GPs active on the website saw the advert; however, a high proportion of those who clicked on the link completed the questionnaire. This method was used to allow comparison with the 2011 data. The linked methodological study using the same questionnaire with direct targeting via the same website found comparable demographics with similar responses to the questionnaire used for those recruited passively. This suggests that passive recruitment did not introduce significant bias.

The decision to complete the survey may have been influenced by the extent to which the responder was interested in the topic. This is unlikely to have affected the validity of the comparison between 2011 and 2015, but may have led to overestimation of the proportion of GPs who use SMBP.

Comparison with existing literature

GPs estimated that just over one-third of their patients with hypertension currently self-monitor BP, which was slightly higher than the results of a cross-sectional survey in the UK in 2011.[20] Despite this, the number who were self-monitoring still fell behind estimates from other countries where the figure is over 70%.[21–23] GPs could help increase this number by communicating the potential benefits of self-monitoring to patients, as well as providing services to support SMBP.

GPs reported being concerned that SMBP may be unsuitable for anxious or neurotic patients. However, a review of qualitative studies found that few patients shared this concern, and that in fact many patients felt empowered by and enjoyed self-monitoring.[24]

Implications for practice

Since the guidelines changed in 2011, GPs appear more aware of the benefits of SMBP, and of the practicalities of incorporating SMBP into routine care. However, there remains room for improvement in implementing appropriate thresholds for diagnosis with SMBP, encouraging and training patients in the use of SMBP, and incorporating new ways of communicating the results of SMBP. Guidance for clinicians and patients could be standardised to provide useful information to guide practice, while not being overburdensome to either group.

Since new NICE guidance in 2011, UK GPs are more likely to use SMBP to diagnose hypertension but significant proportions continue to use different diagnostic and monitoring thresholds than recommended. The use of out-of-office methods to improve the accuracy of diagnosis is unlikely to be beneficial if suboptimal thresholds are used.

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Ethical approval

This study was approved by the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford, reference number MSD-IDREC-C1-2014-120.

Provenance

Freely submitted; externally peer reviewed.

Competing interests

FD Richard Hobbs has received limited research support in terms of BP devices from Microlife and BpTRU. Richard J McManus has received research funding in the form of BP monitoring equipment from LloydsPharmacy Limited and Omron. All other authors have declared no competing interests.

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REFERENCES

1. National Institute for Health and Care Excellence. *Hypertension in adults: diagnosis and management. CG127.* https://www.nice.org.uk/guidance/cg127?unlid=80569458620162252164 (accessed 5 Aug 2016).
2. Daskalopoulou SS, Rabi DM, Zarnke KB, *et al.* The 2015 Canadian Hypertension Education Program recommendations for blood pressure measurement, diagnosis, assessment of risk, prevention, and treatment of hypertension. *Can J Cardiol* 2015; **31(5):** 549–568.
3. Guidelines (JSH 2009). Chapter 2. Measurement and clinical evaluation of blood pressure. *Hypertens Res* 2009; **32:** 11–23. http://www.nature.com/hr/journal/v32/n1/pdf/hr20082a.pdf (accessed 5 Aug 2016).
4. Siu AL, U.S. Preventive Services Task Force. Screening for high blood pressure in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med* 2015; **163(10):** 778–786.
5. Ohkubo T, Imai Y, Tsuji I, *et al.* Home blood pressure measurement has a stronger predictive power for mortality than does screening blood pressure measurement: a population-based observation in Ohasama, Japan. *J Hypertens* 1998; **16(7):** 971–975.
6. Niiranen TJ, Hänninen MR, Johansson J, *et al.* Home-measured blood pressure is a stronger predictor of cardiovascular risk than office blood pressure: the Finn-Home study. *Hypertension* 2010; **55(6):** 1346–1351.
7. Boubouchairopoulou N, Karpettas N, Athanasakis K, *et al.* Cost estimation of hypertension management based on home blood pressure monitoring alone or combined office and ambulatory blood pressure measurements. *J Am Soc Hypertens* 2014; **8(10):** 732–738.
8. Nasothimiou EG, Karpettas N, Dafni MG, Stergiou GS. Patients' preference for ambulatory versus home blood pressure monitoring. *J Hum Hypertens* 2014; **28(4):** 224–229.
9. Jones MI, Greenfield SM, Bray EP, *et al.* Patients' experiences of self-monitoring blood pressure and self-titration of medication: the TASMINH2 trial qualitative study. *Br J Gen Pract* 2012; DOI: 10.3399/bjgp12X625201.
10. Juhanoja EP, Puukka PJ, Johansson JK, *et al.* The impact of the day of the week on home blood pressure: the Finn-Home study. *Blood Press Monit* 2016; **21(2):** 63–68.
11. 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.
12. Uhlig K, Patel K, Ip S, *et al.* Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. *Ann Intern Med* 2013; **159(3):** 185–194.
13. Fletcher BR, Hartmann-Boyce J, Hinton L, McManus RJ. The effect of self-monitoring of blood pressure on medication adherence and lifestyle factors: a systematic review and meta-analysis. *Am J Hypertens* 2015; **28(10):** 1209–1221.
14. 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.
15. McManus RJ, Wood S, Bray EP, *et al.* Self-monitoring in hypertension: a web-based survey of primary care physicians. *J Hum Hypertens* 2014; **28(2):** 123–127.
16. Workforce and Facilities Team, Health and Social Care Information Centre. General and Personal Medical Services, England 2004–14. http://www.hscic.gov.uk/catalogue/PUB16934/nhs-staf-2004-2014-gene-prac-rep.pdf (accessed 5 Aug 2016).
17. Staessen JA, Den Hond E, 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.
18. Omboni S, Gazzola T, Carabelli G, Parati G. Clinical usefulness and cost effectiveness of home blood pressure telemonitoring: meta-analysis of randomized controlled studies. *J Hypertens* 2013; **31(3):** 455–467, discussion 67–68.
19. Pare G, Jaana M, Sicotte C. Systematic review of home telemonitoring for chronic diseases: the evidence base. *J Am Med Inform Assoc* 2007; **14(3):** 269–277.
20. Baral-Grant S, Haque MS, Nouwen A, *et al.* Self-monitoring of blood pressure in hypertension: a UK primary care survey. *Int J Hypertens* 2012; **2012:** 582068.
21. Viera AJ, Cohen LW, Mitchell CM, Sloane PD. How and why do patients use home blood pressure monitors? *Blood Press Monit* 2008; **13(3):** 133–137.
22. Cuspidi C, Meani S, Lonati L, *et al.* Prevalence of home blood pressure measurement among selected hypertensive patients: results of a multicenter survey from six hospital outpatient hypertension clinics in Italy. *Blood Press* 2005; **14(4):** 251–256.
23. Breaux-Shropshire TL, Brown KC, Pryor ER, Maples EH. Prevalence of blood pressure self-monitoring, medication adherence, self-efficacy, stage of change, and blood pressure control among municipal workers with hypertension. *Workplace Health Saf* 2012; **60(6):** 265–271.
24. Fletcher BR, Hinton L, Hartmann-Boyce J, *et al.* Self-monitoring blood pressure in hypertension, patient and provider perspectives: a systematic review and thematic synthesis. *Patient Educ Couns* 2016; **99(2):** 210–219.

APPENDICES

Appendix 1.1 – Systematic review protocol (1)

UNIVERSITY of York
Centre for Reviews and Dissemination

NHS
National Institute for Health Research

PROSPERO International prospective register of systematic reviews

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Effect of home blood pressure monitoring on medication adherence, medication persistence and lifestyle factors in hypertensives: systematic review protocol

Benjamin Fletcher, Jamie Hartmann-Boyce, Nia Roberts, Lisa Hinton, Richard McManus

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Citation

Benjamin Fletcher, Jamie Hartmann-Boyce, Nia Roberts, Lisa Hinton, Richard McManus. Effect of home blood pressure monitoring on medication adherence, medication persistence and lifestyle factors in hypertensives: systematic review protocol. PROSPERO 2014:CRD42014007567 Available from http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42014007567

Review question(s)

What effect does home blood pressure monitoring have on medication adherence and persistence in hypertensive patients compared with control/usual care?

What effect does home blood pressure monitoring have on lifestyle change (i.e. change in diet [including alcohol consumption], physical activity and/or smoking status) in hypertensive patients compared with control/usual care?

How does adherence/lifestyle change vary based on the components of home monitoring interventions?

Searches

The following electronic databases will be searched from inception to 07/02/2014:

MEDLINE, EMBASE, PsycINFO, CINAHL, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effectiveness (DARE), Cochrane Central Register of Controlled Trials (CENTRAL), Dissertation and Theses. The MEDLINE strategy (see accompanying document) will be translated into the other databases (BF and NR).

Reference lists of included studies, and any related systematic reviews will be checked for additional studies.

Ongoing and completed studies without related publication will be identified through searches of clinical trial databases (i.e. ClinicalTrials.gov, WHO trials portal, UKHTA, Current Controlled Trials [ISCRTN]).

Link to search strategy

http://www.crd.york.ac.uk/PROSPEROFILES/7567_STRATEGY_20140301.pdf

Types of study to be included

Randomised or quasi-randomised controlled trials (RCTs) are eligible: if the intervention group includes home blood pressure monitoring; if the control/usual care group does not include home monitoring*; and if a medication adherence/lifestyle factor outcome measure is available.

*The control group may use HBPM to measure BP outcome at the end of a trial, but this must not exceed 1 week.

Trials will be eligible if HBPM is a sole intervention or is used as an adjunct to other interventions (i.e. telemonitoring, education, etc.).

Antihypertensive medication adherence or lifestyle factors may be primary or secondary outcomes of included trials.

Appendix 1.2 – PRISMA reporting guidelines

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

Appendix 1.3 – Ovid MEDLINE search strategy (1946-present)

1. Hypertension/
2. exp *Antihypertensive Agents/
3. high adj3 (blood pressure or bp)).ti,ab.
4. hypertensi*.ti,ab.
5. 1 or 2 or 3 or 4
6. (self adj3 monitor*).ti,ab.
7. (home adj3 monitor*).ti,ab.
8. (ambulatory adj3 monitor*).ti,ab.
9. (self adj3 measure*).ti,ab.
10. (home adj3 measure*).ti,ab.
11. (ambulatory adj3 measure*).ti,ab.
12. (self adj3 determin*).ti,ab.
13. (home adj3 determin*).ti,ab.
14. (ambulatory adj3 determin*).ti,ab.
15. (self adj3 manage*).ti,ab.
16. (home adj3 manage*).ti,ab.
17. (ambulatory adj3 manage*).ti,ab.
18. (self adj3 device*).ti,ab.
19. (home adj3 device*).ti,ab.
20. (ambulatory adj3 device*).ti,ab.
21. 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
22. Telemedicine/
23. Telemonitor*.ti,ab.
24. Tele-monitor*.ti,ab.
25. Telemedicine.ti,ab.
26. Tele-medicine.ti,ab.
27. Telehealth.ti,ab.
28. Tele-health.ti,ab.
29. 22 or 23 or 24 or 25 or 26 or 27 or 28
30. 21 or 29
31. Medication Adherence/
32. ((Medication* or Therap* or Treatment* or Medicin* or Anti-hypertensi* or antihypertensi*) adj2 (Adhere* or Complian* or Comply or Persistence or Concordance)).ti,ab.
33. Diet/
34. exp Exercise/
35. Life Style/ or *Health Behavior/
36. Smoking Cessation/ or Smoking/
37. Diet*.ti,ab.
38. Health* eating*.ti,ab.
39. Physical activit*.ti,ab.
40. Physical inactivity.ti,ab.
41. Exercis*.ti,ab.
42. (Behavio?r* adj2 change).ti,ab.
43. Lifestyle.ti,ab.
44. Life-style.ti,ab.
45. Smok*.ti,ab.
46. Alcohol.ti,ab.

47. Nonpharmacologic*.ti,ab.
48. Non-pharmacologic*.ti,ab.
49. 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49
50. Blood Pressure Monitoring, Ambulatory/
51. Home blood pressure.ti,ab.
52. Self blood pressure.ti,ab.
53. Ambulatory blood pressure.ti,ab.
54. ABPM.ti,ab.
55. SBPM.ti,ab.
56. HBPM.ti,ab.
57. 50 or 51 or 52 or 53 or 54 or 55 or 56
58. 49 and 57
59. 5 and 30 and 48
60. 58 or 59

Appendix 1.4 – Data extraction form

Author and publication year	
Data extracted by	
Trial ID (if provided)	
Link to published protocol or other associated reports (Y/N) *if Y give details*	

Risk of bias

Domain	Rating (high, low, or unclear risk)	Detail (reason for decision – quote if possible)
Random sequence generation		
Allocation concealment		
Blinding of outcome assessment *only for outcomes of interest		
Selective reporting (are all outcomes of interest* presented in results if mentioned in protocol or methods?) *Medication adherence; change in diet (incl. alcohol); change in physical activity; change in smoking status.		
Attrition (high risk if >20% lost to follow up) *If attrition >20 and comparison of completers v drop-outs carried out, give details.		
Other (optional)		

Recruitment and setting

Recruitment method		
Setting	Primary care	
	Outpatient clinic	
	Community	
	Unclear (give details)	
Country		
Inclusion/exclusion criteria (list everything)		
Numbers of participants screened and numbers agreeing to take part.		
Unit of randomisation		

Participants at baseline

	Intervention	Control
N randomized		
Gender (%F)		
Age (years)		
BP Systolic (s.d.)		
BP Diastolic (s.d.)		
Ethnicity (e.g. % white)		
Medication adherence *Proportion of meds taken		
Medication persistence *Proportion discontinuing treatment		
Diet (including alcohol) *i.e. number drinks per day, calories		
Physical activity		
Smoking status		
Co-morbidities (e.g. diabetes, etc)		
Other/notes		

Intervention characteristics

Programme characteristics	
Target of intervention? Patient only (physician not aware of HBPM) Intermediate (physician *may in some cases* be made aware of HBPM measurements) Both (physician *explicitly provided* with HBPM measurements for all participants)	
Type of monitor used	
Brief narrative description (abstract)	
HBPM protocol (i.e. number of measurements, frequency of measurement, how is BP recorded, etc) (copy quote from text)	
Medication titration protocol used? (how to adjust meds based on BP beyond titration practiced in usual care – specific drug change/increase based on HBPM)	
Training provided to healthcare professionals as part of trial? *If Yes, specify	
Length of programme	
Goals set?	
Theoretical model of behaviour change mentioned?	

Control characteristics

Programme characteristics	
Brief narrative description (abstract)	
BP protocol (i.e. number of measurements, frequency of measurement, who takes readings, numerous research follow-ups beyond normal monitoring)	
Medication titration protocol used?	
Training provided to physicians? *If Yes, specify	

Outcome	Measured and/or reported?	Measure Used	Results				Statistically significant?
			N	Intervention	N	Control	
Medication adherence							
Medication persistence							
Diet (including alcohol)							
Physical activity							
Smoking status							
Systolic BP							
Diastolic BP							
Achieving BP target (%)							
Adherence to intervention							

Outcome measures

List all other trial outcome measures: (primary/secondary/unclear)	

Notes

Appendix 1.5 – Characteristics of included studies

1. Bailey (1999)

Methods	Parallel trial, randomised by individual, study duration 8 weeks, follow-up at 8 weeks
Participants	62 patients with uncomplicated hypertension, about to be commenced on either ACE inhibitor or diuretic, age 55, 54% female, multi-centre, Australia
Interventions	**HBPM alone** Patients started on new treatment (perindopril or indipamide). Record sitting BP twice daily (before morning medications and between 6-8pm) Home BP measurements provided to GPs. No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention.
Outcomes	**Medication adherence [pill count]**: proportion of available tablets taken: 88% (sd27.4) in intervention group compared to 94% (sd21.2) in control group, not statistically significant, p value not reported **BP**: At follow up, systolic BP was significantly higher in the intervention group compared to the intervention group: office sitting 148 (sd16) v 142 (sd16), p<0.05; office standing 145 (sd16) v 138 (sd16), p<0.05; 24h ABPM 141 (sd16) v 133 (sd16), p<0.05 Mean change from baseline was significantly greater in the control group: office sitting -8 v -13, p<0.05; office standing -7 v -13, p<0.05 At follow up, diastolic BP was not significantly different between intervention and control groups: office sitting 89 (sd11) v 89 (sd11), p>0.05; office standing 89 (sd11) v 87 (sd11), p>0.05; 24h ABPM 83 (sd11) v 81 (sd11), p>0.05 Mean change from baseline in diastolic BP did not differ significantly between groups: office sitting -4 v -6, p>0.05; office standing -4 v -7, p>0.05 **Adherence to intervention**: 77% of intervention subjects took all HBPM measurements
Notes	Study aimed at physician behaviour

2. Bove (2013)

Methods	Parallel trial, two recruiting centres, randomised by individual, study duration 6 months, follow-up at 6 months
Participants	241 patients with systolic BP >140mmHg and no overt CVD, age 60, 65% female, predominantly African American 80%, USA
Interventions	**HBPM, telemedicine, and education (print/on-line materials)** Self-monitoring and an internet and telephone based communication system. Patients reported BP, heart rate, weight, steps/day and tobacco use twice weekly. BP education through the internet. Physicians receive monthly report on patient's BP status and a reminder of BP goals. No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention.
Outcomes	**Medication adherence [self-report]**: medication adherence self-efficacy scale (MASES). 4 item scale, total score is average across responses; higher scores indicate greater level of self-efficacy. No significant difference in scores in intervention and control group: 3.56 (sd0.81) v 3.59 (sd0.85), p=0.86 **BP**: no significant difference between intervention and control groups in: office systolic BP change from baseline, -18.2 (sd20.3) v -13.9 (sd18.2), p=0.12;

	diastolic BP change from baseline, -7.1 (sd11.8) v -4.9 (sd10.2), p=0.17; or proportion achieving target BP (systolic BP<140), 58.2% v 52.1%, p=0.26
Notes	NCT00644267 Kashem 2011 (conference abstract) Bove 2013a (conference abstract) Bove 2013b (journal article results)

3. de Souza[15] (2012)

Methods	Parallel trial, single centre, randomised by individual, study duration 12 months, 6 and 12 month follow-up
Participants	57 patients with arterial hypertension under drug treatment, at regular follow-up appointments, age 60, Brazil (proportion female not reported)
Interventions	**HBPM alone** Participants asked to measure and record BP at least twice a week (Mondays and Fridays), at random times and quiet place, and to write down the values for delivery every three months during clinic appointment to research staff. No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Home monitoring intervention targeted patients only.
Outcomes	**Medication adherence [self-report]**: Proportion of participants who reported "regular use daily" of antihypertensive medication. No significant difference between intervention and control at 6 months (94.7% v 83.3%, p=0.15), but significantly higher self-reported adherence in intervention group at 12 months (100% v 88.2%, p=0.031) **Diet**: no significant differences between intervention and control groups in proportion reporting food intake according to dietary guidelines at 6 months (97.4% v 88.9%, p=0.21) or 12 months (97.3% v 100%, p=0.68) **Physical activity**: no significant differences between intervention and control groups in proportion reporting exercising three times weekly at 6 months (67.6% v 61.1%, P=0.22) or 12 months (67.6% v 58.8%, p=0.19) **Smoking status**: no significant differences between intervention and control groups in proportion reporting smoking at 6 months (5.3% v 0%, p=0.45) or 12 months (5.3% v0%, p=0.31) **BP**: Office systolic BP was significantly lower in the intervention group compared to control at 6 months (135.5 [sd12.7] v 145.7 [sd19.3], p=0.022), with no significant difference at 12 months (131.6 [sd19.3] v 134.9 [sd23.2], p=0.592) Office diastolic BP was significantly lower in the intervention group compared to control at 6 months (81.7 [sd10.9] v 89.6 [sd11.6], p=0.020), with no significant difference at 12 months (80.31 [sd11.8] v 86.0 [sd13.4], p=0.121) No significant difference between intervention and control groups for systolic ABPM at 6 months (123.4 [sd11.2] v 125.2 [14.1], p=0.672) or 12 months (126.3 [sd13.3] v 131.8 [sd16.9], p=0.504) No significant difference between intervention and control groups for diastolic ABPM at 6 months (74.4 [sd8.8] v 76.1 [sd5.9], p=0.498) or 12 months (78.0 [sd10.9] v 80.0 [sd10.6], p=0.749)

4. Dusing (2008)

Methods	Parallel group trial, multi-centre, randomised by centre, study duration 34 weeks, follow-up at 34 weeks (9 months)
Participants	206 patients with stage 1 hypertension newly diagnosed or not treated for at least 1 year, age 51, 46% female, predominantly white 97%, Germany/Switzerland.

Interventions	**HBPM, education (print/on-line materials), medication titration protocol, adherence reminders, and physician education** Protocol for home monitoring not reported. Pharmacological treatment with a set of supportive measures including structured patient-physician interaction, printed information about hypertension, reminder stickers, 24 hour timer, and home BP measurement device for patients, and booklet to document home BP measurements. HBPM protocol unclear. Trial titration protocol used: at baseline visit patients were started on a study treatment with valsartan 160mg daily for 4 weeks. Patients with controlled BP were continued on treatment with valsartan 160mg. Patients not achieving BP values less than 140/90 by week 4 were uptitrated to valsartan 160mg and HCTZ 12.5mg as a fixed dose combination (usual care used office measures to titrate) Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention.
Outcomes	**Medication adherence [Electronic]**: MEMS caps. No significant difference between intervention and control for proportion taking medication daily between 0700 and 1100, 57% v 54%, p=NS. No significant difference between intervention and control for proportion taking medication daily with no time restriction, 86% v 77%, p=NS. **Medication persistence**: Proportion of persistent patients (i.e. not discontinuing medication by end of trial) was not significantly different between intervention and control groups, 95.9% v 88.3%, p=NS. **BP**: mean change in office BP from baseline to follow-up was not significantly different between intervention and control; systolic -19.5 v -14.7, p=NS; diastolic -13.4 v -9.5, p=NS. There was no significant difference between intervention and control in the proportion of participants achieving "BP normalisation" (sitting BP <140/90) at final study visit, 84.5% v 66.3%, p=NS.
Notes	NCT00394823

5. Fikri-Benbrahim (2013)

Methods	Parallel group, quasi-experimental, randomised by individual, multi-centre, study duration 20 weeks, follow-up at 6 months
Participants	180 treated hypertension patients who visited participating community pharmacies, age 62, 63% female, Spain
Interventions	**HBPM, education (verbal), education (print/on-line materials)** Patient education about hypertension – oral and written education about causes, importance and consequences of hypertension; lifestyle habits (PA, smoking cessation, diet, reduction of salt and alcohol intake); importance of medication adherence; and were given a home BP monitor. HBPM protocol: measure BP over 20 weeks at least one day per week; on two occasions measure BP over 5 consecutive days (at beginning and 8 weeks later). Pharmacist used 5 day average to calculate BP, and referral to GP if elevated. No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention.
Outcomes	**Medication adherence [Pill count]**: significantly more patients were adherent in intervention compared to control, 96.5% v 85.4%, p=0.011. Adherence defined as taking 80-110% of medications. Mean change from baseline to follow up in proportion adherent: intervention +10.5% v control -1.1%

	BP: mean change in office BP from baseline to follow up was significantly greater in the intervention participants compared to controls: systolic -6.8 (sd13.7) v -2.1 (sd9.3), p=0.01; diastolic -2.1 (sd8.9) v +0.1 (sd6.2), p=0.013. Significantly more participant achieved BP control at the end of the study in the intervention group, 71.3% v 55.1%, p=0.026. **Adherence to intervention**: 85% measured BP at least one day per week. 85% completed the two sessions of 5 consecutive days of monitoring.
Notes	Fikri-Benbrahim 2012 (journal article – methods and partial results) Fikri-Benbrahim 2013 (journal article – adherence results)

6. Friedman (1996)

Methods	Parallel group, multi-centre, randomised by patient, study duration 6 months, follow-up at 6 months
Participants	299 patients aged >60 under the care of a physician for hypertension, age 77, 77% female, USA
Interventions	**HBPM, telemedicine** BP measured weekly before telemedicine call (subjects also reported knowledge and adherence to medication and medication side-effects). This information was sent to their physicians regularly. No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Both patient and physician targeted by home monitoring intervention.
Outcomes	**Medication adherence [Pill count]**: no significant difference in unadjusted change in medication adherence (each patient had adherence assessed at baseline and follow-up) between intervention and control, +2.4% v -0.4%, p=0.29 **BP**: unadjusted mean change in office BP from baseline to follow up was not significantly different in control and intervention groups; systolic -11.0 v -10.6, p=0.85; diastolic -5.4 v -3.3, p=0.09.
Notes	The intervention was associated with a statistically significant improvement in adherence for those who were non-adherent at study entry.

7. Green (2014)

Methods	Parallel group, multi-centre, randomised by individual, study duration 6 months, 6 month follow-up
Participants	101 patients aged 35-69 with at least 2 years of enrolment and one primary care visit in the previous two years; systolic BP >140 and/or diastolic BP >90; BMI >26; Framingham risk 10-25%; registered web-site users. Age 57, 42% female, USA
Interventions	**HBPM, education (verbal)** Patients provided with a scale, pedometer and HBPM. This data was shared with a dietician once a week for two months, followed by every two weeks for 2 months, and then every month for 2 months. Dieticians responded to questions, reminded patients to share self-monitoring data, provided resources and encouraged participants to achieve their goals. HBPM performed three days a week. No trial specific medication titration protocol reported. Both patients and physicians targeted by home monitoring intervention (dieticians and physicians could view results in electronic health record). Intervention developed using Chronic Care Model.
Outcomes	**Medication adherence [Self-report]**: Morisky 8 item measure used – higher score equals lower adherence. No significant difference in mean change from baseline between intervention and control, -0.1 (sd2.0) v -0.2 (sd1.9), p=0.79.

	Diet: Fruit and vegetable intake increased significantly in the intervention compared to control – change from baseline number of daily servings of fruit and vegetables, 2.3 (sd3.0) v 0.0 (sd1.9), p<0.01 **Physical activity**: no difference between intervention and control in proportion "often working up a sweat", 27.9 (sd44.1) v 20.5 (sd40.2), p=0.40 **BP**: no significant difference between intervention and control for office systolic BP, 136.4 (sd13.9) v 139.1 (sd14.1); or for office diastolic BP, 84.0 (sd10.2) v 84.6 (sd9.5); no p values reported. No significant differences for mean change from baseline between intervention and control for office systolic BP (-13.9 [sd13.7] v -11.4 [sd13.6], p=0.40) or for office diastolic BP (-8.5 [sd9.1] v -6.6 [sd8.9], p=0.32) No significant difference between intervention and control at follow up in the proportion of patients achieving BP control: 54.5% v 39.1%, p=0.16
Notes	NCT01077388 Green 2012 – conference abstract Green 2014 – journal article results

8. Haynes (1976)

Methods	Parallel group, single centre, randomised by individual, study duration 6 months, follow-up at 6 months
Participants	39 hypertensive steelworkers, neither compliant with medications (pill counts less than 80%) nor at goal diastolic BP (>90mmHg), 6 months after starting treatment; 0% female; Canada
Interventions	**HBPM, education (verbal)** Patients taught to measure BP, asked to chart their BP and pill taking daily, and taught to tailor their pill taking to daily habits and rituals. Also seen fortnightly by researcher who reinforced experimental manoeuvers and rewarded improvements in compliance and BP. No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Home monitoring intervention targeted patients only.
Outcomes	**Medication adherence [pill count]**: Mean adherence (proportion of available meds taken) at follow-up was, 65.8% (sd36.7) in the intervention v 43.2% (sd42.9) in controls. Mean change from baseline in adherence was significantly greater in the intervention: +21.3 (sd29.1) v -1.5 (sd33.1), p=0.025 (1-tailed) 80% of intervention and 39% of control subjects had improved compliance, p value not reported. **BP**: Office diastolic BP did not differ significantly between intervention and control, 93.1 (sd5.5) v 96.4 (sd5.5), p value not reported. Mean change from baseline to follow-up in office diastolic office BP was also not significantly different between intervention and control, -5.4 (sd7.6) v -1.9 (sd8.5), p=0.12 (1-tailed)

9. Hosseininasab (2014)

Methods	Parallel group, single centre, randomised by individual, study duration 24 weeks, with follow-up at 4, 12 and 24 weeks
Participants	196 new cases with diagnosis of mild to moderate hypertension, or those already on antihypertensive treatment but uncontrolled according to JNC7 guidelines, age 59, 61% female, Iran
Interventions	**HBPM alone**

	Patients instructed how to measure their own BP, and asked to measure and document readings daily. Patients were advised to measure at a specific time every day. No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Home monitoring intervention targeted patients only.
Outcomes	**Medication adherence [pill count]**: adherence (defined as proportion of available medications consumed) was significantly higher in the intervention group at 4 weeks (99.6% [sd3] v 97.1% [sd9], p=0.01), 12 weeks (98.9% [sd5] v 96.5% [sd7], p=0.005), and 24 weeks (99.0%[sd5] v 97.8% [sd3], p=0.04) **BP**: office systolic BP did not differ significantly between intervention and control at 4 weeks (132.6 [sd7.4] v 133.4 [sd7.0], p=NR), 12 weeks (131.9 [sd5.8] v 132.0 [sd6.0], p=NR), or 24 weeks (132.0 [sd4.4] v 132.5 [sd3.8], p=NR) office diastolic BP did not differ significantly between intervention and control at 4 weeks (77.4 [sd6.2] v 77.1 [sd7.9], p=NR), 12 weeks (76.7 [sd6.0] v 76.6[sd5.1], p=NR), or 24 weeks (76.1 [sd4.6] v 76.6 [sd4.0], p=NR) Systolic and diastolic BP decreased significantly in both groups at the first follow-up visit.
Notes	NCT01525108

10. Johnson (1978)

Methods	2x2 factorial trial, randomised by individual, study duration 6 months, follow-up at 6 months
Participants	136 previous volunteers for blood pressure screening in shopping centres, receiving antihypertensive therapy for a minimum of one year, diastolic BP >95 at two home visits 1-3 days apart, age 53, 40% female, Canada
Interventions	Four groups; 3 intervention and 1 control. Two intervention groups included in analysis plus control: **i) HBPM alone** Patients were shown how to keep charts of their daily BP readings, and were requested to take these to physician at each appointment. **ii) HBPM alone** Patients monitored own blood as in group ii, plus were visited in their homes every 4 weeks to have BP measured by visitor, and the results were reported to both the subject and the treating physician. iii) home visit only group excluded from analysis. No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention.
Outcomes	No significant differences were apparent between groups in either compliance or diastolic BP. **Medication adherence [pill count]** Mean adherence (% of pills consumed) was estimated by comparing pills on hand with prescription records of pills dispensed and the regimen prescribed. Results were similar in group i, group ii, and control: 78.0% (sd31.5), 76.3% (sd27.2), 68.5 (sd42.6) (p=NS across groups) Mean change from baseline was also similar across the groups: +11.8 (sd26.2), +10.1% (sd30.0), +1.0% (sd40.8) (p=NS across groups) **BP**: mean clinic diastolic BP was not significantly different between the two intervention groups (i and ii), and control – 94.1 (sd9.3), 95.9 (sd9.5), 95.7 (sd12.8)

	Mean change from baseline also did not differ significantly – group i (-8.9 [sd8.7]), group ii (-8.1 [sd8.9]), control (-7.6 [sd11.1]) **Adherence to intervention**: BP charts were reviewed in last 4 weeks of trial. There was a significantly higher proportion of patients in group ii (self-monitoring and home visit) than group i (self-monitoring)who charted their BP everyday (72% v 50%, p=0.07) and charted BP on at least 14 days (46% v 15%, p<0.01)

11. Kirscht (1981)

Methods	3x2x3x2 factorial trial, multi-centre, randomised by individual, study duration 2 weeks, follow-up at two weeks
Participants	417 hypertensive patients of cooperating private practitioners (hypertension defined by each physician), 78% over 50 years old, "nearly all white", USA
Interventions	For self-monitoring component of trial there were three groups tested: control, BP self-monitoring and behavioural self-monitoring. Results for the former two groups are presented. **HBPM alone** Patients were requested to measure and record their BP twice daily for two weeks. No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Home monitoring intervention targeted patients only.
Outcomes	**Medication adherence [pharmacy fill and self-report]:** No significant difference between intervention and control for proportion adherent according to pharmacy score (66.5% v 66.5%, p=NR) or self-report (94.4% v 94.3%, p=NS) **Diet**: No significant difference between intervention and control in proportion adherent to dietary recommendations (75.2% v 77.2%, p=NS)

12. Magid (2011)

Methods	Parallel group, block randomised, multi-centre, study duration 6 months, follow-up at 6 months
Participants	338 patients with hypertension who were taking 4 or fewer antihypertensive medications and who had elevations in 2 of the 3 most recent electronic BP measurements (>140 systolic or >90 diastolic; for patients with diabetes mellitus or chronic kidney disease, >130 for systolic or >80 diastolic), age66, 35% female, USA
Interventions	**HBPM, telemedicine, education (verbal, medication titration protocol** Patient education, HBPM, HBPM reporting to an IVR phone system, clinical pharmacist management of hypertension with physician oversight. Patients measured BP 3-4 times per week, and were encouraged to measure their BP on different days of the week and various times of day. Measurements were reported by telephone weekly. Pharmacists reviewed the BP data and made treatment adjustments where necessary, and provided counselling on healthy therapeutic lifestyle changes. Patients' primary care provider was notified of any medication changes. "Preapproved drug therapy management protocols" were used to titrate medication. Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention.
Outcomes	**Medication adherence [pharmacy fill]**: MPR, total number of days supplied for each medication divided by period for which the medication was prescribed, was used to measure adherence.

	The proportion of patients classified as adherent (>0.80 MPR score) at follow-up was not significantly different in intervention and control, 69.9% v 69.4%, p=0.93. Intervention and control groups were also similar for MPR score, 0.85 (sd0.19) v 0.84 (sd0.19), p=0.88. **BP**: Mean change in office systolic BP was significantly greater in the intervention group compared to control, -13.1 (sd20.4) v -7.1 (sd16.6), p=0.006 No significant differences between groups for: Office systolic BP at follow-up, 137.4 (sd19.4) v 136.7 (sd17.0), p=0.85 Office diastolic BP at follow-up, 82.9 (sd12.9) v 81.1 (sd11.7), p=0.14 Mean change in office diastolic BP, -6.5 (sd11.7) v -4.2 (sd10.4), p=0.89 **Adherence to intervention**: 94% of intervention subjects uploaded BP measurements at least once during the study period.
Notes	NCT00520988 Medication adherence data were from 2 of the 3 study sites.

13. Marquez-Contreras (2006)

Methods	Parallel group, randomised by individual, multi-centre, study duration, follow-up at 1, 3 and 6 months
Participants	200 ambulatory patients, newly diagnosed hypertensive patients or those already on antihypertensive treatment but not controlled; patients with phase I or II AHT according to JNC VI criteria; age 59 ; 49% female; Spain
Interventions	**HBPM alone** Patients received a kit containing the monitor, an instruction manual, and a card on which to note their measurements. Patients were asked to measure BP three days a week (Tues, Thurs, Sat) twice before breakfast (0800-1000) and twice before supper (2000-2200) and record data on card. All patients started on single anti-hypertensive medication at start of study, which was to be taken in the morning. Four study visits for control and intervention where BP was measured and medication increased if necessary. If BP uncontrolled at visit then a second drug was added. Theoretical basis for intervention not reported. Home monitoring intervention targeted patients only.
Outcomes	**Medication adherence [electronic monitoring]**: Significantly more patients were adherent (patients taking 80-100% of meds) at follow-up in the intervention group, 92% (sd14.2) v 74% (sd18.2), p=0.0007 Proportion of doses taken was significantly higher in the intervention group, 93.53% (sd15.7) v 87.68% (sd23.6), p=0.0001. Proportion of correct days and correct time was also higher in the intervention group: 89.44% (sd15.15) v 83.65 (sd23.3), p=0.0001; and 88.06 (sd21.58) v 79.89 (sd28.2), p=0.006 Therapeutic cover defined as % of hours in which the patient had true cover by therapeutic medication effect, was also significantly higher in the intervention group, 93.18% (sd14.8) v 86.72 (sd23.2), p=0.001 **BP**: there were no significant differences in office systolic BP between intervention and control groups at 1 month (145.2 [sd17.9] v 142.2 [sd13]), 3 months (140.7 [sd18.4] v 139.1 [sd13.3]) and 6 months (135.6 [sd13.8] v 136.7 [sd11.2]). Similarly there were no significant differences in office diastolic BP between intervention and control groups at 1 month (85.1 [sd10.2] v 83.7 [sd7.7]), 3 months (81.9 [sd9.4] v 81.6 [sd8]) and 6 months (79.5 [sd8.4] v 81.3 [sd7.6]).

	There was no significant difference between intervention and control for mean change in office systolic BP (-23.4 [sd15.9] v -18.9 [sd15.9], p=0.163). However mean change in office diastolic BP was significantly greater in the intervention group (-12.8 [sd9.9] v -9.7 [sd9.8], p<0.05). No difference between intervention and control in the proportion of patients at follow-up with controlled BP, 67% (sd46.9) v 56% (sd49.5)

14. McKenney (1992)

Methods	Two phase, parallel group, two centre, study duration 12 weeks, follow-up at 12 weeks.
Participants	70 hypertensive patients undergoing therapy for 12 months or longer with one or more BP lowering agent, age 75, 59% female, USA
Interventions	**HBPM alone** Phase two of the trial had four groups: control [1], medication in vials with timepiece cap [2], medication in with timepiece cap and card to record clinic BP at each visit [3], medication in vials with timepiece cap and card to record HBPM measurements [4]. Data was extracted for group 2 and 4, with the former acting as a control HBPM protocol not reported. No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Home monitoring intervention targeted patients only.
Outcomes	**Medication adherence [pill count]:** overall study compliance (doses consumed/doses prescribedx100) was higher in the intervention group, 100.2% (sd7.02) v 93.6% (sd8.67), p=0.02 **BP**: Office systolic and diastolic BP were not significantly different between groups: 138.1 (sd18.83) v 145.1 (sd17.95) and 75.7 (sd8.04) v (77.5 (sd10.2). Mean change in office systolic BP did not significantly differ in intervention and control groups, -15.00 (sd12.96) v -7.80 (sd23.62). However, mean change in office diastolic BP was significantly greater in the control group, -6.60 (sd6.05) v -13.13 (sd9.19), p=0.03

15. McManus (2005)

Methods	Parallel group, block randomised, multi-centre, study duration 12 months, follow-up at 6 and 12 months
Participants	441 patients receiving treatment for hypertension – those with at least one clinic BP reading >140/85 in past year were invited to clinic and were eligible if BP10/86 to 200/100; age 63, 53% female, UK
Interventions	**HBPM alone** Patients were asked to attend their practice every month to measure their own BP. Patients received a record card showing their target BP, and the cards also had space for recording monthly BP readings as well as advice to contact GP or nurse if recorded BP above target on successive months, or earlier in the case of very high readings. Monitoring was conducted in waiting room or side room of practice. No trial specific medication titration protocol was reported. Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention – patients could inform their GP or nurse if readings were high.

Outcomes	**Diet**: no significant difference between intervention and control for mean change in proportion adding salt to food or cooking at 6 months (-2% v -2%, p=0.82), or 12 months (-8 v -3, p=0.11). Reported alcohol intake [proportion of men >21 units/week; women >14 units/week] reduced significantly in the intervention group compared with the control group in the first six months (-4 v +3, p=0.03) but not at 12 months (-6 v -2,p=0.56) **Physical activity**: no significant difference between intervention and control for mean change in proportion exercising >3 times weekly at 6 months (+9% v +13%, p=0.53), or 12 months (+4 v +3, p=0.49). **Smoking status**: no significant difference between intervention and control for mean change in proportion smoking >1 cigarette a day at 6 months (+1% v -2%, p=0.10), or 12 months (+2 v -1, p=0.50). **BP**: no difference between intervention and control for unadjusted change in office systolic BP at 6 months (-13.4 v -10.3) or 12 months (-8.9 v -6.2), or for unadjusted change in office diastolic BP at 6 months (-5.5 v -4.7) or 12 months (-5.7 v -4.6) Adherence to intervention: 74% measured own BP at least 8 times over 12 months (predefined definition of adequate compliance)

16. Mehos (2000)

Methods	Parallel group, single centre, study duration 6 months, follow-up at 6 months
Participants	41 patients on current therapy with at least one antihypertensive drug, 42% aged over 50, 70% female, USA
Interventions	**HBPM alone** Patients were asked to measure BP each morning before food, coffee or drugs, after a five minute rest in a seated position, and again after 2-5 minutes. Each subject was given a predated diary in which to document the two morning values and missed medication doses. Clinical pharmacists contacted each subject after one month to evaluate BP response, and patient's family physician was contacted with recommendations if monthly values 140/90 or higher. No trial specific medication titration protocol was reported. Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention – physicians informed if HBP above target.
Outcomes	**Medication adherence [pharmacy fill]**: mean compliance during study period (no. tablets refilled/amount prescribed during studyx100) was not significantly different between intervention and control, 82% v 89%, p=0.29. **BP**: No significant difference in mean change in office systolic BP between intervention and control, -17.1 v -7.0, p=0.069 Mean change in office diastolic BP was significantly greater in the intervention, -10.6 v -3.8, p=0.022. No significant difference between intervention and control in proportion of patients achieving target office BP (<140/90) at follow up, 44% v 22%, p>0.1. **Adherence to intervention**: Number of days of home measurement – median 184 (range 121-196)

17. Midanik (1991)

Methods	Parallel group, single centre, study duration 12 months, follow-up at 12 months

Participants	204 untreated 'mild' hypertensives (average of two consecutive clinic BP readings below 180 systolic and diastolic between 90-99), age 47, 53% female, USA
Interventions	**HBPM alone** Patients trained to use a HBPM device and asked for two consecutive BP readings twice a week following at least five minutes of rest and not less than one hour after any significant exercise and to send in their readings every 4 weeks for a year. A breakout protocol was given to patients that instructed them to call their providers if any readings were unusually high (sys >220; dia >120). Patients were also told that their providers would receive copies of the home BP reports and would contact them if necessary. Providers received copies of all reports as they were received throughout the study period. No study specific medication titration protocol reported. Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention.
Outcomes	**Diet**: alcohol consumption (drinks/day) was not significantly different in intervention and control groups at follow-up, 0.6 (sd1.0) v 0.6 (sd0.9), p=0.91. The intervention group consumed significantly more coffee (drinks/day) at follow-up 1.8 (sd1.6) v 1.0 (sd1.0), p=0.004 Mean change in alcohol and coffee consumption were not significantly different in intervention and control; -0.2 (sd0.9) v -0.2 (sd0.8), p=0.87; -0.1 (sd1.4) v -0.5 (sd1.4), p=0.05. **Physical activity**: no difference between groups for physical activity, but data not reported **Smoking status**: no difference between groups, but data not reported **BP**: Neither systolic nor diastolic office BP differed significantly at follow-up between intervention and control; 142.6 (sd15.6) v 144.8 (sd18.0), p=0.42; 92.3 (sd9.5) v 93.6 (sd9.3), p=0.39. Mean difference in systolic and diastolic office BP were also not significantly different between intervention and control; -1.6 (sd14.5) v +0.8 (sd14.2), p=0.33; +1.0 (sd10.0) v +0.9 (sd8.0), p=0.96. **Adherence to intervention**: About half of the intervention participants returned 12 or 13 of the 13 required BP reports.

18. Migneault (2012)

Methods	Parallel group, multi-centre, study duration 8 months, follow-up at 8 and 12 months (8 month primary outcome)
Participants	337 African American (self-report) with a diagnosis of hypertension; one or more office visit in previous 2 months; prescription of one or more antihypertensives, age 57, 70% female, USA
Interventions	**HBPM, telemedicine, education (verbal)** Culturally adapted, automated telephone system to improve adherence to medication and evidence based guidelines for dietary behaviours and physical activity. Totally automated, computer based system, designed to monitor, educate and counsel adults with hypertension and to provide summary data regularly to the patient's primary care provider. The intervention delivered one call per week for 32 weeks. The first three calls introduced the three targeted behaviours and their role in BP control, and described the system. Subsequent calls were arranged as models on medication adherence, physical activity, and diet, and were delivered in the order chosen by the participant.

	Each call consisted of an introduction; a section for reporting health information collected on study-issued home measurement devices (pedometer, BP, weight); and the theory based interactive education and counselling on the targeted behaviour. In addition, participants and their primary care providers received printouts of the participant's progress in each health behaviour, sent at beginning and end of each of the three behavioural modules. HBPM protocol not reported. No trial specific medication titration protocol reported. The intervention incorporates principles of social cognitive theory, the Transtheoretical model of behaviour change, and motivational interviewing. Both patients and physicians targeted by home monitoring intervention.
Outcomes	8 month data (end of intervention) results are reported adjusted for covariates used in regression model. 12 month data (4 months post intervention period) are raw data taken from graphs. **Medication adherence [self-report]:** Mean change from baseline to 8 months for Morisky 7 (higher score indicates better adherence) did not significantly differ between intervention and control, +0.45 v +0.26, p=NS At 12months Morisky 7 scores were similar in intervention and control, 5.4 v 5.28, P=NR **Diet**: Mean change in overall diet quality score was significantly higher in the intervention, +2.8 v -0.74, p=<0.05. Overall diet quality scores at 12months were 57.2 in the intervention and 56.0 in controls (p=NR). **Physical activity**: Mean change from baseline to 8 months in moderate or greater intensity activity time (min/week) was not significantly different in intervention and control, -3.44 v +2.77, p=NS. Mean moderate or greater intensity activity (mins/week) at 12 months was 141 in the intervention group and 133 in controls (p=NR). Change from baseline to 8 months in the proportion of patients exercising >150 minutes/week did not differ in intervention and control, -2 v +5, p=NS. Change from baseline to 8 months in total energy expenditure (kcal/day) was significantly greater in the intervention group, +43.8 v -36.2, p=<0.05 Mean total energy expenditure at 12 months (kcal/day) was 3180 in intervention and 3180 in controls (p=NR) **BP**: Mean change from baseline to 8 months did not differ between intervention and control for office systolic BP (-2.06 v +0.25, p=NR) or office diastolic BP (-1.28 v -0.1, p=NR) Office systolic BP at 12months was 131.5 in the intervention and 130.4 in controls. Office diastolic BP at 12months was 80.5 in intervention and 79.8 in controls. Mean change from baseline to 8 months in proportion achieving systolic BP control, diastolic BP control, or control of both did not differ between intervention and control: +0.7 v +1.9, p=NS; +6.4 v +5.1, p=NS; +5.8 v +5.0, p=NS respectively. **Adherence to intervention**: 84.6% of intervention participants called the automated system at least once. Average number of completed calls (out of total of 32 planned calls) was 11.4. 8% of participants completed at least 70% of calls.
Notes	NCT00207194

19. Niiranen (2014)

Methods	Parallel group, quasi-cluster-randomised (2 health centres), study duration 12 months, follow-up at 12 months
Participants	229 patients with an untreated systolic office BP ≥160 and/or a diastolic office BP ≥100, or antihypertensive treatment and controlled or uncontrolled hypertension, age 68, 55% female, Finland.
Interventions	**HBPM, education (verbal)** Participants received repeated individual and group counselling on healthy lifestyles. In addition their antihypertensive drug therapy was guided by home BP measurements performed at 3 month intervals. Home BP was measured twice in the morning and evening on 4 consecutive days for a total of 16 measurements. BP readings were mailed to treating physician and the participant contacted by telephone. Medication titration – if home BP was higher than target the drug therapy was intensified. Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention.
Outcomes	**Diet**: No differences between intervention and control in mean changes in the following outcomes: Alcohol intake (g/d), -0.1 (sd8.2) v +3.2 (sd16.5), p=0.06 Total energy intake (MJ/day), -0.3 (sd1.8) v -0.1 (sd1.3), p=0.37 Total carbohydrate (%MJ/day), +1.5 (sd6.3), +0.0 (sd6.8), p=0.10 Total protein (%MJ/day), +0.0 (sd1.8) v +0.7 (sd2.6), p=0.12 Total fat (%MJ/day), -0.8 (sd6.1) v -0.2 (sd2.1), p=0.41 Total saturated fat (%MJ/day), -0.7 (sd2.6) v -0.1 (sd2.9), p=0.11 **Physical activity**: No difference between intervention and control for mean change in leisure activity (MJ/day), +0.00 (sd0.4) v +0.07 (sd0.3), p=0.15 **BP**: no difference between intervention and control for mean change in systolic or diastolic BP; -8 (sd17) v -11 (sd17), p=0.25; -7 (sd8) v -7 (sd8), p=0.16 Also no difference in proportion of patients achieving target BP at follow-up between intervention and control, 52.7% v 60.2%, p=NR **Adherence to intervention**: proportion successfully measuring HBPM at 0, 3, 6, 9 and 12 months respectively – 98.2%, 97.3%, 97.3%, 94.6%, 77.7%
Notes	NCT01915199

20. Ogbuokiri (1980)

Methods	Parallel group, single centre, study duration 5 months, follow-up at 5 months
Participants	29 patients with essential hypertension, age 47, 85% female, predominantly (95% black), Nigeria
Interventions	**HBPM alone** Patients taught to take their own BP. No HBPM protocol reported. No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Home monitoring intervention targeted patients only.
Outcomes	**Medication adherence [pharmacy fill]**: Frequency of refill percentage value arbitrarily chosen and defined before the study: Refill within 1-10 days of due date = 100%FR Refill within 2 weeks of due date = 50%FR Refill within 4 weeks of refill = 25%FR Mean frequency of refill did not differ between intervention and control at follow-up, 72.56% v 59.26%, p=NR.

	Change from baseline was also not significantly different in intervention and control, +34.56 v +27.66, p=NR **BP**: office systolic BP did not differ significantly between intervention and control groups at follow up, 129.03 v 127.42, p=NR BP change from baseline was also not significantly different between intervention and control, +0.36 v +1.42, p=NR

21. Ogedegbe (2014)

Methods	Parallel group, multi centre, cluster randomised (by community health centre), study duration 12 months, follow-up at 6 and 12 months
Participants	1,039 self-identified as black, with a diagnosis of hypertension, taking at least one antihypertensive medication, receiving care at participating community health centre for at least 6 months, age 56, 72% female, USA
Interventions	**HBPM, education (verbal), education (print/on-line materials), physician education** Patient components included: HBPM; interactive computerised educational program about causes, complications and treatment of hypertension, side effects of medications and methods for adopting lifestyle change; and individual and group behavioural sessions on adoption of healthy lifestyle modifications Physicians had: monthly case rounds with continuing medical education based on JNC7 guidelines; and provision of feedback on patient's home BP recordings Patients were encouraged to record their weekly BP readings (twice daily, three times a week), in a diary that was provided. They were asked to bring this with them to each study visit. No trial specific medication titration protocol reported. Intervention developed using Chronic Care Model. Both patients and physicians targeted by home monitoring intervention.
Outcomes	**Medication adherence [self-report]:** Morisky 4 scale (0= perfect adherence) There were no significant differences in Morisky 4 scores between intervention and control at either 6 months (0.87 [sd2.4] v 1.05 [sd2.3], p=0.19) or 12 months (0.77 [sd2.3] v 0.98 [sd2.2], p=0.15) There were also no significant differences between intervention and control for change in Morisky score from baseline to 6 months (-0.14 v -0.13, p=0.87), and baseline to 12 months (-0.24 v -0.20, p=0.71) **BP**: Change in systolic BP and diastolic BP from baseline to 12 months did not differ significantly between intervention and control; -16.1 v -16.0, p=0.96; -9.6 v -8.9, p=0.46. Proportion of patients achieving BP control (mean BP <140/90 or <130/80 for diabetes/kidney disease) also did not differ, 45.3% v 50.2%, p=0.18 **Adherence to intervention**: 38% of intervention participants returned home BP diaries for all four study visits.
Notes	Ogedegbe 2009 – journal article protocol Ogedegbe 2011 – conference abstract results Ogedegbe 2014 – journal article results Fernandez 2011 – journal article baseline data

22. Rinfret (2009)

Methods	Parallel group, multi-centre, individually randomised, study duration 12 months, follow-up at 12 months.
Participants	223 patients with an office diagnosis of hypertension according to American and Canadian guidelines (mean 24 hour BP >130/80 and daytime BP >135/85 confirmed by ABPM), age 56, 46% female, Canada

Interventions	**HBPM, telemedicine, education (print/on-line materials)** Participants received a BP monitor, and educational booklet and access to an IT supported adherence and BP monitoring system providing, nurses, pharmacists and physicians with monthly reports. The system collected self-recorded and self- assessed adherence data weekly and generated reports which were faxed monthly to professionals. Based on a predefined algorithm the system also emailed study nurses in the event of poor BP control after 4 weeks or reports of non-adherence. Nurses could subsequently contact subjects to inquire about BP or adherence difficulties and to deal with them or refer subjects to their physician or pharmacist as specified in the study algorithm. Subjects were followed at their usual point of care by their primary care physician throughout the study period. HBPM protocol was unclear; however data were to be uploaded weekly. No study specific medication titration protocol was reported. Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention.
Outcomes	**Medication adherence [pharmacy fill]:** Adherence was expressed as continuous medication availability (CMA) and measures of gaps (CMG) scores calculated from actual pharmacy data, which estimate the proportion of time that subjects have or do not have medication available. CMAs and CMGs are expressed as median [IQR]. No significant difference was found between groups for CMA (0.95 [0.76-1.00] v 0.91 [0.54-1.04], p=0.07), or CMG (0.04 [0.00-0.19] v 0.09 [0.00-0.38], p=0.12) **BP**: mean change from baseline for systolic BP was significantly greater in the intervention group measured by 24h ABPM (-11.9 [sd10.5] v -7.1 [sd10.6], p<0.01), daytime ABPM (-13.4 v -7.5, p<0.01), nocturnal ABPM (-9.0 v -5.2, p<0.01), or office (-18.7 v -13.8, p=0.05) Mean change from baseline for diastolic BP was significantly greater in the intervention group measured by 24h ABPM (-6.6 [sd11.6] v -4.5 [sd11.6], p=0.07), daytime ABPM (-7.6 v -5.1, p=0.05), and office (-9.1 v -5.6, p=0.02); but not when measured by nocturnal ABPM (-5.0 v -3.1, p=0.06) A significantly higher proportion of intervention participants achieved target (office BP <140/90), 46.0% v 28.6%, p=0.006
Notes	NCT00374829; ISRCTN75436659

23. Rudd (2004)

Methods	Parallel group, two centre, randomised by patient, study duration 6 months, follow-up at 6 months
Participants	150 patients eligible for hypertensive drug treatment according to JNC VI criteria, BP threshold >150 systolic, >95 diastolic, or both, on two screening visits conducted on separate days at least one week apart, age 60, 53% female, USA
Interventions	**HBPM, education (verbal), education (print/online materials), medication titration protocol** Baseline counselling and printed materials on patients' correct use of BP device, regular return of the automatically printed BP reports, tips for enhancing drug adherence, and recognition of potential drug side effects. Nurse followed up by phone at 1week and, 1, 2 and 4months. Calls averaged 10 mins – nurse asked patients about medication dosage and any problems experienced. Nurse care manager contacted physician to obtain permission to initiate any new BP drug but not regarding changes in dosage.

	BP measured twice daily at the same times each day. These values were mailed to the nurse care manager every 2 weeks. Trial specific medication titration protocol used: when <80% of BP readings in two week period met target, the nurse increased drug dose to the maximal level recommended for each drug, or added one or more additional drugs. Intervention developed using Social Cognitive Theory. Both patients and physicians targeted by home monitoring intervention.
Outcomes	**Medication adherence [electronic monitoring]:** Daily adherence (average number of days patients took correct dose) was significantly higher in the intervention group, 80.5% (sd23) v 62.9% (sd31.1), p=0.03 **BP**: Mean change from baseline for office systolic and diastolic BP was significantly greater in the intervention group; -14.2 (sd16.9) v -5.7 (sd18.4), p<0.01; and -6.5 (sd9.8) v -3.4 (sd7.9) respectively.

24. Stewart (2014)

Methods	Parallel group, cluster randomised (by pharmacy), study duration 6 months, follow-up at 6 months
Participants	395 patients who were using or having used in past 6 months at least one antihypertensive medication, age 67, 49% female, Australia
Interventions	**HBPM, education verbal, adherence reminders** Participants received a HBPM with capacity to store and download BP readings for discussion at follow-up. Motivational interviewing and education from pharmacist to help improve adherence and achieve target BP. Pharmacist initiated home medicines review (HMR), dose administration aid (DAA) and/or patient medication profile (PMP) where necessary. HBPM protocol unclear, although reported data at 3 and 6 months follow-up No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention – pharmacists also referred patients to a GP where needed.
Outcomes	**Medication adherence [self-report and pharmacy fill]**: four measures of medication adherence used – Morisky (4 item scale, 0 = good adherence, >1 = suboptimal adherence); TABS (two subscales, adherence and non-adherence, TABS differential >15 = good adherence, <15 = suboptimal adherence), MedsIndex (scores patient out of 100 calculated from prescription refill history, score <100 = suboptimal adherence); MPR (sum of days' supply obtained over a series of intervals, divided by the total number of days from beginning to the end of time period, MPR >80 good adherence). No significant difference was found between intervention and control for any of the following assessments: Proportion adherent using Morisky, 73.5% v 63.6%, p=0.09 Change from baseline in proportion adherent using Morisky, +13.5 v +6.4, p=NS Morisky total score, 0.36 (sd0.67) v 0.44 (sd0.64), p=NR Mean change in Morisky total score -0.20 v -0.15, p=0.31 TABS adherence 18.83 (sd2.15) v 19.07 (sd1.68), p=NR Mean change in TABS adherence, +0.48 v -0.05, p=0.234 TABS non-adherence, 7.74 (sd2.98) v 7.52 (sd2.60), p=NR Mean change in TABS non-adherence, -0.36 v -0.68, p=0.580 TABS differential, 11.10 (sd3.83) v 11.59 (sd3.33), p=NR Mean change in TABS differential , +0.85 v +0.67, p=0.856 MedsIndex score for BP medications, 84.75 (sd17.13) v 82.86 (sd19.42), p=NR Mean change in MedsIndex score for BP medications, +4.60 v +2.44, p=0.228 Medication possession ratio (MPR), 0.94 (sd0.35) v 0.89 (sd0.21), p=NR Mean change in MPR, +0.13 v +0.08, p=0.496

	BP: Mean change from baseline in office systolic BP was significantly greater in the intervention group compared to control, -10.0 (sd25.0) v -4.6 (sd25.3), p=0.05 Mean change in office diastolic BP was not significantly different between intervention and control, +4.5 (sd14.5) v -4.2 (sd14.7), p=0.85
Notes	ACTRN12609000705280 Lau 2010 (journal article – protocol) George 2010 (conference abstract – results) Stewart 2014a (journal article – adherence results) Stewart 2014b (journal article – BP results)

25. van Onzenoort (2010)

Methods	Parallel group, multi-centre, individually randomised, study duration 12 months, follow-up 12 months
Participants	430 patients with average systolic BP 139-200 and/or systolic BP 90-120, age 55, 45% female, Netherlands
Interventions	**HBPM, medication titration protocol** Antihypertensive therapy based on home BP measurements. Treatment decisions are taken by an independent physician at coordinating centre who is blinded to intervention group. Previous medication discontinued and study medication withheld during one month run-in period. HBPM measurements recorded during the week preceding study visit. Recordings are performed for 7 consecutive days in the morning and evening, with each session consisting of three readings in a sitting position. Patients register BP on a special case report form. Home BP is defined as the mean of all home measurements. Trial specific medication titration protocol: Patients followed up monthly for BP measurements, and drug treatment is adjusted according to the treatment schedule: In patients who are above the target BP treatment will be intensified by one step. If patients are on target their treatment remains unchanged. Step 1 – Lisinopril 10mg once daily plus one tablet of placebo once daily Step 2 – Lisinopril 20mg once daily plus one tablet of placebo once daily Step 3 – Lisinopril 20mg once daily plus hydrochlorothiazide 12.5mg Step 4 – Lisinopril 10mg once daily plus amlodipine 5mg Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention.
Outcomes	**Medication adherence [pill counts and electronic monitoring]**: Medication adherence by pill count (proportion of available medication taken by patient) was not significantly different in the intervention and control groups, 87.3% v 88.1%, p=0.62 Adherence was measured in a single centre (228 participants) using MEMS caps. Adherence defined as proportion of days with correct dosing, was significantly higher in the intervention, 92.3% (IQR 86.9-94.4) v 90.9% (IQR 92.9-93.7), p=0.043. Proportion adequately adherent (i.e. >85% adherent by electronic monitoring) was not significantly different in intervention and control groups for the sub study, 81% v 74%, p=NR **BP**: At follow-up systolic BP was significantly lower in the control group measured by 24h ABPM (125.9 [sd9.0] v 123.8 [sd12.2], p=0.04), day ABPM (131.2 [sd10.7] v 129.1 [sd12.8], p=0.03), and night ABPM (112.3 [sd10.1] v 110.1 [sd12.5], p=0.03); but not when measured in the office (143.8 [sd18.4] v 142.2 [sd20.0], p=0.29)

	Diastolic BP was not significantly different in intervention and control groups at follow-up, office (85.4 [sd10.4] v 84.3 [sd9.6], p=0.13), 24h ABPM (77.2 [sd7.4] v 76.1 [sd7.9], p=0.05), day ABPM (81.6 [sd8.6] v 80.4 [sd8.4], p=0.05), night (66.4 [sd7.5] v 65.5 [sd8.8], p=0.14) **Adherence to intervention**: participants averaged 39 measurements out of a possible total of 43.
Notes	HOMERUS trial Verberk 2003 – journal article (protocol) Verberk 2007 – journal article (results) Van Onzenoort 2010 (results for electronic drug monitoring) Data extraction on Verberk 2007b

26. Vrijens (1997)

Methods	Parallel group, individual patient randomisation, study duration 6 weeks, follow-up at 6 weeks
Participants	628 patients with BP>95, sub population of 127 chosen for adherence sub study, Belgium
Interventions	**HBPM, education (verbal)** All patients in the trial received the same antihypertensive agent (Renitec), prescribed at one tablet of 20mg a day. "Basic notions about SBP, DBP, pulse, variations in these measures, etc., were taught to the patients" in the intervention. HBPM was performed every morning before taking medication. Measures were to be taken in the sitting position after five minutes rest. Patients received a form to transcribe daily BP and pulse measurements. No trial specific medication protocol used in the adherence sub study. Theoretical basis for intervention not reported. Home monitoring intervention targeted patients only.
Outcomes	**Medication adherence [electronic monitoring]:** MEMS track caps used. Average number of pills taken in the final week (maximum of 7), was similar in the intervention and control groups, 6.78 v 6.20, p=NR (data from chart) Change in average number of pills was -0.12 in the intervention group and -0.78 in the control group, p=NR.

27. Wakefield (2012)

Methods	Parallel group, single centre, study duration 6 months, follow-up at 6 and 12 months
Participants	302 patients with coexisting hypertension and diabetes, in receipt of primary care from VA in previous 12 months, age 67, 2% female, USA
Interventions	**HBPM, telemedicine, education (print/online materials)** Three groups: control and two groups that combined telehealth device with nurse care management (low and high intensity). Patients received a home telehealth device, for patients to enter their BP and blood glucose (BG) measurements and respond to standardised questions based on their group assignment. Patients then received automated responses based on how they answered the device prompt. In the high intensity group the device used a branching disease management algorithm which focussed on diet, exercise, smoking cessation, behaviour modification and lifestyle adjustments. The Low intensity group had a small subset of the questions used in the high intensity group.

	Both intervention groups received care management from a study nurse. Each weekday the study nurse reviewed responses from participants and determined if the subjects needed follow-up (additional health information, increased monitoring, compliance strategies, problem resolution facilitation, or contact with the subjects). Participants monitored their BP daily. No trial specific medication titration protocol reported. Theoretical basis for intervention not reported. Both patients and physicians targeted by home monitoring intervention - physicians set BP and BG parameters for their patients. If these were exceeded then the nurse could contact the physician for changes in treatment plant.
Outcomes	**Medication adherence [self-report]**: for their hypertension medications participants were asked, ''Are you taking your medications as prescribed?'' Adherence scores represent the proportion of medications for which the responses agreed with the directions for use on the VA Pharmacy medication profile. Proportions of medications taken according to directions did not differ between the low intensity, high intensity and usual care groups at 6 months (99.8% [sd1.4] v 99.6% [sd2.0] v 99.6 [sd2.2], p=0.79) or 12 months (99.7% [sd1.4] v 100% [sd0] v 98.9% [sd6.0], p=0.20). **BP**: At 6 months, mean change from baseline in office systolic BP was significantly different between the high intensity intervention and control (-6.05 v +4.48, p=0.001), but not between the low intensity group and control (-0.29 v +4.48, p=0.06). Similarly, at 12 months, mean change from baseline in systolic BP was significantly different between the high intensity intervention and control (-4.92 v +3.34, p=0.006), but not between the low intensity group and control (+0.76 v +3.34, p=0.08). **Adherence to intervention**: On average patients in the low intensity intervention group entered 69% of data into the telehealth system, and patients in the high intensity group entered 70%
Notes	Wakefield 2011 – journal article results BP Wakefield 2012 – journal article results adherence

28. Zarnke (1997)

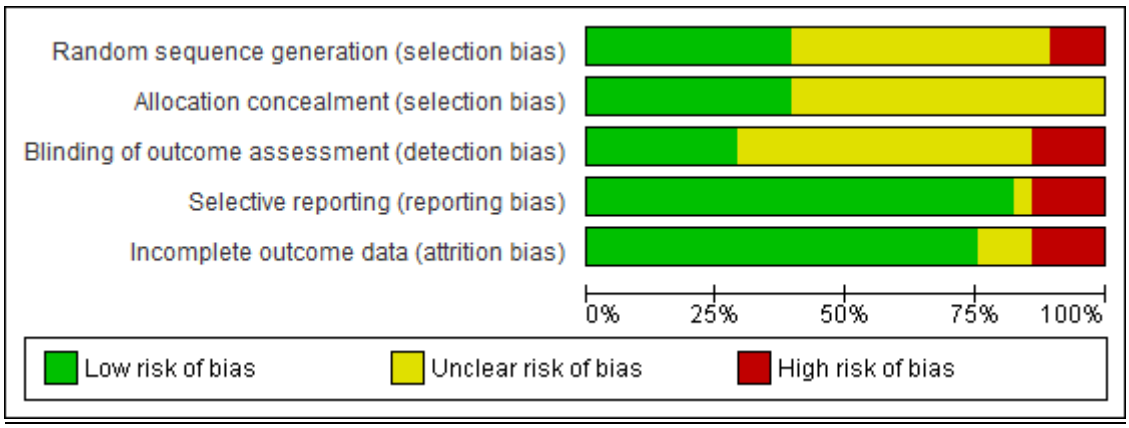
Methods	Parallel group, multi-centre, study duration 8 weeks, follow-up at 8 weeks
Participants	31 patients with mild to moderate hypertension for at least 6 months, BP<160/95 at the time of screening, receiving non-pharmacological or one or two antihypertensive medications, age 55, 65% female, Canada
Interventions	**HBPM, medication titration protocol** Patients were instructed to make alterations in drug therapy when BP values consistently exceeded specific limits according to an algorithm specific for each patient's medications. Patients measured BP twice daily, and recorded values in a diary. The algorithms specified increasing drug therapy in a stepwise fashion by standard dosage increments for sustained BP above 160mmHg systolic, or above 95mm diastolic for a 2 week period. They also specified decreasing therapy for sustained BP less than 110 sys or 70 dia for more than a one week period. If subjects found their BP elevated over a sustained interval despite maximising initial therapy, they were asked to visit their physician for consideration of adding a Ca channel blocker. Once started they were then asked to titrate the new drug according to directions in their individual algorithm if necessary. Theoretical basis for intervention not reported.

	Both patients and physicians targeted by home monitoring intervention – subjects informed their physician if their BP remained over target.
Outcomes	**Medication adherence [self-report]**: The mean number of self-reported doses missed per week did not differ significantly between intervention and control, 0.05 (sd0.2) v 0.2 (sd0.4), p=NS **Diet**: there was no significant difference between intervention and control for change from baseline in alcohol intake (standard drinks per week), -0.25 (sd1.59 v +0.10 (sd0.32), p=NS **BP**: Mean change from baseline in daytime (12h) mean arterial pressure (ABPM) did differed significantly between intervention and control, -0.95 (sd5.8) v +1.90 (sd4.6), p=0.039

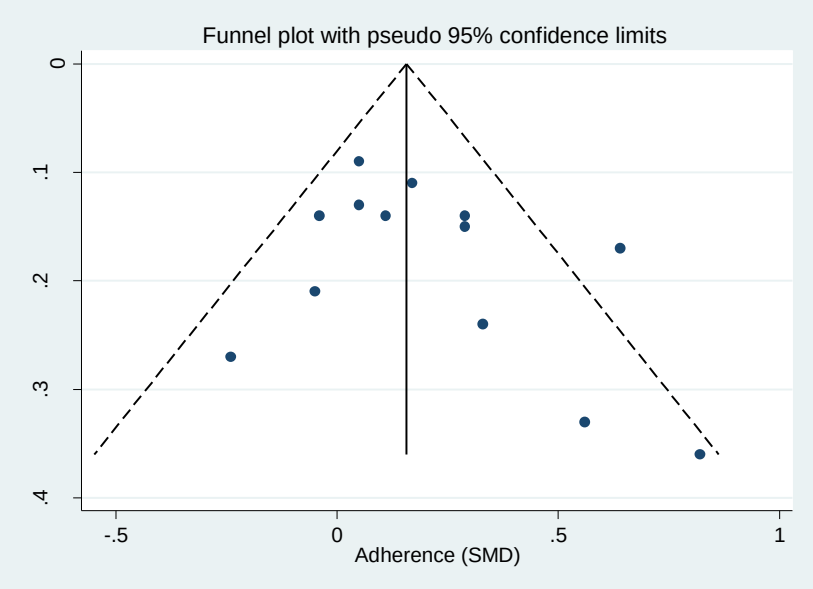
Appendix 1.6 – Adherence to SMBP intervention

Study i.d.	Measure	Follow-up	Result
Bailey 1999	Proportion taking all home blood pressure measurements	2 months	77%
Fikri-Benbrahim 2013	Proportion measuring BP at least one day per week (i) Completed the two sessions of 5 consecutive days of monitoring (ii)	6 months	i: 85% ii: 85%
Johnson 1978	Proportion charting their BP every day (i) Proportion charting BP on at least 14 days (ii)	6 months	i: 72%/50% ii: 46%/15%
Magid 2011	Uploaded home BP measurements at least once during trial	6 months	94%
Mehos 2000	Number of days of home measurement [median/range]	6 months	184 (121 to 196)
Wakefield 2012	Proportion of required data entered into telehealth system	6 and 12 months	69%/70%
Migneault 2012	Called automated system at least once (i) Average number of completed calls [out of a total of 32 planned calls] (ii) Proportion of participants who completed at least 70% of calls (iii)	8 and 12 months	i: 84.6% ii: 11.4 iii: 8%
Midanik 1991	Returned 12 or 13 of required BP reports	12 months	"about half"
Niiranen 2014	Proportion successfully measuring HBPM at 0 (i), 3 (ii), 6 (iii), 9 (iv), and 12 months (v)	12 months	i: 98.2% ii: 97.3% iii: 97.3% iv: 94.6% v: 77.7%
Ogedegbe 2014	Proportion returning home BP diaries for all four study visits	12 months	38%
Van Onzenoort 2010	Mean number of measurements (maximum of 43)	12 months	39

Appendix 1.7 – Risk of bias



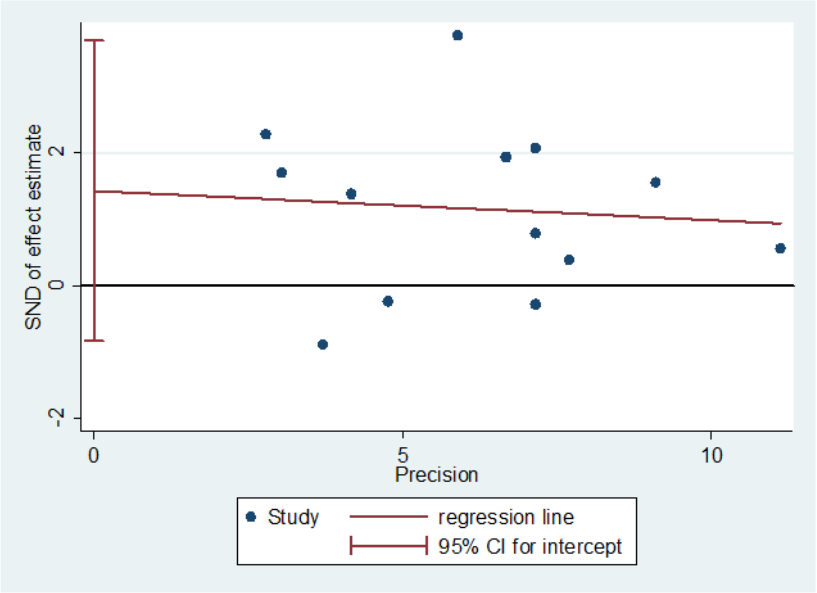
Appendix 1.8 – Funnel plot and Egger's test



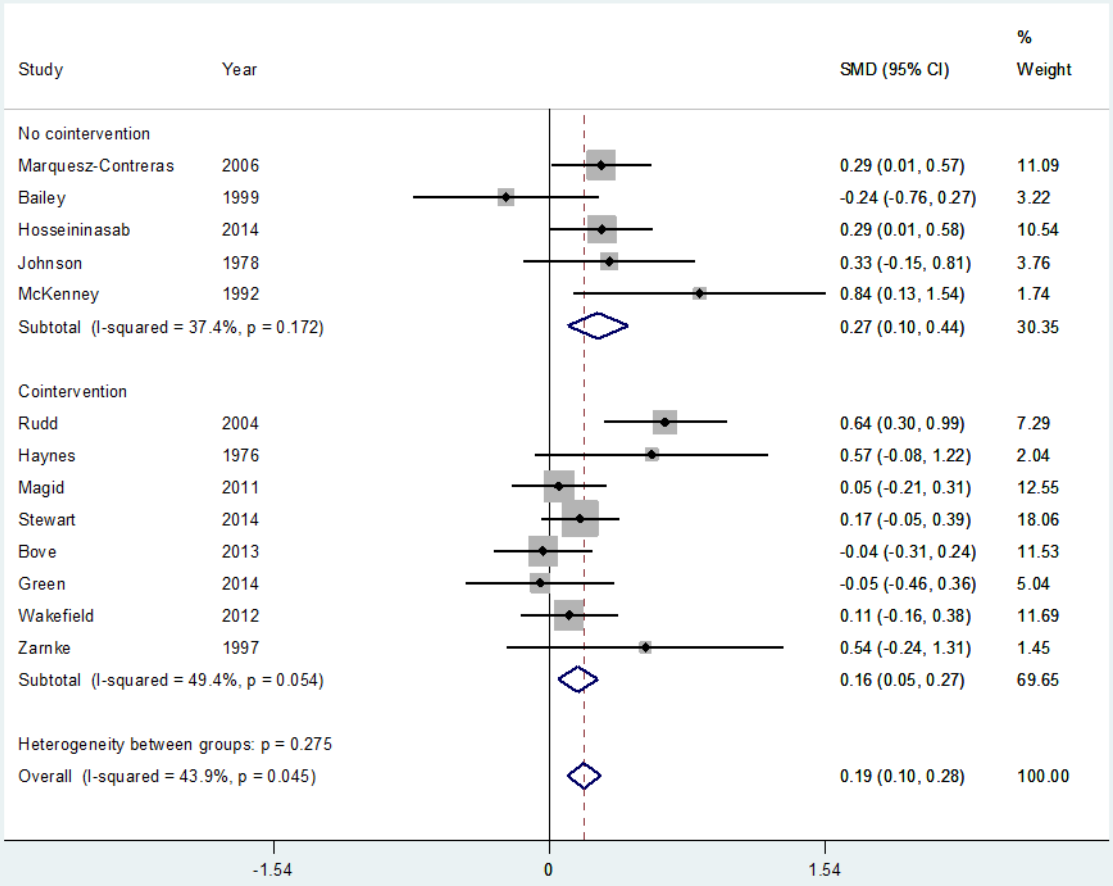

```
. metabias adherencesmd adse, egger graph

Note: data input format theta se_theta assumed.

Egger's test for small-study effects:
Regress standard normal deviate of intervention
effect estimate against its standard error

Number of studies =  13                                 Root MSE      =     1.32
```

Std_Eff	Coef.	Std. Err.	t	P>|t|	[95% Conf.	Interval]
slope	-.044187	.1556482	-0.28	0.782	-.3867664	.2983924
bias	1.425124	1.028868	1.39	0.193	-.8393987	3.689647

```
Test of H0: no small-study effects          P = 0.193
```



Appendix 1.9 – Subgroup analysis: effect of co-interventions on medication adherence test



Appendix 1.10 – SMBP v control, outcome: clinic systolic BP

Study i.d.	BP outcome measure	Follow-up	Results		Sig. diff?
			Intervention	Control	
Bailey 1999	Office	2 months	-13	-8	Y (p<0.05)
McKenney 1992	Office	3 months	-15.0 (sd13.0)	-7.8 (sd23.6)	NR
^Ogbuokiri 1980	Office	5 months	+0.36	+1.42	NR
Hosseininasab 2014	Office	1, 3, and 6 months	1m: -11.6 (sd8.6) 3m: -12.5 6m: -12.4 (sd6.9)*	1m: -12.5 (sd8.2) 3m: -13.9 6m: -8.4 (sd6.0)*	1m: N (p value not reported) 3m: N (p value not reported) 6m: N (p value not reported)
Marquez-Contreras 2006	Office	6 months	-23.4 (sd15.9)	-18.9 (sd15.9)	P=0.63
Bove 2013	Office	6 months	-18.2 (sd20.3)	-13.9 (sd18.2)	P=0.12
Fikri-Benbrahim 2013	Office	6 months	-6.8 (sd13.7)	-2.1 (sd9.3)	P=0.01
Friedman 1996	Office	6 months	-5.4	-3.3	P=0.85
Green 2014	Office	6 months	-13.9 (sd13.7)	-11.4 (sd13.6)	P=0.40
Magid 2011	Office	6 months	-13.1 (sd20.4)	-7.1 (sd16.6)	P=0.006
Mehos 2000	Office	6 months	-17.1	-7.0	P=0.07
Rudd 2004	Office	6 months	-14.2 (sd16.9)	-5.7 (sd18.4)	P<0.01
Stewart 2014	Office	6 months	-10.0 (sd25.0)	-4.6 (sd25.3)	P=0.05
McManus 2005	Office	6 and 12 months	6m: -13.4 12m: -8.9	6m: -10.3 12m: -6.2	6m: NR 12m: NR
^De Souza 2012	Office	6 and 12 months	6m: -4.52 (sd19.8)* 12m: -8.37	6m: +3.90 (sd25.4)* 12m: -6.91	NR
Wakefield 2012	Office	6 and 12 months	6m: -0.29 12m: +0.76	6m: +4.48 12m: +3.34	6m: p=0.06 12m: p= 0.08
Migneault 2012	Office	8 months	-2.06	+0.25	N (p value not reported)

Study i.d.	BP outcome measure	Follow-up	Results		Sig. diff?
			Intervention	Control	
Dusing 2009	Office	9 months	-19.5	-14.7	N (p value not reported)
Midanik 1991	Office	12 months	-1.6 (sd14.5)	+0.8 (sd14.2)	P=0.33
Niiranen 2014	Office	12 months	-8 (sd17)	-11 (sd17)	P=0.25
Ogedegbe 2014	Office	12 months	-16.1	-16.0	P=0.96
Rinfret 2009	Office	12 months	-18.7	-13.8	p=0.05
^Van Onzenoort 2010	Office	12 months	-22.4	-22.9	NR

Appendix 1.11 – SMBP v control, outcome: clinic diastolic BP

Study i.d.	BP outcome measure	Follow-up	Results		Sig. diff?
			Intervention	Control	
Bailey 1999	Office	2 months	-4	-6	N (p value not reported)
^McKenney 1992	Office	3 months	-6.6 (sd6.1)	-13.1 (sd9.2)	NR
Marquez-Contreras 2006	Office	6 months	-12.8 (sd9.9)	-9.7 (sd9.8)	Y (p<0.05)
Hosseininasab 2014	Office	1, 3, and 6 months	1m: -8.1 (sd6.7) 3m: -8.8 6m: -9.4 (sd6.6)*	1m: -7.9 (sd8.6) 3m: -8.4 6m: -8.4 (sd7.1)*	1m: N (p value not reported) 3m: N (p value not reported) 6m: N (p value not reported)
Bove 2013	Office	6 months	-7.1 (sd11.8)	-4.9 (sd10.2)	N (p=0.17)
Fikri-Benbrahim 2013	Office	6 months	-2.1 (sd8.9)	+0.1 (sd6.2)	Y (p=0.013)
Friedman 1996	Office	6 months	-5.4	-3.3	P=0.09
Green 2014	Office	6 months	-8.5 (sd9.1)	-6.6 (sd8.9)	P=0.32
Haynes 1976	Office	6 months	-5.4 (sd7.6)	-1.9 (sd8.5)	P=0.12
Johnson 1978	Office	6 months	-8.9 (sd8.7)	-7.6 (sd11.1)	NA (p value not reported)
Magid 2011	Office	6 months	-6.5 (sd11.7)	-4.2 (sd10.4)	P=0.069
Mehos 2000	Office	6 months	-10.6	-3.8	P=0.022
Rudd 2004	Office	6 months	-6.5 (sd9.8)	-3.4 (sd7.9)	P<0.05
Stewart 2014	Office	6 months	-4.5 (sd14.5)	-4.2 (sd14.7)	P=0.85
^McManus 2005	Office	6 and 12 months	6m: -5.5 12m: -5.7	6m: -4.7 12m: -4.6	NR
^De Souza 2012	Office	6 and 12 months	6m: -2.44 (sd12.4)* 12m: -3.82	6m: +3.32 (sd13.3)* 12m: -0.29	NR
Migneault 2012	Office	8 months	-1.28	-0.10	N (p value not reported)

Study i.d.	BP outcome measure	Follow-up	Results		Sig. diff?
			Intervention	Control	
Dusing 2009	Office	9 months	-13.4	-9.5	N (p value not reported)
Midanik 1991	Office	12 months	+1.0 (sd10.0)	+0.9 (sd8.0)	P=0.96
Niiranen 2014	Office	12 months	-7 (sd8)	-7 (sd8)	P=0.16
Ogedegbe 2014	Office	12 months	-9.6	-8.9	P=0.18
Rinfret 2009	Office	12 months	-9.1	-5.6	p=0.02
^Van Onzenoort 2010	Office	12 months	-11.7	-13.5	NR

Appendix 2.1 – Systematic review protocol (2)

UNIVERSITY of York
Centre for Reviews and Dissemination

PROSPERO International prospective register of systematic reviews

How do patients and clinicians use home monitoring in the management of hypertension, and what are the barriers and facilitators to its use, both in trials and real-world settings: a systematic review and thematic synthesis

Benjamin Fletcher, Jamie Hartmann-Boyce, Nia Roberts, Lisa Hinton, Richard McManus

Citation
Benjamin Fletcher, Jamie Hartmann-Boyce, Nia Roberts, Lisa Hinton, Richard McManus. How do patients and clinicians use home monitoring in the management of hypertension, and what are the barriers and facilitators to its use, both in trials and real-world settings: a systematic review and thematic synthesis. PROSPERO 2014:CRD42014012864
Available from http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014012864

Review question(s)
How do patients and clinicians use home blood pressure monitoring (HBPM) in the management of hypertension, both in trials and real-world settings, and what are the barriers and facilitators to its use?

What motivates patients to initiate home monitoring?

What motivates physicians to recommend HBPM to their patients?

How do hypertensive patients use self-measurement of BP to aid in the management of their condition?

What are the perceived benefits of HBPM to patients and physicians?

What are the barriers and facilitators to the use of HBPM?

How do clinicians use HBPM measurements in the management of hypertension?

Is there a difference in barriers and facilitators to HBPM use in trials as opposed to 'real-world' settings?

Searches
OVID MEDLINE, OVID EMBASE, OVID PsycINFO, CINAHL, Web of Science, SocAbs

Restricted to English language only.

Link to search strategy
http://www.crd.york.ac.uk/PROSPEROFILES/12864_STRATEGY_20140624.pdf

Types of study to be included
Studies presenting primary data and involving qualitative data collection methods will be included if they report patient and/or clinician experiences of home blood pressure monitoring.

Condition or domain being studied
Hypertension in adults.

Participants/ population
Patients with hypertension with experience of using HBPM, either as part of a clinical trial, or in "real-world" settings.

Physicians managing the care of hypertensive patients using HBPM, either in a clinical trial, or in "real-world" settings.

Intervention(s), exposure(s)
Home blood pressure monitoring.

Exclude: use of 24 hour ambulatory monitoring.

Comparator(s)/ control
Not applicable

Outcome(s)

Primary outcomes

Patient motivation for initiation of HBPM.

Physician motivation for recommendation of HBPM to patients.

Barriers and facilitators to HBPM use.

Secondary outcomes

Not applicable.

Data extraction, (selection and coding)
Data extraction and synthesis will follow the methods proposed by Thomas and Harden (2007). Data extraction will first be carried out using the QARI (qualitative assessment and review instrument) data extraction tool designed by the Joanna Briggs Institute for Evidence Based Practice. This form will be piloted in order to check its adequacy for this review. The form allows broad themes to be identified from the studies which can be used to guide the first stage of data analysis. Secondly all text will be extracted from sections labelled as 'results' or 'findings' in the included reports, according to the method suggested by Thomas and Harden (2007). The results will then be entered into NVivo software for qualitative thematic analysis.

Risk of bias (quality) assessment
There have been several quality assessment strategies suggested for qualitative reports e.g. CASP, Joanna Briggs Institute, Seale (1997), Popay (1998), Pearson (2004), Dixon-Woods (2004). For this review quality assessment will carried out in accordance with the CASP qualitative research appraisal tool. The checklist includes ten questions that cover: rigour, key research methods used, credibility and relevance. Quality assessment will be carried out in order to achieve an understanding of each study in its own terms, rather than to produce a quality score for each individual study. Quality assessment will be carried out independently by two researchers (BF, LH).

Strategy for data synthesis
Line-by-line coding of the extracted data will be carried out. These codes are then organised into related areas in order to construct descriptive themes. Abstracted, analytical themes are then created. Finally, "sensitivity analysis" can be used to examine the relative contributions of studies to the final analytic themes.

Data extraction will be carried out by one reviewer (BF) and assessed by another (JHB). Coding and development of analytical themes will be carried out by three members of the review team (BF, LH, RM).

Appendix 2.2 – ENTREQ reporting guidelines

No.	Item	Reported
1	Aim	
2	Synthesis methodology	
3	Approach to searching	
4	Inclusion criteria	
5	Data sources	
6	Electronic search strategy	
7	Study screening methods	
8	Study characteristics	
9	Study selection results	
10	Rationale for appraisal	
11	Appraisal items	
12	Appraisal process	
13	Appraisal results	
14	Data extraction	
15	Software	
16	Number of reviewers	
17	Coding	
18	Study comparison	
19	Derivation of themes	
20	Quotations	
21	Synthesis output	

Appendix 2.3 – Medline search strategy

1	Hypertension/
2	hypertens*.ti,ab.
3	(high adj3 (blood pressure or bp or sbp or dbp)).ti,ab.
4	*Blood Pressure/
5	(blood pressure or bp or sbp or dbp).ti.
6	1 or 2 or 3 or 4 or 5
7	*Self Care/
8	(self* adj3 (monitor* or measure* or determin* or manage*)).ti,ab.
9	(home* adj3 (monitor* or measure* or determin* or manage*)).ti,ab.
10	(self* adj4 device*).ti,ab.
11	(home adj4 device*).ti,ab.
12	7 or 8 or 9 or 10 or 11
13	6 and 12
14	(hbpm or sbpm).ti,ab.
15	13 or 14
16	(Qualitative systematic review* or (systematic review and qualitative)).ti,ab.
17	(evidence synthesis or realist synthesis).ti,ab.
18	(Qualitative and synthesis).ti,ab.
19	(meta-synthesis* or meta synthesis* or metasynthesis).ti,ab.
20	(meta-ethnograph* or metaethnograph* or meta ethnograph*).ti,ab.
21	(meta-study or metastudy or meta study).ti,ab.
22	systematic review*.ti,ab. and qualitative research/
23	16 or 17 or 18 or 19 or 20 or 21 or 22
24	15 and 23
25	qualitative research/
26	*interviews as topic/ or focus groups/ or narration/
27	observation.ti.
28	interview?.ti.
29	((qualitative or semi-structured or semistructured or unstructured or informal or in-depth or indepth or "face-to-face" or structured or guide*) adj3 (interview* or discussion* or questionnaire*)).ti,ab.
30	(qualitative or focus group? or story or stories or narration or narrative* or discourse or discursive or grounded theory or ethnogra* or phenomenolog* or fieldwork or field work or key informant*).ti,ab.
31	25 or 26 or 27 or 28 or 29 or 30
32	15 and 31
33	limit 32 to english language

Appendix 2.4 Comprehensiveness of reporting assessment (Consolidated criteria for reporting qualitative studies checklist) COREQ checklist

No.	Item	In article?
Domain 1: research team and reflexivity		
Personal characteristics	1. Interviewer/facilitator	
	2. Credentials	
	3. Occupation	
	4. Gender	
	5. Experience and training	
Relationship with participants	6. Relationship established	
	7. Participant knowledge of the interviewer	
	8. Interviewer characteristics	
Domain 2: study design		
Theoretical framework	9. Methodological orientation and theory	
Participant selection	10. Sampling	
	11. Method of approach	
	12. Sample size	
	13. Non-participation	
Setting	14. Setting of data collection	
	15. Presence of non-participants	
	16. Description of sample	
Data collection	17. Interview guide	
	18. Repeat interviews	
	19. Audio/visual recording	
	20. Field notes	
	21. Duration	
	22. Data saturation	
	23. Transcripts returned	
Domain 3: analysis and findings		
Data analysis	24. Number of data coders	
	25. Description of the coding tree	
	26. Derivation of themes	
	27. Software	
	28. Participant checking	
Reporting	29. Quotations presented	
	30. Data and findings consistent	
	31. Clarity of major themes	
	32. Clarity of minor themes	

Appendix 2.5 – Data extraction form

Study ID:	
Method:	
Methodology:	
Data analysis:	
Setting and context:	
Participants (number/description):	
Interventions/phenomena of interest:	
Findings	**Narrative description**
Authors' conclusions:	
Comments:	
Reference list checked?:	

Appendix 3.1 – Questionnaire

CEB01205587 BLOOD PRESSURE MONITORING QUESTIONNAIRE

Doctors.net.uk invites you to participate in a survey commissioned by Oxford University concerning blood pressure. The survey will take about 10 minutes to complete. Members completing the survey will receive 400 eSR points and will be entered into a prize draw with a 1 in 50 chance of winning 6,000 eSR points

Please read the following text, which explains the intent of this research:

- This research is sponsored by Oxford University and is being carried out within the code of conduct of the Market Research Society and the British Healthcare Business Intelligence Association.
- The research is not intended to be promotional and any information presented is done so solely to explore reactions to such information.
- Any information shown during the course of this research should be assumed to represent hypotheses about what can be said about patient management and should not be used to influence decisions outside the research setting.
- The identity of respondents is confidential: no details of respondents are passed to any third party.
- Results are aggregated to provide an overall picture of attitudes to the areas being discussed.
- Respondents have the right to withdraw from the interview at any time during the interview process and to withhold information as they see fit.
- The aggregated findings of this research will be used for market research purposes only.
- For further details of ethics clearance at the University of Oxford, please mouse over here

For additional information or help with any problems, please contact this email address SurveyHelp@mess.doctors.org.uk (Subject line 01205874)

All results will be anonymised in accordance with Doctors.net.uk's zero-tolerance **privacy policy** (*http://about.doctors.net.uk/Assets/Privacy-Policy*) and the Market Research Society Code of Practice.

The prize draw details are as follows:

- The prize draw is open for entries (via this survey) until 21st October 2014
- Respondents will be notified via email if they have won one of the prizes within 14 days of the survey closing
- Respondents can request to be emailed to be told of who won the prizes (if they themselves do not win them) – to do this, please send the email request to the Doctors.net.uk helpdesk at: help@doctors.org.uk

Please confirm that you have read and understood this information, and you agree to proceed with this survey.

Yes

No (CLOSE)

MOUSE OVER TEXT

Researchers: Ben Fletcher (Doctoral student, Principal Investigator), Lisa Hinton (Research Fellow), Richard McManus (Professor of Primary Care)

Nuffield Department of Primary Care Health Sciences, University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, OX2 6GG

What will happen if you take part?.

Your answers are important to us, and may help improve information offered to GPs and the public in relation to monitoring blood pressure in hypertension.

All responses will be treated in complete confidence and your answers will only be seen by the research team. Your personal details will be kept confidential and will never be published. The research has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee.

The University of Oxford is committed to the dissemination of its research for the benefit of society and the economy and, in support of this commitment, has established an online archive of research materials. This archive includes digital copies of student theses successfully submitted as part of a University of Oxford postgraduate degree programme. Holding the archive online gives easy access for researchers to the full text of freely available theses, thereby increasing the likely impact and use of that research.

If you agree to participate in this project, the research will be written up as a thesis. On successful submission of the thesis, it will be deposited both in print and online in the University archives, to facilitate its use in future research. The thesis will be published with open access.

No risks are anticipated from taking part in the study. If you feel uncomfortable with a question, you can skip that question or withdraw from the study altogether. If you decide to quit before you complete the survey, your answers will not be recorded.

By beginning the survey, you acknowledge that you have read this information and agree to participate in this research. You are free to choose to participate, and to withdraw your participation at any time, for any reason, without penalty.

What if there is a problem?

If you have a concern about any aspect of this project, please speak to the relevant researcher (Ben Fletcher, tel. no. 01865 289300), who will do his best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how he intends to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the chair of the Research Ethics Committee at the University of Oxford (Chair, Medical Sciences Inter-Divisional Research Ethics Committee; Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD). The chair will seek to resolve the matter in a reasonably expeditious manner.

Info 2 - Preamble and Definitions:

This is a questionnaire survey about blood pressure monitoring in primary care in the UK.

You have been asked to part as you are a UK general practitioner who has been involved with managing hypertensive patients.

There are a number of similar and sometimes interchangeable terms relating to the measurement of patients' blood pressure. For the purposes of this study:

*Clinic blood pressure monitoring***:** this is standard blood pressure monitoring as performed by a GP / other physician / nurse / allied health professional.

*Ambulatory blood pressure monitoring***,** relates to the measurement of blood pressure as the patient is moving around, living their normal daily life. It is usually carried out over 24 hours with readings taken every 20-30 minutes or so (less frequently at night) using a digital BP monitor that is attached by a belt or carrying strap to the patient's body.

Self-measurement of blood pressure (or home blood pressure monitoring), relates to patients using other forms of blood pressure monitor, as directed by their clinician, or to their own schedule, away from the clinic environment.

S1 Speciality confirmation
Are you a...
Single question, drop down list

GP
Hospital Doctor THANK AND CLOSE

S3 Region (radar buttons only on double indented codes for England; overcode to single indents)
Whereabouts are you currently practicing?

NHS London
    London
NHS South of England
    South East Coastal
    South Central
    South West
NHS Midlands and East SHA
    West Midlands
    East Midlands
    East of England
NHS North of England
    Yorkshire & Humber
    North East
    North West
Scotland
Wales
Northern Ireland
Retired *THANK AND CLOSE*
Not practicing in the UK *THANK AND CLOSE*
Single response

S2 GP type
Which of the following best describes your role?
Single question, drop down list

GP Principal
Salaried GP
GP Registrar
Locum GP
Academic GP
Other THANK AND CLOSE

[DISPLAY TO ALL]
We would firstly like to ask you about what services you currently offer with regard to diagnosing and monitoring hypertension

[ASK ALL]
B1 Management of hypertension
Are you involved in the management of hypertension for your patients?
Single question

Yes (1)
No [IF NO SKIP TO G1]

[ASK IF B1=1]
B2 Self measurement

Do any patients in your clinical practice self-measure their own BP with your encouragement? Single question

Yes (1)
No (2) SKIP TO E1]

[ASK IF B2=1]
B3 Proportion self measuring
Approximately what proportion of hypertensives do you encourage to self-measure? Single question

_____ Numeric 0dp; range 0-100%

[ASK IF B2=1]
B4 Services available for hypertension
Which of the following services are available in your area to support measurement of blood pressure for diagnosis of hypertension and/or monitoring of blood pressure control? *Please select all that apply*
Multiple question except 'none'; randomise except 'other' and 'none'

Clinic blood pressure measurement by GP
Clinic blood pressure measurement by nurse/allied healthcare professional
Ambulatory Blood Pressure Monitors for 24 hour measurement
Blood pressure monitors to lend to patients
Patient training for self-monitoring
BP monitor in waiting room
BP monitors available for use in local pharmacies
BP taken by pharmacy staff
GP training
Other (please specify)
None of the above

[ASK IF B2=1]
B5 Self monitoring vs. ambulatory
Do you see self-monitoring of blood pressure as an alternative to 24-hour ambulatory monitoring or as complementary?
Single question

Alternative
Complementary
Other (please specify)

[ASK IF B2=1]
B6 Self-monitoring of blood pressure
For which of the following reasons, if any, do you use **self-monitoring of blood pressure?** *Please select all that apply*
Multiple question except 'none';

For diagnosis of hypertension (1)
To exclude or confirm white coat hypertension (2)

To monitor control in treated patients (3)
As an aid to medication adherence (4)

Other (please specify)
None of the above

[ASK IF B2=1]
B7 Also, do you use **self-monitoring of blood pressure** for either of the following? (The previous question repeats a survey we carried out in 2011, and in addition we have added two further options this time)
Multiple question except 'neither'

To exclude or confirm masked hypertension (1)
As an aid to lifestyle change adherence (diet/exercise) (2)
Neither

[ASK IF B6=1,2 OR B7=1]
C11 Frequency of measurement
For diagnosis, what self-monitoring protocol do you use (i.e. how often do you ask people to self measure)?
Numeric; range 0-99

How many times a day?	
How many days at a time?	

[ASK IF B6=1,2 OR B7=1]
C12 Threshold for hypertension
What would be your threshold *target* for defining hypertension with self-measurement of BP?
Numeric; range 0-200

Systolic (mmHg)	
Diastolic (mmHg)	

[ASK IF B6=1,2 OR B7=1]
C13 Groups that would benefit
Are there any groups of patients where you would have a different diagnostic threshold?
Single question

Yes (1)
No

[ASK IF C13=1]
C13a Details of groups that would benefit
Please list the thresholds for the group or groups where you have a different diagnostic threshold
First row should be mandatory; second and third optional

Group	**Threshold Systolic (mmHg)**	**Diastolic (mmHg)**
Free text	Numeric; range 0-200	Numeric; range 0-200
Free text	Numeric; range 0-200	Numeric; range 0-200
Free text	Numeric; range 0-200	Numeric; range 0-200

[ASK IF [B6=3,4 OR B7=2] AND [B6 NOT 1,2 AND B7 NOT 1]]
C21 Treatment target for hypertension
What is your treatment target for self-measurement of BP?
Numeric; range 0-200

Systolic (mmHg)	
Diastolic (mmHg)	

[ASK IF [B6=3,4 OR B7=2] AND [B6 NOT 1,2 AND B7 NOT 1]] **C22 Frequency of measurement**
What is your protocol for monitoring control in treated patients?
Numeric; range 0-99

How many times a day?	
How many days at a time?	

[ASK IF [B6=3,4 OR B7=2] AND [B6 NOT 1,2 AND B7 NOT 1]] **C23 Suggested set of measurements**
For monitoring control in treated patients, how often so you typically suggest a set of measurements?
Single question

Monthly
3 monthly
6 monthly
Yearly
Other
Don't suggest a set of measurements

[ASK IF [B6=1,2 OR B7=1] AND [B6=3,4 OR B7=2]]
C34 Treatment target for hypertension
What is your treatment target for self-measurement of BP?
Single code; if "different" selected must also complete the grid

Same as diagnostic threshold
Different to diagnostic threshold

Systolic (mmHg)	Numeric; range 0-200
Diastolic (mmHg)	Numeric; range 0-200

[ASK IF [B6=1,2 OR B7=1] AND [B6=3,4 OR B7=2]]
C35 Frequency of measurement
What is your monitoring protocol?
Single code; if "different" selected must also complete the grid

Same as diagnostic protocol
Different to diagnostic protocol

How many times a day?	Numeric; range 0-99
How many days at a time?	Numeric; range 0-99

[ASK IF [B6=1,2 OR B7=1] AND [B6=3,4 OR B7=2]]

C36 Suggested set of measurements

For monitoring, how often so you typically suggest a set of measurements?

Single question

Monthly
3 monthly
6 monthly
Yearly
Other
Don't suggest a set of measurements

[ASK IF B6=1-4 OR B7=1,2]

C40 Groups that would benefit

Are there any groups of patients that you believe **would especially benefit** from self-monitoring of blood pressure?

Single question

Yes (please specify)
No

[ASK IF B6=1-4 OR B7=1,2]

C50 Groups that would not benefit

Are there any groups of patients that you believe **would not benefit** from self-monitoring of blood pressure?

Single question

Yes (please specify)
No

[ASK IF B6=1-4 OR B7=1,2]

C60 Use measurements

In interpreting blood pressure levels obtained by self-measurement, do you use the self-measurements directly in making clinical decisions or do you adjust for home versus clinic BP differences?

Single question; if "adjust" selected must also complete the grid

Use the measurements directly
Adjust for home versus clinic BP differences
Any further comment (specify)

Please specify the adjustment from home to clinic reading

Systolic (mmHg)	Numeric; range 0-200
Diastolic (mmHg)	Numeric; range 0-200

[ASK IF B6=1-4 OR B7=1,2]

C70 Number of readings

How many clinic readings do you routinely make in confirming a diagnosis of hypertension in the clinic?

Must complete the grid OR say "I don't use"

Number of occasions	Numeric; range 1-10
Readings per occasion	Numeric; range 1-10

I don't use clinic readings to confirm a diagnosis of hypertension

[ASK IF B6=1-4 OR B7=1,2]

D1 Type of monitor

Do you recommend a particular type of monitor?

Single question

Upper arm monitor
Wrist monitor
Other monitor *(please specify)*
Don't recommend a particular monitor

[ASK IF B6=1-4 OR B7=1,2]

D2 Monitors not recommended

Are there any types of monitors that you specifically warn against?

Single question

Yes (please specify)
No

[ASK IF B6=1-4 OR B7=1,2]

D3 Accuracy of monitor

Do you recommend that the accuracy of the patient's machine be checked?

Single question

Yes (1)
No

[ASK IF D3=1]

D3a Frequency of checking for accuracy

How often do you suggest the patient's machine should be checked for accuracy?

Single question

Weekly
Monthly
3 monthly
6 monthly
Yearly
Other (please specify)

[ASK IF D3=1]

D3b Person checking the machine for accuracy

Who do you recommend checks the patient's machine for accuracy?

Single question

The patient themselves
A member of the patient's family
A GP
A practice nurse
Other (please specify)

[ASK IF B6=1-4 OR B7=1,2]

D4 Advise on how to use the monitor

What advice do you give patients about how and when to monitor?

open text

[ASK IF B6=1-4 OR B7=1,2]

D6 Advise on abnormal readings

Do you advise patients what to do if their home readings are abnormal (i.e. fluctuating; very low/high BP)?

Single question

Yes (please specify)
No

[ASK IF B6=1-4 OR B7=1,2]

D7 method of collecting readings

How do you ask patients to record and communicate their BP measurements? (*please select all that apply)*

Multiple question (except don't ask)

- Written diary
- Computer (i.e. spreadsheet)
- Utilise built-in device memory if available
- Bring results to consultation
- Phone in measurements
- Text measurements
- Email measurements
- Other (please specify)
- Don't ask for measurements to be communicated

[ASK IF B6=1-4 OR B7=1,2]

D8 How interpret results

How do you interpret the results of home monitoring? For example how many readings do you use, and which readings do you use?

Open end

[ASK IF B1=1 AND [[B6 NOT 1-4 AND B7 NOT 1-2] OR B2=2]]

E1 Barriers to introducing home blood pressure measurement

You have stated that you do not currently use self-blood pressure measurement to aid in the diagnosis of hypertension, or in monitoring blood pressure control in hypertensive patients.

What are the barriers to introducing home blood pressure measurement into everyday practice, in your opinion?

Open end

[DISPLAY IF B1=1]
We would now like to ask a couple of questions about the training you receive and what influences your current practice.

[ASK IF B1=1]
F1 Specific training in home monitoring
Have you received any specific training in the use of home/self-blood pressure monitors?

Yes (please specify)
No

[ASK IF B1=1]
F2 Influences on current practice with regards to hypertension
What influences your current practice with regard to diagnosing and monitoring hypertension (i.e. what would likely lead to change in your practice)? *Please select your 1st, 2nd and 3rd most important influences*
Drag and drop ranking -1st, 2nd , 3rd choices; must select on drag and drop OR "Nothing influences"

Practice policy
Local guidance
GP Colleagues
Cardiologists or other specialists
Primary research (i.e. results of individual randomised controlled trial)
Secondary research (i.e. results of systematic reviews/meta-analyses)
National guidance (i.e. NICE/ National Heart Foundation guidelines)
International Guidance (European Society of Hypertension, JNC8)
Patient request
Other (specify)

Nothing influences my current practice

[DISPLAY TO ALL]
Finally we would like to ask you a few demographic questions to aid in our analysis.

[ASK ALL]
G1 Gender
Are you...
Single question, drop down list

Male

Female

[ASK ALL]
G2 Year of qualification
When did you qualify as a doctor?

Single question. Show drop down list for all dates between 1950 to 2010

[ASK ALL]
G3 Age

What age are you?

Single question, drop down list

Under 30
30 – 39
40 – 49
50 – 59
60 or over

[ASK ALL]
G4 Country trained in

In which country did you train as a doctor?

Single code

UK
Other (please specify)

[ASK ALL]
G5 Year of qualification
How many years have you been practicing as a GP?

Numeric; range 1-50

If S2 equals 'Locum GP' Add text

"Thinking about the practice where you spend most of your time …"

[ASK ALL]

G7 Number of patients on practice list
What is the practice list size?

Please write in the number of patients

_____

Range of 1 to 99999

[ASK ALL]
G8 Practice Location
Is your practice based in a...

Single question, drop down list

Rural area

Urban area

Semi-rural area

Suburban area

Other

If D2 equals 'Other' show a single line text box

[ASK ALL]

G9 Clinical trials

In the past 5 years have you or your practice been involved in clinical trials involving:

	Yes	No	Don't know
Anti-hypertensive treatment			
24 hour ambulatory monitoring			
Home monitoring of blood pressure			

Thank you, you have now reached the end of the study. We would like to ask if we may recontact you if clarification of your answers is required and if you have any comments about the topics covered or the study itself.

Show H1 and H2 on the same page

[ASK ALL]

H1 Recontact

May we recontact you for clarification on any of your answers or for data quality purposes?

Please select one option

Yes

No

Single

[ASK ALL]

H2 Final feedback question

Is there any further feedback that you would like to give about the topic of the survey, or about the survey itself?

Open text – not coded. Blank answers allowed

Single

Appendix 3.2 – Comparison of samples in 2011, 2014 and 2015 surveys

Characteristic	Detail	2015 survey	2014 survey		Comparison between Direct v Passive	Comparison between 2014 v 2015 - passive only
		Passive recruitment	Direct recruitment	Passive recruitment		
Participants		300	237	559		
No. years practising	0-10	147 (49%)	110 (46%)	261 (47%)	*p=0.86	*p=0.83
	11-20	85 (28%)	67 (28%)	161 (29%)		
	21-30	52 (17%)	45 (19%)	110 (20%)		
	31+	16 (5%)	15 (6%)	27 (5%)		
Age	<30	1 (0%)	3 (1%)	4 (1%)	^p=0.84	^p=0.48
	30-39	114 (38%)	90 (38%)	204 (36%)		
	40-49	99 (33%)	70 (30%)	162 (29%)		
	50-59	65 (22%)	56 (24%)	148 (26%)		
	>60	21 (7%)	18 (8%)	41 (7%)		
Practice role	GP principal/partner	200 (67%)	146 (62%)	353 (63%)	**^p=0.02**	^p=0.21
	Salaried GP/ locum	71 (24%)	71 (30%)	125 (22%)		
	GP registrar	28 (9%)	20 (8%)	80 (14%)		
	Other (GP retainers)	1 (0%)	0 (0%)	1 (0%)		
Sex	Male	181 (60%)	131 (55%)	303 (54%)	$p=0.80	$p=0.09
	Female	119 (40%)	106 (45%)	256 (46%)		
Region	East Midlands	20 (7%)	12 (5.1%)	39 (7.0%)	*p=0.07	*p=0.11
	East of England	26 (9%)	21 (8.9%)	70 (12.5%)		
	London	36 (12%)	29 (12.2%)	47 (8.4%)		
	North East	13 (4%)	8 (3.4%)	33 (5.9%)		
	North West	35 (12%)	30 (12.7%)	40 (7.2%)		
	South Central	20 (7%)	15 (6.3%)	44 (7.9%)		
	South East Coast	19 (6%)	16 (6.8%)	29 (5.2%)		
	South West	29 (10%)	25 (10.6%)	46 (8.2%)		
	West Midlands	26 (9%)	20 (8.4%)	61 (10.9%)		
	Yorkshire and Humber	25 (8%)	22 (9.3%)	59 (10.6%)		
	Northern Ireland	8 (3%)	6 (2.5%)	10 (1.8%)		
	Scotland	29 (10%)	22 (9.3%)	40 (7.2%)		
	Wales	14 (5%)	11 (4.6%)	41 (7.3%)		
Country of training	UK	259 (86%)	205 (86%)	475 (85%)	^p=0.43	**P=0.003**
	Asia	11 (4%)	16 (7%)	49 (9%)		
	Europe	23 (8%)	11 (5%)	19 (3%)		
	Africa	5 (2%)	5 (2%)	13 (2%)		
	Other	2 (1%)	0 (0%)	6 (1%)		
Practice list size	Median	8500	8000	8000		
	Mean (sd)	8590 (4100)	8963 (6119)	8785 (4612)	&p=0.89	&p=0.54
Practice setting	Rural	31 (10%)	25 (11%)	50 (9%)	^p=0.08	^p=0.38
	Urban	128 (43%)	108 (46%)	217 (39%)		
	Semi-rural	63 (21%)	43 (18%)	147 (26%)		
	Suburban	78 (26%)	59 (25%)	143 (26%)		
	Other	0 (0%)	2 (0%)	2 (0%)		
Involved in research in past 5 years	Antihypertensive treatment	17 (6%)	12 (5%)	25 (4%)	$p=0.52	$p=0.19
	24 hour ambulatory monitoring	9 (3%)	5 (2%)	20 (4%)	$p=0.15	$p=0.46
	Home monitoring of blood pressure	11 (4%)	4 (2%)	21 (4%)	$p=0.15	$p=0.99
Involved in hypertension management		299 (100%)	237 (100%)	556 (99.5%)	$p=0.28	$p=0.22
Have patients who self-monitor		291/299 (97%)	229/237 (97%)	542/556 (98%)	$p=0.39	$p=0.36

Chi2 *; Fisher's exact ^; z test $; Ranksum &; t test @

Appendix 4.1 – Interview topic guide

[First ask some background questions]:

Background

So I want to start of asking you to tell me a little bit about yourself. How old are you, who lives with you, are you working or retired?

How well are you? Or, how would you describe your general health? What are your main health concerns? Do you have any health concerns?

How often do you go and see your GP?

How long have you been a patient at your current practice?

Diagnosis

Could you tell me about the time that you first found out you had high blood pressure (who, when, where, how?).

Who else did you talk to about your diagnosis (if so ask for more information)? Who did you talk to at the time about your diagnosis.

How has having a diagnosis of hypertension affected your everyday life?

Understanding

What do you understand by the phrase ”normal blood pressure”? What does normal BP mean for you?

What do you understand when people talk about “high blood pressure”? (numbers, risks)

Can you tell when your BP is high, how do you feel?

What do you understand about the potential risks of high blood pressure?

Management

Monitoring

Are you concerned about managing your blood pressure?

How important is managing your BP alongside your other health conditions (co-morbidities)?

Can you tell me about the things you do to manage your blood pressure?

What medications or treatments are you taking?

Are you making any adjustments or changes to your lifestyle?

You have said that you have experience of measuring your own blood pressure – can you tell me about a little about when you decided to start and why.

Where did you seek information about how to self-monitor? (Why?)

Do you have your own monitor? If so, how did you choose it? Choose to make the investment?

Can you tell me about how you measure your blood pressure currently – when, where, how does it fit into your daily life.

How easy is it to fit into daily life?

Could you tell me/show me where your monitor is? (what room, what is next to the monitor)

How do you interpret the results of self-monitoring? What do the numbers mean to you?

Do you have a point at which you would act on the results of self-monitoring, for example too high, or too low? And if so what action would you take?

What do you do with the results of monitoring? (Action, recording, communication)

Is it problematic in any way? (does it cause you any anxiety or worry? Do you find it reassuring?)

Action/communication

Who do you talk to at the practice about your blood pressure (is it the GP or nurse as well)?

Have you discussed self-monitoring with your GP/nurse (if so how did this go)?

How well do you think your self-measured BP is used to guide your treatment? Are there any improvements that can be made?

Do you talk to anyone other than your GP/nurse (family/friends) about self-measurement?

Do you have any concerns about self-monitoring?

Would you recommend self-monitoring to others?

Closing statement

Is there anything that I haven't covered in this interview that you would like to take the chance to tell me?

If you have any further questions please contact me – my details are on the patient information sheet.

I would like to thank you for taking part in the research.

Appendix 4.2 Standards for reporting qualitative research (SRQR) checklist

	Item	In report? (Y/N/unclear)
1.	Title	
2.	Abstract	
3.	Problem formulation	
4.	Purpose or research question	
5.	Qualitative approach and research design	
6.	Researcher characteristics, reflexivity	
7.	Context	
8.	Sampling strategy	
9.	Ethical issues pertaining to human subjects	
10.	Data collection methods	
11.	Data collection instruments/technologies	
12.	Units of study	
13.	Data processing	
14.	Data analysis	
15.	Techniques to enhance trustworthiness	
16.	Synthesis and interpretation	
17.	Links to empirical data	
18.	Integration with prior work, implications, transferability and contributions	
19.	Limitations	
20.	Conflicts	
21.	Funding	

Appendix 5.1 Orthogonal main effects plan and shifted design

Attribute 1: model of care (0=GP, 1=Pharmacy, 2=Teleheatlh, 3=Self-management)

Attribute 2: Frequency of BP measurement (0=Monthly, 1=Three monthly, 2=Six monthly, 3= Yearly)

Attribute 3: 5 year cardiovascular risk reduction: (0=5%, 1=10%, 2=15%, 3=25%)

Attribute 4: Cost (0=£50, 1=£100, 2=£250, 3=£500)

4x4x4x4 orthogonal array [A] (OMEP from Hahn and Shapiro catalogue) with second choice set created by using 1313 shifting [B]

	A					B			
	Attribute 1	Attribute 2	Attribute 3	Attribute 4		Attribute 1	Attribute 2	Attribute 3	Attribute 4
1	0	0	0	0		1	3	1	3
2	0	1	1	2		1	0	2	1
3	0	2	2	3		1	1	3	2
4	0	3	3	1		1	2	0	0
5	1	0	1	1		2	3	2	0
6	1	1	0	3		2	0	1	2
7	1	2	3	2		2	1	0	1
8	1	3	2	0		2	2	3	3
9	2	0	2	2		3	3	3	1
10	2	1	3	0		3	0	0	3
11	2	2	0	1		3	1	1	0
12	2	3	1	3		3	2	2	2
13	3	0	3	3		0	3	0	2
14	3	1	2	1		0	0	3	0
15	3	2	1	0		0	1	2	3
16	3	3	0	2		0	2	1	1

Appendix 5.2 Choice set following randomisation

Position of choice within set (A v B) and position of choice (1-16) following randomisation.

	A					B			
	Attribute 1	Attribute 2	Attribute 3	Attribute 4		Attribute 1	Attribute 2	Attribute 3	Attribute 4
1	3	0	3	3		0	3	0	2
2	1	0	2	1		0	1	1	2
3	3	3	3	1		2	0	2	2
4	0	1	2	3		3	2	1	0
5	2	1	0	1		1	2	3	2
6	1	1	0	3		2	0	1	2
7	1	1	3	2		0	2	2	3
8	3	1	1	0		2	2	0	1
9	3	0	0	3		2	1	3	0
10	1	2	0	0		0	3	3	1
11	2	3	1	3		3	2	2	2
12	3	1	2	1		0	0	3	0
13	1	3	1	3		0	0	0	0
14	1	3	2	0		2	2	3	3
15	0	2	1	1		3	3	0	2
16	2	3	2	0		1	0	1	1

Appendix 5.3 Simulation

100 participants (50/50 in each question)

```
. clogit final Pharmacist Telehealth Self threeMonthly sixMonthly Yearly tenrisk fifteenrisk twentyrisk cost, group(ques
> tion)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood = -2172.0518
Iteration 1:   log likelihood = -2172.0518

Conditional (fixed-effects) logistic regression   Number of obs   =       3200
                                                  LR chi2(10)     =       0.00
                                                  Prob > chi2     =     1.0000
Log likelihood = -2172.0518                       Pseudo R2       =     0.0000
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Pharmacist	-1.95e-17	.1221679	-0.00	1.000	-.2394447	.2394447
Telehealth	-2.93e-17	.1410674	-0.00	1.000	-.2764869	.2764869
Self	-2.12e-17	.1221679	-0.00	1.000	-.2394447	.2394447
threeMonthly	-1.61e-18	.1221679	-0.00	1.000	-.2394447	.2394447
sixMonthly	-5.67e-18	.1410674	-0.00	1.000	-.2764869	.2764869
Yearly	9.57e-18	.1221679	0.00	1.000	-.2394447	.2394447
tenrisk	-1.19e-17	.1221679	-0.00	1.000	-.2394447	.2394447
fifteenrisk	-3.83e-18	.1410674	-0.00	1.000	-.2764869	.2764869
twentyrisk	-1.29e-17	.1221679	-0.00	1.000	-.2394447	.2394447
cost	1.01e-21	.000262	0.00	1.000	-.0005134	.0005134

```
. xi: clogit final i.model i.freq i.risk cost, group(question)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood = -2172.0518
Iteration 1:   log likelihood = -2172.0518

Conditional (fixed-effects) logistic regression   Number of obs   =       3200
                                                  LR chi2(10)     =       0.00
                                                  Prob > chi2     =     1.0000
Log likelihood = -2172.0518                       Pseudo R2       =     0.0000
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Imodel_1	-1.07e-18	.1221679	-0.00	1.000	-.2394447	.2394447
_Imodel_2	1.35e-17	.1410674	0.00	1.000	-.2764869	.2764869
_Imodel_3	1.39e-17	.1221679	0.00	1.000	-.2394447	.2394447
_Ifreq_1	-8.12e-18	.1221679	-0.00	1.000	-.2394447	.2394447
_Ifreq_2	-3.06e-18	.1410674	-0.00	1.000	-.2764869	.2764869
_Ifreq_3	1.07e-18	.1221679	0.00	1.000	-.2394447	.2394447
_Irisk_1	1.99e-18	.1221679	0.00	1.000	-.2394447	.2394447
_Irisk_2	-5.21e-18	.1410674	-0.00	1.000	-.2764869	.2764869
_Irisk_3	1.30e-17	.1221679	0.00	1.000	-.2394447	.2394447
cost	-2.66e-20	.000262	-0.00	1.000	-.0005134	.0005134

100 participants (95% 1 in GP comparisons)

```
. clogit final Pharmacist Telehealth Self threeMonthly sixMonthly Yearly tenrisk fifteenrisk twentyrisk cost, group(ques
> tion)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood =  -1481.163
Iteration 1:   log likelihood = -1390.3083
Iteration 2:   log likelihood = -1387.2956
Iteration 3:   log likelihood =  -1387.285
Iteration 4:   log likelihood =  -1387.285

Conditional (fixed-effects) logistic regression   Number of obs   =       3200
                                                  LR chi2(10)     =    1569.53
                                                  Prob > chi2     =     0.0000
Log likelihood =  -1387.285                       Pseudo R2       =     0.3613
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Pharmacist	-5.794057	.241701	-23.97	0.000	-6.267783	-5.320332
Telehealth	-5.794057	.2450869	-23.64	0.000	-6.274419	-5.313696
Self	-5.794057	.241701	-23.97	0.000	-6.267783	-5.320332
threeMonthly	2.50e-16	.1796133	0.00	1.000	-.3520356	.3520356
sixMonthly	6.46e-16	.2450869	0.00	1.000	-.4803614	.4803614
Yearly	1.42e-16	.1796133	0.00	1.000	-.3520356	.3520356
tenrisk	3.73e-16	.1818281	0.00	1.000	-.3563765	.3563765
fifteenrisk	1.77e-16	.1974108	0.00	1.000	-.386918	.386918
twentyrisk	-2.71e-16	.1818281	-0.00	1.000	-.3563765	.3563765
cost	2.59e-19	.0003784	0.00	1.000	-.0007417	.0007417

```
. xi: clogit final i.model i.freq i.risk cost, group(question)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood =  -1481.163
Iteration 1:   log likelihood = -1390.3083
Iteration 2:   log likelihood = -1387.2956
Iteration 3:   log likelihood =  -1387.285
Iteration 4:   log likelihood =  -1387.285

Conditional (fixed-effects) logistic regression   Number of obs   =       3200
                                                  LR chi2(10)     =    1569.53
                                                  Prob > chi2     =     0.0000
Log likelihood =  -1387.285                       Pseudo R2       =     0.3613
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Imodel_1	-5.794057	.241701	-23.97	0.000	-6.267783	-5.320332
_Imodel_2	-5.794057	.2450869	-23.64	0.000	-6.274419	-5.313696
_Imodel_3	-5.794057	.241701	-23.97	0.000	-6.267783	-5.320332
_Ifreq_1	-1.70e-15	.1796133	-0.00	1.000	-.3520356	.3520356
_Ifreq_2	-2.62e-15	.2450869	-0.00	1.000	-.4803614	.4803614
_Ifreq_3	-1.30e-15	.1796133	-0.00	1.000	-.3520356	.3520356
_Irisk_1	-1.91e-15	.1818281	-0.00	1.000	-.3563765	.3563765
_Irisk_2	-1.50e-15	.1974108	-0.00	1.000	-.386918	.386918
_Irisk_3	7.15e-16	.1818281	0.00	1.000	-.3563765	.3563765
cost	-1.17e-18	.0003784	-0.00	1.000	-.0007417	.0007417

100 participants (random numbers)

```
.
. clogit final Pharmacist Telehealth Self threeMonthly sixMonthly Yearly tenrisk fifteenrisk twentyrisk cost, group(ques
> tion)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood = -2161.8847
Iteration 1:   log likelihood = -2159.1002
Iteration 2:   log likelihood = -2159.1001

Conditional (fixed-effects) logistic regression   Number of obs   =       3200
                                                  LR chi2(10)     =      25.90
                                                  Prob > chi2     =     0.0039
Log likelihood = -2159.1001                       Pseudo R2       =     0.0060

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
  Pharmacist |  -.1304582   .1225848    -1.06   0.287    -.3707199    .1098036
  Telehealth |  -.0408052   .1416401    -0.29   0.773    -.3184148    .2368044
        Self |  -.1511579   .1228385    -1.23   0.218    -.3919169    .0896011
threeMonthly |   .3300311   .1227273     2.69   0.007       .08949    .5705723
  sixMonthly |   .0806655   .1416402     0.57   0.569    -.1969441    .3582752
      Yearly |  -.2498168   .1225815    -2.04   0.042    -.4900721   -.0095614
     tenrisk |   .2709469   .1227877     2.21   0.027     .0302874    .5116063
 fifteenrisk |   .1604343   .1416402     1.13   0.257    -.1171754    .4380439
  twentyrisk |  -.0097663   .1225347    -0.08   0.936    -.2499299    .2303973
        cost |   .0000959   .0002627     0.37   0.715     -.000419    .0006107
------------------------------------------------------------------------------

. xi: clogit final i.model i.freq i.risk cost, group(question)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood = -2161.8847
Iteration 1:   log likelihood = -2159.1002
Iteration 2:   log likelihood = -2159.1001

Conditional (fixed-effects) logistic regression   Number of obs   =       3200
                                                  LR chi2(10)     =      25.90
                                                  Prob > chi2     =     0.0039
Log likelihood = -2159.1001                       Pseudo R2       =     0.0060

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Imodel_1 |  -.1304582   .1225848    -1.06   0.287    -.3707199    .1098036
    _Imodel_2 |  -.0408052   .1416401    -0.29   0.773    -.3184148    .2368044
    _Imodel_3 |  -.1511579   .1228385    -1.23   0.218    -.3919169    .0896011
     _Ifreq_1 |   .3300311   .1227273     2.69   0.007       .08949    .5705723
     _Ifreq_2 |   .0806655   .1416402     0.57   0.569    -.1969441    .3582752
     _Ifreq_3 |  -.2498168   .1225815    -2.04   0.042    -.4900721   -.0095614
     _Irisk_1 |   .2709469   .1227877     2.21   0.027     .0302874    .5116063
     _Irisk_2 |   .1604343   .1416402     1.13   0.257    -.1171754    .4380439
     _Irisk_3 |  -.0097663   .1225347    -0.08   0.936    -.2499299    .2303973
         cost |   .0000959   .0002627     0.37   0.715     -.000419    .0006107
------------------------------------------------------------------------------
```

250 participants (50/50 in each question)

```
.
. clogit final Pharmacist Telehealth Self threeMonthly sixMonthly Yearly tenrisk fifteenrisk twentyrisk cost, group(ques
> tion)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood = -5491.8399
Iteration 1:   log likelihood = -5491.8399

Conditional (fixed-effects) logistic regression   Number of obs   =       8000
                                                  LR chi2(10)     =       0.00
                                                  Prob > chi2     =     1.0000
Log likelihood = -5491.8399                       Pseudo R2       =     0.0000
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Pharmacist	-7.43e-18	.0773822	-0.00	1.000	-.1516663	.1516663
Telehealth	2.91e-19	.0893532	0.00	1.000	-.1751291	.1751291
Self	-7.28e-19	.0773822	-0.00	1.000	-.1516663	.1516663
threeMonthly	-2.09e-18	.0773822	-0.00	1.000	-.1516663	.1516663
sixMonthly	-1.83e-17	.0893532	-0.00	1.000	-.1751291	.1751291
Yearly	-3.74e-18	.0773822	-0.00	1.000	-.1516663	.1516663
tenrisk	3.40e-19	.0773822	0.00	1.000	-.1516663	.1516663
fifteenrisk	-3.79e-18	.0893532	-0.00	1.000	-.1751291	.1751291
twentyrisk	-6.75e-18	.0773822	-0.00	1.000	-.1516663	.1516663
cost	-1.09e-20	.0001659	-0.00	1.000	-.0003252	.0003252

```
. xi: clogit final i.model i.freq i.risk cost, group(question)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood = -5491.8399
Iteration 1:   log likelihood = -5491.8399

Conditional (fixed-effects) logistic regression   Number of obs   =       8000
                                                  LR chi2(10)     =       0.00
                                                  Prob > chi2     =     1.0000
Log likelihood = -5491.8399                       Pseudo R2       =     0.0000
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Imodel_1	6.16e-18	.0773822	0.00	1.000	-.1516663	.1516663
_Imodel_2	-1.08e-17	.0893532	-0.00	1.000	-.1751291	.1751291
_Imodel_3	5.29e-18	.0773822	0.00	1.000	-.1516663	.1516663
_Ifreq_1	1.21e-18	.0773822	0.00	1.000	-.1516663	.1516663
_Ifreq_2	2.04e-18	.0893532	0.00	1.000	-.1751291	.1751291
_Ifreq_3	2.28e-18	.0773822	0.00	1.000	-.1516663	.1516663
_Irisk_1	-6.31e-19	.0773822	-0.00	1.000	-.1516663	.1516663
_Irisk_2	-2.82e-18	.0893532	-0.00	1.000	-.1751291	.1751291
_Irisk_3	-2.13e-17	.0773822	-0.00	1.000	-.1516663	.1516663
cost	1.96e-20	.0001659	0.00	1.000	-.0003252	.0003252

250 participants (95% 1 in GP comparisons)

```
Conditional (fixed-effects) logistic regression   Number of obs   =       8000
                                                  LR chi2(10)     =    3990.91
                                                  Prob > chi2     =     0.0000
Log likelihood = -3496.3841                       Pseudo R2       =     0.3633
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Pharmacist	-5.935157	.1575247	-37.68	0.000	-6.243899	-5.626414
Telehealth	-5.935157	.1595006	-37.21	0.000	-6.247772	-5.622541
Self	-5.935157	.1575247	-37.68	0.000	-6.243899	-5.626414
threeMonthly	-7.39e-16	.1156215	-0.00	1.000	-.226614	.226614
sixMonthly	-3.62e-16	.1595006	-0.00	1.000	-.3126154	.3126154
Yearly	3.24e-16	.1156215	0.00	1.000	-.226614	.226614
tenrisk	9.47e-17	.1171095	0.00	1.000	-.2295304	.2295304
fifteenrisk	3.13e-16	.126316	0.00	1.000	-.2475748	.2475748
twentyrisk	4.43e-16	.1171095	0.00	1.000	-.2295304	.2295304
cost	1.96e-19	.0002426	0.00	1.000	-.0004754	.0004754

```
. xi: clogit final i.model i.freq i.risk cost, group(question)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood = -3737.6724
Iteration 1:   log likelihood = -3504.7835
Iteration 2:   log likelihood = -3496.4242
Iteration 3:   log likelihood = -3496.3841
Iteration 4:   log likelihood = -3496.3841

Conditional (fixed-effects) logistic regression   Number of obs   =       8000
                                                  LR chi2(10)     =    3990.91
                                                  Prob > chi2     =     0.0000
Log likelihood = -3496.3841                       Pseudo R2       =     0.3633
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Imodel_1	-5.935157	.1575247	-37.68	0.000	-6.243899	-5.626414
_Imodel_2	-5.935157	.1595006	-37.21	0.000	-6.247772	-5.622541
_Imodel_3	-5.935157	.1575247	-37.68	0.000	-6.243899	-5.626414
_Ifreq_1	-2.08e-15	.1156215	-0.00	1.000	-.226614	.226614
_Ifreq_2	-3.74e-15	.1595006	-0.00	1.000	-.3126154	.3126154
_Ifreq_3	-1.88e-15	.1156215	-0.00	1.000	-.226614	.226614
_Irisk_1	-2.22e-15	.1171095	-0.00	1.000	-.2295304	.2295304
_Irisk_2	6.30e-16	.126316	0.00	1.000	-.2475748	.2475748
_Irisk_3	1.55e-15	.1171095	0.00	1.000	-.2295304	.2295304
cost	3.89e-18	.0002426	0.00	1.000	-.0004754	.0004754

250 participants (random numbers)

```
.
. clogit final Pharmacist Telehealth Self threeMonthly sixMonthly Yearly tenrisk fifteenrisk twentyrisk cost, group(ques
> tion)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood = -5484.1105
Iteration 1:   log likelihood = -5483.0789
Iteration 2:   log likelihood = -5483.0789

Conditional (fixed-effects) logistic regression   Number of obs   =       8000
                                                  LR chi2(10)     =      17.52
                                                  Prob > chi2     =     0.0636
Log likelihood = -5483.0789                       Pseudo R2       =     0.0016

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
  Pharmacist |   .1618338   .0774684     2.09   0.037     .0099985    .3136691
  Telehealth |  -.0120075   .0894511    -0.13   0.893    -.1873284    .1633134
        Self |   .0539046     .07749     0.70   0.487    -.0979731    .2057822
threeMonthly |  -.0499854   .0774834    -0.65   0.519    -.2018501    .1018794
  sixMonthly |  -.1958692   .0894511    -2.19   0.029    -.3711901   -.0205483
      Yearly |  -.0619245   .0774437    -0.80   0.424    -.2137113    .0898623
     tenrisk |  -.0460501   .0774792    -0.59   0.552    -.1979065    .1058064
 fifteenrisk |   .0599606    .089451     0.67   0.503    -.1153602    .2352815
  twentyrisk |    .005991    .077443     0.08   0.938    -.1457945    .1577765
        cost |   .0002246   .0001662     1.35   0.177    -.0001011    .0005503
------------------------------------------------------------------------------

. xi: clogit final i.model i.freq i.risk cost, group(question)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood = -5484.1105
Iteration 1:   log likelihood = -5483.0789
Iteration 2:   log likelihood = -5483.0789

Conditional (fixed-effects) logistic regression   Number of obs   =       8000
                                                  LR chi2(10)     =      17.52
                                                  Prob > chi2     =     0.0636
Log likelihood = -5483.0789                       Pseudo R2       =     0.0016

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
   _Imodel_1 |   .1618338   .0774684     2.09   0.037     .0099985    .3136691
   _Imodel_2 |  -.0120075   .0894511    -0.13   0.893    -.1873284    .1633134
   _Imodel_3 |   .0539046     .07749     0.70   0.487    -.0979731    .2057822
    _Ifreq_1 |  -.0499854   .0774834    -0.65   0.519    -.2018501    .1018794
    _Ifreq_2 |  -.1958692   .0894511    -2.19   0.029    -.3711901   -.0205483
    _Ifreq_3 |  -.0619245   .0774437    -0.80   0.424    -.2137113    .0898623
    _Irisk_1 |  -.0460501   .0774792    -0.59   0.552    -.1979065    .1058064
    _Irisk_2 |   .0599606    .089451     0.67   0.503    -.1153602    .2352815
    _Irisk_3 |    .005991    .077443     0.08   0.938    -.1457945    .1577765
        cost |   .0002246   .0001662     1.35   0.177    -.0001011    .0005503
------------------------------------------------------------------------------
```

500 participants (50/50 in each question)

```
.
. clogit final Pharmacist Telehealth Self threeMonthly sixMonthly Yearly tenrisk fifteenrisk twentyrisk cost, group(ques
> tion)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood = -11031.476
Iteration 1:   log likelihood = -11031.476

Conditional (fixed-effects) logistic regression   Number of obs   =      16000
                                                  LR chi2(10)     =       0.00
                                                  Prob > chi2     =     1.0000
Log likelihood = -11031.476                       Pseudo R2       =     0.0000

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
  Pharmacist |   3.85e-18   .0547449     0.00   1.000     -.107298     .107298
  Telehealth |  -1.06e-17   .0632139    -0.00   1.000     -.123897     .123897
        Self |  -3.30e-18   .0547449    -0.00   1.000     -.107298     .107298
threeMonthly |   1.19e-17   .0547449     0.00   1.000     -.107298     .107298
  sixMonthly |   8.66e-18   .0632139     0.00   1.000     -.123897     .123897
      Yearly |   6.60e-18   .0547449     0.00   1.000     -.107298     .107298
     tenrisk |  -1.12e-17   .0547449    -0.00   1.000     -.107298     .107298
 fifteenrisk |  -1.21e-17   .0632139    -0.00   1.000     -.123897     .123897
  twentyrisk |  -4.88e-18   .0547449    -0.00   1.000     -.107298     .107298
        cost |  -5.23e-21   .0001174    -0.00   1.000    -.0002301    .0002301
------------------------------------------------------------------------------

. xi: clogit final i.model i.freq i.risk cost, group(question)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood = -11031.476
Iteration 1:   log likelihood = -11031.476

Conditional (fixed-effects) logistic regression   Number of obs   =      16000
                                                  LR chi2(10)     =       0.00
                                                  Prob > chi2     =     1.0000
Log likelihood = -11031.476                       Pseudo R2       =     0.0000

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
   _Imodel_1 |   3.97e-18   .0547449     0.00   1.000     -.107298     .107298
   _Imodel_2 |   1.65e-17   .0632139     0.00   1.000     -.123897     .123897
   _Imodel_3 |  -1.98e-18   .0547449    -0.00   1.000     -.107298     .107298
    _Ifreq_1 |   1.19e-18   .0547449     0.00   1.000     -.107298     .107298
    _Ifreq_2 |  -2.85e-18   .0632139    -0.00   1.000     -.123897     .123897
    _Ifreq_3 |   1.11e-17   .0547449     0.00   1.000     -.107298     .107298
    _Irisk_1 |  -8.42e-19   .0547449    -0.00   1.000     -.107298     .107298
    _Irisk_2 |   1.73e-17   .0632139     0.00   1.000     -.123897     .123897
    _Irisk_3 |  -3.26e-19   .0547449    -0.00   1.000     -.107298     .107298
        cost |   3.08e-20   .0001174     0.00   1.000    -.0002301    .0002301
------------------------------------------------------------------------------
```

500 participants (95% 1 in GP comparisons)

```
. clogit final Pharmacist Telehealth Self threeMonthly sixMonthly Yearly tenrisk fifteenrisk twentyrisk cost, group(ques
> tion)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood =  -7562.609
Iteration 1:   log likelihood = -7097.4999
Iteration 2:   log likelihood = -7081.1378
Iteration 3:   log likelihood = -7081.0637
Iteration 4:   log likelihood = -7081.0637

Conditional (fixed-effects) logistic regression   Number of obs   =      16000
                                                  LR chi2(10)     =    7900.83
                                                  Prob > chi2     =     0.0000
Log likelihood = -7081.0637                       Pseudo R2       =     0.3581

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
  Pharmacist |   -5.86993   .1100123   -53.36   0.000     -6.08555    -5.65431
  Telehealth |   -5.86993   .1114631   -52.66   0.000    -6.088394   -5.651466
        Self |   -5.86993   .1100123   -53.36   0.000     -6.08555    -5.65431
threeMonthly |   1.65e-16   .0812002     0.00   1.000    -.1591494    .1591494
  sixMonthly |  -1.24e-15   .1114631    -0.00   1.000    -.2184637    .2184637
      Yearly |  -1.49e-15   .0812002    -0.00   1.000    -.1591494    .1591494
     tenrisk |  -1.20e-15   .0822257    -0.00   1.000    -.1611595    .1611595
 fifteenrisk |  -1.98e-15   .0889579    -0.00   1.000    -.1743543    .1743543
  twentyrisk |   1.41e-17   .0822257     0.00   1.000    -.1611595    .1611595
        cost |  -8.72e-19   .0001707    -0.00   1.000    -.0003346    .0003346
------------------------------------------------------------------------------

. xi: clogit final i.model i.freq i.risk cost, group(question)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood =  -7562.609
Iteration 1:   log likelihood = -7097.4999
Iteration 2:   log likelihood = -7081.1378
Iteration 3:   log likelihood = -7081.0637
Iteration 4:   log likelihood = -7081.0637

Conditional (fixed-effects) logistic regression   Number of obs   =      16000
                                                  LR chi2(10)     =    7900.83
                                                  Prob > chi2     =     0.0000
Log likelihood = -7081.0637                       Pseudo R2       =     0.3581

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
   _Imodel_1 |   -5.86993   .1100123   -53.36   0.000     -6.08555    -5.65431
   _Imodel_2 |   -5.86993   .1114631   -52.66   0.000    -6.088394   -5.651466
   _Imodel_3 |   -5.86993   .1100123   -53.36   0.000     -6.08555    -5.65431
    _Ifreq_1 |   4.46e-16   .0812002     0.00   1.000    -.1591494    .1591494
    _Ifreq_2 |   6.29e-16   .1114631     0.00   1.000    -.2184637    .2184637
    _Ifreq_3 |  -2.78e-16   .0812002    -0.00   1.000    -.1591494    .1591494
    _Irisk_1 |  -1.92e-15   .0822257    -0.00   1.000    -.1611595    .1611595
    _Irisk_2 |  -2.99e-15   .0889579    -0.00   1.000    -.1743543    .1743543
    _Irisk_3 |  -2.54e-15   .0822257    -0.00   1.000    -.1611595    .1611595
        cost |  -4.19e-18   .0001707    -0.00   1.000    -.0003346    .0003346
------------------------------------------------------------------------------
```

500 participants (random numbers)

```
. clogit final Pharmacist Telehealth Self threeMonthly sixMonthly Yearly tenrisk fifteenrisk twentyrisk cost, group(ques
> tion)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood =   -11022.9
Iteration 1:   log likelihood = -11020.879
Iteration 2:   log likelihood = -11020.879

Conditional (fixed-effects) logistic regression   Number of obs   =      16000
                                                  LR chi2(10)     =      21.19
                                                  Prob > chi2     =     0.0198
Log likelihood = -11020.879                       Pseudo R2       =     0.0010

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
  Pharmacist |   .0099958   .0547911     0.18   0.855    -.0973929    .1173844
  Telehealth |  -.0080023   .0632558    -0.13   0.899    -.1319814    .1159768
        Self |    .025999   .0547831     0.47   0.635    -.0813739    .1333719
threeMonthly |  -.0219993   .0547775    -0.40   0.688    -.1293613    .0853627
  sixMonthly |  -.0480056   .0632558    -0.76   0.448    -.1719846    .0759735
      Yearly |  -.0059959   .0547852    -0.11   0.913     -.113373    .1013811
     tenrisk |  -.0339528   .0547606    -0.62   0.535    -.1412816     .073376
 fifteenrisk |   .0440007   .0632558     0.70   0.487    -.0799784    .1679797
  twentyrisk |   .2099729    .054808     3.83   0.000     .1025512    .3173946
        cost |  -.0000496   .0001174    -0.42   0.673    -.0002798    .0001805
------------------------------------------------------------------------------

. xi: clogit final i.model i.freq i.risk cost, group(question)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)
note: multiple positive outcomes within groups encountered.

Iteration 0:   log likelihood =   -11022.9
Iteration 1:   log likelihood = -11020.879
Iteration 2:   log likelihood = -11020.879

Conditional (fixed-effects) logistic regression   Number of obs   =      16000
                                                  LR chi2(10)     =      21.19
                                                  Prob > chi2     =     0.0198
Log likelihood = -11020.879                       Pseudo R2       =     0.0010

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
   _Imodel_1 |   .0099958   .0547911     0.18   0.855    -.0973929    .1173844
   _Imodel_2 |  -.0080023   .0632558    -0.13   0.899    -.1319814    .1159768
   _Imodel_3 |    .025999   .0547831     0.47   0.635    -.0813739    .1333719
    _Ifreq_1 |  -.0219993   .0547775    -0.40   0.688    -.1293613    .0853627
    _Ifreq_2 |  -.0480056   .0632558    -0.76   0.448    -.1719846    .0759735
    _Ifreq_3 |  -.0059959   .0547852    -0.11   0.913     -.113373    .1013811
    _Irisk_1 |  -.0339528   .0547606    -0.62   0.535    -.1412816     .073376
    _Irisk_2 |   .0440007   .0632558     0.70   0.487    -.0799784    .1679797
    _Irisk_3 |   .2099729    .054808     3.83   0.000     .1025512    .3173946
        cost |  -.0000496   .0001174    -0.42   0.673    -.0002798    .0001805
------------------------------------------------------------------------------
```

1000 participants (50/50 in each question)

```
. clogit final Pharmacist Telehealth Self threeMonthly sixMonthly Yearly tenrisk fifteenrisk twentyrisk cost, group(ques
> tion)
note: multiple positive outcomes within groups encountered.
2000 (group size) take 1000 (# positives) combinations results in numeric overflow; computations cannot proceed
r(1400);
```

1000 participants (95% 1 in GP comparisons)

```
. clogit final Pharmacist Telehealth Self threeMonthly sixMonthly Yearly tenrisk fifteenrisk twentyrisk cost, group(ques
> tion)
note: multiple positive outcomes within groups encountered.
2000 (group size) take 1000 (# positives) combinations results in numeric overflow; computations cannot proceed
r(1400);
```

Appendix 5.4 – Full data analysis

DUMMY CODING

Conditional logit

```
. xi: clogit final i.model i.freq i.risk cost, group(c_id)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)

Iteration 0:   log likelihood = -1657.2351
Iteration 1:   log likelihood = -1565.8646
Iteration 2:   log likelihood = -1547.2345
Iteration 3:   log likelihood = -1547.1816
Iteration 4:   log likelihood = -1547.1816

Conditional (fixed-effects) logistic regression   Number of obs   =       5344
                                                  LR chi2(10)     =     609.82
                                                  Prob > chi2     =     0.0000
Log likelihood = -1547.1816                       Pseudo R2       =     0.1646
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Imodel_1	-.0984353	.0745798	-1.32	0.187	-.244609	.0477384
_Imodel_2	-.2225383	.0880755	-2.53	0.012	-.3951631	-.0499134
_Imodel_3	-.1588662	.0783138	-2.03	0.043	-.3123584	-.0053739
_Ifreq_1	-.1215457	.0806855	-1.51	0.132	-.2796863	.036595
_Ifreq_2	-.2274286	.0890821	-2.55	0.011	-.4020264	-.0528309
_Ifreq_3	-.6122221	.073898	-8.28	0.000	-.7570595	-.4673847
_Irisk_1	.7679972	.0796097	9.65	0.000	.6119651	.9240293
_Irisk_2	.7580194	.0891439	8.50	0.000	.5833006	.9327382
_Irisk_3	1.290903	.0815087	15.84	0.000	1.131149	1.450657
cost	-.0022183	.0001709	-12.98	0.000	-.0025533	-.0018832

```
. wtp cost _Imodel_1 _Imodel_2 _Imodel_3 _Ifreq_1 _Ifreq_2 _Ifreq_3 _Irisk_1 _Irisk_2 _Irisk_3

      _Imodel_1   _Imodel_2   _Imodel_3    _Ifreq_1    _Ifreq_2    _Ifreq_3    _Irisk_1    _Irisk_2    _Irisk_3
wtp  -44.374822  -100.32068  -71.617182  -54.793027  -102.52526  -275.99092   346.21463   341.71663   581.94169
ll   -110.72327  -180.79924  -140.61201  -127.87899  -184.35153  -353.87977   262.39863   251.77298   477.57111
ul    21.973626  -19.842128  -2.6223499   18.292935  -20.698988  -198.10207   430.03063   431.66029   686.31226
```

```
. estat ic
```

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	5344	-1852.089	-1547.182	10	3114.363	3180.201

Note: N=Obs used in calculating BIC; see **[R] BIC note**

Mixed logit

```
. xi: gmnl final, group(c_id) id(id) rand(i.model i.freq i.risk cost) mixl
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)

Iteration 0:   log likelihood = -2023.9843  (not concave)
Iteration 1:   log likelihood = -1781.5694  (not concave)
Iteration 2:   log likelihood = -1567.1807  (not concave)
Iteration 3:   log likelihood =  -1484.659  (not concave)
Iteration 4:   log likelihood = -1479.2397
Iteration 5:   log likelihood = -1449.5067
Iteration 6:   log likelihood = -1447.9132
Iteration 7:   log likelihood =  -1447.885
Iteration 8:   log likelihood =  -1447.885

Generalized multinomial logit model               Number of obs   =       5344
                                                  Wald chi2(10)   =     356.79
Log likelihood =  -1447.885                       Prob > chi2     =     0.0000

                                        (Std. Err. adjusted for clustering on id)
------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
Mean
   _Imodel_1 |  -.1351667   .1019045    -1.33   0.185    -.3348958    .0645623
   _Imodel_2 |  -.2392196   .1094571    -2.19   0.029    -.4537517   -.0246876
   _Imodel_3 |   -.220063   .1428371    -1.54   0.123    -.5000185    .0598925
    _Ifreq_1 |  -.0594538   .0942005    -0.63   0.528    -.2440833    .1251757
    _Ifreq_2 |  -.2138525   .1050127    -2.04   0.042    -.4196736   -.0080314
    _Ifreq_3 |  -.7979185   .0894269    -8.92   0.000    -.9731921   -.6226449
    _Irisk_1 |   1.044449   .0970756    10.76   0.000     .8541847    1.234714
    _Irisk_2 |   1.057516   .1090138     9.70   0.000     .8438529    1.271179
    _Irisk_3 |   1.768238   .1252951    14.11   0.000     1.522664    2.013812
        cost |  -.0031364   .0002878   -10.90   0.000    -.0037003   -.0025724
-------------+----------------------------------------------------------------
SD
   _Imodel_1 |   .7666169   .1165926     6.58   0.000     .5380995    .9951342
   _Imodel_2 |  -.4984158    .160435    -3.11   0.002    -.8128626    -.183969
   _Imodel_3 |  -1.416635   .1397264   -10.14   0.000    -1.690494   -1.142776
    _Ifreq_1 |   .0138505   .0965056     0.14   0.886    -.1752971     .202998
    _Ifreq_2 |  -.0694857   .1036152    -0.67   0.502    -.2725678    .1335964
    _Ifreq_3 |  -.1363577   .1310894    -1.04   0.298    -.3932882    .1205728
    _Irisk_1 |   -.021136   .1215308    -0.17   0.862     -.259332      .21706
    _Irisk_2 |  -.0007834   .1161823    -0.01   0.995    -.2284965    .2269297
    _Irisk_3 |   .8819439   .1250945     7.05   0.000     .6367632    1.127125
        cost |   .0023287    .000319     7.30   0.000     .0017034     .002954
------------------------------------------------------------------------------
The sign of the estimated standard deviations is irrelevant: interpret them as
being positive

. wtp cost _Imodel_1 _Imodel_2 _Imodel_3 _Ifreq_1 _Ifreq_2 _Ifreq_3 _Irisk_1 _Irisk_2 _Irisk_3

      _Imodel_1   _Imodel_2   _Imodel_3    _Ifreq_1    _Ifreq_2    _Ifreq_3    _Irisk_1    _Irisk_2    _Irisk_3
wtp  -43.096758  -76.273142  -70.165214  -18.956331  -68.185043  -254.40953   333.01379   337.17995   563.78757
ll   -107.12504  -146.63299  -159.09421  -78.410007   -136.1441  -325.06443   255.26512   253.05701   449.24572
ul    20.931524   -5.913298   18.763784   40.497345  -.22599168  -183.75463   410.76247   421.30289   678.32941

. estat ic

-----------------------------------------------------------------------------
       Model |    Obs    ll(null)   ll(model)     df          AIC          BIC
-------------+---------------------------------------------------------------
           . |   5344           .   -1447.885     20      2935.77     3067.445
-----------------------------------------------------------------------------
                Note:  N=Obs used in calculating BIC; see [R] BIC note
```

S-MNL

```
. xi: gmnl final i.model i.freq i.risk cost, group(c_id) id(id)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)

Iteration 0:   log likelihood =  -1537.762  (not concave)
Iteration 1:   log likelihood = -1517.1957
Iteration 2:   log likelihood = -1502.9756
Iteration 3:   log likelihood = -1497.0142
Iteration 4:   log likelihood = -1495.7146
Iteration 5:   log likelihood = -1495.3324
Iteration 6:   log likelihood = -1495.3107
Iteration 7:   log likelihood = -1495.3104
Iteration 8:   log likelihood = -1495.3104

Generalized multinomial logit model               Number of obs   =       5344
                                                  Wald chi2(10)   =      33.41
Log likelihood = -1495.3104                       Prob > chi2     =     0.0002

                                    (Std. Err. adjusted for clustering on id)
------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Imodel_1 |   .8386949   .4054347     2.07   0.039     .0440575    1.633332
    _Imodel_2 |   .4253173   .3580372     1.19   0.235    -.2764226    1.127057
    _Imodel_3 |    .249085    .240585     1.04   0.301     -.222453     .720623
     _Ifreq_1 |   .6593404   .4526361     1.46   0.145      -.22781    1.546491
     _Ifreq_2 |  -.3237923   .2806321    -1.15   0.249    -.8738211    .2262365
     _Ifreq_3 |   -1.09678   .3314333    -3.31   0.001    -1.746377   -.4471826
     _Irisk_1 |   1.864692   .5411628     3.45   0.001     .8040326    2.925352
     _Irisk_2 |    2.35953   .7423055     3.18   0.001     .9046377    3.814422
     _Irisk_3 |   3.723827   1.127211     3.30   0.001     1.514534     5.93312
         cost |  -.0037669   .0011999    -3.14   0.002    -.0061186   -.0014151
-------------+----------------------------------------------------------------
         /tau |   1.668077   .3007291     5.55   0.000     1.078659    2.257495
------------------------------------------------------------------------------
The sign of the estimated standard deviations is irrelevant: interpret them as
being positive

. wtp cost _Imodel_1 _Imodel_2 _Imodel_3 _Ifreq_1 _Ifreq_2 _Ifreq_3 _Irisk_1 _Irisk_2 _Irisk_3

      _Imodel_1   _Imodel_2   _Imodel_3    _Ifreq_1    _Ifreq_2    _Ifreq_3    _Irisk_1    _Irisk_2    _Irisk_3
wtp   222.65138   112.91052   66.125495   175.03748  -85.958318  -291.16613   495.02656   626.39291   988.57788
ll    112.64871  -26.442164  -56.743989   33.643808   -231.3416  -404.53415   351.67145    434.327   773.59133
ul    332.65404    252.2632   188.99498   316.43115    59.424962  -177.79812   638.38167   818.45883   1203.5644


. estat ic

-----------------------------------------------------------------------------
       Model |    Obs    ll(null)   ll(model)     df          AIC         BIC
-------------+---------------------------------------------------------------
           . |   5344           .   -1495.31     11     3012.621    3085.042
-----------------------------------------------------------------------------
               Note:  N=Obs used in calculating BIC; see [R] BIC note
```

G-MNL

```
. xi: gmnl final, group(c_id) id(id) rand(i.model i.freq i.risk cost)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.risk            _Irisk_0-3          (naturally coded; _Irisk_0 omitted)

Iteration 0:   log likelihood = -2033.6281  (not concave)
Iteration 1:   log likelihood = -1688.9735  (not concave)
Iteration 2:   log likelihood = -1511.2287  (not concave)
Iteration 3:   log likelihood = -1500.2802  (not concave)
Iteration 4:   log likelihood = -1482.8754  (not concave)
Iteration 5:   log likelihood = -1467.6151  (not concave)
Iteration 6:   log likelihood = -1455.2537  (not concave)
Iteration 7:   log likelihood = -1433.6347  (not concave)
Iteration 8:   log likelihood = -1432.6353  (not concave)
Iteration 9:   log likelihood = -1422.1495
Iteration 10:  log likelihood = -1411.2711  (not concave)
Iteration 11:  log likelihood = -1403.8801  (not concave)
Iteration 12:  log likelihood =  -1402.661
Iteration 13:  log likelihood = -1401.5886
Iteration 14:  log likelihood = -1398.4953
Iteration 15:  log likelihood = -1397.6881
Iteration 16:  log likelihood = -1397.6169
Iteration 17:  log likelihood = -1397.6138
Iteration 18:  log likelihood = -1397.6138

Generalized multinomial logit model               Number of obs   =       5344
                                                  Wald chi2(10)   =      30.26
Log likelihood = -1397.6138                       Prob > chi2     =     0.0008

                                        (Std. Err. adjusted for clustering on id)
------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
Mean
   _Imodel_1 |    .5958698   .2942621     2.02   0.043     .0191268    1.172613
   _Imodel_2 |   -.0080797   .2965208    -0.03   0.978    -.5892497    .5730904
   _Imodel_3 |    .4563033   .2756885     1.66   0.098    -.0840362    .9966429
    _Ifreq_1 |    .3203752   .3364332     0.95   0.341    -.3390216    .9797721
    _Ifreq_2 |   -.3391953   .3299073    -1.03   0.304    -.9858017    .3074111
    _Ifreq_3 |   -1.305853   .3004125    -4.35   0.000    -1.894651   -.7170555
    _Irisk_1 |    2.187089   .5434223     4.02   0.000        1.122    3.252177
    _Irisk_2 |    2.835159   .7187161     3.94   0.000     1.426501    4.243817
    _Irisk_3 |    4.263754   .9841748     4.33   0.000     2.334806    6.192701
        cost |   -.003198   .0010034    -3.19   0.001    -.0051646   -.0012314
-------------+----------------------------------------------------------------
SD
   _Imodel_1 |    .3806804   .1149502     3.31   0.001     .1553822    .6059786
   _Imodel_2 |    .0421935   .1914575     0.22   0.826    -.3330562    .4174433
   _Imodel_3 |   -.7295718   .2287295    -3.19   0.001    -1.177873   -.2812703
    _Ifreq_1 |    .0139673   .0542752     0.26   0.797    -.0924101    .1203448
    _Ifreq_2 |    .0085664   .0576973     0.15   0.882    -.1045181     .121651
    _Ifreq_3 |   -.1816935   .0817354    -2.22   0.026    -.3418919   -.0214951
    _Irisk_1 |   -.0789576   .0678199    -1.16   0.244    -.2118822     .053967
    _Irisk_2 |   -.0867613   .0773684    -1.12   0.262    -.2384006    .0648781
    _Irisk_3 |   -.1204439   .0743127    -1.62   0.105    -.2660941    .0252064
        cost |   -.0018846   .0005862    -3.22   0.001    -.0030335   -.0007357
-------------+----------------------------------------------------------------
        /tau |    1.77571   .2373233     7.48   0.000     1.310565    2.240856
      /gamma |    2.287889   .6409284     3.57   0.000     1.031693    3.544086
------------------------------------------------------------------------------
The sign of the estimated standard deviations is irrelevant: interpret them as
being positive
```

```
. do "C:\Users\bfletcher\AppData\Local\Temp\STD0s000000.tmp"

. wtp cost _Imodel_1 _Imodel_2 _Imodel_3 _Ifreq_1 _Ifreq_2 _Ifreq_3 _Irisk_1 _Irisk_2 _Irisk_3

      _Imodel_1   _Imodel_2   _Imodel_3    _Ifreq_1    _Ifreq_2    _Ifreq_3    _Irisk_1    _Irisk_2    _Irisk_3
wtp   186.32611  -2.5264787   142.68423   100.18005  -106.06502  -408.33508   683.89389   886.54291   1333.2588
 ll   53.803413  -184.89544  -54.919888  -59.505577  -326.89768  -609.01959     422.169   539.21294   903.59494
 ul   318.84881   179.84248   340.28834   259.86568   114.76764  -207.65057   945.61878   1233.8729   1762.9226
```

```
. estat ic

-----------------------------------------------------------------------------
       Model |     Obs    ll(null)   ll(model)      df          AIC         BIC
-------------+---------------------------------------------------------------
           . |    5344           .  -1397.614      22     2839.228     2984.07
-----------------------------------------------------------------------------
               Note:  N=Obs used in calculating BIC; see [R] BIC note
```

EFFECTS CODING

Conditional logit

```
. clogit final effcodPharm effcodTele effcodSelf effcodFreqThree effcodFreqSix effcodFreqTwelve effcodRiskTen effcodRiskFifteen effcodRiskTwenty c
> ost, group(c_id)

Iteration 0:   log likelihood = -1657.2351
Iteration 1:   log likelihood = -1565.8646
Iteration 2:   log likelihood = -1547.2345
Iteration 3:   log likelihood = -1547.1816
Iteration 4:   log likelihood = -1547.1816

Conditional (fixed-effects) logistic regression   Number of obs   =       5344
                                                  LR chi2(10)     =     609.82
                                                  Prob > chi2     =     0.0000
Log likelihood = -1547.1816                       Pseudo R2       =     0.1646
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
effcodPharm	.0215246	.0480702	0.45	0.654	-.0726912	.1157405
effcodTele	-.1025783	.049679	-2.06	0.039	-.1999474	-.0052092
effcodSelf	-.0389062	.0517176	-0.75	0.452	-.1402708	.0624583
effcodFreqThree	.1187534	.0507351	2.34	0.019	.0193144	.2181925
effcodFreqSix	.0128705	.0492718	0.26	0.794	-.0837004	.1094414
effcodFreqTwelve	-.371923	.0485374	-7.66	0.000	-.4670546	-.2767914
effcodRiskTen	.0637672	.0488686	1.30	0.192	-.0320135	.1595479
effcodRiskFifteen	.0537895	.0469197	1.15	0.252	-.0381714	.1457503
effcodRiskTwentyFive	.5866733	.0498002	11.78	0.000	.4890666	.6842799
cost	-.0022183	.0001709	-12.98	0.000	-.0025533	-.0018832

```
. wtp cost effcodPharm effcodTele effcodSelf effcodFreqThree effcodFreqSix effcodFreqTwelve effcodRiskTen effcodRiskFifteen effcodRiskTwentyFive
```

	effcodPharm	effcodTele	effcodSelf	effcodFreqThree	effcodFreqSix	effcodFreqTwelve
wtp	9.7033495	-46.242511	-17.53901	53.534275	5.8020446	-167.66362
ll	-32.762482	-91.641384	-62.911658	9.1239122	-37.676037	-215.18148
ul	52.169181	-.84363757	27.833638	97.944639	49.280126	-120.14576

	effcodRiskTen	effcodRiskFifteen	effcodRiskTwentyFive
wtp	28.746391	24.248397	264.47345
ll	-14.653823	-17.262703	208.62052
ul	72.146606	65.759498	320.32637

```
. lincom effcodPharm + effcodSelf + effcodTele - 0

 ( 1)  [final]effcodPharm + [final]effcodTele + [final]effcodSelf = 0
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
(1)	-.1199599	.0489878	-2.45	0.014	-.2159743	-.0239456

```
. lincom effcodFreqThree + effcodFreqSix + effcodFreqTwelve - 0

 ( 1)  [final]effcodFreqThree + [final]effcodFreqSix + [final]effcodFreqTwelve = 0
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
(1)	-.2402991	.050098	-4.80	0.000	-.3384893	-.1421089

```
. lincom effcodRiskTen + effcodRiskFifteen + effcodRiskTwenty - 0

 ( 1)  [final]effcodRiskTen + [final]effcodRiskFifteen + [final]effcodRiskTwentyFive = 0
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
(1)	.7042299	.0526466	13.38	0.000	.6010444	.8074155

```
. estat ic
```

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	5344	-1852.089	-1547.182	10	3114.363	3180.201

Note: N=Obs used in calculating BIC; see **[R] BIC note**

Mixed logit

```
. do "C:\Users\bfletcher\AppData\Local\Temp\STD0s000000.tmp"

. gmnl final, group(c_id) id(id) rand(effcodPharm effcodTele effcodSelf effcodFreqThree effcodFreqSix effcodFreqTwelve effcodRiskTen effcodRiskFif
> teen effcodRiskTwenty cost) mixl

Iteration 0:   log likelihood = -2034.4972  (not concave)
Iteration 1:   log likelihood = -1808.5917  (not concave)
Iteration 2:   log likelihood = -1535.7026  (not concave)
Iteration 3:   log likelihood = -1518.5482  (not concave)
Iteration 4:   log likelihood = -1495.3892  (not concave)
Iteration 5:   log likelihood = -1419.9974
Iteration 6:   log likelihood = -1402.4062
Iteration 7:   log likelihood = -1400.8946
Iteration 8:   log likelihood = -1400.8872
Iteration 9:   log likelihood = -1400.8872

Generalized multinomial logit model              Number of obs   =       5344
                                                 Wald chi2(10)   =     324.52
Log likelihood = -1400.8872                      Prob > chi2     =     0.0000

                                              (Std. Err. adjusted for clustering on id)
------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
Mean         |
  effcodPharm |   .0503627   .0699728     0.72   0.472    -.0867814    .1875068
   effcodTele |  -.1012096   .0697459    -1.45   0.147    -.2379091    .0354899
   effcodSelf |  -.0756692   .0966097    -0.78   0.433    -.2650209    .1136824
effcodFreqThree |   .1967983   .0631329     3.12   0.002     .0730602    .3205365
 effcodFreqSix |   .0193923   .0609633     0.32   0.750    -.1000935     .138878
effcodFreqTwelve |  -.5674102   .0621423    -9.13   0.000    -.6892069   -.4456136
 effcodRiskTen |   .0349719   .0593599     0.59   0.556    -.0813714    .1513151
effcodRiskFifteen |   .0776266   .0569414     1.36   0.173    -.0339765    .1892298
effcodRiskTwentyFive |   .9678398    .094227    10.27   0.000     .7831582    1.152521
        cost |  -.0031099   .0002596   -11.98   0.000    -.0036187   -.0026011
-------------+----------------------------------------------------------------
SD           |
  effcodPharm |   .5331393   .0858892     6.21   0.000     .3647995    .7014792
   effcodTele |    -.53497   .1001596    -5.34   0.000    -.7312791   -.3386609
   effcodSelf |  -.907969   .0918409    -9.89   0.000    -1.087974   -.7279642
effcodFreqThree |    .002162   .0808237     0.03   0.979    -.1562496    .1605736
 effcodFreqSix |  -.0030231   .1223152    -0.02   0.980    -.2427564    .2367102
effcodFreqTwelve |   .0379933   .1227272     0.31   0.757    -.2025477    .2785343
 effcodRiskTen |  -.0698202   .0811712    -0.86   0.390    -.2289128    .0892725
effcodRiskFifteen |   .0568496   .1137902     0.50   0.617    -.1661752    .2798743
effcodRiskTwentyFive |   .8625238   .0995764     8.66   0.000     .6673576     1.05769
        cost |  -.0018594   .0003926    -4.74   0.000     -.002629   -.0010899
------------------------------------------------------------------------------
The sign of the estimated standard deviations is irrelevant: interpret them as
being positive

. wtp cost effcodPharm effcodTele effcodSelf effcodFreqThree effcodFreqSix effcodFreqTwelve effcodRiskTen effcodRiskFifteen effcodRiskTwentyFive

             effcodPharm      effcodTele      effcodSelf  effcodFreqThree   effcodFreqSix  effcodFreqTwelve
wtp            16.194267      -32.544231      -24.331662        63.281068        6.23564       -182.45238
ll            -27.971774      -77.296157      -84.799823        23.619364      -32.128232       -227.33334
ul             60.360307       12.207696        36.136499        102.94277       44.599512       -137.57141

           effcodRiskTen  effcodRiskFifteen  effcodRiskTwentyFive
wtp            11.245299          24.961068             311.21164
ll            -26.21736          -11.200703             238.47422
ul             48.707959          61.122838             383.94906


. lincom effcodPharm + effcodSelf + effcodTele - 0

 ( 1)  [Mean]effcodPharm + [Mean]effcodTele + [Mean]effcodSelf = 0

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         (1) |  -.1265161   .1065476    -1.19   0.235    -.3353456    .0823133
------------------------------------------------------------------------------

. lincom effcodFreqThree + effcodFreqSix + effcodFreqTwelve - 0

 ( 1)  [Mean]effcodFreqThree + [Mean]effcodFreqSix + [Mean]effcodFreqTwelve = 0

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         (1) |  -.3512196   .0629202    -5.58   0.000     -.474541   -.2278982
------------------------------------------------------------------------------

. lincom effcodRiskTen + effcodRiskFifteen + effcodRiskTwenty - 0

 ( 1)  [Mean]effcodRiskTen + [Mean]effcodRiskFifteen + [Mean]effcodRiskTwentyFive = 0

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         (1) |   1.080438   .0966177    11.18   0.000     .8910711    1.269805
------------------------------------------------------------------------------
```

```
. estat ic
```

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	5344	.	-1400.887	20	2841.774	2973.449

Note: N=Obs used in calculating BIC; see **[R] BIC note**

S-MNL

```
. gmnl final effcodPharm effcodTele effcodSelf effcodFreqThree effcodFreqSix effcodFreqTwelve effcodRiskTen effcodRiskFifteen effcodRiskTwenty cos
> t, group(c_id) id(id)

Iteration 0:   log likelihood =  -1537.762  (not concave)
Iteration 1:   log likelihood =  -1515.881
Iteration 2:   log likelihood = -1502.2392
Iteration 3:   log likelihood = -1496.7077
Iteration 4:   log likelihood = -1495.6096
Iteration 5:   log likelihood = -1495.3237
Iteration 6:   log likelihood = -1495.3105
Iteration 7:   log likelihood = -1495.3104

Generalized multinomial logit model              Number of obs   =       5344
                                                 Wald chi2(10)   =      33.40
Log likelihood = -1495.3104                      Prob > chi2     =     0.0002

                                          (Std. Err. adjusted for clustering on id)
------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
effcodPharm |   .4603993   .2087629     2.21   0.027     .0512316     .869567
effcodTele |   .0470317    .159582     0.29   0.768    -.2657433    .3598067
effcodSelf |  -.1291771     .18629    -0.69   0.488    -.4942988    .2359446
effcodFreqThree |   .8496027   .4163544     2.04   0.041     .0335631    1.665642
effcodFreqSix |  -.133474    .182218    -0.73   0.464    -.4906147    .2236667
effcodFreqTwelve |  -.9064379   .3087382    -2.94   0.003    -1.511554   -.3013221
effcodRiskTen |  -.1223116   .1189428    -1.03   0.304    -.3554353     .110812
effcodRiskFifteen |   .3725041    .165903     2.25   0.025     .0473401     .697668
effcodRiskTwentyFive |   1.736754   .5390935     3.22   0.001     .6801505    2.793358
cost |  -.0037667   .0012002    -3.14   0.002    -.0061191   -.0014143
-------------+----------------------------------------------------------------
/tau |   1.668051   .3008019     5.55   0.000      1.07849    2.257611
------------------------------------------------------------------------------
The sign of the estimated standard deviations is irrelevant: interpret them as
being positive

. wtp cost effcodPharm effcodTele effcodSelf effcodFreqThree effcodFreqSix effcodFreqTwelve effcodRiskTen effcodRiskFifteen effcodRiskTwentyFive

             effcodPharm     effcodTele     effcodSelf  effcodFreqThree   effcodFreqSix  effcodFreqTwelve
wtp            122.22828      12.486129      -34.294353       225.55527      -35.435112      -240.64404
ll             68.773885     -65.669417       -119.2075       129.45711      -122.8986      -297.74533
ul             175.68268      90.641676        50.61879       321.65342       52.028377      -183.54276

           effcodRiskTen  effcodRiskFifteen  effcodRiskTwentyFive
wtp           -32.47169          98.893573             461.07913
ll           -85.568498          31.562619             367.17863
ul            20.625119          166.22453             554.97964

. lincom effcodPharm + effcodSelf + effcodTele - 0

 ( 1)  [Mean]effcodPharm + [Mean]effcodTele + [Mean]effcodSelf = 0

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         (1) |   .3782539   .2221579     1.70   0.089    -.0571676    .8136753
------------------------------------------------------------------------------

. lincom effcodFreqThree + effcodFreqSix + effcodFreqTwelve - 0

 ( 1)  [Mean]effcodFreqThree + [Mean]effcodFreqSix + [Mean]effcodFreqTwelve = 0

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         (1) |  -.1903092   .1354574    -1.40   0.160    -.4558008    .0751824
------------------------------------------------------------------------------

. lincom effcodRiskTen + effcodRiskFifteen + effcodRiskTwenty - 0

 ( 1)  [Mean]effcodRiskTen + [Mean]effcodRiskFifteen + [Mean]effcodRiskTwentyFive = 0

------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         (1) |   1.986947   .5972362     3.33   0.001     .8163854    3.157508
------------------------------------------------------------------------------


. estat ic

-----------------------------------------------------------------------------
       Model |  Obs    ll(null)   ll(model)     df          AIC          BIC
-------------+---------------------------------------------------------------
           . | 5344           .   -1495.31     11     3012.621     3085.042
-----------------------------------------------------------------------------
                Note:  N=Obs used in calculating BIC; see [R] BIC note
```

G-MNL

```
. gmnl final , group(c_id) id(id) rand(effcodPharm effcodTele effcodSelf effcodFreqThree effcodFreqSix effcodFreqTwelve effcodRiskTen effcodRiskFi
> fteen effcodRiskTwentyFive cost)

Iteration 0:   log likelihood = -2043.7662  (not concave)
Iteration 1:   log likelihood = -1744.9993  (not concave)
Iteration 2:   log likelihood = -1619.3987  (not concave)
Iteration 3:   log likelihood = -1587.4909  (not concave)
Iteration 4:   log likelihood = -1556.0947  (not concave)
Iteration 5:   log likelihood = -1465.5336  (not concave)
Iteration 6:   log likelihood = -1447.7817  (not concave)
Iteration 7:   log likelihood = -1439.5102  (not concave)
Iteration 8:   log likelihood = -1421.1429  (not concave)
Iteration 9:   log likelihood = -1410.3569  (not concave)
Iteration 10:  log likelihood = -1408.6316  (not concave)
Iteration 11:  log likelihood =  -1401.418  (not concave)
Iteration 12:  log likelihood = -1395.8711  (not concave)
Iteration 13:  log likelihood = -1391.4769  (not concave)
Iteration 14:  log likelihood = -1387.6217
Iteration 15:  log likelihood = -1385.7526  (not concave)
Iteration 16:  log likelihood = -1385.2169
Iteration 17:  log likelihood = -1385.0074
Iteration 18:  log likelihood = -1384.9851
Iteration 19:  log likelihood = -1384.9849
Iteration 20:  log likelihood = -1384.9849

Generalized multinomial logit model              Number of obs   =       5344
                                                 Wald chi2(10)   =      39.33
Log likelihood = -1384.9849                      Prob > chi2     =     0.0000

                                          (Std. Err. adjusted for clustering on id)
------------------------------------------------------------------------------
             final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------------+----------------------------------------------------------------
Mean               |
        effcodPharm |   .2001921   .1051855     1.90   0.057    -.0059677    .4063518
         effcodTele |   .1203987   .1095099     1.10   0.272    -.0942368    .3350342
         effcodSelf |  -.1835766   .1428821    -1.28   0.199    -.4636203    .0964671
     effcodFreqThree |   .3567808   .1338272     2.67   0.008     .0944843    .6190773
       effcodFreqSix |   .0198909   .0969329     0.21   0.837    -.1700941     .209876
    effcodFreqTwelve |  -.9550163   .1774227    -5.38   0.000    -1.302758   -.6072741
       effcodRiskTen |   .0313615   .0969339     0.32   0.746    -.1586254    .2213485
   effcodRiskFifteen |   .2046318   .0952232     2.15   0.032     .0179978    .3912657
effcodRiskTwentyFive |   1.743348   .3213911     5.42   0.000     1.113433    2.373263
                cost |  -.0067477   .0011804    -5.72   0.000    -.0090612   -.0044342
-------------------+----------------------------------------------------------------
SD                 |
        effcodPharm |  -.3395326    .116579    -2.91   0.004    -.5680234   -.1110419
         effcodTele |   .4464709    .180872     2.47   0.014     .0919682    .8009736
         effcodSelf |   1.227798   .4734132     2.59   0.010      .299925    2.155671
     effcodFreqThree |  -.1268801   .0619335    -2.05   0.040    -.2482675   -.0054926
       effcodFreqSix |  -.0079873   .0624265    -0.13   0.898    -.1303411    .1143665
    effcodFreqTwelve |  -.0269551   .0399333    -0.68   0.500     -.105223    .0513128
       effcodRiskTen |    .089088   .0604883     1.47   0.141    -.0294669     .207643
   effcodRiskFifteen |  -.0583095   .0550776    -1.06   0.290    -.1662596    .0496405
effcodRiskTwentyFive |   .9484805   .3435338     2.76   0.006     .2751667    1.621794
                cost |   .0022526   .0008707     2.59   0.010     .0005461    .0039591
-------------------+----------------------------------------------------------------
               /tau |   1.419895   .1799247     7.89   0.000     1.067249    1.772541
             /gamma |  -1.377493   .5910348    -2.33   0.020      -2.5359    -.219086
------------------------------------------------------------------------------
The sign of the estimated standard deviations is irrelevant: interpret them as
being positive


. wtp cost effcodPharm effcodTele effcodSelf effcodFreqThree effcodFreqSix effcodFreqTwelve effcodRiskTen effcodRiskFifteen effcodRiskTwentyFive

             effcodPharm      effcodTele      effcodSelf   effcodFreqThree    effcodFreqSix   effcodFreqTwelve
wtp            29.668284       17.842976      -27.205883         52.874586        2.9478197        -141.53254
ll              2.2795433      -12.396839      -67.936821         20.926565       -25.161207        -167.89668
ul             57.057024        48.082792       13.525055         84.822606        31.056846        -115.16839

           effcodRiskTen  effcodRiskFifteen  effcodRiskTwentyFive
wtp            4.6477476           30.32624             258.36256
ll            -23.498321          3.1860016             218.95101
ul             32.793816           57.466479             297.77412
```

```
. lincom effcodPharm + effcodSelf + effcodTele - 0

 ( 1)  [Mean]effcodPharm + [Mean]effcodTele + [Mean]effcodSelf = 0
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
(1)	.1370142	.1300729	1.05	0.292	-.1179239	.3919523

```
. lincom effcodFreqThree + effcodFreqSix + effcodFreqTwelve - 0

 ( 1)  [Mean]effcodFreqThree + [Mean]effcodFreqSix + [Mean]effcodFreqTwelve = 0
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
(1)	-.5783446	.1292877	-4.47	0.000	-.8317439	-.3249452

```
. lincom effcodRiskTen + effcodRiskFifteen + effcodRiskTwenty - 0

 ( 1)  [Mean]effcodRiskTen + [Mean]effcodRiskFifteen + [Mean]effcodRiskTwentyFive = 0
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
(1)	1.979341	.3520006	5.62	0.000	1.289433	2.66925

```
. estat ic
```

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	5344	.	-1384.985	22	2813.97	2958.812

Note: N=Obs used in calculating BIC; see **[R] BIC note**

Appendix 5.5 – Willingness to risk

RISK and BOTH RISK/COST AS CONTINUOUS VARIABLE AND WILLINGNESS TO RISK (DUMMY CODED)

Conditional logit

```
. xi: clogit final i.model i.freq i.cos riskcontinuous, group(c_id)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.cos             _Icos_0-3           (naturally coded; _Icos_0 omitted)

Iteration 0:   log likelihood = -1593.7342
Iteration 1:   log likelihood = -1553.9862
Iteration 2:   log likelihood = -1552.2935
Iteration 3:   log likelihood = -1552.2926
Iteration 4:   log likelihood = -1552.2926

Conditional (fixed-effects) logistic regression

                                                Number of obs     =      5,344
                                                LR chi2(10)       =     599.59
                                                Prob > chi2       =     0.0000
Log likelihood = -1552.2926                     Pseudo R2         =     0.1619
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Imodel_1	-.119414	.0785336	-1.52	0.128	-.2733369	.034509
_Imodel_2	-.2535099	.0883749	-2.87	0.004	-.4267215	-.0802983
_Imodel_3	-.1431919	.0754753	-1.90	0.058	-.2911208	.0047371
_Ifreq_1	-.1301476	.0788428	-1.65	0.099	-.2846768	.0243815
_Ifreq_2	-.2501711	.0880013	-2.84	0.004	-.4226505	-.0776917
_Ifreq_3	-.6251887	.0757216	-8.26	0.000	-.7736002	-.4767771
_Icos_1	.2766045	.0735662	3.76	0.000	.1324173	.4207917
_Icos_2	-.3036458	.0883867	-3.44	0.001	-.4768805	-.1304111
_Icos_3	-.9252574	.0787638	-11.75	0.000	-1.079632	-.7708831
riskcontinuous	-.0625229	.0039344	-15.89	0.000	-.0702342	-.0548115

```
. wtp riskcontinuous _Imodel_1 _Imodel_2 _Imodel_3 _Ifreq_1 _Ifreq_2 _Ifreq_3 _Icos_1 _Icos_2 _Icos_3
```

	_Imodel_1	_Imodel_2	_Imodel_3	_Ifreq_1	_Ifreq_2	_Ifreq_3	_Icos_1	_Icos_2	_Icos_3
wtp	-1.9099249	-4.0546758	-2.290232	-2.0816008	-4.0012745	-9.999361	4.4240537	-4.8565568	-14.798704
ll	-4.3938582	-6.9067719	-4.6641283	-4.5965802	-6.82325	-12.70057	2.063182	-7.6584097	-17.668161
ul	.57400841	-1.2025797	.08366428	.4333785	-1.1792989	-7.2981525	6.7849255	-2.0547039	-11.929247

```
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. estat ic

Akaike's information criterion and Bayesian information criterion
```

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	5,344	-1852.089	-1552.293	10	3124.585	3190.422

Note: N=Obs used in calculating BIC; see **[R] BIC note**.

```
.  xi: clogit final i.model i.freq cost riskcontinuous, group(c_id)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)

Iteration 0:   log likelihood = -1603.4008
Iteration 1:   log likelihood = -1568.8151
Iteration 2:   log likelihood = -1567.9863
Iteration 3:   log likelihood = -1567.9861
Iteration 4:   log likelihood = -1567.9861

Conditional (fixed-effects) logistic regression

                                                Number of obs     =      5,344
                                                LR chi2(8)        =     568.21
                                                Prob > chi2       =     0.0000
Log likelihood = -1567.9861                     Pseudo R2         =     0.1534
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Imodel_1	-.1059443	.076789	-1.38	0.168	-.2564481	.0445594
_Imodel_2	-.2380249	.0876692	-2.72	0.007	-.4098534	-.0661965
_Imodel_3	-.1396042	.075607	-1.85	0.065	-.2877913	.0085828
_Ifreq_1	-.1278794	.0790774	-1.62	0.106	-.2828682	.0271095
_Ifreq_2	-.2461952	.0872565	-2.82	0.005	-.4172148	-.0751756
_Ifreq_3	-.6265417	.0748759	-8.37	0.000	-.7732958	-.4797875
cost	-.0022253	.000171	-13.01	0.000	-.0025604	-.0018901
riskcontinuous	-.0623756	.003927	-15.88	0.000	-.0700723	-.0546788

```
. estat ic

Akaike's information criterion and Bayesian information criterion
```

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	5,344	-1852.089	-1567.986	8	3151.972	3204.642

Note: N=Obs used in calculating BIC; see **[R] BIC note**.

Mixed logit

```
. xi: gmnl final, group(c_id) id(id) rand(i.model i.freq i.cos riskcontinuous) mixl
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.cos             _Icos_0-3           (naturally coded; _Icos_0 omitted)

Iteration 0:   log likelihood = -1528.2596  (not concave)
Iteration 1:   log likelihood = -1526.6009  (not concave)
Iteration 2:   log likelihood = -1476.4395  (not concave)
Iteration 3:   log likelihood = -1472.0511
Iteration 4:   log likelihood = -1448.2571
Iteration 5:   log likelihood = -1443.9755
Iteration 6:   log likelihood = -1443.2819
Iteration 7:   log likelihood = -1443.2784
Iteration 8:   log likelihood = -1443.2784

Generalized multinomial logit model             Number of obs     =      5,344
                                                Wald chi2(10)     =     332.15
Log likelihood = -1443.2784                     Prob > chi2       =     0.0000

                                        (Std. Err. adjusted for clustering on id)
------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
Mean
    _Imodel_1 |   -.137676   .1081168    -1.27   0.203    -.3495811     .074229
    _Imodel_2 |  -.3042159   .1121594    -2.71   0.007    -.5240444   -.0843875
    _Imodel_3 |  -.2041213    .135142    -1.51   0.131    -.4689948    .0607523
     _Ifreq_1 |  -.0786601    .092733    -0.85   0.396    -.2604135    .1030932
     _Ifreq_2 |  -.2422379   .1061898    -2.28   0.023     -.450366   -.0341097
     _Ifreq_3 |  -.7933145   .0922642    -8.60   0.000    -.9741491   -.6124799
      _Icos_1 |   .3146486   .0868911     3.62   0.000     .1443451    .4849521
      _Icos_2 |  -.4511674   .1063694    -4.24   0.000    -.6596475   -.2426872
      _Icos_3 |  -1.234804   .1044957   -11.82   0.000    -1.439612   -1.029996
riskcontinuous |  -.0946941   .0085567   -11.07   0.000    -.1114649   -.0779233
-------------+----------------------------------------------------------------
SD
    _Imodel_1 |   .8069321   .1214343     6.65   0.000     .5689252    1.044939
    _Imodel_2 |  -.5390007   .1574784    -3.42   0.001    -.8476526   -.2303488
    _Imodel_3 |   1.435436   .1462961     9.81   0.000     1.148701    1.722171
     _Ifreq_1 |  -.0081977   .0919848    -0.09   0.929    -.1884845    .1720892
     _Ifreq_2 |   .0003078   .1201336     0.00   0.998    -.2351498    .2357654
     _Ifreq_3 |   .1461419   .1414823     1.03   0.302    -.1311583     .423442
      _Icos_1 |   .0248782   .1565875     0.16   0.874    -.2820278    .3317841
      _Icos_2 |  -.0257617    .102311    -0.25   0.801    -.2262876    .1747642
      _Icos_3 |  -.5654576   .1334302    -4.24   0.000    -.8269759   -.3039392
riskcontinuous |   .0894966   .0100864     8.87   0.000     .0697276    .1092656
------------------------------------------------------------------------------
The sign of the estimated standard deviations is irrelevant: interpret them as
being positive

. wtp riskcontinuous _Imodel_1 _Imodel_2 _Imodel_3 _Ifreq_1 _Ifreq_2 _Ifreq_3 _Icos_1 _Icos_2 _Icos_3

      _Imodel_1   _Imodel_2   _Imodel_3    _Ifreq_1    _Ifreq_2    _Ifreq_3     _Icos_1     _Icos_2     _Icos_3
wtp  -1.4539026  -3.2126173  -2.1555856  -.83067626   -2.558109  -8.3776541   3.3227896  -4.7644711  -13.039926
ll   -3.7157395  -5.6056451  -4.9690333  -2.7635045  -4.8056826  -10.711132   1.4396396  -7.0667979  -15.924062
ul    .80793418  -.81958954   .65786209    1.102152  -.31053544  -6.0441763   5.2059396  -2.4621443  -10.155791

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. estat ic

Akaike's information criterion and Bayesian information criterion

------------------------------------------------------------------------------
       Model |        Obs  ll(null)  ll(model)      df         AIC        BIC
-------------+----------------------------------------------------------------
           . |      5,344         .  -1443.278      20    2926.557   3058.231
------------------------------------------------------------------------------
               Note: N=Obs used in calculating BIC; see [R] BIC note.
```

```
.  xi: gmnl final, group(c_id) id(id) rand(i.model i.freq cost riskcontinuous) mixl
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)

Iteration 0:   log likelihood = -2196.7307  (not concave)
Iteration 1:   log likelihood = -1523.0481  (not concave)
Iteration 2:   log likelihood = -1493.6217  (not concave)
Iteration 3:   log likelihood =  -1479.945
Iteration 4:   log likelihood = -1462.9998
Iteration 5:   log likelihood = -1451.5828
Iteration 6:   log likelihood = -1450.8392
Iteration 7:   log likelihood = -1450.8369
Iteration 8:   log likelihood = -1450.8369

Generalized multinomial logit model             Number of obs     =      5,344
                                                Wald chi2(8)      =     295.62
Log likelihood = -1450.8369                     Prob > chi2       =     0.0000

                                        (Std. Err. adjusted for clustering on id)
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Mean						
_Imodel_1	-.1628163	.106497	-1.53	0.126	-.3715465	.045914
_Imodel_2	-.3116733	.1134742	-2.75	0.006	-.5340786	-.089268
_Imodel_3	-.3237601	.1442049	-2.25	0.025	-.6063965	-.0411237
_Ifreq_1	-.0842107	.0930847	-0.90	0.366	-.2666532	.0982319
_Ifreq_2	-.24545	.1056257	-2.32	0.020	-.4524726	-.0384274
_Ifreq_3	-.8523519	.0937713	-9.09	0.000	-1.03614	-.6685635
cost	-.0030016	.0002632	-11.40	0.000	-.0035176	-.0024857
riskcontinuous	-.0985193	.0083895	-11.74	0.000	-.1149623	-.0820763
SD						
_Imodel_1	-.8004995	.1204536	-6.65	0.000	-1.036584	-.5644147
_Imodel_2	.569198	.1230306	4.63	0.000	.3280624	.8103336
_Imodel_3	1.533394	.164206	9.34	0.000	1.211556	1.855232
_Ifreq_1	.0443193	.1003607	0.44	0.659	-.152384	.2410226
_Ifreq_2	.0570385	.11004	0.52	0.604	-.1586359	.2727129
_Ifreq_3	-.1804095	.1518972	-1.19	0.235	-.4781226	.1173035
cost	-.0021962	.000319	-6.88	0.000	-.0028215	-.0015709
riskcontinuous	.0881652	.0090043	9.79	0.000	.0705172	.1058133

```
The sign of the estimated standard deviations is irrelevant: interpret them as
being positive

. estat ic

Akaike's information criterion and Bayesian information criterion
```

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	5,344	.	-1450.837	16	2933.674	3039.013

Note: N=Obs used in calculating BIC; see **[R] BIC note**.

S-MNL

```
. xi: gmnl final i.model i.freq i.cos riskcontinuous, group(c_id) id(id)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.cos             _Icos_0-3           (naturally coded; _Icos_0 omitted)

Iteration 0:   log likelihood = -1544.6741  (not concave)
Iteration 1:   log likelihood = -1527.1122
Iteration 2:   log likelihood = -1515.7233
Iteration 3:   log likelihood =  -1507.737
Iteration 4:   log likelihood = -1503.1931
Iteration 5:   log likelihood = -1500.6119
Iteration 6:   log likelihood = -1500.1496
Iteration 7:   log likelihood = -1500.0659
Iteration 8:   log likelihood = -1500.0635
Iteration 9:   log likelihood = -1500.0635

Generalized multinomial logit model             Number of obs     =      5,344
                                                Wald chi2(10)     =      14.16
Log likelihood = -1500.0635                     Prob > chi2       =     0.1658

                                        (Std. Err. adjusted for clustering on id)
------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Imodel_1 |   3.784937   1.721912     2.20   0.028     .4100506    7.159823
    _Imodel_2 |   3.095937   1.602022     1.93   0.053    -.043969     6.235844
    _Imodel_3 |   .9092951    .445124     2.04   0.041     .0368681    1.781722
     _Ifreq_1 |   1.724764   1.013694     1.70   0.089    -.2620388    3.711567
     _Ifreq_2 |  -.9984242   .6194598    -1.61   0.107    -2.212543    .2156947
     _Ifreq_3 |  -1.803061   .7699053    -2.34   0.019    -3.312048   -.2940743
      _Icos_1 |   .8253196   .3811386     2.17   0.030     .0783017    1.572338
      _Icos_2 |  -.7326091   .6096564    -1.20   0.229    -1.927514    .4622954
      _Icos_3 |  -3.904222   1.762554    -2.22   0.027    -7.358765   -.4496789
riskcontinuous |  -.3843068   .1569367    -2.45   0.014    -.6918972   -.0767165
-------------+----------------------------------------------------------------
         /tau |   2.314509    .311135     7.44   0.000     1.704695    2.924322
------------------------------------------------------------------------------
The sign of the estimated standard deviations is irrelevant: interpret them as
being positive

. wtp riskcontinuous _Imodel_1 _Imodel_2 _Imodel_3 _Ifreq_1 _Ifreq_2 _Ifreq_3 _Icos_1 _Icos_2 _Icos_3

      _Imodel_1   _Imodel_2   _Imodel_3    _Ifreq_1    _Ifreq_2    _Ifreq_3     _Icos_1     _Icos_2     _Icos_3
wtp   9.8487368   8.0558999   2.3660655   4.4879873   -2.597987  -4.6917224   2.1475538  -1.9063131  -10.159127
ll    7.9980803   5.2714061   .78706154   2.0789538  -5.1052832  -6.2198455   .80914387  -4.3415754  -11.685912
ul    11.699393   10.840394   3.9450694   6.8970209  -.09069079  -3.1635992   3.4859638   .52894928  -8.6323427

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. estat ic

Akaike's information criterion and Bayesian information criterion

------------------------------------------------------------------------------
       Model |        Obs  ll(null)  ll(model)      df         AIC        BIC
-------------+----------------------------------------------------------------
           . |      5,344         .  -1500.064      11    3022.127   3094.548
------------------------------------------------------------------------------
               Note: N=Obs used in calculating BIC; see [R] BIC note.
```

```
. xi: gmnl final i.model i.freq cost riskcontinuous, group(c_id) id(id)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)

Iteration 0:   log likelihood = -1560.3565  (not concave)
Iteration 1:   log likelihood = -1540.5201
Iteration 2:   log likelihood = -1529.3157
Iteration 3:   log likelihood = -1523.0094
Iteration 4:   log likelihood =  -1517.475
Iteration 5:   log likelihood = -1514.1733
Iteration 6:   log likelihood = -1513.3947
Iteration 7:   log likelihood = -1512.9568
Iteration 8:   log likelihood = -1512.9363
Iteration 9:   log likelihood = -1512.9326
Iteration 10:  log likelihood =  -1512.931
Iteration 11:  log likelihood = -1512.9306  (backed up)
Iteration 12:  log likelihood = -1512.9305  (backed up)
Iteration 13:  log likelihood = -1512.9305  (not concave)
numerical derivatives are approximate
flat or discontinuous region encountered
Iteration 14:  log likelihood =   -1512.93  (not concave)
numerical derivatives are approximate
flat or discontinuous region encountered
Iteration 15:  log likelihood = -1512.9292  (not concave)
numerical derivatives are approximate
flat or discontinuous region encountered
Iteration 16:  log likelihood = -1512.9288  (not concave)
Iteration 17:  log likelihood = -1512.9285  (not concave)
numerical derivatives are approximate
flat or discontinuous region encountered
Iteration 18:  log likelihood = -1512.9284  (not concave)
```

G-MNL

```
. xi: gmnl final, group(c_id) id(id) rand(i.model i.freq i.cos riskcontinuous)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)
i.cos             _Icos_0-3           (naturally coded; _Icos_0 omitted)

Iteration 0:   log likelihood = -1524.8468  (not concave)
Iteration 1:   log likelihood = -1513.5337  (not concave)
Iteration 2:   log likelihood = -1497.4876  (not concave)
Iteration 3:   log likelihood = -1460.0928  (not concave)
Iteration 4:   log likelihood = -1455.8808  (not concave)
Iteration 5:   log likelihood = -1454.4595
Iteration 6:   log likelihood = -1436.0288
Iteration 7:   log likelihood =  -1432.687  (not concave)
Iteration 8:   log likelihood = -1431.6403
Iteration 9:   log likelihood = -1430.9486
Iteration 10:  log likelihood = -1430.3619  (not concave)
Iteration 11:  log likelihood = -1429.5985
Iteration 12:  log likelihood = -1429.4385
Iteration 13:  log likelihood = -1429.4066
Iteration 14:  log likelihood = -1429.4065

Generalized multinomial logit model             Number of obs     =      5,344
                                                Wald chi2(10)     =     138.73
Log likelihood = -1429.4065                     Prob > chi2       =     0.0000

                                        (Std. Err. adjusted for clustering on id)
------------------------------------------------------------------------------
       final |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
Mean
    _Imodel_1 |   .0524259   .1411923     0.37   0.710    -.2243059    .3291576
    _Imodel_2 |  -.2254554   .1394397    -1.62   0.106    -.4987522    .0478413
    _Imodel_3 |  -.1907685   .1486734    -1.28   0.199     -.482163     .100626
     _Ifreq_1 |  -.1684082   .1184086    -1.42   0.155    -.4004848    .0636684
     _Ifreq_2 |  -.3921682   .1357122    -2.89   0.004    -.6581592   -.1261772
     _Ifreq_3 |  -1.011844   .1288854    -7.85   0.000    -1.264455   -.7592329
      _Icos_1 |    .316949   .1080331     2.93   0.003     .1052081     .52869
      _Icos_2 |  -.5862007   .1398851    -4.19   0.000    -.8603703    -.312031
      _Icos_3 |  -1.548066   .1674874    -9.24   0.000    -1.876335   -1.219797
riskcontinuous |   -.122275   .0132608    -9.22   0.000    -.1482657   -.0962844
-------------+----------------------------------------------------------------
SD
    _Imodel_1 |   1.151701   .1594984     7.22   0.000     .8390899    1.464312
    _Imodel_2 |  -.1529017   .2225147    -0.69   0.492    -.5890224    .2832191
    _Imodel_3 |   1.728325   .2075282     8.33   0.000     1.321577    2.135073
     _Ifreq_1 |   .0375462   .0989851     0.38   0.704     -.156461    .2315533
     _Ifreq_2 |   .0063629   .1275223     0.05   0.960    -.2435762    .2563021
     _Ifreq_3 |   .1000488   .1249345     0.80   0.423    -.1448183    .3449159
      _Icos_1 |  -.1936379   .1629506    -1.19   0.235    -.5130152    .1257394
      _Icos_2 |  -.0200114   .1196024    -0.17   0.867    -.2544277     .214405
      _Icos_3 |  -.6062498   .1801655    -3.36   0.001    -.9593677   -.2531319
riskcontinuous |   .1028282   .0131765     7.80   0.000     .0770026    .1286537
-------------+----------------------------------------------------------------
         /tau |   .7159681   .1102554     6.49   0.000     .4998714    .9320647
       /gamma |   .1669712   .1215723     1.37   0.170    -.0713061    .4052485
------------------------------------------------------------------------------
The sign of the estimated standard deviations is irrelevant: interpret them as
being positive

. wtp riskcontinuous _Imodel_1 _Imodel_2 _Imodel_3 _Ifreq_1 _Ifreq_2 _Ifreq_3 _Icos_1 _Icos_2 _Icos_3

      _Imodel_1   _Imodel_2   _Imodel_3    _Ifreq_1    _Ifreq_2    _Ifreq_3     _Icos_1     _Icos_2     _Icos_3
wtp   .42875368  -1.8438383  -1.5601588  -1.3772902  -3.2072628  -8.2751449   2.5920992  -4.7941153  -12.660524
ll   -1.8167319  -4.1398584  -3.9232448  -3.2851002  -5.3833559  -10.347514   .79719141  -6.9368585  -15.162523
ul    2.6742392   .45218177   .80292718   .53051986  -1.0311697  -6.2027761   4.3870069   -2.651372  -10.158525

.
end of do-file
```

```
. estat ic

Akaike's information criterion and Bayesian information criterion
```

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	5,344	.	-1429.407	22	2902.813	3047.655

Note: N=Obs used in calculating BIC; see **[R] BIC note**.

```
.  xi: gmnl final, group(c_id) id(id) rand(i.model i.freq cost riskcontinuous)
i.model           _Imodel_0-3         (naturally coded; _Imodel_0 omitted)
i.freq            _Ifreq_0-3          (naturally coded; _Ifreq_0 omitted)

Iteration 0:   log likelihood = -2173.2507  (not concave)
Iteration 1:   log likelihood = -1849.3591  (not concave)
Iteration 2:   log likelihood = -1517.4343  (not concave)
Iteration 3:   log likelihood = -1507.1634  (not concave)
Iteration 4:   log likelihood = -1474.2678  (not concave)
Iteration 5:   log likelihood = -1464.7804  (not concave)
Iteration 6:   log likelihood = -1459.1932  (not concave)
Iteration 7:   log likelihood = -1447.8704  (not concave)
Iteration 8:   log likelihood = -1441.0256
Iteration 9:   log likelihood = -1436.5643
Iteration 10:  log likelihood = -1434.4114
Iteration 11:  log likelihood = -1433.7572
Iteration 12:  log likelihood = -1433.5438
Iteration 13:  log likelihood = -1433.5431
Iteration 14:  log likelihood = -1433.5431

Generalized multinomial logit model             Number of obs     =      5,344
                                                Wald chi2(8)      =      88.39
Log likelihood = -1433.5431                     Prob > chi2       =     0.0000

                                        (Std. Err. adjusted for clustering on id)
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Mean						
_Imodel_1	-.026399	.1463017	-0.18	0.857	-.3131451	.260347
_Imodel_2	-.2212008	.1522302	-1.45	0.146	-.5195664	.0771649
_Imodel_3	-.1253786	.1733087	-0.72	0.469	-.4650575	.2143003
_Ifreq_1	-.2060518	.1227652	-1.68	0.093	-.4466672	.0345637
_Ifreq_2	-.4570768	.1379203	-3.31	0.001	-.7273956	-.186758
_Ifreq_3	-1.185754	.1557029	-7.62	0.000	-1.490926	-.880582
cost	-.0041621	.0005177	-8.04	0.000	-.0051767	-.0031474
riskcontinuous	-.1211822	.0150048	-8.08	0.000	-.150591	-.0917734
SD						
_Imodel_1	1.03915	.1643149	6.32	0.000	.7170987	1.361201
_Imodel_2	-.339106	.2132279	-1.59	0.112	-.757025	.078813
_Imodel_3	1.828193	.2366962	7.72	0.000	1.364277	2.29211
_Ifreq_1	.0574786	.1035146	0.56	0.579	-.1454064	.2603635
_Ifreq_2	.0120362	.1162215	0.10	0.918	-.2157538	.2398261
_Ifreq_3	.1323729	.1381611	0.96	0.338	-.1384179	.4031636
cost	.0023628	.0004214	5.61	0.000	.001537	.0031887
riskcontinuous	.1109146	.0149841	7.40	0.000	.0815462	.140283
/tau	.8219814	.1299867	6.32	0.000	.5672122	1.076751
/gamma	.2209229	.1117482	1.98	0.048	.0019005	.4399454

```
The sign of the estimated standard deviations is irrelevant: interpret them as
being positive

. estat ic

Akaike's information criterion and Bayesian information criterion
```

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	5,344	.	-1433.543	18	2903.086	3021.593

Note: N=Obs used in calculating BIC; see **[R] BIC note**.

```
. lincom effcodPharm + effcodSelf + effcodTele - 0

 ( 1)  [Mean]effcodPharm + [Mean]effcodTele + [Mean]effcodSelf = 0
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
(1)	.2783286	.2223546	1.25	0.211	-.1574783	.7141355

```
. lincom effcodFreqThree + effcodFreqSix + effcodFreqTwelve - 0

 ( 1)  [Mean]effcodFreqThree + [Mean]effcodFreqSix + [Mean]effcodFreqTwelve = 0
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
(1)	-.5814833	.1590627	-3.66	0.000	-.8932405	-.2697262

```
. lincom modeleffcodCost100 + modeleffcodCost250 + modeleffcodCost500 - 0

 ( 1)  [Mean]modeleffcodCost100 + [Mean]modeleffcodCost250 + [Mean]modeleffcodCost500 = 0
```

final	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
(1)	-.6034043	.1744164	-3.46	0.001	-.9452543	-.2615544

```
.
end of do-file

. do "C:\Users\Benjamin\AppData\Local\Temp\STD01000000.tmp"

. estat ic

Akaike's information criterion and Bayesian information criterion
```

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	5,344	.	-1378.528	22	2801.056	2945.898

Note: N=Obs used in calculating BIC; see **[R] BIC note**.

Appendix 5.6 Sample size calculation for full study

α	1-β	Model			Frequency			Reduction in 5 year CVD risk			Cost (£)
		Pharmacist	Telehealth	Self-management	Three monthly	Six monthly	Yearly	10%	15%	25%	
		A1	A2	A3	B1	B2	B3	C1	C2	C3	D
0.1	0.6	30	10,153	1,354	14	579	3	58	22	2	2
0.05	0.6	45	15,529	2,070	21	885	5	88	34	3	3
0.025	0.6	62	21,112	2,814	29	1,203	7	120	46	4	4
0.01	0.6	84	28,681	3,824	40	1,635	10	163	62	5	6
0.1	0.7	41	14,056	1,874	19	801	5	80	31	2	3
0.05	0.7	59	20,280	2,704	28	1,156	7	115	45	3	4
0.025	0.7	78	26,600	3,546	37	1,516	9	151	58	4	6
0.01	0.7	102	35,024	4,670	48	1,996	12	199	77	6	7
0.1	0.8	57	19,427	2,590	27	1,107	6	110	43	3	4
0.05	0.8	78	26,645	3,552	37	1,519	9	152	58	4	6
0.025	0.8	99	33,827	4,510	47	1,928	11	192	74	6	7
0.01	0.8	126	43,253	5,767	60	2,465	14	246	95	7	9
0.1	0.9	83	28,313	3,775	39	1,614	9	161	62	5	6
0.05	0.9	108	36,908	4,921	51	2,104	12	210	81	6	8
0.025	0.9	132	45,284	6,038	63	2,581	15	258	99	8	9
0.01	0.9	164	56,100	7,479	78	3,197	19	319	123	9	12

Appendix 6.1 Summary of main findings

Research question (from 1.10.2)	**Methods**	**Main findings**	**Implications**
1. What is the effect of SMBP on medication adherence and lifestyle change?	Systematic review and meta-analysis of controlled trials	<u>Medication adherence</u> Effect of SMBP on medication adherence available from twenty-five trials. SMBP resulted in a small but significant improvement in medication adherence (13 studies: SMD = 0.21 (95%CI 0.08 to 0.34). Effect was greatest when objective measures of adherence used. <u>Lifestyle change</u> Evidence for the effect of SMBP on diet and physical activity was available in only eight trials, and where significant effects in favour of the intervention were found, few were clinically significant.	SMBP may contribute to improvements in medication adherence in hypertensives. However, evidence for the effect of SMBP on lifestyle change and medication persistence is scarce, of poor quality, and suggests little clinically relevant benefit. SMBP likely to have greater effect at a patient level on improving medication adherence than lifestyle change. Information provided to patients who self-monitor should emphasise this and provide specific advice.
2. What are patient and clinician attitudes to SMBP?	Systematic review and thematic synthesis of primary qualitative studies	Twelve studies were included in the synthesis involving 358 patients and 91 clinicians. Three broad analytical themes were presented: The first was pragmatic and described how patients and clinicians used SMBP, how they interpreted the results, to what patients attributed high/low/change in BP, and what actions are taken based on SMBP. The second theme described the balance between SMBP being perceived as convenient and reassuring contrasted with the potential for causing anxiety and uncertainty. The final theme dealt with patient empowerment, autonomy and self-efficacy, and how SMBP changes the traditional patient-clinician dynamic.	SMBP was successful facilitating the interaction in consultations about hypertension, bridging a potential gap in the traditional patient-clinician relationship. Uncertainty could be reduced by providing information specifically about how to interpret SMBP, what variation is acceptable, adjustment for home-clinic difference, and for patients, what they should be concerned about and how to act.

Research question (from 1.10.2)	Methods	Main findings	Implications
3. How is SMBP currently used in UK general practice?	Regionally representative web-based survey of UK general practitioners	Results were available for 300 GPs (94% of those who started the survey). GPs reported using self-monitoring to diagnose hypertension (169/291; 58%; 95%CI 52 to 64) and to monitor control (245/291; 84%; 95%CI 80 to 88), the former having significantly increased since 2011 (from 37%; 95%CI 33 to 41; P<0.001) with no change in monitoring for control. More than half of GPs used higher systolic thresholds for diagnosis (118/169; 70%; 95%CI 63 to 77) and treatment (168/225; 75%; 95%CI 69 to 80) than recommended in guidelines, and under half (120/289; 42%; 95%CI = 36 to 47) adjusted the SMBP results to guide treatment decisions.	Since new UK national guidance in 2011, GPs are more likely to use SMBP to diagnose hypertension. The proportion using SMBP to monitor control to treatment remained high. However, significant proportions of GPs continue to use non-standard diagnostic and monitoring thresholds. The use of out-of-office methods to improve the accuracy of diagnosis is unlikely to be beneficial if suboptimal thresholds are used.
4. What are patient experiences of SMBP in UK general practice?	Framework analysis of semi-structured interviews with hypertensive patients	Eleven participants were interviewed from two practices in Oxfordshire. Seven broad codes were created, three analytical codes exploring components of the Chronic Care Model directly relevant to patients, and four describing individual context and experiences of SMBP. SMBP was often taken up by patients at the request of their GP, but otherwise patients did not monitor regularly. Patients were empowered when they felt in control of their BP, however felt anxious and unable to enact positive change when their BP was high. Community support for SMBP was lacking, as was specific information for patients to utilise SMBP to improve their BP control	Patients were happy to use SMBP to provide information for clinical decision making. When patients were well controlled, SMBP was empowering and enjoyable for many. Patients were concerned about the risks of high BP, particularly stroke, and often overestimated the risk. SMBP for those with high BP could be disempowering as patients felt unable to make positive change. Information must be tailored to individual patients, and include action planning and goal setting.

Research question (from 1.10.2)	Methods	Main findings	Implications
5. What are patient preferences for hypertension management including SMBP?	Online survey including discrete choice experiment: pilot study	The on-line survey was completed by 167 participants. All attributes contained levels with significant coefficients showing that they were all important in decision making (attributes: model of care, frequency of BP measurement, five year risk of stroke/heart attack, cost). Risk reduction was a significant driver of choice, and patients were willing to pay £1,130 for 25% reduction in five year risk of cardiovascular events. Participants preferred pharmacist management over the other options, and perhaps surprisingly GP management was the least preferred.	Patients were willing to choose, and make trade-offs in terms of cost and risk, between new models of care for hypertension. Pharmacist management was most preferred, perhaps representing greater convenience, although this needs further investigation. Reduction of CVD risk was a significant component of choice. Models of care outside the clinic environment were preferred to the standard GP management option, and the reasons for this require further investigation in order to provide the package of care that is provides the greatest utility, and therefore high levels of uptake/adherence.

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