EXPLORING THE ROLE OF BLOOD PRESSURE SELF-MONITORING IN THE MANAGEMENT OF WOMEN WITH HYPERTENSIVE PREGNANCIES

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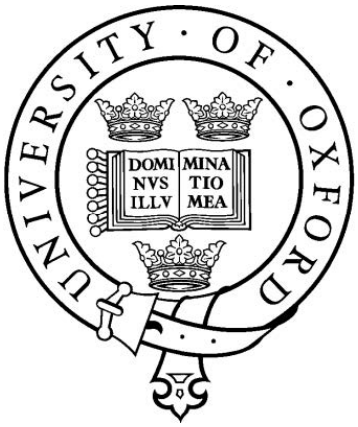

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Dedication

To Stephen, Peter and Joseph Hobbs – for your unfailing support, love and joy.

To my parents and brother – for providing the belief, opportunities and inspiration.

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I owe a large debt of gratitude to many people for their support and guidance throughout the journey of this research, without whom this work and thesis would not have been possible. I am immensely grateful to my three supervisors for their unstinting patience, encouragement and generosity with their time. From the very beginning, Professor Richard McManus has provided me with the opportunities and the faith, that I could complete this work. Richard, you will be glad to know that I have finally learned the benefit of a GANTT chart and thank you for all your support and wisdom over the years. Professor Lucy Chappell has been a constant source of inspiration, motivating me to push through the challenges. Thank you Lucy, for going above and beyond when sharing your expertise and your time. Professor Sue Ziebland has been a constant font of wisdom. Sue, I learned very quickly to write down your pearls. Thank you for patiently guiding me to think critically, and for raising the standard of my qualitative enquiry.

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Statement of Contribution

This thesis reports on a mixed methods study which compromised of a randomised controlled feasibility trial (OPTIMUM-BP) and parallel qualitative studies including ethnographic observations and interviews. Chapters 2-4 concern the OPTIMUM-BP trial and Chapters 5-8 report the qualitative studies.

I was the Principal Investigator for OPTIMUM-BP, the randomised controlled feasibility study with parallel qualitative studies, reported in this thesis. I designed and wrote the protocol for the mixed methods study, building on previous BP self-monitoring study materials and learnings from the hypertension research group at the Nuffield Department of Primary Care Health Sciences, led by my supervisor Professor Richard McManus. I received feedback and was supported in these activities by all three supervisors (Professor Richard McManus, Professor Lucy Chappell, and Professor Sue Ziebland), and by Senior Researcher, Dr Katherine Tucker. The technical telemonitoring component of the BP self-monitoring intervention for OPTIMUM-BP was developed by a team from the Institute of Biomedical Engineering led by Professor Lionel Tarassenko and including Dr Carmelo Velardo and Dr Mauro Santos; with contributions from myself, my supervisors, Oxford site PI Dr Lucy MacKillop and my DPhil colleague and obstetrician Dr Alexandra Cairns. I was responsible for obtaining ethics and research and development approvals. I started as trial manager and then this role became the responsibility of first Dr Marloes Franssen and then Eleanor Temple from the Primary Care Clinical Trials Unit. See Appendix 1 for details of the full trial management group and their roles. I contributed to initial recruitment and quantitative data collection, then this was wholly carried out by the research midwives from each site: Carole Crawford, Layla Lavallee, Jude Kemp, Hannah Wilson, Laura Gardiner and Polly Kay. I wrote the statistical analysis plan with support from trial statistician, Dr Alecia Nickless. I conducted the quantitative data management and analysis, with input and second analysis check by Dr Nickless.

For the qualitative studies, I developed the interview topic guide with support from all three supervisors and the Oxford site PI Dr Lucy Mackillop. Recruitment was again supported by the site research midwives. I conducted all the ethnographic observations and informal and semi-structured interviews. I performed the qualitative analysis with reflexive joint discussions with all three supervisors, and with particular input from Professor Sue Ziebland, and these discussions supported the development and interpretation of themes.

The primary and secondary quantitative analysis for the feasibility trial have been published (see Appendices 9 and 10). Dr Liza Bowen, GP and Academic Clinical Fellow at Guy's and St Thomas' NHS Foundation Trust led on the secondary analysis. The qualitative findings are being developed into three separate publication submissions.

Abstract

This thesis aimed to examine the role of blood pressure self-monitoring (SMBP) for the management of hypertension in pregnancy. Hypertensive disorders of pregnancy (HDP) affect around one in ten pregnancies. They contribute to considerable maternal and fetal morbidity and mortality. Currently, pregnant women with hypertension have more frequent clinic surveillance to monitor for any deterioration in blood pressure and emerging pre-eclampsia or fetal complications. This places a considerable burden on both the woman and the health service and deterioration may occur between visits. An SMBP intervention for use in pregnancy hypertension was developed and tested using a mixed methods approach comprising a randomised controlled feasibility study and parallel qualitative studies.

The pilot randomised controlled trial compared SMBP with usual care (2:1) recruiting pregnant women from four UK maternity centres. 86 women with chronic hypertension (55 SMBP, 31 control) and 72 with gestational hypertension (49 SMBP, 23 control) were randomised and outcome data and analysis were completed for 154 (97%). There were high recruitment (71%), adherence (SMBP 5.5 days per week) and persistence rates (SMBP for >80% of enrolment time). There were similar quality of life scores between randomised groups and greater preference shown by participating women for BP self-monitoring versus usual clinic monitoring. There were no overall group differences in BP control.

Parallel qualitative studies explored the experiences and perceptions of pregnant women and their clinicians using the self-monitoring intervention. These included observations of 38 clinics and semi-structured interviews with 24 women and 8 clinicians. Women with hypertension were highly motivated to use BP self-monitoring. This enthusiasm was in the context of valued continuity of care from expert clinicians. Despite women's and clinicians' joint goal for a healthy mother and baby, there wasn't always consensus regarding how best to achieve this. For example women and clinicians gave difference precedence to home and clinic BP readings with important

implications for antihypertensive medication adherence which could ultimately affect maternal BP control.

These findings together suggest that SMBP is a feasible and acceptable intervention to trial on a larger scale for the management of hypertension in pregnancy. However, because women and their clinicians could ascribe different meanings to the home and clinic BP readings this in turn influenced subsequent perspectives around treatment. Clinicians could better support shared decision making with enhanced awareness of and discussion around women's experiences of home monitoring and treatment concerns. Further research is needed to understand the relationship between home blood pressure readings and clinical outcomes to inform these discussions.

Abbreviations

ABPM	……	Ambulatory blood pressure monitoring
ACOG	……	American College of Obstetricians and Gynecologists
AHT	……	Antihypertensive
ARBs	……	Angiotensin receptor II blockers
BMI	……	Body mass index
BNF	……	British national formulary
BP	……	Blood pressure
CCF	……	Congestive cardiac failure
CHIPS	……	Control of Hypertension in Pregnancy Study
CHTN/CH	……	Chronic hypertension
CI	……	Chief Investigator
95% CI	……	95% confidence interval
CRF	……	Case report form
CTG	……	Cardiotocography
CVA	……	Cerebrovascular accident
CVD	……	Cardiovascular disease
DBP/DIA	……	Diastolic blood pressure
DDD	……	Defined daily dose
EFW	……	Estimated fetal weight
EPAU	……	Early pregnancy assessment unit
ESC	……	European Society of Cardiology
ESH	……	European Society of Hypertension
GDM	……	Gestational diabetes mellitus
GH	……	Gestational hypertension
GP	……	General practitioner
HBPM	……	Home blood pressure monitoring
HCP	……	Health care provider
HDP	……	Hypertensive disorder of pregnancy
HDU	……	High dependency unit
HELLP	……	Haemolysis, elevated liver enzymes and low platelets
HTN	……	Hypertension
ICF	……	Informed consent form
ID	……	Identification
IMD	……	Index of multiple deprivation
IOL	……	Induction of labour
IQR	……	Interquartile range
ISSHP	……	International Society for the Study of Hypertension in Pregnancy
IUGR	……	Intrauterine growth restriction
MAP	……	Mean arterial pressure
MAU	……	Maternity assessment unit
MMR	……	Maternal mortality ratio
MRI	……	Magnetic resonance imaging
NHS	……	National Health Service
NICE	……	National Institute of Health and Care Excellence
NICU	……	Neonatal intensive care unit
NIHR	……	National Institute for Health Research

NS	……	Not specified
OP	……	Out-patients
OR	……	Odds ratio
OSOP	……	One sheet of paper (method)
PC-CTU	……	Primary Care Clinical Trials Unit
PCR	……	Protein:creatinine ratio
PET	……	Pre-eclampsia
PI	……	Principal Investigator
PIS	……	Participant information sheet
PPI	……	Patient and public involvement
PRECOG	……	Pre-eclampsia Community Guidelines
RCOG	……	Royal College of Obstetricians and Gynaecologists
RCT	……	Randomised controlled trial
SAE	……	Serious adverse event
SAP	……	Statistical analysis plan
SBP/SYS	……	Systolic blood pressure
SCT	……	Social cognitive theory
SD	……	Standard deviation
SGA	……	Small for gestational age
SMBP	……	Self-monitoring blood pressure
SMFM	……	The Society for Maternal-Fetal Medicine
SMS	……	Short message service
SOGC	……	Society of Obstetricians and Gynaecologists of Canada
SOMANZ	……	Society of Obstetric Medicine of Australia and New Zealand
TMG	……	Trial Management Group
UC	……	Usual care
USS	……	Ultrasound scan
VAS	……	Visual analogue scale
WCHTN	……	White coat hypertension
WHO	……	World Health Organisation

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Chapter 1: Introduction

1.1 Overview

Hypertensive disorders of pregnancy (HDP) affect around one in ten pregnancies(1). They contribute to considerable maternal and fetal morbidity and mortality. Currently, screening and monitoring for HDP is undertaken using antenatal clinic blood pressure and proteinuria measurements. However, development or deterioration of HDP can occur between clinic assessments.

This thesis will examine the role of blood pressure self-monitoring for the management of hypertension in pregnancy, using a mixed methods approach comprising a randomised controlled feasibility study and parallel qualitative studies. Chapters 2-3 describe the randomised controlled feasibility trial and Chapters 4-8 report the parallel qualitative studies including ethnographic observations, which provide an in depth exploration of the perceptions and use of the intervention in the context of pregnancy hypertension.

In this introductory chapter, I provide an overview of the hypertensive disorders of pregnancy: their definitions, epidemiology, pathophysiology and associated complications, before discussing the clinical practice guidelines for their management. I then discuss the existing evidence base for blood pressure self-monitoring in the general adult population with chronic hypertension and the knowledge that is accruing about its possible use in pregnant women.

1.2 Definitions

The hypertensive disorders of pregnancy (HDP) include: chronic hypertension (CHTN), gestational hypertension (GH), white-coat and masked hypertension and pre-eclampsia. Broadly, hypertension in pregnancy can be chronic (pre-dating pregnancy or diagnosed in the first 20 weeks' of pregnancy) or newly diagnosed after 20 weeks' gestation and particular to that pregnancy (gestational hypertension and pre-eclampsia). There are multiple definitions for these different disorders but the current classification from ISSHP(2) are:

Chronic hypertension: diagnosis predating pregnancy or diagnosed within pregnancy before 20 weeks' gestation with a clinic measured systolic blood pressure (SBP) ≥ 140 mmHg and/or a diastolic blood pressure (DBP) ≥ 90 mmHg

Gestational hypertension: raised blood pressure as defined above but arising de novo at or after 20 weeks' gestation and without proteinuria or any biochemical or haematological abnormalities

White-coat hypertension: raised office/clinic blood pressure as defined above but a normal blood pressure measured at home/work (<135/85 mmHg)

Masked hypertension: normal blood pressure at office/clinic but a raised blood pressure at other times, usually diagnosed by 24-hour ambulatory blood pressure monitoring (ABPM) or self-monitoring blood pressure (SMBP)

Pre-eclampsia: is gestational hypertension with one or more of the following new-onset conditions at or after 20 weeks' gestation: proteinuria[1]; other maternal organ dysfunction[2]; uteroplacental dysfunction[3].

The ISSHP recommendations and the UK National Institute for Health and Care Excellence (NICE) hypertension in pregnancy guidelines(3) also define *severe* hypertension as a SBP 160 mmHg and/or DBP 110 mmHg or greater.

Pre-eclampsia is a prodromal syndrome for eclampsia, which describes a convulsive condition characterised by generalised tonic-clonic ('grand-mal') seizures, which are not attributable to any

[1] Proteinuria is the presence of protein in the urine, optimally assessed with automated dipstick urinalysis and then if positive quantifying with a urine protein/creatinine ratio. A ratio of ≥30 mg/mmol (0.3 mg/mg) is abnormal.
[2] Acute kidney injury (AKI) (creatinine 90 µmol/L; 1 mg/dL); liver involvement (elevated transaminases, e.g. ALT or AST > 40 IU/L) with or without right upper quadrant or epigastric abdominal pain); neurological complications (examples include eclampsia, altered mental status, blindness, stroke, clonus, severe headaches, persistent visual scotomata); haematological complications (thrombocytopenia (platelet count < 150,000/µL, disseminated intravascular coagulation, haemolysis).
[3] Such as fetal growth restriction, abnormal umbilical artery Doppler wave form analysis, or stillbirth.

other cause. In the UK, the majority of women with pre-eclampsia do not progress to eclampsia, as monitoring and intervention (including delivery) is available and utilised.

Another serious complication of pre-eclampsia (and considered to be a manifestation of severe pre-eclampsia that characterises its multisystem nature) is HELLP syndrome(2) which includes haemolysis, elevated liver enzymes and low platelets on blood testing.

There are differences between national clinical guidelines(4-6) and ongoing debate over the exact timing and labelling of the pregnancy hypertensive conditions including pre-existing/chronic hypertension first identified in the first half of pregnancy, transient gestational hypertension, and severe pre-eclampsia and the need for and extent of multi-organ involvement for the diagnosis of pre-eclampsia. The ISSHP recommendations, whilst acknowledging that using a broader diagnostic basis for pre-eclampsia could capture derangement from other underlying causes, seeks to ensure individual women are investigated and managed along the lines commensurate with their increased risk given the unpredictable and potentially serious consequences of the hypertensive disorders of pregnancy. For the purposes of this thesis, the above definitions will be used.

Additionally, the concept of the white-coat effect is pertinent to a body of work exploring the role of blood pressure self-monitoring and the interpretation of home readings. This term describes the phenomena which can affect those with both normotension or a diagnosis of (treated) hypertension, where the clinic blood pressure is higher than a home reading(7, 8).

1.3 Epidemiology of the hypertensive disorders of pregnancy

The hypertensive disorders of pregnancy are an important cause of maternal and fetal morbidity and mortality and are often quoted as affecting approximately one in ten pregnancies(1, 9). However this figure masks regional differences in prevalence and relative changes in incidence of the individual hypertensive disorders that reflect substantial inroads into improving outcomes for many women and their babies.

There is debate in the literature about whether HDP, with the exception of eclampsia, are on the rise(10, 11). Accurate estimates of the rates of pre-eclampsia and eclampsia have been difficult to obtain due to the different definitions employed in the literature and population databases(12, 13) and incomplete ascertainment in low and middle income countries. Abalos et al(14) conducted a systematic review including 78 databases representing nearly 39 million women from 40 countries over the period 2002-2010, which found global estimates for pre-eclampsia and eclampsia of 4.6% and 1.4% respectively, but with wide regional variation. Pre-eclampsia incidence varied from 1.0% in the Eastern Mediterranean region to 5.6% in the African region; and eclampsia ranged from 0.1% in the European and Western Pacific regions to 2.9% in the African region. This variation in rates points towards access to obstetric care playing some part, particularly for incidence of eclampsia. A recent population based cohort study using the National Hospital Discharge Survey (NHDS) datasets in the United States (US), representing 120 million births between 1980-2010, found rates of severe, and to a lesser extent mild, pre-eclampsia, increased over this period, only partly explained by period trends in obesity and smoking(15).

Rates of gestational hypertension also vary across the literature from 2%-15%(13, 16). In a large (n=2,985) randomised controlled trial assessing prevention of pre-eclampsia with low-dose aspirin in healthy nulliparous women in the United States, the incidence of gestational hypertension was 6.3% across both trial groups(17). A more recent retrospective cohort study using hospital discharge data from the US found that gestational hypertension complicated 30.6 per 1000 deliveries (3.1%) between 2003-2004(18). This last study also looked at changes in incidence of gestational hypertension over the period 1987-2004 and found the age-adjusted incidence had increased three-fold.

The age association with chronic hypertension can be seen in the pregnant population as with the general population. In the Fourth National Health and Nutrition Examination Survey (1999-2004) using a nationally representative group of 7,200 women from the US, amongst women of

reproductive age, between 1-4% aged 18-29 years and 5-15% aged 30-39 years in the US had chronic hypertension(19, 20). In this same survey, there were increases in age-standardised prevalence rates for chronic hypertension in all ethnic-by-gender subgroups since the last survey ten years earlier, but increases were greatest for women with average relative increases of 19%. A retrospective cohort analysis using routinely collected discharge data from the US Nationwide Inpatient Sample containing approximately 56.5 million deliveries between 1995-2008, found that the age-adjusted prevalence of all cause (primary and secondary) chronic hypertension increased significantly throughout the period, from 1.0% in 1995-1996 to 1.8% in 2007-2008(21). A more recent study using the US hospital discharge data for 151 million deliveries in the period 1970-2010, found an increase in chronic hypertension age-adjusted prevalence from 0.11% in 1970 to 1.52% in 2010. This represents a 13 fold increase, and importantly there was a persistent 2 fold difference in prevalence between black compared with white women over this period. The most recent published prevalence data from the US comes from a population-based cross-sectional study using 2017 US birth certificate data from more than 3.6 million live births which sought to look at state-specific variation in the pregnancy hypertensive disorders. The authors found Hawaii had the lowest adjusted prevalence of chronic hypertension at 1.0% and Alaska had the highest at 3.4%(22).

These data support a conservative summary figure of 10% for the prevalence of hypertensive disorders of pregnancy (approximately 1-3% for chronic hypertension, 2-6% gestational hypertension, 2-4% for pre-eclampsia and 0.5-1.5% for eclampsia). The increasing incidence, except for eclampsia, likely reflects changes in maternity population characteristics (increasing age and obesity) and improvements in obstetric care (structured antenatal assessments and magnesium sulfate prophylaxis for eclampsia), at least for the high-income countries(23).

1.4 Physiology of blood pressure in pregnancy

The maternal cardiovascular system undergoes major structural and haemodynamic changes during pregnancy, including a decrease in the systemic vascular resistance associated with vasodilation of the systemic and renal vasculature and an increase in heart rate and cardiac output(24). These changes start to occur as early as 5 weeks' gestation and therefore precede full placentation (at average of 10 weeks' gestation)(25). Previous work had suggested a decrease in arterial pressures: systolic (SBP), diastolic (DBP), and mean arterial pressures (MAP). A recent longitudinal prospective study of cardiovascular measurements from 54 healthy women from preconception using pregnancy-validated measurement devices and objectively defined gestational age, showed that arterial pressures decreased to a nadir during the second trimester (dropping 5–10 mmHg below baseline), but the majority of the decrease (75-80%) occurred early in pregnancy (at 5 to 8 weeks' gestation) compared with preconception values(26). Arterial pressures began to increase during the third trimester and returned close to preconception levels postpartum.

In the course of developing early warning scores for pregnant women using vital signs, a recent systematic review of 39 studies found great heterogeneity between studies, including in mean longitudinal blood pressure values, influenced by differences in measurements from manual and automated devices and specification of gestation(27). The authors found that overall decreases in mid-pregnancy blood pressure were smaller than previously postulated in the literature, approximately 5 mmHg for SBP and DBP, and that over the 48 year period of the included studies there had been an increase in diastolic blood pressure. A recent UK longitudinal cohort study using pregnancy-validated measuring devices and a healthy representative pregnant population (n=1,041) generated gestation-specific average ranges for vital signs for the development of an obstetric early warning score system and found only a ~1 mmHg SBP and DBP drop from 12 weeks' gestation(28).

1.5 Pathophysiology of hypertensive disorders of pregnancy

The focus of this section is a brief summary of the risk factors for pre-eclampsia and gestational hypertension and these two conditions will be considered together. These pregnancy specific hypertensive disorders are thought to lie along a continuum of clinical manifestations of maladaptive maternal and placental interactions.

Cases of pre-eclampsia have been documented for more than 2000 years. It has also long been established that a placenta, but not a fetus, is required and the syndrome usually resolves shortly after removal of the placenta(29). Despite acknowledgement that pre-eclampsia results from a disorder of placentation, the exact pathophysiology remains ill defined. A recent review by Burton et al(30) describes emerging evidence of at least two subtypes: early and late onset pre-eclampsia, and that other subtypes are likely to be identified. The early form is thought to be of a primarily placental cause and the late onset form related to the interactions between placental senescence and a maternal genetic predisposition to cardiovascular and metabolic disease. However, these subtypes are again considered to exist along a continuum of related underlying cellular mechanisms.

In early-onset pre-eclampsia there is a deficient remodelling of the spiral arteries (terminal branches of the uterine vasculature within the endometrium) that supply the placenta. This was first described by Brosens et al in the 1960s(31). Instead of the low-velocity and -pulsatile maternal blood flow that results from effective remodelling and dilatation of the spiral arteries, there is altered haemodynamics in the placental bed often associated with the high resistance uterine artery Doppler waveforms seen on ultrasound scan before the clinical onset of pre-eclampsia. MRI (magnetic resonance imaging) and histological studies have also shown acute atherosis along with microthrombi in the placental bed in cases of early pre-eclampsia(32). The maternal malperfusion is associated with focal necrosis of the syncitiotrophoblast with loss and

distortion of the microvilli of the placenta. These morphological changes are reflective of placental ischaemia and stress at the molecular level.

It is unclear why there is deficient placentation and cardiovascular, genetic and immunogenic factors have been postulated and are supported by the diverse range of risk factors associated with pre-eclampsia including: advanced maternal age, pre-gestational diabetes, maternal BMI>30 kg/m^2, chronic hypertension, chronic kidney disease, previous pre-eclampsia, family history of pre-eclampsia, primiparity, short duration of sexual relationship previous to pregnancy, primipaternity(1, 33, 34). Candidate gene and genome wide association studies (GWAS) have been performed but no maternal sequences have been reliably associated with the disorder. Pregnancy involves the interaction between maternal and fetal genes, which might explain why studies exploring the maternal genome alone have met with limited success. Recently some authors have focused on the interaction between maternal cardiometabolic and placental dysfunction(35, 36). This focus was stimulated by the fact that typical placental lesions are not specific to or found in many cases of pre-eclampsia(37), that many cardiovascular risk factors also increase the risk for pre-eclampsia(38, 39) and acknowledging the poor long-term cardiovascular outcomes for this group of women(40, 41). A longitudinal Norwegian population-based study including 3,225 women with singleton pregnancies, found that the positive association between women affected by pre-eclampsia or gestational hypertension and postpartum poor cardiovascular risk factors (including raised systolic and diastolic blood pressures and unfavourable lipid profiles) was all but removed when adjusting for pre-pregnancy measurements, suggesting that the positive association is strongly influenced by antecedent shared factors rather than reflecting a direct influence of the HDP on the maternal cardiovascular system(42).

Notwithstanding the exact ordering of events, placental stress is associated with release of a complex mix of factors, including pro-inflammatory cytokines, exosomes and anti-angiogenic

agents. The relative importance and causal mechanisms of these factors remains poorly understood. Release of these factors leads to dysfunction of the maternal peripheral endothelial cells, and alongside a systemic inflammatory response, this leads to the clinical syndrome of pre-eclampsia(43). Due to involvement of the maternal endothelium, pre-eclampsia is a systemic syndrome with poor perfusion to virtually all organs importantly including the central nervous system, liver and kidneys and many of the changes are similar to those seen in hypovolaemic shock. Concomitant activation of the coagulation cascade to varying amounts in individual women, gives rise to microthrombi which further reduce organ perfusion. Numerous placental factors could trigger the systemic syndrome and there has been a protracted search for this 'link' between abnormal placentation, placental ischaemia and the maternal syndrome. Previous proposed mediators have included the pro-inflammatory cytokines (e.g. IL-6)(44), asymmetric dimethylarginine (ADMA)(45), fibronectin(46), and placental exosomes(47).

Of the potential mediators the most promising current candidates are soluble fms-like tyrosine kinase-1 (sFlt1) and placental growth factor (PlGF) and their relative balance(48). Angiogenesis (physiological development of new vessels from pre-existing vessels) is promoted by angiogenic factors including PIGF and VEGF-1 (vascular endothelial growth factor 1). sFlt binds and antagonises VEGF and PlGF reducing their supply to the maternal systemic endothelium, and is therefore antiangiogenic(43). In pre-eclampsia, maternal circulating sFlt1 expression is increased(49) and levels of PlGF are decreased. Circulating levels of these factors change in advance of the clinical manifestations of pre-eclampsia(50) and recent observational(51-53) and trial data(54, 55) support their use as adjunctive diagnostic tests as part of care pathways for pre-eclampsia.

There are no proven therapies to prevent all cases of pre-eclampsia, but low dose aspirin is of benefit for women at increased risk of pre-eclampsia(56, 57). Clinical management has focused on maternal and fetal surveillance, efficient treatment of hypertension, eclampsia prophylaxis

with intravenous magnesium sulfate and tests to predict poor outcomes and to guide expedited delivery in the presence of early clinical signs.

1.6 Complications of hypertensive disorders of pregnancy

The HDP carry a significant burden of adverse outcomes for the mother, fetus and offspring throughout the pregnancy journey into the postnatal period and for future long-term cardiovascular risk.

A recent systematic review of pregnancy outcomes for women with chronic hypertension (n=795,221 pregnancies), including 55 studies over the period from first publication to 2013, confirmed the burden of maternal and perinatal morbidity and mortality associated with this condition(58). The authors found a nearly 8 fold increased risk for superimposed pre-eclampsia, and all adverse neonatal outcomes (preterm delivery< 37 weeks, birth weight<2500g, neonatal unit admission and perinatal death) were at least twice as likely for pregnancies affected by chronic hypertension compared with the general pregnant population. One of the included studies, followed up 763 women with chronic hypertension through their pregnancy and found the rate of superimposed pre-eclampsia was significantly greater in women who had hypertension for at least four years (31% versus 22%)(59).

Pregnancies complicated with chronic hypertension are also at increased risk from placental abruption and stillbirth. A systematic review which included nine observational studies, revealed the odds of abruption are doubled for women with chronic hypertension, compared with a normotensive population(60). This risk is increased further with superimposed pre-eclampsia. Sibai et al(59) completed a trial including 763 women with chronic hypertension and the rate of placental abruption was 3% for those with superimposed pre-eclampsia versus 1% for those without this complication. A retrospective cohort study looking at risk factors for term stillbirth in more than 150,000 singleton pregnancies in the U.S. found chronic hypertension to be

independently associated and it doubled the background risk from 0.8 to 1.7 per 1000 pregnancies(61).

There is ongoing debate about the exact contribution superimposed pre-eclampsia makes to the poor maternal and perinatal outcomes for pregnancies complicated with chronic hypertension. Some authors suggest that a subset of women with 'high risk' chronic hypertension characterised by secondary hypertension, previous perinatal loss, SBP≥180 mmHg or DBP≥110 mmHg, or target organ damage, are at an increased risk of developing serious long-term maternal complications such as pulmonary oedema, encephalopathy, acute renal failure or cerebral haemorrhage, independent of developing pre-eclampsia/eclampsia(62-65). However, review of this literature reveals at least a proportion of the included cases from the information provided would now be diagnosed with pre-eclampsia according to current definitions.

Similar to chronic hypertension, women with gestational hypertension are at increased risk of transitioning to pre-eclampsia, although there are different rates reported in the literature for this progression, from 17% to 42%(18, 66) . There is ongoing debate regarding whether GH is an earlier manifestation of pre-eclampsia along a spectrum, or whether these disorders are distinct entities(67). Severity of hypertension is an important predictor of poor outcome in gestational hypertension. Pregnancies affected by severe gestational hypertension (defined as SBP≥160 mmHg or DBP≥110 mmHg) were found to be at greater risk of poor maternal and perinatal outcomes compared with pregnancies with mild pre-eclampsia (SBP<160mmHg and DBP<110 mmHg, proteinuria ≥300mg protein in 24 hour urine collection or ≥2+ protein urine dipstick)(68). In the presence of severe hypertension, proteinuria did not increase the rates of preterm delivery or delivery of small-for-gestational-age infants.

Several epidemiological studies have shown the increased risk of both haemorrhagic and ischaemic stroke associated with pregnancy and with the HDP in particular, compared with age-matched non-pregnant populations (69-72). Liu et al(69) examined the incidence and risk factors

for pregnancy-related strokes using a large Canadian Hospitals Discharge Database for 2003-2016. In that period they identified 524 stroke cases among 3,907,262 deliveries and incidence had increased from 10.8 per 100,000 to 16.6 per 100,000 deliveries and the temporal trend remained after adjustment for age. Haemorrhagic strokes made up the majority of cases (307 cases, 58.6%) and most occurred in the postpartum period (270 cases, 51.5%). Risk factors included older maternal age, hypertensive disorders of pregnancy including chronic hypertension, and maternal congenital heart disease. The case fatality rate was substantial at 7.4%. In a large population-based cohort study of women of reproductive age in England (age 15–49 years), the authors found that the baseline incidence of stroke was 25.0/100,000 person-years during non-pregnant time. The incidence rate dropped during early pregnancy (postulated by the authors due to the slight reduction in blood pressure at this time), but was 9-fold higher in the peripartum period (161.1/100,000 person-years). Approximately 25% of the women with pregnancy-related-stroke had diagnoses of hypertension, much higher than expected in an age-matched general population, indicating that hypertension is an important risk factor for pregnancy-related stroke(73). There is some evidence to suggest that stroke amongst women with HDP may be reducing, at least within a US population(74). Wu et al analysed over 4.2 million HDP delivery hospitalisations (2004-2014) and found that although incidence of HDP was increasing, the rate of stroke within this population was decreasing (10 to 6 per 10,000)(74). The authors hypothesised this may be because of improved cardiovascular disease (CVD) optimisation, but were wary of a reversal in this trend due to increasing obesity and sedentary lifestyles.

In addition to antepartum and peripartum complications, several large epidemiological studies have found a consistent association between hypertensive disorders of pregnancy and long-term maternal cardiovascular disease and mortality. Meta-analyses have shown an overall fourfold increase in rate of heart failure and twofold increased risk of coronary heart disease, stroke and death from cardiovascular disease in women with previous pre-eclampsia(75). A large UK pregnancy cohort using linked electronic health records covering a 20 year period (1997-2016) of

1.3 million women with nearly 1.9 completed pregnancies, looked at risks for cardiovascular disorders following a pregnancy complicated by a hypertensive disorder, including pre-eclampsia. For women with pregnancies affected by pre-eclampsia they had a nearly twofold increased risk of any stroke, heart failure and cardiovascular death and more than fourfold increased risk for incident chronic hypertension, with similar patterns of association seen for the other HDP(76). The authors highlighted that these findings support the use of HDP as a screening tool for future cardiovascular risk.

The American Heart Association updated their 2011 guidelines for the prevention of cardiovascular disease in women emphasising that a history of pre-eclampsia or gestational hypertension should be considered a risk factor as part of the evaluation of cardiovascular risk for a woman(77). It is still unclear how any affected individual woman should be screened and followed-up and this is the focus of current research(78-82).

The infants from pregnancies affected by a hypertensive disorder are also at increased risk for future cardiovascular disease, although the relationship is not as well established as it is for the mother. These infants have higher blood pressures in the first five years and into young adulthood(83) and an increased risk for stroke in later years(84). Up to one third of infants born to mothers with pre-eclampsia are growth restricted and have the same increased risks of obesity, diabetes and hypertension as growth restricted infants from other causes(85).

In addition to the burden of morbidity, the hypertensive disorders of pregnancy are also a major cause of maternal mortality worldwide. The most recent World Health Organisation (WHO) systematic analysis of causes of global maternal death covered the period 2003-2009 and included data from 60,799 deaths(86). This analysis found that of the estimated 2.4 million maternal deaths in this period, nearly three quarters (73%) were due to direct causes. After haemorrhage (27%), hypertensive disorders were the second commonest direct cause of death (14%), but the most prominent cause in the Latin America and Caribbean regions. A similar

pattern (although different absolute numbers due to their contrasting methodologies) of maternal mortality was found by the systematic analysis for the Global Burden of Disease Study 2013(87) which sought to track progress towards the Millennium Development Goal (MDG5) of a 75% reduction in the maternal mortality ratio (MMR) between 1990 to 2015. The authors found an overall worldwide decrease in maternal mortality of 1.3% per year since 1990 but with large regional variation. Although the absolute numbers of deaths from hypertensive disease have fallen in most areas, they still account for around 40,000 maternal deaths each year(88).

In the UK, confidential enquiries carried out over the last six decades into the causes of maternal deaths, have sought to identify avoidable factors in clinical care and make recommendations with the aim of reducing maternal morbidity and mortality. Over this period the hypertensive disorders contributed towards about a fifth of all direct maternal deaths until 2012-2014 when they fell to only 4.5% of direct maternal deaths, and in the report covering the triennium 2015-2017 they had fallen to sixth place accounting for six direct maternal deaths, reflecting a rate of 0.24 per 100,000 maternities(23, 89). Over the entire 65 year period covered to date by the confidential enquiries, intracranial haemorrhage has been the single most common specified cause of death from hypertension, responsible for 336 of 1063 maternal hypertensive deaths (21.7%). Other specified causes of hypertensive death, mainly related to complications from pre-eclampsia/eclampsia have been renal failure, hepatic failure or necrosis, pulmonary failure including acute respiratory distress syndrome and pulmonary oedema. Reductions in maternal deaths in the UK from hypertensive disorders over this period are likely multifactorial but improvements have been made following recommendations for earlier recognition of hypertension and reducing treatment thresholds from 160 to 150 mmHg(23).

In the last 15 years, cardiovascular disease has remained the leading cause of maternal deaths both during and after pregnancy (within 42 days of delivery) in the UK and Ireland. Seven of the nine women who died from aortic dissection in the triennial report 2015-2017 also had

hypertension or pre-eclampsia(89). Thus for a proportion of those women who died from cardiac disease, hypertension will have complicated their condition.

Given the considerable maternal and perinatal morbidity and mortality burden of the pregnancy hypertensive disorders, the scientific and clinical communities have committed to a sustained effort to improve outcomes for this group of women and their babies producing several international and national clinical guidelines, discussed below.

1.7 Management of hypertensive disorders of pregnancy

There have been considerable improvements in reducing maternal morbidity and mortality from HDP in the developed world and particularly in the UK as detailed above, mainly through structured antenatal care, early involvement of senior clinicians, awareness of fluid overload with attention to strict fluid balance and use of magnesium sulfate for the prophylaxis of eclampsia. In the UK, from 2000 onwards, the maternal mortality reports focused on the need to effectively control hypertension, as other organ-specific causes of hypertensive death had all reduced leaving cerebral, the majority intracranial haemorrhage, as the main cause(23). Recommendations from the reports have been incorporated into the National Institute for Health and Care Excellence (NICE) Guideline for the management of hypertension in pregnancy, first published in 2010(16) which makes recommendations for the diagnosis, monitoring and management of pregnancy hypertension and recently updated in 2019(3).

A systematic review of international and national clinical practice guidelines was published in 2014(90). I updated the findings from this with an on-line search up to December 2020, and the sections pertinent to antenatal blood pressure monitoring and antihypertensive management for the seven identified English-language guidelines have been summarised and presented in Tables 1 and 2. The mixed methods study presented in this thesis was designed in 2015, thus guidelines summarised in Table 1 were in use at this time(4, 16, 91-95). Table 2 presents summaries for the most recent updates (2020) for these guidelines(2, 3, 5, 6, 96-98). There is consistency across

these guidelines for the definitions of hypertension, proteinuria, chronic and gestational hypertension and recommendations to initiate antihypertensive treatment for systolic blood pressure ≥160 mmHg or diastolic blood pressure ≥110 mmHg. However from these summaries it is evident that despite recent updates of most guidelines in 2018-2020, currently there is no international consensus on regimens for monitoring and managing the hypertensive disorders of pregnancy. There are different blood pressure thresholds for treatment initiation (for non-severe hypertension) and blood pressure targets whilst on treatment, and variation in recommendations for choice of antihypertensives.

The NICE guidelines (both 2010 and 2019 versions)(3, 16) offer the most comprehensive recommendations for blood pressure monitoring for the HDP. NICE recommend additional antenatal consultations for women with chronic hypertension dependent on individual circumstances; and these might need to be weekly for poor or every 2-4 weeks if good blood pressure control, as recommended in the 2019 update. Home blood pressure monitoring is mentioned in the American College of Obstetricians and Gynecologists (ACOG) 2013 guidelines(99) as a possible method for providing blood pressure measurement in addition to clinic measurement for twice weekly monitoring for gestational hypertension and also suggests using home blood pressure monitoring in the context of poorly controlled chronic hypertension, but no further details are provided. In the 2018 update of the guidelines, ACOG suggest that home monitoring may reduce the frequency of clinic visits in the case of *"marginal blood pressure control",* but provide no more details(6). The International Society for the Study of Hypertension in Pregnancy (ISSHP) 2018 guideline offers further advice regarding home blood pressure monitoring (HBPM) stating "*it is a useful adjunct in the management of chronic hypertension and is mandatory in the management of white coat hypertension*"(2). ISSHP advise using an average BP over several days rather than acting on single raised readings for women using HBPM in the context of non-severe hypertension (SBP≥ 160 mmHg or DBP≥ 110 mmHg). No other specific

regimens regarding HBPM are provided. These recommendations are made in the absence of evidence of benefit.

Table 1: Clinical practice guidelines (English language national/international) current in 2015 for monitoring and management of HDP

	WHO (2011) (91)	ISSHP (2014) (92)	ESC (2011) (100)	NICE (2010) (16)	ACOG (2013) (94)	SOGC (2014) (95)	SOMANZ (2014) (4)
	International	International	European	UK	USA	Canada	Australasia
BP monitoring							
Chronic hypertension	Not specified	Not specified	Not specified	Schedule additional antenatal consultations based on individual needs	If "poorly controlled"* BP and CHTN suggest HBPM. *Not defined.	Admit women with severe HTN SBP≥160 mmHg AND/OR DBP≥110 mmHg	Frequency of review determined by factors such as blood pressure control, number of agents used, associated disorders (e.g. renal disease, proteinuria) and by the gestation
Gestational hypertension	Not specified	Not specified	Not specified	Mild HTN (140/90 to 149/99 mmHg) not more than once per week. Moderate HTN (150/100 to 159/109 mmHg) at least twice per week. Severe HTN (≥160/110 mmHg) admit to hospital until BP<159/109 mmHg, and monitor BP at least four times per day	Twice weekly BP measurement (one in clinic and additional measurement in clinic or at home)	Admit women with severe HTN	Not specified
Pre-eclampsia/ eclampsia	Hospital care and close maternal and fetal monitoring to identify indications for delivery (e.g. uncontrolled hypertension, deterioration in mother's condition)	Not specified	Not specified	Admit and monitor BP at least four times/day (mild and moderate HTN) and more than four times/day depending on circumstances (severe HTN)	Pre-eclampsia without severe features: twice weekly BP measurement as above	Admit women with severe HTN	Not specified

	WHO (2011) (91)	ISSHP (2014) (92)	ESC (2011) (100)	NICE (2010) (16)	ACOG (2013) (94)	SOGC (2014) (95)	SOMANZ (2014) (4)
Symptom monitoring	Not specified	Inform women antepartum and postpartum, about pre-eclampsia, its signs and symptoms, and the importance of timely reporting of symptoms to health care provider	Not specified	Pregnant women should be made aware to seek immediate advice from HCP if they experience any symptoms of pre-eclampsia	Women to monitor symptoms and fetal movements daily	Not specified	Not specified
HBPM	Not specified	Standardised cut-offs for HBPM monitoring have not been established	Not specified	Not specified	As above	Not specified	Not specified
White coat hypertension	Not specified	Elevated clinic or office BP with normal BP by 24hr ABPM in the first half of pregnancy	Not specified	Not specified	Hypertension primarily in the presence of HCP	BP elevated in the office but consistently normal outside of the office: <135/85 mmHg by ABPM or HBPM	Elevated BP in the presence of a clinical attendant but normal BP otherwise as assessed by ABPM or HBPM

	WHO (2011) (91)	ISSHP (2014) (92)	ESC (2011) (100)	NICE (2010) (16)	ACOG (2013) (94)	SOGC (2014) (95)	SOMANZ (2014) (4)
BP management							
Starting treatment	Recommended for severe hypertension (not defined) No recommendation made for non-severe hypertension – pending further evidence	Recommended for severe hypertension (SBP≥160 mmHg or DBP≥110 mmHg) May treat non-severe hypertension without comorbidities (SBP 140-159 mmHg or DBP 80-105 mmHg) Recommended for non-severe hypertension with comorbidities	SBP≥140 or DBP≥90 mmHg with GH (+/- proteinuria) or CHTN with superimposition of GH or hypertension with subclinical organ damage or symptoms at any point Any other circumstance SBP≥150 mmHg and DBP≥95 mmHg Severe hypertension (SBP≥170 mmHg or DBP≥110 mmHg) requires hospitalisation	Uncomplicated CHTN, aim to keep BP<150/100 mmHg Do not aim to lower DBP<80 mmHg Women with CHTN and target organ damage aim to lower BP< 140/90 mmHg Refer women with secondary CHTN to specialist In women with GH, treat moderate HTN (150/100-159/109 mmHg) to keep SBP <150 mmHg and DBP 80-100 mmHg Treat women with pre-eclampsia as for GH above	Do not treat mild GH or pre-eclampsia with SBP<160 mmHg or DBP<110 mmHg Treat if severe HTN, sustained SBP≥160 mmHg or DBP≥110 mmHg Refer women with secondary CHTN to specialist Do not treat CHTN without organ damage if BP<160 mmHg or DBP<105 mmHg Treat if CHTN and sustained SBP≥160 or DBP≥105 mmHg	Recommended for severe hypertension (SBP≥160 mmHg or DBP≥110 mmHg) For non-severe HTN without comorbidities (CHTN or GH): treatment may be started to keep SBP 130-155 mmHg and DBP 80-105 mmHg For women with comorbidities keep SBP<140 mmHg and DBP<90 mmHg	Treat all women with SBP≥160 mmHg or DBP≥110 mmHg (Severe HTN defined as SBP≥170 mmHg or DBP≥110) Treatment of mild to moderate hypertension in the range 140-160/90-100 mm Hg should be considered an option and will reflect local practice
BP target	Not specified	Non-severe hypertension no comorbidities, aim to keep SBP 130-155 mmHg and DBP 80-105 mmHg Non-severe hypertension with comorbidities aim for SBP<140 mmHg and DBP<90 mmHg, lower limits unclear	Not specified	As above	For treated women with CHTN maintain SBP 120-160 mmHg and DBP 80-105 mmHg	As above	Not specified, except decisions about target BP for women with CHTN and other conditions, decisions to aim for levels such as SBP 130-140 and DBP 80-90 mmHg (such as outside pregnancy) must be weighed individually

	WHO (2011) (91)	ISSHP (2014) (92)	ESC (2011) (100)	NICE (2010) (16)	ACOG (2013) (94)	SOGC (2014) (95)	SOMANZ (2014) (4)
Antihypertensive medication	Reasonable choices are hydralazine, methyldopa, beta blockers and nifedipine Avoid ACEi, ARBs and sodium nitroprusside	Initial treatment for severe hypertension includes short-acting nifedipine capsules, iv hydralazine or iv labetalol. Refractory hypertension may be treated with sodium nitroprusside. For non-severe hypertension +/- comorbidities: methyldopa, labetalol and beta-blockers except*, nifedipine. Avoid ACEi, ARBs, atenolol* and prazosin.	Mild-moderate hypertension: methyldopa, labetalol or metoprolol. 2nd line nifedipine or isradipine ACEi and ARBs contraindicated Severe hypertension: iv labetalol or oral methyldopa or nifedipine iv sodium nitroprusside if hypertensive crisis	1st line oral labetalol, 2nd line methyldopa or nifedipine For women with severe HTN in critical care, use labetalol (oral or iv) hydralazine (iv) or nifedipine (oral) Advise against ACEi, ARBs and chlorothiazide	For CHTN, recommend labetalol, nifedipine or methyldopa In women with CHTN avoid ACEi, ARBs, renin inhibitors, mineralocorticoid receptor inhibitors unless compelling reason such as proteinuric renal disease Treat acute severe hypertension with iv hydralazine or labetalol or oral nifedipine	For severe HTN (160/110 mmHg) use iv labetalol or hydralazine or oral nifedipine Alternatives are nitroglycerin infusion, oral methyldopa, oral labetalol, oral clonidine, or if refractory, sodium nitroprusside For non-severe HTN can use methyldopa, labetalol, other beta-blockers (not atenolol) and calcium channel blockers (nifedipine) ACEi, ARBs and prazosin are not recommended before delivery	1st line: methyldopa, labetalol and oxprenolol 2nd line: hydralazine, nifedipine and prazosin ACEi and ARBs are contraindicated

Abbreviations: HDP: hypertensive disorders of pregnancy; BP: blood pressure; HBPM: home blood pressure monitoring; SBP: systolic blood pressure; DBP: diastolic blood pressure; HTN: hypertension; CHTN: chronic hypertension; GH: gestational hypertension; APBM: ambulatory blood pressure monitoring; HCP: health care provider; iv: intravenous; ACEi: angiotensin converting enzyme inhibitors; ARBs: angiotension II receptor blockers; mins: minutes.
WHO: World Health Organisation; ISSHP: International Society for the Study of Hypertension in Pregnancy; ESC: European Society of Cardiology; NICE: National Institute for Health and Care Excellence (UK); ACOG: American College of Obstetricians and Gynecologists; SOGC: Society for Obstetricians and Gynaecologists of Canada; SOMANZ: Society for Obstetric Medicine Australia and New Zealand.

Table 2: Updates up to December 2020 for clinical practice guidelines for monitoring and management of HDP

WHO (2020) (96)	Women require regular outpatient monitoring and review. Offer treatment for non-severe hypertension in context of good quality antenatal care follow-up Recommends methyldopa or beta-blockers but guided by individual circumstances. Avoid ACEi, ARBs and sodium nitroprusside
ISSHP (2018) (2)	HBPM is a useful adjunct in the management of chronic hypertension and is mandatory in the management of white-coat hypertension In the absence of severe hypertension (≥160/110 mmHg), suggest using average BP over several days rather than acting upon single readings for women using HBPM Urgent treatment in monitored setting if BP>160/110 mmHg. Oral nifedipine, iv labetalol or iv hydralazine. Oral labetalol 2nd line BP consistently ≥ 140/90 (clinic) or ≥135/85 mmHg (home) should be treated. Target BP DBP 85 mmHg (SBP 110-140 mmHg) in clinic Recommend oral methyldopa, labetalol, oxprenolol, nifedipine, 2nd line hydralazine or prazosin
ESC (2018) (97)	Start treatment if SBP≥140 or DBP≥90 mmHg with GH (+/- proteinuria) or CHTN with superimposition of GH or hypertension with subclinical organ damage or symptoms at any point Any other circumstance then only treat if SBP≥150 mmHg and DBP≥95 mmHg 1st line: methyldopa, beta-blockers (most data for labetalol), and calcium antagonists (most data for nifedipine) Best avoid atenolol, ACEi and ARBs still contraindicated Severe hypertension still defined as (SBP≥170 mmHg or DBP≥110 mmHg) and requires hospitalisation
NICE (2019) (3)	Women with CHTN: offer additional appointments, may need weekly if BP is poorly controlled or every 2-4 weeks if well controlled Keep on antihypertensive medication unless sustained SBP<110 or DBP<70 mmHg or symptomatic hypotension. Offer treatment if sustained SBP≥140 or DBP≥90 mmHg Aim for target BP of 135/85 mmHg. Use labetalol, if not nifedipine or if neither suitable then methyldopa Women with GH: review once-twice/week depending on BP until BP≤135/85 mmHg. Offer treatment if SBP≥140 mmHg or DBP≥90 mmHg. Aim for target BP of 135/85 mmHg If GH with severe HTN (BP≥160/110 mmHg) admit until BP<160/110 mmHg and aim for BP of 135/85 mmHg. Monitor BP every 15-30 mins until BP<160/110 mmHg. Pre-eclampsia: with BP 140-159/90-109 mmHg admit if any concerns, aim for target BP as above, monitor BP at least every 48 hours, more frequently if admitted Pre-eclampsia and BP≥160/110 mmHg admit until BP<160/110 mmHg aim for same BP target, monitor BP every 15-30 mins. If BP<160/110 mmHg at least four times/day
ACOG (2019/2020) (5, 6)	Women with CHTN: start treatment if persistent SBP≥160 or DBP≥110 mmHg. If co-morbidities or renal dysfunction may treat at lower BP thresholds 1t line labetalol and nifedipine Treat sustained SBP≥160 or DBP≥110 mmHg expeditiously. For treated women with CHTN maintain SBP 120-160 mmHg and DBP 80-110 mmHg
Hypertension Canada (2019) (98)	CHTN, GH or PET: recommend treating if SBP≥140 mmHg or DBP≥90 mmHg 1st line: labetalol, methyldopa, long acting nifedipine or other betablockers (not atenolol) Target DBP of 85 mmHg for women with CHTN or GH, similar target could be considered for women with PET Women with severe HTN, SBP≥160 or DBP≥110 mmHg, require admission and urgent antihypertensive treatment
SOMANZ (2014) (4)	Not updated

BP: blood pressure; HBPM: home blood pressure monitoring; SBP: systolic blood pressure; DBP: diastolic blood pressure; HTN: hypertension; CHTN: chronic hypertension; GH: gestational hypertension; iv: intravenous; HCP: health care provider; ACEi: angiotensin converting enzyme inhibitors; ARBs: angiotension II receptor blockers; mins: minutes

There is agreement about the need and urgency for treating SBP≥ 160 mmHg or DBP≥ 110 mmHg because of the evidence that these blood pressure levels (more conservative than those used for expeditious treatment in the nonpregnant population) are a risk factor for poor maternal and fetal outcomes, including maternal stroke(6, 101). Evidence related to the differential effects of various antihypertensive drugs when used for the treatment of very high blood pressure in pregnancy have come from a 2013 Cochrane systematic review of 35 RCTs involving 3573 women with 15 comparisons(102) and more recently a 2018 systematic review and network meta-analysis(103). Whilst the review showed that antihypertensive drugs are effective in lowering blood pressure there is insufficient evidence to show which is most effective. All the trials were small, apart from one large study (1750 women). There was considerable variation regarding the various drug regimens. Analysing the evidence base for the treatment of the hypertensive disorders of pregnancy is further complicated by trying to study relatively rare events as outcomes.

There is no clear consensus across clinical guidelines regarding the management of non-severe hypertension (clinic SBP 140-160 mmHg or DBP 90-110 mmHg), reflecting controversy in the wider literature in this area(62, 63). For non-severe blood pressure levels, the concern is that lowering blood pressure further, in line with clinical guidance for the nonpregnant population, may reduce uteroplacental blood flow leading to detrimental effects on the fetus, such as growth restriction. Some authors propose that it is likely that these women had more elevated blood pressures at baseline and therefore placental vasculature remodelling has taken place in this physiological milieu and caused uteroplacental perfusion to be dependent on these higher pressures(63). Two earlier meta-analyses found an association between greater antihypertensive induced reductions in mean arterial pressure and decreased fetal growth velocity(104, 105).

Other concerns include the possible effects of placental transfer of maternal antihypertensives and their short and long-term sequelae for infants. There have been no studies confirming

teratogenicity of any of the commonly used antihypertensives, including methyldopa, labetalol and nifedipine, supported by a recent systematic review and meta-analysis of the safety of in-utero exposure to antihypertensives(106). Several studies reported increased odds of preterm birth, low birth weight, and congenital malformations in treated patients compared with normotensive untreated reference groups, but these adverse effects were not uniformly observed across different studies of same class of medication. Importantly, similar adverse events were also observed in untreated hypertensive women suggesting confounding by indication and that the underlying hypertension was the cause(107). However, no studies to date have been powered or of sufficient duration to investigate potential more subtle and protracted neurodevelopmental effects in the children born to mothers taking antihypertensives during pregnancy, so uncertainty remains(108).

The recently updated Cochrane review studying the effect of antihypertensive treatment of mild-moderate pregnancy hypertension (defined as SBP 140-169 or DBP 90-109 mmHg), included data from 58 trials (5909 women)(109). The authors found the use of antihypertensives halved the risk of developing severe hypertension (risk ratio 0.49; 95% CI 0.4-0.6) but had little or no effect on other clinically important outcomes such as pre-eclampsia, maternal death, fetal or neonatal death (including miscarriage), small-for-gestational-age babies or preterm birth less than 37 weeks. The Control of Hypertension in Pregnancy Study (CHIPS) trial published in 2015 (not included in the Cochrane review) aimed to evaluate the impact of blood pressure control on pregnancy outcomes, particularly of tighter blood pressure control on fetal outcomes to address concerns about possible fetal growth restriction with tighter maternal blood pressure control(101). Overall, 987 women with non-severe hypertension (75% with chronic and 25% with gestational hypertension) were randomised to “tight” (target DBP 85 mmHg, and SBP<160 mmHg) or “less tight” (target DBP 100 mmHg) blood pressure control using labetalol as the first drug of choice. Women in the “tight” blood pressure control group had reduced incidence of severe hypertension (27.5% vs 40.6%; adjusted odds ratio (aOR) 0.56; 95% CI 0.42-0.74),

thrombocytopenia (platelet count < 100 x 10/L; 1.6% vs 4.3%; aOR 0.38; 95% CI 0.17-0.87) and symptomatic elevation of liver transaminases (1.8% vs 4.3%; aOR, 0.43; 95% CI 0.19-0.95); although there was no significant reduction in serious maternal complications (including death, eclampsia, uncontrolled hypertension, transient ischaemic attack or stroke, pulmonary oedema and renal failure; 2.0% vs 3.7%; aOR 0.57; 95% CI 0.26-1.27). Importantly within the trial there was no impact of "tight" control on perinatal mortality or morbidity (pregnancy loss or high level neonatal care for >48 hours; 30.7% vs 31.4%; aOR 0.98; 95% CI 0.71-1.30) or birthweight <10th percentile or preterm birth. Blood pressure remained consistently lower in the "tight" control group compared with the "less tight" group from randomisation to delivery, although it is of note that even the "less tight" group did not have particularly high mean blood pressure, 139/90 mmHg versus 133/85 mmHg in the tight control group.

The CHIPS investigators also consider the results to be pertinent to women with pre-eclampsia, although this was an exclusion criterion for randomisation, as pre-eclampsia developed in 30% or 48% of women, based on new proteinuria or the broader definition respectively, and these women remained in the treatment groups to which they had been originally randomised after diagnosis. In secondary analyses of the CHIPS trial data, the authors explored outcomes associated with severe hypertension adjusted for randomisation group, and found the occurrence of severe hypertension was associated with an increased risk of pregnancy loss, need for high-level neonatal care > 48 hours, low birth weight, and preterm delivery, independent of pre-eclampsia diagnosis(110).

Four of the recently updated English-language (inter)national clinical practice guidelines (see Table 2: WHO, ISSHP, NICE and Hypertension Canada) now recommend "tight" blood pressure control for all forms of pregnancy hypertension, on the basis of the CHIPS trial results. However, controversy remains, with other organisations considering the current evidence base to be insufficient confirming maternal or fetal benefit from treatment balanced against the theoretical

concerns of reduced fetal growth. The US Society for Maternal-Fetal Medicine (SMFM) has not endorsed comprehensive "tight" control for all forms of pregnancy hypertension(62, 111), but supports the approach recommended by the ACOG Hypertension Task Force which made practice bulletin updates in 2018 and 2020(5, 6). ACOG recommend initiation of antihypertensive therapy for persistent chronic hypertension when SBP ≥160 or DBP ≥110 mmHg, or both, and advise that treating at lower thresholds may be required in the context of co-morbidities. The guidance also recommends *"treatment should be initiated expeditiously for acute-onset severe hypertension"* (SBP ≥160 or DBP ≥110 mmHg or both). However, the college recognises that recent changes made by the American College of Cardiology and American Heart Association for the diagnosis of hypertension outside of pregnancy, including defining elevated (SBP 120-129 mmHg and DBP < 80 mmHg) and stage 1 hypertension (SBP 130-139 mmHg or DBP 80-89 mmHg) groups and recommending starting treatment for patients with stage 1 hypertension and other risk factors for cardiovascular disease(112), means that maternity care providers can be expected to see more women entering pregnancy with treated chronic hypertension and it is reasonable to continue to manage them along these lines. However as one editorial commented, *"To manage BP expectantly at < 160/110 mmHg but emergently at ≥160/110 mmHg, is logically inconsistent*"(113). The approach endorsed by ISSHP in treating mild-moderate hypertension, is to seek "*to reduce the likelihood of developing severe maternal hypertension*"(2). This recognises that blood pressure exists along a continuum (for the individual as well as the population) and severe and non-severe hypertension are not separate clinical entities(114). Also severe hypertension has been used as an important endpoint in its own right as it is prohibitive to power studies for stroke and major morbidity which are rare outcomes in high income settings.

Notwithstanding lack of consensus over thresholds for initiating treatment, the optimal approach to obtaining blood pressure control in pregnancy and avoiding severe hypertension is uncertain. Currently, pregnant women with hypertension usually have more frequent clinic surveillance, as recommended in several guidelines (see Tables 1 and 2) to monitor for any deterioration in blood

pressure, assessing for emerging pre-eclampsia and associated fetal complications(3, 16). Not only does this place a considerable burden on both the health service and importantly the woman herself, but deterioration may occur between clinic visits(115, 116). The current COVID-19 pandemic has also highlighted that face-to-face assessments are not always possible or desirable. Self-monitoring blood pressure may have an important role in the management of pregnancy hypertension. Possible advantages include convenience for the woman, improved medication adherence, increased knowledge and understanding of their condition and health, confirmation and monitoring of white coat or masked hypertension, improved blood pressure surveillance and control with targeted titration of antihypertensive medication, and importantly women's involvement and empowerment within their pregnancy care. A summary of the evidence base for self-monitoring blood pressure in the general adult population with chronic hypertension and in the pregnant population with hypertension (up to inception of this study in 2015) are discussed in the subsequent sections.

1.8 Self-monitoring and self-management of blood pressure in the general adult population

In the general adult population with chronic hypertension, evidence shows that blood pressure self-management that includes self-monitoring and titration of antihypertensives is feasible, leads to significantly improved blood pressure control and higher patient satisfaction than usual care(117-120). The TASMINH2 randomised controlled trial showed that self-management of blood pressure including self-titration of antihypertensives and telemonitoring of home measurements in poorly controlled hypertension resulted in a greater reduction in blood pressure at 12 months follow-up when compared with usual care (mean difference in systolic blood pressure 5.4 mmHg; 95% CI 2.4-8.5; p=0.0004)(121). A randomised controlled trial in patients with high cardiovascular risk (previous history of stroke, coronary heart disease, diabetes, or chronic kidney disease) randomised to self-monitoring combined with an individualised self-titration algorithm or usual care demonstrated an even greater effect on systolic blood pressure

in this at-risk cohort (mean difference SBP 9.2 mmHg; 95% CI 5.7-12.7 as 12 months)(122). A recent systematic review and individual patient data meta-analysis including 25 trials and data from 7,138 patients found that self-monitoring alone was not associated with improved blood pressure control but when combined with co-interventions (including systematic medication titration by HCPs or patients; education or lifestyle coaching) lead to clinically significant reductions in systolic blood pressure at 12 months (up to a 6.2mmHg reduction with the most intense support; 95% CI -9.0 to -3.2)(118).

In addition to improved blood pressure control, home blood pressure monitoring is superior for diagnosis(112) and may better predict cardiovascular disease and mortality than clinic measurement(123-126). HBPM also has high reproducibility and has been shown to be as reliable as ABPM(127). Self-initiated home blood pressure monitoring is becoming increasingly common amongst patients. A UK primary care survey (2016-2017) found that 42% of patients with hypertension were self-monitoring blood pressure(128). An earlier UK survey found SMBP was more common amongst younger groups (aged 18-60 years), ethnic minorities and those in employment(129). Rates were even higher in a cardiovascular health survey in the US, where 54% of respondents with hypertension were self-monitoring, and those who believed that lowering BP could reduce risk of heart attack and stroke were much more likely to self-monitor (56% vs 33%, P=0.01)(130). Several studies have shown patients prefer self-monitoring over both clinic and ambulatory blood pressure monitoring; reasons include clinic monitoring being less convenient, perceived as less reliable, ABPM causing discomfort and disrupting daily activities and home monitoring is easy and gives patients more control(131-133) and these preferences were not influenced by patient demographics(134). SMBP may also be more cost-effective(135). For these considerations, several international and national hypertension clinical practice guidelines recommend home blood pressure monitoring for the routine management of chronic hypertension, including European, American, UK, Canadian and Japanese hypertension societies(112, 136-140).

1.9 Self-monitoring and self-management of blood pressure in pregnancy

Given the clear advantages and effectiveness of self-monitoring in the general adult population with chronic hypertension, self-monitoring of blood pressure may have an important role in the management of women at risk of or with hypertensive disorders of pregnancy. Theoretical advantages for benefit and implementation for SMBP in or around pregnancy include: improved detection of emerging or deteriorating hypertension over intermittent clinic visits, developing greater understanding of HDP and possible adherence with antihypertensive regimens and improved blood pressure control, greater convenience over increased face-to-face consults, improved adherence to a time-limited course of monitoring, a younger age-group more conversant with self-care technological platforms, and leveraging the window of opportunity of pregnancy for life-long awareness and involvement in cardiovascular health. An ambitious aim would be that SMBP could contribute to improved clinical outcomes for women and their babies both within pregnancy and for the life-course.

Similar to the general adult population, pregnant women are increasingly taking up blood pressure home monitoring. In the CHIPS RCT, 38% women (379/987) reported blood pressure monitoring at baseline, with prevalence increasing to 46% (456/986) equally across study groups, during the study(101). Although it is not clear whether this self-monitoring was voluntary or initiated by the clinical teams to achieve the target BP. A recent study surveyed 5181 women in antenatal clinics across England and found 19% were currently self-monitoring and this rose to nearly half of all surveyed women with hypertension(141, 142). Healthcare professionals are also increasingly using home blood pressure monitoring in pregnancy. A recent on-line survey of obstetricians and fetal-maternal medicine specialists across Canada in 2016, found that although clinic measurements were preferred for diagnosis, 60% of clinicians (20/32) relied upon home blood pressure monitoring for ongoing monitoring and management of hypertension during pregnancy(143).

The relevance and potential for BP self-monitoring in pregnancy has been raised in a joint statement from the American Heart Association, American Society of Hypertension, and Preventive Cardiovascular Nurses Association: self-monitoring is *"theoretically ideal for monitoring changes in BP during pregnancy because it is the best technique for providing multiple readings recorded at the same time of day over prolonged periods of time"* but it was noted "*the extent to which it will improve the evaluation and management of hypertension during pregnancy has yet to be shown"(144)*. At the time of developing the studies reported in this thesis, the clinical practice guidelines for the management of HDP did not mention or recommend BP self-monitoring (see Table 1), except for suggesting its use in the context of poorly controlled chronic hypertension but without details(94), and noting that BP thresholds for home monitoring in pregnancy had not yet been established(92).

Concerns have been raised about the accuracy of the blood pressure monitors being used for home monitoring in pregnancy(145) and also about the accuracy of the readings reported by some women(146). A recent study analysed the accuracy of home monitors being used by 127 pregnant women with hypertension, and found that a wide variety of devices were being used (40 different models), but only 25 (20%) of the participants had models validated for general home use, and none of the monitors were validated for use in pregnancy. Despite this, the majority of devices (70-80%) provided accurate BP within 5mmHg systolic and diastolic, but this meant up to one in four women had devices measuring at least 5 mmHg difference compared with sphygmomanometry (as the gold standard), which was not related to the absolute BP(145). It is also of note that appropriate sized cuffs were provided to the women in the study. Only a small number of devices have been formally validated for home use in pregnancy(147-149) and even fewer in pre-eclampsia(150).

Inaccurate or selective reporting of home blood pressure measurements has been reported within the general adult population self-monitoring(151). However, the few studies exploring

integrity of reporting in the pregnant population support women being able to follow self-monitoring guidance and reporting measurements accurately(146, 148). A prospective cohort study of 72 women with pregnancy hypertension were asked to monitor their home blood pressure three times daily, and compared with the 979 readings taken from the monitor memory, only 28 (2.9%) of the reported readings were inaccurate, and these readings were limited to three women, two of whom admitted other family members had shared their monitor(146). A later cohort study by the same group, recruited 21 pregnant women at a mean of 31 weeks' gestation, comprising four groups: hypertension alone/high risk, proteinuria alone, mild pre-eclampsia and uncertain BP(148). Participants had scheduled antenatal clinic review, but additionally were asked to self-monitor BP (and proteinuria in the hypertension/at risk group only) for the remainder of their pregnancy. BP monitoring involved measuring blood pressure daily up to six times per day, and they were advised to seek clinical advice with specific BP thresholds or proteinuria on urine dipstick self-testing. Despite the requested high frequency of self-measurement, the devices were used between 1-54 days, 38% of women monitored longer than four weeks and 81% of participants self-monitored their BP daily with an average of six daily measurements for the duration of their monitoring. Eleven participants contacted the maternity assessment unit (MAU) appropriately for raised readings according to the protocol, but ten participants did not: three contacted with raised blood pressure but below the protocol threshold; the remaining seven participants did not make contact for BP readings above threshold, either due to their measuring subsequent readings below threshold, waiting until a prebooked appointment the next day or for two women a severe language barrier lead to inadequate understanding of the protocol. The authors noted that those women who had been adherent with self-monitoring received far greater surveillance than routine clinical care, but the biggest challenge of the study was appropriate participant education and the impact of significant language barriers(148).

Tucker et al performed a prospective cohort study examining the feasibility and acceptability of blood pressure self-monitoring (BuMP pilot) in a group of 201 pregnant women defined as higher

risk for developing pre-eclampsia(152), according to the NICE 2010 pregnancy hypertension guidelines(16). The analysis of the BuMP pilot study was conducted during the design of the study in this thesis. Women were recruited in their first trimester and were asked to take two readings per day, three times weekly for the remainder of their pregnancy. Although 80% remained in the study at 36 weeks, only two thirds (66%) persisted with monitoring up to this gestation and for the 23 who developed gestational hypertension, 9 (39%) were detected by raised home BP before clinic readings. Self-monitored BP readings were similar to their matched clinic readings with overlapping confidence intervals and to within 5mmHg for both systolic and diastolic. A parallel qualitative study explored women's experiences of self-monitoring, and semi-structured postnatal interviews were conducted with 15 women from the study(153). Women reported willingness to engage with their own care and said they were able to incorporate self-monitoring into their weekly routines. Self-monitoring made women more aware of the risks associated with pregnancy hypertension and pre-eclampsia, and yet provided feelings of reassurance and empowerment, rather than anxiety, particularly in the context of previous experience of HDP(153). The results from the mixed methods BuMP pilot supported the feasibility and acceptability of trialling a BP self-monitoring intervention in this higher risk group of women.

When designing the study described in this thesis (in 2015) there were only two previously published randomised controlled trials of blood pressure self-monitoring in the pregnant population (as reported in a recent 2019 systematic review by Kalafat et al(154)). A French study published by Denolle and colleagues in 2008, recruited 57 women in their third trimester with new onset non-proteinuric hypertension in the clinic and trained all women to perform daily blood pressure self-monitoring for 7 days; the results were centrally randomised with a telemonitoring system either forwarding them to the obstetrician or storing them (details not provided)(155). The primary aim was to study the prevalence and prognosis of white coat hypertension (WCHTN) and the secondary objectives were to study the feasibility and safety of home blood pressure monitoring with telemetry in newly hypertensive pregnant patients.

Pregnancy outcomes were recorded along with participant satisfaction with self-monitoring using questionnaires. There was a high prevalence of WCHTN (76%) which appeared to have a benign course, but the authors concluded telemetry for home readings was necessary as the system alerted the obstetrician for 5 (9%) women, triggered by three successive home readings with a mean value >160/100 mmHg. Participant satisfaction with home monitoring was high with 92% describing self-monitoring as “very easy” and 75% were “very satisfied” and the remainder “satisfied” after the week of home monitoring.

The second pilot randomised study published by UK researchers, Ross-McGill and colleagues in 2000, was designed to assess the acceptability and compliance with a weekly self-monitoring blood pressure intervention designed to reduce scheduled antenatal appointments in 80 randomised normotensive low risk pregnant women(156). The intervention was successful in reducing the need for scheduled appointments whilst providing more blood pressure observations in the home monitoring group and most women expressed a preference for the intervention with no significant group differences in anxiety. However, despite this pilot supporting the feasibility and acceptability of this approach, the authors did not proceed with a substantive trial as the predicted number of low risk women required to appropriately power an efficacy trial was 10,000(147). The authors considered that further trials would be more appropriate for higher risk pregnant women who are more likely to receive clinical benefit from this intervention and it would be feasible to power these studies.

Despite the potential for blood pressure self-monitoring, and the apparent motivation of pregnant women to take up this tool and be involved in their care, there continues to be a lack of clear evidence and related guidance on its role in pregnancy. Questions remain over even the most basic components of this intervention in the context of pregnancy, such as the most appropriate frequency and BP thresholds. In the general adult population with hypertension, blood pressure recorded at home is significantly lower than clinic values; the NICE 2019 guideline

for the diagnosis and management of hypertension in adults currently recommends a threshold of 135/85 mmHg for diagnosis and BP control using home readings(140). Currently there are no data quantifying this possible difference for self-monitoring in pregnancy, although ambulatory home monitoring best predicts adverse pregnancy outcomes also using a threshold of 135/85 mmHg(157). The BuMP pilot study used the same home blood pressure thresholds as clinic of 140/90 mmHg, acknowledging the evidence gap for pregnancy and as a practical means to avoid unnecessary contact with maternity services and avoid triggering increased maternal anxiety, and this was in the context of home monitoring being supplemental to usual care(152). A systematic review and individual patient data meta-analysis conducted in 2016 comparing home and clinic blood pressures in pregnancy included self-monitored and clinic readings from eight studies (758 women) and found a mean self-monitoring clinic difference of ≤1.2 mmHg systolic BP throughout pregnancy, although there was significant heterogeneity between studies, supporting an equivalence between home and clinic BP readings in unselected pregnant populations. Subgroup analysis suggested much larger clinic-home differences for hypertensive pregnant women, but data were too few for a definitive analysis(118).

Given the importance of the hypertensive disorders of pregnancy, and demographic changes likely to impact on the incidence of these disorders globally, coupled with the potential and increasing voluntary use of blood pressure self-monitoring, it would seem this presents an opportunity and responsibility to further evaluate the role of blood pressure self-monitoring in the management of women with hypertensive pregnancies.

1.10 Telemonitoring in pregnancy

Our study design was originally conceived and instituted as paper-based, drawing on earlier methods used in the TASMIN and BuMP pilot studies(121, 122, 152). However, due to success in recruiting to the first part of the study and given growing experience with the technology amongst our wider research group, the study was expanded, with the design adapted to include a

telemonitoring system for women to report home blood pressure readings and receive timely and individualised feedback (see Chapter 2).

Mobile phone technology is increasingly being used and is particularly prevalent amongst young UK women of reproductive age (16-54 year olds), increasing from 81% in 2016 to 99% in 2020(158). The UK has the highest percentage of smartphone users in the world, with 83.9% of the population (~ 55,504,000 people) owning a smartphone(159). This is a growing global trend(160). Mobile technology has the potential to contribute towards narrowing the historic under-representation of pregnant women in research, due to concerns around potential harms of novel interventions to the fetus, and additionally allowing access to research to the most underserved groups such as those from socioeconomically disadvantaged groups both in the UK and in overseas settings. Furthermore, due to the ubiquity of mobile and smart phones, e-health interventions can arguably reduce health inequalities, making it easier for all women to access high quality health education and care, as long as access to the digital intervention in the first place does not amplify inequity. Digital health technologies have been touted as playing a vital role in the ongoing journey to move away from doctor and disease centric health care and towards an approach of partnership with patients, recognising and prioritising their values and expertise in managing their care(161).

Over recent years the UK Department of Health and Social Care has placed digital technologies in the foreground for driving through improvements in care and the nation's health. In the previous five years that provided the context for this study, the Department's "NHS Five Year Forward View" published in 2014(162), aimed to close the gaps in the nation's health, care quality and funding. The plan stated the ambition to *"exploit the information revolution"*, using digital technologies to empower patients, provide them with access to high quality personalised health and care information and thus support people to manage their own health. NHSD (NHS Digital) and NHSX (NHS user experience) are charged with driving digital transformation in the health and

social care sector(163). One of the key aims is the digitalisation of the maternity record, allowing women access to their notes through their smart phones or other devices(164). Maternity (Choice and Personalisation) Pioneers have been selected and commissioned with rolling out apps to support women to access services and information and to have control and choice over their maternity care.

Telemonitoring has been successfully developed and adopted by patients and clinicians alike in other health care areas in the UK, for example there are several apps for heart failure(165), DigiBete in paediatric diabetes(166), TiM telehealth for motor neuron disease(167) and the True Colours, a remote mood monitoring system integrated into secondary mental health care(168). In the area of maternity care there are well adopted apps such as QuiPP for monitoring women at high risk of preterm birth(169), the IFDC (Integrated Family Delivered Care) app for empowering parents of preterm infants requiring neonatal intensive care to be the primary care givers(170), and GDm-health, a remote blood glucose monitoring system for use in women with gestational diabetes(171, 172). The current COVID-19 pandemic has seen a rapid rollout of digital tools and remote monitoring and consultations across the breadth of primary and secondary care, including maternity care(173, 174) and the results and learnings from these will be a key focus for researchers and policy makers for the foreseeable future. Despite the growing interest and application of mobile technologies and telemonitoring in maternity care, there remains a dearth of evidence for their association with improved health outcomes, safety and impact on health care costs(175).

1.11 The mixed methods approach

In starting with the research questions around the feasibility and acceptability of evaluating blood pressure self-monitoring in hypertensive pregnancies, it became clear that I should have a multidimensional perspective of this intervention and how it might work and be implemented. Petticrew described that "*there are no 'simple' or 'complex' interventions…..simplicity and*

complexity are instead pragmatic perspectives adopted by researchers" to help define the sorts of questions and explanations they are studying(176). Embracing a complex perspective meant appreciating the interacting components and actors of the intervention, the likelihood of important contextual factors both in the clinics and at home and recognising implicit presumptions about causal mechanisms behind the intervention, for example shared perspectives around pregnancy hypertension from women and their clinicians. Neither quantitative nor qualitative approaches alone would provide adequate insights or understanding of the self-monitoring intervention and therefore how best to develop, evaluate and consider factors important to implementation. I thus adopted a mixed methods approach, recognising this would offer complementary data.

There are many descriptions of mixed methods research and Johnson et al sought to demarcate this field of research asking leaders in the field to provide their working definitions(177): Valerie Caracelli defined it thus: "*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".*

My approach was also informed by the Medical Research Council guidance for developing and evaluating complex interventions(178, 179). The authors emphasise the importance of a thorough process evaluation for identifying potential barriers to implementation and the need for a range of outcome measures in order to assess efficacy and also explore unintended consequences. The guidance also recognises that a certain degree of flexibility and adaptation to local context may be required and will be important to capture. Key factors that have been previously identified for the successful adoption or non-adoption of digital health technologies have centred on the culture of an organisation, how it functions, the constraints, the individuals using the technology, more often than limitations or attributes of the technology itself(180). Thus the methods

described in this thesis needed to be sensitive for and designed specifically to capture these important social elements.

1.12 Thesis aims and objectives

In this thesis I aim to explore the role of blood pressure self-monitoring in the management of hypertension in pregnancy. In order to achieve this aim, I have the following objectives using a mixed methods approach to:

Test the feasibility and acceptability of a blood pressure self-monitoring intervention for the management of hypertension in pregnancy as preparation for a future large randomised controlled trial (Chapters 2 and 3).

A BP self-monitoring intervention was developed that used a validated home blood pressure monitor and customised paper-based and telemonitoring reporting systems. It was tested in a feasibility randomised controlled trial to inform the further development of the intervention and processes for use in a future large-scale multi-centre randomised controlled trial, where the primary objective will be to compare the efficacy and safety of self-monitoring versus usual care for blood pressure control during pregnancy.

Explore participants' experiences of blood pressure self-monitoring within the randomised study: how the intervention was perceived and used by pregnant women and their clinicians and the acceptability of the study processes (results in Chapter 5).

As well as interviewing women and clinicians, I also completed ethnographic observations of clinics including conducting informal interviews at the clinics. It quickly became apparent that these qualitative studies were producing a wealth of data that provided important and some unexpected insights around BP self-monitoring in this context, and thus I concluded there was scope to:

Explore additional themes arising from further inductive analysis of the qualitative data focusing on different perspectives and meanings of women and clinicians in relation to self-monitoring blood pressure (results in Chapters 6 and 7).

Chapter 2: Randomised study quantitative methods and results

2.1 Overview

I led the design of a randomised study, OPTIMUM-BP (OPtimising TItration and Monitoring of Maternal Blood Pressure) to test the feasibility and acceptability of a blood pressure self-monitoring intervention for managing pregnancy hypertension. It aimed to inform the further development of the intervention and processes for use in a future large randomised controlled trial (RCT), to investigate the effectiveness of this intervention for blood pressure control during pregnancy.

The intervention was developed based on earlier work from other self-monitoring and self-management of BP trials where this has been shown to be safe, effective and acceptable(118, 119, 121, 122). In the general adult population with chronic hypertension, BP self-monitoring with self-management interventions that include both measurement at home of blood pressure combined with titration of antihypertensives by the patient or their GP, are cost-effective and leads to significantly improved BP control and higher patient satisfaction(117, 118, 181, 182). Previous small, mostly non-randomised studies of BP self-monitoring in the pregnant population(152, 156, 183) suggest a similar approach may be feasible and acceptable.

We used an unmasked randomised controlled trial design to compare blood pressure self-monitoring against usual care. Women with chronic (CHTN) or gestational hypertension (GH) from four UK maternity centres were randomised (2:1) intervention to control. Self-monitoring involved pregnant women randomised to the intervention taking daily home blood pressure (BP) measurements and recording these in a study diary or reporting readings via telemonitoring. Clinicians at these centres were asked to use the home readings in clinical and antihypertensive initiation and titration decisions. The primary feasibility outcomes were recruitment, retention, adherence and persistence with the intervention.

This chapter will briefly describe the self-monitoring intervention development, followed by presentation of the feasibility study including quantitative methods, statistical analyses and results.

2.2 Trial set-up and management

As Chief Investigator (CI), I was supported in trial set-up and management by members of the PC-CTU and TMG (see Appendix 1 for details). I developed a study protocol (Appendix 2) along with participant-facing documents, including: study advert with logo, participant and clinician randomisation study and optional interview PIS, ICFs and GP/midwife letter (see Appendices 3-6). A set of working instructions and associated training documents and presentation were created to be used at staff training during site initiation visits before site recruitment started. I developed paper case report forms (CRFs) specific to each study visit and final maternal notes review from a data point list derived from the protocol, which were iteratively reviewed by the TMG and PC-CTU (for an example CRF see Appendix 7). The CRFs were annotated by an experienced Data Manager and a database was created and tested by a Clinical Trials Programmer, using the *OpenClinica* software. Anonymised trial data were continuously returned from sites to the PC-CTU for the duration of the study, and data were contemporaneously entered onto the trial database, and data queries were raised and checked with the site PIs. The database was cleaned at the end of the trial and locked, before I conducted any masked analyses.

The protocol and participant-facing study documents underwent internal PC-CTU quality assurance and risk assessment checks and sign-off before these materials were submitted to the study sponsor, University of Oxford. As study sponsor, the University had specialist insurance in place, which would operate in the event of any participant suffering harm as a result of their involvement in the research. NHS indemnity would operate in respect of any clinical treatment that was provided.

2.3 Intervention development

The self-monitoring intervention deployed successfully by our research team for other populations with or at risk of hypertension(121, 122, 152) was adapted for use in the OPTIMUM-BP study. Several components and characteristics of the intervention needed to be considered and adapted for use in a pregnant population with hypertension, including: monitoring frequency, home blood pressure thresholds to trigger clinical assessment and telemonitoring capability and design.

At the time of development of the OPTIMUM-BP protocol, paper-based and telemonitoring techniques had been successfully utilised in the general adult population with hypertension(121, 122). A pilot cohort study using both paper-based and text-based self-monitoring in women with higher risk pregnancies for the *diagnosis* of hypertension (BuMP pilot)(152) had been completed and a pilot randomised study evaluating the feasibility of self-management for postnatal hypertension (SNAP-HT)(184) was recruiting women. Increasing levels of digitisation of the intervention occurred during this research journey due to the growing experience and expertise with the methods and technology amongst the research team, and the development of the technology itself. This was also reflected in the life-time of the OPTIMUM-BP study where the initial cohort of women recruited with chronic hypertension were randomised to a paper-based intervention or usual care and the second cohort of women with gestational hypertension were randomised to a text and app enabled intervention with additional paper-based back-up. Some key changes were made to the protocols and materials used in the earlier hypertension studies for the OPTIMUM study to reflect the more rapidly developing and acute risks of pregnancy hypertension and these are described below.

Due to the haemodynamic and vascular changes that occur during pregnancy, it is vital to use a BP measurement device that has been specifically validated for use in pregnancy and associated hypertensive disorders, such as pre-eclampsia. Several devices have been validated for use in

pregnancy and a few also in pre-eclampsia(145, 149). We used the Microlife WatchBP® Home monitor, which is an automated oscillometric device which can store up to 200 readings and is validated for use in pregnancy and pre-eclampsia according to the British Hypertension Society protocol, achieving a grade A/A validation rating in pregnancy and grade B/A in pre-eclampsia(148).

2.3.1 Patient and public involvement (PPI)

PPI was crucial in the development of the study materials. Several women with or with a history of pregnancy hypertensive disorders were asked to provide feedback on the study PIS, CRF and BP self-monitoring instructions and diaries. They recommended some minor edits to these materials that made the language more straight-forward and suggested adding summary bullet points to the front of the PIS. Earlier PPI work had been completed by the CI for the SNAP-HT feasibility study(184) that used telemonitoring for postnatal blood pressure self-management, that found 100% of 31 respondents owned a mobile phone (for 97% this was a smart-phone), confirming the initial technical feasibility of a self-monitoring study using participants' mobile phones. This PPI feedback was used in the development of the telemonitoring app for use by the women in OPTIMUM-BP with gestational hypertension.

2.3.2 Frequency of monitoring

Frequency of home blood pressure monitoring was a key aspect of the intervention that needed to be established: the frequency and pattern of BP monitoring used in the TASMIN trials (in adult hypertension) was: daily measurements for the first week of each month, two readings taken at a time, five minutes rest in-between, recording the second reading. This format was suited to the monitoring of a long-term condition, subject to only gradual change or deterioration. However, in pregnancy, the vasculature undergoes significant physiological changes at the different gestations, and these can be rapid in pathological states such as evolving pre-eclampsia, so it was important to have a BP monitoring strategy that reflected this.

The 2010 NICE Hypertension in Pregnancy clinical guideline in use at the time of protocol development(16) stated that the frequency of antenatal contacts (and therefore opportunities for clinic blood pressure measurement) for the group with chronic hypertension could not be specified as the care needs should be individualised. The guidelines recommended that there should be *additional* antenatal consultations over and above those advised in the 2008 NICE Antenatal Care for Uncomplicated Pregnancies clinical guideline CG62(185), (three-weekly appointments up to 34 weeks' for nulliparous women and fortnightly appointments for all women from 34 weeks' gestation). Similarly, there were no specific guidelines regarding monitoring frequency in those who develop gestational hypertension, but instead a summary in the NICE 2010 guideline recommended individualised follow-up on the basis that "*the frequency of blood pressure measurement will depend on the degree of hypertension and may also be influenced by history and assessment of risk factors*".

The first antenatal trial of self-monitoring used weekly measurement but this was in a group of low risk women without hypertension and was felt to reduce the potential benefit of self-monitoring(156). The BuMP pilot cohort study asked pregnant women with risk factors for developing hypertension, to measure their home blood pressure three times per week(152). For women with chronic or gestational hypertension, their risk for developing pre-eclampsia is increased, with around 25% of women with chronic hypertension(58) and 18% of women with gestational hypertension(186) developing pre-eclampsia. Furthermore both groups are likely to need antihypertensive medication. These data provided support for an increased frequency of blood pressure monitoring. Furthermore, as daily readings are more habit forming(187, 188) we designed a once daily schedule of monitoring, asking women to monitor at roughly the same time each day. As in the TASMIN trials, women were asked to take two readings (to allow for the reduction in blood pressure that happens over multiple readings)(189), one minute apart (the minimum recommended interval to prevent blood pooling in the arm)(190). It was considered that there would be improved adherence to the monitoring schedule (and therefore

standardisation between participants), for a shorter between-readings interval given the likely time-constraints on pregnant women who may have small children to look after or are busy with work.

2.3.3 Blood pressure thresholds

The previous blood pressure self-monitoring trials had used a traffic light system for the classification of home blood pressure readings to provide guidance to both the participants and clinicians over any recommended action such as further clinical assessment and/or titration of antihypertensives. A green category denoted readings within or below the target thresholds, an amber category denoted readings above target and a red category signified readings above the safety thresholds. The thresholds were informed by the NICE guidelines (2010).The BP threshold categories needed to be expanded for the pregnant population to allow for the recommendation for clinical advice and assessment in the event that blood pressure was falling too low, giving rise to symptoms or potential placental circulation compromise. Thus a *rainbow* chart was designed with a new blue category for the low blood pressure range (see Table 3).

Table 3: Blood pressure thresholds for self-monitoring

COLOUR	RANGE	BLOOD PRESSURE	ACTION
RED	**HIGH**	**SYS 150 or more OR DIA 100 or more**	▪ Your blood pressure is high ▪ Sit quietly for 5 minutes then measure it again ▪ Record a RED if your second reading is also high ▪ **Contact your maternity unit for urgent assessment today**
YELLOW	**RAISED**	**SYS 140-149 OR DIA 90-99**	▪ Your blood pressure is raised ▪ Sit quietly for 5 minutes then measure it again ▪ Record a YELLOW if your second reading is also raised ▪ **Contact your midwife, GP or maternity unit within 24 hours**
GREEN	**NORMAL**	**SYS 110-139 OR DIA 70-89**	▪ Your blood pressure is in the target range ▪ Record a GREEN reading if this is your second reading ▪ This is fine provided you have no side-effects or symptoms
BLUE	**LOW**	**SYS less than 110 AND DIA less than 70**	▪ Your blood pressure is low ▪ Sit quietly for 5 minutes then measure it again ▪ Record a BLUE if your second reading is also low ▪ **If you are taking blood pressure medication, contact your midwife, GP or maternity unit within 24 hours** ▪ **If you are not taking medication this blood pressure is fine**

It remains uncertain as to whether different home blood pressure thresholds should be used for home versus clinic measurements within pregnancy, or for different pregnancy populations, such as those with hypertension. The BuMP pilot study used the same BP thresholds for home and clinic readings; the study findings confirmed that home and clinic systolic and diastolic readings were within 5 mmHg of each other and with overlapping confidence intervals for mean BP estimates across the antenatal period. However this study recruited an initially normotensive population. In OPTIMUM we were interested in hypertensive women for whom it might be expected a white coat effect might be more prominent but at the time of the trial there was little additional evidence to draw on beyond retrospective cohorts(191).

In discussion with the TMG it was decided that on the basis of insufficient evidence to the contrary, OPTIMUM-BP would also use the same thresholds for clinic and home blood pressures to avoid possible anxiety and too frequent contact with clinical services amongst those self-

monitoring. This decision was also supported by a design that used the self-monitoring intervention in addition to all usual care including usual structured antenatal visits.

The BP threshold categories were based on the *lower* BP values recommended by the NICE(16) and PRECOG(192, 193) guidelines for clinic BP thresholds used to trigger further investigation for pre-eclampsia. As the systolic and diastolic readings could fall within different blood pressure ranges, the algorithm for categorisation was designed such that a blood pressure reading could only fall within one category, related to the most 'severe' BP category to ensure the least risk associated with the interpretation of home readings. This conservative approach was achieved by using the Boolean operator 'OR' for the systolic and diastolic readings for the normal (green), raised (yellow) and high (red) categories, and 'AND' for the low (blue) category.

2.3.4 Paper-based recording and telemonitoring

Women were provided with a paper-based blood pressure diary containing space to record the date, their daily readings for 8 to 42 weeks' gestation, and any free text regarding symptoms or thoughts about their home readings. Women were also prompted to tick which category their reading fell into and to follow any attendant advice, with a laminated copy of the BP rainbow thresholds attached to their diary. The diary also contained a reminder in bold at the top that if they were experiencing any symptoms consistent with pre-eclampsia including severe headache, visual disturbance, vomiting, upper abdominal pain or swelling of the face, hands or feet, feeling generally unwell, or any other worrying symptoms associated with pregnancy (e.g. vaginal bleeding) then to contact their maternity unit for urgent assessment regardless of their BP reading.

Women with gestational hypertension randomised to the intervention were further supported in their self-monitoring with a telemonitoring system using a mobile phone system, developed in collaboration with the Institute of Biomedical Engineering, University of Oxford. All intervention participants had access to an SMS (short messaging system) service and those with a smart phone

also had access to an app. Both services were free and the app was available for both Apple and Android operating systems. The app had the same functionality as the SMS service but in addition participants could view a graph of their previous submitted BP readings and with the 'green' thresholds highlighted, whether they had any readings pending and a record of any logged 'adverse events'. These services were also linked with the study website, which was available to participants to view their own data via their login and had additional back-end research management functionality, where authorised members of the research team could access data inputted by participants from the SMS or app services.

Participants were asked to input their second BP reading into the SMS or app service following the format <SYS><space><DIA>. Any readings falling outside the 'green' category triggered the system to request the participant to take a repeat reading after five minutes rest. Instructions were then based on this inputted repeat reading unless a repeat reading was not sent in which case after 30 minutes the system would provide instructions based on the original out-of-range reading. Any inputted nonsensical readings, including SBP > 230 mmHg or < 70 mmHg, or DBP > 140 mmHg or < 40 mmHg, were rejected by the system and a repeat requested. A similar request was made in the event SYS and DIA readings appeared to be switched around. Any repeat readings entered into the system within the 24 hour period, over and above the first or if requested, second readings, were subjected to the same algorithm and safety instructions. When a participant entered a blood pressure reading, the system sent an automated response dependent on the level of the reading and any previous readings (see Table 4 for examples). Unlike the BP paper diary, participants could not enter free text symptoms. In the event that participants experienced any symptoms, they were advised to seek immediate medical assessment, regardless of their BP values.

Table 4: Automated SMS responses

Response to green / blue reading	Thank you for your last reading: SYS/DIA. Your blood pressure is satisfactory provided you have no symptoms (and no medication if blue reading). Please repeat your blood pressure tomorrow.
Initial response to red reading	Please sit quietly for 5 minutes and repeat your blood pressure, and then re-enter the repeat values.
Response to repeat red reading	Please contact your local maternity unit immediately and arrange urgent assessment today.

2.3.5 Oversight of home readings

Women with chronic hypertension using the BP paper diary to record their home readings, brought these diaries to their clinic visits for review with their clinical teams. During study visits the research team recorded the diary data, and when women completed the study their diaries were collected to ensure complete data collection. During initial training and as part of their written instructions in their self-monitoring diary, women were made aware of when and how to seek clinical advice or assessment in the event of any concerning symptoms or out-of-range BP readings. Women were responsible for making contact and there was no clinical oversight of home readings outside of clinic visits.

The telemonitoring system used by the women with gestational hypertension, was designed to send automated reminders and 'flag' repeat raised or high readings or 'adverse events' such as severe hypertension to the research team. The system sent a reminder to the participant if no readings were entered for two consecutive days. On the third day a second reminder was sent and a safety 'flag' was sent to the research team web-based management system. If repeat raised (yellow) or high (red) readings were entered for more than three sets of readings over two days, and were not interposed by normal (green) or low (blue) readings, then a safety 'flag' was sent to the research team for that participant after 24 hours with no receipt of normal range readings. 'Adverse events' were also sent to the research team, which included any SBP ≥ 160 mmHg or DBP ≥ 110 mmHg. Members of the research team could access their site-specific participant list or

overall participant list on the website dependent on their designation, and view 'flags' and 'adverse events' in real-time, if they wished. 'Flags' and 'adverse events' were also communicated to the research team by means of a once daily summary email sent at a fixed time. A specified member of the research team contacted the participant to provide initial assessment and advice and 'active flag' status could only be removed when the participant had been successfully contacted and the time logged.

Clinical teams at the study maternity units did *not* have access to the web-based management pages, unless they were designated PIs, and they were not responsible for checking the submitted readings; to reflect how it was suspected this intervention would be pragmatically and sustainably conducted in a large RCT and in real-life implementation if shown to be safe and effective. Pregnant women with chronic or gestational hypertension have a structured and continual antenatal care pathway with their maternity centre under the leadership of an obstetric consultant, and as our intervention was over- and-above usual care, the TMG agreed that this design fulfilled the highest safety standards. Furthermore this design was consistent with the underlying principles of empowering pregnant women with their own data, whilst retaining safety features during evaluation. Participant women were also reminded during their initial baseline visit and training how and when to make contact with their maternity services in the event of out-of-range BP readings or any symptoms, and they were not advised that the research team would be checking flagged summary data.

Given the level of individualisation and directive nature of the telemonitoring system (versus the BP paper diary) it was essential it went through rigorous testing, to ensure it would behave appropriately in the face of the possible wide range of clinical scenarios: abnormal BP readings, missed or multiple readings, switched and nonsensical readings and adverse events. The TMG constructed several dummy patients which were tested across both the SMS, app and web-based management systems, and the TMG met to discuss and finalise any required system updates.

2.3.6 Logic model for SMBP in pregnancy hypertension

As described in Chapter 1 I chose a mixed methods approach to explore the feasibility and acceptability of evaluating blood pressure self-monitoring in hypertensive pregnancies. This approach was informed by the Medical Research Council guidance for developing and evaluating complex interventions(178, 194, 195). This guidance also recommends a 'pre-clinical' or theoretical phase that will help the design of an intervention that *could* work, or one that is logically plausible, however the authors also advise this step might not be necessary if an intervention is already in successful use within the health service. A blueprint for the intervention already existed from the previous TASMIN trials in the general adult population with hypertension. At the time of design of this study (2015), no previous published observational or trial studies of SMBP in the pregnant population had reported any underpinning theory or accompanying logic diagram for their intervention. A recent scoping review of the use of theory in self-care research (from 2008 to 2019) found limited use of theory in the published literature(196). Only 76 (33%) of the 233 included studies used theory in their design. From ten chronic conditions, hypertension had the least number of studies including theory, only 7 (22%) of 32. The most frequently used theory by a considerable margin, was Bandura's social cognitive theory (SCT)(197) used in 48 (63%) of the studies.

A systematic review and thematic analysis of patient and provider perspectives for SMBP in the general adult population with hypertension(198) published during the design of this study found convenience, reassurance, autonomy and self-efficacy to be dominant facilitative themes from the qualitative literature. These concepts informed our design and chime with the constructs of SCT, particularly self-efficacy which forms a pivotal self-regulatory role in initiating and maintaining behaviour change(197). SCT not only considers the individual but also the reciprocal interaction between the person, their environment and the behaviour which I aimed to study through the ethnographic observations. The ingredients of the intervention promoted self-efficacy including patient-facing information explaining the rationale for SMBP, instruction and

demonstration of monitoring, guidance for actions for out-of-range readings, biofeedback through monitoring their BP data, automatic feedback and prompts for the women with GH using telemonitoring, and arguably the most important ingredient the ongoing interactions with their health care professional(s). The proposed mechanisms of action and the methods for their assessment are represented in the logic diagram below (Figure 1).

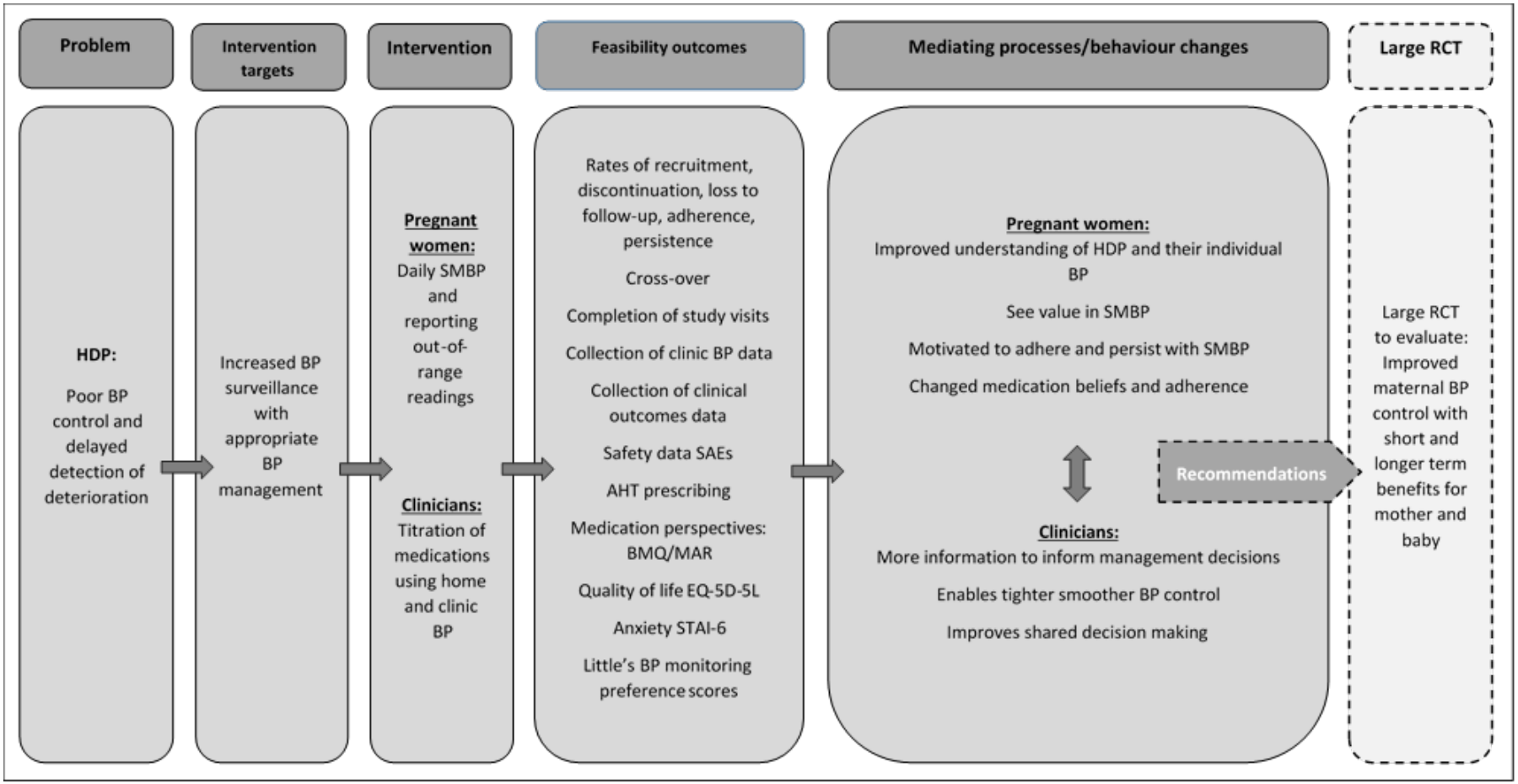


Figure 1: Logic diagram for OPTIMUM-BP[1]

[1] HDP: hypertensive disorders of pregnancy; BP: blood pressure; SMBP: self-monitoring blood pressure; SAE: serious adverse event; AHT: antihypertensive; BMQ: beliefs about medications questionnaire(206); MAR: medication adherence rating(207); EQ-5D-5L: quality of life sore(199); STAI-6: state trait anxiety index score(200); RCT: randomised controlled trial.

2.4 Methods

2.4.1 Study oversight and funding

OPTIMUM-BP was registered on a publicly accessible database (isrctn.com) and assigned an International Standard Registered Clinical/social sTudy Number (ISRCTN16018898)(199). I was registered as the Chief Investigator and study oversight and monitoring were provided by a trial management team which met monthly and included my supervisors and members of the Primary Care Clinical Trials Unit (PC-CTU) of the Nuffield Department of Primary Care Health Sciences, Oxford.

The trial protocol and materials were approved by the National Research Ethics Service (NRES) Committee (15/EM/0490) and separate approval was granted by the Research and Development (R&D) divisions of the NHS trusts of the four hospital maternity centres where women were recruited.

There were no amendments to the protocol during the course of the trial that affected the scientific basis of the work, but one major amendment to allow for the additional recruitment and follow-up of a group of up to 80 women with gestational hypertension, as detailed above. This was approved by the NRES and R&D services.

The study and CI were funded by the National Institute of Health Research (NIHR) Oxford Collaboration for Leadership in Applied Health Research and Care (CLAHRC) and Professor Richard McManus' NIHR Professorship (NIHR-RP-R2-12-015). The study was accepted for adoption onto the NIHR portfolio.

2.4.2 Study participants

Pregnant women with hypertension were enrolled from four National Health Service (NHS) maternity units in England. Eligibility criteria included women aged ≥18 years with a singleton pregnancy and with chronic or gestational hypertension, without pre-eclampsia. Women with chronic hypertension (treated or not) could have a prenatal diagnosis of hypertension or

sustained BP readings ≥140 mmHg systolic and/or ≥90 mmHg diastolic before 20 weeks' gestation, and were recruited any time between their booking appointment and up to 23+6 weeks' gestation. Women with gestational hypertension, defined as sustained BP readings ≥140 mmHg systolic and/or ≥90 mmHg diastolic after 20 weeks' gestation and without proteinuria, were recruited between 20 and 37+6 weeks' gestation. Women were excluded if they were unwilling to self-monitor or had pre-eclampsia (as defined by the International Society for the Study of Hypertension in Pregnancy 2014 statement)(92) at time of enrolment. Women were also excluded from the trial if they had insufficient understanding of the study including poor English language skills as there were insufficient resources to translate study materials in this pilot study.

2.4.3 Study procedures

A flow diagram of the study procedures (with further details) is provided in Appendix 2. Women receiving maternity care at the four participating NHS hospitals were approached. The study was advertised through posters and information leaflets in participant and clinic areas. Clinicians were also provided with information leaflets and presentations before and during the study to raise awareness and explain study procedures.

The clinical team initially identified potential participants through GP referral letters, antenatal booking and follow-up visits, Early Pregnancy Assessment Unit (EPAU) and Maternity Assessment Unit (MAU) attendances. Women with hypertension may have been triaged to a specialist medical obstetrics clinic at the study hospitals so they were also identified in these clinics. The clinical team provided potential participants with a study participant information leaflet (PIS, Appendix 3) and then took verbal consent to share the details of interested women with the research team.

Written and verbal versions of the PIS and Informed Consent Forms were presented to women detailing no less than: the exact nature of the study; what it would involve for them; the implications and constraints of the protocol, and any risks involved in taking part. It was clearly

stated that they were free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal. The participant was allowed as much time as they wished to consider the information, and the opportunity to question the investigator, their obstetric team, or other independent parties to decide whether they wanted to participate in the study.

If women wished to take part they had to sign and date the most recent approved version of the Informed Consent Form prior to any study related procedures, including screening for eligibility. Consent forms were also signed and dated by the person who obtained consent; this was the CI, site PI (Principal Investigator) or named person with delegated authority. A copy of the signed ICF was given to the participant. A further copy was retained in their maternity records and the original was stored securely at the CTU (with participant's consent) along with the personal identification form and separately from the trial data which was stored under participant ID number.

All study participants provided written, informed consent, including clinicians who were to participate in the parallel qualitative study. Women who declined to participate in the randomisation study were asked if they would volunteer any information around their decision so that the study design could be improved in the future to reflect and accommodate women's needs and priorities. However, it was emphasised that they were under no obligation to provide any reason or information around their decision.

Eligible and consented women completed a baseline assessment including questionnaires on quality of life scores (EQ-5D-5L™)(200), measurement of anxiety (STAI-6)(201) and medication beliefs (BMQ)(202) and medication adherence (MARS)(203). Members of the research team obtained study BP measurements and data on demographics, medical and obstetric history, current and past antihypertensive therapy and socioeconomic status (Index of Multiple Deprivation)(204). Study BP was measured three times, at one minute intervals, using the same

model of automated monitor (Microlife WatchBP Home®) validated for use in pregnancy and pre-eclampsia(148) that women randomised to intervention were loaned. All women had their upper arm circumference measured and recorded and this was used to provide women randomised to self-monitoring with the appropriate cuff size for use with their home monitors(148). The initial study visit was up to 40 minutes including explanation of the study, gaining informed written consent, training in BP self-monitoring for those in the intervention arm and completion of the baseline questionnaires.

All women, depending on their gestation at recruitment, were asked to attend up to three further antenatal study visits at approximately 20, 28 and 34 weeks' gestation, and one six week postnatal face-to-face or telephone study visit. Study visits were planned to coincide with women's routine clinic visits so as to reduce any burden on participating women. Consent was reconfirmed at all subsequent study visits. At the study visits, BP measurement was taken by the research team in the same way as described above and the following information was recorded: clinic and DAU visits and blood pressure measurements since the last study visit, current antihypertensive and medication changes since last visit and questionnaires. For women in the intervention arm we also downloaded their home BP monitor memory and collected their participant BP diary counterfoils. The MARS and BMQ questionnaires were repeated at the 28 and 32 week study visits, and the EQ-5D-5L™ and STAI-6 at the 6 week postnatal visit, alongside a questionnaire about blood pressure monitoring preference (Little's questionnaire)(131). Follow-up study visits were planned to be 15 minutes duration. Delivery outcome data were collected from the maternity record by the study team within three months of delivery.

We aimed to follow women for a maximum of 44 weeks (from an 8 weeks' gestation booking appointment for those with chronic hypertension, up to 12 weeks postnatal qualitative interview).

2.4.4 Randomisation

Women were randomised, stratified for recruiting centre and type of hypertension (CH or GH), in permuted blocks of random size (3 or 6) with sequence length of 30 in a 2:1 ratio to BP self-monitoring or usual care. Women randomised to the intervention also received all usual care, and no antenatal visits were removed from their schedule, thus the intervention was over-and-above usual care. The randomisation sequence was computer-generated, and a secure web-based system was developed by the CTU (Sortition: https://ctu1.phc.ox.ac.uk/sortition/login), and was used to ensure allocation concealment, although due to the nature of the intervention, neither participants nor investigators or clinicians were masked. Outcome measurements were not masked although analysis was.

To our knowledge, OPTIMUM-BP represented the first randomised study of BP self-monitoring in pregnant women with hypertension and so it was decided to use a 2:1 randomisation of intervention to usual care to gain maximum experience with the intervention for this group of women whilst preserving the benefits of randomisation.

2.4.5 Study intervention

Women allocated to usual care had their BP monitored by their local clinical team, and these BPs measured by healthcare professionals were used to inform care and decisions around antihypertensive medication. Clinical teams at the study sites received updated training on the standardised method for measuring BP(205) and were advised to record three readings at each antenatal follow-up visit. The average of all three clinic readings on any single occasion was taken as the clinic BP for that episode.

Women randomised to the intervention were additionally asked to measure their BP daily, at approximately the same time each day, using the loaned automated BP monitor (Microlife WatchBP Home). Details of the self-monitoring intervention and blood pressure thresholds are described above. The digital readings were available for use by the clinical team at follow-up

appointments via the woman's app or the study website. Women recording their home readings in a diary were asked to bring their diary to their antenatal follow-up visits to share their readings with their clinical team. Clinicians were requested to consider a woman's home readings when formulating their management plans, whilst following all local and national guidelines as per usual care (see letter to clinicians, Appendix 6).

The self-monitoring regimen was not designed to trigger clinical assessment for home BP that was falling outside of the narrow range of *optimal* BP control. The optimal target BP was specific to the individual. It is likely that clinicians would have been aiming to maintain *clinic* diastolic BP around 85 mmHg, based on the findings from the CHIPS study(101) which was published at the time of development of our feasibility study.

2.4.6 Outcome measures

The primary outcomes were for feasibility, measured by recruitment, discontinuation, and adherence and persistence with the self-monitoring protocol. These were measured using trial screening and recruitment logs, and through completion and return of withdrawal and loss-to-follow-up forms from all four study sites. Adherence and persistence with the self-monitoring protocol were determined using the home monitoring data.

Secondary outcomes included several different measures of BP control (to best inform the design and analysis of a future large multi-site RCT), delivery outcomes and safety, health resource use, antihypertensive prescribing behaviour, and scores on self-reported questionnaires for: quality of life and anxiety(200, 201, 206), medication beliefs(207) and adherence(208) and Little's BP monitoring preference score(131).

Exploratory analyses included exploring different measures of BP self-monitoring adherence and accuracy, and any associations with self-reported medication beliefs or adherence scores, and comparing home and clinic BP measurements throughout pregnancy for women in the intervention arm. This work is now published(209).

2.5 Statistical analysis

A statistical analysis plan (SAP, see Appendix 8) was made by the Chief Investigator with the support of the TMG and CTU statistician, and this was completed and signed off before database lock.

2.5.1 Sample size

No formal sample size calculation was used because this was a feasibility study(210). After the study protocol amendment to include a group of women with gestational hypertension, we aimed for a target sample size of 160 (approximately half with gestational hypertension and half with chronic hypertension) and withdrawals could be replaced if new recruitment could occur within the study period. This sample size was consistent with the feasibility design and supported by recommendations made in the literature suggesting that a total sample size of at least 70 participants is required to estimate the standard deviation of a normally distributed variable and 60-100 for proportions(210, 211).

In discussion with the site PIs who were familiar with the referral and incidence rates of women with CH and GH respectively at their centres and the typical recruitment rates within their centres amongst these populations, it was predicted that it would be feasible to recruit 2 women per month from the larger sites and 1 per month from the smaller site for both CH and GH groups. Given the amendment to the design of the study, these groups were recruited in series, and we projected that recruitment would occur over a 24 month period, thus allowing for a target sample size of 160, allowing for withdrawals.

2.5.2 Primary and secondary analysis

An intention-to-treat analysis was performed, with the woman as the unit of analysis using all available data and with no imputation for missing data. Analyses were primarily descriptive with continuous variables summarised as means with standard deviations (or medians with interquartile ranges if data were skewed) and categorical variables as counts and percentages.

Due to the feasibility design and small numbers, differences between randomisation groups were reported with 95% confidence intervals (95% CI) and with no formal hypothesis testing with P-values.

The pre-specified statistical analysis plan aimed to analyse data from both hypertension groups together (chronic and gestational hypertension) using interaction terms between hypertension type, study randomisation group and time for the BP analyses, but early analyses showed these models to be unstable, due to the lack of data available for the gestational hypertension group at the early and mid-gestational times. Thus all analyses were conducted separately for the two hypertension groups. I (the Chief Investigator) performed all but the exploratory analyses and the statistical software Stata/SE version 14 was used for all analyses.

2.5.2.1 Blood pressure analyses

Several different measures comparing blood pressure control between randomisation groups were explored to inform a future large trial and included: adjusted differences in mean systolic and diastolic study BP at 20, 28 and 34 weeks' gestation (there was only sufficient data for the 34 weeks' gestation for the GH group); adjusted differences in mean systolic and diastolic, mean highest systolic and time-weighted mean systolic and diastolic blood pressure for clinic BP measurements.

Analyses for study and clinic BP used a linear mixed effects model with unstructured covariance. The model accounted for repeated measurements by means of random effects and adjusted for site and study baseline BP as fixed effects, with interaction between randomisation group and categorical study visit for study BP or interaction between randomisation group and continuous quadratic time measured in weeks' gestation for clinic BP analyses, allowing the model to accommodate a physiological mid-trimester BP dip. Study BP analysis for the group with gestational hypertension used a linear regression model, adjusted for recruiting centre and study

baseline BP. A linear mixed effects model was not used for this group as there were insufficient study visit data at earlier gestational times due to their later enrolment into the study.

For study BP, collected according to the study protocol which required three repeated readings for each measurement, the mean of the second and third readings at visits were modelled, and for clinic BP analyses the mean of the three clinic-recorded readings for that episode were modelled. Differences in adjusted means were reported for the separate visit time points for study BP, and overall mean differences across pregnancy for the clinic BP analyses. Mean highest clinic systolic BP was also compared between study groups using a linear regression model adjusted for study site and baseline BP. Time-weighted systolic and diastolic clinic BP were calculated using the area under the curve with the "trapezium rule"(212) and study groups compared using linear regression adjusted for study site and baseline BP.

Post-hoc sensitivity analyses were conducted for clinic BP for the group with chronic hypertension, using only clinic visit data and removing maternity assessment unit (MAU) visit data, to explore if detection bias may be playing a role in these analyses with women attending MAU after measuring higher BP readings at home. I conducted further exploratory analyses, accounting for chance baseline imbalances in ethnicity and history of previous hypertensive pregnancy disorders in the group with chronic hypertension, both factors being strongly predictive for delivery outcomes (both in our dataset and the literature), by adjusting for these two factors in these analyses.

2.5.2.2 Delivery clinical outcomes, safety and health resource use

For binary delivery and health resource use outcomes, logistic regression was used and the models adjusted for study site and baseline clinic systolic BP, to calculate odds ratios and their 95% confidence intervals. Continuous delivery and health resource use outcomes were analysed using a linear regression model, similarly adjusted, to calculate mean differences between randomisation groups.

Descriptive data concerning maternal and perinatal adverse outcomes for both groups were used including counts and percentages. Reporting of serious adverse events (SAEs) to the research team was to occur throughout the study if thought to be related to the research processes or intervention. The particular group being studied are high risk for serious pregnancy complications and several expected SAEs are reported amongst the secondary maternal and perinatal outcomes.

2.5.2.3 Antihypertensive prescribing and self-reported questionnaires

Prescribed antihypertensive medications were recorded at baseline, follow-up (20, 28, 34 weeks' gestation) and pre-delivery. The amount of antihypertensive (AHT) medications prescribed were compared between the intervention and control groups by comparing number of medications prescribed and also converting individual drug doses into defined daily doses (DDD – a World Health Organisation measure defined as the average maintenance dose per day for a drug used for its main indication in adults)(213). Time of exposure to particular DDDs were taken into account for each individual as women were in the study for varying lengths of time and antihypertensive drug use was compared at the different study follow-up visits. Adjusted mean difference between randomisation groups were compared using linear regression, adjusted for site and study baseline BP, with interaction between randomisation group and study visit. The model for AHT DDD included additional adjustment for baseline DDD and the model for AHT number of medications included additional adjustment for baseline number of medications.

Self-reported medication belief (for the two domains of necessity and concern) and medication adherence questionnaires scores, were calculated as per the methods described in Jamous et al(207) and Tommelein et al respectively(208). Mean scores between randomisation groups were compared using a linear regression model adjusted for site and baseline scores.

Mean scores for quality of life measures using the EQ-5D-5L crosswalk index and VAS scores(200, 206) and anxiety scores using the STAI-6(201) were also compared between study groups, using linear regression models adjusted for baseline scores.

Assessment of participant BP monitoring preferences were made by comparing Little's "problem" scores(131) between randomisation groups using non-paired two sample t-tests.

2.6 Results

2.6.1 Study participants

Between December 2015 and December 2017, 1140 women were screened for trial eligibility (see CONSORT diagram in Figure 2) of whom 226 were eligible and 162 provided written consent (target 160). Most women did not provide a reason for declining study enrolment, but the number of women stating they were declining due to specifically not wanting to be randomised (to either intervention group) were 15% (20/134) and 7% (6/92) for those with chronic and gestational hypertension respectively (details in Figure 2). Four women were recruited in error [as ineligible] and excluded from further analysis leaving one hundred and fifty-eight women; for women with chronic hypertension: 55 were randomised to self-monitoring and 31 to usual care and for women with gestational hypertension: 49 were randomised to self-monitoring and 23 to usual care. Participants not included in the analysis of clinical outcomes were three with chronic hypertension (two for early miscarriages and one early withdrawal by clinician on medically unrelated grounds) and one with gestational hypertension (lost early to follow-up as emigrated).

Baseline characteristics were generally similar between the allocation groups (Table 5) for women with chronic and gestational hypertension, except within the group with chronic hypertension, where there were relative imbalances in ethnicity and previous diagnosis of a pregnancy hypertensive disorder. Overall, women identifying as a non-white ethnicity accounted for 35% (55/158) and the mean IMD decile score was 4.8 (SD 2.8) across groups (see Table 5 for details).

Thirty-eight percent (60/158) had performed BP home monitoring at least once in the current pregnancy prior to enrolment, the majority of these from the group with chronic hypertension.

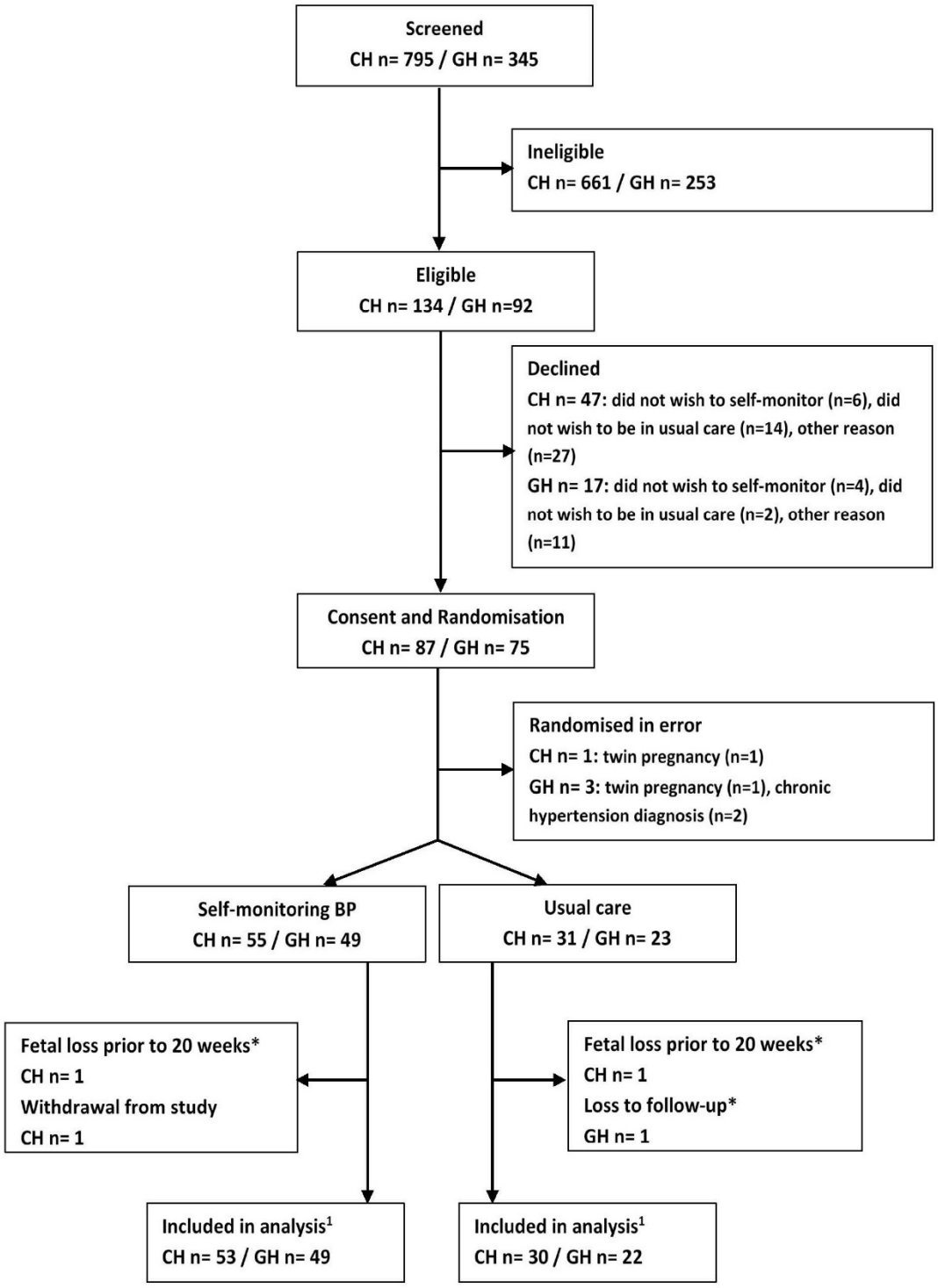


Figure 2: CONSORT flowchart (enrolment, randomisation, follow-up and analysis)*

**No data available after baseline*

Table 5: Baseline characteristics at enrolment of all 158 randomised participants

Characteristic	Chronic Hypertension		Gestational Hypertension	
	Randomised to SMBP (n=55)	Randomised to usual care (n=31)	Randomised to SMBP (n=49)	Randomised to usual care (n=23)
Age in years[a]	35.9 (5.6)	35.5 (4.2)	33.4 (5.9)	34.2 (5.1)
Gestation at recruitment in weeks[b]	16.6 (12.9 to 20.1)	14.9 (13.0 to 20.0)	35.0 (32.4 to 36.1)	34.7 (32.1 to 36.4)
Body mass index (kg/m^2)	31.0 (7.0)	31.9 (7.0)	29.5 (7.1)	27.6 (6.4)
Ethnicity				
White	27 (49%)	21 (68%)	37 (76%)	18 (78%)
Black	21 (38%)	8 (26%)	11 (22%)	4 (18%)
Asian	6 (11%)	2 (6%)	1 (2%)	1 (4%)
Other	1 (2%)	0 (0%)	0 (0%)	0 (0%)
Deprivation quintile[c]				
1st – most deprived	18 (33%)	7 (23%)	13 (27%)	4 (17%)
2nd	13 (24%)	7 (23%)	10 (20%)	6 (26%)
3rd	7 (13%)	9 (29%)	7 (15%)	5 (22%)
4th	9 (16%)	6 (19%)	9 (18%)	3 (13%)
5th – least deprived	6 (10%)	2 (6%)	9 (18%)	3 (13%)
Unknown	2 (4%)	0 (0%)	1 (2%)	2 (9%)
Highest educational qualification				
Professional/Higher qualifications	36 (65%)	16 (52%)	37 (76%)	20 (87%)
School qualifications	15 (27%)	14 (45%)	9 (18%)	3 (13%)
No formal qualifications	3 (6%)	1 (3%)	1 (2%)	0 (0%)
Unknown	1 (2%)	0 (0%)	2 (4%)	0 (0%)
Smoking history				
Never smoked	39 (71%)	26 (84%)	40 (82%)	17 (74%)
Quit before pregnancy	9 (16%)	4 (13%)	8 (16%)	4 (18%)
Smoking during pregnancy	5 (9%)	0 (0%)	0 (0%)	1 (4%)
Not known	2 (4%)	1 (3%)	1 (2%)	1 (4%)

Characteristic	Chronic Hypertension		Gestational Hypertension	
	Randomised to SMBP (n=55)	Randomised to usual care (n=31)	Randomised to SMBP (n=49)	Randomised to usual care (n=23)
Other self-reported medical history[d]				
Diabetes type 1	0 (0%)	1 (3%)	0 (0%)	1 (4%)
Diabetes type 2	2 (4%)	3 (10%)	1 (2%)	0 (0%)
Chronic kidney disease	1 (2%)	1 (3%)	0 (0%)	0 (0%)
Asthma	7 (13%)	4 (13%)	5 (10%)	1 (4%)
Parity				
0	17 (31%)	9 (29%)	20 (41%)	14 (61%)
≥1	38 (69%)	22 (71%)	29 (59%)	9 (39%)
Diagnosis of pre-eclampsia or gestational hypertension in previous pregnancy	20 (53%)	16 (73%)	15 (52%)	5 (56%)
Proportion prescribed antihypertensive medication at enrolment[e]	40 (73%)	21 (68%)	30 (61%)	15 (65%)
Blood pressure at enrolment in mmHg[a]				
Systolic	136.6 (13.8)	139.5 (13.1)	139.5 (14.0)	137.3 (1.3)
Diastolic	85.9 (10.1)	87.4 (11.5)	86.9 (9.9)	87.9 (8.0)
Previous SMBP in this pregnancy at least once	25 (45%)	16 (52%)	14 (29%)	5 (21%)

Abbreviations: CH: Chronic hypertension; GH: gestational hypertension; SMBP: Self-monitoring blood pressure; SD: Standard deviation; N: Number; IQR: Interquartile range.

[a] Mean and SD.

[b] Median and interquartile range.

[c] Deprivation measured as Index of Multiple Deprivation score using Office of National Statistics for England data.

[d] Participants' self-reported medication history.

2.6.2 Feasibility outcomes

The main feasibility outcomes are described using the combined groups (i.e. all participants both chronic and gestational hypertension). The proportion of those eligible that were recruited was 71% (222 eligible, 158 randomised, see Table 6). The overall randomisation rate was 2.5 participants per site per month.

Although there were relatively high adherence rates with the follow-up study visits (see Table 6), these rates were calculated on the basis of "applicable" visits: a participant recruited at 23 weeks' and delivered at 37 weeks, would have two applicable antenatal study visits to attend (the 28 and 34 weeks' gestation visits), but a participant recruited at 32 weeks' and delivered at 37 may not have any applicable study visits to attend. On the basis of an analysis looking to compare outcome measures at different study visits these varying enrolment periods in the study could produce few data at specific gestations, particularly for the group with gestational hypertension for the earlier time points in pregnancy.

Formal discontinuation of self-monitoring of BP by women randomised to the intervention group was low, with a combined rate of 6% (6/104), three of whom still supplied some home BP monitoring data until discontinuation. None of these women withdrew consent for maternity notes review follow-up. The women with chronic hypertension who provided home readings reported BP measurements on a median of 5.5 days per week (IQR 3.1 to 6.5) and median of 2.2 readings per day (IQR 2.1 to 2.5). Three women (7%) from the intervention group provided no home readings at all (two who formally discontinued with intervention very early in follow-up and one who never supplied home data). There were 43 women with gestational hypertension who provided home readings on a median of 6.1 days per week (IQR 4.5 to 6.7) with a median of 2.9 readings per day (IQR 2.5 to 4.6). Six women (12%) from the gestational hypertension intervention group provided no home readings (one who formally discontinued with intervention very early and five who never supplied data). In terms of cross-over from control to some form of

self-initiated BP self-monitoring, there was evidence of this in the maternity notes from 12/31 (39%) randomised to usual care from the chronic hypertension group, and four from the 23 (17%) from the gestational hypertension group.

Table 6: Feasibility outcomes for 158 pregnant women

Overall recruitment	71% (158 randomised, 222 eligible*)		
Chronic hypertension recruitment	65% (86 randomised, 133 eligible*)		
Gestational hypertension recruitment	81% (72 randomised, 89 eligible*)		
Recruitment totals per centre n (%)	**Total**	**CH**	**GH**
Guy's and St Thomas' NHS Foundation Trust	68 (43%)	47 (55%)	21 (29%)
Oxford University Hospitals NHS Foundation Trust	51 (32%)	27 (31%)	24 (33%)
New Cross Hospital, Royal Wolverhampton NHS Trust	19 (12%)	12 (14%)	7 (10%)
King's College Hospital NHS Foundation Trust	20 (13%)	0 (0%)	20 (28%)
Overall recruitment rate per site per month	2.5 (158 randomised, cumulative 64 months recruitment period over four sites)		
Chronic hypertension recruitment rate per site per month	2.8 (86 randomised, 31 months recruiting)		
Gestational hypertension recruitment rate per site per month	2.2 (72 randomised, 33 months recruiting)		
Adherence with study visits	**Total**	**SMBP**	**Usual Care**
Chronic hypertension group	**N=83**	**N=53**	**N=30**
Applicable antenatal study visits	89% (175/197)	88% (107/121)	90% (68/76)
6 weeks postnatal study visit	72% (60/83)	72% (38/53)	73% (22/30)
Gestational hypertension group	**N=71**	**N=49**	**N=22**
Applicable antenatal study visits	83% (19/23)	77% (13/17)	100% (6/6)
6 weeks postnatal study visit	73% (52/71)	74% (36/49)	73% (16/22)
Discontinuation with SMBP intervention**			
Chronic hypertension group	7% (4/55 originally randomised to SMBP)		
Gestational hypertension group	4% (2/49 originally randomised to SMBP)		
Fidelity with assigned randomisation group***			
Chronic hypertension group	39% (12 started SMBP/31 randomised to usual care)		
Gestational hypertension group	17% (4 started SMBP/23 randomised to usual care)		

Adherence with SMBP protocol[α]	
Chronic hypertension group	**N=50**
Median (IQR) number of BP readings days per week[β]	5.5 (3.1 to 6.5)
Median (IQR) number of monitor readings per day on days monitored[β]	2.2 (2.1 to 2.5)
Gestational hypertension group [α]	**N=43**
Median (IQR) number of BP readings days per week[β]	6.1 (4.5 to 6.7)
Median (IQR) number of monitor readings per day on days monitored[β]	2.9 (2.5 to 4.6)

* Deducting 4 women who were found later not to be eligible (see Figure 1).

** Participants who actively withdrew from SMBP and completed a study discontinuation form.

*** Proportion of usual care group starting SMBP with evidence of SMBP readings recorded in clinical notes.

α From women who supplied home data using BP monitor, app or BP diary data where available.

β Deducting any antenatal admission dates for a woman where she was not expected to self-monitor.

There was high persistence with the self-monitoring intervention (see Figure 3) with 86% (43/50 of those supplying home data) of women with chronic and 88% (38/43) of women with gestational hypertension providing home BP readings for 80% or more of their time from enrolment until delivery.

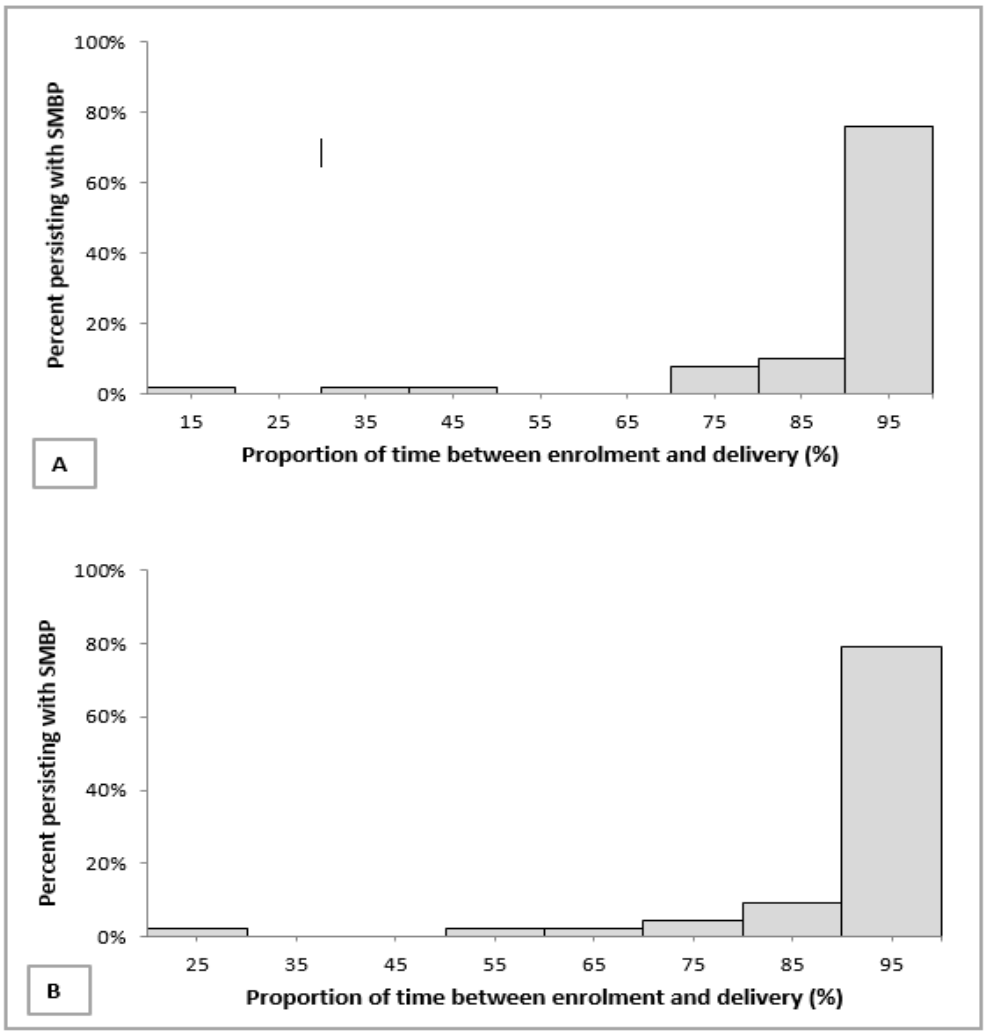


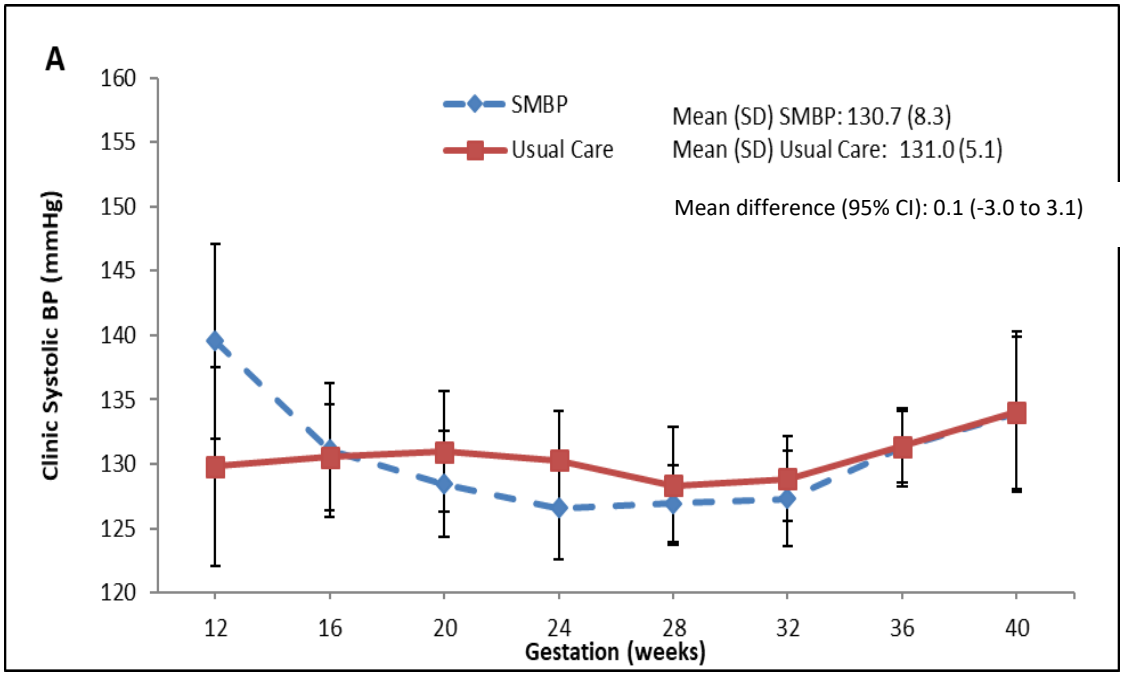
Figure 3: Persistence with SMBP

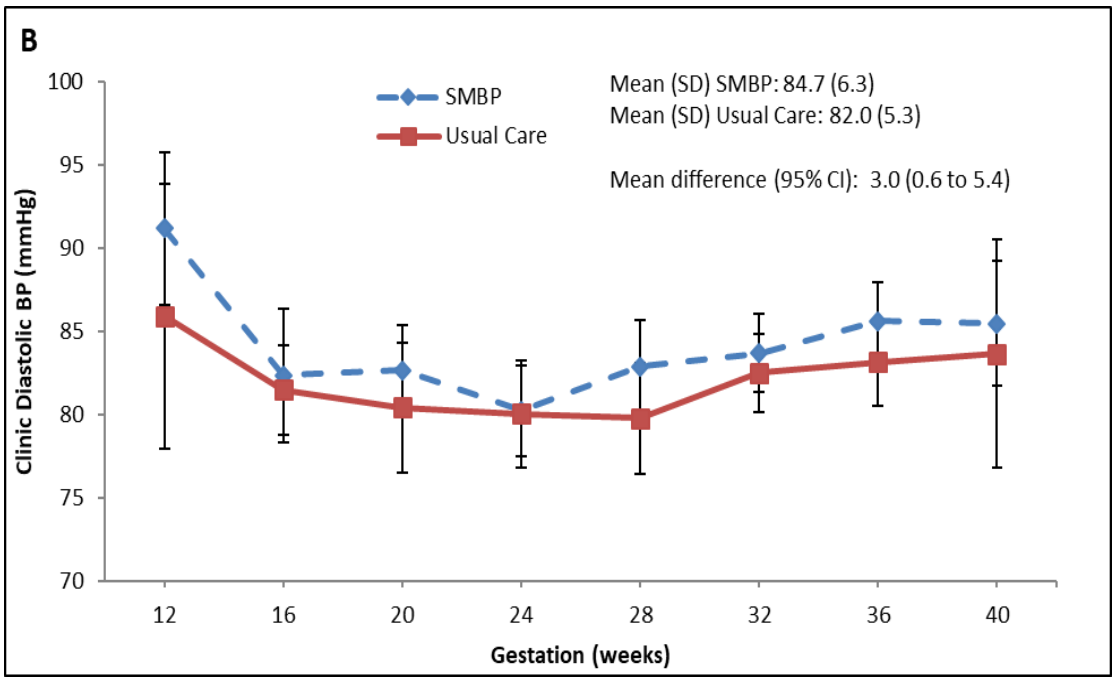
A: Proportion of time women with chronic hypertension persisted with SMBP
B: Proportion of time women with gestational hypertension persisted with SMBP

2.6.3 Blood pressure outcomes

The mean clinic systolic and diastolic BP profiles throughout pregnancy by allocation group are presented in Figures 4 A-D. For both the chronic and gestational hypertension groups, no difference was observed between intervention groups for any measures of systolic BP control for either study or clinic measurements (see Figures 4A and 4C and Tables 7-10). In terms of diastolic BP, there was no difference between groups for those with gestational hypertension but for chronic hypertension, diastolic BP was higher in the self-monitoring group compared to usual care (mean and time-weighted mean clinic diastolic BP) (see Table 9). A post-hoc sensitivity analysis

excluding those readings taken in the maternity assessment unit subsequent to women reporting high home BP measurements, seeking to reduce possible detection bias between groups, had no discernible impact on the pattern of the original results.





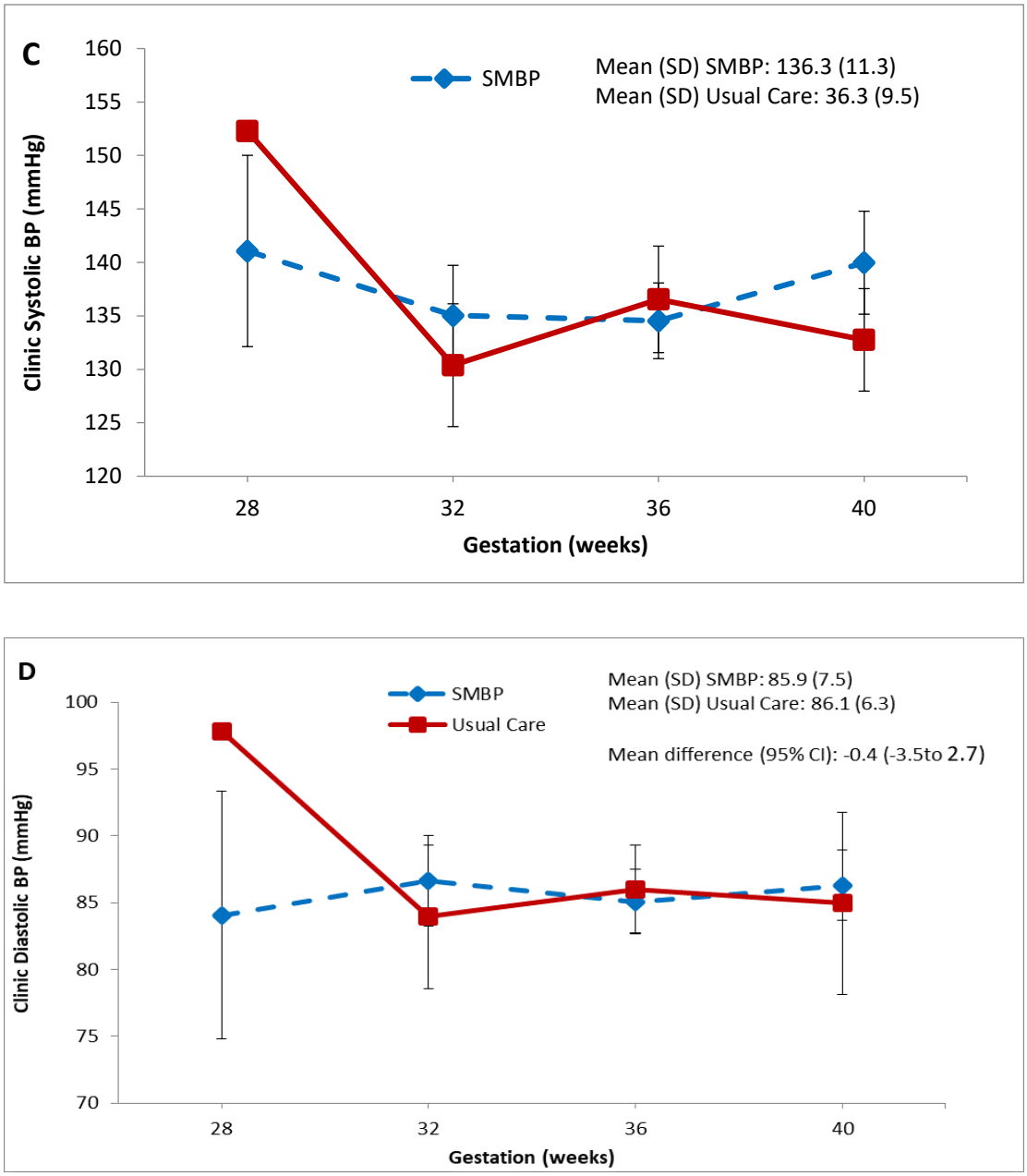


Figure 4: Mean clinic blood pressure (and standard errors) across gestation by randomisation group.[1] (A-B) women with chronic hypertension and (C-D) women with gestational hypertension

[1] The number of participants with chronic hypertension (A&B): 10-13.9 weeks' (8 SMBP, 5 usual care); 14-17.9 weeks' (23 SMBP, 16 usual care); 22-25.9 weeks' (45 SMBP, 27 usual care); 26-29.9 weeks' (44 SMBP, 28 usual care); 30-33.9 weeks' (42 SMBP, 25 usual care); 34-37.9 weeks' (44 SMBP, 28 usual care); 38-41.9 weeks' (22 SMBP, 10 usual care). The number of participants with gestational hypertension (C&D): 26-29.9 weeks' (6 SMBP, 1 usual care); 30-33.9 weeks' (17 SMBP, 7 usual care); 34-37.9 weeks' (44 SMBP, 20 usual care); 38-41.9 weeks' (24 SMBP, 8 usual care).

Table 7: Comparing study visit blood pressure measurements for 83 participants with chronic hypertension

	Baseline		20 weeks' gestation		28 weeks' gestation		34 weeks' gestation		Adjusted* difference between study groups		
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	20 weeks (95% CI)	28 weeks (95% CI)	34 weeks (95% CI)
SBP in mmHg											
Usual Care	30	135.1 (14.9)	16	126.4 (11.0)	26	130.0 (10.0)	26	134.5 (11.5)	3.4 (-3.0 to 9.9)	-2.3 (-7.4 to 2.8)	-0.6 (-5.7 to 4.5)
SMBP	53	134.2 (13.6)	25	128.3 (11.4)	40	126.9 (10.2)	41	132.5 (11.4)			
DBP in mmHg											
Usual Care	30	86.6 (9.4)	16	82.9 (5.9)	26	83.1 (7.6)	26	88.1 (6.5)	0.0 (-4.7 to 4.8)	0.6 (-3.2 to 4.3)	0.1 (-3.6 to 3.9)
SMBP	53	87.4 (9.0)	25	82.5 (8.9)	40	83.8 (8.1)	41	87.6 (9.8)			
AHT in WHO DDD	**AHT n (%)**		**AHT n (%)**		**AHT n (%)**		**AHT n (%)**				
Usual Care	21 (70)	1.0 (1.2)	12 (75)	0.9 (0.8)	22 (85)	1.0 (0.8)	23 (88)	1.2 (0.9)	0.3 (-0.3 to 1.0)	0.2 (-0.4 to 0.7)	0.2 (-0.3 to 0.8)
SMBP	40 (75)	1.0 (1.0)	21 (84)	1.2 (1.1)	30 (75)	1.1 (1.3)	35 (85)	1.2 (1.5)			
AHT num. meds	**AHT n (%)**		**AHT n (%)**		**AHT n (%)**		**AHT n (%)**				
Usual Care	21 (70)	0.9 (0.5)	12 (75)	0.9 (0.6)	22 (85)	0.9 (0.5)	23 (88)	1.0 (0.5)	0.0 (0.3 to 0.3)	0.0 (-0.3 to 0.2)	0.0 (-0.2 to 0.3)
SMBP	40 (75)	0.9 (0.5)	21 (84)	0.9 (0.6)	30 (75)	0.9 (0.7)	35 (85)	1.0 (0.6)			

Abbreviations: SBP: systolic blood pressure; DBP: diastolic blood pressure; AHT: antihypertensive medication; WHO: World Health Organisation; DDD: defined daily dose; num, n: number; SD: standard deviation; CI: confidence interval.

* Mixed effects liner regression model with repeated measures, adjusted for site and study baseline BP as fixed effects, with interaction between randomisation group and study visit.

Model for AHT DDD includes additional adjustment for baseline DDD. Model for AHT number of meds includes additional adjustment for baseline number of meds.

Table 8: Comparing study visit blood pressure measurements for 71 participants with gestational hypertension

	Baseline		34 weeks' gestation		Adjusted* difference between study groups at 34 weeks' (95% CI)
	No. of participants	Mean (SD)	No. of participants	Mean (SD)	
SBP in mmHg					
Usual Care	22	137.1 (9.9)	6	131.0 (16.0)	-0.4 (-12.9 to 12.0)
SMBP	49	135.7 (11.0)	12	129.0 (13.1)	
DBP in mmHg					
Usual Care	22	87.4 (7.2)	6	80.9 (9.2)	2.1 (-7.9 to 12.0)
SMBP	49	87.1 (7.4)	12	83.3 (10.5)	
AHT in WHO DDD	**AHT treatment n (%)**		**AHT treatment n (%)**		
Usual Care	15 (68)	0.8 (1.3)	6 (100)	1.5 (1.3)	-0.1 (-0.9 to 0.8)
SMBP	30 (61)	0.5 (0.8)	10 (83)	1.1 (1.5)	
AHT number of meds$^{\alpha}$	**AHT treatment n (%)**		**AHT treatment n (%)**		
Usual Care	15 (68)	0.7 (0.6)	6 (100)	1.3 (0.5)	-0.1 (-0.7 to 0.6)
SMBP	30 (61)	0.6 (0.5)	10 (83)	1.1 (0.7)	

Abbreviations: SBP: systolic blood pressure; DBP: diastolic blood pressure; AHT: antihypertensive medication; WHO: World Health Organisation; DDD: defined daily dose; num, n: number; SD: standard deviation; CI: confidence interval.
*Linear regression model adjusted for site and study baseline BP, with interaction between randomisation group and study visit.
Model for AHT DDD includes additional adjustment for baseline DDD. Model for AHT number of meds includes additional adjustment for baseline number of meds. Models for BMQ and MARS-5 scores include additional adjustment for baseline scores.

Table 9: Comparing clinic blood pressure control for 83 participants with chronic hypertension

Blood pressure control measure	SMBP group N= 53	Usual Care group N= 30	Adjusted comparison (95% CI)
Mean systolic blood pressure (SBP) (SD)[1]	130.7 (8.3)	131.0 (5.1)	0.1 (-3.0 to 3.1)
Mean diastolic blood pressure (DBP) (SD)[1]	84.7 (6.3)	82.0 (5.3)	3.0 (0.6 to 5.4) †
Mean highest SBP of all clinic/assessment unit/admission readings between randomisation and delivery in mmHg (SD)[2]	159.9 (18.7)	156.4 (9.1)	4.5 (-2.7 to 11.6)
Time-weighted mean SBP in mmHg (SD)[3]	129.0 (8.2)	130.2 (5.2)	-0.4 (-3.6 to 2.7)
Time-weighted mean DBP in mmHg (SD)[3]	83.5 (6.3)	81.4 (4.9)	2.6 (0.2 to 4.9) †
† 95% CI around adjusted mean difference does not cross zero.			

Table 10: Comparing clinic blood pressure control for 71 participants with gestational hypertension included

Blood pressure control measure	SMBP group N= 49	Usual Care group N= 22	Adjusted comparison (95% CI)
Mean systolic blood pressure (SBP) (SD)[1]	136.3 (11.3)	136.3 (9.5)	0.1 (-4.3 to 4.4)
Mean diastolic blood pressure (DBP) (SD)[1]	85.9 (7.5)	86.1 (6.3)	-0.4 (-3.5 to 2.7)
Mean highest SBP of all clinic/assessment unit/admission readings between randomisation and delivery in mmHg (SD)[2]	159.4 (16.6)	154.4 (14.3)	3.2 (-3.7 to 10.1)
Time-weighted mean SBP in mmHg (SD)[3]	136.6 (11.0)	136.4 (11.4)	-1.0 (-6.0 to 3.8)
Time-weighted mean DBP in mmHg (SD)[3]	86.2 (7.2)	86.7 (7.0)	-0.4 (-3.7 to 2.8)

[1] Compared using a linear mixed effects model with repeated measures adjusting for study site and baseline BP as fixed effects including interaction terms between time and randomised group and quadratic time and randomised group.
[2] Compared using a linear regression model adjusted for study site and baseline SBP.
[3] Calculated using area under the curve with the trapezium rule and compared using linear regression adjusted for study site and baseline BP.

2.6.4 Delivery clinical outcomes, safety and health resource use

Maternal and perinatal outcomes and health resource use (Table 11) for women with chronic and gestational hypertension were also similar between groups.

There was one unrelated serious adverse event reported for a woman from the BP self-monitoring arm in the gestational hypertension group with a case of postnatal influenza. Three women had adverse maternal outcomes (unrelated to the intervention).

Table 11: Maternal and perinatal outcomes for 154 pregnant women with chronic or gestational hypertension and their babies

Characteristic	Chronic Hypertension			Gestational Hypertension		
	SMBP Group N = 53	Usual Care Group N = 30	Adjusted[α] Odds Ratio or Difference in Mean/Median (95% CI)	SMBP Group N = 49	Usual Care Group N = 22	Adjusted[α] Odds Ratio or Difference in Mean/Median (95% CI)
Maternal outcomes						
Time between randomisation and delivery*, days	142 (34)	150 (32)		31 (24)	25 (17)	
Need for IV antihypertensive drugs week before delivery	5 (9%)	0 (0%)		0 (0%)	0 (0%)	
Onset of delivery:						
Spontaneous	3 (5%)	2 (7%)		6 (12%)	7 (32%)	
Induction	30 (57%)	22 (73%)		32 (66%)	7 (32%)	
Pre-labour caesarean section	20 (38%)	6 (20%)		11 (22%)	8 (36%)	
Indication for induction of labour/pre-labour caesarean section (all that apply):						
Pre-eclampsia	15 (28%)	2 (7%)		15 (31%)	8 (36%)	
Hypertension	12 (23%)	2 (7%)		4 (8%)	1 (5%)	
Fetal growth restriction	4 (8%)	3 (10%)		4 (8%)	2 (10%)	
Pre-eclampsia						
Total	19 (36%)	5 (17%)	2.9 (0.9 to 9.1)	19 (39%)	8 (36%)	1.1 (0.4 to 3.4)
Defined by new proteinuria only	5 (9%)	2 (7%)		8 (16%)	2 (9%)	
Other maternal organ dysfunction	10 (19%)	2 (7%)		9 (18%)	3 (14%)	
With fetal growth restriction	6 (11%)	2 (7%)		4 (8%)	4 (18%)	
Adverse maternal outcome¥	0 (0%)	1 (3%)		1 (2%)	1 (4%)	
Admitted to ITU	0 (0%)	0 (0%)		1 (2%)	0 (0%)	
Total admission nights‡	5 (3 to 8)	4 (2 to 5)		4 (3 to 6)	3 (2 to 6)	

Table 11 continued: Maternal and perinatal outcomes for 154 pregnant women with chronic or gestational hypertension and their babies

Characteristic	Chronic Hypertension			Gestational Hypertension		
	SMBP Group	Usual Care Group	Adjusted$^{\alpha}$ Odds Ratio or Difference in Mean/Median (95% CI)	SMBP Group	Usual Care Group	Adjusted$^{\alpha}$ Odds Ratio or Difference in Mean/Median (95% CI)
Perinatal outcomes	**N=53**	**N=30**		**N=49**	**N=22**	
Gestation at delivery* (weeks)	36.9 (4.2)	37.9 (2.4)	-1.1 (-2.8 to 0.6)	38.0 (2.0)	37.6 (2.4)	0.4 (-0.7 to 1.5)
Preterm birth (<34 weeks)	7 (13%)	2 (7%)	2.5 (0.5 to 13.7)	2 (4%)	2 (9%)	0.4 (0.1 to 3.2)
Mode of delivery, n (%)						
Spontaneous vaginal delivery	13 (25%)	15 (50%)		21 (43%)	9 (41%)	
Assisted vaginal delivery	1 (2%)	4 (13%)		4 (8%)	4 (18%)	
Emergency pre-labour caesarean section	15 (28%)	4 (13%)		4 (8%)	5 (23%)	
Emergency caesarean section in labour	10 (19%)	2 (7%)		11 (22%)	1 (4%)	
Elective pre-labour caesarean section	14 (26%)	5 (17%)		9 (18%)	3 (14%)	
Total with caesarean section, n (%)	39 (74%)	11 (37%)	4.9 (1.8 to 13.2)	25 (51%)	13 (59%)	1.4 (0.5 to 3.9)
Birth weight* (grams)	2808 (940)	3086 (628)	-300.2 (-690.7 to 90.2)	3061 (738)	3003 (851)	54.2 (-341.7 to 450.0)
Birth weight<10th centile†	8 (15%)	1 (3%)	5.3 (0.6 to 45.8)	9 (18%)	4 (18%)	1.3 (0.3 to 5.4)
Birth weight<3rd centile†	2 (4%)	1 (3%)		2 (4%)	0 (0%)	
Perinatal death:						
Stillbirth	2 (4%)	0 (0%)		0 (0%)	0 (0%)	
Neonatal death	1 (2%)	0 (0%)		0 (0%)	0 (0%)	
Admitted to neonatal unit	9 (17%)	4 (13%)	1.4 (0.4 to 5.3)	9 (18%)	2 (9%)	2.2 (0.4 to 11.5)
Total admission nights‡**	3 (2 to 6)	2 (1 to 4)		2 (2 to 4)	3 (2 to 4)	

Abbreviations: N, n: number; SD: standard deviation; CI: confidence interval; IV: intravenous; ITU: intensive care unit.

Stillbirth: death after 24 weeks' in-utero. Neonatal death: death of baby within first 28 days of life. α Adjusted for study site and baseline clinic SBP.

¥Adverse maternal outcome: eclampsia=2, 1 CHTN and 1 GH usual care; HELLP=1 in GH SMBP (haemolysis, elevated liver enzymes, low platelets syndrome)

* Mean and SD. ‡ Median and IQR. † Using intergrowth-21st, accessed https://www.intergrowth21.org.uk/. ** Does not contain data for the two stillbirths.

2.6.5 Antihypertensive prescribing and self-reported questionnaires

No between-group differences were seen in mean defined daily dose, nor the mean number of antihypertensive medications (Tables 7-8). Similarly, the medication adherence and beliefs about medication scores showed no difference between study groups (Tables 12-13)

No between-group differences were seen at baseline, or at six weeks postnatal in participants' mean self-reported overall five-domain EQ-5D-5L, visual analogue score (VAS) or STAI-6 scores in either hypertension group (Table 14). Assessment of participant BP monitoring preferences (from respondents to Little's 'problem score' questionnaire undertaken postnatally), indicated that clinic BP monitoring caused more anxiety than home monitoring (related to waiting around, worrying about knowing what the BP was), whereas home monitoring scored more highly on all three positive factors: feeling in control, good use of clinician time, worth the trouble to get accurate readings (Table 15). There was a lower overall 'problem score' for the home BP monitoring group compared with usual care clinic monitoring , for both chronic and gestational hypertension groups: mean difference score (95% CI) -0.3 (-0.5 to -0.02) and -0.7 (-0.9 to -0.4) respectively.

This work is now published (see Appendix 9)(209).

2.6.6 Exploratory outcomes

See published secondary analysis (Appendix 10)(214).

Table 12: Comparing study visit medication belief and adherence scores for 61 participants with chronic hypertension with completed questionnaires

	Baseline		20 weeks' gestation		28 weeks' gestation		34 weeks' gestation		Adjusted* difference between study groups		
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	20 weeks (95% CI)	28 weeks (95% CI)	34 weeks (95% CI)
BMQ necessity score$^{\beta}$											
Usual Care	21	17.0 (4.2)	-	-	22	17.6 (3.4)	23	18.8 (3.6)	-	0.1 (-1.5 to 1.7)	-1.2 (-2.7 to 0.4)
SMBP	40	15.3 (3.2)	-	-	28	16.7 (3.2)	34	17.0 (2.7)			
BMQ concern score$^{\beta}$											
Usual Care	21	14.0 (3.9)	-	-	22	13.3 (2.9)	23	12.3 (3.3)	-	0.7 (-0.6 to 2.1)	1.1 (-0.2 to 2.4)
SMBP	40	13.9 (4.2)	-	-	28	12.9 (3.8)	34	13.0 (4.7)			
MARS-5 score$^{\mu}$											
Usual Care	21	23.5 (1.4)	-	-	21	24.2 (1.2)	23	24.0 (1.6)	-	-0.4 (-1.3 to 0.4)	-0.1 (-1.0 to 0.7)
SMBP	40	23.7 (1.4)	-	-	28	24.1 (1.1)	36	24.0 (1.7)			

Abbreviations: SMBP: self-monitoring blood pressure; n: number; SD: standard deviation; CI: confidence interval.

β BMQ: Beliefs about Medication Questionnaire necessity and concern scores. Each score is made up from 5 statements with 5-point Likert scale answers (strongly disagree, disagree, uncertain, agree and strongly agree). The answers are scored from 1 (strongly disagree) to 5 (strongly agree). Points on each scale are summed to give a scale score, range from 5 to 25. Higher scores indicate stronger beliefs in the concepts of the scale, either how necessary their specific medication is or strength of concerns regarding this specific medication.

μ MARS-5: Medication Adherence Report Scale consists of 5 common patterns of non-adherent behaviour scored on a 5-pointLikert scale (with 1 = always, 2 = often, 3 = sometimes, 4 = rarely, and 5 = never). The first statement of the MARS-5 questions patients about unintentional non-adherence, whereas the other 4 statements question intentional non-adherence. Scores are summed, and totals range from 5 to 25. Higher scores indicating higher self-reported adherence.

* Mixed effects liner regression model with repeated measures, adjusted for site and study baseline BP as fixed effects, with interaction between randomisation group and study visit. Models for BMQ and MARS-5 scores include additional adjustment for baseline scores.

Table 13: Comparing study visit medication belief and adherence scores for 41 participants with gestational hypertension with completed questionnaires

	Baseline		34 weeks' gestation		Adjusted* difference between study groups at 34 weeks' (95% CI)
	No. of participants	Mean (SD)	No. of participants	Mean (SD)	
BMQ necessity score$^{\beta}$					
Usual Care	13	17.2 (3.4)	6	15.0 (3.2)	0.8 (-5.8 to 7.4)
SMBP	28	15.8 (3.1)	11	16.8 (4.9)	
BMQ concern score$^{\beta}$					
Usual Care	13	13.3 (4.2)	6	9 (3.2)	1.2 (-4.1 to 6.4)
SMBP	28	12.0 (3.9)	11	10.9 (3.9)	
MARS-5 score$^{\mu}$					
Usual Care	11	24.5 (1.0)	6	24.0 (2.0)	1.4 (-0.3 to 3.1)
SMBP	29	24.0 (1.5)	10	24.1 (1.4)	

Abbreviations: SMBP: self-monitoring blood pressure; No: number; SD: standard deviation; CI: confidence interval.
β BMQ: Beliefs about Medication Questionnaire necessity and concern scores. Each score is made up from 5 statements with 5-point Likert scale answers (strongly disagree, disagree, uncertain, agree and strongly agree). The answers are scored from 1 (strongly disagree) to 5 (strongly agree). Points on each scale are summed to give a scale score, range from 5 to 25. Higher scores indicate stronger beliefs in the concepts of the scale, either how necessary their specific medication is or strength of concerns regarding this specific medication.
μ MARS-5: Medication Adherence Report Scale consists of 5 common patterns of non-adherent behaviour scored on a 5-pointLikert scale (with 1 = always, 2 = often, 3 = sometimes, 4 = rarely, and 5 = never). The first statement of the MARS-5 questions patients about unintentional non-adherence, whereas the other 4 statements question intentional non-adherence. Scores are summed, and totals range from 5 to 25. Higher scores indicating higher self-reported adherence.
*Linear regression model adjusted for site and study baseline BP, with interaction between randomisation group and study visit.
Models for BMQ and MARS-5 scores include additional adjustment for baseline scores.

Table 14: EQ-5D-5L cross-walk index, VAS quality of life and STAI-6 scores for pregnant women with chronic or gestational hypertension

Questionnaire	Women with chronic hypertension with questionnaire data		Women with gestational hypertension with questionnaire data	
	SMBP N=38	**Clinic monitoring N=22**	**SMBP N=36**	**Clinic monitoring N=16**
EQ-5D-5L cross-walk index score at baseline*	0.9 (0.2)	0.8 (0.1)	0.7 (0.2)	0.8 (0.1)
EQ-5D-5L cross-walk index score postnatal*	0.9 (0.1)	0.8 (0.2)	0.9 (0.1)	0.9 (0.1)
Adjusted mean difference (95% CI)†	0.1 (-0.04 to 0.1)	-	0.0 (-0.1 to 0.1)	-
	N=37	**N=21**	**N=36**	**N=16**
EQ-5D-5L visual analogue score (VAS) at baseline*	78.0 (13.9)	73.1 (20.9)	70.5 (20.5)	72.8 (15.6)
EQ-5D-5L visual analogue score (VAS) at postnatal*	77.6 (16.4)	81.5 (14.7)	80.5 (13.9)	81.2 (12.8)
Adjusted mean difference (95% CI)†	-5.5 (-13.4 to 2.5)	-	-0.7 (-8.1 to 6.6)	-
	N=38	**N=22**	**N=36**	**N=16**
STAI-6 score at baseline*	33.5 (9.9)	34.5 (12.2)	37.8 (12.4)	33.8 (13.5)
STAI-6 score postnatal*	30.4 (9.1)	31.2 (13.5)	30 (13.1)	27.1 (9.5)
Adjusted mean difference (95% CI)†	-1.4 (-7.4 to 4.5)	-	1.7 (-6.0 to 9.3)	-

Abbreviations: SMBP: self-monitoring blood pressure; N: number; SD: standard deviation; CI: confidence interval; VAS: visual analogue scale; STAI-6: abbreviated state trait anxiety index.

* Mean (SD). Compared using a linear regression model adjusted for study site, baseline SBP and baseline score.

Table 15: Little's questionnaire rating different methods of BP monitoring for pregnant women with chronic or gestational hypertension

Characteristic	Women with chronic hypertension		Women with gestational hypertension	
	SMBP N=37	Clinic monitoring N=59 (SMBP 37, usual care 22)	SMBP N=36	Clinic monitoring N=52 (SMBP 36, usual care 16)
Disturbance and discomfort				
It made me anxious	2.7 (2.1)	3.2 (2.2)	2.6 (1.9)	3.6 (2.2)
It disturbs home life or everyday activities	2.2 (1.6)	2.1 (1.5)	2.1 (1.5)	2.7 (2.0)
It disturbs sleep	1.6 (1.2)	1.9 (1.3)	1.7 (1.4)	2.2 (1.7)
It disturbs work	1.9 (1.5)	1.7 (1.2)	1.6 (0.9)	2.5 (1.9)
I was uncomfortable	1.5 (0.6)	1.7 (1.2)	1.7 (1.1)	2.6 (2.1)
Self-consciousness				
I felt self-conscious	2.3 (1.9)	2.6 (1.9)	2.1 (1.7)	3.0 (2.2)
Uncertainty				
I felt unsure what to do	1.7 (1.0)	1.7 (1.1)	1.9 (1.5)	1.9 (1.5)
There is a lot of waiting around	1.9 (1.3)	2.5 (1.8)	1.8 (1.2)	3.5 (2.2)
It worried me knowing the blood pressure	3.6 (2.3)	3.9 (2.2)	3.2 (2.2)	4.0 (2.3)
It was difficult to remember to do it	2.7 (1.9)	2.4 (1.5)	2.8 (2.0)	2.3 (1.7)
Accuracy				
It was worth the trouble to get accurate readings	5.7 (1.6)	5.3 (1.9)	5.7 (1.6)	5.1 (2.2)

Table 15 continued: Little's questionnaire rating different methods of BP monitoring for pregnant women with chronic or gestational hypertension

Characteristic	Women with chronic hypertension		Women with gestational hypertension	
	SMBP N=37	Clinic monitoring N=59 (SMBP 37, usual care 22)	SMBP N=36	Clinic monitoring N=52 (SMBP 36, usual care 16)
Control and efficiency				
I felt in control	5.7 (1.5)	5.3 (1.5)	5.8 (1.7)	5.3 (1.9)
It is a good way to use or save doctor or nurse time	6.0 (1.3)	5.5 (1.5)	5.8 (1.7)	5.2 (2.0)
Analysis				
Mean (SD) item problem score*	2.2 (0.6)	2.5 (0.6)	2.1 (0.4)	2.8 (0.6)
Difference in mean item problem score (95% CI)†	-0.3 (-0.5 to -0.02)	-	-0.7 (-0.9 to -0.4)	-

Abbreviations: SMBP: self-monitoring blood pressure; number; SD: standard deviation; CI: confidence interval.
Ratings: 1=disagree strongly; 2=disagree; 3=disagree slightly; 4=unsure or not applicable; 5=agree slightly; 6=agree; 7=agree strongly.
*Scoring reversed for positive items (control, good use of time, worth the trouble). †Analysed with non-paired two sample t-test.

2.7 Conclusion

The findings are discussed in the context of the wider literature in the next chapter. These results from the randomised study suggest that blood pressure self-monitoring for the management of hypertension in pregnancy is feasible and do not highlight any safety concerns with the intervention. The data presented here also provide initial support that the self-monitoring intervention and trial processes are broadly acceptable to (both) women and their clinical teams. As far as I am aware, this work represents the first randomised study investigating the use of BP self-monitoring in a pregnant population with hypertension. These results suggest that expanding this study to a larger scale trial powered to explore the effectiveness and cost-effectiveness of self-monitoring for improved BP control in this population would be practicable.

Chapter 3: Discussion of feasibility study

In this chapter, I summarise and discuss the findings from the randomised feasibility study described in chapter 2, discussing these data within the context of the larger literature.

3.1 Summary of findings

This was the first randomised controlled trial looking at BP self-monitoring for the management of women with pregnancy hypertension and showed this intervention was feasible in this context. Overall recruitment (71%) and follow-up (95%) in the study were much greater than average rates quoted for UK randomised trials(215). The recruitment rate of 2.5 per site per month suggests that this is a feasible intervention to trial on a larger scale. Adherence and persistence with the self-monitoring intervention was high across both types of hypertension group and supports the hypothesis that self-monitoring is also acceptable in this population. This is consistent with women reporting no differences in anxiety or quality of life scores between randomised groups, and indicating a greater preference with lower 'problem scores' for BP self-monitoring versus usual clinic monitoring(131).

Systolic BP in all groups and diastolic BP in gestational hypertension did not show any differences, although we saw a small and statistically significant increase in mean diastolic and time-weighted mean diastolic clinic BP for the group using self-monitoring versus usual care in women with chronic hypertension. The greater proportion of caesarean sections within the self-monitoring versus usual care group for women with chronic hypertension is likely to be a chance finding. However there was a consistent trend for higher rates of pre-eclampsia, greater proportion of babies born prematurely less than 34 weeks' and with reduced birth weight. Although these data could suggest an iatrogenic cause secondary to the use of SMBP, the greater proportion of babies less than tenth centile for weight in the self-monitoring group suggests these were pregnancies correctly identified as affected by pre-eclampsia, giving rise to lower birthweight babies, and consequently underwent more operative deliveries as would be expected. It seems unlikely that self-monitoring of BP in itself increases adverse outcomes of this nature, particularly as our

prescribing and medication adherence data did not reveal any difference between the randomisation groups, which would have suggested a medication cause for these data. Although our study was not powered to look at these outcomes. Safety data from the study were encouraging with no differences in reported rates of serious adverse events, although it is acknowledged that this study represents a small sample and traditionally it is difficult to capture these relatively rare events even in larger randomised trials.

3.2 Strengths and limitations

The main strength of this study is that to our knowledge, it was the first randomised study of blood pressure self-monitoring in the pregnant population with hypertension.

Participant randomisation using allocation concealment limited selection bias. It was not possible to mask the participants or clinicians to randomisation group due to the nature of an intervention that requires behaviour change and resultant interactions between the two parties. However, providing additional reminders to clinical teams during site visits regarding best practice for BP measurement helped to limit detection bias in clinic BP measurement. Statistical analysis was performed masked to randomisation group.

The study benefited from being run across four NHS sites including tertiary level and district general hospitals, suggesting that different types of clinical infrastructure are able to implement self-monitoring into management pathways. The trial was also successful in recruiting women with a range of ethnicities and socioeconomic and educational backgrounds, supporting the concept that BP self-monitoring is feasible and acceptable for a wide range of women whose pregnancies are complicated by hypertension. The high adherence and persistence with the self-monitoring intervention is reassuring given the high recruitment proportion of more than 70% of those eligible. Together these data provide support for the external validity of the feasibility study findings for the larger target population who might benefit from this intervention. However, it is important to consider that those sites and individuals who agree to participate in a feasibility

study likely represent more motivated groups(216) and thus although our study has found self-monitoring to be practicable, larger scale effectiveness studies are needed.

The trial was run pragmatically using clinic measurements in addition to study BP readings and has shown the feasibility of collecting and using routine clinical data. This is important in pregnancy where attendance at study visits is problematic and affected by later study entry and premature delivery (for example <25% of those with gestational hypertension attended a study visit at 34 weeks' gestation whereas all had clinic BP data). The rapidly dynamic nature of BP change is such that intermittent study visits less accurately portray underlying BP trends. We were also able to successfully collect postpartum data from both randomised groups, with over 70% completion, compared with the lower rates of 50-60% usually reported in the literature, even in remunerated follow-up(217, 218). This is likely due to the nature of the intervention promoting ongoing participation, but for the control group also we maintained contact at antenatal clinic visits to reduce differential Hawthorne effect(219), and postpartum follow-up was flexible with women able to choose between a home visit and telephone call.

While it is possible that there may be some inaccuracy of reporting BP readings by participating women, via the text message service, app or recorded in BP diaries, accuracy in similar studies has been shown to be high (94% identical and only 1% submitted at a different BP threshold)(184). In this study, accuracy (within 5 mmHg) between supplied SMBP readings and monitor downloads was 95% for women with chronic hypertension and 98% for those with gestational hypertension(214). More recent studies of blood pressure self-monitoring in both the general and pregnant populations, published after the design of this study, have increasingly used Bluetooth technology to automatically transmit BP readings to an app(220-222). At the time of this study there were no BP monitors validated for use in pregnancy and pre-eclampsia with this capability. The use of Bluetooth technology is promoted as reducing the work patients have to do entering their readings, and to protect against data inaccuracies. However automatic data upload does

have implications for patient autonomy and empowerment, which are further discussed in chapter 8.

Our study was able to detect cross-over between groups with 17–39% of our usual care group with gestational and chronic hypertension respectively taking up some form of home monitoring. Evidence from the non-pregnant hypertensive population has shown that informal self-monitoring alone has limited impact on BP control as opposed to self-monitoring combined with active intervention(118, 223). However it is not known if this might be an important factor affecting the ability to study self-monitoring within pregnancy which benefits from more structured and frequent follow-up than occurs in the general adult population with hypertension, particularly amongst a higher risk group such as those with HDP. It would be difficult and unethical to try to enforce no voluntary self-monitoring amongst women or to counsel that their health care providers do not engage when presented with these measurements. A study design that has been used previously in both the general and pregnancy populations, trained all participants to self-monitor but randomised whether patients or clinicians were able to view the home readings(155, 224). However, the pregnancy study only asked women to self-monitor for a seven day period(155). An intervention that requires women to perform daily BP monitoring throughout their pregnancy without sharing readings would be unlikely to appeal to women. Parallel or stepped wedge cluster trial designs are sometimes used to avoid 'contamination' but these designs require considerably larger sample sizes and are susceptible to recruitment bias(225, 226).

Chance imbalances in baseline characteristics between randomisation groups are likely in feasibility trials with smaller sample sizes(227); evidence for this was noted for two known important predictors of perinatal outcome (ethnicity and previous pregnancy hypertensive disorder) within the group with chronic hypertension(58, 228). The small numbers used for feasibility studies also reduce the chance of being able to successfully minimise at randomisation

(whereby random allocation to next participant is dependent on characteristics of those already enrolled to try and minimise imbalance in important factors between groups) or adjust for all important confounders in the analyses of such studies.

3.3 Comparisons with the literature

Previous studies in the non-pregnant population with hypertension have shown that self-monitoring accompanied with self-management produces improved BP control, is preferred by participants to usual care(118, 119, 223) and provided the impetus for this study. To our knowledge, the only previous published *randomised* controlled trial of self-monitoring of BP throughout pregnancy included a low risk pregnant population and was designed to evaluate the feasibility of a reduced clinic visit schedule(156) rather than effects on BP control or clinical outcomes.

Since the development of the feasibility study described in this thesis, several other controlled studies evaluating blood pressure self-monitoring in pregnancy have been published reflecting the fast developing interest in this area. These studies form a heterogeneous body of work and are summarised in Table 16. They differ from our own study in that they are predominantly small observational studies conducted in single centres, mostly including a lower risk group of women from a narrower demographic. The interventions have also varied, with the most recent studies using telemonitoring with automated Bluetooth technology and designed with considerable oversight of monitoring, with same-day clinician review of data. This compares with our study which had invited women with hypertension to monitor their own results, with additional support from automated responses for out-of-range readings for women with GH using the telemonitoring service. Importantly, ours has been the only study to focus on the use of SMBP for the *control* of blood pressure within pregnancy. The focus of these other studies has been principally around the redesign of antenatal services, specifically seeking to reduce antenatal visits and admissions through remote monitoring. Kalafat et al published a systematic review of

antenatal and postpartum blood pressure monitoring studies in January 2020, conducting their search from journal start to May 2019 (just before publication of the OPTIMUM-BP feasibility trial(209)), and included English language studies comparing HBPM with usual care for low risk or women with HDP(154). They included observational studies with suitable controls and randomised controlled trial designs. This identified 11 studies published between 1985 to 2019: seven in the antenatal population(35, 155, 156, 229-232), two related cost-effectiveness studies(233, 234) and two in the postpartum population(184, 235). The seven antenatal studies are summarised in Table 16. The most recent antepartum studies included in this analysis were two case-control studies by the UK authors of the review(35, 229), and one Belgian cohort study(231).

Table 16: A - Characteristics of controlled studies evaluating antenatal SMBP in pregnancy

Reference, country	Design	Participants	Comparability	Gestation at enrolment (weeks)	Duration follow-up	Inclusion criteria	Exclusion criteria	SMBP device: validated in pregnancy?	Tele-monitoring
Rayburn, 1985, USA	Case-control	77 total 33 SMBP 34 historic controls Single centre	Comparable at baseline	NS	SMBP group: 24 weeks (8-35 weeks)	Chronic hypertension, no other details	NS	NS	No
Ross McGill, 2000, UK	RCT	80 total 40 SMBP 40 control Single centre	Comparable at baseline	24-28 weeks No other details	13 weeks' until delivery	Low risk population	Multiple pregnancy, established hypertension ≥ 140/90 mmHg, previous early onset pre-eclampsia (<34 weeks), serious medical disease, previous pregnancy loss >24 weeks	Omron, no other detail. NS	No
Fukushima, 2002, USA	Cohort	199 total 19 SMBP 180 control Single centre	19 selected for SMBP as the highest risk patients: SBP ≥ 170 or DBP ≥ 115 or MAP ≥ 120 mmHg	SMBP: 19.6 +/-9.8 Control: 27.5 +/- 9.3	7.9 weeks' until delivery	CHTN/GH with severe hypertension: BP ≥160/110 mmHg or MAP > 100 mmHg on at least 3 tests, delivery occurred at least 8 days after first test, were outpatients for at least 4 days, gestation ≥ 20 weeks' and outcome data available	Those who remained hospitalised until delivery	Oscillometric Accutor 3, Datascope. Not validated	Yes, sent their readings by fax machine
Denolle, 2008, France	RCT	48 total 24 SMBP with teletransmission 24 SMBP without transmission Single centre	NS	Mean of both groups: 29 +/-5	7 days	Recently diagnosed hypertension > 18 weeks' gestation, without albuminuria or history of hypertension in current or previous pregnancies	Obesity (BMI >30 kg/m^2), nephropathy or chronic disease, receiving hypertension treatment	Automated oscillometric OMRON 705C. Yes, validated.	Yes

Reference, country	Design	Participants	Comparability	Gestation at enrolment (weeks)	Duration follow-up	Inclusion criteria	Exclusion criteria	SMBP device: validated in pregnancy?	Tele-monitoring
Lanssens, 2018, Belgium	Cohort	301 total 86 SMBP 215 traditional care Single centre	Significantly more with GH in SMBP vs control (69.8% vs 42.8%, p<0.01) and significantly less with pre-eclampsia in SMBP vs control (19.8% vs 44.2%, p<0.01).	NS	Until delivery, no other details	Gestational hypertension and > 10 weeks' gestation and initiated SMBP at behest of responsible obstetrician	Excluded if missing data	CE-approved device. Not validated.	Yes Predetermined alarm signals reviewed by midwife.
Perry, 2018, UK	Case-control	166 total 108 SMBP 58 historic controls Single centre	Significantly more women with CHTN in SMBP vs control (49.1% vs 25.9%, p<0.01). Significantly fewer women in SMBP group developed pre-eclampsia (20.4% vs 34.5%, p=0.05)	SMBP: 30.0 (22.0-35.0) Control: 33.6 (28.2-36.1)	SMBP: 8.9 (3.4-16.5) Control: 4.9 (3.3-9.3)	Chronic hypertension or gestational hypertension (ISSHP), at risk of developing pre-eclampsia (no details), no significant proteinuria	Maternal age < 16, SBP > 155 mmHg, DBP > 100 mmHg, significant proteinuria, signs for severe PET, EFW < 10th centile, significant mental health concerns, insufficient understanding of English	Automated Microlife Watch BPHome. Yes, validated.	Yes Hamilton app Warning given if inputted abnormal BP reading. No other details
Kalafat, 2019, UK	Case-control	143 total 80 SMBP 63 historic controls with GH Single centre	No significant differences at baseline other than gestational age at enrolment SMBP vs control, 34.0 vs 36.0 (p<0.01)	SMBP: 34.0 (28.2-36.3) Control: 36.0 (33.0–37.3)	SMBP: 4.8 (1.8-8.6) Control: 3.6 (2.2-5.3)	Gestational hypertension (ISSHP), no significant proteinuria	CHTN, maternal age < 16, SBP > 155 mmHg, DBP > 100 mmHg, significant proteinuria, signs for severe PET, EFW < 10th centile, significant mental health concerns, insufficient understanding of English	Automated Microlife Watch BPHome. Yes, validated.	Yes Hamilton app No further details

Reference, country	Design	Participants	Comparability	Gestation at enrolment (weeks)	Duration follow-up	Inclusion criteria	Exclusion criteria	SMBP device: validated in pregnancy?	Tele-monitoring
Van den Heuvel, 2019, the Netherlands	Single cohort	14 SMBP (analysed 13 due to new diagnosis chronic hypertension) Single centre	NA	21.2 (10-32)	15 weekdays	Low risk and <34 weeks' gestation. Can read and speak Dutch. Access to smartphone or tablet with internet access.	Chronic hypertension, HDP previous pregnancy, cardiac or renal pathology, obesity (BMI>35 or arm circumference>42cm)	iHealth Track automated monitor. Yes, validated.	Yes Bluetoothed readings, in-app symptom checklist and trend graphs. Push alerts at 7am.
Butler Tobah, 2020, USA	RCT	267 total 134 SMBP 133 control Single centre	Comparable at baseline	<13 weeks' gestation, no details	Until delivery	Low risk pregnancies. English-speaking between 18-36 years and <13 weeks' gestation, no concurrent medical or obstetric complications	Any chronic medical condition, including hypertension, coagulopathies, diabetes, class 3 obesity, or obstetrician judgement that pregnancy at high risk of complications	OBNest bundle with "Home digital sphygmomanometer and handheld fetal Doppler". NS	Yes Women reported their home BP through online messaging on institution's electronic medical records.
Van den Heuvel, 2020, the Netherlands	Case-control	236 total 103 SMBP 133 historic controls Single centre	More women with kidney disease in SMBP vs control group (16.5% vs 4.5%, p<0.01)	SMBP: 17.9 (3.9) weeks	20.2 (4.0) weeks	Singleton pregnancy, >18 years, one or more of: chronic hypertension, pre-eclampsia in previous pregnancy, maternal cardiac or kidney disease. Can read and speak Dutch/English. Access to smartphone or tablet with internet access.	Kidney transplant patients, arm circumference>42cm	iHealth Track automated monitor. Yes, validated.	Yes Bluetoothed readings, in-app symptom checklist and trend graphs. Push alerts at 7am.

Table 16: B - Outcomes of controlled studies evaluating antenatal SMBP in pregnancy

Reference, country	Primary outcome	Additional outcomes	SMBP frequency	SMBP regime	SMBP triggers	SMBP clinical oversight	Clinical follow-up	Outcomes
Rayburn, 1985, USA	NS	Need for antihypertensives, maternal and perinatal outcomes	Twice daily	No details	Asked to telephone obstetrician/nurse if increased BP or symptoms of pre-eclampsia, no other details	Asked to telephone obstetrician/nurse if increased BP or symptoms of pre-eclampsia, no other details	Clinic visit frequency NS. Hospitalisation if persistent average clinic and home > 140/90 mmHg or >30 mmHg or >15 mmHg rise in SBP or DBP on 2 occasions 6 hours apart	Comparing SMBP vs control: antihypertensive medication at initial evaluation 55% vs 21%(p=0.01), and before delivery 45% vs 50%; maternal morbidity (CCF, CVA, worsening renal function) 3% vs 0; superimposed pre-eclampsia/eclampsia 18% vs 15%; antenatal hospitalisation 24% vs 62% (p=0.01). No significant difference in perinatal outcomes: delivery before 37 weeks, IUGR, stillbirth, neonatal deaths.
Ross McGill, 2000, UK	NS	Recruitment, total number of clinic visits, frequency of BP measurement, schedule preference, anxiety.	Weekly	SMBP with reduced number of visits to 34, 38 and 41 weeks	If SBP between 140-160 mmHg or between DBP 90-100 mmHg then instructed to repeat their measurement after 4 hours and if second reading SBP >140 or DBP > 90 mmHg then to contact midwife. If single SBP ≥ 160 or DBP ≥100 mmHg then to make contact.	NS	NS	Significantly reduced number of antenatal visits SMBP vs control (4.5 vs 7.4, p<0.01), non-significantly reduced visits to GP/midwife (3.2 vs 5.6, p=NS), non-significant increased mean telephone contact SMBP vs control (0.65 vs 0.45, p=NS). Significantly more weeks measured BP SMBP vs control (10 vs 6.9, p<0.01) No difference in anxiety scores. More women 'pleased' to be in reduced visit group SMBP vs control (18 vs 6) and fewer women 'less pleased' (6 vs 22).
Fukushima, 2002, USA	NS	Delivery outcomes	Several times daily	NS	NS	Faxed SMBP results reviewed daily by study author	NS	SMBP vs control: Gestation at delivery: 35.8 +/- 3.4 vs 38.2 +/- 5.4 (p=0.06), birth weight: 2323 +/- 833 vs 2943 +/- 819 (p<0.01), MAP mmHg 115.3 +/- 12.2 vs 100.7 +/- 11.7 (p<0.01). Stillbirths: 1 in each group.

Table 16: B - Outcomes of controlled studies evaluating antenatal SMBP in pregnancy

Reference, country	Primary outcome	Additional outcomes	SMBP frequency	SMBP regime	SMBP triggers	SMBP clinical oversight	Clinical follow-up	Outcomes
Denolle, 2008, France	Prevalence and prognosis of white coat hypertension (WCHTN)	Feasibility, safety, tolerance and acceptability of SMBP, costs	3 times before breakfast, once after dinner	Also dipped urine daily at home for protein. Transmission group readings sent daily to obstetrician	Three successive readings BP >160/100 mmHg obstetrician immediately alerted	Transmission group readings sent daily to obstetrician	NS	Prevalence of WCHTN 76% (32/42) 92% described SMBP as 'very easy', 8% as 'easy', 75% 'very satisfied' and 25% 'satisfied'
Lanssens, 2018, Belgium	Prenatal follow-up: visits, CTGs, prenatal admissions, days hospitalised	Delivery outcomes	Morning and evening	NS	Alarms at SBP> 140 mmHg, DBP >90 mmHg	Predetermined alarm signals reviewed by same midwife daily.	NS	Comparing SMBP vs control: less total number of antenatal visits 6.9% vs 7.6%, p<0.01; less prenatal admissions 51.6% vs 71.6%, p<0.01; same days hospitalised 5.1 vs 4.1, p=0.88, less admission until delivery 31.4% vs 57.7%, p<0.01; less inductions 32.6% vs 46.5%, P<0.01, no difference in mode of delivery, birthweight or NICU admissions.
Perry, 2018, UK	NS	Adverse fetal, neonatal, maternal outcomes and number of antenatal hospital visits of various types	Individualise d schedule of hospital visits and SMBP	Individualised schedule of hospital visits and SMBP e.g: woman with well controlled CHTN, measure SMBP 2-3 times/week e.g. woman starting new treatment SMBP twice/day and reviewed 1 week later.	SBP > 155 mmHg or DBP > 100 mmHg or symptoms of pre-eclampsia	NS But same midwife reviewed patients at interim visits and reviewed SMBP readings	NS	No difference between groups: in HDU admission (p=0.35) or BP-related admission days (p=0.20), or composite adverse fetal (p=0.90), neonatal (p=0.98) or maternal outcomes (p=0.25). Difference in DAU visits: SMBP < control group (4 vs 6, p<0.01), difference in antenatal visits: SMBP < control (6.5 vs 8.0, p<0.01), fewer visits per week, SMBP < control (0.8 vs 1.6, p<0.01).
Kalafat, 2019, UK	NS	Adverse fetal, neonatal, maternal outcomes and number of antenatal hospital visits of various types	Individualise d schedule of hospital visits and SMBP	Individualised schedule of hospital visits and SMBP	SBP > 155 mmHg or DBP > 100 mmHg or symptoms of pre-eclampsia	NS But same midwife reviewed patients at interim visits and reviewed SMBP readings	NS	No difference between groups in HDU admission (p=0.99), birth weight centile (p=0.80), IUGR (p=0.99), NICU admission (p=0.51), composite neonatal (p=0.65), fetal (p=0.99), maternal (p=0.99) adverse outcome. Difference in MAU visits, SMBP<control (4.0 vs 5.0, p=0.01), No difference in total OP number visits (p=0.36), triage visits (p=0.24). Total number antenatal visits adjusted for monitoring duration SMBP< control (1.4 vs 1.8, p=0.02).

Table 16: B - Outcomes of controlled studies evaluating antenatal SMBP in pregnancy

Reference, country	Primary outcome	Additional outcomes	SMBP frequency	SMBP regime	SMBP triggers	SMBP clinical oversight	Clinical follow-up	Outcomes
Van den Heuvel, 2019, the Netherlands	Feasibility measured as compliance	Usability and satisfaction	Submit BP and symptom checklist before 10am Mon-Fri for three weeks	NS	Alerts set for SBP>140 mmHg or DBP>90 mmHg or increase 20 mmHg compared with previous. Alarms if ≥1 of 10 symptom checklist.	Same HCP reviewed readings every morning	NS	Compliance rate: 93% for BP, 85% symptom checklist. Accuracy of alarm system: no false positives or negatives. Usability of BP monitor 8.9, (8-10), of app 7.7 (5-10), 11/13 felt involved in antenatal care, 12/13 strongly agreed "I would use the telemonitoring platform if there would be a reason for frequent monitoring".
Butler Tobah, 2020, USA	Acceptability measured by comparing satisfaction with care, perception of stress, perceived quality of care.	Effectiveness measured by adherence to ACOG recommendations for lab tests, USS, immunisation and patient education.	OBNest bundle: reduced schedule of 8 clinic (versus usual 12) and 6 virtual visits with home BP and fetal heart rate	Virtual visits at 16, 24, 33, 38, 40 and 41 weeks. No details about how many BP readings asked to measure at these visits.	NS	Women took their readings and reviewed them with OBNest nurse during virtual visits.	NS	Control group seen according to ACOG guideline: 12 clinic visits vs OBNest group: 8 clinic and 6 virtual visits. OBNest vs control: higher satisfaction (93.9% vs 78.9%, p<0.01), lower pregnancy related stress at 14 and 36 weeks, p<0.0. No significant difference in perceived quality of care. Comparable provision of ACOG antenatal services and maternofetal outcomes between groups. Total nursing time higher in OBNest vs control (171.2 vs 108.2 minutes, p<0.01)
Van den Heuvel, 2020, the Netherlands	Healthcare consumption and user experiences	Maternal and perinatal outcomes	Submit BP (and symptom checklist if BP raised, no details) before 10am Mon-Fri	SMBP until delivery. Predefined scheduled visits: 16, 20, 26, 30, 34, 36, 38, 40 weeks' and USS at 20, 26, 30, 34 weeks.	Alerts set for SBP>140 mmHg or DBP >90 mmHg or increase 20 mmHg compared with previous. App alarms if ≥1 of 10 symptom checklist.	Same HCP reviewed readings every morning	NS	Visits every 2 weeks with increased frequency if needed. AHT medication prescribed if SBP> 160 or DBP >110 mmHg Comparing SMBP vs control: Significantly less total number of visits (13.7 vs 16.0, p<0.01), less USS (6.3 vs 7.4, p<0.01), less admissions for BP observation (2.9% vs 13.5%, p<0.01). 47/51 (92%) satisfied with use of app and platform. Median number of uploaded BP readings 4.5/week (IQR 3.6-5.0) and median compliance rate for all BP readings 91.2% (IQR 70-100). Diagnosis of GH, pre-eclampsia, CHTN similar between groups, ~20% across groups developed pre-eclampsia. Induction of labour more in SMBP (56.3% vs 38.3%, p<0.01) but not for HTN. No other differences.

In their meta-analysis of these studies (which are observational studies with a control group, and therefore where the findings should be interpreted with considerable caution), Kalafat et al reported four statistically significant associations for antenatal outcomes: the use of HBPM versus usual care was associated with reduced odds of induction of labour (IOL) (OR: 0.55, 95% CI 0.36-0.82, 2 studies, 444 women), prenatal hospital admissions (OR: 0.31, 0.19-0.49, 3 studies, 416 women), diagnosis of pre-eclampsia (OR: 0.50, 0.31-0.81, five studies, 725 women) and reduced antenatal visits (standard mean difference: -0.49, -0.82 to -0.16, five studies and 738 women). They found no significant differences between HBPM and usual care for any fetal outcomes or composite adverse maternal outcome. However, as the authors noted there was *"significant clinical heterogeneity and low quality evidence".* The Belgian PRENOM cohort study from Lanssens et al(231) contributed the largest numbers of women and events to the analyses for induction of labour, prenatal admissions and incidence of pre-eclampsia and without inclusion of this study it is doubtful the meta-analyses would be significant for these outcomes. The Lanssens study included all women diagnosed with GH attending antenatal follow-up at a single site. However the authors found evidence of considerable selection bias. The treating obstetrician allocated women, without randomisation, to either HBPM (n=86) or the standard care model (n=215) and there were significantly more women diagnosed with gestational hypertension (70% vs 43%) but less with pre-eclampsia (20% vs 44%) in the HBPM compared to the standard care group, in this non-masked study. This selection bias should prompt caution when interpreting the findings associated with the use of HBPM as the women *chosen* by obstetricians to follow the HBPM model appear to be a lower risk group. Definitive conclusions on outcomes cannot be drawn without randomised trial evidence.

The two case-control studies included in the meta-analyses and detailed in Table 16 were from the review authors themselves(35, 229). Both studies conducted at a single site compared HBPM

with historic controls who followed the unit's traditional care pathway. Both studies found HBPM to be associated with significantly fewer hospital visits, but similar to the Lanssens study above, there was evidence of selection bias, particularly in the earlier case-control study(229). There were significantly more women with chronic hypertension (rather than gestational hypertension) in the HBPM group than in the control group (49.1% vs 25.9%, P=0.0004). As the authors noted it is hard to make comparisons between the HBPM and control groups given this bias, so that any differences may reflect management of these underlying conditions rather than the effect of HBPM. Women with GH are likely to be recruited at later gestations and therefore require more frequent assessment. Neither study found an increase in adverse maternal or fetal outcomes associated with the use of HBPM, but similar to our study, these are relatively rare events and are difficult to study. No blood pressure outcomes were reported for comparisons with our own findings.

The only randomised controlled trial included in the meta-analysis evaluating SMBP in pregnancy was the 2000 UK study by Ross-McGill(156). This study used HBPM combined with a reduced schedule of antenatal visits for monitoring a low risk pregnant population (40 HBPM: 40 usual care). Thus, the mainly small observational studies with significant selection bias included in this review and meta-analysis make it difficult to draw any meaningful conclusions about the causal role for an association between HBPM and any reduction in adverse pregnancy outcomes or reduced visits. No blood pressure control data were reported by any of the included studies. Together these data and the authors of the systematic review highlight the need for robust randomised controlled trials of SMBP within the pregnant population with hypertension.

Since the Kalafat review conducted in May 2019, I performed a review of the quantitative literature to date (December 2020, see Appendix 11) of completed studies evaluating the use of BP self-monitoring in pregnancy compared with a control group and found a further three reports published by two research groups demonstrating the accelerating interest in the use of remote

monitoring in pregnancy. These studies are also summarised in Table 16. These included two small observational studies by the same Dutch group(222, 236) and a small randomised controlled trial by a US group(237), evaluating a reduced antenatal visit model for a low risk group of women that incorporated remote monitoring. This latter study did not invite women to continuously self-monitor their BP but instead to perform their home readings with nurse guidance during intermittent virtual assessments designed to replace traditional clinic visits. Similar to the studies included in the Kalafat review, these most recent studies did not focus or publish data around blood pressure control but instead were interested in healthcare delivery and resource use. Perhaps reflecting these different models, only one other study published data on BP self-monitoring adherence and persistence(222) and found similar results to our own (Table 3.1) with the caveat that this study included daily home BP data review and follow-up by a clinician which is likely to influence women's adherence behaviour.

An important aspect of evaluation for any health care intervention is cost effectiveness. This was not part of the feasibility work presented here but will be a necessary component of a larger randomised trial of SMBP in pregnancy. Three costing studies have been published to date based on the data from observational studies(233, 234, 238). Two of the studies are based on Belgian health care costs which includes a health insurance scheme and the third study is UK-based. These studies generally found SMBP to be cost neutral, however the original cohort studies, as discussed more fully above, suffered selection bias with the women chosen to perform home readings being at lower risk than those using the traditional care models(35, 231). These few studies highlight the need for robust costing analysis using data from fully powered randomised controlled trials.

3.4 Conclusion

To our knowledge, OPTIMUM-BP represents the first randomised controlled trial evaluating the use of SMBP in the antenatal management of pregnancy hypertension and also the first

randomised study specifically reporting antepartum BP *control* using this intervention. Self-monitoring could be one way to achieve tighter blood pressure control as shown to be beneficial in the general adult population with chronic hypertension(118) and the CHIPS study in pregnancy(101). Our study supports the feasibility and broad acceptability of using BP self-monitoring when combined with clinic monitoring in antenatal care pathways, as shown by previous observational studies in pregnancy, but importantly provides the first step in bridging the gap in evidence from randomised studies.

In the following chapters I discuss the methods and findings from the parallel qualitative studies which used ethnographic observations of antenatal consultations and interviews with pregnant women and clinicians who participated in the OPTIMUM trial, to explore the experiences and use of BP self-monitoring in this context. These findings provided an in-depth exploration of the acceptability of the intervention and will further inform the development of the intervention and processes for a large randomised trial and considerations for future implementation.

Chapter 4: Qualitative studies methods

4.1 Overview

In this chapter I discuss the methods I used for the qualitative studies that ran in parallel to the feasibility trial. I start by outlining the theoretical and philosophical standpoint that I adopted which informed my choice of qualitative methods and the implications that this had for the data collected and its analysis and interpretation. I then discuss my specific methods of consent, recruitment, data collection and analysis and describe the challenges I faced with these various steps and how I sought to overcome or minimise their bearing on the quality and validity of the data. I include a summary of the women and clinician participants whose observational and interview data contributed to the qualitative analysis. I also provide a brief description of where the self-monitoring was practised, specifically in the maternity clinics and women's homes, as context for the three qualitative results chapters.

By way of background, during the design phase of this study, a few colleagues questioned whether self-monitoring of blood pressure (SMBP) was sufficiently complex to merit the potentially labour-intensive and time-consuming proposed mixed methods including ethnographic observations. However, early discussions with obstetric colleagues and observing a few antenatal clinics affirmed that pregnancy provided a very different context for the practice of BP self-monitoring compared with its previous use for the management of chronic hypertension in the general population. These early clinic observations convinced me that broadening and deepening my approach by combining interview data with ethnographic observations was the best way to explore and understand perceptions and use of SMBP in this setting.

The logic model in Chapter 2 proposed how SMBP might work to improve BP control in pregnancy. As is conventional the feasibility trial contained a qualitative study to:

Explore participants' experiences of blood pressure self-monitoring within the randomised study: how the intervention was perceived and used by pregnant women and their clinicians and the acceptability of the study processes (results in Chapter 5).

As well as interviewing women and clinicians, I also observed clinics and conducted informal interviews at the clinics. It quickly became apparent that these qualitative studies were producing a wealth of data that provided important and some unexpected insights around BP self-monitoring in this context, and thus I concluded there was scope to:

Explore additional themes arising from further inductive analysis of the qualitative data focusing on different perspectives and meanings of women and clinicians in relation to self-monitoring blood pressure (results in Chapters 6 and 7).

4.2 Theoretical perspective

All research disciplines are underpinned by ontological and epistemological foundations. Consideration of these informs the theoretical perspective taken when considering a particular research question and the sorts of enquiry and methods we think are legitimate. I was interested in how women and their clinicians were using the blood pressure self-monitoring intervention and how perspectives and behaviours were shaped by their interactions. In short, I was studying a social phenomenon. In order to explore the different and sometimes divergent perspectives there was an acceptance that 'truth' or reality is something not simply to be discovered but something that is interpreted. And not only were the study participants constantly making and reworking these interpretations but I as the researcher studying these phenomena could only come to them through interpretation. One ontological perspective which acknowledges this stance is termed relativism, which in its strictest form propounds that there are multiple realities with equal validity(239).

The relativistic line of argument can sometimes lead to conclusions that any resultant exploration and analysis create merely subjective accounts. A common and enduring criticism of qualitative research by those from more positivist disciplines supporting an objective realism, is that due to this subjectivity qualitative findings lack generalisability. Instead of the unhelpful opposing views of relativism versus realism, many researchers of both qualitative and quantitative persuasion

argue for a "subtle realism"; a term introduced by Hammersley(240). This view holds that there *is* an underlying reality which can be studied, interpreted and represented, but not reproduced, through our multiple perspectives and methods. Therefore I acknowledge that my approach to the research question is one of subtle realism; that multiple perspectives exist, and indeed I am interested in exploring these and how these guide the behaviour and responses of the study participants. My research aims to *understand* the experiences of the participants and to appreciate the social context and relevance. The findings should have internal validity based on plausibility and credibility and external validity, based on relevance and applicability.

When discussing research issues it is difficult to distinguish between ontology and epistemology and Crotty(239) claims the two are conflated and mutually dependent: "*to talk about the construction of meaning* [epistemology] *is to talk of the construction of a meaningful reality* [ontology]". My ontological stance of subtle realism is consistent with an epistemological viewpoint of constructionism. Constructivists argue that the production of knowledge is socially constructed, and that meanings are embedded and shaped by our backgrounds, culture and conventions. As social animals we constantly create and negotiate collective meaning through our interactions. There is no unimpeded view of reality. My ontological position, therefore, is subtle realism and my epistemological perspective is one of constructionism. My viewpoint affected my choice and conduct of methods for the qualitative studies and the types of data I collected, which included:

- Observations of antenatal consultations
- Informal interviews with women and clinicians (during my clinic observations)
- Formal semi-structured interviews with women (in the postnatal period)
- Formal semi-structured interviews with clinicians

4.3 Ethnography – a background

As I was a newcomer to the method of ethnography when starting this study, I make a brief description of it here.

Ethnography was traditionally a field method employed by anthropologists in the nineteenth and twentieth centuries to study non-western cultures, by living amongst them for extended periods and partaking in their practices. The term can be confusing as it refers to both the process, which can include a number of methods, and the product. The method was further developed in the 1940s to 60s by the 'Chicago School' of interactionist sociologists who used it to study local communities, e.g. William F. Whyte, describing life in street gangs(241) and Julias A. Roth, studying the rhythms of hospital life when admitted as a patient for tuberculosis(242). But through these developments, the defining tool of the ethnographer remains participant observation (whether overt or covert), requiring the researcher to observe and interact, or traditionally fully participate, in the life or focused activities of the studied group, gathering data by watching, listening and asking questions through both formal and informal interviews. In this way ethnography can be argued to be an extension of how we normally learn and make sense of the world, and is an example of *naturalistic* enquiry; taking place in and true to the social context.

However, the label 'ethnography' does not just refer to participant observation and further data collection through formal and informal interviews, but also includes the processes of theoretical analysis, interpretation and judgement around these data to produce what Bosk described as a "resonant description"(243). Through these processes the ethnographic method can produce a 'thick description', a term made famous by Clifford Geertz in his essay: *Thick Description: towards an interpretive theory of culture(244)*. The term 'thick description' should not be misunderstood as a purely descriptive account of observed events and narratives, no matter how detailed. Instead the goal of 'thick description' is to get at the *significance* of practices and events; to describe in detail the context, intention and motivations underlying social interactions and

culture in order to reveal their underlying meaning. The best known example of the role of an ethnographer to understand and interpret meaning is Geertz's description of the distinction between a twitch and a wink: *"...the difference, however un-photographable, between a twitch and a wink is vast; as anyone unfortunate enough to have had the first taken for the second knows*":

> "A mere twitch, on the other hand, is neither a failure nor a success; it has no intended recipient; it is not meant to be unwitnessed by anybody; it carries no message. It may be a symptom but it is not a signal. The winker could not not know that he was winking; but the victim of the twitch might be quite unaware of his twitch. The winker can tell what he was trying to do; the twitcher will deny that he was trying to do anything."

What Geertz's description makes clear is the importance of understanding the social meanings that inform human behaviour. As social agents, researchers may be able to explore and discern these meanings or "webs of significance"(244) that are not amenable to surveys, counting or probabilistic inference from randomised controlled trials. Human behaviour is also best understood in its natural context, complete with the multiple and necessary interactions that shape it. In this way, it can *only be* that the researcher is the primary tool of qualitative, and particularly ethnographic research, both collecting, describing and interpreting the data and that observation in the 'natural setting' affords the greatest fidelity to the phenomena under study.

In this mixed methods study I aimed to understand the potential role(s) of blood pressure self-monitoring in the management of hypertension in pregnancy, which included exploring the experiences of the pregnant women and clinicians using this intervention. Although there was previous quantitative, and some qualitative, literature about blood pressure self-monitoring in the general adult population with hypertension (see Chapter 1), the novelty of using this intervention in the pregnant population with hypertension called for fresh perspectives and specifically an inductive approach to qualitative data collection. Arguably, the inductive stance can more strongly introduce the effects of the researcher into the data. In account and defence of

this stance, I chose to adopt an approach informed by constructivist grounded theory for my data collection and analysis. I discuss this in the next section.

4.4 Constructivist grounded theory

Grounded Theory was developed by Glaser and Strauss during their studies of terminally ill patients in the 1960s(245, 246). Grounded theory provides a systematic strategy for generating theory that is grounded in the data, rather than *beginning* with theory or hypotheses. It uses the techniques of constant comparison where data collection and analysis happen flexibly and concurrently and support each other. Analytic codes are generated from and assigned to the data and emerging codes are compared between and within cases. The outcomes of these comparisons are used to guide further data collection in an iterative process. Data sampling is done with the aim of developing theory ('theoretical sampling'), and often seeks to sample to a point of 'data saturation'. This contrasts with the aim of *numerically* representing populations that is typical of quantitative approaches. In traditional grounded theory, it is proposed that the resultant abstracted theory needs to be reproducible and testable and can contribute to 'formal generalisations' which can then be used to predict future events, similar to the generalisability proposed by quantitative research paradigms(246).

Since its conception, grounded theory has undergone several revisions and my approach to the research questions and analysis was informed by constructivist grounded theory developed by Charmaz(247) which recognises the origins and purpose of grounded theory to generate theory from data, but also explicitly recognises the effect of the researcher on the data. In her 2006 book (p10), Charmaz states:

> "My approach explicitly assumes that any theoretical rendering offers an interpretative portrayal of the studied world, not an exact picture of it.....I argue for building on the pragmatist underpinnings in grounded theory and advancing interpretative analysis that acknowledges these constructions."

In following these principles, I strived to continually adopt a position of reflexivity (see below), reflecting and reporting the influence that I might have on the research. The effects of the researcher can occur at many levels of the scientific process: from the original research proposition to the study design, data gathering and interactions with participants, to the final analysis and reporting.

The techniques and practice of thick description and reflexivity help both the researcher and the reader to make judgements about the validity and applicability (or borrowing language from more positivist disciplines, generalisability) of study findings. These concepts are discussed in more detail in the next section.

4.5 Validity and generalisability

Often the term validity is used in a narrow sense to describe the closeness of fit between the report of a phenomena and the actual phenomena. However the concept of validity is far broader when considering the quality of a particular piece of research and should include the appropriateness of the original research questions, and method, the accuracy of the data recorded, and the reliability and credibility of the final interpretation and report. Here I explain the validity of the ethnographic method as used in my project.

Qualitative research concerns itself with understanding human experience and meaning-making with all its contingencies and complexity. In the interpretivist paradigm, findings are nuanced and will inevitably be linked to context. The quality and applicability should be judged according to the questions the study was seeking to explore. The in-depth and multifaceted nature of qualitative analysis, using reflexivity and thick description, lends itself to judgements around *applicability*, for any clinician, researcher or health policymaker, asking "*how do these findings relate to my question in my setting?*"

The processes underpinning generalisations are there from the outset within qualitative analysis. Exploring meaning and significance through studying action and narratives using observational

and interview data, requires "*abstracting the general from the particular*"; as described by Delmar(248). It is important to note that the original scope of my research was to produce findings of both local and wider significance; to inform the development of the intervention and research processes for a substantive randomised controlled trial in a similar population, but also with the ambition of furthering our understanding of the experiences and potential role of self-monitoring in general in pregnancy. Thus I aim for my findings to be applicable to other settings, and to provide developments towards a theory rather than toward one intervention or population(249).

4.6 Data collection

4.6.1 Recruitment

Study ethical approval and participant inclusion and exclusion criteria are described in Chapter 2. While the feasibility trial included women with chronic hypertension and gestational hypertension, only the women with chronic hypertension were included in the qualitative studies.

There were two separate Participant Information Sheets (PIS) and consent forms for pregnant women with chronic hypertension, one for the feasibility trial, which included a section about observations of antenatal clinics and visits and a second specifically about the formal postnatal interviews. The consent form for the feasibility trial sought separate consent for the ethnographic observations of clinic visits so that women could specifically opt-out of this part of the study (though none did).

The separate PIS for the formal postnatal interviews was usually given to women alongside the RCT PIS, but either myself or the research midwife explained that this was an additional and optional part of the study that would occur in the postnatal period. We approached women again about this part of the study later on in their pregnancy, usually in the third trimester. Sometimes women delivered earlier than expected or had complicated or poor outcomes and in these instances, I liaised with their lead consultant about the appropriateness of making an approach

for an interview. Although the aim was to provide all women taking part in the randomised study with initial information about the interview study, sampling for this part of the study was not intended to include every woman in the trial, but instead was theoretically led (see below).

Clinicians involved in the care of pregnant women with hypertension at the study sites were invited and consented to be part of the study with involvement in the ethnographic observations and formal clinician interviews.

4.6.2 Sampling

I followed a two stage sampling process. Initially, I followed a convenience sample, both for the ethnographic observations which included informal interviews/conversations and initial postnatal interviews across all three included study sites. In this way, participants were included opportunistically in order to begin analysis and to familiarise myself with the work of the clinic and the broad events and experiences of antenatal care for this group of women and clinicians. During these initial stages, due to how management of pregnancy hypertension tends to be centralised in specialist clinics, and the wide geographic and socioeconomic catchment of my study sites, I achieved a broad spread of participants in terms of demographic and obstetric backgrounds. As analysis progressed and initial concepts were identified, I wanted to critically explore and test these, so I sought to sample both within and between cases. For example, in some of the earlier cases, I noted that the theme of medication aversion was common. Further scrutiny suggested that women's perceptions around medications in pregnancy appeared to be linked to their parity and any previous pregnancy experience with medications. Therefore I sought to include observations and interviews from women with different medication histories and parity to better understand this relationship.

Sampling and data collection proceeded in all three study sites concurrently where pregnant women with chronic hypertension were being recruited into the randomised study. I decided that to sample and analyse data from all three study sites concurrently was better than studying sites

in series as this would help explore any between-site differences and guard against introducing differences more concerned with the bedding-in of the intervention over time.

Initially, I was aiming to achieve 'theoretical saturation', which is the point at which new interviews or observations no longer contribute additional perspectives to the key analytic themes(250). However 'saturation' is defined in a multitude of ways within the qualitative literature and the researcher can never be sure that further data collection will not provide new insights. It is perhaps more helpful to consider what is the goal of sampling and analysis for a particular study and how the question of saturation might relate to the validity of the study findings(251). Dey(252) employs the term "theoretical sufficiency" and within the context of my study, I interpret this to mean that for the specific themes I explored: feasibility of the trial (Chapter 5), trumping and tensions (Chapter 6) and perspectives on antihypertensives in pregnancy (Chapter 7), I continued until I was confident that new interviews were not adding to the analysis.

One approach to sampling would have been to collect data from approximately equal numbers of women randomised to usual care and intervention. It is quite common in the qualitative analysis of mixed methods studies of complex interventions to include a focus on the 'usual care' group with the aim of revealing and understanding what is involved within this umbrella term in order to provide context for the intervention. Given that the aim was to understand more about the role and scope of self-monitoring in hypertensive pregnancies, I decided to purposively sample more from the intervention arm but nevertheless to include some women from the usual care arm.

I did encounter challenges when sampling. I had to be careful not to choose only more 'sensational' or 'crisis' cases to interview, although these sometimes came more readily to mind. This would not have provided a representative account of the more routine work of the clinic. I had wanted to obtain interviews and observations from the few women who formally withdrew

from using the intervention. I approached a couple of these women for an interview and while they initially agreed, I was not ultimately successful in confirming follow-up arrangements. This is perhaps reflective of the many competing demands of the postnatal period but also their interest in the study given that they had decided to discontinue monitoring.

4.6.3 Observations

I undertook non-participant observation of clinic attendances of pregnant women with chronic hypertension across the three clinical sites (A-C) recruiting to the trial between December 2015 to May 2017. I observed 38 clinics which included 36 antenatal clinics and 2 day assessment clinics, which meant I was able to observe the consultations/assessments of 41 women in the study (as detailed in Table 17) with some of these women observed over several clinical encounters. The 9 clinicians, who were observed and/or interviewed, are also described in Table 17.

At each clinic, women were made aware if I was performing observations. In all three sites this involved the research midwife or myself informing women as they registered at the clinic reception. At these introductions I was described as either a researcher or clinician researcher or by name for those women who had met me before at the clinic. Women were asked to provide verbal consent for me 'sitting in to observe'. In all three centres, there was a maximum of two observers per consulting room (including myself, students or clinical colleagues), but in many instances I was the sole observer. All women attending clinic that day, not just those in the study, were asked for permission to be observed, as practically it was sometimes difficult for me to leave the room between consultations. Verbal consent was invariably asked again by the consulting clinician when women entered the room, as is usual practice when medical students or trainees are observing. Permission to observe was never declined. On two occasions I chose to leave the room before the consultation as the consultant had forewarned me they were going to provide some distressing news. In those two instances I decided that my presence was not in the best interests of the woman (and observing bad news delivery was not a focus of my study).

Whenever possible I tried to sit in an unobtrusive position where I could see the faces of both the pregnant woman and clinician so as to help with understanding their non-verbal communications. I did not audio-record consultations but instead made quick field notes by hand, and tried to note conversation verbatim as much as possible as well as describing events and body language. I tried to make note-taking unobtrusive, often looking up as I wrote. If I had informal chats with women or clinicians before or after consultations, I did not take contemporaneous notes so as not to spoil the flow of natural communication or encourage self-consciousness in the informant. Instead I made notes immediately afterwards where possible. In these informal discussions I was able to question participants (clinicians and women) individually about their thoughts or actions around events I had just witnessed, as I tried to glean and understand meaning through action. After each observation period, I reviewed my field notes and made reflective and analytic memos. Field notes were transcribed and data anonymised using participant ID, before analysis.

4.6.4 Informal interviews

During my field visits I was able to regularly ask informal questions of participating women and clinicians, for example around their perspectives of the consultation and recommendations or to explore their reasoning around a certain management decision respectively. There were opportunities to discuss with clinicians before or after consultations, and often clinicians would summarise a case for my benefit before a participant entered the room and during these discussions would explain their previous management plans. In two of the three sites there was a team of clinicians managing this group of patients and they would come together to discuss cases at the end of clinic. I was able to be present and take field notes from these "backstage"(253) discussions which explored specific clinical reasoning and concerns between colleagues. These data provided a valuable insight into the dynamics of the teams and how a culture of clinical management was created.

I was able to have informal discussions with women as they waited to go into their consultations or sometimes after their consultations whilst they waited to have scans or have their study visit with the research midwife. These discussions took place in the waiting room or as brief informal chats in corridors journeying to other departments. On the whole, women appeared eager to talk during these times, but I was sensitive to their initial response and if they appeared stressed or reticent to talk, I kept our exchange to friendly greetings. These spaces were busy with sufficient ambient noise, that I judged we could maintain the privacy of our discussions. After these discussions I would move away to the staff areas to quickly write up the exchange in my field notes as faithfully as possible. These informal interactions could provide rich data on participant perspectives around clinic attendance and certain ambivalence around proposed management plans and allowed me to identify and clarify how perspectives could change over a series of clinic visits.

4.6.5 Formal interviews

Semi-structured interviews allow for depth of enquiry but also have a clear framework (topic guide) to help structure within and across interviews(254). The topic guide contains areas or themes for discussion or specific questions and this evolves in an iterative and flexible manner as data collection progresses, and themes are developed through constant comparison. An example of my initial topic guide is presented in Appendix 12 and was informed by published literature and through discussion with the research team and evolution of the data(255). With this scaffold the interviewer can then encourage the participant to talk in more depth on certain subjects and to follow leads. In this way, semi-structured interviews provide rich data that is comparable across participants and data sources(256). Formal interviews with 24 participating women and 8 clinicians, were performed after I had spent some time in the field observing, so that data could be compared and it was possible to ask women and clinicians their perspectives on scenarios representing specific phenomena I had witnessed in the field.

Formal interviews took place in women's homes in the postnatal period around 10-12 weeks after delivery, at a date and time of their choosing. Women were invited to have a partner/family member present if they wished. Only one woman chose to be accompanied and had her husband present to help care for the baby during the interview. Women were reminded about the contents of the interview PIS, highlighting the anonymity of data analysis and storage and the use of specific quotes, removing any identifying features, and were asked to provide written consent. Interviews were audio-recorded and transcribed verbatim. As part of the consent process, women were offered a copy of their interview transcript to comment on if they wished(257). Only one woman requested a transcript and did not wish to make any clarifications or comments, only to say that it was faithful to her account. I also made additional field notes straight after my interviews to record the details of women's self-monitoring demonstrations or certain domestic arrangements which might have informed how self-monitoring was enabled or made more challenging. These interviews had quite an informal atmosphere and could last from 60-90 minutes as some degree of childcare was usually involved and invariably I was rocking a baby or had a toddler sitting on my lap whilst the woman spoke. I started interviews by asking women to describe their recent pregnancy experience in general terms and any previous obstetric experience and then women were asked to describe their understanding and experiences of hypertension and BP self-monitoring in pregnancy.

Formal interviews with individual participating clinicians took place at their respective study sites, usually in their office, at a time that fitted with their clinical commitments. Similar processes of consent and audio-recording took place as described above. These interviews took place towards the end of the study to allow sufficient time for the intervention to bed-in to routine clinical practice and also so as to avoid possibly contaminating clinician behaviour around the intervention by any line of inquiry from interviews. Case anchors were referred to from the observational data to help explore clinician perspectives and reasoning around integrating home monitoring into their clinical practice(258).

4.7 Data analysis

The process of data analysis started with my first ethnographic observations. Through constant comparison as data accumulated and emerging concepts were actively explored, the process evolved from descriptive organisation to one of increasing abstraction(259). Throughout the process I recorded thoughts and queries about my data and unfolding analysis in memos. Informed by a constructivist grounded theory approach, I conducted a thematic analysis across and combining the three different data sources (observations, formal and informal interviews)(259-261). The steps I followed are described below. The qualitative data analysis software package, NVivo, was used to help store and organise the data to aid analysis.

4.7.1 Stage 1: reading

I transcribed my paper ethnographic field notes (observational and informal interview data). The formal audio-recorded interviews were transcribed by a professional transcriber allied to the university department. I read through all of the transcriptions at least once before coding.

4.7.2 Stage 2: coding

After initial reading and familiarisation with the observational and interview data transcripts, I started to assign codes inductively, meaning that the codes used were derived directly from the data and were not predetermined. Initially I assigned labels sentence by sentence and the codes were very descriptive but with growing familiarity with the data and analytical confidence, several sentences or segments were coded at a time using more analytical (higher level) codes. I reviewed several early transcripts with my supervisors and discussed how codes could be assigned alongside some of the possible nascent emerging themes. I was encouraged and challenged to keep asking what my data was about, rather than assigning a descriptive summary word. I kept a diary of codes to aid the constant comparison process, and to help begin to organise the codes into categories.

4.7.3 Stage 3: categorisation and themes

Codes which shared characteristics or were part of the same phenomena were grouped together to produce categories. Codes could be in one or more categories and categories could be inter-related to produce themes. NVivo was used to produce reports of all the transcribed text from observations, informal and formal interviews identified under these themes and categories.

4.7.4 Stage 4: creating an OSOP

These reports were re-read and all the different issues under one theme were collated along with the respondent IDs. These subthemes were then pieced together using a mind mapping approach known as the OSOP (One Sheet of Paper) method(262) looking for connections, contingencies and explanations. It was important to include all the relevant data, not just the most dominant discourse. It was particularly relevant to include the cases that appeared to contradict the main narrative, sometimes described non-pejoratively as the 'deviant case'(263) as these cases were particularly useful to test my 'story' to make sure it did not ignore nuance and variance within the data.

4.7.5 Stage 5: seeking analytical depth

Guided by my supervisors, I returned to the qualitative literature (for example, Townsend's et al exploration of attitudes to drug use in the context of living with multimorbidity(264)) to look for further insights and to explore extant theories and how these might inform and develop my findings (see Chapter 8 for discussion of the qualitative findings and current literature).

4.8 Qualitative study participants

Table 17 below describes the characteristics of the pregnant women and clinician participants from the three study sites (A-C) who took part in the ethnographic observations (which included informal interviews for some) and formal interviews. Participants are not listed by study site which are also referred to as sites A-C, to retain anonymity.

Table 17: Characteristics of pregnant women and clinicians included in the observations and formal interviews

Identifier	Age (years)	SMBP/UC	Ethnicity	IMD	Educational qualification	Primip	AHTs	Brief clinical history	Observed	Formal interview
1	48	SMBP	Asian	2	Degree	Yes	Yes	Delivered early and HELLP, long postnatal stay	X	✓
2	37	SMBP	Black Caribbean	1	GCSE	No	No	First pregnancy had complications and prematurity	X	✓
3	33	UC (own SMBP)	White British	3	A-Level	No	Yes	First pregnancy had postnatal admission with high BP	X	✓
4	32	SMBP	White other	3	Professional	Yes	Yes	Delivered early, baby had IUGR and low blood sugar levels	X	✓
5	36	UC	Black Caribbean	2	A-Level	No	Yes	Previous pregnancy antenatal admission with high BP, also gestational diabetes	✓	✓
6	32	SMBP	Black African	2	A-Level	No	Yes	Pre-eclampsia in previous pregnancy	✓	✓
7	33	SMBP	White other	1	Degree	No	No	Pre-eclampsia in previous pregnancy	✓	✓
8	42	SMBP	Black African	2	GCSE	No	Yes	High BP in previous pregnancies with early delivery, and rheumatoid arthritis	✓	✓
9	38	SMBP	White other	4	Degree	Yes	Yes	Long-standing CHTN, friend had pre-eclampsia	✓	✓
10	33	SMBP	Black African	1	Degree	No	Yes	Fourth pregnancy with CHTN and gestational diabetes, previous stillbirth	✓	✓
11	31	SMBP	White British	4	Vocational	No	Yes	Previous pre-eclampsia, IUGR and gestational diabetes	✓	✓
12	32	UC	White British	4	Degree	No	Yes	Previous GH, IUGR and gestational diabetes	X	✓
13	33	SMBP	White British	5	Professional	No	Yes	CHTN in previous pregnancy	X	✓
14	41	SMBP	Asian	4	Postgrad	Yes	Yes	Recurrent early miscarriages and difficult to control BP	X	✓
15	33	SMBP	White British	4	Vocational	No	Yes	Pre-eclampsia in previous pregnancy, background of Crohn's disease	✓	✓

Identifier	Age (years)	SMBP/UC	Ethnicity	IMD	Educational qualification	Primip	AHTs	Brief clinical history	Observed	Formal interview
16	29	UC	White British	3	A-Level	No	No	Fourth pregnancy, previous pre-eclampsia in postnatal period	✓	✓
17	37	UC (own SMBP)	White other	1	Postgrad	No	Yes	Previous pregnancy long postnatal admission for high BP	✓	✓
18	40	SMBP	White other	4	Postgrad	Yes	Yes	Developed pre-eclampsia and IUGR and required admissions for high BP	✓	✓
19	41	SMBP	White British	1	Postgrad	No	Yes	Pre-eclampsia in previous pregnancy, needed early delivery for high BP this pregnancy	✓	✓
20	41	SMBP	Black African	3	A-Level	No	Yes	Previous stillbirth, longstanding CHTN and diet-controlled gestational diabetes in pregnancy	✓	✓
21	40	SMBP	Black Caribbean	1	Degree	No	Yes	Longstanding chronic hypertension not needing treatment previously, 4 pregnancies	✓	✓
22	33	SMBP	White other	1	Degree	Yes	Yes	Longstanding CHTN delivered early with pre-eclampsia	✓	✓
23	30	SMBP	White British	1	GCSE	No	Yes	Second pregnancy with longstanding CHTN	✓	✓
24	31	SMBP	White British	1	Degree	Yes	Yes	Longstanding CHTN, family history of pre-eclampsia	✓	✓
25	39	SMBP	White British	3	Degree	No	Yes	Longstanding CHTN	✓	X
26	35	SMBP	Black African	2	Vocational	No	Yes	Previous pre-eclampsia, early delivery with high BP	✓	X
27	41	SMBP	White other	4	Postgrad	Yes	No	Longstanding CHTN and previous SMBP	✓	X
28	32	SMBP	White British	1	A-Level	No	Yes	Second pregnancy, longstanding CHTN	✓	X
29	36	SMBP	Asian	5	Postgrad	Yes	Yes	Longstanding CHTN, not needing treatment previously	✓	X
30	38	SMBP	Black Caribbean	1	GCSE	No	Yes	Third pregnancy, pre-eclampsia in previous pregnancy	✓	X
31	40	UC (own SMBP)	White other	2	Degree	No	Yes	Second pregnancy, previous GH	✓	X

Identifier	Age (years)	SMBP/UC	Ethnicity	IMD	Educational qualification	Primip	AHTs	Brief clinical history	Observed	Formal interview
32	37	UC	White British	3	Vocational	No	Yes	Second pregnancy, longstanding CHTN	✓	X
33	41	UC	Black Caribbean	2	A-Level	No	Yes	Third pregnancy, previous transient ischaemic attack ('mini-stroke')	✓	X
34	27	UC	White British	1	GCSE	Yes	No	Previous recurrent miscarriage, untreated CHTN	✓	X
35	33	SMBP	Black African	1	Vocational	No	Yes	Previous pre-eclampsia, longstanding CHTN	✓	X
36	31	UC	Black Caribbean	2	A-Level	No	Yes	Previous GH and early delivery for rising BP	✓	X
37	28	SMBP	White British	2	Vocational	No	Yes	Previous pre-eclampsia, longstanding CHTN	✓	X
38	36	SMBP	White other	3	Degree	No	Yes	Previous pregnancy high BP, now gestational diabetes	✓	X
39	37	SMBP	White British	4	Postgrad	No	Yes	Previous GH, pre-eclampsia this pregnancy	✓	X
40	45	UC	White other	2	A-Level	No	Yes	Third pregnancy, previous GH	✓	X
41	24	SMBP	White British	2	Degree	Yes	Yes	CHTN on treatment before pregnancy	✓	X
42	30	SMBP	Black Caribbean	1	A-Level	No	Yes	Third pregnancy, recent diagnosis of CHTN and rising BP	✓	X
43	44	SMBP	White British	4	Degree	No	Yes	Fourth pregnancy, previous postnatal admissions for high BP	✓	X
44	37	SMBP	Black African	3	Vocational	No	Yes	Second pregnancy, diagnosed CHTN in this pregnancy	✓	X
45	32	SMBP	White British	1	GCSE	No	Yes	Third pregnancy, previous pregnancies with CHTN	✓	X
46	26	SMBP	White British	1	GCSE	No	Yes	Second pregnancy, previous GH	✓	X

Identifier	Age (years)	SMBP/UC	Ethnicity	IMD	Educational qualification	Primip	AHTs	Brief clinical history	Observed	Formal interview
47	31	UC (own SMBP)	Asian	3	Degree	No	Yes	Third pregnancy, recent diagnosis of CHTN	✓	X
48	29	SMBP	White other	2	A-Level	Yes	No	First pregnancy, longstanding CHTN	✓	X

SMBP: self-monitoring blood pressure; UC: usual care; IMD: index of multiple deprivation quintile using Office of National Statistics for England data (ref), 1= most deprived; primiparous: delivered only one child (index pregnancy in the study); AHTs: required antihypertensive treatment(s) in index pregnancy

Clinicians	Role	Observed	Formal interview
001	Midwife	✓	✓
002	Doctor	✓	✓
003	Midwife	✓	✓
004	Doctor	✓	✓
005	Doctor	✓	✓
006	Doctor	✓	✓
007	Doctor	✓	✓
008	Midwife	✓	✓
009	Doctor	✓	X

4.9 Reflexivity and challenges with data collection and analysis

I acknowledge here my relevant personal relationship to the original research topic; I am a white British woman of reproductive age with chronic hypertension, and I had two pregnancies, one of these complicated by pre-eclampsia and both by gestational diabetes, during my DPhil research. Both of these conditions required elements of self-monitoring during my pregnancies. My gender, pregnancy status, obstetric and medical history have undoubtedly affected my interest and approach towards this research and some of these characteristics would have been apparent to the study participants. I have embodied experience of many similar events and decisions shared by the study participants. In addition I have clinical experience in obstetrics, having trained in the specialty for 12 months albeit in a different centre to the ones included in the study, so have experience of antenatal clinics, labour ward and the pregnancy journey from a clinician perspective. I am also a practising general practitioner, regularly involved in the community care of pregnant women and also diagnosing and managing, chronic hypertension in the general adult population, including involvement with self-monitoring. Of course my roles as researcher and student provide me with yet other hats to wear, and a personal interest in the 'success', however that might be defined, of the study and a hope and impetus to reveal, and co-construct, novel and useful findings for the wider research and clinical communities.

In this thesis, I acknowledge these personal and professional attributes before discussing the qualitative data. I will reflect below how they benefited, challenged or otherwise might have impacted on the research data collection and analysis. Throughout the research process, as is expected when using qualitative research methods, and specifically any form of grounded theory, I concurrently made memos as I developed my analysis and in these I also made reflections about my position towards the data. Given my close personal experience with the research topic, I also kept auto-ethnographic accounts within my field diary as the study and my own pregnancies

unfolded. Although I do not specifically quote from my field diary I used these notes to maintain a critical and personal reflection on what I was hearing and seeing.

My clinical background might have eased my access to the clinic areas and data as I was familiar with the clinical journey and language and comfortable talking with clinician colleagues. As part of the set-up for the randomised controlled trial, there were training visits before the site was opened for recruitment, to familiarise the clinical teams with the study protocol and activities. The site Principal Investigators, who were senior clinicians in the clinics being observed, were present at these meetings and their 'gatekeeper' role and positive stance towards the study certainly eased my access to the antenatal clinics and team(265).

One criticism levelled against the ethnographic method is the possible bias introduced from what is known as the "observer effect"(266). This label refers to the phenomena whereby the naturalistic behaviour that one is hoping to capture and interpret is influenced by the presence of the observer, and shaped by social norms. I tried where possible to 'blend into the background' during observations to minimise my possible contamination of the field. To some extent I did become part of the backdrop as it was normal practice to have trainee 'observers' in the clinic. During my interactions with women when seeking verbal consent for observations, their responses frequently demonstrated they were untroubled by my presence, expecting others to be present in these teaching centres and as one woman put it: she was "*used to lots of people at these things*". It might be that the busyness of the clinics and the respective agendas of both the clinicians and women might have led to some necessary habituation of being observed. A few times at the beginning of the study, a specific line of questioning was posed by the clinician during consultations, no doubt intended to be helpful for my study, where the clinician would ask women what they thought of BP self-monitoring or how they were finding it. Whilst these 'staged performances'(266) are not recommended, these sometimes provided interesting insights to the phenomena of self-monitoring in pregnancy. For example, on several occasions women who were

not enrolled in the feasibility RCT shared that they were also self-monitoring, and most said that they had not considered sharing these readings with their clinical team.

Sometimes I was called upon to 'help' in the work of the clinic by collecting something or information from reception, or I offered to do simple activities such as 'dipstick' a urine sample or help a woman onto the examination couch if the clinician was finishing writing notes. I performed these actions for several reasons and I reflected at the time on how this might have shaped the data I was able to collect. As a clinician I was used to 'helping' my colleagues in ways that would support clinics to run efficiently. I also felt a debt of gratitude to both the clinicians and the women for allowing me to be part of their experience and being aware of the busyness of the clinics I was keen not to add any further burden. This provided me with some first-hand experience of the pressures of clinic, for example when I had quite a challenge to find an extra-large blood pressure cuff from within the clinic. These behaviours might have aligned my role more with the clinic in the eyes of the women, changing the nature of the sorts of information and opinions they were willing to share with me during informal chats and later formal interviews. While this possible criticism cannot be dismissed, several women either after their consultations or during interviews shared accounts of forgetting to self-monitor, disagreeing with some management plans or sometimes not taking their medications as prescribed, suggesting that at least some women were not deterred.

My dual role as clinician-researcher posed the greatest challenge during interviews (formal and informal). Most participants knew that I was a doctor; this was usually because I had been introduced as such during clinic observations. At other times it appeared to be assumed by the woman. On a few occasions during the postnatal interviews I found it necessary to reveal my clinical background as I felt in a position to help. In these cases, women were usually sharing distressing experiences and airing their unanswered concerns. These instances could pose challenges in terms of balancing my dual roles. My task as researcher was to collect good quality

data truthful to the woman's perspective and not moulded through discussion with myself. And yet my personal desire as a clinician was to provide comfort and dispel any misconception that could be causing distress, unnecessarily spoiling their pregnancy experience or that could unduly influence future pregnancy decisions. On these few occasions I acknowledged and validated the distress at the time of sharing and indicated we would could come back to these important experiences at the end of the interview. Although I have had experience as a trainee in obstetrics, maternity care is not my specialty area and I was not clinically responsible for these women, so for two women I agreed with them that I would discuss their concerns with their clinical teams directly. In both cases the woman's lead clinician arranged a postnatal consultation so that experiences and remaining concerns could be discussed.

A potential challenge during interviews with clinicians was to guard against idealised accounts. Clinicians might have felt compelled to provide more positive views around self-monitoring and their use of the intervention due to its proposed advantage for including women in their care. They probably perceived me to be a fellow health professional who strongly endorsed joint decision-making due to my involvement with the trial design and delivery. I tried to guard against these idealised accounts by asking very open-ended questions and proffering hypothetical different viewpoints to provide space for negative feedback and a wide range of perspectives. As evidence against this positive bias, I found that some clinicians readily shared less-than-positive perspectives about the role of SMBP, gave accounts of not using the home readings and also voiced their doubts about the representativeness, if not veracity, of some of the home BP data provided by women.

Similar to clinician interviews, women's postnatal interview accounts might have been overly favourable to the intervention, again as they perceived my close involvement with the study. As with the clinicians, women appeared comfortable to share accounts of behaviour that departed

from that requested in the study protocol. However my data must be interpreted in light of this possible bias.

My own concurrent pregnancy provided some advantages in terms of my recognising and understanding some of the pregnancy experiences of the research participants, and arguably a greater acceptance and rapport with the women I was observing and interviewing. However, it also had the potential to threaten my analytical distance. It is important to be able to see the situation through the eyes of the 'stranger'(267). In this way, tacit understandings of the studied group and seemingly trivial or commonplace occurrences can be explicated and understood; so as to 'explain the things which seem obvious'(241). I hope by making a parallel auto-ethnographic account of my own pregnancy experiences I was able to see afresh, although from a personal perspective, events that might later become mundane or taken-for-granted.

I draw attention to these reflections and challenges, not to highlight deficiencies in my data and analysis, but to demonstrate I was aware of the challenges integral to the ethnographic method and my own personal biography for their possible impact on the data collected, and took steps to continuously acknowledge them and address them where possible.

4.10 Setting the scene

By way of context for the qualitative results chapters (5, 6, 7), I briefly describe my observations of one clinic setting (study site A) and some of the home environments where I interviewed participant women.

4.10.1 Antenatal clinic

The observations here of clinic A are presented as a whole, although they were taken from several field notes. It is hoped this gives the reader the 'feel' for the antenatal clinic setting.

> Field note describing centre A 'choreography' and 'feel':
>
> The antenatal hypertension clinic takes place on the 8th floor. It is a small clinic area of approximately 35 m^2, with the waiting area sitting within the "L" mapped out by the consulting rooms, three on one side and 4 on the adjoining side. There are approximately 20 chairs in the waiting area, 10 in the centre, back-to-back like 'musical chairs', the remainder along the wall areas. A reception desk sits in the corner where patients enter the clinic area. A clinic list is kept taped to the desk where the health care assistant marks off women's arrival times, and accepts the hand-held maternity notes to put them in the relevant clinician in-tray. Women are then handed urine sample bottles and asked to provide a sample using the clinic facilities, then take a seat and wait for their BP to be measured before their appointment.
>
> Much activity takes place around the desk, and due to the small area of the clinic, with only 1-1.5m between where waiting patients sit and the desk and consulting rooms, all of this activity can be observed by the waiting patients. Clinicians take maternity notes from reception into their consulting rooms to review details before calling women into their appointments. Most commonly there are medical or midwifery trainees sitting in with the consultants, or sometimes researchers like myself, and these are given a précis of the woman before she is called in for the consultation. Due to the small size and varied activities and personnel the clinic can feel very busy (if not hectic) at times, although everyone appears to know their role and move around each other efficiently; all except the trainees and visitors who are conspicuous by their stillness and meek smiles or staring expressions.
>
> For a waiting woman, there is plenty to look at on the walls: health information posters for example advertising help to stop smoking in pregnancy with an upsetting picture of a fetus in a smoke-filled womb, and another "have you had your flu jab yet?"; several adverts for research projects; a white board with the latest percentages of positive and negative feedback about the clinic services and waiting times; and a large rack of information leaflets regarding all manner of pregnancy ailments and available antenatal classes and activities.

4.10.2 Women's homes

My visits to participants' homes to conduct the postnatal interviews revealed striking differences between the socioeconomic contexts in which the women lived. A few participants had very comfortable standards of living, exhibited by large, detached properties and multiple car ownership. In contrast several of the women I visited were contending with challenging domestic and social circumstances including insecure housing tenure, unemployment or zero-hours contracts and single parenthood and a few were also managing multiple co-morbidity.

Two women I visited both had families of four living in two rooms in hostels with shared bathrooms. One of these women, whom we shall call [AA] here, showed me her second room, which was full floor to ceiling storing all the family belongings. They had been waiting for re-housing on the local authority list for more than a year. The remaining room the family lived in was nearly as full and very organised, AA explaining, *"I know where everything is, so I can find things easily*". AA, who worked long shifts within social care, described the shape of her typical day when she had been pregnant with her son and how she had fitted in the home blood pressure monitoring in addition to managing her rheumatoid arthritis:

> "Because I'll have to wake up early to have to go to work. I start work 7:30, but I have to wake up like 5:30, get myself and my daughter ready. Go drop my daughter to the childminder. Because you know, 7:30 - school is not yet open. And then I will have to like then to find my way back to work. So, and then I have to be there until 8:30 [pm] when I finish work. I have to go pick her up. By the time I get home it's like 10:00. Such a long day. So doing those - each time I'm going to work it's a little bit stressful. And then it [the BP] would go up a little. It will go up a little at night, so."
>
> "Even with everything, I'm just meticulous. As long as I know I have to do something, I always try to make sure I get it right. So I leave everything - this is the three-seater chair. Normally I sit on the three-seater. And then I just put every books, and my [um] maternity notes, and the monitor on top of these books. So it's right in my face. So I never forget. My tablets are here too. All together so I don't forget. So I do the blood pressure then I take the arthritis tablet, then the one for blood pressure. I do it again at night and sometimes I see it [the BP] is a little bit up at the night time."
>
> (Participant interview with AA)

Whilst AA may have been a particularly motivated participant, she has, for me, come to represent the importance and value many women placed on taking an active role in their own care. This could be despite considerable socioeconomic constraints, as the above extract demonstrates.

4.11 Conclusion

In this chapter I have described the epistemological and ontological foundations which informed my qualitative methods. I have explained my choice of qualitative methods and provided a reflexive and transparent account of how these were enacted. My ethnographic approach respected the principles of naturalistic enquiry, placing me directly in the study setting and allowing me to observe meaning through action and to compare what people do alongside what they say they do.

My status as a clinician-researcher and pregnant woman (for at least part of the study) presented me with challenges during data collection and analysis. I sought to mitigate these where possible, and recognise and acknowledge these potential threats to the validity of my findings through repeated reflexive enquiry. I consider that my status afforded me with more benefits than it did harms in relation to my analysis.

My qualitative work created a wealth of data. In the next chapter I will present the first part of my analysis which used deductive reasoning to explore the broad perceptions and use of the self-monitoring intervention by women and clinicians. This chapter will then lay the foundations to look at the more nuanced and inductive themes explored within Chapters 6 and 7.

Chapter 5: Perceptions and Use of BP Self-Monitoring within the OPTIMUM Trial

5.1 Overview

The aims of the qualitative part of the feasibility trial were to explore participants' experiences of blood pressure self-monitoring and understand the acceptability of the intervention and study processes to inform the design of a large randomised controlled trial. In this chapter I address the following objectives:

1. To explore how the intervention was perceived and used by pregnant women and their clinicians
2. To evaluate perspectives and acceptability of study processes.

This chapter draws on the data from interview transcripts with 24 women and 9 clinicians alongside field notes of 38 periods of observation from 3 maternity centres (A-C) involved in the feasibility study. I used a deductive thematic analysis (see Chapter 4).

In this chapter I explore acceptability by considering women's reasons for joining the study, their views and practices of self-monitoring and preferences for future monitoring and the trial procedures. I then turn to clinicians' views about the intervention and trial procedures. The safety of the intervention is examined within three specific scenarios.

The overall acceptability of the intervention to both women and their clinicians quickly became clear. SMBP has become widespread in the general adult population with hypertension, but the uptake and acceptability by pregnant women was uncertain before this trial, and the motivations for initiating and continuing with SMBP may be different.

The data suggest that women with HDP are strongly motivated to self-monitor blood pressure and that there is a need for further evaluation of the effects of self-monitoring within a large randomised controlled trial.

5.2 Results

5.3 Acceptability of SMBP to pregnant women

Our quantitative data showed high rates of recruitment, adherence and persistence with SMBP, indicating the face value acceptability of the intervention (see Chapter 3). These quantitative findings, assessing the feasibility and acceptability of SMBP, were supported and illustrated by my qualitative data.

Women were asked about their reasons for joining the study, any perceived advantages and disadvantages with home blood pressure monitoring, and their preferences around monitoring for future pregnancies.

In addition, some women from the usual care group shared experiences of taking up their own form of BP self-monitoring; several women said they had continued monitoring into the postnatal period.

5.3.1 Reasons for joining the study

Women described altruistic and personal motivations for joining the study. They referred to the gravity of high blood pressure in pregnancy and did not perceive any personal risk from joining the study:

> "Well I wanted to do something that would also help others with high blood pressure to [um] know more about high blood pressure, and how it will affect you during pregnancy. Because it's a very serious condition."
>
> *(Participant 8 interview: high BP in her previous pregnancies)*

> "And I mean, there was nothing that I was concerned about with the study. It all seemed a good idea and safe to do. It wasn't [um] like a drug study or anything."
>
> *(Participant 15 interview: second pregnancy, works as a nurse)*

Women who perceived their pregnancies to be at increased risk (e.g. due to hypertension and previous obstetric experiences) said they were motivated by the self-monitoring aspect of this

study which they hoped would reduce risks in their pregnancy. Whilst acknowledging the process of randomisation, several were clearly motivated to self-monitor. In the following extract the woman reports that her doctor had previously told her there was no process for her to self-monitor but she was keen to do so:

> "When I was pregnant this time around, for the second time, I saw Dr AA at XX and he started aspirin straight away. I asked then if I could monitor my own blood pressure and he said there isn't any process for doing this. So I was advised not to do this….. I was always curious about what had caused the pre-eclampsia last time and I really wanted to try to keep this pregnancy safe. And because Dr AA advised not to monitor, this study was going to be the only way I would do this…. Yes, I was happy with randomisation. I knew this meant I might not get to monitor."
>
> *(Participant 7 interview: pre-eclampsia in previous pregnancy with early delivery)*

One woman who had had complications from hypertension in her previous pregnancy said she had asked her GP to refer her to centre B which she knew to be a research active centre. She was hoping to benefit from involvement in any studies or early adoption of any findings:

> "For the reasons I said about the last pregnancy….I wanted to come here. I knew about all the research. You know, I wanted to try something so it was not like last time. I wanted it so that I could keep an eye on it [the blood pressure], and the doctors would be able to see how it was at home as well.
>
> *(Participant 15 interview: high BP in her previous pregnancy)*

5.3.2 Perceived benefits from self-monitoring

Mostly, women were very positive about their experiences of SMBP and expressed a preference for self-monitoring over solely clinic BP measurement. Many women viewed it as a convenient and easy means to check the health of their pregnancy. In this regard, a couple of women drew parallels with daily checking of their baby's movements. Positive comments included the following:

> "And I was very happy to do it. It was no bother. And [um] to be honest with you I thoroughly enjoyed having that machine and diary of monitoring myself [um] on a daily basis. And I think that gave me a lot of confidence, should I say? Yeah, it was very good to keep an eye, and I was able to do this throughout the whole pregnancy."
>
> *(Participant 2 interview: previous pregnancy complicated by prematurity)*

> "I definitely think that it was measuring in my case, measuring blood pressure in the house, that really helped me. In the sense of keeping - knowing that he's well, in the sense that he was moving fine, counting his kicks, and [er] my pressure wasn't that - It was in the rate that they said that it should be. I could check [er] these things for myself."
>
> *(Participant 4 interview: first pregnancy, long-standing chronic hypertension)*

In addition to being a convenient and easy means for checking on the health of their pregnancy, women described several other reasons for preferring home monitoring to solely clinic monitoring. Many appreciated the greater control over *how* and *when* blood pressure measurements were taken, which they also thought would lead to what they perceived as more valid measurements (discussed in more detail in Chapter 6). Women also talked about the benefit of improved knowledge of blood pressure in pregnancy in general and their own readings in particular.

5.3.2.1 Control and knowledge

Home monitoring could provide a sense of 'control', a term that peppered most women's accounts. There were practical aspects that women had control over such as the circumstances and timing of their blood pressure readings. Feelings of control were also linked to increased awareness and knowledge about their blood pressure in general. Women became aware of the variability of blood pressure and knowledgeable about their own particular patterns of readings. As women gained a greater knowledge and insight into their own blood pressure, many also described feeling more in control of being able to take practical steps to try and help control their

blood pressure. Some women described making dietary changes such as further reducing caffeine, changing work hours or practices, or simply resting more.

> "I got to really know more about blood pressure this way..I hadn't thought about it so much before. It really helps me to feel in control if I have an understanding of my own blood pressure and why it changes, and that it fluctuates quite a bit during the day. I became quite the expert about me! [laughing]"
>
> *(Participant 19 interview: previous pregnancy with gestational hypertension)*

> "I now don't feel like I'm ambling through pregnancy being none-the-wiser. I'm not worried about having the high blood pressure now as I can see the readings and I can make changes, I am more in control. I can rest some more, try to be less stressed and I can talk to someone who is an expert in this sort of thing if I need to."
>
> *(Participant 25 informal interview: second pregnancy with chronic hypertension)*

Most women from the intervention arm derived a sense of control from being able to use self-monitoring to help interpret any symptoms: *"And I felt more in control. Because I really knew, I was able to like know what my body's doing at a particular time. So I was, if I maybe felt unwell or weird…and I would start thinking "oh, maybe it's my BP?" But when I checked I found out my BP was normal…the monitor it helped me know." (Participant 10 interview: fourth pregnancy, previous stillbirth).* One woman said she was certain that without the ability to check her blood pressure at home she would have made many more visits to the hospital: *"I would have been feeling 'Oh, I'm feeling this, I'm feeling that…let me just go and check'. I would have been going in too much to the hospital"* (Participant 20: third pregnancy and previous intrauterine death). Additionally most, but importantly not all, women were aware that high blood pressure was commonly without symptoms, and an important aspect of control came from home monitoring providing the ability for timely detection of any silent deterioration: *"…I knew from with my son that things could seem absolutely fine when they're not. But this time around things were totally different, yeah much more under control as I could just keep checking the numbers and slowly I*

could see them creeping up…but yeah that's the thing, still I felt fine. But now we knew I wasn't fine before the whole pre-eclampsia took off." (participant 26, previous pre-eclampsia).

Not only had some sense of control been gained over the disorder but some women also observed a shift in the doctor-patient relationship. Beyond simply controlling the collection of measurements, some women appreciated feeling in charge of the monitoring, the context, timing, frequency, recording and reporting (discussed further in chapter 6) and being knowledgeable about their condition and their own readings:

> "But I was in control. I would go and see the doctor, report to them that after all it's [the BP] been stable. It's fine, I have no questions. I have the knowledge."
>
> *(Participant 4 interview: first pregnancy, SMBP previous to pregnancy)*

> "I preferred being able to do it at home. Because it felt like there is something I can control. It's not really I – I know I can't actually control it, but I can – I can control when, I can keep an eye on what's happening. So I'm not dependent on the snapshot moment where someone else takes my blood pressure in clinic and it might be high, and when I know it's normal at home."
>
> *(Participant 16 interview: second pregnancy with chronic hypertension, usual care group and started her own SMBP)*

The value placed on being able to control their home monitoring was evidenced by some women's annoyance if they perceived control had been taken away from them, for example either when clinicians took clinic readings (and acted solely on those) or if home readings appeared to be overlooked:

> "[um]…they quite annoyed me a little bit. Every…like when I…because I did [um] sometimes say I didn't want to do it at the hospital when they wanted to do it. Because I felt that if I wanted to do the reading it should have been my choice as such. I felt like I wasn't in charge anymore, do you understand what I mean, it was a bit weird.
>
> *(Participant 2 interview: previous pregnancy complicated with prematurity)*

5.3.3 Reassurance

During the design phase of the study, some clinicians voiced concerns that the intervention may provoke anxiety for pregnant women, either due to the unwanted responsibility of self-monitoring or in the event of a raised home reading. The qualitative data did not support the view that these concerns were a major factor amongst this group of women with chronic hypertension. All of the interviewed women related positive experiences of home monitoring. Women described feeling reassured by routinely keeping an eye on their blood pressure. In contrast, many said that having their blood pressure measured in clinic provoked anxiety (discussed more in Chapter 6). Comments included:

> "I think the opposite from anxious. I think it did make me feel that I don't need to worry about it. So I would take my medication, I would follow it up. And it was something that you would always go, check it when you want to, fine, let's move on. And it would make me not [sigh] - like for example if you were expecting to go to the doctor, for him to tell you is everything okay, that waiting for somebody else to tell you made me worry instead."
>
> *(Participant 6 interview: pre-eclampsia in previous pregnancy)*

> "I was much more relaxed doing it at home….whereas I'm going there and I'm thinking like "oh no, I hope it's going to be good, I hope it's going to be good". Kind of that feeling like, "I hope it's not going to be high, blah, blah". Sort of worried, "oh, they're going to keep me in if it's really bad" sort of thing. But I suppose at home you don't sort of think about it like that…you just do it."
>
> *(Participant 9 interview: first pregnancy, friend with pre-eclampsia)*

Even two women who described themselves as anxious and another being treated for anxiety, said they found home monitoring reassuring:

> "I mean, I'm a constant worrier, you know it's just the downfall that I have. And I had problems at the birth of my son and I think that obviously projected into this pregnancy as well, and maybe that's what gained the…me having a bit of high…you know high blood pressure. But I think being able to check on things myself at home made me worry much less. Yeah, it definitely helped me I think…be more calm."
>
> *(Participant 2 interview: previous pregnancy complicated by prematurity)*

There were two more ambivalent accounts from women who reported mixed feelings, one of whom had a history of stillbirth. However, despite confiding some anxiety with the monitoring process or on receiving raised readings, both chose to persist with the self-monitoring:

> "To me, whenever I have higher readings, it makes me think more. It makes me start panicking the more 'oh, this thing is high'….Yeah, so if I check and I see oh, from – I'm on the red, it scares me. Yeah, I used to check it most times in a day. To see what is going on. If it's going down….
>
> ……I was very okay with taking it home. Because I knew it was going to help me to like monitor. And I wouldn't want any same story for me, that I've experienced some stillbirth before, so I wouldn't want anything to happen to my baby. So I knew with that [er] monitor I would be able to be checking, is my BP high? Once it's too high, I will just ring the doctors, to let them know. Yeah. So as I say, I was happy to."
>
> *(Participant 10 interview: previous stillbirth)*

> "I think my problem maybe is that I can't really deal with insecurity. And I guess insecurity and loss of control. And I guess what pregnancy is, is kind of insecurity and loss of control, right? So. [um] I think this [SMBP] gave me back some of that control if you know what I mean? Like because it does make me feel really anxious to take my blood pressure. Even if I do it myself. But at the same time I was less on edge all the time being able to take back this tiny bit of control."
>
> *(Participant 17 interview: high BP previous pregnancy)*

Unfortunately, none of the four women who formally discontinued from the self-monitoring intervention (55 with chronic hypertension were randomised to SMBP) agreed to be interviewed. However, reasons were recorded in free text on the study discontinuation form; three women recorded lack of time and the fourth woman noted:

> "I feel that having to do my blood pressure is stressing me out and making my blood pressure worse."

In conclusion, self-monitoring increased women's knowledge and sense of autonomy, and could provide reassurance, even amongst those with anxiety. However self-monitoring may be perceived by some healthcare professionals as anxiety-inducing and contributed to at least one participant (of 55 women) discontinuing the intervention.

5.3.4 Monitoring in future pregnancies; amongst usual care group and postpartum

Women were asked what sort of blood pressure monitoring they would want for any future pregnancies. *All* women interviewed from the intervention group and 3 out of the 5 interviewed from the usual care group, said they would choose to self-monitor in any future pregnancies.

> "Yeah, definitely I would keep an eye on it. It's like now, it's - It's part of pregnancy now, to me, checking it at home. Kind of that's how - Sort of I'd be shocked if it didn't happen in my future pregnancies. With the pre [pre-eclampsia] - Because it can happen anyway, like without having it before, it can happen to anyone. So, I'd say yeah. It's an important thing to be able to keep an eye on."
>
> *(Participant 39 interview: developed pre-eclampsia in current pregnancy)*

An important distinction made by several women, was their preference for *both* home and clinic monitoring in any future pregnancy, appreciating the autonomy with self-monitoring but valuing the clinical oversight from concurrent clinic monitoring:

> "[um] To be honest with you I'm not going to pick one or the other; I'd say both. I would say both because obviously you have to get it checked at [um]…with the medical people you know, that's very important. But I personally, that's when I was doing it myself, preferred that way."
>
> *(Participant 23 interview: second pregnancy)*

The three women interviewed from the usual care group reporting they would choose to use SMBP in any future pregnancies, also said that they were doing some form of blood pressure monitoring during their current pregnancy. The quantitative feasibility study data suggested contamination (uptake of the intervention in the usual care arm); estimates from clinical notes review showed that 12 out of 31 (39%) randomised to usual care took up independent self-

monitoring (see Chapter 2). Some women had their own devices or had borrowed them to use in the current pregnancy. Those who had monitored before pregnancy wanted to continue, while difficulties with BP control motivated some others to start monitoring.

> "So with the blood pressure was trying, to kind of control. We had every few weeks appointment. To check it. It was going up and up. I started tablets. So I wasn't the lucky one to get the blood pressure monitor. So I decided I got it myself. And I was writing in a diary. So every time I went there I was showing her. The diary. So she was checking, she said "It's fine, it's fine"….I was trying to buy the similar to what the hospital has. But we just choose the lower price one, with higher memory. So it was like sixty readings. I got it from Amazon. [um]"
>
> *(Participant 5 interview: usual care group doing her own SMBP, previous pregnancy admitted with high BP)*

None of the three blood pressure devices that these usual care group women showed me at interview visits were models validated for use in pregnancy and pre-eclampsia, and only one device was validated for use in the general adult population.

The two women interviewed from the usual care group who reported not taking up any sort of antenatal self-monitoring said that they had access to one (from family members) but felt no need to monitor at home due to close clinician monitoring and good blood pressure control. However participant 16 below started monitoring postnatally as this was when she had developed complications in her previous pregnancy:

> "[um] No. Just - I just didn't think to use it, to be fair. Because obviously my blood pressure was being checked often. I felt that [um] if something was wrong, or - or needed [um] to be looked at, and then - I felt well looked after. So I didn't need to do it. So. I probably would have kept an eye on it a bit more, if it was going up, or if I was being treated."
>
> *(Participant 16 interview: previous postnatal pre-eclampsia)*

Several women continued to monitor into the postnatal period, as evidenced by their monitor downloads and from comments they made as I collected monitors during my interview visits:

> "So it's been very good to have the monitor through afterwards as well. Because - Especially the first two months I had him, because you want to check everything is fine. And the blood pressure's been always [um] on the, on the range, the normal range. It sounds funny, but I'm going to miss the machine. It feels like it should go in the baby box."
>
> *(Participant 4 interview: first pregnancy)*

Women's preference for using self-monitoring in any future pregnancies, being motivated to take up some form of monitoring if they were in the usual care arm, and many continuing with monitoring into the postnatal period attest to the broad acceptability of the intervention.

While on balance the women I talked with were certainly in favour of SMBP in pregnancy, they were also aware that there could be some disadvantages, but these were theoretical in nature and did not reflect their own experiences. These possible disadvantages included becoming 'obsessive' with monitoring, or monitoring itself causing anxiety, and if support wasn't available when needed:

> "I did worry at the beginning when I was thinking about whether to join or not…whether I'd get a bit you know, obsessive about the whole blood pressure and checking it. I can be a bit like that anyway and was really quite obsessive about things in my first pregnancy…what I was eating and any caffeine…feeling if movements were the same…but this hasn't happened with the monitoring…. I'm not sure why…maybe having that clear set of instructions to follow."
>
> *(Participant 11 informal interview: previous gestational hypertension)*

> "I worried when I started that I might not know what to do…if I got some high readings that this would make me really panic. But it was only a couple of times I got a few highish numbers and I just spoke with the day unit…[who] gave me help."
>
> *(Participant 8 interview: previous early delivery with high BP)*

5.4 How women used the trial SMBP

Women were asked about *how* they used the self-monitoring: what were the drivers, with what frequency they measured, the timing relative to other activities, and how they remembered to

self-monitor. An important theme for informing the large trial was that of persistence and women were asked around their reasons for sticking with, or obstacles to their being able to continue with, the self-monitoring throughout their pregnancy.

Women were also asked for feedback regarding the components of the intervention including learning to use the monitor, traffic light system and recording and reporting their readings.

5.4.1 Proactive, purposeful and frequent self-monitoring

Many women described not just taking measurements once per day at a fixed time as per protocol, but instead taking additional readings at more sporadic times, which went mostly unreported through the study system. This was confirmed by downloads from the BP monitors that showed that many women from the intervention group were taking multiple readings per day, throughout the day, for extended periods (see Chapter 3). Women reported these extra readings were for specific self-care purposes, which included trying to interpret any physical symptoms, to monitor the effects of stress and stress-relieving activities, before clinic visits to compare against clinic readings, and to check if medication was working and to help decide when and whether to take medication (perspectives around medication are discussed more fully in Chapter 7).

> "[um] So, it was reassuring the fact that I had to do it and I could look at numbers and I was writing them down, and I think in my head how I felt, if say it went up whether I had a stressed day or…because I was thinking about it more; I wasn't just taking my blood pressure; I was actually noting it down and thinking generally more about my pressure and about more of how I felt…. it helped me a lot, to be more pro-active in looking after myself – pregnancy and baby."
>
> *(Participant 1 interview: first pregnancy)*

In this way, home measurement was *not* used passively to provide BP readings for the clinical team, but instead many women described using it proactively and often, to aid self-knowledge and self-care.

5.4.2 Timing and experimentation

Home monitoring was undertaken at all different times of day, and whereas some stuck to a fixed pattern, others described taking it at variable times or *"whenever I could get five minutes peace" (Participant 11)*. A few women gave accounts of quite elaborate measuring routines, as a means of fitting it into busy schedules juggling work and young families, challenging domestic circumstances or both:

> "It was when I, [er] all the time wake up. Between half past five, quarter six. When I wake up, go to toilet, and stay sit down for ten minutes to give body chance and check. It is in bathroom so to not get my husband up...Everything..it is ready on the bin..[laughing] and extra pen as he took them. After when I wake up, take my medication, sit in there and after that I check when ready."
>
> *(Participant 22 informal interview: first pregnancy, living in one bedroom hostel)*

A common theme was that of experimentation. Timing, place, posture, pre- or post-medication, were all varied as women sought to understand their blood pressure better. Many women expressed surprise and some disquiet on discovering that their blood pressure could vary considerably in these different circumstances, and not always as they had expected. This led some women to try to recreate conditions that they believed had given them the "best" (lower) blood pressure readings, although they were not sure this was the 'right' thing to do for the study purposes. This variability led to some scepticism about their clinic readings (discussed further in chapter 6).

> "But then I was quite surprised. I mean, that's the other thing that was my sort of query on the blood pressure side of things. I know from taking it at different times of the day in all sorts of situations, it varies a lot. And I know from having done twenty four hours monitors in the past it varies a lot. So how - how do you get a true representation of whether the blood pressure is overall high, and you're not just managing it at the peak points like in clinic? It's so difficult to measure. I'm just not sure about it."
>
> *(Participant 19 interview: previous pregnancy complicated with high BP)*

> "I got to learn that if I didn't sleep enough, my pressure was higher. So when I was much more tired too after work as well, even taking it after medicine was not helping. I found the best time for me to get my best readings was to take it in the evening when I had that bit of time in front of the telly."
>
> *(Participant 8 interview: early delivery previous pregnancy due to high BP)*

As part of their personal experimentation process, many women described taking multiple readings (more than the two advised in the protocol) and most did not see any need to record these. Instead they chose what they considered to be their "best" or most representative readings, i.e. the lower ones. This was borne out by comparing the monitor downloads with the reported readings (see Chapter 3). Women gave several reasons for this selection process, including imitating observed practice in the clinic, following trial instructions, anticipating that readings would come within target range on repeat testing, perceiving earlier higher readings reflected stress (themes discussed further in Chapter 6):

> "There was one time when I thought I was going to have to phone. Because it was quite high. And I did what it said in the diary – waited five minutes and took it again. But I know in myself – Five minutes and a couple of readings isn't long enough. I know that I'd be really nervous and just anxious, because I saw a high reading. That's not really my proper one. So I'd wait longer, say half an hour, and maybe take the third or fourth reading."
>
> *(Participant 24 interview: first pregnancy)*

Women described not wanting to bother clinical services with borderline measurements, especially alongside frequent clinic appointments. Women's perspectives and behaviour around out-of-range readings are discussed further below.

> "Sometimes you just feel like 'why am I going to bother someone with this about?' Yeah, so if it was a reading a couple of times, like 92 or something. I know it's going to just come down I hope, if I measure it a few more times or a bit later. Or if it was just a tiny bit up – like the day before I had an appointment anyway, so I thought 'oh, I'll just wait to the appointment'."
>
> *(Participant 14 interview: previous early recurrent miscarriage)*

5.4.3 Remembering and persisting with monitoring

Women reported a range of regimens and behaviours for remembering and timetabling self-monitoring. Some women had clearly incorporated measurements into their daily lives e.g. monitoring first thing in the morning or last thing at night when they could be sure they would not be interrupted. Medication was frequently taken around the same time, either just before or after measurements, so matters of blood pressure management were bundled together. Some women reported trying to time blood pressure measurement at what they deemed a suitable interval of time after taking medication (discussed more in Chapter 7):

> "I would try to do for example after doing everything in the house and I wouldn't be interrupted. It became a habit. It would be late in the evening. Also in the morning too. When I wake up in the morning I would always do it, because then that level that you can link to how well you sleep."
>
> *(Participant 4 interview: first pregnancy)*

> "Yeah, got into a routine. Just like the tablets. I just done it in the morning. I'd take my tablets - eat breakfast, take my tablets and then about an hour or so roughly after, I'd take the first reading to see if tablets worked. And then in the evening I'd take a reading, before I - that was before I took my last tablets in the evening. Just to see before - So there was a bit of a gap."
>
> *(Participant 3 interview: usual care group doing her own SMBP, previous pregnancy admitted with high BP)*

Women often placed the monitor somewhere prominent in an area associated with relaxation, where conditions were perceived as favourable for blood pressure measurement:

> "It was - to me, it wasn't really difficult. Because I had to keep it very close to where I would be seeing it every time to check. So sometimes I would feel very lazy to do it. Yeah. [laughing]…But I kept it just on top of my telly - the moment I'm entering my room, I will see it on, on the telly there. So, entering my room, that's one thing staring at me, yeah. I didn't like hide it. Because if I hide it, I know definitely I would forget. So I kept it at the position that I would see it constantly then that means I do it. It wasn't difficult. I'd relax sitting. Then get my partner to get it off the telly [laughing]."
>
> *(Participant 10 interview: previous pregnancy with chronic hypertension and gestational diabetes)*

Women also set mobile phone reminders for both monitoring and taking medication. A couple of times women's alarms went off during their consultations:

> *[The midwife is measuring the second blood pressure, but has asked the woman (participant 20) to uncross her feet and rest her lower arm against the table. A buzzing sound keeps repeating.]*
>
> Midwife: "Is that your phone? Do you need to answer it, as it sounds like it might be important?"
>
> Woman: " Ah..it's just my alarm. It reminds me to take my tablet and measure my blood pressure. It's the only way I remember!"
>
> *(Field note: antenatal clinic midwife and participant 20)*

It was notable that, despite some women having shift patterns of work or several children to care for, they were highly motivated in their blood pressure monitoring and devised work-arounds to enable monitoring, such as taking readings after children had gone to bed or in the car during work hours:

> "Very rarely I would forget, if I had different shifts at work, a couple of days I think only, I forgot…but it just takes two minutes… to check myself, and for my baby too, that's all, it's very important and I can do it quick. In the end I kept it in the car... I know that's when I can get the two minutes to do it."
>
> *(Participant 7 interview: pre-eclampsia in previous pregnancy)*

Those women who reported forgetting to take their blood pressure and similarly found it more of a struggle to persist with measuring as time went on, tended to be those not taking antihypertensive medication. It could be that both activities mutually reinforced the other as suggested above, but might also be that those taking medication were more invested in general in the notion of blood pressure as something to be monitored and managed. This was supported by comments made by one woman below, who became more motivated after starting medication:

> "I think once you got into the habit of it, doing it every day, after a week, it was just sort of like natural. Just a natural thing to do. I definitely got into a habit more after I started the tablets. Then it was like, it's important I get this right. It's for me and my baby and it's very important to get the right level of treatment with this."
>
> *(Participant 21 interview: previous pregnancies did not require antihypertensive treatment)*

Women's reasons for persisting with the monitoring throughout the pregnancy included a sense of duty to the study, but overwhelmingly women described the importance of monitoring for their own health and that of their baby. Women's perceptions that high blood pressure put them and their baby at risk, which appeared to take on additional meaning when they started medication, were highly motivating. As described, forming a habit, along with using various strategies to aid remembering, all helped with persistence, but over and above this automatic activity, women reported their intrinsic motivation to continue with the monitoring.

> "I was just continuing, because I mean as I said, I have this kind of diligent attitude [laughing], so if I'm attending - I was attending the study, so I felt I have to do it, so. But honestly, I just did it because [er]. I mean I know it's for my health. This is the main trigger. It's because it's going to be for your health. And the baby of course. Probably this is [laugh] the main driving force. Yeah, even more diligent, because it was not just for me, but also for the baby."
>
> *(Participant 18 interview: previous pregnancy, needed early delivery with pre-eclampsia)*

However, some women found they forgot more frequently as the pregnancy progressed. These accounts came mainly from women facing many demands including younger children to take care of and working long hours. There was also the sense that continuing with blood pressure monitoring was less of a priority for those whose blood pressure had remained stable and within-range throughout pregnancy and did not need medicine:

> "I did forget, as the pregnancy went on. Things just took over, what with all the things that need doing all the time for the others too. Yeah, I think there was many more missed readings than what there was. At the beginning, I did it religiously. [laughing]"
>
> *(Participant 13 interview: previous uncomplicated pregnancies)*

> "I suppose it became less..of an issue maybe? Strangely my blood pressure seemed to be better behaved in pregnancy than it was out of it. So I never needed the tablets at all and all the readings were spot on…so it didn't seem as crucial to keep this close eye on it.
>
> *(Participant 48 informal postnatal interview: did not require antihypertensives in pregnancy)*

5.4.4 Using the trial monitor and reporting system

All women interviewed from the intervention group reported finding it quick and easy to learn how to measure their blood pressure*:*

> "It was very simple really. I could do it straight away after being shown it once."
>
> *(Participant 2 interview: second pregnancy)*

Some made specific comments about preferring their home monitor with reference to how it inflated the cuff "*gently and steadily*" compared to some of the clinic automated monitors. One participant who described herself as a "*dyed-in-the-wool white coater*" expressed her preference for her home monitor compared with the larger machines typically used in the maternity assessment unit, in quite anthropomorphic terms:

> "I've struck up quite a relationship with this one now….he's quite calming. Yeah, it's these machines that do lots of - you know, the really tall ones that do loads of like - they do a tune when they turn on. And I think why does blood pressure machine need to play a tune? And then they go [grrrr] to blow up the thing, like they're going to blow and I can feel my blood pressure going up with it, where as this one [patting the monitor] he's quite discreet."
>
> *(Participant 17 interview: high BP in previous pregnancy)*

The majority also described that the traffic light system within the blood pressure diaries, for assessing and recording their blood pressure range, was intuitive and helpful with clear instructions about *when* and *who* to call for out-of-range readings:

> "So I think. Yeah. Red, amber, green - simple, straight forward. Easy for you to glance back at and say, "Oh I've had a few amber readings, maybe I need to do something."
>
> *(Participant 19 interview: gestational hypertension in previous pregnancy)*

But a couple of women said the traffic light system for blood pressure ranges took some time to work out and could be burdensome:

> "…I have to engage brain [laughing] which doesn't always work by the time I get the kids to bed and get around to doing it [measuring BP]."
>
> *(Participant 11 informal interview: previous pregnancies with pre-eclampsia)*

One of the clinicians I interviewed wondered if there was some mismatch in understanding amongst women around how to record measurements within the traffic light categories. This was supported by analysis of the accuracy of the blood pressure categorisation in the diaries compared with monitor data (see Chapter 3):

> "So, some women were recording blood pressure – sometimes they'd been recorded in the wrong colour box, sounds a bit pejorative, I don't mean that. But given there were categories, and sometimes through a lack of understanding, or you know, just a mistake, the blood pressure wasn't in the box that you'd expect."
>
> *(Clinician 003 interview)*

Women gave mixed feedback regarding the blood pressure paper diary. Some women wanted to retain this feature for any future monitoring, stating they were a "pen and paper" sort of person or they found it helped adding notes around medication or activities before measuring, and was easy to glance at and gain an idea of their usual pattern of blood pressure in the coloured boxes. Others quickly replaced the diary with their own smaller bits of paper that they could leave in the

monitor case, or which they brought with them to clinics. Some women said they found it much easier to record it in their phones and others just used the monitor memory function and transposed readings into the study diary the morning of their clinic appointment:

> "[um] I think that worked very well [the paper diary]. I think, yeah I always had my bits of paper near me, and no problems with doing that. I think I filled it in the comments bit quite a bit too, about tablets and some symptoms…I am a pen and paper person [laughing]. Yeah, I would prefer writing, as technology can always fail."
>
> *(Participant 7 interview: pre-eclampsia in previous pregnancy)*

> "I prefer putting it down on the paper, on just a sheet of my paper, and writing the date. I'd write the score. Using that diary was [laughing], was - no, no, no. No, I can count the number of days I use it. I think one [laughing]. It's too - it's too big, to start with. So I would - I just left it in my hospital bag."
>
> *(Participant 10 interview: pre-eclampsia and gestational diabetes in previous pregnancies)*

5.5 Acceptability of SMBP to clinicians

The acceptability of the intervention for clinicians is paramount for its successful adoption and effective use for hypertension management. Clinicians were asked about their views on advantages and disadvantages for BP self-monitoring in clinical practice, and workload considerations were specifically explored.

5.5.1 Fuller discussions and workload considerations

Clinicians were guardedly positive about the HBPM during interviews. They said that it appeared that the home monitoring intervention had been readily adopted by women who wanted to share and discuss home readings with them. The apparent acceptability of the intervention to women and ready recruitment to the trial strongly shaped clinicians' perspectives. *All* clinicians said that it was desirable to engage women in their own care, and many commented that self-monitoring could help foster fuller and more open discussion about blood pressure and its management.

These discussions could then be used as the basis for "shared decision making", a phrase which was regularly used by clinicians:

> "I think it really helped with engagement and empowerment, and shared decision making. Because the women had bought in to the whole self-monitoring…I would just present them [home readings] as additional useful bits of information that would help us to make treatment decisions together. Because they were an active partner in it. [um] So I would say the benefits appeared on the most part to outweigh the disadvantages."
>
> *(Clinician interview 002)*

Clinic observations found that clinicians engaged study women in conversations around their home blood pressures and invited women's thoughts around management decisions. The clinic field note below demonstrates one such "fuller discussion", where the clinician uses the home readings as a basis for education around BP and medication and emphasises their shared goal of blood pressure management: a healthy pregnancy and baby.

> Clinician: "And how have you been getting along with the Labetalol? So I can see it has been a bit on the lowish side and it is quite low today…." [clinician running her fingers along the home readings]
>
> Woman: "Ah, yes, but look as you can see, this morning it was all normal [pointing at this morning's home reading]. So just now in clinic, yes it was lower, but I haven't had breakfast yet."
>
> Clinician: "So should we back off a bit on the Labetalol? My concern is that if we reduce the BP too much we can start to run into trouble. How about we split the difference? 100mg three times rather than 200mg twice a day?"
>
> Woman: "But do you think on one clinic reading today….?"
>
> Clinician: "I know, but you're always running a bit lowish, despite being in the green at home [study range depicting "normal" home BP] and actually I think 100mg three times will smooth it all out a bit rather than it doing this" [motioning up and down with her hand in the air]."
>
> "So what we try to do with all of this blood pressure, is mimic normal pregnancy…we don't want the blood pressure to be too low or even too high as this can affect the baby's growth, so we are always trying to keep things on an even keel, as that is best for you and baby."
>
> *(Field note: antenatal clinic with clinician 005 and participant 37, previous pregnancy complicated with pre-eclampsia, now 21 weeks' gestation)*

Due to the emphasis and energies that women placed in their home readings most clinicians recognised the importance of actively acknowledging the home readings in consultations. Commonly, I observed clinicians asking women if they were home monitoring and if they had any home readings to share. However, this was not always the case, despite my presence possibly reminding clinicians to introduce the topic of home monitoring. Below a clinician describes a scenario where level of blood pressure may influence whether they ask further about home readings when seeing women from the trial:

> "If their blood pressure was normal on clinic visit, I would be less likely to be rooting round their notes to see if there was other information, or to ask them [about home readings]. If it was abnormal, I'd say "Are you taking your blood pressure at home at all?" Usually I wouldn't go looking further unless there was abnormality on the page in front of me to worry about."
>
> *(Clinician interview 005)*

Having extra clinical data available within the consultation and increasing the opportunities for shared decision making does raise the spectre of lengthening clinic appointments and increasing clinician workload. This had been one of the considerations around acceptability for clinicians, and the wider healthcare system, when designing the study.

Clinicians were asked if they had noticed their workload increasing as a result of women self-monitoring and whether they were having different, maybe lengthier, conversations during consultations as a result of the intervention. No clinicians reported noticing any substantial change to their workload or the consultation dynamic:

> "I don't think it particularly added to the time, substantially. I don't know. I, I would like to think that I tried wherever possible to get some sort of shared decision making, or at least a nod towards it, as far as I could. In all women, regardless of whether they were home-monitoring, because I think it's just right, that sort of principle. "
>
> *(Clinician interview 002)*

> "I didn't notice any change to be honest. Again, I may be biased because of the diabetes side, and the way I [er] - the way we look at their blood sugars in appointments already. So I didn't notice any particular change in the dynamic or time. Other than it was just an extra bit of information I got from them."
>
> *(Clinician interview 007)*

Clinicians were often aware of highly motivated women outside of the study who were already self-monitoring and wanting to discuss their readings. A few clinicians also made comparisons with gestational diabetes where they were accustomed to women bringing blood sugar data to appointments.

My clinic observations did not suggest any stark differences to length or tone of consultations between women in the self-monitoring or usual care groups. Nor was there an obvious divergence in consultation type or duration between women in the study and my clinic observations during the earlier design phase of the study. However, consultation length was not formally assessed, and it would probably be hard to achieve valid comparisons. My analyses comparing *numbers* of clinic and MAU attendance between study groups showed no differences (see Chapter 2) and in this respect the quantitative and qualitative data provided no evidence for increased health system workload with the introduction of the self-monitoring intervention.

5.5.2 Reassurance and false reassurance

Clinicians said that they felt reassured, that women in the study were using BP monitors validated for use in pregnancy and pre-eclampsia, and receiving training in how to measure blood pressure correctly and within a structured system that advised women what to do if they had out-of-range readings. All these factors helped clinicians feel more confident in the home readings and the process for self-monitoring:

> "And I did use them [home readings], particularly because I knew it was being done properly, and they had been given – you know – shown how to do it, and a proper blood pressure monitor, and all those things, that's why I kind of don't take much notice of other people's blood pressures at home normally."
>
> *(Clinician interview 005)*

Clinicians also raised concerns including that women might be falsely reassured by 'normal' home readings and ignore important symptoms, possible disagreement over best management if home and clinic readings were interpreted differently and women inappropriately changing their use of medicines. The latter two concerns are discussed in Chapters 6 and 7 respectively.

Given these misgivings, one clinician provided examples of women whose past experiences might make them more suitable for SMBP, those whose outlook arguably might be more aligned with the clinician's:

> "It's got advantages to reassure women that their blood pressure is not getting wildly out of control. And that's really useful for [um] people with a clinical background who are maybe over-worried. And it's also really useful for women who've had previous problems with severe pre-eclampsia and they're really scared that it's going to be missed, or they know somebody in whom it's been missed or diagnosed late."
>
> *(Clinician interview 004)*

This account portrays the sense shared by some of the clinicians that worried women needed reassurance while others might not be wary enough. Certainly, some of the women's accounts, irrespective of their obstetric backgrounds, described an almost constant vigilance, *"always worried something might be wrong"* (Participant 9), during pregnancy, wanting to avoid conditions that were perceived as not 'the best for the baby'. They reported changing their behaviours accordingly such as resting more, trying to avoid stressful situations, or (where feasible) stopping work earlier and using their home readings to help inform these decisions.

My interviews with women did not provide any evidence that they were falsely reassured by normal home readings whilst ignoring important ongoing symptoms. There were multiple accounts of appropriate reassurance, where headache symptoms motivated women to measure their own blood pressure, which was found to be normal, and this prompted drinking more fluids and symptoms quickly resolved. During interviews, five women described attendances at the Maternity Assessment Unit (MAU) prompted by symptoms, three with reduced fetal movements,

one with upper abdominal pains and another with headache. All of these visits were in the context of normal home blood pressure readings, which women checked to help interpret their symptoms.

However, there was evidence from interviews with women that with continued normal home blood pressure profiles there was the possibility of women being overly reassured, perceiving less benefit and becoming less motivated to continue with self-monitoring. One clinician noted that a participant developed pre-eclampsia the following week after returning her monitor:

> "..she had been monitoring really regularly and it [home blood pressure] had been normal all along, until about 36 weeks' and she brought the monitor back to us at clinic saying she didn't have time anymore and she didn't need it and somebody else should get benefit from it…..the next week she was admitted with pre-eclampsia."
>
> *(Clinician interview 001)*

5.6 How clinicians used SMBP

I was interested to understand how clinicians integrated women's home readings along with clinic measurements into their clinical assessments and decisions around medication and follow-up. This would help further explore acceptability of the intervention and clinicians' current views around the place of home readings and blood pressure control in pregnancy as the evidence base evolves.

5.6.1 Integrating home readings into consultations

Clinicians reported using a variety of strategies when integrating home readings into their management plans. The study protocol had advised them simply to consider the home readings when deciding antihypertensive titration and clinical management whilst continuing to adhere to their local and national clinical guidelines. Clinicians described employing a mixture of heuristics such as looking at home blood pressure trends and patterns, deciding what the approximate average readings were or within which range the bulk of the home readings lay. Some were also

specifically looking for outliers whereas other clinicians didn't consider these significant.

Examples included:

> "I think you're always anxious about a one-off reading in clinic. And you do try to give people the benefit of the doubt, where you get them to sit for half an hour and recheck, and see what the change is. But ultimately you're treating a couple of readings in a short space of time. But if you've got recent home monitoring readings that do reflect a trend or a pattern, then that is all helpful information."
>
> *(Clinician interview 006)*

> "So I did use them to see what the trend over time was, and really if they were maintaining normotension, or if they were on treatment what their sort of steady state was. Yeah and I looked at more, an overall picture of an average of what level they were at. So I wouldn't pay particular attention to one-off highs. If over the week or whatever it was most of them [er] were within the normal range, I'd be fine. I don't pay any attention to low blood pressure. I know there is some evidence that it can cause growth problems, but that level of lowness, if you like, is very rare. So it was more of a reassurance for me that I'm classifying them appropriately. So single measurements that are high, I don't really – you know – that's just part of the parcel of variation of blood pressure. "
>
> *(Clinician interview 007)*

> "So I would look at the numbers. And sometimes the context. So [um], if particular things had been happening over the last week, or since the last visit, that might have explained the readings. And I would then integrate them in some sort of algorithm in my head into diagnostic and treatment decisions. And I would have reasonably open ended discussions about what the home readings meant in the context of the clinic readings. So if they'd just rushed in, and I mean, I feel differently from others about this, but – although I completely get why there is a protocol for measuring blood pressure, and that treatment decisions and predicted algorithms all come off that way of measuring blood pressure. Personally, I don't find first readings which might be a bit higher, for example when somebody's just walked in, uninformative. I just put them into the context of several readings. And I do the same with the home readings."
>
> *(Clinician interview 002)*

During my observations I noted how clinicians integrated the two sets of readings. I saw examples of clinicians dismissing 'one-off' high blood pressure readings, whether from home or clinic

readings. I also observed instances where these sorts of readings became the focus and clinicians sought possible underlying reasons for unusually high readings; and instances where patterns and trends were discussed and used for prediction of BP behaviour. Some examples are provided below.

> *[Clinician and patient are leaning over the desk and looking at the home readings together.]*
>
> Clinician: [nodding] "Right. Yes, I can see there's been a few weeks now where this bottom figure is sitting in the 90s. There's a slow upward trend isn't there. And we might expect it to continue to creep up over the coming weeks."
>
> Woman: "Yes, I thought so too."
>
> Clinician: "So. Yes, I think it's right that we increase the blood pressure medication at this time. The community midwife to see you in two weeks. See us again back here in four weeks. And a scan also on…. But you do need to see us before, if the home blood pressure is not responding to this new increase in medication. And are you otherwise okay?"
>
> *(Field note: antenatal clinic with clinician 006 and participant 18)*

> Clinician: "How are you doing? Have you got your diary with you? And how is baby? Are they moving well?"
>
> Woman: "Yes. Yes, thank you." [hands over the BP diary from her shopping bag]
>
> Clinician: "And any headaches or visual problems?"
>
> Woman: "No. No, all is fine."
>
> Clinician: "You're on the labetalol? [opens up the blood pressure diary] And it all looks like it's going very well. The pressure's been good." [BP range in diary from 121-142/68-83]
>
> Woman: [nods] "Yes, it's all been normal." [leans over the BP diary]
>
> Clinician: [points to the high reading that she had today in clinic, measured by the research midwife, which is the first reading 148/92] "What happened here?"
>
> Woman: "XX made me laugh. I have to get - I have to sit in silence, because if I laugh, it really goes up."
>
> Clinician: "I'll have to tell her off." [laughing]

(…… continued…….)

Midwife: "The urine is all fine." [She has been checking the urine sample in the background]

Clinician: "I'm not going to do anything today LD, as everything is normal. All the readings look fine. These are a couple of blips [pointing to 2 higher home readings] and no laughing in clinic, it's not allowed. So it's just a matter of waiting now. Are you feeling fed up yet?"

(Field note: antenatal clinic with clinician 007 and participant 45)

As the above extracts reveal, there was some ambivalence on the part of clinicians about the relevance of context for explaining blood pressure behaviour and the importance of a single or few high readings. These uncertainties and their impact on clinical decision making are discussed more in Chapter 6.

5.6.2 Home monitoring as part of follow-up

I asked clinicians about any changes they might have made to their usual monitoring and follow-up practices for women who were self-monitoring, as a proposed benefit of self-monitoring is the possibility of reducing the burden of clinic visits for women and the health system. In terms of monitoring schedules, clinicians generally claimed not to have advised women perform home monitoring in place of a face-to-face consultation. There was mention of a *"wide safety net"* and *"tight rope"* when describing clinic monitoring practices and concerns regarding the robustness of communication needed for models of remote monitoring. Some clinicians did report using home monitoring in place of asking women to attend the maternity assessment unit on a weekly or twice weekly basis as readings were trending upwards or to review the effects of medication changes. However, it was of note that *all* clinicians described recommending an upper limit of home monitoring for 2 weeks between seeing a heath professional. This is the frequency of visits that is advised for the second half of pregnancy in the NICE clinical guidelines for hypertension in pregnancy(205).

> "I would definitely personally be happier about sort of just treatment decisions – changes in treatment being safe, using home readings. But I may have used it to say 'I'll see you at two weeks rather than one week, but get in touch if your home readings are above such and such.' So I would, yes, occasionally did use it like that. But with a caveat, with caution. Because it wasn't – it wasn't entirely replacing my follow-up regime."
>
> *(Clinician interview 002)*

> "I suppose I did use it in the monitoring sense sometimes. But I don't think we have a robust way that women can actually contact us…. [um] the communication lines between the hospital and the patients have to be better for us to be able to do remote monitoring."
>
> *(Clinician interview 005)*

Observations of clinicians providing advice during consultations were consistent with the above descriptions. I also observed instances where home monitoring in *addition* to frequent clinic visits was used instead of admission where women were very keen to remain at home as long as possible, especially when they had other childcare responsibilities. These practices developed in the context of a close working partnership between the clinician and woman. Relationships appeared key to the confident and flexible use of the home monitoring intervention by both clinicians and women (as discussed below in section 5.9).

5.7 Out-of-range home readings: exploring safety

An important aspect of the intervention was the ability to flag out-of-range readings that might pose more of an immediate threat to the health of the woman and her pregnancy. The traffic light system was designed with graded categories where yellow and red were used to denote high readings advising women to make contact with clinical services (described in Chapter 2). In the design phase of the study there was much discussion with obstetric colleagues around suitable thresholds for these out-of-range categories, seeking to balance reducing risks and not creating unsustainable workloads with women making contact with assessment units, clinics or midwives for these readings.

As described above, women performed repeat testing when measurements were just above thresholds. Women frequently reported reluctance to make contact for marginal readings and not wanting *"to bother someone with this" (participant 14).* There was nothing in my data to suggest this was the impression clinical services wanted to give. On the contrary, both my interview and observational data indicated that clinicians repeatedly expressed the importance of making contact for *any* out-of-range readings or concerns that women might have:

> "And I didn't have any time where I was told not to come in. I think they always preferred to check even if it was just above. They didn't make you feel like a nuisance, like you're an over-obsessed person thinking something's wrong."
>
> *(Participant 21 interview: long standing chronic hypertension)*

> "It's great to hear that you're getting on so well with the home readings. And if ever the readings are high or even just a little raised and - especially if you have any symptoms, [um] any at all, please don't keep it to yourself. Just phone us or come in.
>
> *(Field note: antenatal clinic with clinician 003)*

This viewpoint from women of what might be legitimate reasons or timing to consult services about home readings appeared to have been arrived at independently but are consistent with the "good citizen" model describing the ambivalence individuals face when making decisions about when it's 'right' to seek health care(268). And some clinical imitation might have also played a part. It was not uncommon for clinicians to explain during clinic observations that they would just "keep an eye on" borderline readings:

> "I'm not going to jump on that today [clinic BP 139/93, 141/91], XX. The overall pattern both in clinic and at home has been very good and stable and we'll be seeing you with your scan in a couple of weeks anyway…so let's both just keep an eye on these….."
>
> *(Field note: antenatal clinic with clinician 006)*

During interviews, several women recalled instances where they had measured home BP readings persistently outside the target range, and they described following the protocol and contacting maternity services. The majority of these women were asymptomatic and were invariably advised to repeat the readings over 1-2 hours and to make repeat contact if readings continued to be raised. Most accounts were very positive about the reception they received during telephone calls with MAU: *"They always said 'please call us back'"* (participant 18). Some of these women, given their experiences of previous contacts with MAU reported independently monitoring their own blood pressure over several hours and only making contact if blood pressure remained raised: *"Because I'd had this experience before, I learned if I got these high readings, just to rest and recheck it in an hour or two. …. But later on when I realised it was always high – For example re-checking in a couple of hours it was still high, then I used to definitely call them." (*participant 18*)*

One woman with complications in a previous pregnancy (participant 19) described being admitted for further assessment after making contact with raised home readings and feeling *"a bit more tense – I don't know, just not quite right"*, and had her medication increased and eventually timing of delivery brought forward. She described *being "so grateful I was on this study. It was much calmer and all more straightforward than last time. I could see the readings had been in the amber range for about a week."*

The above examples describe women using the intervention as intended and the 'system' responding appropriately, when blood pressures were out-of-range. Women were advised to self-monitor over a longer period to check the behaviour of the blood pressure, or if they had symptoms were asked to attend their local assessment unit for clinical review.

However, there were also a minority of cases which came to light during interviews and observations where despite the home monitoring intervention, high blood pressure and/or pre-eclampsia were not flagged earlier, as described in the three examples below.

5.7.1 Example 1: Raised home blood pressure and symptoms

One woman (participant 22), who described phoning the assessment unit with *both* symptoms and a high blood pressure provided one remarkable and concerning account. Although we do not have first-hand details of this exchange, from her interview portrayal an opportunity for earlier intervention was missed:

> "Yeah. And one day I felt so, so weird. And my head, it was like - my brain, yeah? But it was like a bomb, like something inside - you know, like my - get into my brain, want to go out. And I start seeing all these like lights flash?"
>
> "And I came back to home, check my blood pressure. And it was - I can't remember number, but it was very, very high. Yeah, and I call to hospital. And they said, "You have high blood pressure that is not so bad." But for me it was so bad, because - you know - I've never before I had so high, yeah? And she said to me, "Don't do anything. Only sit down, yeah? And check another hours. Yeah. And I re-check. But it was going down. I felt better."
>
> "And when I had my appointment on Friday with doctor, that he said that why I have to be induced, because my blood pressure start playing up. And he said that it mean that you have to, you know, give birth now. But it was thirty seven weeks. I think it was Wednesday, my high blood pressure, my very high. And Friday I had appointment here with doctor. And decide me to come in on the Monday, start to induce."
>
> *(Participant 22 interview: first pregnancy, induced early for rising blood pressure)*

This woman's description was fairly phlegmatic with no apparent concern that anything had been missed and fortunately outcomes for her and her baby were good. With her permission, I discussed this episode with the site lead clinician and research team as a learning opportunity for the whole team, but particularly for those responsible for initial assessments within the assessment unit. I was able to corroborate her description with the readings from her BP monitor, which showed when she initially made contact with her symptoms, her blood pressure readings were 163/105 and 160/112. Her blood pressure settled a couple of hours later with her final reading for that day 145/93; but still in the range the protocol recommended contacting maternity services.

5.7.2 Example 2: Not making contact for raised home BP

In another account, one woman (participant 10, fourth pregnancy, previous stillbirth) was reluctant to make contact with her higher home readings. She became fearful and demotivated using the home blood pressure diary when she could see her readings were in the red range, despite her efforts to bring her blood pressure down by resting and taking medication. Despite her aversion to the diary, she remained committed to the home monitoring: *"I don't even check just once. Sometimes I check up to three, to four times in a day, just to be sure. To see what is going on".* Her blood pressure became difficult to control as her pregnancy progressed requiring an increasing frequency of clinic visits which she found both difficult and stressful to accommodate around her other childcare responsibilities. However, a strong partnership formed between participant 10 and her consultant and together they were able to use the home monitoring to avoid admission and more safely extend the pregnancy (see section 5.9):

> "It makes me start panicking the more 'oh, this thing is high'. It would prompt me to take my medication – but if I'm taking the medication and still seeing is not still bringing it down to a point I would have loved. Yeah, so if I check and I see oh, from – I'm on red, it scares me. That's why most times I didn't even want to be looking at the diary, I'm seeing I'm on danger….So I didn't even contact the hospital for one day. Not one."
>
> *(Participant 10 interview: fourth pregnancy, previous stillbirth)*

5.7.3 Example 3: Not using home monitoring and presenting with pre-eclampsia

In the third example, participant 46 (previous pregnancy with gestational hypertension), had a history of erratic use of home monitoring coupled with inconsistent attendance at the clinic. Below is an excerpt of the field note made at an appointment when P46 presented with pre-eclampsia. The appointment had been coordinated after several chasing phone calls to the pregnant woman by the research midwife and illustrates competing demands which may impact on use of home monitoring:

[The Clinician and I are sitting in the consulting room waiting for the next patient. RM (Research Midwife) comes in.]

RM: "I think there is something wrong with TT's monitor. The blood pressure is very high, it measures 182/103".

Clinician: "Is she home monitoring?"

RM: "Well yes, but she's not very compliant with this."

Clinician: "Well, let's see her."

Clinician (turning to me whilst RM leaves the room to bring patient in): "This does not surprise me. There was something similar with her blood pressure in her last pregnancy…well let's see.]

Clinician: "Hello [*name*], please sit down. Are you measuring your blood pressure at home [*name*]?"

Woman: "Yes, sometimes. Because when I checked it the once, it was 166. And that's when I came up to the hospital that time, remember?"

Clinician: [nods] "Well, what is it normally, if you check it at home?"

Woman: "Between 140s and 150s and 160s."

Clinician: [nods] "Are you having any headaches?"

Woman: "Yeah, but not much."

Clinician: "What do you mean?"

Woman: "Some. One or two."

Clinician: "And how long do they last, about?"

Woman: "One, two hours, maybe."

Clinician: "Do you take anything?"

Woman: [shaking her head] "No. They just go."

Clinician: "And any flashing lights with these?"

Woman: "What do you mean?"

Clinician: "Like flashes, or anything unusual in your vision?"

Woman: "Yeah. I can't really describe. Like it's something - I can't really get my words out. It's like dim." [does a flashing action with her hands]

Clinician: [nodding] "And any sickness?"

Woman: "Yeah. Most of the time." [rubbing her tummy area]

(…..*continued*……)

Clinician: “Can you pop your arm in here, and we'll test the blood pressure again. [He checks it. It's quiet. He writes it down. I can't see what the monitor says.] We'll leave it there and do it again in a minute. [leaving the blood pressure cuff on P46 arm]. And is the baby moving okay?”

Woman: “Yeah. Yeah. All fine.”

Clinician: *[looking at the scan report] “Baby's growing well. That's good. “*

[Patient is sitting down, looking down at the floor, waiting while the clinician is looking at the screen to look up blood tests. There is silence. The clinician repeats the blood pressure a second and then a third time. There is no discussion between them. The clinician turns to the midwife:]

Clinician: *“RM, I can't get this to print out again. What's happening today? If I go to the new request page - oh, I hate these computers.”*

RM: “Okay, let me try in Room 1. It keeps doing this. Is it PET bloods you want?”

Clinician: *[nods] “Yes, please. [turns to P46] I think we need to get you in, [name]. Your blood pressure is up, and we need to get you some treatment. Is anybody with you today?”*

Woman: *“Yes, my partner and my son.”*

Clinician: *So they could go and get your stuff, and then come back here. So we need to do some bloods, and we need to start you on something. And also check your urine. Will you be able to do a urine for us now, [name]? You go and do that [handing P46 a specimen pot], and then pop back here and I'll examine you.*

[P46 just nods once and leaves room with specimen pot]

Clinician: *[picks up the phone, dialling a number] “Yeah [name1], it's me,….. I've got a lady I need to admit for blood pressure control. She is well. But she could go into triage. I'm going to give her nifedipine here. And she needs blood pressure measurements hourly. And then the ward, if that is stable. But if I say go to the ward now directly, they'll get the heebeegeebies. You know what they're like. I'm on later, so I will follow her up. Yeah. Yeah. Cheers. Thank you. [then calls another number] Hi, is that [name2]? I've just chatted to [name1] . I've got a lady here, she's going to come into triage. She's hypertensive, but she's well with it. I will be sending her to the ward, but not directly. If I send her to the ward directly, there'll be the usual flap. [listens] 157 to 182. 101 to 119. But don't get worried about it. You worry too much, [name2]. Don't worry. You'll look at her. She's fine, you'll see. We'll get her bloods, and we'll do her urine here. Alright, thanks. Thanks very much [name2].” [puts the phone down]*

(Field note: antenatal consultation with clinician 007 and participant 46)

I was able to talk briefly with P46 after her consultation when she was waiting to be reviewed again in triage. She described how life was currently very hectic for her and her partner, juggling looking after their toddler, attending job interviews all whilst living with her family as they were waiting for local housing. P46 was enthusiastic about home monitoring and had started off doing it regularly but then it appeared too many other competing demands on their time and resources took over. She attributed her high BP and symptoms to the stress of these employment and housing uncertainties rather than to possible pre-eclampsia:

> "It's all kicking off. We're all on top of each other's heads…..Of course my blood pressure is up and yeah, I've got headaches. Who wouldn't? This one isn't sleeping either [pointing to her toddler]…I think it's all rubbing off on him too."
>
> *(Field note of informal interview with participant 46 in antenatal clinic)*

The occasions when interventions have shown limited success perhaps serve as the best sources of information for learning and future improvements. In the three examples above, there are potential changes that could be made to the intervention to help guard against the pitfalls of failures in communication with or from health services, patient anxiety and demotivation with high readings, and inconsistent use allowing for missed or delayed diagnosis.

5.8 Perspectives on study processes

Women described the processes of randomisation and using the monitor as straight forward. However, views were more mixed about the study visits and questionnaires. Several women and clinicians suggested reducing or removing study visits, agreeing about the importance of minimising any additional time needed for completion of study materials. Most women said the questionnaires could be completed quickly but a few wondered about the relevance of some of the questions, and they had had to check with the researcher how to interpret these questions. One research midwife said she would prefer to collect most clinical data from postnatal notes

review as this was more efficient, possibly more complete and meant women were waiting around less as she looked through their notes.

> "I got a bit stressed a few times fitting in seeing the [study] midwife then getting back downstairs again in time to the clinic…because by then it had got busy and I worried about missing my slot. So I think if this could be changed that would be better..maybe only having one visit?"
>
> *(Participant 20 interview: gestational hypertension in previous pregnancies)*

However, several women appreciated the time with the research midwife, particularly the continuity this offered, and sometimes this also meant they spent *less* time in clinic as their consultations were prioritised:

> "I think from my personal experience, [um] it [the study visit] was - it was something positive. You know, I'm going all the way to hospital to check is everything good with me and my baby so I felt seeing the Midwife is a positive outcome to that treatment. It was - It never took long. It just went along with being there anyway…It was really good to have the same person all along. I felt [XX] really got to know all about me and what was going on with my pregnancy and I could ask her any questions at all, not just study questions."
>
> *(Participant 9 interview: first pregnancy, friend had pre-eclampsia)*

> "Yeah. Yeah, good. [um] Actually, [the midwife] used to rush me through so it was much quicker. So you know, normally you have to sit there and wait like three hours in clinic? I'd just be half an hour, because she knows me and that I'm doing the study, so she was like 'I get all the study people through first'."
>
> *(Participant 24 interview: first pregnancy)*

Women were asked their views around further technological development of the intervention reporting readings using an app or text service as planned for those randomised to self-monitoring in our study with gestational hypertension. Women's responses were congruent with their use of the diary monitoring system; for those who said they preferred paper and pen and had concerns that technology could fail, they said they would always prefer to have the option of sticking with the paper diary. But for women who had already adapted their monitoring to include recording their readings in their phones or using the monitor memory function, they

welcomed the idea of an app; however several stressed the importance of it not taking up much phone memory and a few said they might struggle to use this method as they had poor connectivity.

5.9 Relationships supporting home monitoring

A cross-cutting theme in the responses from both women and clinicians and enacted during consultations, was that of the value of relationships and their role in supporting the effective and flexible use of self-monitoring. It was of note that the women in the study across all sites, received considerable continuity of care due to the design of the services. Relationships were established early on in the pregnancy or even from previous pregnancies where women had been looked after by the same clinician. During interviews women frequently referred to their specific clinician and (research) midwife valuing the continuity of care with this individual and they viewed them as pivotal in managing their hypertension and pregnancy appropriately:

> "Dr [*name*] really knows me. I mean…they've seen me in my other two pregnancies. They know what my blood pressure does. I knew I could always ask about any symptoms..my [home] readings…[um]..they listened to my side of things."
>
> *(Participant 21 interview: fourth pregnancy under same maternity team)*

Within the most effective relationships, both parties acknowledged the expertise of the other and trusted the shared information. This was communicated to women during consultations and was used to develop the relationship. In the few cases described above where women said they had some anxiety around the self-monitoring itself or in the event they had high home readings, these women described the central role played by their specific clinicians in building their confidence with the intervention.

> "And it's really good that we see you here regularly, because we want to get to know you, and your blood pressure."
>
> *(Field note: antenatal early consultation, clinician 002 and participant 10)*

> "This is all great. You're getting really good at the monitoring and it's really helpful for us to have all these extra readings so we can make sure…together we're keeping on top of the blood pressure."
>
> *(Field note: antenatal clinic, later consultation, clinician 002 and participant 10)*

> "In the end I did get to really enjoy it…yeah it was really good for me. Yeah I was worried in the start when I got these higher readings but then I got to learn at the clinic with *[name*] what it meant and I knew what to do if it [BP] was going up more. Yeah [*name*] really helped us get to the end."
>
> *(Participant 10 interview: fourth pregnancy, previous stillbirth)*

In contrast, several examples were given around dissatisfaction or concern with self-monitoring when there was an absence of a relationship between the woman and a clinician, most notably when a woman contacted the assessment unit with out-of-range readings and were hesitant about the advice they received. Several women contrasted this part of the self-monitoring process with the system they used for gestational diabetes monitoring where there was a specific midwife they could always contact about their condition and readings.

> "And some of them, they were not really fully aware about the study as well, so. I had to explain about the self-monitoring, the three colours and the ranges. I had to tell them about my normal numbers, you know. But my feeling was 'oh probably I should receive some extra information or guidance, something more personal and focused about me'".
>
> *(Participant 18 interview: talking about times she contacted maternity assessment unit with higher readings)*

> "I think it would be better with a dedicated person like with the diabetes….a direct number you can call not just a general one, and it's somebody who knows you and your background. And they also contact you if they've not had any readings for a while or there's a few high readings."
>
> *(Participant 20 informal interview: previous and current pregnancy complicated by gestational diabetes)*

Similarly when asked about possible technological development of the intervention, on the whole women welcomed this as discussed above, but they also talked about the importance of there being somebody specific to support them with the self-monitoring but also with the app/technology if there were any problems.

> "Yeah, yeah I like the idea of having it on the phone because I always have it on me, but I don't think it should just all be the app though. Because I had lots of problems in the first place with the app for my diabetes. But it was okay because I could always call [*name*] and in the end we sorted that all out but even then we have all that contact in the clinic or by phone and this way I think really works well. I don't want that sort of feeling where you feel you're left with it..you know all myself."
>
> *(Participant 38 informal interview: gestational diabetes in both pregnancies)*

5.10 Conclusion

Through the course of this chapter I have discussed the deductive analysis around acceptability and use of the self-monitoring intervention. My qualitative data provide considerable support for the broad acceptability of the intervention and trial processes to both pregnant women with chronic hypertension and clinicians as practised within the context of this trial.

Women valued being able to monitor their own blood pressure, motivating them to join the trial and in some instances to continue to monitor into the postnatal period, or take up voluntary monitoring if they were in the usual care arm. Women used the intervention pro-actively to guide self-care practices such as resting more or changing work practises, and also experimented with different monitoring times, particularly around medication. Benefits were perceived in terms of safeguarding their pregnancy and doing what was best for the baby, and included: improved knowledge of their individual blood pressure, ability to interpret symptoms, a sense of control and reassurance. Over and above these benefits, women also described persisting with the intervention when they had poorly controlled or treated hypertension. Women could envisage potential disadvantages with SMBP, but these did not chime with their own experiences. However some women were hesitant about making contact with clinical services for borderline

readings and one woman described becoming anxious and discouraged when she saw raised BP readings. Women were encouraged in seeking advice and to use the intervention confidently by supportive working relations with their clinicians, and these relationships were highly valued by women and seen as integral to the intervention.

Clinicians described that self-monitoring could contribute towards greater shared decision-making and provide contextual data without increasing clinical workloads. They were more reassured about the accuracy of home readings due to women being provided with validated monitors and training. Methods for integrating home readings into clinical decisions varied, particularly around the meaning of isolated or few high readings, causing some clinicians to consider white coat hypertension and treat less and others to aim for tighter blood pressure control. Clinicians were confident in using home monitoring to supplement usual practice but not to replace usual clinic visits and there were theoretical concerns around false reassurance for women provided by self-monitoring, who might then ignore important symptoms.

Participating women and clinicians shared both positive and negative experiences around the trial processes. All women found the monitor easy to use but experiences were mixed around the traffic light reporting system with some finding it complicated or onerous. Similarly, opinions varied around the paper diary with some women preferring this method and others rapidly adopting digital recording using their BP monitor memories or phones. These practices were congruent with perspectives on further technological development of the intervention. Some women appreciated the continuity of contact with the research midwife but others found repeat study visits and questionnaires time-consuming and hence stressful. Specific examples exposed potential weaknesses in the system including ignoring raised readings and inappropriate management after a woman contacted for raised readings.

Together these data provide considerable support for the broad acceptability of the intervention to both women and clinicians and provide the basis for recommended changes to the

intervention for use in a large trial, including streamlining and simplifying trial processes. These findings are discussed further in Chapter 8, together with those from Chapters 6 and 7, in the context of related literature.

Whilst presenting the data so far, I have drawn on the deductive analysis using largely interview data. A large amount of data was collected in the process of answering the main objectives for the qualitative study as described in this chapter. Using an ethnographic approach allowed for more inductive exploration and in Chapters 6 and 7 I have chosen to write about two important emergent themes. These are 'Trumping and Tensions' described in Chapter 6 which covers the different meaning-making of pregnant women and clinicians around home and clinic blood pressure measurements, particularly when there were differences between these sets of readings; and perspectives around medication in pregnancy and impacts of self-monitoring are covered in Chapter 7. The data from these more inductive themes have wider relevance and implications for the role of SMBP in pregnancy beyond the feasibility of an RCT.

Chapter 6: Trumping and tensions

6.1 Overview

In Chapter 5 I described the acceptability of the BP self-monitoring intervention to both pregnant women and clinicians and the ways in which both parties used the intervention. As is common with the introduction of new technology into the arena of health care, more nuanced and unexpected human factors played their part. Whilst blood pressure self-monitoring was acceptable to both women and clinicians, it was clear from the data that perspectives differed around meaning-making of the different sets of blood pressure readings. In this chapter I move the focus onto these more nuanced themes.

Specifically in this chapter, I discuss how women and health professionals constructed meaning out of the various blood pressure data and acted accordingly to safeguard the pregnancy. When home and clinic readings were not closely aligned, women tended to privilege their home readings whilst most clinicians took greater account of the clinic readings. Definitive evidence as to which measurements are most informative in determining maternal and perinatal outcomes is lacking. These differences surfaced some interesting tensions, which I examine in relation to which set of readings were seen as 'trumping' the other. Divergent perspectives were influenced by different awareness and understanding of risks (often unspoken), yet do not suggest a simple information deficit model whereby with more information women would fall into alignment with clinicians.

6.2 Results

6.3 For women the experience of home readings trumps clinic readings

All of the women interviewed from the intervention group said they privileged the home readings over measurements taken in clinic. There were a number of reasons why home readings were preferred by women. Women came to see the readings they recorded at home as more representative of 'normal life' and therefore valid, and the process of self-monitoring made women aware of the natural variability of blood pressure throughout the day. The environment of clinics, as well as the process of attending them, could be stressful and this was perceived by women to lead to falsely elevated clinic readings.

6.3.1 Perceptions about the influence of clinic and home environments

Attending clinics was generally perceived to be stressful. Women described experiencing long periods of waiting around for their appointments, or on occasion, being rushed into consultations without time to rest. The process of attending clinics, including driving, parking and timekeeping were also identified as creating stress, all of which might result in higher clinic blood pressure. It was notable that women drew a clear distinction between 'normal' readings taken at home and those taken in clinic, and that they perceived that it was 'normal' that blood pressure would be raised in response to the stress of clinic attendance:

> *"I think the home readings were most valid for me. Because they were done in a regular way. Of course in the hospital you're always a bit more stressed – you drive there, dreadful traffic, and then maybe you're late, you're rushed in, and then you're worried something might be wrong, and then of course it's normal that it's going to be higher there."*
>
> *(Participant 18 Interview: first pregnancy, developed pre-eclampsia)*

> *"I suppose I really trusted the readings from home more, because that's normal life isn't it? I mean it's not normal to sit in a waiting room for up to an hour is it? It's not though is it?"*
>
> *(Participant 7 interview: pre-eclampsia in previous pregnancy)*

"And even before leaving the house, I measure it and [er] I would show them. And I say this is – you know – I measure with my monitor here even and it goes up. It's just about the way I am."

(Participant 4 interview: first pregnancy, long-standing chronic hypertension)

These accounts illustrate the implicit assumption that home or 'normal life' conditions will likely be calmer, hence providing more valid or trustworthy readings. Importantly, women viewed this 'white coat' effect as something that was explainable and hence normal, therefore not placing them at risk nor requiring treatment.

Women's home monitoring experiences also made the variable nature of blood pressure more apparent to them. Even when home readings were raised, in most instances they were seen to settle to a lower value with further readings. This lived experience often reinforced the idea for women that differences in their blood pressures at different times of day or under varying circumstances (such as clinic visits) were to be expected, rather than suggesting any sort of problem or pathology. For example, comments included:

"So you'll see there were a few streaks of when it's gone up for a couple of days (pointing to home readings). And I just thought, I can explain that to myself, I know why it's gone up. Because I've been busy, in a rush. And after a few days it will just go back down again. So I started doing them after I'd had a couple of hours rest in front of the telly. I know from taking it at all different times of the day that it varies a lot. "

(Participant 19 interview: gestational hypertension in a previous pregnancy)

"So I think the problem with blood pressure is some people consistently have high blood pressure, but most people it can go up and down, just because of what they're doing or where they are, or just from putting the cuff on with me! I could do one that would be really high. Couple of minutes later, by the time I've done four more, it's calmed back down to a manageable level and I feel fine. So it's where do you class that…where do you draw that line that you've got high blood pressure? Does it have enough time to settle down when you're in clinic with just on those one or two checked there?"

(Participant 13 interview: chronic hypertension in previous pregnancies)

In this way, lower home readings trumped higher readings, particularly higher clinic readings, as the more valid and believable measure for women. Higher readings could be explained away, normalized, and therefore deemed lower risk by attributing them to the stressful but short-lived context of clinic, and being part-and-parcel of everyday variability that appeared to have no consequence and was congruent with lack of symptoms: *"and I feel fine" (participant 13).*

Women also acknowledged a general sense of apprehension attached to clinic visits, describing a heightened sense of expectation and anxiety and a desire for "*everything to be OK, and you just want the blood pressure to be normal" (participant 14).*

6.3.2 Clinical practices reinforce women's preferences for home readings

As well as their lived experiences with home and clinic blood pressure variability, women's descriptions showed how the advice and practice they experienced around blood pressure measurement with clinical staff influenced their behaviours and view of readings. Inconsistencies in approach to monitoring in the clinical setting such as taking readings reclining on a bed in an assessment unit or sometimes taking a single measurement, as well as the language of 'good' and 'bad' readings used by professionals all helped shape women's understanding and evaluation of the readings they collected at home versus those taken in clinic.

During my ethnographic observations at the clinic I usually observed blood pressure being measured using the standardised method with the correct sized cuff, after the women had been seated for some time. In two of the three sites, a health care assistant or midwife initially measured the blood pressure in the waiting room, and then the doctor would always repeat the measurement at least once during the consultation. In the third research site, the research midwife would invariably see the participant before their consultation, and they would take three blood pressure measurements for the study. The doctor would then take three further readings during the consultation.

Across the three sites, during clinical measurement it was not uncommon for the health care provider to make a commentary indicating that initial readings could be high and sometimes that the stress around clinic attendance might exacerbate this effect:

> *"So that's 144 over 90, that's a little bit up. What was it last time? [looking back through notes] Oh…much more typical in the 120s. Don't worry, we'll repeat that in a few moments after we've done the other bits, as it's quite common the first few readings might be a bit up, and things can all settle down when given a bit of chance. You did explain the car park was particularly bad today. I'm so sorry about that, we have similar issues as staff even….so I understand how frustrating it is. Importantly though, how are you feeling today, are you well?"*
>
> *(Field note: antenatal clinic midwife taking measurements for participant 40)*

Clinical practices like these that I observed during antenatal clinic and MAU visits, reinforced the rationale that blood pressure was variable, affected by stress, and multiple readings and time were needed to allow it to settle to a 'true' value. Many women reported being advised when contacting the assessment unit with raised readings, to rest and repeat the readings at varying intervals (as discussed in Chapter 5). The study protocol also encouraged these behaviours as it advised discarding the first reading but recording the second and repeating this reading after five minutes rest if this was out-of-range. These practices might have informed the view that some women expressed that high readings need not always be trusted or even recorded.

> *"So I would contact the MAU and I was told basically to rest and recheck in an hour and then to give them a call back if it was still high. I mean they were very nice, they said always call us, don't keep it to yourself. And you know because I'd had this experience before, I learned if I got these high readings, just to rest and recheck it in an hour or two. I would only bother them again if it was still up…about 150."*
>
> *(Participant 18 interview: first pregnancy)*

"Because it says – in the book [study instructions given to women], it says, like do it once, and if it's high, you've got to [um] – well, just take a five minute breather. And then take it again. Was it three times? I can't remember. I did it at least three times."

(Participant 1 interview: first pregnancy, developed pre-eclampsia)

"Yeah…I don't always write down the first few [readings]. I allow myself to have a bit of a practice run if you know what I mean…as I know they're not going to be my real level."

(Participant 10 informal interview: fourth pregnancy and gestational diabetes)

Although mostly I observed clinic blood pressure being measured in a standardised way, and as depicted above women mimicked these practices of repeating home readings and allowing what they judged to be a sufficient time for rest, I also observed departures from this practice in the clinical setting. Women remarked on these inconsistencies during interviews and these caused them to cast doubt on the validity of some clinic readings:

"I think position just affects the blood pressure so much. And I think when you're in hospital, they lie you on a bed and put your feet up, don't they? Basically that's what they'd do to me and strap me to the machine at the same time [CTG monitor]. And I'd certainly noticed that when I'd forgotten once or twice to do it in the evening and took it upstairs to bed with me. If I did it laid back on my pillow like they do it at the hospital, my blood pressure readings were a bit higher than when I do it properly at the kitchen table.....So I think you've got to be really careful how you measure it and really get people to understand and make sure they get the correct training. It seems like such a simple thing but even in the hospital they don't always do it right."

(Participant 19 interview: admission for high BP in previous pregnancy)

"So that's the funny thing, they only ever took it once. Even though my notes had the "white coat" splashed all over them. Because that – I think that would've – that would've generally made a difference. So that's why it was really nice to do my own at home and those blood pressures with [name…research midwife taking blood pressures at the study visit], that she would always do it the three times and then the clinic would use hers."

(Participant 17 interview: postnatal admission for high BP previous pregnancy)

Over and above the cues from what clinicians *did,* was the possible impact on women of what they *said* around blood pressure. Language often used by clinicians to describe higher ('bad') or lower ('good') readings may have compounded women's views about the value or importance of different readings. Some clinicians were aware of this and regretted that professional communication around blood pressure could characterise lower readings as "good", possibly helping to reinforce women's preferences for the lower readings, which tended to be their home recordings:

> *"Because somebody will give them feedback as "that's a bad blood pressure", of that type. So they get praise when they get a blood pressure, or what we perceived as a good blood pressure. And some sort of negative reinforcement if they have a bad blood pressure."*
>
> *(Clinician interview 002)*

Below, I provide a case example to illustrate the part played by clinician communication. The woman (here referred to as MA) had a poor obstetric history and she was being reviewed in clinic one week after a medication change due to ongoing high blood pressure. The clinician encouraged the woman around her regular home monitoring, but also described the now in-range home readings as "good":

> *Clinician: It looks like you're getting really good at this home monitoring.*
>
> *Woman: Oh yes I check every day, I don't skip a day.*
>
> *Clinician: So these 150 ones here, what do you think was happening here?*
>
> *Woman: Yeah I wondered if that was nerves, just getting anxious about coming in today.*
>
> *Clinician: That could just be anxiety-related, and it's good again today. So if it's higher like that, like 150ish, then have a rest, put your feet up for half an hour, then check it a third time, or if you're not feeling well in any way…then call us.*
>
> *(Field note: antenatal clinic, clinician 002 with participant 8, three previous pregnancies, one stillbirth with pre-eclampsia)*

The clinician remarks were clearly aimed at encouraging the woman with her home monitoring and it can be difficult to avoid value-laden language when commenting on any clinical reading, but perhaps possible through commenting on whether the numbers are in the target range (or not). When talking with the woman after her consultation, she was clearly relieved with her improved blood pressure and buoyed by the clinician's remarks:

> *"Thank the Lord. I was really worried I'd have to be kept in…It's so good it has finally come down…..It was just time for a different tablet, the last one was not working for me….Yeah, it feels really good…. Feels like I've passed the test today."*
>
> *(Informal interview with participant 8 after the antenatal consultation)*

As described, a combination of factors including the environment of clinics, the natural variability of blood pressure readings and clinical inconsistencies and language cues all had an effect on shaping women's preference for home over clinic readings. An additional important factor for women's confidence in their home readings, was the powerful influence of *self*-measurement versus measurement taken by others, as discussed below.

6.3.3 The effect of doing on believing home readings

For many women, the act of taking their own readings appeared to reinforce the validity of these readings, especially in the absence of any guiding symptoms. Women talked about 'belief' in their own readings much more frequently than mentioning belief in their clinic readings. The variability of blood pressure meant that judgement had to be exercised, in terms of where this particular reading at this particular time sat in the hierarchy of information and in most instances through the act of self-measurement, home readings were 'believed' or trumped clinic readings as far as women were concerned:

"Yeah; it's programmed my head to think, because I could see. When you do it, when you can see with your own eyes, it's different to you going to the clinic and them just saying "oh, your blood pressure's high, you need to increase -." When you can actually do it and see – Well for me, to see it, it's different, I believe it. Because it's actually about you, your body, and what's going on inside."

(Participant 24 interview: first pregnancy, long-standing chronic hypertension)

"But if it's high [the home reading], I choose to believe it anyway. I like to believe it's not high, but I can see the number is high and it may mean something is wrong. It shouldn't go that high.

(Participant 14 interview: recurrent miscarriages and difficult to control BP)

"I know that when I go to the doctor my blood pressure is higher. And if I do it at home and I can see sometimes it is higher even if I feel fine, I think 'oh, but maybe that one in clinic it was real – maybe it was, as that is how my blood pressure is at home as well'."

(Participant 17 interview: postnatal admission for high BP previous pregnancy)

Many women invoked the concept of 'belief' in certain blood pressure readings in a way that they did not when talking about many of their other biophysical measurements taken during pregnancy, such as ultrasound scans or various blood tests. Women noted that blood pressure was a more subjective measure, and would place the readings into a wider hierarchy of evidence that they used to interpret the health of their pregnancy, as discussed below.

6.3.4 Hierarchies of evidence for monitoring pregnancy

There was the sense from many women's accounts that in pregnancy the body became somewhat 'other' and unknown. This 'otherness' was illustrated by women referring to themselves as "the body" or "the system". Some women described a state of hypervigilance of attempting to self-monitor in the broader sense and interpret all manner of mundane and new bodily sensations and what they could mean in this altered state of pregnancy. Within this self-inquiry, home blood pressure monitoring was frequently reported as providing reassurance and provided some women with confidence in interpreting bodily sensations:

> *"I'd forgotten from the last time how different things feel when you're pregnant. Because if I didn't have the monitor, sometimes I used to feel.... well, not sure what I was feeling. And I would start thinking, 'Oh, maybe it's my blood pressure, maybe something's wrong'. So it was good for me to be able to just check the blood pressure if something felt not quite right....But with the monitor it helped me to know what the body is doing. Most of the times I just hadn't drank enough that day or had forgotten to have lunch and I was just hungry."*
>
> *(Participant 7 interview: pre-eclampsia in previous pregnancy)*

In a similar way, this 'otherness' made *lack* of symptoms and "feeling fine" during pregnancy equally untrustworthy prompts for many. Many women expressed surprise around the lack of symptoms associated with high blood pressure, but for some this was expected, given previous experiences of pre-existing hypertension or hypertensive pregnancies. Several women described how helpful it was to "keep an eye" using self-monitoring, understanding that *lack* of symptoms was not a reliable indicator of their blood pressure control:

> *"I mean that's the funny thing about blood pressure, you can just feel absolutely fine. My GP has explained this to me before, not to trust feeling normal or fine….Without this monitor I just wouldn't know what was going on inside. I mean, anything could be happening couldn't it!...This way I am able to just keep an eye and know for sure that the blood pressure is okay."*
>
> *(Participant 27 informal interview: first pregnancy, previous SMBP)*

As if trying to render their body knowable again, women's descriptions portrayed internal hierarchies of evidence ordering their various pregnancy measurements. Home and clinic blood pressures featured within these hierarchies. The most trustworthy form of assessment for women appeared to be imaging (namely ultrasound scans), and within this hierarchy home readings were privileged over or 'trumped' clinic readings as illustrated below:

> *"When they said 'oh you've got high blood pressure' I was thinking – I was a bit confused, because I felt like totally normal, and I'd been sat down for quite a while. But when I could see my ones at home were going up then it made me believe something was up. And then obviously when I found out – when we went for our thirty six week scan. Obviously we found out [name of baby] wasn't growing enough so something was really wrong."*
>
> *(Participant 4 interview: first pregnancy and early delivery for growth restriction)*

Only two women gave accounts of elevating how they *felt* above other forms of assessment, including home or clinic blood pressure readings. Both women had provided descriptions of previous pregnancies complicated by pre-eclampsia where they had quickly developed symptoms and required expedited delivery, although both recovered fully and their babies had been well. In light of raised clinic or even home readings, they took reassurance from their previous experience of pre-eclampsia, taking their absence of symptoms to mean they were not especially at risk, or at least not developing pre-eclampsia:

> *"Because we got a few weeks that [um] the blood pressure was very high in the hospital. And I'm thinking 'hold on a minute, I'm not feeling that it's high'. Because I would know when it was high. Basically, I'd get that pressure or that tension feeling. That's what happened the last time."*
>
> *(Participant 6 interview: pre-eclampsia previous pregnancy)*

> *"If I did get the odd one that was high, I didn't immediately rush there, unless it was you know – would have been stupidly high. [um] I went a lot on how I felt, as well. Because previously I know when I'd had spikes in high blood pressure because I got the stars. The flashy lights. I could almost tell when my blood pressure was going to be high when I measured it, because I just had a different feeling. But [name of husband] always said to me, "It's better to do that than not." [attend maternity assessment unit]. And I think he was – I think it reassured him more than it did for me. I don't think I needed the reassurance because I knew how I felt."*
>
> *(Participant 19 interview: pre-eclampsia previous pregnancy)*

6.4 Clinic readings trump for clinicians

While for women, home readings trumped clinic readings, for clinicians the opposite tended to be true. In interviews, clinicians expressed a number of reasons for their preference for clinic readings, including most notably a lack of evidence base for self-monitoring in pregnancy, which produced uncertainty in their use for clinical decision-making.

When there were differences between clinic and home readings, clinicians were divided over the value of and process for using additional contextual data provided by home readings, in the face of acute risks posed by higher readings, especially when they were bound by existing clinical guidelines that were based on clinic readings. Some also expressed concern that women might be reporting only selected readings when self-monitoring so that home data could represent a skewed rather than a fuller picture.

However, clinicians did frequently acknowledge the importance of home readings to women and some clearly valued the additional contextual data when assessing women in clinic and making decisions around possible treatment. Although, as we shall see, clinicians could attach different meanings and implications to discrepancies in home versus clinic readings than women.

6.4.1 The importance of clinical guidelines

Clinicians commonly characterised their stance towards home readings as “cautious” or “uncertain” when it came to assessing overall blood pressure risks. Their accounts described the paucity of the evidence base for self-monitoring in pregnancy.

Common to all clinician accounts was the mention and reliance on clinical guidelines in use at the time of the study(16) and more recent research (published after the guidelines) on tighter blood pressure control in pregnancy(101). The use of national guidelines was used to explain why clinic readings took precedence, as guidelines are based on research using these sorts of readings. The lack of an evidence base for home readings, knowledge of appropriate thresholds and relating how they might be associated with pregnancy outcomes, were given as reasons to view these

readings as "useful additional bits of information", and "a way to engage the women in their care" but that mostly clinic readings trumped for decision-making, as the accounts below demonstrate:

> *"But we've known for quite a long time the importance of a systolic less than 160. Those were clinic readings. We suspect that home readings are lower [um]. Certainly in other areas of medicine home blood pressure readings tend to be lower than clinic readings in the guidelines. But we just don't know what predicts poor outcome in pregnancy. I'm uncertain but I think we just don't know what's a normal home reading in pregnancy….So I tend to treat them on their clinic reading [um] with getting some reassurance from their home readings……so in the end I use the clinic reading. Because that's what the studies tell me I need to be managing……"*
>
> *(Clinician interview 004)*

> *"I think we've been a bit reluctant to accept, because of the lack of evidence or guidelines, what home blood pressure readings really mean. Outcome evidence on the basis of home monitoring – I – I just don't know."*
>
> *(Clinician interview 007)*

6.4.2 Contextual home data, acute risks and reconciling blood pressure differences

During interviews, all clinicians expressed ambivalent views about how to explain and accommodate differences in home and clinic readings, including whether context of readings was even relevant in the face of acute risks posed by higher readings. The timing of the BP reading was also cited as important by a few clinicians, with concern that blood pressure could change very quickly in pregnancy, particularly in cases of fulminant pre-eclampsia, so that the most recent blood pressure, usually the one just measured by the clinician, should take precedence over other readings. Clinicians' perspectives around context and timing and the place of clinic versus home blood pressure reading differences were shaped by their concerns about the dynamic and critical risk posed by high blood pressure in pregnancy. This is illustrated by the extract below:

> *"So, my general feeling is that - particularly if the systolic is up - I never want the systolic to be up. Don't care what's putting it up. I don't care if your systolic's up because somebody's just dropped a brick on your foot. Or if your systolic's up because you've got chronically raised systolic. [um] A very high - a systolic of 180 could easily give you a stroke in pregnancy. Even if it's transient, a one-off. So if the systolic's raised, then I'd like to bring it down. And I really want to keep their systolic less than 160, which means I'm aiming for under 150, ideally nearer 140."*
>
> *(Clinician interview 004)*

A few clinicians said they gave equal weight to the home and clinic readings while most described privileging clinic readings, but in either case differences between home and clinic readings needed to be acknowledged and accommodated. Clinicians talked in interviews about grappling with blood pressure variability between the different sets of readings. Usually this involved trying to reconcile lower home with higher clinic readings and they listed some of the same reasons that women gave for the higher clinic readings, recognising that women were often anxious in clinic and some practical aspects of clinic visits all played their part:

> *"Sometimes it's stress, or situation related. I can remember one time a woman's blood pressure was very high. And she'd been stuck in the lift for forty minutes [laughing]. And actually, when she'd had a chance to recover from all that, then – But at the same time, she was in OPTIMUM home-monitoring, and her home readings had been fine."*
>
> *(Clinician interview 003)*

However, accounts varied around the meaning and strategies to reconcile these differences and *all* clinicians voiced uncertainty. Some clinicians sought to *explain* the discrepancy, considering the context of different readings. Others described more formally considering white coat hypertension as an underlying diagnosis and considering reducing medication accordingly. Yet others described using the difference to know how high they could increase medication to control the higher clinic readings without possibly lowering home readings so much that women might become symptomatic. Clinicians described these different perspectives and approaches during interviews:

"And of course it can be that the readings can be fine all week, then come Wednesday's clinic there is a peak. And that's a genuine peak and we need to respond to and treat it. But sometimes it's – it's stress or situation related."

(Clinician interview 003)

"I think I used a little less medication, [um] not a vast difference maybe, but less….If my clinical impression of them having white coat would be, shall we say reinforced by the information I was receiving from the home BPs, in those cases I would use treatment less. But if I think they are trending high at home, when I would expect them to be lower, that would push me into the genuine hypertension sort of feeling. So, if I was having a woman who was in the clinic measuring say 145/100 and then her home readings were starting to go up too, and therefore these are genuinely high readings. So it's cross-referencing the two really."

(Clinician interview 007)

"So probably going on a mixture of the two, but going mainly on home, but also taking into account the potential spikes in clinic. So it's a balance of what's the gap? And is there [um] space, is there an option to increase treatment to cover clinic readings if her home blood pressures are sitting too low? Can I increase treatment without them falling over?"

(Clinician interview 002)

"So I tend to treat them on their clinic reading [um] with getting some reassurance from their home readings as to whether they need more or less treatment. There are a few women who have blood pressures of 110/60 at home, and 145/95 in hospital. And I don't know how to treat them!"

(Clinician interview 004)

My observations from clinic supported clinician descriptions above around the mix of strategies used to reconcile and incorporate the two sets of differing blood pressure readings into management plans. It was interesting to note that the full range of strategies described by the group were enacted by individual clinicians at varying points and the range of difference between the two sets of readings that was tolerated or accommodated changed, dependent on the specifics of the scenario. There was not a catch-all method employed consistently by any one clinician. Examples are provided below:

Clinician: "Now because your blood pressures at home have been so good [flicking through the diary, range 128-136/78-87], I'm actually not going to increase your medications today based on that one off reading we have in clinic today [142/89]. So it looks like we might actually be causing your high blood pressure here! [laughing]."

(Field not: antenatal clinic consultation with 005)

Clinician: Thank you for doing all these lovely home readings, this is really useful. So how are you finding it?

Woman: Easy, I enjoy it! I wake up, take my meds, then about half an hour later take my blood pressure, …before I leave for work.

Clinician: There's a bit of a range here [running finger along home readings]. So started off with a couple of 130s, then 140s range and the bottom number is sitting around 86-90. None above 90…[hhhmm]

….Well it is really useful to have these, as you're a bit borderline at the moment. On clinic readings alone I would be increasing it, but with these home readings you're mostly greens, so I'm sitting on the fence, we could leave it a bit longer. Let's just try another one in clinic now…[previous 143/93, 144/95, 142/90]….153 over 102, just see how variable blood pressure can be! See if I didn't have these home readings I'd be more worried but I would like to get all your home readings in the green range, I now suspect you might be getting some more erratic changes happening at home too which you won't be aware of necessarily. So rather than big jumps in your medication, it's better if we can get smoother control, so we can increase it a little today. How do you feel about that?

Woman: Yes, that's okay, yes, I can keep an eye on it and hopefully this will do the trick and get them all in the green range.

Clinician: Now increasing the dose today is part of pregnancy care, it's not that you've failed in any way, it's what I expect to have to do as pregnancy progresses, and it's great if we can get this nice smooth control."

(Field note: antenatal consultation with clinician 002 and participant 28, second pregnancy)

6.4.3 Home readings as a skewed or fuller picture

While many clinicians reported it was potentially helpful to have many more home readings on which to base treatment decisions, they sometimes cast doubt on whether they were receiving the whole picture or just more of the same sort of readings. Similar to women's concerns about

representativeness of clinic readings, clinicians had concerns around the representativeness of *home* readings. Several clinicians commented in interview that home readings were probably performed at rest times when blood pressure is expected to be at its lowest. And some conjectured that a few women were purposefully monitoring at times of day they had learned their blood pressure would be lower or discarding earlier higher readings and reporting the 'best' readings for the day (as discussed in Chapter 5):

> *"So – I would put it in the context of do I want this pregnant woman having spikes of the sort that we've got in clinic today? And these wouldn't necessarily be captured by home-monitoring. Because most women don't monitor at spike times, they monitor at quieter times. So it's helpful to know the gap and is it possible to treat these higher readings without risking their falling over at home when they might have lower readings."*
>
> *(Clinician interview 002)*

> *"Not everybody becomes profoundly hypertensive as soon as they come into clinic. It's not all white coat. So then you've got the question of well actually, if they are sitting watching TV for an hour and they take their blood pressure and it's normal and then they go to bed, is that a fair reflection of how it is during the day? Then we see them at 10 o'clock in the morning and it's higher..and that's how it is, every day. So I think we have to be careful, there is the need for some cautious interpretation here."*
>
> *(Clinician interview 005)*

> *"I am sure that women were not writing down initial higher readings, I'm aware of that."*
>
> *(Clinician interview 004)*

6.5 Tensions around blood pressure monitoring

Perhaps inevitably, tensions emerged between women and clinicians based on these divergent perspectives to achieving the shared goal of keeping the woman and baby safe. As described, when home and clinic readings differed, women and clinicians privileged different sets of readings in coming to an understanding of potential blood pressure risks. This conflict of 'beliefs'

(based on differing interpretations of the two sets of readings) led to misalignment at times between the women and their clinicians regarding their care.

6.5.1 Women's concerns around the role of clinic readings for treatment

The majority of women felt that clinicians *were* considering their home readings in decision making during consultations (see Chapter 5) but they (accurately) perceived that clinicians tended to put greater store by the clinic readings: "Oh yes, they were much more relying on what they have seen in the hospital" (participant 18). Many women voiced concerns about this strategy, as their impression was that clinical care was being tailored around unrepresentative "peak" clinic readings rather than their generally lower home readings. This misalignment of perspective around which blood pressures took precedence sometimes led to tensions for both parties. Sometimes women were unconvinced about the need for starting or increasing medication on this basis:

> *"So how do you know that you're getting a true representation of whether the blood pressure is really high, and you're not just managing it at the peak times like in clinic? It's so difficult to know isn't it! "*
>
> *(Informal interview: participant 19, pre-eclampsia previous pregnancy)*

One woman was quite convinced she did not require medication and described using her lower home readings as justification with her clinician to allow for a longer period of observation with the increased surveillance of home monitoring:

> *"They wanted to increase the tablets for the high readings [in clinic] but we agreed to see how things were going, they know I am checking every day at home. I was quite sure I didn't need it. Then it all settled down. I was right."*
>
> *(Informal interview: participant 29, first pregnancy)*

Different perspectives around clinical management went mostly unaired in the clinical encounter where the exchange appeared straightforward, and instead concerns were shared retrospectively during interviews. However, some women said they would proffer their home readings as an

alternative to higher clinic readings during consultations as in the example above, or occasionally even bring their monitors to clinic to show their home readings using the monitor memory function. My clinic observations revealed women downplaying the importance of higher clinic or even higher home readings if these were perceived as "one-offs":

> *Clinician: So that's a little bit up (measuring BP, reading 151/93). But we will take it again in a few moments. Do you have any of your home readings with you also?*
>
> *Woman: Sorry I don't as I've left my phone in the car [she normally records home readings in her phone].*
>
> *Clinician: Can you tell me the worst readings?*
>
> *Woman: Oh, so it's usually between 130 to 140 and about 93 or 94 on the bottom.*
>
> *Clinician: So does it ever go over 100 on the bottom or 150 on the top?*
>
> *Woman: No…Well, there was the odd couple of occasions but it's much more around 90s on the bottom and 130s on the top at the moment. I know it's always higher here too.*
>
> *(Field note: antenatal consultation with clinician 005 and participant 40, second pregnancy, no complications)*

As the above encounter demonstrates and I commonly observed during consultations, clinicians orientated towards the abnormal high readings, whether from home or clinic, and women towards the lower readings.

Tensions arose as both women and clinicians wanted to base treatment around what they perceived as the most representative picture of blood pressure, but had different perspectives about the emphasis of home versus clinic readings. Clinicians tended to base treatment around the clinic readings, as they perceived these higher readings carried the most risk. Although the exact risk posed by these different readings and blood pressure variability had a large degree of uncertainty. In contrast, women during interviews and as shown above in consultations, typically highlighted the lower end of blood pressure readings that they recorded at home, feeling these were more representative and should most inform treatment decisions.

Additionally, women were often highly motivated to avoid antihypertensive medication or hospital admission. The specific ambivalences that pregnant women expressed regarding the use of antihypertensive medication are discussed in Chapter 7. During interviews, a few women expressed relief that they had been monitoring at home, as in some cases they felt having done so meant they had been able to use these readings to avoid unwanted interventions such as medication or hospital admission:

> *"When it was measured in clinic it was always higher, 95, 96. When I was measuring it at home it was always lower, around 85, 86. So because I joined the study I never needed tablets in my pregnancy and this was a big relief to me."*
>
> *(Participant 7 interview: pre-eclampsia in previous pregnancy)*

> *"I was more anxious in clinic, going there thinking like "oh no, I hope it's going to be good, and not going to be high, blah, blah" Always worrying they were going to keep me in if the blood pressure was up. It was all much smoother this time around, like I knew my blood pressure at home was normal."*
>
> *(Participant 3 interview: usual care doing her own SMBP, admitted in first pregnancy with high BP)*

6.5.2 Clinicians seeking to treat clinic readings

Most clinicians were aware of these different perspectives and described the challenges of being aware of potential risks posed by high blood pressure and proposing treatment plans that women might not agree with or follow, based on their interpretation of their home readings:

> *"It can be really difficult. So if you believe that we should be treating their clinic blood pressures and they've got a set of home readings that are lower, then even though I might think I need to be treating this clinic reading, [um] it can be potentially more difficult to convince them to be treated."*
>
> *(Field note: clinician informal interview 009)*

For the most part, interviewed clinicians recognised and understood women's preference for their home readings coupled with a reluctance to take any medication perceived as unnecessary (medication perspectives are discussed further in Chapter 7):

> *"I do think that women were more persuaded, responded, to their own blood pressure recordings. So that sort of was for a lot of women, was the trump card.…….particularly if that means they can avoid medication…..it can produce anxiety for a lot of women because of course the message these women have heard for years is that medicines are not safe in pregnancy."*
>
> *(Clinician interview 003)*

My clinic observations showed how clinicians attempted to walk the line between acknowledging a woman's own readings but nevertheless privileging their own clinic readings The below excerpt demonstrates several strategies that were commonly used during consultations: acknowledging women's home monitoring efforts, explaining thinking, reminding of the shared goal of healthy baby and pregnancy, providing context and reassurance that only small doses of medication are being recommended, and inviting the woman to voice concerns but ultimately acting on clinic readings:

> *Clinician: So we have three readings here with a bit of a range [name], 139-151/80-92 (pointing to the clinic readings in the notes). Yes, the home readings have been slightly lower, but these are not as good as 2 weeks ago. So I'm absolutely amazed that we've not needed an increase all the way along to now and it's been stable since 16 weeks, but I think a tweak now would do the trick. So it's not at a dangerous level now, remember we wrote our target was 140 on the top and 85 on the bottom number, so we can improve this slightly. So it's not just about the numbers, it's about you and the baby getting you as far along on the pregnancy path, safely. And you'd still be on a small dose, 20mg twice a day. The highest dose is 40mg twice per day so you can see you are far off that…. And just because the blood pressure has gone up a bit today does not mean we are chomping at the bit to admit you and bring your delivery forward. Is there anything you're worried about?*
>
> *(Field note: antenatal clinic consultation between clinician 002 and participant 30, third pregnancy, previous gestational hypertension)*

When talking with the woman after the consultation, she voiced several internal conflicts most notably between her own belief in the lower home readings- as she thought the stress associated with hospital visits increased her clinic blood pressures – combined with concern about any effects of medication on the baby, but tempered by the desire to abide with clinician advice and appreciation for the care she had received. The tension was how to reconcile these different viewpoints to do what was best for her baby:

> *"I just worry about the tablets and it's difficult to keep coming here and then get back to pick up the kids so that gets me all stressed…..But I know they're doing everything they can, taking great care of us……I send my home readings to [AB]. They can see my home readings are better…..They've been brilliant I really can't fault that. But whatever goes into me goes into the baby doesn't it?"*
>
> *(Field note: antenatal clinic informal interview with participant 30 after consultation)*

6.6 Conversations about blood pressure risks in pregnancy

The sometimes misaligned perspectives around which readings were most important for informing treatment decisions, were influenced by the perceived and communicated risks associated with high blood pressure in pregnancy.

6.6.1 Clinicians talking about blood pressure risks in pregnancy

As might be expected, there was much discussion around risks posed by high blood pressure in pregnancy, when clinicians were considering the role of self-monitoring. Clinicians talked about the importance of making women aware of these risks so that they could look out for important early symptoms and signs, especially in the case of pre-eclampsia, which could present in many different ways and develop rapidly. As discussed previously (Chapter 5), some clinicians had been wary that self-monitoring might offer false reassurance if women ignored such developments in light of normal home readings. Communication tactics commonly specified were asking women to

describe their knowledge and understanding of risks, expanding on these, and providing a written record of these discussions in the hand-held maternity notes:

> *"For my own peace of mind, I have a low threshold for telling everybody what pre-eclampsia means. Because I find that if you ask somebody if they've heard of pre-eclampsia and know what it is, they always nod, and say 'yes'. But actually, their understanding of having heard of it is not what I would say or hope that they knew when checked. So I tend to, to make sure that any women I think is at risk of pre-eclampsia, I would have a discussion of high blood pressure needs treatment, but also anything about pre-eclampsia. And I document it. I've discussed it, and I know that I've told them as best I can."*
>
> *(Clinician interview 004)*

> *"Talking about the potential risks is very important, this in itself can reduce risk. Of course, you don't want to scare women, there can be so much anxiety in pregnancy anyway, so it's always a balance and you try to offer reassurance where that's appropriate…..Information is key, and if you explain to the patient what you're both doing and why you're both doing it, then adherence is likely to improve. I think the people who are going to do it worst [the home monitoring], they have no idea of the consequences of the high blood pressure. Therefore have no idea of the motivation."[for monitoring in the first place]*
>
> *(Clinician interview 006)*

A striking feature of the clinician interviews was that they all contained recollections of specific severe cases of hypertensive pregnancy complications and these experiences shaped clinician views of the unpredictable and serious risks posed by high blood pressure in pregnancy. Many of these accounts referred to cases of maternal stroke and its devastating impact, even though these past cases had not involved home blood pressure monitoring:

> *"Yes, and she died of a cerebral haemorrhage. It was just utterly tragic….we'd struggled to control the blood pressure all the way through and she had lost several babies beforehand…and after going home she was found collapsed."*
>
> *(Clinician interview 005)*

"We have a reasonably tight sort of safety net here, because – the clinic was set up because of the gap in care that ended with a woman having a stroke."

(Clinician interview 002)

"We've had women previously who won't stay in hospital, and won't come up to the hospital every day so we can check their blood pressure, so we end up sending a midwife out to them every day. And I can't imagine anything worse than being the person thinking 'I don't know if the woman behind this door's had a stroke'."

(Clinician interview 004)

6.6.2 Women talking about blood pressure risks in pregnancy

Interview accounts from women conveyed their understanding of risks associated with high blood pressure during pregnancy. Women drew on personal experiences from previous pregnancies or those of close friends and family in addition to recalling discussions with their clinical teams and their own on-line searches. These narratives described the risks of pre-eclampsia, prematurity, small babies and stillbirth, with the focus around risks to the baby. Examples included:

"Yeah I knew the risks..a close family friend had a really bad pre-eclampsia, because her body all changed. And then we took her to our family doctor, and he said, "You're not well. And be safer for the both of you if we would just, you know, deliver." And then she asked for a couple of days to think about it. And then baby died. So I had that in – in the back of my mind, and motivation of, you know, I want to get the right advice, I want to know I'm fine and I'm not developing pre-eclampsia and risking the baby. So checking [blood pressure] regular at home really helped."

(Participant 9 interview: first pregnancy, friend had pre-eclampsia)

"But my cousin, like she had the pre-eclampsia. I mean, she was stuck in hospital for over a month before she actually gave birth. So, yeah. If that can be avoided, I'd say [laugh] yeah, checking my own blood pressure is a small price to pay, than having to move into the hospital for so long. [laughing]"

(Participant 3 interview: one previous pregnancy with severe gestational hypertension)

"It was very well explained to me…about the risks. I know all about the pre-eclampsia, I was asked about this all the time….It was explained about the pressure in the placenta and how that can affect the good flow going to the baby…[um] that babies can be smaller and come early and might need oxygen for breathing…or be in an incubator. I was very worried about this. The last thing I wanted was to have to leave my baby in hospital after he was born. I really didn't want that."

(Participant 6 interview: pre-eclampsia in previous pregnancy)

The above extracts illustrate that clinicians and women talked about two parallel and not completely overlapping sets of risks. Clinicians' descriptions were comprehensive, but orientated towards the severe end of risks to the woman, especially stroke, with vivid accounts of how this had shaped care practices and services. However, women's accounts centred around pre-eclampsia and risks to the baby, and the challenges that came with hospital admission.

6.6.3 Discussions around risks in the consultation

From interview data, it was clear that clinicians placed great importance on explaining possible risks associated with hypertension in pregnancy (relating to the woman and to the baby), and saw this as an integral step to enabling shared decision-making. I observed clinicians discussing the risks associated with high blood pressure during women's initial consultations in the antenatal clinic. These topics were revised regularly throughout their antenatal follow-up, with more detailed explanation if blood pressure was rising, as illustrated below:

Clinician: So we know women with high blood pressure in pregnancy are at higher risk of pre-eclampsia and smaller skinny babies, and we want to try and improve things by keeping BP tight and smooth. So you'll find in this clinic we are nicely obsessed with the numbers, not just for numbers' sake but for you both, to try and keep the top number below 140 and the bottom number around 85….

So I'm going to write here…[writing in maternity notes] discussed new diagnosis of chronic hypertension, [looking up and stops writing] but we may not sort out the exact diagnosis until after baby is born…[continues writing..] discussed risks, so I'm going to write target blood pressure less than 140 and around 85 on the bottom.

(Field note: antenatal booking clinic consultation between clinician 002 and participant 31, one previous pregnancy without complications)

Clinician: Oh I can see this lady was seen in the pre-pregnancy counselling clinic…[she] has chronic hypertension taking nifedipine and co-amiloride outside of pregnancy. It is written here [pointing to clinic notes] risks discussed: 25% superimposed pre-eclampsia, 30% SGA [small for gestational age] and 30% pre-term delivery.

(Field note: antenatal clinic, clinician 003 explaining background to me before patient called into room, participant 32, previous miscarriage)

Clinician: And how is the blood pressure going?

Woman: Well, I think.

Clinician: How are the home readings? The clinic one today I can see is 130/80, which is good.

Woman: Oh yes that sounds about right for me. I've got my home readings here….

Clinician: And do you know what to look out for with pre-eclampsia?

Woman: Oh yes, headaches, flashing lights, pains around here [pointing to upper abdomen], swelling of hands, feet or face, feeling generally unwell, oh and of course I'd measure my blood pressure too, if I thought there was a problem.

Clinician: Exactly perfect! You're an expert now.

Woman: Oh every time it's mentioned, it's pretty much sunk in now.

(Field note: antenatal clinic consultation between clinician 005 and participant 41, first pregnancy)

These conversations demonstrate clinicians concentrating on the risks of pre-eclampsia and reduced fetal growth associated with high blood pressure during their discussions in consultations. This corresponded with what women remembered about advice around risks from their consultations.

In the two examples given below, women had presented with severe hypertension, and the observations suggest that clinicians were wary of the risk of stroke and wanted to make immediate changes to treatment but the sense of urgency is communicated without the specifics. General vascular processes in the elderly are alluded to for the first woman and no details about the potential "trouble" she faced were provided to the second woman:

> *Clinician: Now we need to get things better for you than they are now [clinic reading 180/120 on manual monitor]*
>
> *It's not very safe for you to walk around with blood pressure like this. It's different from older people whose blood pressure goes up gradually and their blood vessels and brain have got used to higher levels, but with younger people and in pregnancy these levels can be more dangerous in the short term…*
>
> *(Field note: antenatal clinic with clinician 005 and participant 42, third pregnancy, no previous complication)*

> *[Before the patient enters the room, the clinician tells me this next lady has high blood pressure (pointing to the readings just recorded in her notes by the clinic midwife: 190/125 and 197/113)]*
>
> *Clinician: Now how are you [name]?*
>
> *Woman: Fine except for these headaches*
>
> *(Patient looks anxious and as though she is in physical discomfort.)*
>
> *Clinician: Have they shown you your numbers today…?*
>
> *Woman: Yeah*
>
> *Clinician: And we don't really want you walking around with these numbers because we worry about you or your baby running into trouble with these…*
>
> *(Field note: antenatal clinic with clinician 002 and participant 8, high BP in previous pregnancies)*

One clinician had described not wanting "*to scare women*" (clinician 006) when discussing risks and there was a general tone of reassurance in all consultations I observed. Throughout consultations many positive comments were passed by all clinicians when performing routine examinations such as symphysis-fundal height measurement: "*oh, they appear to be a baby that's growing beautifully well*" (clinician 003) or fetal heart auscultation: "*great rate and lovely variability"* (clinician 002). Similarly, when talking specifically about blood pressure or its treatment, clinicians were attuned to women's anxieties around their blood pressure and especially medication, and frequently employed minimizing language such as "*the blood pressure is just slightly up"* (clinician 008) and "*I think we only need a very small increase in medication today"* (clinician 009).

This contrasted with the sorts of accounts clinicians gave during interviews which were much more cautionary and where the severe end of potential complications and the specific concern of stroke were mentioned several times.

6.6.4 Considering a potential deviant case: talking about stroke in the consultation

There was only one instance where stroke was referred to directly in my observations of consultations. In this instance, a participant at her first antenatal clinic in the hypertension service brought up the topic of stroke. The woman was relaying advice from another specialty physician, who had mentioned the risk of stroke to her in what appears to have been an 'upping the ante' tactic to encourage treatment concordance:

Clinician: What's your understanding of what we do in clinic here?

Woman: It's got all the research hasn't it?

Clinician: Yes, that's right, but our role is to care for women with high blood pressure during their pregnancy…..

Woman: You see, I'm very convinced this is not a chronic problem, as it was not a problem in my previous pregnancy and I've been monitoring it at home and it's been normal at home. But I had a headache and came to A&E and it was 197/122 [pointing to maternity note] but I thought it isn't an issue as there was a very, very long wait and I was anxious so I went home and saw my GP the next day and he wrote a letter and sent me packing to A&E and said I mustn't leave until I was seen. I stayed the night, they did some tests and they started me on medicine three times per day and since then it's been under control.

Woman: So you seem very switched on and if I just paint a bit of a broad picture for you. Firstly, I'm quite sure they did the right thing. Is it real? Is it just the Doctor? It's not just numbers, it's a label, so it's quite a big thing for you… What I care about is the next 9 months that we get you to the end of your pregnancy with you and your baby safe.

Woman: To be honest I've been torn taking any sort of tablets in pregnancy apart from folic acid, but when in hospital the Dr said to me, your baby's health is dependent on your health and you're at risk of a stroke. That shocked me!

(Field note: antenatal clinic, consultation between clinician 002 and participant 31, second pregnancy no previous complications)

From the woman's (participant 31) account, she describes being "shocked", that she was at risk of stroke. Although this is presented as the deviant case it shines a light on the usual perceptions of risk discussed in the section above, where women were well versed in the risks of pre-eclampsia and possible effects on fetal growth from hypertension from discussions with their clinicians. However, clinicians were aware of the rare but severe complications such as stroke, but discussions around these risks tended not to feature in consultations.

6.6.5 Contrasting hypertension risks in and out of pregnancy

During interviews, a few women contrasted the risks of high blood pressure inside and outside of pregnancy, describing them as quite different entities, with the focus of care being the baby within pregnancy:

> *"And I've got family history. So, my Dad's got it but he's got heart problems and had a stroke. But it's different when pregnant, you have to think of the baby and you take different tablets more to stop the pressure affecting them than anything."*
>
> *(Participant 8 interview: gestational hypertension in previous pregnancies)*

Two women mentioned personal risk of stroke. One described previously considering the risk of stroke after pregnancy when her GP was finding it hard to manage her postnatal blood pressure but that this was not her focus during pregnancy. The second woman had suffered a 'mini-stroke' outside of pregnancy, but when pregnant, her main expressed concerns were about any effects on the baby from either high blood pressure or its treatment:

> *"And then they kind of constantly ask you, 'Do you have any headaches?' [laugh] Like, 'Yes, but not the sort that you're after.' [laughing] Like I know I, - I guess I know, you know, they're really worried about [um] post-eclampsia, is that what it's called? [um] Well pre-eclampsia before, but then post - like after birth do they also call it eclampsia, or? I don't quite know, but. Yeah. So [um] yeah. So I was like, 'Am I going to get - is a stroke imminent now', kind of thing. [laugh]"*
>
> *(Participant 17 interview: well-controlled blood pressure in pregnancy, erratic high blood pressure postnatally)*

> *"I found out I had high blood pressure after I had a mini-stroke. I didn't know before. I don't really think about it. I take different tablets now so the baby can keep safe."*
>
> *(Field note, informal interview with participant 33, previous transient ischaemic attack outside pregnancy)*

These accounts reveal that women appeared to view blood pressure risks differently during and outside of pregnancy with their focus almost entirely on the health of the baby whilst pregnant,

over any possible effects to themselves. These views appeared to be informed by their experiences and understanding of the types of problems occurring to pregnant and non-pregnant women, and their responsibility and desire to prioritise and guard the safety of the baby, including from perceived risks such as antihypertensive medication (discussed more in Chapter 7).

6.6.6 Clinicians as overly cautious

When describing their approach to integrating home monitoring, clinicians were generally uncertain and cautious, tending to trump home readings with their own clinic readings. This stance was explained mainly in terms of the lack of available evidence base and concordance with clinical guidelines. Clinicians orientated towards the higher clinic readings and "peaks" and described how management decisions and services were designed to minimise risk. Their accounts portrayed how these risks were unpredictable and could be "devastating", the more so in pregnancy as there were two potential persons affected (the woman and baby). With awareness of these risks and incomplete knowledge about the place of home readings, the cautious and conservative approach of clinicians was presented as understandable and appropriate when seeking to safeguard the pregnancy:

> *"To be honest you could probably ignore quite a lot and get away with it. But this comes back to our safety net in maternity, it's cast quite wide. And that's fine, that's as it should be"*
>
> *(Clinician interview 002)*

On the other hand, the meaning of home and clinic BP readings for women, and what these were representative of in terms of risk to the baby, was informed by their lived experience, first- and second-hand and the information they received from their clinical teams. With knowledge of their home blood pressure readings, women appeared to feel they knew the fuller picture of their blood pressure than clinicians could gauge from sporadic clinic readings. Women were usually aware that clinicians were looking out for signs or evidence suggesting pre-eclampsia or poor fetal growth. All of this knowledge was weighed against their perceived risks of medication in

pregnancy (discussed in Chapter 7). Yet some women suspected clinicians were being overly cautious in their decision-making around blood pressure, especially when medication or admission decisions appeared to be informed mainly by clinic readings. And the risks of stroke were not always clearly explained.

> *"I do think the doctor were more concerned about that reading during the day, than the one at home. Probably because they want to be extra sure that you know, there was nothing going on. I get that. But then you worry about what's going to happen to the tablets."*
>
> *(Participant 18 interview: developed pre-eclampsia in pregnancy)*

> *"And I think it was all over my notes that I had this [um] white coat response. And I think they did, they did take it into account sometimes, but to some extent I guess equally you don't want them to take it into account too much if they actually think there is a problem for the baby. It's a very tricky one, because I guess it's perhaps better to over medicate, or to be overly cautious, than to think, oh yeah, this is just white coat syndrome, never mind."*
>
> *(Participant 7 interview: previous pre-eclampsia but also white-coat effect)*

The above extracts illustrate that women recognised these were not simple decisions. But they were sometimes left unsure and conflicted about what was their desired level of caution from their clinical team to safeguard the pregnancy, especially when this could translate to interventions that were perceived as undesirable by the women.

6.7 Protecting the pregnancy

A strong over-arching theme was the primacy for both clinicians and women of keeping the woman and unborn baby safe. This was borne out by the ethnographic observations and may seem obvious; after all, this is what the maternity services are designed and aim for, and the rationale for the trial. However, it is worth highlighting, as it is through this perspective that the data can be best understood. This was the main driver for women to initially join the study, as discussed in Chapter 5:

> *"It felt really good, because it made me worry, like, having this high blood pressure in pregnancy. I felt less worried this time around, more happy, as I felt I was doing the right thing for my baby, monitoring my blood pressure."*
>
> *(Participant 2 interview: previous pregnancy complicated with prematurity)*

Despite the different perspectives of women and their clinicians about which readings should be privileged, everyone was aligned to the same goal of protecting the pregnancy. The differential trumping of home versus clinic BP readings and potential tensions over management decisions can be appreciated, explained and become almost inevitable, within the constraints of what either party 'knows' and is able to control at any one time as women and their clinicians strive towards their shared goal of guarding the safety of the pregnancy:

> *"At the end of the day, you just want what's best for the baby, don't you? You are just trying to keep things on an even keel for that reason."*
>
> *(Informal interview participant 15, pre-eclampsia in previous pregnancy)*

> *"What I care about is that we get you to the end of your 9 months of pregnancy with both you and your baby safe."*
>
> *(Field note: antenatal clinic consultation, clinician 001)*

6.8 Conclusion

Pregnant women and clinicians sought to make sense of the different sets of blood pressure readings. When there were differences, home readings trumped those from clinic for women, whereas clinicians tended to privilege clinic readings. Women viewed their home measurements as more representative and valid than those obtained in clinic. Women considered that clinic readings could be falsely elevated due to the stresses associated with hospital attendance, not least that higher readings might lead to recommendations for unwelcome treatment. These assessments of validity were further shaped by their experience of their own blood pressure variability and some variance in clinical measurement practises. Clinicians however were more disposed towards the clinic readings, citing the lack of evidence base for home readings in

pregnancy and relying on guidelines based on clinic readings. Similar to women's concerns around representativeness of clinic readings, clinicians suggested home readings might not represent a fuller picture but a more skewed snapshot of blood pressure behaviour, taken or reported during relative rest. Given these misgivings, clinicians were uncertain how best to integrate or prioritise the two sets of blood pressure measurements when making treatment decisions.

The different perspectives around the relative importance of home or clinic readings were influenced by awareness and understanding of blood pressure risks in pregnancy. Clinicians considered the discussion of risks essential for shared-decision making, balancing this with not wanting to alarm women. Symptoms and signs of pre-eclampsia were consistently checked for in consultations and this monitoring was a clear agenda in all antenatal consultations. However during interviews, clinicians described how personal and clinic practice were strongly influenced by the rare but impactful experiences of maternal stroke which was seldom alluded to in consultations or in ambiguous terms. Women's accounts of risk also centred on pre-eclampsia and risks to the baby, but drew on information received from their clinicians, personal experience from previous pregnancies or that of family and friends. Importantly, women described blood pressure risks as different in and outside of pregnancy and did not mention risk of stroke during pregnancy (except for the 'deviant' case I presented).

Pregnant women and clinicians' accounts demonstrated their shared goal of safeguarding the pregnancy. However, with different perspectives and understanding of risks associated with hypertension in pregnancy this contributed to women and their clinicians using different measurements as trumps which could lead to possible tensions over proposed treatment.

Women's and clinicians' specific perspectives and experiences of the use and prescribing of antihypertensives in pregnancy, and their relationship with self-monitoring practices and interpretation are discussed in the next chapter.

Chapter 7: Medication perspectives in pregnancy

7.1 Overview

The analysis in the previous chapter concentrated on how pregnant women and clinicians perceived home and clinic blood pressures and made sense of the readings, particularly when there were differences between home and clinic readings. Divergent perspectives emerged, informed by embodied and professional experiences and differing understanding of risk. In this chapter I move the focus of my analysis to consider what we might call the *'effector'* component of BP self-monitoring for the control of hypertension in pregnancy, namely changes to adherence with antihypertensive medication. Perceptions and experiences around taking any medicine during pregnancy was a prominent theme from the interviews, and discussion about the use of antihypertensives constituted no small part of observed consultations.

A few women said that taking antihypertensives during their pregnancy was unproblematic and even welcomed it, but most expressed unwillingness to taking any potentially unnecessary drugs in pregnancy. Concerns centred around possible untoward effects on the health of the pregnancy and baby. Women's views were shaped by several factors, including their embodied experience, balancing perceived risks of high blood pressure versus medication and conversations with their direct and wider clinical teams. In turn, clinicians sought to reassure, citing guidelines, specialty experience with antihypertensive medications and improved outcomes with good blood pressure control. Against this background, home blood pressure monitoring could help develop therapeutic relationships and provided reassurance to women that treatment was effective and of benefit. However, the home readings were also sometimes used by women to justify avoiding or minimising their use of antihypertensive medication.

7.2 Results

7.3 Women's perspectives around medications in pregnancy

When asking women about their views of hypertension in pregnancy and their experiences of self-monitoring, the theme of antihypertensive medication arose early and often. *All* interviewed women reported strong views around the place of medication in pregnancy, and all but one described reluctance and some dislike of drugs.

7.3.1 General concerns around medication use

Women's concerns about taking any sort of medication echoed those of other cohorts described in the literature, including the non-pregnant population with chronic hypertension(264, 269). These included general concerns around the concept of medications as 'unnatural,' as well as the hope that medication could be avoided through lifestyle changes such as resting more and minimising exposure to stressful situations. Women described stopping work earlier in the course of their pregnancy than they would have done otherwise, or altering their hours or requesting workplace adjustments. Several women had tried 'natural remedies' such as apple cider vinegar and pomegranate juice which they hoped would help them to avoid the need for starting or increasing antihypertensive medicines.

> *"I did want to try natural things first really. Just resting and being less busy just generally."*
>
> *(Informal interview with participant 3: first pregnancy)*

> *"In those first few weeks I did stop my tablets even though they said they were safe…I was just worried you know…of any effects…I just tried to get along with the apple cider vinegar drink…something just natural. I had even used this before I was pregnant and it was quite good then…and I thought I'll just see how far along this can get me."*
>
> *(Participant 20 interview: long standing chronic hypertension and diet-controlled gestational diabetes)*

It was commonly believed that medications of any sort had the ability to generate tolerance and dependence:

> *"And I didn't want my system to be too used to medication and maybe then keep needing more of it."*
>
> *(Participant 10 interview: previous pregnancies with high BP)*

> *"It was good to keep it clean and not to take medicines in pregnancy."*
>
> *(Participant 7 interview: previous pre-eclampsia)*

Women's accounts also revealed a moral dimension to avoiding medication and this appeared to be supported by the notion that blood pressure might be amenable to lifestyle changes, so a 'could' became a 'should': *"..when I didn't get all worked up about stuff then I saw this made a difference to my pressures…they did come down a bit.. so that made me realise this is really up to me to try and help myself and not just rely on tablets to get it down" (participant 23).* Many women said they were not "the sort" who takes medication and displayed their stoicism with a preference to feeling symptoms such as pain over using any medication:

> *"And because I'm not a medication person. If I don't - If I've got a headache or something, I'd rather get through the pain, or lie down, than take medication. No, I've never been a tablet, medication person."*
>
> *(Participant 21 interview: previous uncomplicated pregnancies)*

> *"Yes. I was still having pain, but I prefer to suffer the pain than to drink the medicine."*
>
> *(Participant 8 interview: discussing trying to avoid disease-modifying medications or painkillers in pregnancy with rheumatoid arthritis)*

7.3.2 Pregnancy being different

Over and above these general concerns, women voiced particular worry about taking medication in pregnancy and framed this in the context of usual advice to avoid medications in pregnancy. Women used strong language to express these concerns, talking of their "worry", "fear", and

"shock" when being prescribed medications and in contrast "relief" and being "very, very happy" when medications were not initiated or increased:

> *"Initially I was very worried [laugh]. I guess normal. Because it's well known you should avoid to take any, as possible. Any medication at all. But otherwise there are very few. And every time you need to check with your GP if it's something that you can. So I was worried. I was not really happy at all that I had to take medication."*
>
> *(Participant 18 interview: first pregnancy, and complicated by pre-eclampsia)*

> *"It's the last thing you want really, is to get on the drugs? So I was quite scared."*
>
> *(Participant 4 interview: first pregnancy and complicated by growth restriction)*

> *"So I'm sure because I joined the study I never needed tablets in my pregnancy. I was very relieved I had no tablets at all."*
>
> *(Participant 2 interview: previous pregnancy complicated by prematurity)*

Several women perceived that their blood pressure in clinic was driven higher due to their specific fears about being started on medication or having their medication increased, and that when they were more relaxed at home and not considering unwanted interventions then their home readings were lower and supported that they might not require medication after all. A couple of women were also certain that their white coat effect/hypertension had been 'cured' by their home monitoring and expressed gratitude that this meant they avoided medication in the current pregnancy.

> *"And I think that's why it makes it more in the hospital – you want the low, just – And it makes it even higher than – because you're nervous about you don't want the drugs, so it [clinic blood pressure] goes even higher then."*
>
> *(Participant 4 interview: first pregnancy and complicated by growth restriction)*

> *"The thing I found very difficult was I was very aware that every time I went in they were going to be checking my blood pressure. And that stressed me out more and more and made it even higher. Because I knew if my blood pressure was going to be high then they would start me on medication. So I felt this fear and this pressure every time in clinic. Whereas this time around being able to monitor at home myself when I didn't have these pressures, it was all so much better, my readings were much better and knowing they were good at home helped me to relax more in clinic too and I never needed any tablets in this pregnancy thankfully."*
>
> *(Participant 7 interview: pre-eclampsia in previous pregnancy)*

Women's concerns centred around any effects of medication on the health of the pregnancy and baby, with very little mention of effects on themselves: *"I was more worried about, about the health of my baby than any effect of the tablets on me*." (participant 12); *"As long as it was the right type of medication, i.e. not one that was going to have negative effects on him, then I wasn't bothered at all."* (participant 19, second pregnancy requiring antihypertensives); *"I was a bit like, 'oh my god, are these going to cause damage to the baby..?'"* (participant 21, fourth pregnancy, first time requiring antihypertensives).

The time-limited nature of pregnancy was referred to as an additional motivation for trying to avoid medication as the perceived potential short-term negative effects for the mother from not taking any medication were compensated for by potential long-term benefits to the baby*: "…just those months anyways it's just better to put up with things and not risk it" (participant 8)*.

Women discussed medication side-effects, such as headaches and dizziness, in terms of interpreting them in the context of pregnancy; women said that they were concerned that these sensations could represent a problem with or a risk to the health of the pregnancy:

> *"Like all the things that have made me feel funny often have been the medication, not the high blood pressure. I had dreadful headaches with the nifedipine and I was really worried and thinking, 'this must be pre-eclampsia'."*
>
> *(Participant 17 interview: second pregnancy)*

"And when I got dizzy a few times with taking the tablets, my first reaction was to worry about the effects on the baby. I thought it might be the anaemia too as I've had this before and it felt sort of the same and I know it's important this is at the right level during pregnancy."

(Participant 47 informal interview: third pregnancy)

The risks posed by medication for the unborn child were perceived in terms of both dose-response and timing of exposure (see below). Women described their anxieties over increasing doses and initiation of medications in the first trimester. Some women also articulated specific perceived risks from medication which included: smaller babies, prematurity, need for supplemental feeding and developmental effects on sight, hearing and cognition. It was unclear on direct questioning, who or what had informed these specific fears for most women. There was the sense that these were commonly shared beliefs about medications in general in pregnancy, as one respondent described:

"Most people know these days, taking any medicines when you're pregnant has… potentially risky. It can affect babies in lots of ways..[um]..physically and mentally. And it's not always obvious straight away is it?"

(Participant 29 informal interview: first pregnancy, and reluctant to increase antihypertensives)

"But I know that especially it's important during the first three months. So I think when I was told that the dosage in that period was really, really low, I felt kind of reassured….but at the end I was taking much more medication. We ended up on labetolol, [sigh] how much was it? I think it was [er] four times a day, 400. It was really high. Yeah, 1600. Plus nifedipine. So it was really a lot, too much."

(Participant 18 interview, first pregnancy, required admission for high BP)

"Yeah, because I didn't want - like I said - my real fear was always 'I hope it's not going to affect the baby, like his growth'. So I was thinking the more they are giving me more, [um] - what do you call it? Milli..? The more that you're giving me more milligrams, it's going to have impact on the baby."

(Participant 10 interview: fourth pregnancy, requiring higher doses of antihypertensives than previous pregnancies)

7.3.3 Previous pregnancies with medication as reassuring

A few women spoke about taking antihypertensives in pregnancy as unproblematic, both during their interviews and observed antenatal consultations. Mostly these women drew on experiences of taking antihypertensive medication in previous pregnancies with good outcomes, or that the current positive pregnancy experience whilst taking medication had provided reassurance.

These previous pregnancy experiences with antihypertensives could make women feel more confident with taking medication in their current pregnancy and were particularly reassuring and salient if women could see their blood pressure following the same trajectory, where they perceived themselves or the pregnancy to be at risk from the high blood pressure and they had had a good response to the same treatment on previous occasions:

> *"Because I'd taken them first time round, and everything was fine, I just wasn't worried."*
>
> *(Participant 12 interview: second pregnancy with chronic hypertension)*

> *"And look she's okay. So I wasn't so worried with this one now, because she turned out alright [laughing]. Yeah I was a lot more worried about her when I had to [take medication] with her [talking about her first child]. I was a lot more stressed out about it. With this one, it was just like '[groan] it's this thing again'."*
>
> *(Participant 3 interview: second pregnancy, and admitted with high BP needing treatment in first pregnancy)*

Participant 43 (P43) was in her third pregnancy and had experiences of antihypertensive medication in her previous two pregnancies where her blood pressure had risen steeply towards term and in the postnatal period she had required admission to the high dependency unit on both occasions. P43 also developed a close working relationship with this specific doctor during this and her previous two pregnancies (relationships are discussed in Chapter 5). The below excerpt is a field note from her consultation with the doctor where they discuss treatment options and illustrate P43 confidently suggesting which antihypertensive suits her best:

Clinician: [nodding] "Mmm, your blood pressure could be a bit better, couldn't it? We could get things better."

Woman: [nodding] "Yes. Yes, I agree. And I would rather be proactive. As my blood pressure tends to go up from about now if you remember, and definitely to rocket as soon as I give birth, to about 180, 120 was at its worst I think, last after my daughter. So I'd rather be proactive and increase medications now, to ward off those problems, if that's possible?"

Clinician: "That seems very sensible. And which, of which - Of the two, which would you rather increase?"

Woman: "Nifedipine, please. I think it acts better, and acts faster for me. I don't know why."

Clinician: "Agreed. I'm sold. So, just double it now."

(Field note: antenatal clinic consultation between clinician 005 and participant 43)

However, these previous pregnancy experiences tended to only be reassuring if medication types and amounts were replicated, and being treated with different antihypertensives and doses in the current pregnancy could leave women unsure and fearful again:

> *"So I knew I was going to be on medication, from last time. But then – But what I wasn't expecting was taking that many. Because the previous one, I was taking just [er], is it 10mg of [um] amlodipine. You know, so from that to [er] labetolol, 200mg three times a day. I did find that one a bit shocking. I thought – when they said that, I said okay, I think I'm definitely dying. You know? [laughing] But then I don't know about – well, the difference between the two medications. So why do I have to be taking that amount?"*
>
> *(Participant 20 interview: long term chronic hypertension, third pregnancy and diet-controlled gestational diabetes)*

My data also supported that if a woman had experience of a previous healthy pregnancy (without hypertension or the need to take antihypertensives), then this did little to reassure about a likely healthy outcome, if she then required medication in her current pregnancy:

"Well, because it [the need for medication] only happened with this pregnancy, they put me on the labetalol, I was a bit like…confused and unsure. The first two had been no problem. A bit of the high blood pressure, but it never needed any tablets."

(Participant 21 interview: previous pregnancies not requiring antihypertensives)

7.4 Weighing high BP risks versus medication

Where women perceived their pregnancies as more at risk from their high blood pressure, including through previous obstetric or family history, their accounts demonstrated more positive perspectives towards the overall benefits of taking medication. However, even amongst these women, their descriptions reflected the importance they placed on a cautious approach to medication in pregnancy and emphasised taking *"the minimum necessary*" (participant 18).

Two women who had no previous experience of medications in pregnancy, appeared confident and reassured that medications had been started in this pregnancy. The first woman (participant 1) had a history of multiple early miscarriages and high blood pressure early on in pregnancy that had been difficult to control and she perceived the two to be related:

"I was actually really pleased to be on medication as I had several miscarriages before and it was explained to me that these might be related to my high blood pressure as it was very high and it was not well controlled with the first few types of tablets I was put on. My GP then referred me to the hypertension clinic at [name of hospital] and they managed to get things under control on the nifedipine and then I got pregnant quite quickly again and things carried on quite smoothly after that."

(Participant 1 interview: previous miscarriages)

The second respondent (participant 3) gave a lengthy description of the failures of two previous GP surgeries to take her pre-pregnancy high blood pressure seriously. She perceived a high risk from her blood pressure given both her parents had suffered strokes and her first pregnancy had been complicated by a postnatal admission for high blood pressure. She was pleased when she

moved to a third surgery and they made an early referral to the specialist maternity hypertension service and treatment was started straight away:

> *"Finally, happy someone was doing something about it. Basically we had few options. Because my new GP and the hospital Dr explained you know, which one is the more safe in pregnancy, having the high blood pressure or the tablets. And which is the more safe medicine and if this doesn't work we have to go on another one. So there are things you can do to help it [the BP], I suppose. Just try and relax. But just take your tablets and you should be okay. [laugh] And listen to your doctor…..if it [home blood pressure] went up I was just thinking 'oh, they're just going to up my dosage, and hopefully that'll do the trick'."*
>
> *(Participant 3 Interview: second pregnancy, developed chronic hypertension between pregnancies)*

7.4.1 Trust in the doctor

Given most women's general reluctance to take medication in pregnancy, I asked what informed their decision-making if they adhered to proposed treatment. Women's accounts described the central role played by their treating clinician in reassuring them that taking their prescribed medication was the best course of action for their pregnancy and unborn baby. There was an implicit notion in many of these accounts that 'doctor knows best' as illustrated by the following examples:

> *"Well I'm guessing just trust the doctor. And just don't - well, I just searched [online] sometimes, like when I started. Because I miscarried three times before she came. But I couldn't really find anything [online]".*
>
> *(Participant 14 interview: difficult to control blood pressure)*

> *"No, no, well I guess I didn't particularly like it, but equally I do feel like, you know, I am going to assume that [er] they've checked it and it's fine, and so. I mean it's better that everybody stays safe, right?"*
>
> *(Participant 17 interview: previous pregnancy complicated by postnatal high BP)*

> *"We did ask whether it was safe, and they said that it was safe to take them. And I thought well obviously they're not going to give it to me if it's going to do something bad to them [the baby]. The doctor seems to know [er] best. You have to trust in the end."*
>
> *(Participant 23 interview: second pregnancy, first pregnancy no complications)*

However, trust was not absolute as many women held contingent views, recognising that knowledge was current and might also be limited. One woman interviewed in the antenatal clinic (participant 29) talked about trusting her doctor's advice around medication but she had ongoing wariness reinforced by a current news story about the harmful effects of taking a specific antiepileptic medication in pregnancy:

> *"That worries me in the news about epilepsy, that medicine that lots of women took and it's affected their babies. I'm sure they also thought it was safe at the time."*
>
> *(Participant 29 informal interview: reluctant to increase her antihypertensives)*

Other women recognised that complications from medications might only emerge over time:

> *"Of course, I've been told they are safe. But you know, you never know, really if there may be any discovered effects later on, so although they are tested and so on. But I know that something could come out later on. But I just take the risk, I feel I have to trust you know, what I am told."*
>
> *(Participant 18 interview: first pregnancy and developed pre-eclampsia)*

7.4.2 Corroboration and understanding

Several women described feeling more reassured about the appropriateness of taking medication due to corroborating discussions with other healthcare professionals and from results of their own online research and talking with friends. These other sources of information were particularly influential if women had been led to *expect* that they might need to take medication in pregnancy, for example by a referral to the hypertension service before pregnancy, following earlier advice from their GP or their own internet research:

"I felt that they were the right thing to do. And [er, um] they were keeping us [er] in a better position than if we were just taking the lucky approach of 'everything is going to be fine', and not take it. And then, you know, having complications, and developing pre-eclampsia and all sorts, so. Yeah, so I was happy to take them. I had this conversation way back with my GP about the blood pressure. And the reasons why she was putting me on that medication, the fact that I was trying for a baby. So I already had – I was already aware of all the studies that had been done with this medication and [er] that should have been fine."

(Participant 9 interview: friend had pre-eclampsia)

"Yes at first I did worry about the aspirin and the labetalol, but when I gave birth to my older daughter, I was told by a Canadian doctor who was working in the hospital at the time, that next time if I became pregnant to take aspirin and I might need tablets for my blood pressure. My GP would give me this the minute I found out I was pregnant. And they did and they changed me to labetalol from my usual one. I didn't understand why I was taking the aspirin, but I knew I should do it and I wasn't surprised."

(Participant 7 interview: pre-eclampsia in previous pregnancy)

"I read too much about blood pressure on the internet, and you know, pregnancy. And not taking medication is very, very, very – you know. Danger. I knew what would be worse, if I'm not going to take it"

(Participant 22 interview: first pregnancy, longstanding chronic hypertension)

Some women also spoke more confidently about taking medication in pregnancy when they were able to offer some account of the direct beneficial or mechanistic effects it was having on the pregnancy and baby. These women's accounts gave a lay perspective about their understanding of how medications improved blood flow to the baby and helped maintain the health of the placenta:

"They told me for the baby that it's [the medication] the best – that is the safest, best thing for the baby. Because if [um] the baby doesn't have a good blood flow from my placenta to be able to grow..they said it's the best. Me being on medication is making my blood to be [um] purify, or whatever – for the baby to have a good blood flow."

(Participant 10 interview: previous pregnancies complicated by high BP)

"Everything would be normal. It's only when you refuse to take it. It might have damage to the blood flowing to the baby. I mean, it can hurt the baby or yourself, because if your blood is not pumping very well to the baby from the high blood pressure. Yeah because it's something that the baby have, if you are not okay, if you are sick, the baby will be sick as well. So the best thing is that, when they tell you something, you need to take your medication or you need to do this, you follow it. It's for your own good and for the baby's sake."

(Participant 6 interview: pre-eclampsia in previous pregnancy)

7.4.3 Information needs and damaged trust

Although women's wariness about taking antihypertensives in pregnancy was reduced by trusting relationships with their clinicians, some lingering concerns remained. All interviewed women who had taken medication in pregnancy said they wanted more specific information about potential risks or side effects to the baby and many said the emphasis during consultations had been about the effects of medication on the blood pressure "numbers", which were not their priority. Very few women could recall having a discussion with their doctor around any specific risks to the baby, instead they remembered general reassurance: *"I was told it was safe, that's all and it's been used for a long time and it looks safe basically"* (participant 15).

"It (the discussion) was more about medication controlling the numbers. Keeping me safe I suppose. But I guess I wanted to know what's happening to the baby more; what's happening to me and then on to the baby while taking the medication."

(Participant 1 interview: first pregnancy and complicated by pre-eclampsia)

> *"But when I was being given the [er] labetolol, I wasn't told about the side effects to the baby. So I had to look that one up. And also with the second medication that they put me on, I did find out about how it works also, basically. By Googling it…"*
>
> *(Participant 20 interview: third pregnancy, previously took apple-cider vinegar to treat high BP)*

In contrast to the examples where women had gained reassurance from corroborating advice, several women gave accounts of heightened anxiety when members of the wider clinical team gave *different* opinions and advice around medication. Sometimes this information was given at particularly vulnerable times, such as at or shortly after delivery, when women were coming into contact with labour ward midwives and paediatricians. When describing these instances there was a sense in the women's accounts that they had to defend that they hadn't known about these medication risks or that they had tried their upmost to check if the medication was safe.

One woman (participant 13) recalled being told by the paediatrician after her caesarean section about how her medication was implicated in her baby's low blood sugar level:

> *"Because [um] mm, I wasn't aware that blood pressure tablets could make [um] – her blood sugars very low. That's what the paediatrician said. So when she was born, she didn't cry. And they had to get the crash team in, to revive her…..They gave her some – a glucose drip, and some – they'd fed her. And by the time I'd been sorted, they [baby and Father] were both coming back, so. But I never got that first hold."*
>
> *(Participant 13 interview: second baby, and born by emergency caesarean section)*

Several women described frequent questions and concerns raised by the community pharmacist about their medication when they went to collect it. One respondent was questioned three times about her amlodipine prescription (participant 24, see below). But she was able to counter this by checking with her doctor again and she described referring to a hierarchy of knowledge around pregnancy information where she placed her obstetrician as foremost. This story is told after she had delivered a normal sized and healthy baby:

"I was a bit worried because [um] when I went into Boots to pick up my normal prescription, [um] I got questioned three times about the amlodipine. "Do you know you shouldn't be taking amlodipine while you're pregnant? You should be on labetolol, not this one." [um} And I asked them why. And they said it was something to do with [um] having small babies. So I said "Well – ." I know they're not just a pharmacist, but I thought well I am being monitored and if the GP thinks it's okay and the consultant thinks it's okay, then obviously that's what I should be taking." And I asked doctor [name of obstetrician] about it. And he said no, it was absolutely fine to take it. "I wouldn't put you on it if it wasn't safe to take during pregnancy." But then actually when I was in labour even the midwife said – because she said, "Oh, you've been taking amlodipine 5mg." This is when I was in labour. And then she said, "Did they mention anything about a baby on the small side with this medication?" And I thought 'yeah, they did, but it's too late now!' Like I'm in labour, there's nothing – And she [the baby] wasn't, she was fine."

(Participant 24 interview: first baby and no complications from chronic hypertension)

One woman's interview account (participant 4) emphasised a strong sense of being misinformed during pregnancy, despite her best efforts to get more information about potential medication risks to the baby. The baby of this woman was admitted after delivery to the neonatal unit with fetal growth restriction and low blood sugar levels. She related a conversation she had with the treating neonatologist at the time:

"So because I was told that it's no harm for your baby at all (from medication), do you know, you just chill out. Because I was very into being explained. But I asked them again you know – I asked them in hospital, and they said "You know, you can – you can have it, it's no – it's no proven to be, you know, none of that." And when the doctor said – in the morning – so I just came out myself from intensive care, he was assessing him – and when he said "Oh, so are you having medication in pregnancy?" I said "labetolol." And the doctor froze. They look at me. And I – you know, it just felt like something was wrong. I said "Okay, I want explanation now, because you've got something to say about it." And he said "Listen, every mother that have been on labetolol, all the children tend to have [um] no sugar [um] levels on their system." I said "Why? Why no one has told me that before?" And he said "Yes, it's something that we still" – he said it's something they were still [um] battling with…..So I think it was a matter of fully explaining the extension of things. Sometimes it can be a bit scary, especially for the mother, but…in that case – I also had my husband with me, so it would be nice if they would open up in a different manner to us, to expect something after birth….They just basically said that my, my placenta, you wouldn't be able – wouldn't get through because of me, not because of the medication."

(Participant 4 interview: first pregnancy and delivered early with growth restriction)

For these individuals left with doubts and queries around their use of medication in pregnancy, there would usually be little or no opportunity to discuss these concerns again with their antenatal teams as postnatal follow-up usually occurs in the community in the UK.

7.5 Clinician perspectives on prescribing in pregnancy

During interviews clinicians acknowledged women's fear and reluctance to take medications in pregnancy and how this created problems for adherence with prescribed medications. They also described grappling with the uncertainties in prescribing in pregnancy in general due to the lack of trial data that included pregnant women.

7.5.1 Guidelines, licensing and colleagues

Communication strategies reported by clinicians for discussing medication choices and their safety profiles included describing issues around licensing of medications in pregnancy, prescribing practices consistent with guidelines from NICE (National Institute for Health and Care

Excellence) and drawing on the collective specialty experience of using certain antihypertensive medications safely in pregnancy for many years:

> *"So I mean if I'm initiating treatment I usually talk [to women] about licensing in pregnancy, some are licensed others are not. And the – usually licensing doesn't really mean much in the context of pregnancy, because very few pharma companies go out and get a license, for various reasons. And so therefore it has to be based on my understanding of the – my experience and my reading of the literature."*
>
> *(Clinician interview 004)*

> *"I talk to them about the guidelines and evidence that bringing down their blood pressure to within target has been shown to improve outcomes…And I talk about the fact that the medications that we're using we've been using for years, so even though it's not licensed, it's – there's no evidence of that medication itself causing any harm, it's probably the disease process that was causing the harm. And I sometimes talk about the potential risk of neonatal bradycardias or hypoglycaemia with the labetolol. But I think neonatologists have stopped worrying about that."*
>
> *(Clinician interview 002)*

All clinicians reported trying to explain balancing the risks of hypertension with taking medication. Several clinicians were aware that women might be receiving conflicting information from friends or colleagues or online sources about potential effects on the baby from antihypertensive medication in pregnancy. There was concern and sometimes frustration that women might not take their tablets if they were told by others that it could cause problems, thus potentially placing themselves and their pregnancy at risk. There was variance across interviews within the clinician group about whether effects on growth or blood sugars in the baby were likely caused by the underlying hypertension or the medication given to control it. A few doctors conceded that the evidence was mixed, which left uncertainty:

"…..because if it was pretty obvious then that would be easy. But obviously there is conflicting data out there."

(Clinician interview 004)

"I discuss the pros and cons of them. I'm getting a bit fed up with my fetal medicine colleagues blaming [um] growth restriction on beta-blockers. So I'm going to [laugh] – going to ask one of then to talk at an educational meeting soon, because that's one of the things that fetal medicine…whenever they go to the Small for Gestational Age (SGA) clinic, they'll say, "Well, she's on beta-blockers, so that's probably one of the reasons why she's – you know – got a small baby." And I'm like, "She's going to stop taking her medication if you say things like that. And the evidence is unsure." So I say that our NICE guidelines say the first line therapy is labetolol. And it's, you now, considered safe. And I talk about how, you know, some of the beta-blockers – particularly atenolol, there was an association with small babies. But I explain that actually maybe it's just an effect of the underlying hypertension, rather than the medication, and the important thing is that we're trying to treat their blood pressures to prevent them from having severe hypertension and stroke. So, that's the reason we're doing it, and we have to weigh up things in the balance….So these babies are born of mothers who have hypertension. They have a vasculopathy. They have small placentas. They have small babies. And the small babies, their temperature is low and their blood glucose is low, they're small. So that's all the spectrum of their placenta disorder. And there isn't good evidence that this is drug-related, in my view….There is uncertainty anyway. And then making sure we're all singing from the same hymn sheet. And so I think – because a higher proportion of them will end up in the SGA clinic, being told something slightly different."'

(Clinician interview 005)

"Unfortunately they do get spooked by neonatologists about the labetolol. Because they get all sorts of stories about bradycardias, and other things. I can't say I've seen any, to be honest, [er] babies affected by beta-blockers. But they – it's in the press, so they tell them, and that's when it gets difficult."

(Clinician interview 007)

"Yeah, well I tend to pre-empt the risks to the baby now. Because I think if you don't do that, they just won't take them. And they'll look it up on the internet. So I try, I find most of my job is being reassuring, of saying I don't use things like the BNF [British National Formulary], it's also going to – always going to tell you to be cautious. Manufacturers always advise caution in pregnancy for almost everything you look up. [um] And I reassure them. I tell them why we're treating and what risks there are if there isn't treatment. But I almost pre-empt their questions now, from the point of view of tablets in pregnancy. Because otherwise I'll find out in about three weeks' time that they haven't taken them."

(Clinician interview 006)

7.6 Therapeutic relationships

During observations of consultations I noted that clinicians drew on guidelines, licensing and their perspective on the importance of treating hypertension when discussing the need to treat high blood pressure. Clinicians also went beyond these factual frameworks and sought to develop trusting relationships with women. Clinicians across all three centres, invited women's opinions regarding medication and showed support and empathy for these views, avoiding judgement or chastisement around reported adherence behaviour. Clinical decision-making was made more transparent as clinicians explained thinking. Clinicians sought to manage expectations and normalise medication taking where necessary, as they put current doses into context and described the likely trajectory of blood pressure to increase in the second half of pregnancy and that increasing doses or several types of medication might be needed. Examples of these conversations are given below:

Clinician: "And how are you getting on with the medication? How's that going?"

Woman: "That's going fine."

Clinician: "And are you okay at taking it? Are there any problems with that?"

Woman: "Well because in her case, I didn't take it that regularly, I didn't take it every day. [pointing towards her daughter] But now, I am so strict. I take it every day, [slapping the back of her hand] regular, like clockwork."

Clinician: [nodding] "I know, we do usually ask women how they find they're taking their medication. We know that women worry about taking the tablets. Especially as the advice is always in pregnancy to try and avoid taking any medication, 'don't take medication, speak to your doctors first', and that's the constant message that we're giving women usually. And then you come here, and then of course we ask you the opposite, we ask you to take medications. Now, we know - we absolutely know - that the risks of high blood pressure for you and your baby are much, much greater than that with the medicine. But it's hard, it's hard to hear that we need to take the medication to help the blood pressure, but it's very, very important, [name]."

Woman: "Yes, yes." [nods in agreement]

(Field note: antenatal clinic consultation between clinician 003 and participant 35, previous pregnancy complicated by pre-eclampsia)

Clinician: "So, [name], as we discussed right at the beginning, we're trying to get this right, to get the best outcomes for your developing baby and for the placenta and so we might need to increase medication as the pregnancy progresses. Now two weeks ago the blood pressure was just beautiful. We'd got the right dose, and everything was just right. And then today you've told [midwife colleague] that you've got a bit more swelling. Is that right?

Woman: "Yeah. And it's not going away now. Before it used to come up and then go away."

Clinician: "So the ankles and hands are a bit swollen?"

Woman: "Yes, yes. And my face a bit, too. And sometimes I'm getting some stars in my eyes."

Clinician: "Right. So your blood pressure is more also today. Your urine today is normal. Your scan shows a baby growing beautifully. But the scan does show that the blood flow to baby is not perfect, but it's good. So I'm sure from all these things that we need to increase your tablets today. What I'm not sure yet is if this is developing pre-eclampsia."

(Field note: antenatal clinic consultation between clinician 004 and participant 36, usual care group, first pregnancy)

7.6.1 Clinicians fostering relationships using BP self-monitoring

As intended, home readings provided additional data that clinicians used along with clinic readings to titrate medications. However, the availability of home readings could also promote closer doctor-patient working relationships as they allowed a responsive and more individualised approach. Clinicians reported that SMBP had the potential to beneficially change the dynamic of consultations allowing for more open discussion around medication adherence. As one clinician reported:

> *"I think it, it [SMBP] sometimes helped lead in to a more honest conversation about adherence during consultations. Because it is an issue. [um] Some women - quite a number of - you know - a number of women don't take the medication as prescribed. For all sorts of understandable reasons. [um]. I do think there was something about talking confidently about their own readings meant they could also share what they were doing with their medication.*
>
> *(Clinician interview 003)*

Across all three study sites, I observed many examples of consultation styles that were explanatory and showed respect and support for women's views, sought to explore women's fears around medication and invited participation in decisions around medication.

In a few cases clinicians also used a more participatory approach by introducing flexibility within the treatment plans suggesting women alter their own medication doses dependent on home blood pressure readings or these combined with symptoms. Clinicians tended to use this tactic of partial self-management, ceding some more responsibility, in two disparate situations: either when they had a long-standing relationship managing hypertension with a woman usually over several pregnancies, or used as a last resort when it appeared the woman was very averse to taking any medications. For example, participant 47 (see field note below) had tried three different sorts and had found that the most recent, nifedipine, was giving her headaches and dizziness:

Clinician: So, your blood pressure is running a bit high [BP 152/93 most recent home reading]. It's not at dangerous levels at all, but it is where I would want to get on top of it. Because by next week it might have gone up to 160 on the top number. So, what we can do is increase the nifedipine. Or we could add on a second medicine called labetalol. And also if you get those feelings again, of dizziness, you could take some home readings then, and we can see what's going on. Now the nifedipine, when it's increased or it's started can cause some of these feelings, headaches and some dizziness. But after a few days, it should all settle down. So we could start off by trying the 20 twice a day. You can keep checking your blood pressure daily as normal, but also if you feel dizzy, take your blood pressure and we can see what's happening. Now if you need to do more than one, as you're feeling dizzy, then do that. You don't need to do it more than once, but if you have these symptoms, just take the blood pressure again if you want to. Now, should we try again with the medicine?

Woman: Absolutely.

Clinician: Should we give it another go with the nifedipine and you can check things with your own readings at home?

Woman: Yes. Yes, okay.

Clinician: So. If the blood pressure is lower than 110 on the top number, or lower than 70 on the bottom number, and you're feeling dizzy, then reduce back down to the 10mg. But if you're okay, then let's continue at the 20mg dose. Now, you feeling dizzy is not dangerous for the baby. And it should all settle, that symptom and any headaches, once you've taken the medication for a couple of days.

(Field note: antenatal clinic consultation between participant 47 and clinician 007)

Participant 44 was in her second pregnancy complicated by hypertension and was seeing the same clinician in this pregnancy. She had not required medication in her first pregnancy. During an informal interview after her consultation, she talked about how she had been advised to start a small dose of labetalol a few weeks previous which she could adapt according to her home readings:

"My readings have been really good until a couple of weeks ago. It was always about 120/70. And then last time I came, it was higher, it was about 140/90. And we weren't sure if it was real or not. So the doctor advised I could start some labetalol 100. And as I was checking it at home, I could see if it was staying up, and start it. But also, if it dropped it too much, just to stop the treatment. I was worried about it dropping it, so I waited until the next few days before starting the tablet. Because I just wanted to measure my blood pressure again a few times in the morning, to check it was real. But I measured it, and it was still up, so I started the medication. And even when I measured it the second time, the reading was still up. So, that one always tends to be lower, so I knew then that taking the medication was probably the right thing. I think I also thought it might all be white coat, as coming here can be a bit stressful. Rushing about, and if I've also been at work beforehand - sometimes I can be rushing over here. But I stopped work two weeks ago, too. And the blood pressure was still up, having stopped work and resting more. I did check my blood pressure again at home, a few hours after taking the tablet. And the tablet did seem to have nudged it down a bit. It was about 82, 85 on the bottom. It really hadn't dropped it like I expected it to and I was frightened of, it just pipped it under the limit. So I've been taking the tablet twice a day since then. And so far, the blood pressure is staying just under. And I feel the same. So, that's all good. It's really good having the monitor, to be able to know myself what it's doing, and to be trusted just to keep an eye on things myself."

(Informal interview participant 44: second pregnancy)

The clinician had trusted participant 44 to use her home readings to guide taking her medication. Using BP self-monitoring had also helped participant 44 to have confidence that medication really was required, that the clinic readings were not all "white coat" and that the blood pressure came down slightly and safely on starting the tablets.

7.6.2 Case study

I was able to observe the consultations of participant 10 (P10) several times during her pregnancy and to interview her in the postnatal period. She was initially quite fearful in her pregnancy and reluctant to take any medications, but within a supportive doctor-patient relationship, she moved towards confidently using the home monitoring and gaining improved blood pressure control with medication. In turn, the clinician agreed to use home monitoring in place of admission and together they successfully managed the pregnancy up to a later gestation and healthy conclusion.

Below are field notes from several observed consultations illustrating the evolving relationship and use of SMBP to titrate the medication of P10 to manage worsening hypertension:

> *Woman: [yawns, quickly covers her mouth] [nods]*
>
> *Clinician: [laughs knowingly] "Now, [name] - are you very tired?"*
>
> *Woman: "Yeah."*
>
> *Clinician: "Is that because you're very busy, or not getting enough sleep?"*
>
> *Woman: "Just busy. Dropping, collecting the girls. Work. That sort of thing. Things in the house."*
>
> *Clinician: [nods knowingly] "And your blood pressure - the lower one's gone up a tiny bit [running finger across home readings]. It's okay, but it's just okay. It is in the normal range, but it's just sitting there. So, remind me - what are you taking at the moment?"*
>
> *Woman: "Labetalol 300, twice a day. The aspirin. Some vitamins."*
>
> *Clinician: "And how are you feeling? How are you feeling with all those? You did have some dizziness last time, I remember you describing this."*
>
> *Woman: "Yeah. Still occasionally some dizziness. It's when I'm busy. It's when I'm doing things in the house, or picking up the girls. It's just when I'm doing things. But it's not always there and I think the labetalol might be making it worse. If I forget the tablet it's not as bad."*
>
> *Clinician: "So remind me, NN, what do you do?"*
>
> *(Field note: antenatal clinic consultation (21 weeks' gestation) between participant 10 and clinician 002)*

During an informal interview with P10 after her consultation, she revealed that she was fearful of taking the medication, despite and maybe because of her poor obstetric history. She had had one previous stillbirth, presumed secondary to gestational diabetes mellitus (GDM) and hypertension:

"I don't want anything like the last time, that happened with [previous child]. I know they're trying their best for me here…I feel much safer here than last time…..I'm really not at all happy about taking tablets. No, no, [shaking head] I don't always want to take them at all. But I do try to, maybe half the days I take them. And sometimes I forget too. But they're not helping the blood pressure really. When it's still higher when I measure it at home then I can see it's not always helping the blood pressure. I think they're making me dizzy too, and this might be bad too."

(Informal interview with participant 10 after her consultation)

P10 then had her medication changed from labetalol to nifedipine at her appointment and then was reviewed again a couple of weeks later:

Clinician: "Now, I'm not too worried about your blood pressure today. We're just going to keep monitoring it here. But truthfully, we will probably have to increase your medication for that, as the pregnancy goes on. Maybe a couple of times."

Woman: "Oh, right. Oh. Okay. And how high could it go? How many tablets?"

Clinician: "Well at the moment, you're on a low dose, relatively, of the nifedipine after we've changed from the labetalol. And there are some women that take - end up with much higher doses than this. And occasionally we have to give women two, maybe even three medications sometimes. But we need to keep monitoring, and keep a close eye on you, and make sure everything's safe. And you're doing a fabulous job with your monitoring too. And about the tiredness we talked about last time, how do you think that's going? Are you getting much support?"

(Field note: antenatal clinic consultation (26 weeks' gestation) between participant 10 and clinician 002)

A couple of appointments following this, P10 still had raised clinic and home blood pressures and was prescribed an additional antihypertensive, methyldopa, and she was reviewed again one week after this medication change:

Clinician: "What have you done? These blood pressures are amazing!"

[And she points to the blood pressure taken just before P10 entered the room, which was 113/78. P10 is smiling broadly, and nodding her head]

Woman: "Yeah. Yes, it looks much better doesn't it?"

Clinician: "Yes it does. How are you getting on with the methyldopa and nifedipine?"

Woman: "Oh good, it's making me sleepy. Now I'm sleeping from eight at night until 6am, sleeping so well. And in my naps at daytime I sleep too. Yeah, so sleepy."

Clinician: "Yes, the labetalol just wasn't working for you, was it. I want to keep you out of hospital if at all possible, and keep this blood pressure under control. And we've got that now, but the cost is sleepiness. And I'm just trying to work out if it's the more normal blood pressure, or this marvellous sleep that's making you look so much better."

Woman: [smiling] "I know, I feel it. It's the sleep. I'm sure it's the sleep. Maybe both. And it's really making the baby active."

Clinician: "Really? Normally it makes both of you a bit sleepy. But that's great news. Fantastic. Everybody is happy. I was really worried about you last week, [name], that we might need to bring you in, so I'm so happy for all of you. Both of you."

[They have a discussion about timing of delivery. P10 is now thirty three plus three weeks.]

Clinician: "But for lots of reasons, not least because we lost [previous child], I would like to get to thirty seven weeks if we can, if we can do that safely."

Woman: "Yeah, half term would be great. And a weekend would be good. But I'm worried that it'll get to the weekend and then I'll phone and there'll be no beds…..

[more discussion re timing of delivery]

Clinician: "But you gave me quite a scare last week. So, if things do change, we just need to be open to the fact things can change. And the one thing that has made such a difference is getting the right medication and you taking your medication."

Woman: "Oh, I always take it. I always take it now. [Picks up an envelope that she's written her home blood pressures down on, pointing to it.] It was time for me to have another agent, that's what's done it."

Clinician: "Well, something's certainly made a huge difference here. And it looks like you're getting really good at this home monitoring, it's fantastic and it's really helpful. Let's check our last blood pressure now."

……..(continued)……..

Woman: [nodding, smiling] "I check every day. I don't skip any day."

[The trainee midwife who's sitting in the room with us then takes the blood pressure on an automated machine. There's some silence while she does that. P10 looks away from the arm that the monitor cuff is on, and towards the wall, as if she doesn't want to look at the reading and affect it at all.]

Midwife: "Lovely, lovely. 120/80." [showing P10 the reading]

Clinician: "Lovely, indeed. [writes it down in the notes, laughing] Now normally when I see that blood pressure written down, it's not real. But that one is. Fantastic. So, nifedipine, methyldopa and aspirin, is that right?"

Woman: "Yes, those."

Clinician: "And how are you for meds? Do you need any more?"

Woman: "Oh, yes please. All of them. Better to have more than to run out."

Clinician: "Oh, I love it when you say that." [laughing]

(Field note: antenatal clinic consultation (33 weeks' gestation) between participant 10 and clinician 002)

From the above excerpts, P10 appears to have had an about-face in her views regarding the antihypertensive medication. However, interviewing P10 postnatally when she could look back on her experiences of pregnancy and the neonatal period, revealed the fragility of her confidence in taking medication during pregnancy. She described her initial fears when her son was delivered small-for-dates:

> *"So when the baby came, and I found out that the baby was on the smaller side, then they said he was actually on – as in the very, very small – I don't know how to say that in medical terms. Yes. So I wasn't happy, though. I wasn't happy. I was really worried. But at the same time, when all the checks went on, [um] and I found out that everything was okay, like hearing and sight. He was well. At that point, I started saying okay, that means this medication was…actually given me for my own good and the baby's, yeah…in the long run I've seen that since it did not affect the baby in any way, it's good."*
>
> *(Participant 10 interview: previous pregnancies and one stillbirth)*

7.7 The role of SMBP in medication concordance

In many instances women took home BP readings around the times they took their medication and were able to see a beneficial effect on their blood pressure (as previously described in

Chapter 5). Women reported that this gave them confidence and assured them that taking medication worked. For some this also reinforced that they should take their medication regularly as they took measurements before and at varying times after medication and could see that as medication presumably wore off, blood pressures were higher and then responded after taking medication. When there were changes of dose, several women described checking their blood pressure more frequently at first to confirm that the increased dose was working to bring blood pressure more under control. Examples are given below:

> *"Because before I thought like that this labetalol doesn't work for me, yeah? Before I did the readings [before enrolment to SMBP]. [Dr XX] had to increase it and I wasn't feeling anything. But I can see it's worked, really. That when I'm checking every day this blood pressure that I knew that [um] this medication is working good for me now. That I'm doing something good for my baby. [laughing]."*
>
> *(Participant 21 informal interview: did not require antihypertensives in previous pregnancies)*

> *"Well I think it [SMBP] made me aware of the benefits [of medication]. And I suppose very important to like taking medication at the right time, and regularly too. I felt more aware that yeah everything was fine, probably because I was taking my medication at the right time. So [clears throat] I think it was reinforcing the fact that the prescription of medication was right. Like okay, you have to take medication and your child and everything is fine, so….I would check blood pressure before and after my medication in the morning. I mean the regular reading was always in the morning. Because they said do same time. So I did it only those two times, before and after."*
>
> *(Participant 18 interview: first pregnancy, rising BP detected by SMBP, developed pre-eclampsia)*

> *"There was a period when I got this increased [er] dosage and I used to do the reading at the same timing, but I also used to check before and after the medication, to see if there was a difference. And I could see that after the like one hour after the medication the blood pressure was going down. So I felt 'okay it is working' [laughing]. It's doing something. Yeah. [clears throat] Yeah, this is what I checked, but not really many times. Literally only after it was increased each time. I was just curious to see if there was kind of a difference."*
>
> *(Participant 4 interview: long-standing chronic hypertension, did not require antihypertensives before pregnancy)*

Home readings also allowed for comparisons between different medications. Some women spoke confidently and knowledgably about medications as they became experts on timings of onset of action of different agents and which medications appeared to suit them better in terms of blood pressure control, as demonstrated below:

> *"So my blood pressure readings were always taken in the evenings to start with. And in theory, the nifedipine should've been a twenty four hour acting medication. [um] While it was once a day, I don't think there was that much variation obvious. I mean for me, I don't think the Adalat [long acting nifedipine] was a key thing in reducing my blood pressure when I checked it, it wasn't until I went onto labetalol. Because interestingly I'd take the Adalat usually at six, or something like that. And then I'd measure my blood pressure at nine. And when I went onto the twice a day Adalat and measured my morning and evening blood pressure, to be honest that additional Adalat hadn't made much difference to it. And then someone said to me, "Oh it's really fast-acting, it should work within half an hour," and on a couple of nights I took the tablet and then did blood pressure about half an hour afterwards, and even that didn't seem to for me - there didn't seem to be any variation with it at all. So I didn't feel this was helping me. So. But then with the labetalol - as soon as I went onto the labetalol, it was noticeable once I'd taken the tablet, my blood pressure came down. And it was a bit of a pain taking it three times a day, but checking it, this seemed to have a much better effect on me and it was [er] all smoother too as it was still better before I took the next dose."*
>
> *(Participant 19 interview: pre-eclampsia in previous pregnancy)*

7.7.1 Medication avoidance and self-management using SMBP

Home readings could provide confidence and reassurance that medication was needed and was working to improve blood pressure control and thus acted to increase concordance. However, some women began to see their home readings as a means to avoid medication, particularly if they were very averse to taking medication. Some of these women reported during interviews that they had taken it on an as-needed basis, when they measured their home blood pressure as very high. For some others, their readings showed they were in the 'normal' range at home for at least some if not all of their measurements, and particularly when they had doubts about the validity of their clinic readings (as discussed in Chapter 6) this provided evidence supporting their idea that they didn't require medication.

One woman (participant 8) described using in-range home BP readings to conclude that BP medication was not needed at that time, but her account shows the apparent conflict in knowing what was the 'best' thing to do for the safety of her pregnancy and also wanting to appear to follow clinical advice:

> *"Oh yeah, it [SMBP] helped me. Yes, it helped me. Because if I've forgotten, then once I use it and I see it's high then I take the medicine. But at times when I've not taken - maybe I've not taken the medication, and I check. And it's, it's low. As in it's normal. I will not just want to take it. Yeah, I wouldn't want - No, I wouldn't want to take the medicine. Because I would see that it's normal that time, so I wouldn't want to. I would want to maybe skip that particular medicine and wait until I see it's high again. But maybe seventy percent of my pregnancy, I was really - I used to take the medication, as in throughout my pregnancy I took the medication like seventy percent. No, I - I really make sure I, I cooperate, with doctors - yeah, to put myself in a good - yeah. So I was taking it most of the time. But I used to have a divided mind….."*
>
> *(Participant 8 interview: previous pregnancies without requiring antihypertensives and also stopped her rheumatoid arthritis medications in current pregnancy)*

A second woman, (participant 23) reduced her own medication in response to low home BP readings and feeling dizzy, and readily admitted she would promptly increase medication if readings became too high:

> *"I actually reduced it, because my blood pressure was that good. Because I was taking two a day. And then I saw, I saw - it was going too low for me. So I felt like dizzy and that too. So I reduced it myself to one. And they said that's fine, as long as I keep an eye on it. Yeah, so it was going into the seventies, where mine was like eighties or nineties normally...So I think it [SMBP] gives you more peace of mind. Unless it's [the blood pressure] through the roof. But then I'd just take another tablet [laughing]."*
>
> *(Participant 23 interview: second pregnancy)*

Participant 29, see field note below, felt confident to keep her medication at a previous dose after being advised to increase it during her previous consultation, when she saw her home readings were mostly within the normal range. In a rarely observed phenomenon, she openly

discussed this with the doctor during the consultation. In this instance the doctor appeared supportive of her actions:

> *Clinician: [Discussing with me before patient enters and pointing through her home readings in the notes] "Oh, I can see she has had blood pressures mostly in the 130s, and I'd increased her nifedipine last time."*
>
> *[Clinician then calls the patient in.]*
>
> *Clinician: "How are you, my dear? How are you doing? I saw you last week?"*
>
> *Woman: "I'm well. I'm very tired, but well."*
>
> *[And then after some time they have a discussion about the medication]*
>
> *Woman: "So, you increased it to 40 last time. But I stayed on the 30, as the pharmacy only had the 10s. And the blood pressure readings have all been lovely too so I thought it best to stick to the 30. Those ones you see there, in my diary there, are all on 30."*
>
> *Clinician: [nods] "That's fine, that's fine. That looks to be a nice blood pressure. Any headaches? Any flashing lights? Any leg or hand swelling? Is baby moving well? Any pains at all?"*
>
> *(Field note: antenatal clinic consultation between 009 and participant 29, first pregnancy)*

Clinicians recognised that some women were titrating their medications in response to home BP readings and although most agreed this was going to be an inevitable result of women being able to measure their blood pressure at home, many were conflicted about whether this was the right thing to do and something to be encouraged. One clinician suspected that women viewed antihypertensives in a similar manner to insulin, only taking it as needed, guided by their home blood pressure readings. This made prescribing decisions difficult if the clinician was unsure the woman was telling the truth about what she was taking:

> *"And it's really difficult sometimes to get the compliance where we need it. And the problem with home-monitoring - the biggest problem with home-monitoring, is the women that take drugs to achieve a blood pressure target. And if their blood pressure's on target, they don't take their drugs. [um] And so people take - Rather than taking the same drug every day, they take the right - what they think is the right amount. "Oh, my blood pressure this morning was 120/80, I don't need anything, it's normal." There are some women who absolutely [um] take - have self-control over their medication. So they take what they think is the right amount. They treat blood pressure treatment [um] like insulin…And most of the time they're honest…but other times they're telling you what you want to hear rather than what's actually happening. And trying to work – trying to work with them, to make sure they understand that all I can do is – I don't care what you're taking, but just tell me so I can actually know where I'm starting from."*
>
> *(Clinician interview 004)*

Thus, self-monitoring could help increase concordance with treatment plans, allowing women to be involved in their care and to see that medication was helping to improve blood pressure control. However given the strong aversion to medication in pregnancy reported by most of the women involved in the qualitative study, especially if combined with compelling evidence of lower home readings in comparison with clinic measurements, women might use their home readings to guide an ad hoc treatment regimen, to reduce their exposure to medication or avoid it altogether. As one woman put it (participant 47): *"it makes complete sense for me that I should try to take as little drugs as possible in pregnancy and taking my own readings helped me to be able to do that. So I could just take the tablets when I really needed them…when it was absolutely necessary".*

7.8 Conclusion

In Chapters 6 and 7, I have outlined two emergent and related themes from the interview and observation data; that of differential trumping, and medication perspectives between pregnant women and their clinicians. In the present chapter, I examined the general and specific concerns and reluctance of pregnant women for taking medications and how these were weighed against the perceived risks of high blood pressure in pregnancy. Similar to their meaning-making around

their home readings, women's views around medication were founded on the diverse information and experiences available to them. Pregnant women had concerns about medicines such as tolerance and dependence and a preference for 'natural' alternatives, views shared by non-pregnant cohorts described in the literature(269-271). Women's narratives also referred to the widespread cultural belief that medications *shouldn't* be taken in pregnancy, except in extremis, due to possible untoward effects on the baby. Many women articulated their specific fears for potential effects on growth, sight and hearing and neurodevelopmental changes that might be subtle and only come to light later in childhood.

Exposure to antihypertension medicines in previous pregnancies with good outcomes, perceptions of high risk from hypertension either due to previous obstetric or family history, and some understanding of the mechanisms of action of medicines all helped shore up women's confidence. Strong working relationships and trust in their doctor, developed throughout the current or previous pregnancies, along with confirmatory views from other health professionals were particularly emphasised by women, and helped reassure that they were acting morally responsibly by adhering to medicine regimens. But trust was contingent, with a general understanding that knowledge was bounded and medical science and understanding evolved; this was weighed by women when making day-to-day decisions around their medicines.

Clinicians were aware of women's fears and reluctance to take medicines in pregnancy and empathised with these during consultations. There was also frustration that women might hear conflicting information from other sources (health professionals, or online) that bolstered women's fears around medicines, although I did not observe these possible different perspectives being raised and confronted during consultations. Guidelines and licensing were frequently referred to by doctors when discussing medications during consultations, although several clinicians noted the relative paucity of research data examining the effects of medicines in pregnancy during their interviews.

Women having access to their home readings could help corroborate the need for and effectiveness of antihypertensive medication (or conversely could lead to women concluding that the medication was not needed). However given their concerns around medication in pregnancy, dissenting professional opinions regarding the safety of certain types of antihypertensive medication and the availability of home readings that might be within the 'normal' range, it was not surprising to find that women were sometimes conflicted around whether to take their antihypertensive medication. Home readings could trump high clinic readings and provide a rationale for women 'self'-managing, avoiding or omitting antihypertensive medication that was deemed both undesirable and unnecessary.

Self-monitoring blood pressure engaged women in their care. However, the availability and accessibility of reliable and consistent information around their condition and medications was lacking. As with discussions around risks from hypertension in pregnancy (discussed in Chapter 6), there was a similar mismatch in information needs around the risks and benefits of antihypertensive medications in pregnancy. Women reported wanting *more* information about possible risks associated with antihypertensive use, and discussions around guidelines and licensing did not address concerns around using these medications during pregnancy.

Using home blood pressure data could allow clinicians to more accurately target and titrate medications, identifying white coat hypertension and reducing medications where they are not needed. However, if self-monitoring blood pressure in pregnancy aims to improve blood pressure control whilst involving women in their care, then simply asking women to measure and report their readings is not sufficient (and could in fact potentially lead to worse blood pressure control if women omit required medications). My data shows the importance of women and their clinicians being able to share information and perspectives to realise the potential of BP self-monitoring. Pregnant women are highly motivated in monitoring their condition and are making daily decisions about how to best safeguard their pregnancy, including taking any medication.

In the next chapter I will discuss the qualitative findings from Chapters 5-7, describing the strengths and limitations of my methods and how these might impact on my study results and put findings into the context of the wider research literature.

Chapter 8: Discussion of qualitative findings

In this chapter, I bring together the findings from the qualitative data (observations in clinics, interviews with women and clinicians) described in Chapters 5-7, discussing these data within the context of the larger literature.

8.1 Summary of findings

The qualitative data supported the broad acceptability of the intervention and trial processes as described in my quantitative findings discussed in Chapters 2-3, and helped explain the appeal and experiences of using this intervention for both women and their clinicians. Findings from the qualitative study also provided unique insights into women's and clinicians' different interpretation of home and clinic BP readings. These insights, which were not gleaned from the seeming face-value success of the randomised feasibility study, have important implications for further design of the intervention and implementation of BP self-monitoring into routine antenatal care.

8.1.1 Perceptions and use of BP self-monitoring and acceptability of trial processes (Chapter 5)

Women reported valuing the ability to monitor their own blood pressure, motivating them to join the trial; indeed several women from the 'usual care' group took up voluntary BP monitoring. Women reported that they monitored frequently and pro-actively outside of the protocol, as evidenced from their monitor downloads, for reasons of self-care practices and their own experiments with timing around daily activities and medication. Women talked about benefits and behaviours in relation to safeguarding their pregnancy and doing what was best for the baby, which included improved knowledge of their individual blood pressure, ability to interpret symptoms, a sense of control and reassurance. Over and above these benefits, women who could see that their blood pressure was poorly controlled or who were taking treatment appeared to be particularly motivated to persist with self-monitoring. However some women were hesitant about contacting clinical services for borderline readings and one woman described becoming

anxious and discouraged when she saw raised home BP readings. Supportive working relationships with their clinicians encouraged women to seek advice and use the intervention confidently, and these relationships were highly valued by women and seen as integral to the intervention.

Trial processes were generally acceptable but many women began to adopt technology to remind them to monitor and take medication, such as setting alarms or entering the BP data into their mobile phones. However, a few of the women interviewed wanted to retain the paper diary, that had been designed for use by the group with chronic hypertension. The continuity of the relationship with the research midwife was valued but sometimes women found additional study visits stressful due to time constraints.

Clinicians described the benefits of self-monitoring for shared decision-making. This did not appear to increase their workloads as they were used to a similar approach for gestational diabetes. Some clinicians were concerned that women might be falsely reassured by normal home readings leading them to ignore important symptoms, although this was not supported by the interview data from women. Clinicians felt more confident in the accuracy of the home BP readings as women had been provided with validated monitors and training.

However, my observations revealed that home readings were not always asked after by clinicians, particularly in the context of normal clinic readings and different clinicians integrated them differently into clinical decisions. Clinicians employed a range of heuristics: looking at BP trends, deciding approximate average levels or time-in-range and varied in their attention to single or few raised readings, interpretation of white coat hypertension and emphasis on 'tight' blood pressure control. Possibly reflecting the lack of familiarity with home readings, there could also be mixed responses from day units when women made contact for out-of-range readings, which left at least one woman with raised home readings without appropriate assessment (see Chapter 5).

8.1.2 Trumping and tensions (Chapter 6)

The detailed qualitative studies enabled an in-depth exploration of women's and clinicians' meaning-making around home and clinic BP readings and how this shaped the practise of self-monitoring. When the two sets of readings were not closely aligned, women tended to privilege their home readings whilst clinicians took greater account of clinic readings. The differential 'trumping' of home versus clinic BP readings and potential tensions and ambivalence over management decisions can be appreciated, explained and become almost inevitable, within the constraints of what each party 'knows' and is able to control at any one time. Both parties shared the goal of guarding the safety of the pregnancy.

Women's knowledge included: the sense of validity of their home readings informed by their lived experience of blood pressure variability, the white coat effect of stressful clinic visits exacerbated by anxieties over medication or admission, observing varied clinical practice and a monitoring protocol advising repeat measurements, combined with their understanding of risks associated with high blood pressure which were perceived differently in and outside of pregnancy. Clinicians' knowledge incorporated professional norms bound by clinical guidelines, an evolving and uncertain evidence base around 'tight' blood pressure control and home BP monitoring and wariness of being seen to 'ignore' contemporaneous raised clinic readings. Clinicians were ambivalent about the representativeness of home readings which might present a skewed view of overall blood pressure profile if measured at *"relative rest times".* Most clinicians had lived experience of caring for women with rare but severe complications of HDP such as stroke, which shaped their perception of risk. Although these risks influenced the design of clinical services they were very rarely mentioned in consultations, which clinicians said was sometimes due to concerns about unduly alarming women.

8.1.3 Perspectives around antihypertensive medication (Chapter 7)

Although a few women said that taking antihypertensives during their pregnancy was unproblematic and even welcome, most expressed concerns and unwillingness to take any potentially unnecessary drugs in pregnancy. Women shared similar concerns to those expressed in the general adult population around tolerance and dependence and preferring 'self'-management with rest and 'natural' remedies(269, 270). More compelling and specific medication concerns centred around possible untoward effects, both acute and long-term, on the health of the pregnancy and baby.

Women's views were shaped by several factors and conveyed the difficulties balancing these considerations, including: current and previous experiences and perceived risks with HDP and antihypertensives, moral identity concerns about taking medication in pregnancy and the sometimes conflicting conversations they reported with their direct and wider clinical teams. In turn, clinicians sought to reassure, citing guidelines, specialty experience with antihypertensive medications and improved outcomes with good blood pressure control. In interviews, clinicians described the challenges of making treatment recommendations that they suspected were unpopular and acknowledged there were important gaps in the evidence-base.

Against this background, home blood pressure monitoring could help reassure women through deepening patient-clinician therapeutic relationships and providing feedback that treatment was beneficial and effective. However, the home readings were also sometimes used by women to justify avoiding or minimising their use of medication, especially when these measurements remained raised (suggesting it was not working) or they had home readings within the 'normal' range (suggesting that medication was not needed).

8.2 Strengths and limitations

The combination of ethnographic observations and qualitative interviews in this study allowed me to compare accounts from participant interviews with observations of consultations and to

see what people do and contrast that with what they say they do. I was able to purposefully sample a wide range of women with different ethnic, socioeconomic and obstetric backgrounds and the range of health professionals involved in the intervention trial. Observing antenatal clinics provided an understanding of some of the cultural practices and 'architecture' of clinical systems and settings which impacted on how home readings were perceived and integrated. As observations occurred usually some months before interviews this helped protect against possibly contrived behaviours designed to uphold interview accounts. Interviews with women were conducted within 12 weeks of delivery, helping to reduce recall bias. The ethnographic design also allowed me to explore participants' interpretations by timely direct questioning after consultations. The fact that interviews with women were conducted in their homes where they were likely more comfortable, allowed them to provide more naturalistic demonstrations of how they performed their BP self-monitoring, but also provided insights into the domestic and wider socioeconomic settings which might enable or constrain women in their self-monitoring efforts.

I observed three very different clinics in terms of number of deliveries, geography, district general and tertiary referral, and wider sociodemographic context (see Chapter 3). I also observed and interviewed a wide variation of women and clinicians to achieve a broad range of perspectives. The findings across the three qualitative results chapters are all based on themes that were extensively covered in the data across these range of perspectives and from all three sites, providing reassurance that there was good data saturation(252) on these issues. Hence the findings might be expected to have resonance and applicability in other clinics and pregnancy populations.

All of the participants I observed or interviewed had consented to take part in a trial of self-monitoring, so might have a positive view of self-monitoring. However, the high recruitment rate into the trial (71%) suggests good external validity. The interview sample included mainly those randomised to the intervention arm. Attempts to interview the few women who had formally

discontinued with the intervention were not successful, and these accounts would likely have provided different and useful insights into concerns and challenges with self-monitoring. Sites and clinical teams that volunteer to take part in research may be more predisposed and motivated towards the use of new interventions and ways of working.

People may behave differently when they know they are being observed, amending behaviour to conform to expected social or professional norms. A similar bias can affect interview accounts. Two aspects of antenatal care might reduce observer bias. First, antenatal consultations are often observed by trainee doctors and midwives and in the case of more specialist clinics such as pregnancy hypertension, this is even more likely. It was not uncommon that I would have to 'share' the clinic with other observers; thus women and clinicians were habituated to an audience. Second, given the repeated nature of antenatal visits women's greater exposure to the clinic environment and observation might engender a 'blindness' to the observer and promote 'naturalistic' behaviour, albeit in a clinical setting. Whilst I saw examples where home readings were not enquired about in consultations, or where women disclosed discontinuing monitoring or taking their medication irregularly, the findings should be interpreted in light of this possible bias.

8.3 Links with other literature

These qualitative findings support and extend those from previous studies exploring the experiences of blood pressure self-monitoring in pregnancy and the general adult population with chronic hypertension(119, 153, 272, 273). When our study was conceived there were no previous published qualitative studies around the use of this intervention in pregnancy, but the recent increase in research evaluating quantitative aspects of feasibility and potential for SMBP in antenatal care redesign (see Chapter 3) have been expanded with parallel explorations of user perceptions and experiences(272-275). These recent, mostly survey studies have highlighted some common themes, also found in our data, related to the experiences of SMBP by pregnant women with HDP. Some are similar to findings from the general adult population with chronic

hypertension: for example benefit from feelings of greater control over their health condition, empowerment from increased knowledge about hypertension and involvement in their care, reduced blood pressure-related anxiety and reassurance particularly in the face of any symptoms and a general preference for self-monitoring versus clinic monitoring(119, 153, 272, 275).

Many of the published studies have been surveys or single method qualitative studies. My study included extensive observations of antenatal consultations and semi-structured interviews with pregnant women as well as clinicians. The intervention invited women to self-monitor without daily clinician oversight, and was able to provide in-depth exploration of the nuanced motivations and meaning-making, practices and interactions around blood pressure self-monitoring in the context of hypertensive pregnancy.

8.3.1 Women's attitudes to SMBP

The study provides a rich and detailed description of pregnant women's behaviour around blood pressure self-monitoring, highlighting frequent and pro-active self-monitoring, experimenting with the effects of daily activities, monitoring with symptoms or perceptions of stress and the influence of antihypertensive medication. Accounts of women's specific BP self-monitoring behaviours and their motivations have not previously been described in the small available pregnancy literature and this exploration was made possible by the considerable autonomy our intervention afforded. There is evidence of similar active and volitional monitoring in other higher risk populations(122), including those monitoring after stroke(276), although in a trial of chronic hypertension in the general adult population, participants did not report monitoring more often than asked to in the trial protocol(119). These populations share the attribute of a strong intrinsic motivation for self-monitoring, which incorporates a sense of personal risk and the belief that self-monitoring will help reduce this risk.

Pregnancy has an uncertain journey and outcome and can be an anxious time for women(277). Self-monitoring interventions are inevitably framed within a biomedical risk-reduction

perspective and are designed to promote self-awareness and the ongoing salience of both the condition being monitored and the monitoring behaviour. Reassurance from self-monitoring was a common theme in the interviews, but this is a dynamic state and needs to be continuously reworked and gained during pregnancy(278). There is (necessary for self-monitoring) ongoing sense of risk and women's accounts and interactions during antenatal consultations were often infused with a sense of anxiety. In turn the observed content and tone of clinicians during consultations appeared intended to reassure. There was an understanding and explanation that their referral to these specific antenatal clinics was designed to monitor and reduce risk, and the corollary: improve outcomes. There are broad and ongoing debates about the medicalisation of pregnancy and childbirth and the challenge of separating what is imposed and what is a 'choice' for women(279-284). There were several instances where women had sought out the specialist hypertension clinics included in our study. And many women appear to be choosing to co-opt the many technologies on offer to self-monitor their pregnancy(283, 285-287), BP self-monitoring included(141, 142, 288). However I recognise that women's use of technology is likely often premised on the hope that any improved knowledge and surveillance will reduce the need for future medical interventions in their pregnancy(289).

The motivations for pregnant women to start or persist with monitoring their blood pressure, particularly those who are identified as higher risk, differ from the general adult population with hypertension(119, 198, 290). Women in our study primarily viewed their risks and motivations through the lens of safeguarding their baby's health. This explains their avidity for, experimentation and persistence with self-monitoring, as it became part of the armamentarium and constant task to provide the best conditions for their pregnancy and offspring. Transitioning to motherhood engenders various forms of self-surveillance, redefining self and "being-for-intimate-others"(283, 291). The profound physiological, psychological and emotional changes associated with pregnancy, as well as social constructions of what is 'good' motherhood, mean

that what is 'normal' may have to be defined, and continuously redefined throughout pregnancy(285, 292).

A dizzying amount of information is available to help the expectant mother protect and optimise her pregnancy. Defining what is normal or pathological is even more pertinent for women with HDP. Home BP readings have become part of that informational landscape. Women used their home readings to become experts about their individual BP, and began to demarcate what was 'normal', explainable, and related (or not) to symptoms. Data didn't always provide explanation, sometimes blood pressure readings were dissonant with their embodied experience or expectations, as has been seen in the general adult population with chronic hypertension(181, 293). This could be problematic, raising questions around perceptions of control and salience.

The women I talked to did not describe self-monitoring as burdensome, and persistence was linked with safeguarding the pregnancy and heightened perception of risk, including when there was a need for medication (irrespective of blood pressure control) or with worsening hypertension. Jongsma et al used a combination of questionnaires and interviews to explore the experiences of women at higher risk of HDP in the Netherlands, taking part in the prospective SAFE@home study, which used a blended care approach of BP self-monitoring with a reduced clinic schedule(275). The authors found that women described daily monitoring as over burdensome if their blood pressure was well controlled on medication, and similar views have been reported in the general adult population. This difference with our findings may be due to different populations since ours was a higher risk group (the majority required medication and many developed pre-eclampsia), or might relate to the specific intervention. Women in our study were able to monitor flexibly around their daily schedules, instigating contact if needed, whereas the SAFE@home intervention required women to monitor at a fixed morning time, when the clinician would be able to review and feedback on results.

Women most commonly attributed higher blood pressure readings (home or clinic) to physical or mental strain (stress), seeing stress as a *"cause, exacerbating factor and consequence"(269)* as has been reported in the general adult population(119, 181, 182, 269) and accordingly used their home readings to 'self' manage. Women commonly curtailed their activities, rested more, altered work patterns or took earlier maternity leave, and drew on their social support, delegating domestic tasks. The reduction in activities was not just secondary to pregnancy fatigue, but instead women described how they sought to reduce or avoid stress by relaxing, avoiding emotionally charged interactions or reducing work hours to help 'control' their blood pressure. These strategies have also been documented in the general adult population with chronic hypertension(269). A key difference was that some women in our study even took to bed-rest. Previously a common intervention for HDP, bed-rest is seldom prescribed now and many national organisations and guidelines recommend against it(3, 5, 294, 295), given the lack of demonstrable benefit and potential harms (physical and psychological). The international CHIPS pilot trial studying 'tight' versus 'less tight' BP control in 132 hypertensive pregnancies found that almost half of women from both groups reported decreasing their activity or taking some form of bed rest(288)(18). Unlike the general adult population, pregnant women are performing what Gatrell calls 'maternal body work', growing and nurturing another being, and concepts of reducing activity and stress to help control blood pressure go hand-in-hand with providing ideal conditions and *conserving* energies for this work(296). This might also help explain why the women in our study did not discuss engaging in lifestyle behaviours such as dietary change and *increased* physical activity which BP self-monitoring hopes to encourage in the general adult population(198, 297).

8.3.2 Clinicians' (general) perspectives and practices around home readings

There is a limited literature on the use and experiences of clinicians using BP self-monitoring during pregnancy either as part of a study or routine clinical pathways(272, 298). A survey of obstetric units within the Netherlands regarding the clinical use of telemonitoring for complicated

pregnancies found a recent steep increase from 4% in 2014 to 23% of all hospitals in 2018(298). Telemonitoring was used to avoid admission, most commonly for pregnancy complications such as fetal growth restriction and pre-eclampsia, and women were invited to monitor their own BP and perform fetal heart rate monitoring via home CTG (cardiotocography). Clinician responses found nearly a third perceived disadvantages for missing direct assessment with the clinical team, and one in five thought women might not be capable of following instructions. A postnatal survey of clinicians' perceptions and experiences of using daily BP self-monitoring for women at risk of HDP, as part of the Belgian PREMOM study(272) found that two thirds of obstetricians felt it added value to patient care, and a similar proportion would recommend it to patients or thought it should be expanded to all women at risk of HDP. These data point to a sizeable minority of clinicians who have reservations about the potential role and value of SMBP in this context.

This recent literature contrasts with the broadly positive perspectives shared by clinicians in our study, and its regular use and integration into observed consultations, although I am mindful of our self-selected sample of clinics and the difficulty with comparing experiences of complex health interventions between different health systems(299). Clinicians welcomed the extra contextual data particularly given the dynamic nature of BP and short time frames for decision-making in pregnancy. Benefits were similar to those reported by clinicians managing chronic hypertension in the general adult population describing how SMBP facilitated discussion and improved clinician-patient alliance enabling and improving shared decision-making(181, 182, 300).

However, clinicians were cautious and voiced concerns for the potential for normal home readings to provide false reassurance to women who might then ignore important symptoms, although interviews with women did not suggest this was happening. There was also uncertainty about *how* to summarise and integrate home readings into clinical decisions and clinicians employed a range of heuristics. Yet, my observations suggest that these approaches allowed

space for patient-centred care and (in the absence of guidelines) clinicians used discussion of home readings to elicit women's perspectives and values around their management(301). I am not aware of other data within the pregnancy literature observing the practices of clinicians around home readings. Clinician perspectives from the general adult population using SMBP also revealed uncertainty in how to integrate home readings and interpret borderline readings around thresholds for the control of chronic hypertension(181, 293), however these studies were conducted before the updated NICE guidance(140) which provides clearer recommendations around the use of SMBP for BP control in chronic hypertension. Paradoxically, outside of pregnancy, having these formalised recommendations for incorporating home readings might now provide primary care physicians more freedom to incorporate clinical judgement and person-centred care. The development of the evidence base and production of such guidelines in the context of pregnancy may provide similar confidence for clinicians managing HDP, enabling them to know general rules and justify when and why they might be veering from these in tailoring management to individual women's needs and preferences(302).

8.3.3 The importance of valued patient-clinician relationships

Our data provided examples where blood pressure self-monitoring could be challenging or abandoned. A key strength of our study was being able to observe the longitudinal interactions between women and their clinicians which demonstrated how relationships were forged (or continued in cases of women returning to the same clinical teams as previous pregnancies) and their function for BP self-monitoring. Women said they valued key clinician-patient relationships in enabling them to most confidently and flexibly use the self-monitoring intervention. In turn, sharing and discussing home data also helped facilitate these relationships. Continuity of care is another guise under which this concept has been studied. Sheehan et al interviewed women about their experiences of completing blood pressure self-monitoring with fortnightly review by the same midwife as part of a clinical care pathway redesign for women at higher risk of developing pre-eclampsia. They found that women valued the improved continuity of care most

over and above self-monitoring per se(273). The importance of supportive clinician-patient relationships, regardless of care setting or intervention, has previously been identified as a key factor in women's satisfaction with their maternity care(303-306). Recent meta-ethnographic and systematic reviews of (digital) self-management interventions for long-term conditions have found that self-management enhances rather than replaces professional care(293, 307). The NHS Long Term Plan aims to increase continuity of care for the most vulnerable mothers and babies, hoping to realise the benefits that have been identified for reduced preterm delivery and hospital admissions(308, 309).

The central role of a supportive clinician-patient relationship has also been highlighted in the diabetes self-management literature(310, 311). My findings echo those reported by Hinder and Greenhalgh, who conducted an extensive ethnography of diabetes self-management drawing on structuration theory, and found that self-managing patients saw specific relationships with their clinicians as pivotal, with established relationships enabling bidirectional trust and acknowledgement of expertise(311). The possibility that some women might become discouraged on getting higher home BP readings, despite their best efforts to rest and take their antihypertensive medication, is predicted by structuration and (social cognitive) SCT theory(197, 312). Both theories propose that the outcomes of an individual's action feedback to reinforce or discourage future actions. A supportive caregiver is paramount for providing verbal persuasion, building confidence and a sense of self-efficacy(313). Relational understandings of autonomy, that de-emphasise the aspects of autonomy commonly espoused in reports of telemonitoring and mhealth interventions: choice and independence, but instead attend to the role of clinician-patient relationships for supporting the formation and maintenance of self-identities and capabilities, have been explored further in the social sciences literature(314, 315). My findings, supported by the broader literature and reflected in policy goals for increasing continuity of care for pregnant women and babies identified as vulnerable, have important implications for any

considerations of using SMBP in this context as a means to *reduce* clinic visits and therefore personal patient-clinician interaction.

8.3.4 Perspectives about blood pressure variability

The problem of blood pressure variability was brought to the fore in my data as women and clinicians were challenged with interpreting home and clinic BP readings that sometimes differed markedly (see Chapter 6). Hopes of introducing more certainty to clinical evaluation, especially for a condition characterised by its lack of symptoms or poorly correlated symptomatology, can be rather undone by the variable nature of blood pressure. BP variability has several dimensions, including: beat-to-beat, visit-to-visit and clinic-home blood pressure variability which have been variously studied within the general adult population with chronic hypertension and variability has been linked to all cause and cardiovascular disease mortality(8, 316-319). But much less is known about the prevalence and impact of the different types of blood pressure variability during pregnancy(320-322). Women and clinicians within our study made meaning out of the varied home and clinic blood pressure data, and understandably their interpretations were not always congruent. This has not been previously reported in the pregnancy literature. Similar to findings from the general adult population, women had a firm belief and attributed much of their blood pressure variability to stress(181, 269) as discussed above. In this way higher blood pressure readings could be explained away as momentary and understandable responses to environmental (e.g. visiting clinic), or internal stressors, rather than representing a pathological state per se that required treatment. Embodied experiences of measuring their own blood pressure at home and the tendency of blood pressure to settle to lower values on repeat measurement, caused women to privilege their home readings. The opposite was true for clinicians, who had guidelines based on clinic readings but an evidence gap for home readings and varying degrees of confidence in and commitment to the recent CHIPS findings supporting 'tight' blood pressure control(101)(56).

There is a large but contentious body of literature studying the links between acute and long term (perception of) stress with hypertension, cardiovascular disease and a range of other physical and mental health outcomes in the general population(323-325). Most women in our study reported trying to reduce or avoid activities they associated with stress as a strategy to help lower and control their blood pressure. Clinicians in our study also frequently engaged with this idea of stress as causally related to higher BP readings during their discussions with women around their home readings and how they might relate to the clinic readings, at the very least in the short term. Our data showed women's understanding of the bi-directional relationship, noting that measuring higher BP could sometimes cause stress. This belief was sometimes supported by their empirical 'evidence' of a tendency for lower home readings, and increased the perceived validity of the home readings. Understandably women wanted their care to be tailored around these (to them, more accurate) readings as opposed to clinic readings (which if higher could be attributed to stress).

These concepts are formalised within the diagnosis of white coat hypertension (WCHTN). In the general adult population, the association between WCHTN and sustained hypertension, target organ damage and cardiovascular outcomes is still unclear although there is consensus that WCHTN is not a benign entity(326, 327). It is also debated as to whether WCHTN is necessarily a precursor stage to sustained hypertension. Part of the challenge in defining these relationships has been the lack of a universally accepted definition of both hypertension and WCHTN(326, 327). There are similar debates for the pregnant population, and an even greater dearth of research around WCHTN(2, 328-330). A recent systematic review and meta-analysis by Johnson et al(331) including 12 observational studies (n=4,830 women) found that women enrolled before 20 weeks' gestation with a diagnosis of WCHTN had a 5-fold greater risk of pre-eclampsia and women with a diagnosis of WCHTN at any gestation had a 2- to 3-fold increased risk of preterm birth and small-for-gestational-age infants compared with those with normotension. However these risks were lower than those associated with either gestational or chronic hypertension. It

was not possible to separate out the effects of pre-eclampsia on the adverse perinatal outcomes associated with WCHTN. As these authors highlighted, there is a lack of reporting on enrolment gestation but the same is true for the treatment status of pregnant women within the various definitions of WCHTN used in studies, with a similar lack of clarity across guidelines (see Table 1, Chapter 1). There are obvious challenges for women and their clinicians interpreting home and clinic readings within this uncertain terrain and these tensions surfaced within the interview and observational data.

My observations supported the view that BP self-monitoring did much more than *"passively registering the facts" (332)*. The "facts" themselves were disputable and became altered. The uncertainty and manipulation engendered by diagnostic devices (brought into the home), about what constitutes normal or abnormal, especially when considering a risk factor defined along a continuum, have been raised in the social sciences literature(333-335). These literature have shown how diagnostic and monitoring devices alter our awareness and perception of disease, particularly for asymptomatic diseases or risk factors(333). Similar issues have been raised in the diabetes literature where blood glucose self-monitoring is considered integral to optimal disease control. Mol completed observations and interviews with patients and clinicians involved in diabetes monitoring outside of pregnancy, and described how the introduction of self-monitoring technologies enabled more fine-tuning of blood glucose, with the chain of patient, clinicians, friends and family and diagnostic device, all doing their bit to alter the *"normality strived after"(332)*. The promise of control afforded by these devices was also questioned, as seen in my own data, as patients could become discouraged when even after their best efforts combining lifestyle change and adherence with medications, they still obtained high home blood glucose readings. Certainly, BP self-monitoring will enable, or may even be vital, to obtain 'tight' control, if that becomes the consensus for best-practice management(2). Meanwhile, the diabetes community has already moved on, recognising that mean HbA1c and daily pre- and post-prandial self-measurements still miss a significant proportion of blood glucose volatility, and so now the

new “normality strived after” in and outside of pregnancy is both being created and chased using *continuous* real-time glucose monitoring(336-338). Could we envisage the same increased (self-) surveillance for BP monitoring in pregnancy, with suggestions for digitally enabled ‘non-invasive’ haemodynamic measurements?(302, 339)

8.3.5 Discussing risk

Women’s and clinicians’ misaligned perspectives around which blood pressure readings were most important for informing management decisions, were influenced by the perceived and communicated risks associated with high blood pressure in pregnancy. During interviews, clinicians’ descriptions of risk were orientated towards the severe end of risks to the woman, especially stroke, with vivid accounts of how this had shaped care practices and services. However, women talked about pre-eclampsia and risks to the baby, and the challenges that came with hospital admission. There were frequent discussions around pre-eclampsia risks and baby’s growth during consultations, but on the few occasions the subject of stroke was raised by clinicians, in the context of trying to improve high blood pressure, this was referred to in ambiguous terms.

Surprisingly, given the considerable morbidity and mortality associated with HDP, there is a limited literature around women’s understanding of the risks associated with HDP(340-345). Carter et al conducted a narrative synthesis of factors affecting women speaking up about early warning signs and symptoms of pre-eclampsia and identified widespread misunderstanding and lack of knowledge amongst pregnant women for both pre-eclampsia and HDP more broadly(343). A common theme was the challenge of timely identification of what could be an asymptomatic condition until the later stages, or difficulty in distinguishing signs and symptoms from ‘normal’ pregnancy changes. These echo similar findings in my study showing women striving to define this new normality and particularly how it related to their hypertensive status and how they used SMBP in these efforts. Carter reported mixed findings from the literature about the impact of

previous personal experience of pre-eclampsia, with a few authors finding this could increase awareness around signs and symptoms and encourage women to seek help(341, 346) and others finding this could act mainly to increase women's fears in subsequent pregnancies without necessarily enabling them to raise concerns(347).

Metcalfe et al conducted a stated treatment preference study which provided educational materials and assessed knowledge about HDP and discovered that women with current or previous experience of HDP had significantly lower mean knowledge scores than those without these experiences(348). The authors wondered if women with HDP paid less attention to the educational materials because they already felt they knew about the topic. Some women in my study who had previous experience of *symptomatic* pre-eclampsia, derived confidence from their current lack of symptoms, even in the face of rising home and clinic BP readings, similarly suggesting that previous experiences do not indicate aligned perspectives with the biomedical model of HDP, nor are they necessarily protective.

8.3.6 Legitimacy and autonomy

Barlow et al interviewed women who were admitted with HDP without symptoms, some of whom said they could "feel like frauds"(341). Women interviewed in our study did not voice similar concerns or reticence, but their accounts suggested that the self-monitoring intervention could help legitimise help-seeking. Ziebland et al(268) have used the metaphor of the 'Goldilocks Zone' to describe the conditions and contradictions inherent when patients make decisions about when it is legitimate to consult a health care professional. The practice of blood pressure self-monitoring touches on these mostly unspoken social 'rules'. As described above, SMBP legitimised women's help-seeking but instead ambivalence could creep in where some women said they felt compelled by the dictats of the intervention to make contact for BP readings just above thresholds, and yet they thought this was unnecessary recognising the arbitrary nature of thresholds, the variable nature of BP and their embodied experience of feeling well. This could

call into question the autonomy enabled by self-monitoring or self-management interventions, where the autonomy is defined in terms of dependence on the technology and the biomedical priorities of its design(292, 349).

In considering the contradictions inherent in enacting the role of a responsible patient, Ziebland et al also drew on the considerable literature describing the neo-liberal discourse of 'responsibilisation', an inelegant term which is used to refer to the multilevel processes and rhetoric whereby nation states create health policy encouraging citizens to be responsible for their own health(350), putting the onus on individuals to embody paradigms of the 'expert patient'(351). Putting aside how this framing can act to side-step the responsibility of states to improve the broader social-determinants of health, there are likely limited options for some patients to affect their own health(268, 352). This concern is particularly pertinent for the HDP, where lifestyle modifications may be neither entertained by women nor currently endorsed by specialist institutions or guidelines. Harris et al(353) report on the psychological burden that can be created when pregnant women were given risk information from a first-trimester pre-eclampsia screening test, intended to 'empower', but in the context of limited personal recourse to affect change. While many women hoped they would be primed to recognise earlier symptoms if they knew themselves to be higher risk, others thought a higher risk result could cause anxiety without any clear benefits where they perceived there were no treatment options or they themselves could not take preventative steps. This feeds into the larger bioethical debate about the place of screening tests for conditions with no clear treatment or risk-reduction strategies(354), but also raises questions about the capabilities and limitations for the practice of autonomy and self-management for pregnant women with hypertension using SMBP. What are the options available to women, other than to adhere with monitoring and their medication or in severe cases accept admission or expedited delivery?

8.3.7 Perspectives around antihypertensives in pregnancy and effects of SMBP

The proposed mechanisms of SMBP for improved blood pressure control in pregnancy and the general adult population, include more appropriate clinician titration and greater patient adherence with antihypertensive medications(118, 355). However, similar to the differential trumping and tensions that permeated women's and clinicians' understanding of home and clinic readings, there were misaligned perspectives around the place of antihypertensive medication in pregnancy. Women's general concerns about taking antihypertensives included those described amongst the general adult population with chronic hypertension(269, 270) namely: tolerance, dependence, a preference for trying natural remedies first (e.g. apple cider vinegar) and to try resting more and reducing or avoiding stress. Over and above these concerns, and similar to other studies within the pregnant population(19, 356-358), *all* women voiced strong beliefs that medications were best avoided in pregnancy, wherever possible. Women's concerns around medication centred around any untoward effects on the baby, presenting as either acute risks or long term effects and they used strong language to describe these concerns: "*fear*", "*anxiety*" and "*shock*". Some women even attributed the white coat effect to their anxieties about being prescribed medications during clinic visits.

The interviews provided unique and rich details around pregnant women's specific medication reservations. There were concerns related to the pharmacology of the drugs: dose-response (e.g. perceiving high exposure when using hundreds of mgs and three-times daily regimens of labetalol), timing of exposure (particularly concerns around first trimester exposure) and the sorts of effects medicines might have, specifically fears about effects on growth, prematurity, sight or hearing or more subtle long-term neurodevelopmental influences on their children. Concerns about side-effects are commonly cited in the literature around patients' experiences of taking antihypertensives both within the general and pregnancy populations(269, 270, 358), but women within our study described an additional dimension. The most common side-effects of headaches, dizziness or feeling faint where perceived as possibly reflecting (similar) untoward effects on the

baby, and some women also struggled to differentiate these effects from important pregnancy complications such as pre-eclampsia or anaemia, causing increased anxiety.

Women also had reservations unrelated to the specific pharmacology but the 'moral identity' issues of using medications in pregnancy. The struggles that individuals face when deciding whether, how and when to take medications have been previously documented in the non-pregnant population with chronic disease(264, 359, 360). Not only did women in my study position themselves as responsible citizens, "not the sort" that normally takes medicines, but this identity took on a particular form in pregnancy where women talked of their moral responsibility to protect their unborn child, including against any unnecessary medication. Women described how they *should* 'self'-manage and reduce stress or rest more to try to avoid medication, but some had to balance this against the necessity of working or caring for other children. The time-limited nature of pregnancy has previously been described as an important factor in women's decisions around medications(361). There was the sense in my interviews with women, that it was right and commonly understood, that the baby's health should trump over their own during the pregnancy and that medications sometimes perceived as playing a role for their long-term health could be forsaken for the short-term. However many women acknowledged the inherent contradictions and struggles in knowing how to best balance looking after themselves in order to safeguard the pregnancy(19).

Women in my study balanced these concerns against the perceived need for medications and risks of hypertension during pregnancy when making decisions about how to use their antihypertensives. Similar to the general adult population with hypertension(270), many women put store by the advice they received from their treating clinicians, and described trusting "*they know best*" and "[they] *wouldn't recommend anything harmful*". For some this represented a more passive role in relation to making decisions around medicines, preferring to defer to their doctor's advice. Pregnancy may impact on this preferred passive role, being experienced as a

highly vulnerable, emotive, high-stakes life-event(274, 362). Women weighed up information from several sources(19) which extended to other clinicians including their GP and pharmacist, friends and family and online professional pages and blogs(19, 348).

Women's previous experience with either HDP or medication in pregnancy could impact on their current medication decisions depending on the degree of similarity and their understanding of these previous events. Similar blood pressure trajectories, medication types and doses to previous pregnancies with good outcomes were reassuring. Also within the current pregnancy journey, our longitudinal data including repeat observations and informal interviews, showed how women's confidence in taking medication could grow with help from supportive clinician relationships, with a pregnancy apparently progressing healthily and with repeatedly reassuring growth scans. Although I did not find any between-group differences for either the Beliefs about Medications Questionnaire (BMQ)(202, 363) or Medication Adherence Rating Scale (MARS)(203), possibly reflecting the small sample sizes (n= 158) in the feasibility study, there was a general trend across groups for increased need and reduced concerns scores within the BMQ as pregnancy progressed (see Chapter 2). The constructs within the BMQ and Bandura's social cognitive theory (SCT)(197), describe how individuals balance perceived risks and benefits. My qualitative findings provide a possible explanation for this increasing trend in BMQ scores, describing the changing and possibly more favourable perceptions of women about taking medication as their pregnancy progressed.

Due to their concerns around using antihypertensive medications in pregnancy, several women in our study described deliberately choosing to avoid or reduce their treatment. This is a well-recognised phenomena in the general adult population with chronic hypertension, with poor adherence with antihypertensive medications converging on 50-60%(269-271). Similarly poor adherence rates are reported in the scant literature within pregnancy(356, 358). A multinational online survey which included 210 pregnant women reporting chronic condition medication use,

found that in women reporting cardiovascular disorders 33% had "low" medication adherence measured with the 8-item Morisky Medication Adherence Scale (MMAS-8), and this increased to 43% when considering asymptomatic conditions such as hypertension(356). Strong determinants of low adherence included previous children, which the authors considered might reflect previous good pregnancy outcomes without adhering to medication, and pregnancy-specific beliefs about medication: "*it is better for the fetus to abstain from using medication whilst pregnant despite being ill*" and "*herbal remedies should be preferred to conventional medications during pregnancy*"(356). These sentiments were echoed in my data. In contrast, Webster et al(364) measured antihypertensive medication adherence using liquid chromatography mass spectrometry on spot urine samples collected from 74 pregnant women with chronic hypertension randomised to either labetalol or nifedipine as part of the PANDA trial(365). The authors found 88% (65/74) concordance between documented prescribing and urine drug metabolites, commenting that these high rates of concordance might reflect selection bias for those willing to take part in a medication trial in pregnancy.

Women's home blood pressure monitoring had an important influence on their understanding of the effects of their antihypertensive medications. As proposed by the social cognitive theory model, for women who were able to see rising home and clinic readings and in turn were able to measure lower home readings after taking their antihypertensive(s), there was reassurance that taking their antihypertensive medication 'worked'. However, for those with home readings in the 'normal' range for at least some of the time, and/or who did not discern any appreciable improvement in their home or clinic BP when taking their antihypertensive(s), there was no such reassurance. Some women described in their interviews (and sometimes observed during consultations) using their home readings to support taking their medication flexibly, and presented this as a responsible and common-sense approach. And for those who described forgetting to take some doses, home monitoring could act as a reminder.

There are no previous literature describing the effects of SMBP on women's medication-taking behaviours in pregnancy. In the general adult population with chronic hypertension, there are mixed findings regarding the effectiveness of SMBP (alone or with co-interventions) for improving medication adherence(198, 366-368). Recent meta-analyses of intervention studies designed to increase medication adherence in chronic disease, found small to medium effect sizes for theory-based interventions that targeted self-regulation, self-monitoring and self-management and personalised feedback(369, 370). Instead, the largest effect sizes were seen for interventions based on the Health Belief Model, although the meta-analysis which included 124 reports and 19,348 participants did not include any studies within pregnancy(369). My interviews with women strongly suggest there are unique motivations and health beliefs around taking medications in pregnancy. This will have important implications for the design and delivery of any interventions (at least partly) aimed at improving antihypertensive medication adherence within pregnancy.

Clinicians in my study acknowledged the considerable dilemmas faced by women when making decisions around their medications but also described grappling with the relative dearth and limitations of effectiveness and safety research for antihypertensive use in pregnancy. Likely due to safety concerns around enrolling pregnant women on drugs trials there has been a previous reliance on observational data for informing treatment choices in pregnancy(371). More recent observational studies have sought to use detailed large datasets to overcome confounding by indication which historically plagues pharmacoepidemiology, and have found compelling evidence for the association of hypertension itself, rather than antihypertensive exposure, with specific birth defects(107, 372) and also possibly longer term increased cardiovascular risks for offspring(83, 84, 373). Clinicians in our study also acknowledged the challenges in recommending medication when women had home readings in the 'normal' range for at least some of the time. This echoed similar dilemmas raised by clinicians involved in the CHIPS trial who despite

knowledge of the trial's results, were uncertain about offering "tight" BP control, recognising women's reluctance around taking medications in pregnancy(303).

During consultations I observed clinicians trying to reassure women by citing guidelines, licensing and their professional experience with antihypertensive use and control in pregnancy. However during interviews, women described wanting to know more about possible *specific* risks to the baby associated with antihypertensive use. Previous literature indicates that women feel they have not received adequate information about medication risks in pregnancy(374, 375). This has emphasised the importance of *balanced* and *full* information around risks and uncertainty and that withholding this does not meet women's information needs or reduce their concerns(340, 376). Women might not always raise specific concerns and clinicians have been advised to actively and repeatedly ask about medication information needs(340, 359). Similar to previous findings(19), our data supported the importance of *consistent* information about medication risks from different health care professionals. Damaged trust and considerable distress could result from conflicting advice from antenatal and neonatal teams about the possible effects of antihypertensive medications for the newborn. These formative experiences will be taken into any future pregnancies where the woman is likely to also require antihypertensive medication. Two large RCT studies in the pipeline evaluating treatment of hypertension in pregnancy should help clinicians and women sharing decisions around hypertension management(377, 378).

8.3.8 Discussing risks about antihypertensives in pregnancy

Even when RCT data become available, there are challenges in discussing and extrapolating average findings from trials to the individual patient. Women discussing preferred treatment options for hypertension in pregnancy value individualised information over "average" information(361). Blood pressure self-monitoring may have a particular role here, as it allows for a more individualised approach. Beyond involving women in their care, SMBP provides more granular data around *their* blood pressure level and response to medications. As my data have

shown however, access to their own readings, may encourage women to make decisions around medication that might not align with those of clinicians(269). Metcalfe et al elicited pregnant women's treatment preferences after providing information and assessing knowledge around hypertension-related health outcomes(348). They found only half (N=90, 49%) of women preferred "tight" BP control; the majority (N= 114, 62%) gave equal priority to pregnancy hypertension-related outcomes versus components of care (e.g. antihypertensive medications), 23% (N=44) prioritised avoiding early delivery and a sizeable minority (n=25, 14%) sought to minimise medication. How information is framed is also known to affect patient's (and clinicians') perceptions of treatment risks and benefits(379). Women provided with negatively framed information on fetal risk of a safe drug had a significantly higher teratogenic risk perception than those presented with positively framed information and where much less likely to want to take the medication(380). Patients from the general adult population with mild chronic hypertension were much less likely to opt for treatment when information was presented as a personal probability of benefit compared with when information was presented using average relative or absolute risk reduction models(381). Thus it is a challenge to know how best to fully and non-coercively inform women about the risks and benefits of both HDP and its treatment, but a decision support tool has recently been developed(382). My findings suggest that these conversations and ongoing shared-decisions can be facilitated and informed by BP self-monitoring.

8.4 Conclusion

My exploration of pregnant women's and clinician's experiences of using blood pressure self-monitoring, speaks to many of the uncertainties raised by the recent James Lind Alliance Priority Setting Partnership for pregnancy hypertension(383). This consensus building exercise emphasised the need for improved information, education and support of women with HDP. The accounts from and interactions between women and clinicians in my study were certainly infused

with uncertainty and informational gaps for women and their clinicians. However it is well known that information alone is insufficient to change perspectives and health behaviours(384).

The findings suggest that pregnant women with hypertension are highly motivated to use BP self-monitoring, in the context of balancing competing information, motivations and social roles. This enthusiasm for self-monitoring was in the context of valued continuity of care from expert clinicians. The joint goal for women and their clinicians is for a healthy mother and baby although there isn't always alignment about how best to achieve that, for example the differential privileging of home versus clinic BP readings or need for medication.

In the next and final chapter the qualitative and quantitative findings from this thesis are integrated to provide suggestions for further development of the intervention for a large randomised controlled trial and their implications for future research and implementation of BP self-monitoring in pregnancy.

Chapter 9: Conclusion

In this thesis I have explored the role of blood pressure self-monitoring in the management of hypertension in pregnancy. I used a mixed methods design which allowed a comprehensive and deep understanding of how the intervention operated in this context and allowed me to answer my original research objectives and contribute new insights from in-depth qualitative studies with pregnant women and their clinicians.

9.1 Findings for objective 1:

To test the feasibility and acceptability of a blood pressure self-monitoring intervention for the management of hypertension in pregnancy for use in a large randomised controlled trial (Chapters 2 and 3).

I designed and conducted the first published randomised controlled feasibility trial of blood pressure self-monitoring for the management of hypertension in pregnancy(209). The high recruitment (71%, 2.5 per site per month), follow-up (95%), adherence (~5.5 days per week with SMBP) and persistence rates (SMBP for >80% of time from enrolment) suggest that this is a feasible and acceptable intervention to trial on a larger scale. Acceptability of the intervention was also supported by there being no differences in reported anxiety or quality of life scores between randomised groups and greater preference and lower 'problem scores' for BP self-monitoring versus usual clinic monitoring.

There were no overall differences in BP control between randomised groups, although in women with chronic hypertension, there was a small but statistically significant increase in mean and time-weighted mean diastolic clinic BP for the group using self-monitoring versus usual care alone. This group also had a greater proportion of caesarean sections, and a trend towards higher rates of pre-eclampsia, greater proportion of babies born prematurely less than 34 weeks' and with reduced birth weight. These are likely chance findings given the small numbers involved in the feasibility study and it is unlikely these data represent iatrogenic complications from SMBP. There were no group differences for prescribing or medication adherence data. Safety data from

the trial were encouraging with no differences in reported rates of serious adverse events, although these relatively rare events are difficult to capture even in large trials. Overall findings from the randomised study suggest that this would be a feasible, acceptable and a safe intervention to trial on a larger scale in this context.

9.2 Findings for objective 2:

To explore participants' experiences of blood pressure self-monitoring within the feasibility study: how the intervention was perceived and used by pregnant women and their clinicians and the acceptability of the study processes (Chapters 4 and 5).

A deductive thematic analysis was performed using data from semi-structured interviews with pregnant women with chronic hypertension and their clinicians, together with field notes from ethnographic observations of antenatal consultations and informal interviews at these clinic visits.

My qualitative data provided considerable support for the broad acceptability of the intervention and trial processes to both pregnant women with chronic hypertension and their clinicians within the context of this trial. Women valued being able to monitor their own blood pressure, motivating them to join the trial and in some instances to continue monitoring into the postnatal period, or take up voluntary monitoring from within the usual care arm. Women used the intervention pro-actively to guide self-care practices such as resting more, and also experimented with different monitoring times, particularly around medication. Benefits were perceived in terms of safeguarding their pregnancy and doing what was best for the baby, and included: improved knowledge of their individual blood pressure, ability to interpret symptoms, a sense of control and reassurance. Women cited these benefits for their continued persistence with monitoring and those with poorly controlled or treated hypertension were also motivated to persist.

Women provided examples of disadvantages with SMBP, but these were theoretical in nature and did not chime with their own experiences. However some women were hesitant about making

contact with clinical services for borderline readings perceiving this was unnecessary, and one woman described becoming anxious and discouraged when she saw raised BP readings. Women were encouraged to seek advice and to use the intervention confidently and flexibly by supportive working relations with their clinicians. These relationships were highly valued by women and seen as integral to the intervention. Some women referred to the example of their gestational diabetes midwife, describing the benefits of access and a supportive on-going relationship.

Clinicians described the contribution of self-monitoring towards greater shared decision-making through providing additional contextual data without increasing clinical workloads. Methods for integrating home readings into clinical decisions varied, particularly around the meaning of isolated or few high clinic readings, causing some clinicians to consider white coat hypertension and treat less and others to aim for tighter blood pressure control. Clinicians were confident in using home monitoring to supplement usual practice but not to replace usual clinic visits and there were theoretical concerns that women might be falsely reassured by self-monitoring and then ignore important symptoms. But these concerns were not borne out by the interview data with women.

Participating women and clinicians shared both positive and negative experiences around the trial processes. All women found the monitor easy to use but experiences were mixed around the traffic light reporting system with some finding it complicated or onerous. Similarly, opinions varied around the paper diary with some women preferring this method and others rapidly adopting digital recording using their BP monitor memories or phones. Many women found repeat study visits and questionnaires time-consuming and this could be stressful. Three specific case examples were discussed which exposed potential weaknesses and limitations of the self-monitoring intervention.

9.3 Findings for objective 3:

To explore additional themes arising from further inductive analysis of the qualitative data focusing on different perspectives and meanings of women and clinicians in relation to self-monitoring blood pressure (results in Chapters 6 and 7).

The combination of observing clinics and informal interviewing along with formal interviews of women and their clinicians produced a wealth of data. Through an inductive thematic analysis of all these data, I was able to draw out more nuanced themes and some unexpected insights around BP self-monitoring in this context that might impact on the further development, implementation, efficacy and safety of blood pressure self-monitoring for the management of pregnancy hypertension. These findings may also contribute to our understanding of self-monitoring in general within the context of pregnancy.

Both parties shared the goal of guarding the safety of the pregnancy but when the two sets of BP readings were not closely aligned, women tended to privilege their home readings whilst clinicians took greater account of clinic readings. The differential 'trumping' of home versus clinic BP readings and potential tensions and ambivalence over management decisions could be explained within the constraints of what each party 'knew' and the meanings ascribed to the blood pressure measurements. Women had a lived experience of the variability of blood pressure, the white coat effect of stressful clinic visits exacerbated by anxieties over medication or admission, observed varied clinical practise and perceived risks associated with high blood pressure differently in and outside of pregnancy. Clinicians' knowledge incorporated professional norms bound by clinical guidelines based on clinic readings, an evolving and uncertain evidence base around 'tight' blood pressure control and wariness of being seen to 'ignore' contemporaneous raised clinic readings. Clinicians were ambivalent about the representativeness of home readings taken at rest times. Most clinicians had lived experience of caring for women

with rare but severe complications of HDP such as stroke, which shaped their perception of risk, but were very rarely mentioned in consultations.

Most women expressed concerns and unwillingness to take any potentially unnecessary medications, including antihypertensives in pregnancy. Women shared similar concerns to those expressed in the general adult population around tolerance and dependence and preferring 'self'-management with rest and 'natural' remedies. Specific medication concerns centred around possible harms, both acute and long-term, to the health of the pregnancy and baby. Women's views were shaped by: current and previous pregnancy experiences, balancing perceived risks with HDP and antihypertensives, moral identity concerns about taking medication in pregnancy and weighing up sometimes conflicting information from their direct and wider clinical teams. Clinicians sought to reassure women, citing guidelines, specialty experience with antihypertensive medications and improved outcomes with good blood pressure control. However clinicians described the challenges of making treatment recommendations that could be unpopular especially given an uncertain evidence-base.

Women self-monitoring blood pressure could find reassurance from feedback that treatment was beneficial and effective and through its strengthening patient-clinician therapeutic relationships. However, women sometimes used their own readings to justify avoiding or minimising their use of medication, especially when these measurements remained raised (suggesting it was not working) or they had home readings within the 'normal' range, (suggesting that medication was unnecessary). In this way BP self-monitoring might contribute to intentional reduced antihypertensive adherence and in some instances this may be appropriate but in others may act to worsen blood pressure control. My findings show that pregnant women who monitor their own BP, do so confidently in the context of a supportive patient-clinician relationship and rather than supporting any benefit in terms of reducing clinic visits, highlight the importance of

developing shared decision tools for ongoing conversations about managing hypertension in pregnancy.

9.4 Considerations of the COVID-19 pandemic

It is necessary to comment on the seismic societal and health care changes that have occurred in the last 18 months in response to the COVID-19 pandemic and which shape the implications of this study. Health systems have been reconfigured to provide more remote care with the aim of reducing transmission, but also there has been a reduction in health care-seeking likely for the same motivations. Specifically within maternity care, the RCOG rapidly mobilised BP self-monitoring as a means to provide safe care at a distance drawing on the learnings from this study amongst others(174).

The effects of COVID-related health-system pressures and changes on different patient groups are still unfolding and will be the subject of research for years to come. There is evidence of worsening global maternal and fetal outcomes during the pandemic(385) and UK qualitative analysis has revealed women's concerns around receiving remote antenatal care during COVID-19, with two-thirds reporting it provided "impersonal care"(386). There will be ongoing debate around the public and political appetite for continuing remote care and the resulting impacts on clinician-patient relationships, the appropriate emphasis on clinician expertise and the role and responsibilities of the 'expert patient', and what this means for satisfaction with care and health outcomes.

9.5 Implications for a large RCT and future research

The findings described in this thesis have several important implications both for the development of the intervention for a substantive large randomised controlled trial and for the role of SMBP, and self-monitoring more broadly, in the pregnant population:

- The randomised feasibility study showed that it was both feasible and acceptable to trial SMBP for the management of hypertension in pregnancy to both pregnant women and

their clinicians and that it was possible to collect and use routine clinical data, including clinic blood pressure, as study outcomes. It was also feasible to collect a range of additional questionnaire data pertaining to medication use and beliefs, anxiety and monitoring preference scores and quality of life profiles. However my qualitative analysis suggests that a future large trial design would benefit from reducing the frequency of antenatal study visits conducted solely for research study purposes; and where possible, quantitative data should be collected remotely and retrospectively in the postnatal period so as to avoid overburdening women participants.

- The quantitative and qualitative studies were able to recruit women from a range of ethnicities and socioeconomic and educational backgrounds which suggests that blood pressure self-monitoring is feasible and desirable for the wide range of women whose pregnancies are affected by hypertension and I was able to capture a plurality of perspectives and experiences. Technology in general and telemonitoring in particular are often touted as providing greater access and equity in healthcare(160). However, it is important to critically assess these claims and be mindful of unequal internet access and hidden normativity in functionality and delivery of these interventions(387, 388). One example of exclusionary practice is the restrictive eligibility criteria commonly used in evaluations or clinical pathways using remote monitoring(389). Our feasibility study did not translate materials for women whose first language was not English. A survey of health services research published in the *British Medical Journal* found that the minority of papers mentioned language, and over half excluded non-English speakers(390). Excluding these voices amongst research participants could compound inequity and fail to create and test (remote monitoring) interventions for the many that might benefit. Further development of the BP self-monitoring intervention should improve inclusivity, by evaluating different formats of information provision alongside/within the intervention including visual information and by providing non-English language options.

- Further technological development of the intervention is planned and broadly supported by women and their clinicians, and telemonitoring features should include clearer summarisation of the blood pressure data, blood pressure thresholds and suggested action for women. However, with the aim of delivering the broadest access to self-monitoring, a paper-based version of the monitoring diary with thresholds should still be offered alongside to accommodate women's preferences or technological resources.

Consideration should be given to using a BP monitor validated for use in pregnancy and pre-eclampsia, that incorporates safety features such as the BP traffic light system and contains some of the app functionality, which could also indicate to women without smart phones whether they need to make contact with health services for further assessment(391, 392).

- Specific case examples of women's hesitancy in making contact for borderline readings, or feeling discouraged or anxious with raised home blood pressure readings or losing impetus with self-monitoring with continued normal home measurements, suggest that motivational messaging within the telemonitoring app may be useful. Using experiences and learning from this study, the intervention was further developed and this functionality added to the app. Automated messages were developed with the aim of normalising, motivating and providing ongoing salience of blood pressure self-monitoring(393) and research will be required to test acceptability and effectiveness of these communications with women.

- My qualitative findings also demonstrated the importance of the wider context and infrastructure for the safe and effective implementation of a self-monitoring intervention. Clinicians within maternity assessment unit teams often provide the initial response when women make contact for out-of-range BP readings, symptoms or concerns and therefore it is vital they are aware of self-monitoring and receive specific training and support around the range of queries women might have and the appropriate clinical assessment and referral pathways.

- Further intervention development needs to consider and incorporate learning from instances where self-monitoring was more challenging, for example where socioeconomic pressures impacted on women's ability to monitor or their interpretation of raised readings, usually attributed to stressful life events and therefore sometimes perceived as self-limiting and low risk. I have demonstrated the importance of key patient-clinician relationships, particularly in these more challenging contexts, for supporting women to use the intervention confidently, flexibly and safely. Therefore consideration should be given for a large trial or for future implementation to the appropriate support for women with hypertension who are self-monitoring, that will include follow-up for missing or raised readings.

- The rich qualitative data provided insights into the different perspectives of pregnant women and their clinicians around (balancing) risks of hypertension and medication in pregnancy. Both parties need to be supported with sharing information and perspectives; women to feel able to talk about their lived experience, what is important to them, and concerns and questions, and clinicians to share their knowledge including areas of uncertainty within the evidence-base, and their professional experience. Further research is needed to develop and evaluate co-interventions that can be used alongside SMBP in pregnancy to help with these conversations and the formulation of concordant decisions, including educational resources and shared decision making tools(358, 382). Future research and service development also needs to consider innovative strategies for delivering some of these co-interventions outside of the time-bounded consultation, leveraging the learning from this study regarding perceptions, concerns and knowledge gaps alongside experiences of remotely delivering care during the COVID-19 pandemic(394, 395). This may involve further development of the telemonitoring app for digital provision of education and co-interventions but is also likely to be additionally/best delivered by interactions (remote or in-person) with trusted health professionals, for example using midwife-led peer-support groups.

- Observations of consultations revealed specific information gaps and inconsistencies, which were supported by women's interview reports, around wanting specific information around risks as well as benefits of antihypertensive medication in pregnancy, and the need for this information to be more personalised (where this might be available). Similarly, clinicians need to make women aware of all risks associated with HDP, including the rare but severe complications such as stroke, as 'protecting' women from this information may lead them to make only partially informed decisions around their home readings and their antihypertensive medications, leaving them more vulnerable. Clinicians in our study reported that these can be challenging conversations particularly when the knowledge base is incomplete, which further demonstrates the need for standardised information resources for use by all health professionals involved in maternity care.

- My qualitative findings highlight the need for more research into the meaning and implications of blood pressure variability in pregnancy, and specifically the role of both white coat and masked hypertension. This research should aim to define appropriate self-

monitoring regimes including diagnostic and blood pressure control thresholds for home and clinic measurements. I have been able to expose some of the differential trumping and privileging that occurs when home and clinic blood pressures are not closely aligned and the underlying differences in understanding and meaning of these data for pregnant women and their clinicians. These different viewpoints are more likely and conversations more challenging whilst the evidence base remains underdeveloped, but my findings can guide clinicians during these consultations, helping them to unpack and understand the possible perspectives of pregnant women.

- The specific perspectives and experiences of women with gestational hypertension using BP self-monitoring need similar attention, as these are likely to differ from women with usually a more longstanding diagnosis of chronic hypertension. The implementation of SMBP and co-interventions for this group of women might need to be tailored differently, given they often start their antenatal care under more generalist teams.

- The role of the patient-clinician relationship for effective and safe BP self-monitoring in pregnancy needs further research, to consider *when* and *if* this intervention is additional or in place of face-to-face care and what this means for relative responsibilities and implementation. The design of our blood pressure self-monitoring intervention allowed women flexibility and autonomy both in terms of their monitoring regime and in making contact with health care services. This compares with the few other studies in this area which describe health professionals remotely monitoring women's submitted daily home readings at fixed times, alongside a reduced visit schedule. These different formats for delivering and supporting SMBP in pregnancy will have profound effects on the roles and responsibilities for this intervention, both in terms of the processes of care but also for the possible psychological burden of pregnancy outcomes.

9.6 Final conclusion

The work presented in this thesis demonstrates the value of conducting a feasibility study as a necessary step before a large RCT. It also highlights the benefits and insights gained from combining observations and informal interviews with formal accounts of participant and clinician experiences of a complex health intervention, such as BP self-monitoring. My findings support

that blood pressure self-monitoring for the management of hypertension during pregnancy is feasible and acceptable to both women and their clinicians, when combined with clinic monitoring and holds promise for improving the significant maternal and perinatal morbidity and mortality associated with HDP. The intervention as described in this thesis would benefit from further development using the findings from the study together with learning from delivering some maternity care services remotely during the COVID-19 pandemic. Future research should focus on developing and evaluating supporting educational materials and co-interventions with BP self-monitoring to facilitate discussions about risk and shared goal-setting between women and their clinicians around the management of BP in pregnancy.

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Appendices

[1] Members of the PC-CTU and TMG *(Chapter 2)*

[2] OPTIMUM-BP feasibility study protocol *(Chapter 2)*

[3] Pregnant woman participant information sheet *(Chapter 2)*

[4] Clinician participant information sheet *(Chapter 2)*

[5] Pregnant woman optional interview participant information sheet *(Chapter 2)*

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[7] Baseline visit participant case report form *(Chapter 2)*

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[10] Publication of OPTIMUM-BP secondary analysis *(Chapter 2)*

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[12] Topic guide for interviews with pregnant women *(Chapter 4)*

APPENDIX 1: Members of the PC-CTU and TMG

Members of PCCTU and OPTIMUM-BP Trial Management Group (TMG)

Name	Role
Trial Management Group, NDPCHS	
Dr Louise Pealing	Chief Investigator
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Professor Lucy Chappell	Supervisor/Principal Investigator GSTT
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Primary Care Clinical Trials Unit, NDPCHS	
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NDPCHS: Nuffield Department of Primary Care Health Sciences, University of Oxford; GSTT: Guy's and St Thomas' NHS Foundation Trust; OUHT: Oxford University Hospitals NHS Foundation Trust; RWT: Royal Wolverhampton NHS Trust New Cross Hospital; KCHT: King's College Hospital NHS Foundation Trust.	

APPENDIX 2: OPTIMUM-BP feasibility study protocol

Date and version no: 12/09/2016_v2.0_REC: 15/EM/0490

Study Title: Blood pressure self-monitoring for the management of women during pregnancy with hypertension: a feasibility study

Internal Reference Number / Short title: OPTIMUM-BP: Optimising Titration and Monitoring of Maternal Blood Pressure

Ethics Ref: 15/EM/0490

Date and Version No: 12/09/2016 V2.0

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Chief Investigator Signature:	The approved protocol should be signed by author(s) and/or person(s) authorised to sign the protocol

No conflicts of interest.

Confidentiality Statement

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1. SYNOPSIS

Study Title	Blood pressure self-monitoring for the management of women during pregnancy with hypertension: a feasibility study	
Internal ref. no. / short title	OPTIMUM-BP: Optimising Titration and Monitoring of Maternal Blood Pressure	
Study Design	Feasibility study	
Study Participants	Pregnant women with hypertension	
Planned Sample Size	80 pregnant women with chronic hypertension and 80 women with gestational hypertension for the randomisation studies Including up to 40 women being interviewed. Additional 10-15 clinicians being interviewed.	
Planned Study Period	October 2015 to October 2018 (36 months)	
Primary research question	• How feasible is the BP self-monitoring intervention and the process of randomisation to self-monitoring in a group of pregnant women with hypertension?	**Outcome Measures** • Recruitment rate per site • Loss to follow-up • Adherence and persistence to self-monitoring protocol • Acceptability of randomisation
Secondary research questions	• Does the use of self-monitored BP readings improve BP control during pregnancy in women with hypertension?	Difference in mean and mean highest systolic blood pressure between groups post-randomisation
	• What is the relationship between self-monitored and clinic BP measurement during pregnancy in women with hypertension?	Difference in self-monitored and professionally measured BP during follow-up
	• Does SMBP improve antihypertensive medication adherence amongst pregnant women with hypertension?	Medication adherence in both groups recorded using MARS and BMQ questionnaires and pharmacy fill data at study follow-up visits
	• What is the effect of SMBP on antihypertensive medication use?	Defined Daily Dose of antihypertensive medication comparing intervention with usual care group
	• What are the effects of SMBP on health resource use and cost?	Number and cost of clinical contacts and admissions and their timing for out-of-range BP readings or all-causes for intervention and usual care groups

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	• How are self-monitored BP readings used in the management of hypertension during pregnancy?	Focused ethnographic study observing antenatal clinic and DAU/MAU consultations
	• What are the experiences of the participants and clinicians using the BP self-monitoring intervention?	Antenatal and postnatal health questionnaires Semi-structured Interviews with women and clinicians
	• What is the safety of an SMBP intervention in this context?	Reporting of serious adverse events and side effects
Exploratory analysis	• What are possible alternative measures for assessing BP control in a future trial?	Proportion developing clinically relevant hypertension in the SMBP and usual care groups (SBP≥150 or DBP≥100 mmHg) The percentage time in range and standard deviation for home and professionally measured BP readings

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2. ABBREVIATIONS

BP	Blood Pressure
CDMS	Computerised Data Management System
CHTN	Chronic Hypertension
CI	Chief Investigator
CRF	Case Report Form
CTRG	Clinical Trials & Research Governance, University of Oxford
DBP	Diastolic Blood Pressure
DAU	Day Assessment Unit
EQ-5D-5L	Standardised instrument for measuring self-reported current health status
EPAU	Early Pregnancy Assessment Unit
GCP	Good Clinical Practice
GP	General Practitioner
GH	Gestational Hypertension
HDU	High Dependency Unit
HTN	Hypertension
ICF	Informed Consent Form
ICH	International Conference of Harmonisation
ICU	Intensive Care Unit
LDU	Low Dependency Unit
Revised-MARS	Revised-Medication Adherence Rating Scale
MASES	Medication Adherence Self-Efficacy Scale
MAU	Maternity Assessment Unit
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NRES	National Research Ethics Service
PC-CTU	Primary Care Clinical Trials Unit, University of Oxford
PIL	Participant/ Participant Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SAE	Serious Adverse Event
SBP	Systolic Blood Pressure
SD	Standard Deviation
SMBP	Self-Monitoring Blood Pressure

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SOP	Standard Operating Procedure
TMG	Trial Management Group

3. BACKGROUND AND RATIONALE

Hypertensive disorders affect 1 in 10 pregnancies and cause significant global maternal and child morbidity and mortality[1, 2]. These disorders include maternal chronic hypertension and new-onset gestational hypertension and both these conditions can progress to severe hypertension, pre-eclampsia and eclampsia. Possible effects on the mother include renal, liver and clotting failure, seizures and cerebrovascular events. Potential effects on the child include intrauterine growth retardation, pre-term delivery and stillbirth.

Chronic hypertension complicates 1-5% of pregnancies[3, 4] and in the UK, pre-eclampsia affects 2-8% of all pregnancies, but up to 25% of pregnancies in women with chronic hypertension[5]. Both globally and in the UK, the number of women entering pregnancy with chronic hypertension is expected to rise as women delay motherhood and obesity rates continue to increase[6-8]. In turn, this will impact the number of pregnancies complicated by severe hypertension and pre-eclampsia/eclampsia. Gestational hypertension (where blood pressure is raised without the presence of proteinuria) is similarly a risk for pre-eclampsia and affects more women than chronic hypertension[9].

There is currently no reliable test to predict which pregnancies will be affected by severe hypertension or pre-eclampsia and are high risk for subsequent complications. Current diagnostic strategies rely on regular blood pressure and urinary protein monitoring at antenatal clinics. But there is evidence that pre-eclampsia can develop between antenatal visits and increasing clinic surveillance for high risk groups can place great demands on the woman and health system.

Earlier detection of rising blood pressure and its progression to severe hypertension and/or pre-eclampsia could reduce complications to the mother and child. But this requires novel approaches. Self-monitoring of blood pressure (SMBP) both as a diagnostic tool and for titrating antihypertensive medication using home readings might be one such approach[10]. Self-monitoring also places women at the centre of their own care, and potentially offers efficiency and economic benefits for the health service.

Literature describing SMBP in the general adult population suggests that self-monitoring improves adherence to antihypertensive medication[11]. SMBP may also encourage healthy behaviour changes[12] and participants report high satisfaction with, and preference for, these methods[13]. These effects can result in reductions in both mean systolic (3.4 mmHg) and diastolic (2.4 mmHg) measurements in the short term[14]. Further reductions in blood pressure occur when clinician behaviours are also targeted, using telemonitoring and/or medication titration to home readings[13, 15]. In the general population, guidelines advise using a lower target for self-monitored blood pressure measurements of 135/85 mmHg as equivalent to clinic measurements of 140/90 mmHg allowing for a white-coat effect seen in hypertensive populations[16, 17].

There are few previous studies exploring the role of SMBP during pregnancy[10, 18-21]. A recent pilot study of initially normotensive women, selected for monitoring on the basis of higher risk for pre-eclampsia, suggests that self-monitored measurements are equivalent to clinic blood pressure readings throughout pregnancy[22]. In the same study, women found a 3x per week BP self-monitoring regimen to be acceptable and achievable. Diagnostic thresholds for home readings were set at the clinic level. On average, clinically important increases in blood pressure were detected around two weeks earlier using home readings compared with clinic visits (results being prepared for publication).

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Pregnant women with chronic hypertension (both pre-existing and diagnosed before 20 weeks pregnancy) and gestational hypertension (new hypertension after 20 weeks) are groups that might benefit from self-monitoring for improved blood pressure control and early detection of clinical deterioration. Anecdotally a number of UK antenatal clinics are already using SMBP for selected women with hypertension, but this is on an ad hoc basis and there are no clear guidelines on how home BP readings should be used in this context. International data also suggest that BP self-monitoring in hypertensive pregnancies is increasing, with one Canadian study finding a prevalence of 40%[23]. Both women and clinical teams recognise the potential utility and convenience of SMBP during pregnancy but there is currently little evidence base to help inform the use of this intervention and its impact for participants and the health service. There is now a window of opportunity for investigating the role of SMBP in pregnancy with growing patient awareness, clinician use and a burgeoning technology market for pregnancy monitoring applications before it is incorporated into clinical practice by default but without evidence.

There are several areas of uncertainty in the clinical management of pregnant women with hypertension that could affect the design and evaluation of a BP self-monitoring intervention:

- There are no internationally agreed thresholds for starting antihypertensives or blood pressure targets when treating pregnancy hypertension[24-28]
- The few studies describing the use of SMBP in pregnancy do not compare home and clinic blood pressure readings throughout pregnancy for the hypertensive group. These data would help identify the presence and impact of any white-coat effect in these groups, which in turn could aid clinicians' interpretation of home blood pressure readings
- It is not clear what the optimal antihypertensive to use in pregnancy is - and whether this differs between ethnic groups[29, 30]
- Finally, there are no robust data describing adherence to antihypertensive medication during pregnancy. Evidence from the general adult population suggests patients on average have possession of medication only 50% of the time and 20% have sufficient adherence to derive any benefit[11]. And self-report evidence from the few studies looking at general medication behaviour in pregnancy found adherence rates of only 40-60%[31].

An appropriately designed SMBP study might help evaluate and address some of the uncertainties and obstacles to optimal antenatal blood pressure control in women with hypertension.

The proposed study will assess the feasibility of using SMBP in the management of pregnant women with hypertension. We will use the framework described in the MRC guidance for developing and evaluating complex interventions[32-35]. Process measures will include investigation of possible intervention mechanisms, such as improved medication adherence and timely medication changes by clinicians. Using SMBP to manage hypertension during pregnancy will require behaviour change from pregnant women and clinical teams along with health system changes and will fundamentally influence their interactions. Embedded qualitative studies will help us understand the context, current practice and views of women and clinical teams to identify potential facilitators and barriers for the successful implementation of an SMBP intervention.

Should the intervention be acceptable and feasible, it will then be optimised for use in a future randomised controlled trial to investigate the effectiveness and cost-effectiveness of SMBP for titrating antihypertensive medication during pregnancy complicated by hypertension.

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4. OBJECTIVES AND OUTCOME MEASURES

Specific objectives and outcomes for this feasibility study are described in the table below. The overall objectives of this feasibility study are:

- **Scientific:** selection of the most appropriate outcome measure for BP control for a future large randomised controlled trial, estimate of parameter standard deviations for sample size calculation for a future trial and safety of intervention;
- **Process:** recruitment, retention and adherence rates; acceptability of the intervention and randomisation; integration into health systems;
- **Resources:** appropriateness and time required for study procedures; testing of medication adherence measures; NHS resource use
- **Management:** centre willingness and capacity; testing of data collection forms and data management system.

Objectives	Outcome Measures	Time point(s)
Primary Objectives		
Feasibility of study (for two groups: those with chronic hypertension and those with gestational hypertension)	Recruitment rate: ○ *Number of participants recruited per site per month, including as proportion of those who were approached and eligible* Loss to follow-up: ○ *Number lost to follow-up after delivery/number of participants recruited* Withdrawal rate: ○ *Number withdrawing consent/number of participants recruited* Adherence and persistence with self-monitoring protocol: ○ *Proportion of intervention participants completing no home BP measurements* ○ *Number of home BP measurements/protocol total measurements for time in study* ○ *Proportion persisting with home BP measurements (at least one reading per week) by week* Acceptability of randomisation: ○ *Proportion citing randomisation as reason for non-participation* ○ *Proportion in usual care arm starting home BP monitoring post-randomisation* ○ *Theme for postnatal interviews*	Recruitment will be assessed continuously Other outcomes will be evaluated at the end of the study

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Objectives	Outcome Measures	Time point(s)
Secondary Objectives		
Does the use of self-monitored BP readings improve BP control during pregnancy?	Difference in mean and mean highest systolic blood pressure between groups post-randomisation	End of the study
What is the relationship between self-monitored and clinic BP measurement during pregnancy in women with hypertension?	Difference in self-monitored and professionally measured BP during follow-up: ○ *Difference in mean BP measured at nearby time-points in the intervention group*	End of the study
What is the medication adherence amongst pregnant women with hypertension comparing BP self-monitoring and usual care groups?	• Medication adherence and persistence recorded using repeat MARS[36] and BMQ[37] questionnaires for each group • Pharmacy fill data for the two groups	End of the study
What is the effect of SMBP on antihypertensive medication prescribing?	Defined Daily Dose of antihypertensive medication comparing intervention with usual care group	End of the study
What are the effects of SMBP on health resource use?	Number and NHS costs of clinical contacts and admissions and their timing for out-of-range BP readings or all-causes for both groups	End of the study
How are self-monitored BP readings used in the management of hypertension during pregnancy?	Focused ethnographic study observing antenatal clinic, MAU and DAU consultations	During and at end of the study
Women's and clinicians' experience of the BP self-monitoring intervention	• Antenatal and postnatal EQ-5D-5L[38] and short-STAI[39] participant quality of life questionnaire • Postnatal Little questionnaire[40] • Semi-structured interviews with women and clinicians (as part of the ethnographic method)	Start and end of the study
Comparison of safety between the control and intervention groups.	Reporting of serious adverse events (including maternal and fetal delivery outcomes) and side effects comparing between the two randomised groups and the observational group	Throughout study
Exploratory Analysis		
What are alternative measures for assessing BP control in a future trial?	• Proportion developing clinically relevant hypertension in the SMBP and usual care groups (SBP≥150 or DBP≥100 mmHg) • Calculating percentage time in range and measures of BP variability including standard deviation using both SMBP and clinic BP	End of the study

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5. STUDY DESIGN

This feasibility study follows a mixed methods design. We will conduct a non-blinded randomised controlled feasibility study with automated assessment of blood pressure and parallel qualitative studies. A study flow chart appears in Appendix A.

5.1. Intervention Study

This study will be a multicentre trial, to aid recruitment and test the feasibility of conducting a future large multi-centre trial. Furthermore, complex interventions are sensitive to context and different facilitators and barriers will likely be identified in the different settings, which will inform the iterative development of the intervention.

The study is pragmatic and designed to reflect real clinical practice in order to be scalable for a future trial and so the intervention, if proved effective, has the potential for being integrated into clinical care.

The nature of the intervention precludes blinding but where possible blood pressure outcomes will be measured using a validated automated electronic sphygmomanometer to reduce bias.

All eligible women with pregnancies complicated by hypertension will be invited to participate in the study. The blood pressure self-monitoring intervention will occur in *addition* to all usual care. Women will be randomised to either the blood pressure self-monitoring intervention or usual care.

We expect that some women may have strong preferences for either one of these study arms and in the case where women are not willing to be randomised they will be invited to join and provide informed written consent for an observational arm where we will collect their pregnancy outcome data to assist assessment of generalisability and safety. The observational arm will contribute data around acceptability of the intervention, in the case where it identifies a group markedly different from the group willing to be randomised, and safety, should we see marked differences between delivery outcomes between the randomised and observational arm related to the sorts of women that choose to enter the randomised part of the study. We do not expect any adverse events to arise from any aspect of the interventional study or the qualitative elements of the study.

Women enrolled into the BP self-monitoring group will be loaned an automated blood pressure monitor, (for example the Microlife WatchBP Home™), which has been validated for use in pregnancy and pre-eclampsia[41]. Women will be trained how to measure their blood pressure, and will be asked to measure their blood pressure daily. Data from each individual's blood pressure machine will be directly uploaded to the study database at follow-up visits. Women will be provided with a diary for recording their home BP readings and actions taken for any out-of-range BP readings. The diary will also contain a free-text section to record any thoughts about BP monitoring or decision-making processes around the protocol. The participant diary will be attached to the maternity notes and will be printed on two-part carbonless copy paper (CCP) to allow one copy to be retained in the participant's maternity notes and one to be collected by the study team at follow-up visits.

We will ask women to measure their BP at home every day aiming for the same time each morning if possible, from enrolment until delivery, and to bring their readings (as part of the maternity notes) with them to all clinical assessments. Two readings will be required each time because blood pressure decreases on repeated measurement. Daily readings will be requested as this will provide close monitoring for the women and it is expected a daily routine within the same context may be more habit forming[42, 43] than an intermittent

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regimen. However, women will be counselled to complete what they can manage alongside their usual activities, aiming for at least three BP measures weekly if possible. One of the outcomes of this study will be to explore the feasibility and adherence to the BP monitoring protocol. Women requiring admission to hospital or additional clinician-led monitoring will be asked to continue SMBP if they are willing and able to do so.

Women will be provided with a chart within their maternity notes describing the target BP range and the BP readings or symptoms which should trigger them to seek clinical advice or assessment and how and when to do this. Clinicians will have access to the same charts which they can use when interpreting women's home and clinic blood pressure readings and making management decisions. The option of using a telemonitoring system (as previously used in our home monitoring BuMP study in pregnant women at higher risk of pre-eclampsia (https://www.phc.ox.ac.uk/research/hypertension/pregnancy/bump) will be offered to women with gestational hypertension. In the telemonitoring system the self-monitoring BP data will be communicated centrally through the use of a smart phone app or text messaging based system. This service will respond to participants regarding the level of their BP and what action is required (if any).
Women randomised to usual care will have their blood pressure measured by the health care professional as usual during routine antenatal assessments.

Study visits will occur at extended routine antenatal appointments at: enrolment (booking-23+6 weeks, clinical terminology for 23 weeks and 6 days gestation for women with chronic hypertension; booking between 20 and 37+6 weeks gestation for women with gestational hypertension), 20, 28, 34 and 6 weeks postnatal, within 3 weeks either side of these gestations to reflect the practicalities of routine clinical care. The initial study visit will be up to 40 minutes including explanation of the study, gaining informed written consent, training in BP self-monitoring for those in the intervention arm and completion of the baseline questionnaires. Subsequent follow-up visits including download of the BP monitor memory, collection of participant diary counterfoils, medication adherence questionnaires and study BP measurements will be up to 15 minutes.

At baseline, women will be asked to complete the EQ-5D-5L[38] questionnaire to assess current health status and the short State-Trait Anxiety Inventory (STAI) questionnaire to assess anxiety[39]. Self-reported medication adherence and persistence, and beliefs about antihypertensive medications will be assessed at the follow-up visits using the MARS[36] and BMQ[37] scales respectively. Acceptability of the intervention will also be measured in the self-monitoring group by the Little questionnaire[40] in the postpartum period.

5.2. Qualitative Studies

Alongside the intervention study, we will employ focused ethnographic methods to understand beliefs and practices around the management of hypertension in pregnancy and how the BP self-monitoring intervention is integrated into antenatal care. Focused ethnography is a time-limited, usually intermittent, exploratory study within a discrete group or context[44]. Our focused ethnographic method will use participant observation (here antenatal consultations and assessments) and semi-structured interviews with the clinicians and women involved in our intervention study.

The qualitative methods are described in more detail in section 9.

6. PARTICIPANT IDENTIFICATION

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6.1. Study Participants

Pregnant women with a diagnosis of chronic or gestational hypertension attending for antenatal care at the study sites.

6.2. Inclusion Criteria

- Women with **chronic hypertension** (defined as sustained diastolic BP≥90 mmHg and/or systolic BP≥140 mmHg, measured in the standardised fashion (section 7.6) present at booking or before 20 weeks gestation, or receiving treatment outside pregnancy and/or at time of referral)
- Recruited at booking-23+6 weeks gestation

OR

- Women with **gestational hypertension** (defined as sustained diastolic BP≥90 mmHg and/or systolic BP≥140 mmHg, measured in the standardised fashion (section 7.6) after 20 weeks' gestation without the presence of proteinuria
- Recruited at 20+0 to 37+6 weeks' gestation

In either case additionally:

- Viable singleton pregnancy
- Willing to be randomised
- Able to give informed written consent
- Age ≥ 18 years

6.3. Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

- Unwilling to self-monitor
- Insufficient understanding of the study
- Confirmed superimposed pre-eclampsia (as defined by the International Society for the Study of Hypertension in Pregnancy (ISSHP) 2014 statement) at time of enrolment.

Inclusion criteria will be the same for women enrolling into the observational group, except that they are not willing to be randomised.

Clinicians enrolled in the study for the clinician interviews will be from the clinical team (Obstetricians and Midwives) involved in the care of pregnant women with hypertension at the study sites.

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7. STUDY PROCEDURES

A schedule of procedures is attached in Appendix B.

7.1. Recruitment

Women receiving obstetric care at participating hospitals will be approached. The study will be advertised through posters and information leaflets in participant and clinic areas. We will also provide clinician information leaflets and presentations before and during the study to raise awareness and explain study procedures including refresher sessions for standardised BP measurement.

The clinical team may initially identify potential participants through GP referral letters, antenatal booking and follow-up visits, Early Pregnancy Assessment Unit (EPAU) and DAU/MAU attendances. Women with hypertension may be triaged to a medical obstetrics clinic at the study hospitals so it is likely they will be identified in these clinics. The clinical team will provide potential participants with a study information leaflet and will take verbal consent to share the details of interested women with the research team. These women will then be consented and screened for their eligibility by the research team.

We aim to follow women for a maximum of 44 weeks (from an 8 week booking appointment up to 12 weeks post-delivery interview).

Women who decline to participate in the randomisation study (who may not wish for any involvement or to enrol as part of the observational group) will be asked if they would volunteer any information around their decision so that the study design can be improved in the future to reflect and accommodate women's needs and priorities. These data are also to be used as part of the primary objective of assessment of acceptability of the intervention. If women are willing to volunteer this information they will be asked to complete a short anonymous tick list.

7.2. Informed Consent

A participant must sign and date the most recent approved version of the Informed Consent Form (ICF) prior to any study related procedures, including screening for eligibility.

Written and verbal versions of the Participant Information and Informed Consent will be presented to women detailing no less than: the exact nature of the study; what it will involve for them; the implications and constraints of the protocol, and any risks involved in taking part. It will be clearly stated that they are free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as they wish to consider the information, and the opportunity to question the Investigator, their obstetric team, or other independent parties to decide whether they will participate in the study. Written informed consent will be obtained by the participant signing and dating the ICF which must also be signed and dated by the person who obtains consent; this will be the PI or HCP with delegated authority. A copy of the signed ICF will be given to the participant. A further copy will be included in their maternity records and the original will be stored at the PC-CTU (with participant's consent).

Clinicians consenting to participate in the clinical observations and structured interviews will keep a copy of the signed and dated ICF and the original will be stored at the PC-CTU (with their consent).

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The focused ethnographic methods will be described in the Clinician and Participant PILs and will form part of the main study ICF. We will reconfirm verbal consent for observations and interviews prior to their use.

7.3. Screening and Eligibility Assessment

Following consent, screening will involve collecting information on: participant demographics including age at entry (years and completed months), self-identified ethnicity[45], weight and height at booking (calculating BMI), medical and obstetric history, current gestation, medication, allergies, social history and socioeconomic status. We will ask women whether or not they are involved in any other medical research studies. Involvement in other research studies does not exclude women from our study.

Further details on the diagnosis of hypertension will be recorded from direct questioning or from the maternity record with participant consent:

- Date of HTN diagnosis (nearest year if known pre-pregnancy or gestation if diagnosed in this pregnancy)
- Blood pressure at diagnosis (if HTN diagnosed this pregnancy)
- Date when any antihypertensive medication started (nearest year or gestation)
- Currently used antihypertensives if relevant
- Current dosage and any changes so far this pregnancy if relevant
- Antenatal referral blood pressure (if known)
- If self-monitoring blood pressure now or in the past and if so details of BP machine and previous readings if known
- Current clinic blood pressure reading and urinalysis (see 7.4).

After confirming all eligibility requirements are met, personal data will be collected to enable contact during the study and to arrange home follow-up visits in those taking part in the interviews. This data will be stored separately at the PC-CTU:

- Full name and address
- Home and mobile telephone number(s)
- Email
- Hospital medical record number (to allow access to medical records for collecting study outcome data).

Women consenting to be part of the observational arm will have their eligibility assessed in line with the criteria detailed in section 6, but will not attend for any study visits, however the consultations may be observed (see section 9).

7.4. Randomisation, masking and code breaking

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A secure web-based randomisation system will be provided by the Oxford PC-CTU. Women will be allocated to one of the two study groups: self-monitoring or usual care on a 2:1 basis respectively with allocation stratified for recruitment site.

Due to the nature of the intervention it will not be possible to mask the participant, the recruiting clinician or research team. At the end of the study a masked end-point committee of experienced Obstetricians, will determine if a participant developed any superimposed pre-eclampsia or other pregnancy-related hypertensive complication.

There will be no code breaking procedure as study follow-up is not masked.

7.5. Usual Care

Routine antenatal visits (i.e. not related to this study) for all pregnant women with hypertension following diagnosis, usually include (as a minimum):

- Booking, 12, 16, 20, 24, 28, 32 weeks
- Then every 1-2 weeks until delivery
- 6 weeks postnatal.

Visits might occur within +/- 2 weeks of stated gestation and additional visits might be required for closer monitoring or investigation. These appointments will take place in the study hospitals except for the postnatal visit which women may choose to have at home.

At the clinic visits, the following would and will be *routinely* performed for women with hypertension:

- Up to three BP readings taken in standardised format
- Urinalysis by dipstick +/- laboratory protein estimation if indicated
- Discussion around any medication (including antihypertensives) side-effects and adherence, if relevant
- Any changes in medication doses, if relevant
- Recording of adverse events (maternal or perinatal)
- Routine blood tests at booking, 12, 20, 28, 34 weeks gestation, at any assessment for suspected pre-eclampsia or other pregnancy-related complication.

7.6. Baseline Assessments (study visit 1)

This assessment will take place at enrolment (CHTN: booking (if < 20 weeks) up to 23+6 weeks gestation; GH 20-37+6 weeks).

In addition to routine care and tests described above, baseline procedures will include:

- Quality of life (EQ-5D-5L) questionnaire[38]
- Short questionnaire on anxiety: STAI[39]
- Medication adherence questionnaires for those taking medication: MARS[36] and BMQ[37]
- Measurement of participant's left mid upper arm (right if left cannot be used) to provide them with the correct blood pressure cuff size for use in clinic and with their home monitor if in intervention group
- Blood pressure will be checked using an automated validated monitor (for example Microlife WatchBP Home™) using the following standard procedure:

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- Participants should have rested for 5 minutes
- Sitting with uncrossed legs, feet on the floor
- The arm should be supported so that the cuff is at the level of the heart (use the same arm and cuff size throughout and recorded on the CRF)
- The appropriately sized cuff should be fitted snuggly before inflating
- Three BP readings will be recorded with approximately 1 minute interval between
- The study outcome measure of BP control will use the mean of the second and third readings where these are available.

If the screening questionnaire has been completed at an earlier visit then any intervening changes to antihypertensive medication or new side-effects will be recorded. At the baseline visit participants will be randomly allocated to the SMBP or usual care groups. Participants in the SMBP group will be provided with their own BP monitor and taught how to use it. It will be emphasised that the home monitor is for their use only and to avoid family members/friends using it to preserve data validity.

7.7. Subsequent Visits (study visits 2-5)

Study specific follow-up will occur as extensions of the following routine visits (+/-3 weeks):

- 20 (study visit 2) – if participant recruited before this gestation
- 28 (study visit 3)
- 34 (study visit 4)
- 6 weeks postnatal (study visit 5) will also be offered

Participants with gestational hypertension will only attend those that follow the point of randomisation.

At each study follow-up visit, the participant will be seen by a member of the research team and their eligibility and consent verbally confirmed.

At each study visit the following will be recorded in addition to usual care:

- Any problems with the SMBP intervention (if in intervention arm)
- Recording details of any DAU/MAU visits or admissions
- Counterfoil of participant BP diary from preceding weeks
- Up to three BP readings will be recorded using the standard procedure and validated BP monitor (see 7.6)
- Repeat medication adherence questionnaires (visits 3 and 4)

Before each study follow-up visit, women will be contacted by the research team to remind them to bring their BP monitor. Data will be uploaded from the device to the study database.

After discharge following delivery, additional information will be recorded (mostly from the medical record) or by contacting the participant:

- Gestation at delivery
- Mode of delivery
- Development of maternal complications (see section 10.2)
- Birth weight and centile
- If fetal demise: intrauterine fetal death or intrapartum stillbirth

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- Neonatal death
- Any admissions with dates to Special Care Baby Units (ICU, HDU or LDU)
- Length of postnatal hospital stay for woman and baby
- Repeat quality of life (EQ-5D-5L) and anxiety (STAI) questionnaires
- Intervention acceptability measured by the Little questionnaire in the self-monitoring group.

We will request that women return the blood pressure monitors and will arrange the timing of the visits for those consenting to participate in the qualitative interviews. This optional study visit (visit 6, or it may coincide with the six week postnatal visit 5 if the participant prefers this) will take place in the woman's home (or clinic if she prefers) and is anticipated to occur around 6-12 weeks postnatal depending on availability and convenience for the participant.

Semi-structured interviews with consenting clinicians will take place in hospital throughout the intervention study and at convenient times for the clinical team.

7.8. Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. In addition, the Investigator may withdraw a participant from the study at any time if the Investigator considers it necessary for any reason including:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Withdrawal of Consent

If a woman withdraws or is withdrawn from the study at any point her usual antenatal care will continue as all study procedures are additional rather than in place of usual care.

We will request consent to continue to include previously recorded study data and record minimal outcome data from the medical notes of women who choose to withdraw from the study, in accordance with HRA guidance (http://www.hra.nhs.uk/documents/2013/09/information-sheet-and-consent-form-guidance.pdf) which describes the different possible types of participant withdrawal.

Withdrawn participants will be replaced if there is sufficient time to recruit new participants in the existing study time-line. Women who wish to withdraw only from using the blood pressure self-monitoring intervention will be asked if they are prepared to continue to attend study follow-up visits. Any withdrawals will be recorded as part of our primary feasibility endpoints.

Women who withdraw from the study will be asked if they would volunteer any information around their decision so that the study design can be improved in the future to reflect and accommodate women's needs and priorities and to assess acceptability of the intervention/study procedures (as described in section 7.1). If women are willing to volunteer this information they will be verbally consented for this specific process and will be asked to complete a short anonymous tick list.

7.9. Definition of End of Study

The end of the study is when the last woman is followed up including the final semi-structured interviews, data queries have been answered and the dataset has been locked.

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8. INTERVENTIONS

8.1. Self-Monitoring of Blood Pressure (SMBP)

Participating women in the intervention arm will be asked to measure their blood pressure, using the standard procedure, once daily at the same time of their choosing. Two readings should be taken and recorded each time and the second reading acted upon if necessary. Two readings will be taken as blood pressure decreases on repeated measurement and two measurements have been shown to be acceptable and feasible in previous self-monitoring studies[46]. A daily schedule of monitoring improves upon NICE guidelines, which recommend twice-weekly BP measurement for women with *gestational* hypertension requiring antihypertensives[24]. The same guidelines make no specific recommendation regarding BP measurement frequency for women with chronic hypertension.

Women will be asked to record their blood pressure readings in the provided diary. Women obtaining repeated out-of-range BP readings will be advised to contact their midwife, GP or MAU/DAU using the following protocol (also see Appendix C):

- If SBP≥150 or DBP≥100 mmHg on repeat measurement contact the MAU for urgent assessment the same day
- If SBP 140-149 or DBP 90-99 mmHg on repeat measurement – contact the midwife, GP or maternity unit within 24 hours
- If SBP 110-139 or DBP 70-89 mmHg on repeat measurement – BP is in the target range
- If SBP <110 and DBP<70 mmHg on repeat measurement and taking antihypertensive medication - contact the midwife, GP or maternity unit within 24 hours. If not on antihypertensive medication and well, these blood pressures are fine.

These ranges are based on the lower BP values recommended by NICE[24] and PRECOG[47, 48] for clinic thresholds used to trigger further investigation for pre-eclampsia. One of the outcomes of the study will be to assess the differences between clinic and home readings in pregnant women with hypertension and this data will help inform if any revisions are required to home BP thresholds for a future large trial.

These thresholds describe limits of home BP that should *trigger* clinical assessment to rule out pre-eclampsia or reduce antihypertensive medication if BP is falling too low. This regimen is not designed to trigger clinical assessment for home BP that is falling outside of the narrow range of optimal BP control. The *target* BP will be specific to the individual. It is likely that clinicians will be aiming to maintain clinic diastolic BP around 85 mmHg, secondary to the recent findings from the CHIPS study[23], and the woman's Lead Obstetrician will be asked to record the target BP in the woman's maternity notes.

Women having any symptoms consistent with pre-eclampsia including severe headache, visual disturbance, vomiting, upper abdominal pain or swelling of the face, hands or feet, feeling generally unwell, or any other worrying symptoms associated with pregnancy (e.g. vaginal bleeding) will be advised to contact their maternity unit for assessment regardless of their BP reading.

Participants and clinicians will be provided with a Freephone number to use in case of any study-related queries, otherwise it is expected for clinical queries women will contact their maternity units via the usual route detailed in their maternity notes.

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The BP target protocol will be shared with the clinical teams at site visits before and during the study, will be made available and visible in the clinical areas and a copy will be in the maternity notes of all participating women. In this way clinicians will be made aware of the same trigger BP values as participating women and the study will explore how these are utilised in conjunction with interpreting the home BP together with clinic readings when managing hypertensive disease.

A schematic of the different components of the SMBP intervention is provided in Appendix D.

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9. FOCUSED ETHNOGRAPHY

9.1. Observation of Consultations

We will use longitudinal, prospective, focused ethnographic methods to observe 'live' interactions between clinicians and women. We hope to understand what is normally communicated during routine antenatal care and how, and how both parties use home readings during the consultation and whether self-monitoring might alter 'usual' interactions.

As part of the description of the study in the PIL it will be explained that the PI will be performing a focused ethnographic study in order to understand routine antenatal care for women with hypertension and how the process of self-monitoring and home BP readings are integrated into this context.

The ethnography will be conducted during clinic consultations, in MAU/DAU assessment areas and in more 'back stage' settings such as the antenatal waiting room during hypertension clinics and in clinical meetings at the end of antenatal clinics. Observing these different environments should provide a fuller picture of the context in which and how self-monitoring is being introduced and also how it might impact on these different activities and settings.

The researcher will familiarise him/herself with the participating maternity units prior to commencing the study. It is hoped that in familiarising him/herself with the teams that the PI will also become 'part of the scenery' during observation periods so that interactions unfold in a more naturalistic way.

Written informed consent from participants will be obtained as part of the main study consenting procedure, and women may opt out of the ethnographic study whilst remaining in the intervention study and vice-versa. Participating clinicians will also be asked to provide written informed consent to have their clinical interactions and consultations observed. On days when a researcher is observing, posters in the waiting area will let participants know observation is taking place. Women who wish to not have their consultations observed will be asked to make the reception staff aware.

The information sheets and consent process will cover how the researcher may take written notes during the periods of observation but there will be no use of audio or video recording. During write up of the study and publication, all reasonable precautions will be taken to protect identity so participants will be anonymised by applying appropriate pseudonyms which will retain essential themes to the clinical case[50] and individual characteristics will not be provided.

We aim to observe most women and clinicians involved in the interventional and observational study, who have provided consent, throughout the antenatal journey, at several time points and at the study sites in a variety of antenatal settings. In this way it is hoped we will gain a broad representation of how the home BP readings are being integrated into consultations and clinical decision making and be able to compare this with the model of usual care.

It is anticipated that observation periods will range from 1-4 hours depending on the clinical context. The frequency and ongoing duration of the observation will be guided by the ability to provide 'thick description' fieldwork notes with concurrent initial analysis exploring for saturation of themes. During the study we will use purposive sampling of participant, clinician and setting to maximise the richness and completeness of the observations. The researcher will work closely will the clinical teams to ensure there is no 'researcher-fatigue' during the observation study.

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Scenarios arising in the observed consultations will allow for informal discussion around these themes in the later semi-structured interviews or even specific instances may be explored in more detail with involved individuals.

Data management and analysis will be through the modified Framework approach[49] using constant comparison. During initial analysis a coding framework will be developed and collaboratively agreed including descriptive and analytic codes. The framework will be refined with the accrual of data and themes will then be sorted and synthesised.

9.2. Clinician Semi-Structured Interviews

We aim to recruit clinicians (obstetricians and midwives) from across the study sites, who have been involved in the care of women participating in the intervention study.

Specific themes to be explored in clinician interviews include: perceived or experienced barriers to implementation of BP self-monitoring, any suggested modifications for the intervention, the sorts of behaviours and information sharing they encountered or adopted around self-monitoring and how home readings affected their management of pregnant women with hypertension. General themes arising during the ethnographic observation will be explored and specific instances will be discussed with the concerned clinicians to try to gain greater understanding of these particular events.

Interviewing will start after an appropriate bedding-in period for clinicians to gain familiarity with the BP self-monitoring intervention. We will conduct interviews in order to capture health care professionals' perceptions and recollection of events and being mindful of possibly contaminating the intervention through the reflective nature of interviewing. It is anticipated that up to 10-15 health care professional interviews will provide data saturation and will include most of the clinical teams across the study sites involved in the care of this high-risk group of women.

9.3. Participant Semi-Structured Interviews

We will conduct semi-structured interviews with consenting participants in intervention and control arms to explore their experience of either usual care or self-monitoring of blood pressure. We will seek women's views on their antenatal care and particularly on aspects around monitoring and treating hypertension and explore factors related to the implementation of BP self-monitoring and the acceptability of the intervention and study procedures. The interviews will also draw on observations made in the ethnographic study and participant diary, which may have highlighted specific barriers and facilitators to the introduction of the intervention or issues (maybe unexpected) arising from self-monitoring.

Women will be interviewed in the postnatal period in their own homes, or at one of the study sites if preferred. The timing of interviews will be between 6-12 weeks postnatal allowing flexibility within that around the woman's needs. Interviews will last approximately 30-60 minutes and will be audio- recorded for later transcription. Women may also choose not to have their interviews audio-recorded.

The participant information leaflet will briefly mention optional postnatal interviews. But to try and avoid information overload at the time of recruitment, a fuller description of the optional interviews will be provided to enrolled women from the second trimester onwards in the form of a specific participant interview information leaflet.

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Within this specific PIL and the associated consent procedure, it will be explained that they can ask for the audio-recording to be stopped at any time and can withdraw from the interview and process at any point without explanation. Any identifying information will be removed from the final transcripts and all information collected during the interviews will be kept strictly confidential.

If more than 30 women enrolled in the intervention studies consent to an interview then we will use purposive sampling to include viewpoints of women from the breadth of ages, ethnicities and socioeconomic backgrounds. It is expected that up to 40 interviews will provide data saturation.

Transcriptions from the interviews will be analysed thematically using the modified Framework approach and Nvivo software. Provisional analytic categories will be iteratively refined using the constant comparative method as new data emerge with continued interviewing. We will use the Framework approach to integrate the data from the observation field notes and the interview transcripts.

10. SAFETY REPORTING

10.1. Definition of Serious Adverse Events

A serious adverse event (SAE) is any untoward medical occurrence that:

- results in death
- is life-threatening
- requires in participant hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- consists of a congenital anomaly or birth defect.

Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

10.2. Expected Serious Adverse Events

We do not anticipate any serious adverse events due to the self-monitoring intervention or the qualitative studies.

The adverse events described below may be expected to occur in this participant population and will not be classified or reported as SAEs unless felt to be directly related to the activities of the study. This will be judged by the CI in the acute situation and ratified by the steering group.

All admissions will be recorded as an outcome.

Maternal outcomes including:

- Admission for monitoring or treatment of hypertension or pre-eclampsia

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- Number of episodes of systolic BP≥ 150 mmHg (including home monitoring)
- Number of episodes of diastolic BP<70 mmHg
- Need for additional oral or parenteral antihypertensive drugs
- Pre-eclampsia
- Intracranial haemorrhage or infarct
- Myocardial ischaemia/infarction
- Intubation
- Pulmonary oedema
- Hepatic dysfunction
- Acute kidney injury
- Neurological dysfunction other than stroke (altered GCS, blindness, hyperreflexia + clonus, severe headache +hyperreflexia, persistent visual scotoma)
- Disseminated intravascular coagulation
- HELLP syndrome (haemolysis, elevated liver enzymes, low platelets)
- Placental abruption
- Post-partum haemorrhage
- Admission for antepartum haemorrhage, suspected pre-term labour or pre-labour rupture of membranes
- Admission for labour, induction of labour or caesarean section
- Admission for assessment of suspected fetal compromise including poor growth or reduced fetal movements
- Admission for psychiatric or social reasons
- Admission for unstable lie or external cephalic version
- Admission for other pregnancy complications not listed

Perinatal outcomes including:

- Neonatal mortality or stillbirth
- Admission to neonatal unit: LDC, HDU, ICU
- Respiratory distress syndrome
- Need for ventilator support
- Intraventricular haemorrhage
- Confirmed infection
- Necrotising enterocolitis
- Seizures
- Encephalopathy
- Other diagnoses related to admission to NNU
- Prematurity and small-for-gestational-age
- Congenital anomalies

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10.3. Recording and Reporting Procedures for Adverse and Serious Adverse Events

Safety reporting will be from enrolment to the end of the participant and clinician interviews.

Adverse events may also be raised directly by the participant or clinician using the trial Freephone number or emailing the CI and study team. Participants will be asked about adverse events at study follow-up visits and as part of routine care.

All serious adverse events thought to be related directly to the activities of the study, whether expected or unexpected, will be reported as soon as possible (no later than 24 hours) by the site or CI, using the PC-CTU SAE report form and faxed to the trial unit's dedicated fax line. After the PC-CTU has performed initial checks, they may request additional information from the CI to ensure that they or the delegated safety officer review and evaluate the event for expectedness and relatedness. The Independent Safety Review Committee, who will be masked to the randomisation group, will also review all SAE reports. SAEs will be followed up until resolution.

An SAE occurring to a participant should be reported to the REC that gave a favourable opinion of the study where in the opinion of the CI the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to those procedures. Reports of related and unexpected SAEs will also be sent to the sponsor and should be submitted to both parties within 15 working days of the CI becoming aware of the event.

11. LONE WORKING POLICY

As part of the qualitative study the research team will perform home interviews if this is acceptable to participants. These will be conducted in line with the University of Oxford Safety Office policy: 'Safety in fieldwork' (UPS S5/07 http://www.admin.ox.ac.uk/safety/policy-statements/s5-07/).

12. STATISTICS AND QUANTITATIVE ANALYSIS

12.1. Description of Statistical Methods

The primary analysis will be carried out on the basis of intention-to-treat. A secondary analysis will be carried out using per-protocol information.

The analyses for this feasibility study will be primarily descriptive and will not include any formal hypothesis testing. Where P-values for group comparisons may be presented, these will be purely exploratory and any publications arising from this work will emphasise the hypothesis-generating rather than -testing nature of this study.

Continuous variables will be reported as means with standard deviations (or medians with interquartile ranges if data are skewed). Categorical variables will be reported as counts and percentages and categories may be collapsed if there are insufficient data to provide meaningful analysis.

Blood pressure comparisons between groups including mean differences in blood pressure, will be estimated using a mixed effects model and will include 95% confidence intervals.

In accordance with the intention-to-treat principle, an analysis will be performed using all participants with outcome data according to their assigned study group regardless of protocol adherence. A secondary exploratory per-protocol analysis will take protocol adherence into account. For participants who choose to withdraw from the study we will not include the data for those choosing to withdraw entirely from the study, as opposed to those

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withdrawing solely from the self-monitoring intervention but providing continued consent for collection of outcome data.

We anticipate minimal loss to follow-up as women with medically complicated pregnancies tend to deliver in their booking hospital, especially at dedicated tertiary centres such as two of our study sites. All women with outcome data providing continued consent will be included in the analysis.

Further exploratory analysis will look at alternative measures of blood pressure control, including 'time in range' for both home and clinic readings using the method of liner interpolation[52] and measures of blood pressure variability[53].

The amount of antihypertensive medications taken will be compared between the intervention and control groups by converting individual drug doses into defined daily doses (DDD – a World Health Organisation measure defined as the average maintenance dose per day for a drug used for its main indication in adults)[50]. Time of exposure to particular DDDs will be taken into account for each individual as women will be in the study for varying lengths of time and antihypertensive drug use will be compared at the different study follow-up visits.

NHS costs will be determined for resources used in the study including hospital and GP consultations, DAU/MAU assessments, hospital admissions, medications, equipment and training. Data for resources used in the intervention group (eg BP monitors and training) will be compiled by the research team. All other resource use will be recorded prospectively in maternity notes, hospital electronic and participant BP diaries and will be collected by the research team after delivery. Cost data will be derived from sources including the British National Formulary[51], the Unit Costs of Health and Social Care (from the PSSRU)[52] and the NHS Tariff[53].

Missing data will be described and explored for associations but will not be imputed.

There is no planned interim analysis for this study given that we do not expect any serious adverse events arising from our study procedures.

A detailed statistical analysis plan will be written with our statistical team and will be completed before receipt of the data.

12.2. The Number of Participants

No formal sample size calculation is required for this feasibility study. We will aim to recruit 160 women for the randomisation study (80 + 80), across the study sites and withdrawals may be replaced if new recruitment can occur within the study period.

12.3. Analysis of Outcome Measures

The primary objective is to assess feasibility measures. For these analyses, descriptive statistics will be used.

There are no a-priori criteria for success for this feasibility study but instead we expect any decisions around the feasibility for a large future trial to be informed by a synthesis of both the quantitative and qualitative study findings.

Potential outcomes from this feasibility study are:

- Stop – the main study is not feasible

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- Continue – the main study is feasible with protocol modifications
- Continue – the main study is feasible without modifications

13. DATA MANAGEMENT

13.1. Access to Data

The qualitative interviews will take place in participants' homes. In order to facilitate these visits the research team will require access to participant identifiable data including names, home addresses and telephone numbers. These will be accessed only when needed. When visiting participant homes only addresses and telephone numbers will be taken without attaching participant names.

The consent form will list the data to be collected and for what purpose. The identifiable data will be held securely at the University of Oxford PC–CTU, with access to this data restricted to specific members of the study team recorded on the delegation log. Identifiable data will be held separately from other research data and anonymised as soon as it is no longer required and in line with PC-CTU SOPs.

Direct access will be granted to authorised representatives from the sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

13.2. Data Recording and Record Keeping

All study data required for analysis will be recorded on paper case report forms (CRFs) and returned to the study team for data entry. CRFs will be held securely in locked filing cabinets, located within office space with restricted entry. All data points will be transferred from the CRFs to a secure computerised database management system (CDMS) hosted by the PC-CTU. Within the CDMS participants will be identified solely by a unique study identifier. No participant identifiable data will be held within the CDMS.

All essential documents related to the study, including CRFs, will be archived for at least 5 years after the conclusion of the study in accordance with PC-CTU_SOP_TM124.

14. QUALITY ASSURANCE PROCEDURES

The CI will ensure the study is conducted in accordance with the current approved protocol, PC-CTU SOPs and all applicable local and national guidelines and regulations. The PC-CTU will conduct a study specific risk assessment prior to study commencement, which will inform the level and nature of monitoring required for this study.

A trial management group (TMG) will be established to support the CI in overseeing the progress and conduct of the study.

15. ETHICAL AND REGULATORY CONSIDERATIONS

15.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

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15.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

15.3. Approvals

The protocol, informed consent form, participant information sheets and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and host institutions for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

15.4. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, host organisation and sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

15.5. Participant Confidentiality

The study staff will ensure that the participants' anonymity is maintained. The participants will be identified only by initials and a participant's ID number on the CRF and any CDMS. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

15.6. Expenses and Benefits

Reasonable travel expenses for any visits additional to normal care will be reimbursed on production of receipts, or a mileage allowance provided as appropriate. There will be no inducements to participate.

15.7. Conflicts of Interest

The CI and study team have no conflicts of interest to declare in relation to this study.

15.8. Other Ethical Considerations

It is possible that blood pressure self-monitoring may increase anxiety in participants but previous work by the study team has found this to be uncommon. Participants will be given clear instructions, as detailed in this protocol, about what to do and who to contact if they obtain consistently high BP readings with the aim of empowering participants and reducing anxiety.

Considerations have been given to the potential sensitivities of pregnant women. We have consulted with women who have had pregnancies complicated by hypertensive disease or pregnancies otherwise defined as 'high risk' about the protocol and information we propose for participants to ensure that these are reasonable, acceptable and respectful. We are mindful of the need not to worry participants unduly and will consider whether we have achieved this in the qualitative parts of this feasibility study. If it becomes apparent during the study that any particular study-related procedures or information are not acceptable then these will be changed

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accordingly and resubmitted to the ethics committee as appropriate. Should an individual feel excessively anxious due to the study procedures or otherwise then they will be free to withdraw at any time.

16. FINANCE AND INSURANCE

16.1. Funding

This study is funded by Professor Richard McManus' NIHR Professorship an NIHR Oxford CLAHRC and an NIHR Programme Grant.

16.2. Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS indemnity operates in respect of the clinical treatment which is provided.

17. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the NIHR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. We will comply with the NIHR open access publishing policy.

At study end, participants will receive a summary of the study's findings and will receive notification of formal publications on request.

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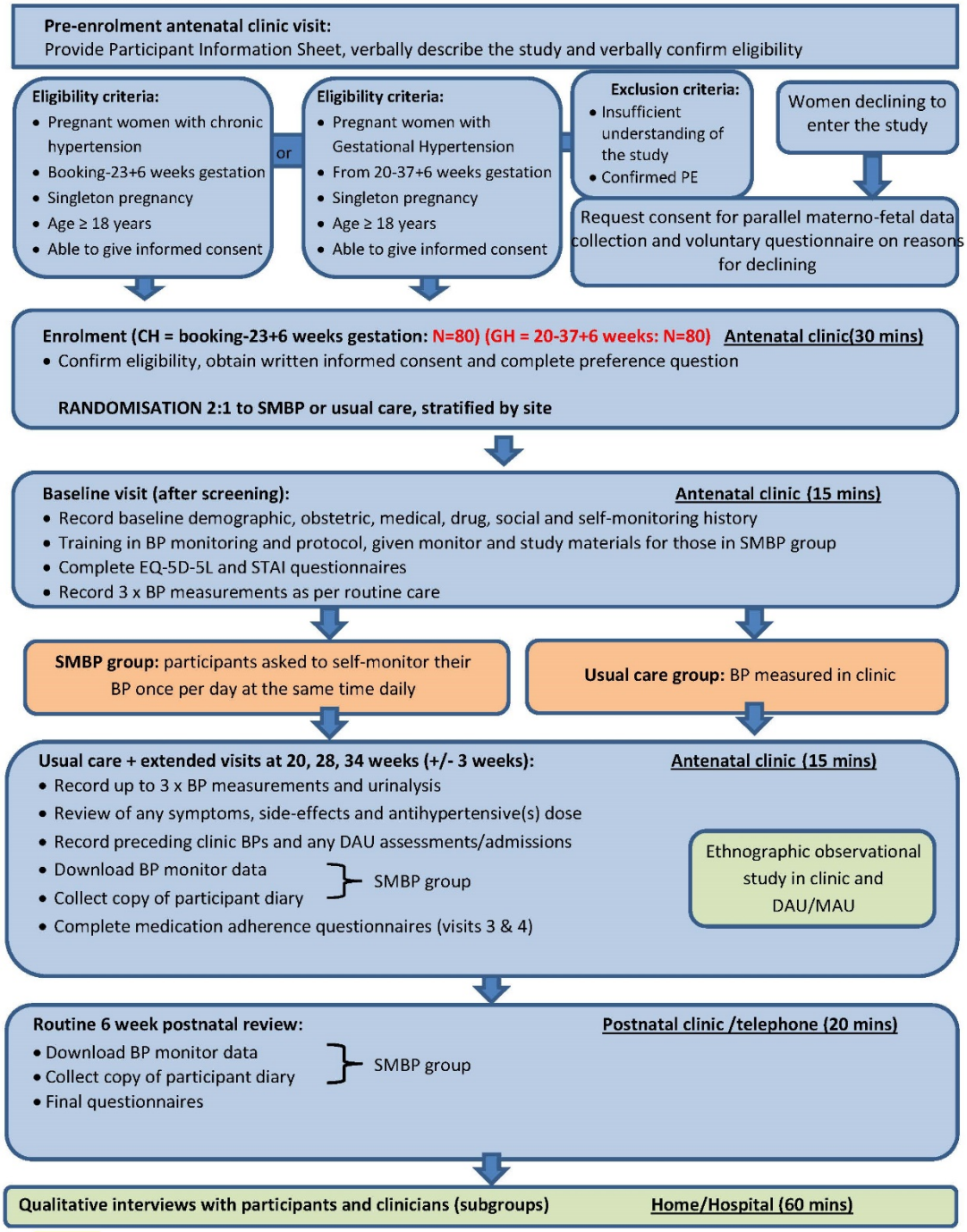
18. APPENDIX A: STUDY FLOW CHART



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19. APPENDIX B: SCHEDULE OF STUDY PROCEDURES (to commence after enrolment)

Procedures	Weeks of gestation +/- 3 weeks													
	Booking	12	16	20	24	28	32	34	36	38	40	41	6 weeks PN	12 weeks PN
Routine clinical visits to include: • BP check • Urinalysis • Medication changes	x	x	x	x	x	x	x	x	x	x	x	x	x	
Informed consent	x													
Screening eligibility	x													
Randomisation	x													
Verbal confirmation of consent				x		x		x					x	
Download home BP monitor data				x		x		x					x	
Collect copy of SMBP diary				x		x		x					x	
EQ-5D-5L & STAI	x												x	
MARS & BMQ	x					x		x						
Little questionnaire													x	
Observational study	x													
Participant interviews													x	
Clinician interviews					x									

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20. APPENDIX C: THRESHOLDS FOR HOME BLOOD PRESSURE MONITORNG

- **SYS is the top and DIA is the bottom number on your machine display**
- **Please measure your blood pressure twice and record the SECOND reading**
- **Please act on the second reading if it is outside of the normal range**

- **SEEK IMMEDIATE MEDICAL HELP (REGARDLESS OF WHAT BLOOD PRESSURE READING YOU MEASURE) IF YOU HAVE ANY WORRYING SYMPTOMS (E.G. VAGINAL BLEEDING OR REDUCED FETAL MOVEMENTS) OR SYMTPOMS THAT MIGHT BE DUE TO PRE-ECLAMPSIA, INCLUDING:**
  - **Feeling generally unwell**
  - **Severe headache**
  - **Problems with vision (blurring or flashing lights)**
  - **Severe pain just below the ribs or other abdominal pain**
  - **Vomiting**
  - **Sudden swelling of the face, hands or feet**

COLOUR	RANGE	BLOOD PRESSURE	ACTION
RED	**HIGH**	**SYS 150 or more OR DIA 100 or more**	▪ Your blood pressure is high ▪ Sit quietly for 5 minutes then measure it again ▪ Record a RED if your second reading is also high ▪ **Contact your maternity unit for urgent assessment today**
YELLOW	**RAISED**	**SYS 140-149 OR DIA 90-99**	▪ Your blood pressure is raised ▪ Sit quietly for 5 minutes then measure it again ▪ Record a YELLOW if your second reading is also raised ▪ **Contact your midwife, GP or maternity unit within 24 hours**
GREEN	**NORMAL**	**SYS 110-139 OR DIA 70-89**	▪ Your blood pressure is in the target range ▪ Record a GREEN reading if this is your second reading ▪ This is fine provided you have no side-effects or symptoms
BLUE	**LOW**	**SYS less than 110 AND DIA less than 70**	▪ Your blood pressure is low ▪ Sit quietly for 5 minutes then measure it again ▪ Record a BLUE if your second reading is also low ▪ **If you are taking blood pressure medication, contact your midwife, GP or maternity unit within 24 hours** ▪ **If you are not taking medication this blood pressure is fine**

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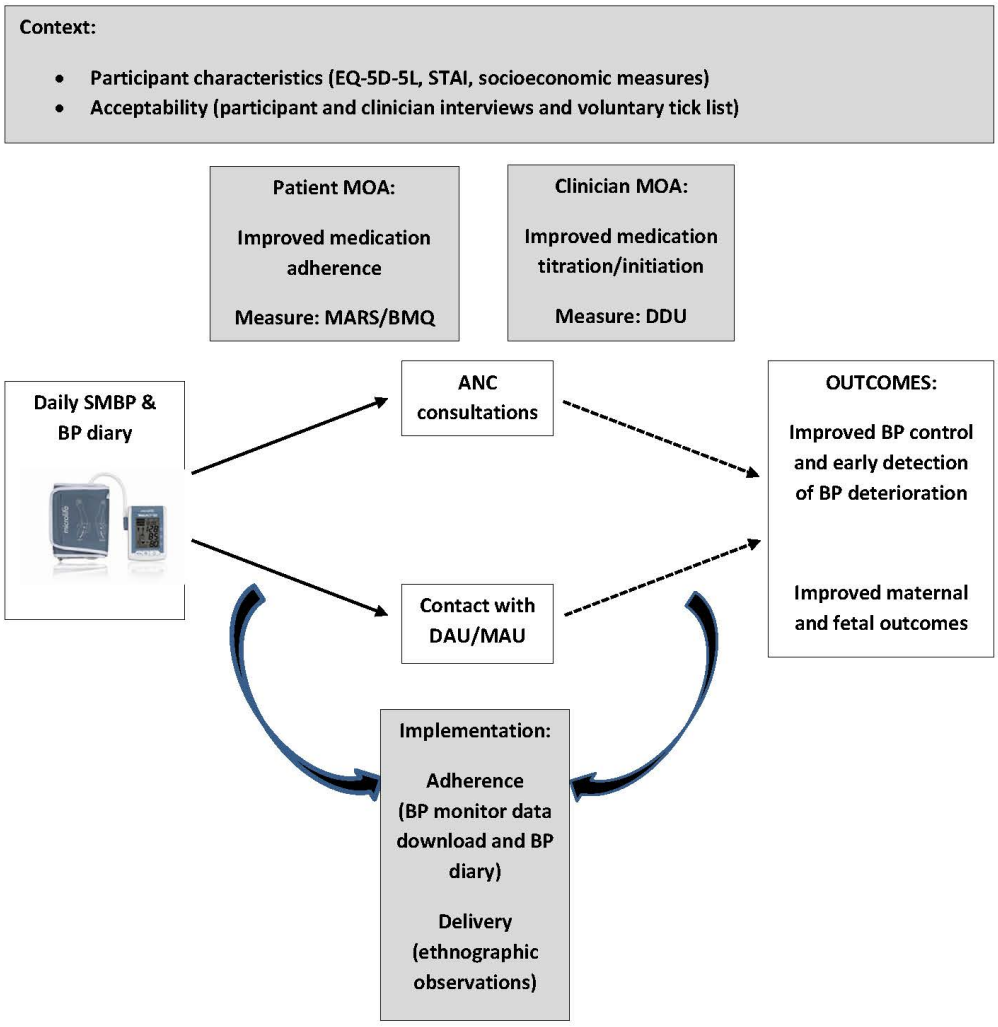
21. APPENDIX D: SCHEMATIC OF COMPONENTS OF BLOOD PRESSURE SELF-MONITORING INTERVENTION AND PROCESS EVALUATION



EQ-5D-5L: Euroqol quality of life questionnaire, STAI: abbreviated State Trait Anxiety Inventory, MARS: Medication Adherence Report Scale, BMQ: Beliefs about Medication Questionnaire, DDU: Daily Defined Dose, MOA: mechanism of action, SMBP: self-monitoring blood pressure, ANC: antenatal clinic, DAU: day assessment unit, MAU: maternity assessment unit.

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22. APPENDIX E: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
SA1	V1.5	12.9.16	Chappell, L.; Franssen, M.; Hinton, L.; Hodginkon, J.; McManus, R.; Ogburn, E.; Pealing, L.	As the OPTIMUM trial to date has been successful in terms of recruitment and well tolerated in chronic hypertension, and further resources are now available, we would like to a) expand recruitment to 80 women with chronic hypertension in pregnancy and b) extend the intervention into gestational hypertension for a further 80 women. The additional resources also allow us to include electronic transmission of blood pressure results rather than using a manual method. In order to achieve these changes we have expanded the inclusion criteria to include gestational hypertension and request a 12-month extension from October 2017 to the end of October 2018. The change in the definition of the end of trial has been amended to ensure that women have completed all aspects of the trial, including the qualitative work, and that all relevant data have been collected. We realised that the original definition could lead to a premature close of the trial. Two operational changes are requested: Firstly we

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				have found that the flow chart mentioned on page 12 of the protocol was not found useful by the midwives and obstetricians and so we are dropping this. This will have no effect on the scientific basis of the research and is a reflection of the developmental nature of the study. Secondly, the original protocol specified a female ethnographer and we would like both male and female staff to be able to undertake this research whilst retaining choice for the women in question.

List details of all protocol amendments here whenever a new version of the protocol is produced. This is not necessary prior to initial REC submission.

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APPENDIX 3: Pregnant women participant information sheet

OPTIMUM-BP

Optimising Titration and Monitoring of Maternal Blood Pressure

Information Leaflet for Pregnant Women

We invite you to take part in a research study
This leaflet explains why we are doing the study and what is involved if you decide to take part
Please take time to read the leaflet carefully and discuss it with friends and family if you wish
Please ask us if anything is unclear or you would like more information

Important things that you need to know:

- We want to find the best way to monitor blood pressure in pregnancy for women with chronic hypertension
- We are studying women monitoring their own blood pressure at home on top of their usual care
- Our study will have two groups: a usual care group and a group that in addition measures blood pressure at home
- Study visits will happen at the same time as routine antenatal care so there are no extra hospital visits
- You can stop taking part in the study at any time

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What is the purpose of this study?

Some women have high blood pressure before pregnancy (chronic hypertension), while others find out about it during pregnancy. Up to 1 in 20 pregnant women have chronic hypertension and most need treatment with blood pressure lowering tablets. It is important to diagnose and treat high blood pressure because it can cause damage to the heart, brain and kidneys as well as complications such as stroke.

Controlling high blood pressure during pregnancy is particularly important in order to reduce a woman's risk of very high blood pressure, which can lead to complications in the mother such as stroke and reduced growth and increased risk of stillbirth in the baby.

Blood pressure naturally changes throughout pregnancy; dropping in early pregnancy but often rising towards the end. Women have more frequent antenatal visits in the later stages of pregnancy in part so that midwives and doctors can keep an eye on blood pressure and signs of pre-eclampsia (a condition arising in pregnancy causing high blood pressure and protein to leak into the urine) and give them treatment as needed.

We would like to compare pregnant women who regularly monitor their own blood pressure at home, and share these readings with their midwives and doctors to help make treatment decisions, with those having normal care, and find out which group has improved blood pressure control and greater overall satisfaction with their antenatal care.

We are inviting around 60 women with chronic hypertension to take part in our study. Those who agree to take part will be randomly assigned to one of two groups for comparison. While both groups will receive usual antenatal care, one group will also be asked to perform additional blood pressure self-monitoring at home.

Why have I been invited?

You have been invited to join our study during your pregnancy because your GP, midwife or hospital doctor has identified that you have chronic hypertension. You might already be on tablets to control your blood pressure – or be about to start them. Or perhaps your blood pressure levels don't currently require treatment but still need careful monitoring.

You might already be monitoring your own blood pressure and considering carrying on these measurements during your pregnancy. We don't know if self-monitoring at home makes any difference to the control of blood pressure, which is why we are doing the study. If you are happy to be randomly assigned to either usual care or continuing to measure your blood pressure at home then we invite you to join the study.

Do I have to take part?

No. It is entirely your decision to take part or not. If you decide not to take part, or if you agree but later change your mind, this will not affect your care in any way. You are free to withdraw from the study at any time without giving a reason.

What will happen if I take part?

If you agree to take part, you will be asked to sign a consent form. You will be randomly assigned (like tossing a coin) by computer to one of two groups - either usual care or the blood pressure self-monitoring group. The computer will randomly choose twice as many women to be in the self-monitoring versus usual care group.

Both groups will be asked to complete short questionnaires about day-to-day life and current feelings. You will also be asked to read some short health information and answer a few questions. This should take no more than ten minutes to complete.

If you are in the **Usual Care Group**, you will have your blood pressure monitored by your midwife or doctor when you come to antenatal clinic. The doctor will make any changes to your medication using your clinic blood pressures.

If you are in the **Self-Monitoring Group**, we will loan you a home blood pressure monitor to use during your pregnancy and show you how to use it. We will ask you to measure your blood pressure every morning and to record your readings in a booklet attached to your maternity notes. Your doctor will be able to use these readings to help guide any medication needs during your routine antenatal clinic visits. You will be asked to measure your blood pressure at home throughout your pregnancy but otherwise you will receive the same care as the Usual Care Group.

We will arrange three study appointments alongside your usual antenatal clinic visits to measure your blood pressure and complete short questionnaires about your medication, during your pregnancy and once after you have delivered (see study flow chart page 7). Study appointments will take less than 10 minutes - and you won't need any extra hospital appointments.

Are there any additional parts to the research study?

Yes. We want to observe antenatal care to understand how issues around high blood pressure are discussed and home blood pressure readings are used in helping decide blood pressure treatment.

What happens during observation of antenatal care?

During the study, the Chief Investigator, Dr Louise Pealing, will be present in the antenatal clinic and assessment units observing consultations. Dr Pealing will be taking notes and these will be anonymised so that no-one can be identified from her notes, similar to the other research data. She will not be directly involved in care and observed consultations will not take any extra time. A notice will be displayed in the clinical areas on the days that Dr Pealing is present and you will be asked if you are happy for Dr Pealing to be present during your consultation. It is up to you whether Dr Pealing is present and you can ask her to leave at any time if there are parts you would prefer her not to observe, without giving a reason. Whatever you decide, this will not affect the care you receive.

How do I monitor my blood pressure at home (in the self-monitoring group only)?

We will loan you a blood pressure monitor that is suitable for use in pregnancy. You will be asked to use the monitor once a day, at roughly the same time each morning. You will be given a simple blood pressure diary to complete attached to your maternity notes and easy-to-follow instructions for what to do in case your blood pressure goes too high or low.

What are the possible benefits and disadvantages of taking part?

This study is trying to work out whether blood pressure self-monitoring is worth testing on a larger scale. Women taking part are unlikely to gain any individual benefit but might find being involved interesting.

Both groups of women in the study will receive usual care. Other than the time taken to undertake the study we do not anticipate any other disadvantage from taking part.

Will my expenses be paid?

All study visits will be alongside your routine hospital appointments at no additional expense to yourself. The postnatal study visit will also take place alongside your routine 6-week postnatal check at hospital or if you prefer at your home or by telephone.

Will my taking part in this study be kept confidential?

Yes, all information that is collected about you during the course of the research will be kept strictly confidential. All data will be kept securely, according to the Data Protection Act 1998.

If you take part in the study, we will collect some personal information such as your name, address and other contact details. These details will be kept securely by the study managers in Oxford and will only be used by

members of the research team to contact you during the study. At the end of the study we will ask your permission to retain your contact details and to contact you for any follow-up studies (*optional*). No other information collected for the study will identify you or your baby.

During the study, the research team will need to access relevant sections of your medical notes. This and the information that you provide will be coded with a unique study number so you cannot be identified from it.

Responsible named representatives from the study sponsor or the NHS Trust may be given access to data for monitoring or audit of the study to ensure we are complying with regulations.

Will my General Practitioner be involved?

With your consent, we will inform your General Practitioner of your participation in the study.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time without giving a reason. If you decide you no longer wish to take part in the study, you can phone, write to or e-mail the study co-ordinator or inform us at your appointments. We will ask if the information already collected about you can still be used or if you want it destroyed.

What if there are any problems?

If at any stage you have any queries or concerns about this study or the way it has been carried out, please contact the study co-ordinator and Chief Investigator (Dr Louise Pealing). You can also contact the University of Oxford Clinical Trials and Research Governance office (CTRG) office on 01865 572224, or the head of CTRG, email ctrg@admin.ox.ac.uk.

Alternatively you can contact the Patient Advice and Liaison Service (PALS) (see contact details at the end of the leaflet).

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

The University of Oxford has arrangements in place to provide for harm arising from participation in any study for which the University is the Research Sponsor. NHS indemnity operates in respect of the clinical treatment which you are provided.

What will happen to the results of the study?

The results will be presented at pregnancy and hypertension conferences and published in scientific journals. We will send you a summary of the results of the study if you wish and these will be posted on our website (http://www.primarycare.ox.ac.uk/). You and your baby will not be identified in any report or publication from this study.

Who is organising and funding the research?

The study is being co-ordinated by **Dr Louise Pealing** (Clinical Fellow, Nuffield Department of Primary Care Health Sciences) as part of her doctoral studies at the University of Oxford. Dr Pealing is supervised by **Professor Richard McManus, Professor Lucy Chappell, Professor Sue Ziebland** and **Dr Lucy Mackillop** from Oxford University Hospitals NHS Trust, University of Oxford and Guy's and St Thomas' NHS Foundation Trust.

The study is the responsibility of the University of Oxford who are acting as Research Sponsor. The research is funded by the National Institute for Health Research.

Who has reviewed the study?

All research in the NHS has to be approved by an independent NHS Research Ethics Committee before it goes ahead. Approval means that the Committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given sufficient information on which to make an informed decision to take part or not. This study has been reviewed and approved by East Midlands – Nottingham 2 Research Ethics Committee (ref: 15/EM/0490).

What happens now?

If you are interested in taking part please let us know and we will arrange your first study appointment to coincide with one of your routine antenatal appointments. You can book this now with the research team at clinic or use the details below to contact the research team.

Contact for further information

A message can be left for the research team (see contact details below). In an emergency if you are very worried and wish to speak to a midwife or doctor about your health, we recommend that you contact your local maternity services as listed on your hand-held maternity notes.

Further information and contact details

Thank you for reading this leaflet – please discuss this study with the research team, doctor or midwife looking after you if you have any questions.

You will be given a copy of this Information Leaflet and your signed Consent Form if you take part.

*****

Chief Investigator and study co-coordinator: Dr Louise Pealing
Nuffield Department of Primary Care Health Sciences, University of Oxford
Radcliffe Observatory Quarter, Woodstock Road, Oxford OX2 6GG

Email: louise.pealing@phc.ox.ac.uk
Freephone: 0800 xxxxxxxx
Study mobile: xxxxxxxxxx

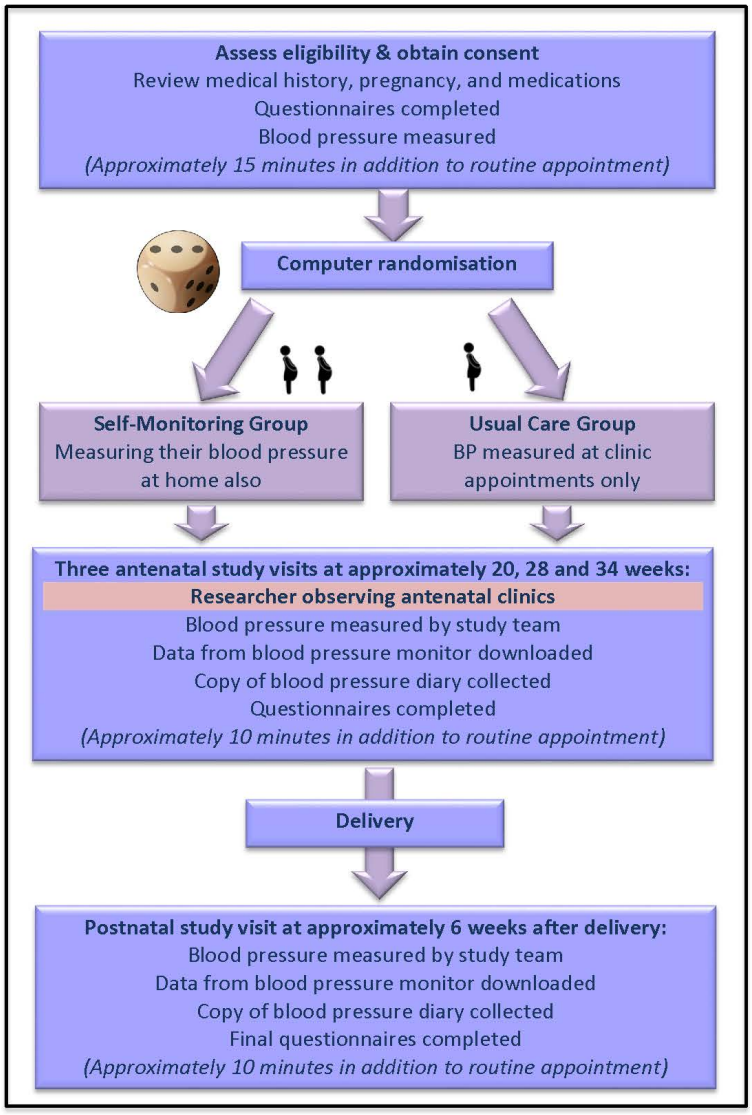
Local Co-Investigator: *insert local details*

Local Lead Research Midwife: *insert local details*

University of Oxford Clinical Trials and Research Governance: (CTRG) office
01865 572245
Or the head of CTRG, email ctrg@admin.ox.ac.uk

Patient Advice and Liaison Service (PALS):
<insert relevant NHS site phone number and email from the PALS website http://www.ouh.nhs.uk/patient-guide/pals.asp or insert local details>

OPTIMUM-BP Study Flowchart



APPENDIX 4: Clinician participant information sheet

OPTIMUM-BP

Optimising Titration and Monitoring of Maternal Blood Pressure

Information Leaflet for Health Care Professionals

We invite you to take part in a research study
This leaflet explains why we are doing the study and what is involved if you decide to take part
Please take time to read the leaflet carefully
Please ask us if anything is unclear or you would like more information

Important things that you need to know:

- We want to find the best way to monitor blood pressure in pregnancy for women with chronic hypertension
- Our study will have two randomised groups: a usual care group and a group that additionally measures blood pressure at home
- Study visits will happen at the same time as routine antenatal care so women have no extra hospital visits
- We want to observe antenatal care so we can understand how blood pressure is managed during pregnancy and how additional self-monitored home readings are used by clinicians
- We would like to interview clinicians to explore their experience of using home blood pressure readings and how they integrate these into clinical care
- You can stop taking part in the study at any time

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What is the purpose of this study?

We would like to find out if pregnant women who regularly monitor their own blood pressure at home, enabling their clinical teams to use these readings as well as clinic readings when making treatment decisions, have improved blood pressure control and greater satisfaction with their antenatal care.

We are inviting around 60 women with chronic hypertension to take part in our study. The study is taking place in the maternity units of the John Radcliffe (Oxford) and St Thomas' (London) Hospitals. Those women who agree to take part will be randomly assigned to one of two groups for comparison. Twice as many women will be assigned to the blood pressure self-monitoring group as the usual care group. While both groups will receive usual antenatal care, one group will also be asked to perform additional blood pressure self-monitoring at home and to record these readings in a blood pressure diary attached to their maternity notes. There will be no other changes to antenatal care and clinicians will be expected to manage study women along standard lines.

Why have I been invited?

You have been invited to join our study as you are a clinician involved in the delivery of antenatal care, including to the group of women with chronic hypertension.

Do I have to take part?

No. It is entirely your decision to take part or not. You can decide not to take part, or you may agree but later change your mind. You are free to withdraw from the study at any time without giving a reason.

What will happen if I take part?

We will describe the study and discuss any questions you have including about the Information Leaflet. If you agree to take part, you will be asked to sign a consent form.

Women under your care may be involved in the randomisation study. There are also two additional parts to the study:

- We want to observe antenatal care to understand how issues around high blood pressure are discussed and home blood pressure readings are used in helping decide blood pressure treatment
- We also want to interview women and clinicians. Specifically we want to explore clinicians' experiences of the study, how they use home readings in their clinical decision-making and perceived barriers and facilitators for the introduction of blood pressure self-monitoring into antenatal care.

A study flowchart is at the end of this leaflet.

Some women under your care may not be included in the study but may have already chosen to monitor their own blood pressure at home. This is fine but we would ask that you don't share study materials with these women as they are for the research study only and do not form part of the current evidence base for antenatal care.

What happens during observation of antenatal care?

During the study, the Principal Investigator, Dr Louise Pealing, will be present in the antenatal clinic and assessment units observing consultations. Dr Pealing will be taking notes and these will be anonymised, similar to the other research data. She will not be directly involved in care and observed consultations will not take any extra time. A notice will be displayed in the clinical areas on the days that Dr Pealing is present so that pregnant women are aware she is in attendance and yourself and the patient will be asked if you are happy for Dr Pealing to be present during the consultation. It is up to you whether Dr Pealing is present and you can ask her to leave at any time.

What is involved in the clinician interviews?

We would like to ask your views about the blood pressure self-monitoring intervention, including how you used home readings in your clinical management of pregnant women, how you found involvement in the study and how you perceive this intervention might be adapted and integrated into future clinical practice.

These interviews will take place at the hospital, at a time that suits you. Dr Louise Pealing will interview you and we expect this to take between 30-60 minutes. You can withdraw from the interview at any time without explanation.

The interviews will be audio recorded for transcription purposes. We will anonymise all transcripts and remove names and other identifiers. You will be invited to read the transcript of your interview to check that you are happy with its content.

The researchers may use some direct quotations in publications. No individuals will be identifiable from the quotations.

What are the possible benefits and disadvantages of taking part?

This study is a feasibility study which will inform the design of a larger study, which could lead to improved antenatal care. Participants might find the study interesting but it is unlikely to give them individual benefit.

Other than the time taken for involvement in the clinician interviews we do not anticipate any other disadvantage from taking part.

Will my taking part in this study be kept confidential?

Yes, all information collected during the course of the research will be kept strictly confidential. All data will be kept securely, according to the Data Protection Act 1998.

Data from the interviews will be anonymised. Electronic or manual study data will be securely stored at the Primary Care Clinical Trials Unit, University of Oxford (the Study Sponsor).

Responsible named representatives from the study sponsor or the NHS Trust may be given access to data for monitoring or audit of the study to ensure we are complying with regulations.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time without giving a reason. If you decide you no longer wish to take part in the study, you can phone, write to or e-mail the study co-ordinator. We will ask if the information already collected from you can still be used or if you want it destroyed.

What if there are any problems?

If at any stage you have any queries or concerns about this study or the way it has been carried out, please contact the study co-ordinator and Chief Investigator (Louise Pealing). You can also contact the University of Oxford Clinical Trials and Research Governance office (CTRG) on 01865 572224, or the head of CTRG, email ctrg@admin.ox.ac.uk.

The University of Oxford has arrangements in place to provide for harm arising from participation in any study for which the University is the Research Sponsor.

APPENDIX 5: Pregnant woman optional interview information sheet

What is the purpose of the optional interview?

Thank you very much for your help with our study so far.

We really appreciate the time you have given.

We would like to interview a group of women who have taken part in the OPTIMUM-BP study. We want to find out more about their personal experiences of going through a pregnancy complicated by chronic hypertension and also how they found being part of the OPTIMUM-BP study. For women who have been self-monitoring at home, we want to know how they found measuring and recording their own blood pressure, and whether this is something they would recommend to others or use again in the future.

At the same time we will be interviewing the obstetricians and midwives from the local team involved in your care. They will similarly be asked to describe their experiences of how they found being in the study and how they found using the home blood pressure readings to help manage your care.

This information can help us adapt and improve any parts of the BP monitoring study so we can understand how best to monitor pregnant women's blood pressure and ultimately improve future care and pregnancy outcomes.

Why have I been invited?

All women who have taken part in the OPTIMUM-BP study are being invited to take part in an optional interview.

Do I have to take part?

No. It is entirely your decision to take part or not. If you decide not to take part, or if you agree but later change your mind, this will not affect your care in any way. You are free to withdraw from the interview process at any time without giving a reason.

What will happen if I take part in the interview?

We will describe what happens during the interview and explain the Information Leaflet. If you agree to take part, you will be asked to sign a consent form. Taking part in the interview will not mean that you have to come for any extra hospital visits.

The interview can take place in hospital after your 6-week postnatal visit or it can take place in your own home, at a time that suits you, after your postnatal visit. Dr Louise Pealing, the Chief Investigator, or one of the local research midwives, whom you would have got to know during the study, will interview you. We expect the interview to take between 30-60 minutes. A partner or companion is welcome to sit in the interview with you.

The interview will be a little like a conversation, in which the interviewer will help you talk about your experiences of going through pregnancy with chronic hypertension and what it is like being in the study, including what have been any good or bad parts of the experience. There are no right or wrong answers. It's your experience and opinions that matter.

The interviews will be audio recorded so that they can be written up (transcribed) later. We will anonymise all transcripts and remove all names and identifying information in them. You will be invited to read the transcript of your interview to check that you are happy with its content. If you wish we can also conduct the interview without audio recording.

We may use some direct quotations in publications arising from the research study. But no individuals will be identifiable from these quotations.

What are the possible benefits and disadvantages of taking part in the interview?

We don't expect any direct benefit for women taking part in an interview although people sometimes find it helpful to talk about their story and experiences. The interview is not the same as counselling. However, we can provide a list of useful contacts about where to get more help if you want.

We do not anticipate any disadvantage from taking part in the interview.

Will my taking part in this study be kept confidential?

Yes, all information that is collected during the interview will be kept strictly confidential. All data will be kept securely, according to the Data Protection Act 1998. The information that you provide will be coded with a unique study number so you cannot be identified from it.

Responsible named representatives from the study sponsor or the NHS Trust may be given access to the anonymised data for monitoring or audit of the study to ensure we are complying with regulations.

What will happen if I don't want to carry on with the interview?

You can withdraw from the interview process at any time without giving a reason. If you decide you no longer wish to take part in the interview, you can phone, write to or e-mail the study co-ordinator or inform us at your appointments. If you decided to leave after an interview has taken place, all audio recordings and transcripts of your interview will be destroyed.

What if there are any problems?

If at any stage you have any queries or concerns about the interview process or any other part of the OPTIMUM-BP study, please contact the study co-ordinator and Chief Investigator (Dr Louise Pealing). You can also contact the University of Oxford Clinical Trials and Research Governance office (CTRG) on 01865 572224, or the head of CTRG, email ctrg@admin.ox.ac.uk.

Alternatively, you can contact the Patient Advice and Liaison Service (PALS) (see contact details at the end of the leaflet).

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

The University of Oxford has arrangements in place to provide for harm arising from participation in any study for which the University is the Research Sponsor. NHS indemnity operates in respect of the clinical treatment which you are provided.

What will happen to the results of the interview?

When we have completed all of the interviews, our findings from them will be summarised with the use of some anonymous direct quotations. These anonymised results will be presented at pregnancy and hypertension conferences and published in scientific journals. We will send you a summary of the results of the study if you wish and these will be posted on our website (http://www.primarycare.ox.ac.uk/). You and your baby will not be identified in any report or publication from this study.

Who is organising and funding the research?

The study is being co-ordinated by **Dr Louise Pealing** (Clinical Fellow, Nuffield Department of Primary Care Health Sciences) as part of her doctoral studies at the University of Oxford. Dr Pealing is supervised by **Professor Richard McManus, Professor Lucy Chappell, Professor Sue Ziebland** and **Dr Lucy Mackillop** from Oxford University Hospitals NHS Trust, University of Oxford and Guy's and St Thomas' NHS Foundation Trust.

APPENDIX 6: General practitioner/midwife OPTIMUM-BP study letter

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Nuffield Department of Primary Care Health Sciences • University of Oxford • New Radcliffe House • Radcliffe Observatory Quarter • Woodstock Road • Oxford OX2 6GG • www.phc.ox.ac.uk

Louise Pealing
+44 (0)1865 289300 • louise.pealing@phc.ox.ac.uk

GP address/community midwife name/team
Date

OPTIMUM-BP

Dear <insert GP name/community midwife name/team>,

This is to inform you that <insert patient name> is taking part in a randomised controlled feasibility study entitled: OPTIMUM-BP, optimising the titration and monitoring of maternal blood pressure. In this study all women get usual maternity care but one group is asked to additionally measure their own blood pressure at home.

<insert patient name> has been selected because she has a diagnosis of chronic hypertension <which has been newly recognised in this pregnancy>. She has been provided with a blood pressure monitor validated for use in pregnancy and pre-eclampsia and has been asked to measure her blood pressure every day in the mornings throughout pregnancy.

It is possible that you might be contacted by <insert patient name> if her home readings are either too high or too low. Should this happen you are asked to check the blood pressure yourself and to follow your usual clinical guidelines based on your own readings and clinical assessment.

A summary of the study is attached. Please contact us for further information if required.

Kind regards

Dr Louise Pealing
Chief Investigator for OPTIMUM-BP
<Trial registration numbers>

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PRIMARY CARE
HEALTH SCIENCES

OPTIMUM-BP

Study Summary

Chronic hypertension usually requires antihypertensive treatment during pregnancy and is a strong risk factor for pre-eclampsia. Women with chronic hypertension are considered a high risk group during pregnancy and NICE guidelines recommend more frequent antenatal visits for these women. Despite more frequent monitoring these women can still have poor blood pressure control and can develop pre-eclampsia between antenatal visits.

Self-monitoring of blood pressure in pregnancy complicated by chronic hypertension could improve the detection and management of hypertension in pregnancy by providing much closer surveillance without appreciably increasing the burden on women or clinicians. Clinicians will be able to make more-informed treatment decisions in light of home and clinic blood pressure readings and women may feel more empowered and involved in their care.

This randomised controlled feasibility study will collect data to inform the design of a future large trial and will also provide qualitative information around the acceptability and feasibility of self-monitoring for this group.

Patients will be invited to participate if they are identified with chronic hypertension at booking or in the first 20 weeks of pregnancy. Patients will be recruited at the hospital antenatal clinic. Potentially eligible women will be provided with study information and invited to attend a screening and consent appointment. Following informed consent, baseline measurements will be recorded and women will be randomised to either the usual care or additional self-monitoring blood pressure group. Women in the intervention arm will be trained in self-monitoring blood pressure. Participants will be asked to measure their blood pressure twice in the morning every day throughout pregnancy and to record these readings in a blood pressure diary. All women will have further study visits at 20, 28 and 34 weeks which will be extensions of their routine hospital antenatal appointments.

All women in the study will continue to receive usual antenatal care according to current national and local guidelines. Triggers for action on the basis of home blood pressure readings have been set at the same level as clinic readings. Women obtaining raised or low home blood pressure readings will be advised to contact their midwife, GP or maternity unit who are asked to follow usual guidelines based on their readings and assessment. Any participant who experiences symptoms compatible with pre-eclampsia, or other serious pregnancy complications, will be advised to seek immediate medical help from their maternity unit regardless of their home blood pressure readings.

For further information please contact the research team:

Dr Louise Pealing, Chief Investigator
louise.pealing@phc.ox.ac.uk, study mobile <XXXXXX>, Freephone <XXXXXX>

APPENDIX 7: Baseline visit participant case report form

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

<<insert trust logo>>

OPTIMUM-BP

BASELINE ASSESSMENT - booking to 23 $^{+6}$ weeks

Date: D D / M M M / 2 0 Y Y VISDAT

Participant ID: OPTIMUM - R _ _ – _ _ _

This section is to be completed with the researcher			
Please ask the participant the following questions and the maternity notes may be used with participant permission:			
Study checks			
Eligible? YES / NO ELIGYN		**Consented? YES / NO** CONSYN	
About You			
1. Date of birth BRTHDAT	D D / M M M / 1 9 Y Y		
2. Weight WEIGHT	_____ Kg (to the nearest Kg)		
3. Height HEIGHT	_____ cm (to the nearest cm)		
4. BMI BMI	Only record if no height or weight data, but BMI data _____ Kg/m^2	BMINK ☐ Not known	

5. Please tick the highest qualification that the participant has achieved. Do not include those that they are currently working towards. EDUCQUAL

No formal qualifications	0	Professional qualifications	4
Vocational qualifications	1	First Degree	5
GCSE, O-Level, or CSE	2	Post-graduate or above	6
A-Level or equivalent	3		

6. Please tick the best description for participant's current occupation: CURROCC

Professional eg *Doctor, Accountant*	6	Partly skilled eg *Traffic warden, Bar staff*	2
Managerial and skilled technical eg *Teacher, Farmer*	5	Non-skilled eg *Cleaner, Window cleaner*	1
Skilled manual eg *Hairdresser, Bus driver*	4	Unemployed/unwaged eg *Not currently working, Home maker*	0
Skilled non-manual eg *Secretary, Sales assistant*	3		

Participant ID: OPTIMUM - R ☐☐–☐☐☐

Please show the participant the following groups to allow them to choose:

ETHNIC

7. Please choose ONE section from A to E, then tick the appropriate box to indicate your ethnic group:

A. White	British	1
	Irish	2
	Other	3
B. Mixed	White and Black Caribbean	4
	White and Black African	5
	White and Asian	6
	Other	7
C. Asian or Asian British	Indian	8
	Pakistani	9
	Bangladeshi	10
	Other	11
D. Black or Black British	Caribbean	12
	African	13
	Other	14
E. Chinese or other ethnic group	Chinese	15
	Other	16

Your Pregnancy and Blood Pressure History

8. Current gestation ☐☐ GESTWK weeks ☐ GESTDAY days EDDMETH

9. EDD date (estimated delivery date) EDDAT D D / M M M / 2 0 Y Y — By scan 1, By date 2

10. Pregnancy history
- No. of pregnancies ≥ 24 weeks ☐☐ PREGHXV
- No. of pregnancies < 24 weeks (NOT including current pregnancy) ☐☐ PREGHXNV
- Primp? YES ☐ NO ☐ PRIMIPYN

11. a) Were they diagnosed with high blood pressure *before* becoming pregnant? YES ☐ NO ☐ HTPPYN

If 'no' go to 12.

11. b) If 'yes', for about how many years have they had high blood pressure? (to the nearest year)

DYNAMIC BASED ON 11A HTPPYRS ☐ Year(s) ☐ < 1 year ☐ Not known HTPPLSYR HTPPNK

If found please post to: OPTIMUM-BP study, DPCHS, University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG or phone Dr Louise Pealing: Freephone XXXXXXXXXXX

Participant ID: OPTIMUM - R ☐☐–☐☐☐

DYNAMIC BASED ON 11A

11. c) If 'yes', were they taking blood pressure lowering medication in the 3 months before becoming pregnant? YES ☐ NO ☐ AHTPPYN

DYNAMIC BASED ON 11C

11. d) If 'yes', how many blood pressure medications? ☐ 1 ☐ 2+ ☐ Not known AHTPPMED

DYNAMIC BASED ON 11D

11. e) If yes, can they remember the names of the medication(s)?
Please tick (all) those that were taking 3 months before pregnancy **and/or currently** taking, if known.
Listed are common generic (brand) drugs:

Medication	Recent	Current	Medication	Recent	Current
Captopril (Capoten)	1	AHTREC AHTCUR	Metoprolol (Betaloc)	11	
Enalapril (Innovace)	2		Amlodipine (Istin)	12	
Lisinopril (Zestril)	3		Diltiazem (Tildiem/Adizem)	13	
Ramipril (Tritace)	4		Nifedipine (Adalat)	14	
Candesartan (Amias)	5		Verapamil (Cardilox)	15	
Irbesartan (Aprovel)	6		Indapamide (Natrilix)	16	
Losartan (Cozaar)	7		Bendroflumethiazide	17	
Propranolol	8		Spironolactone (Aldactone)	18	
Atenolol (Tenormin)	9		Doxazocin (Cardura)	19	
Labetolol (Trandate)	10		Methyldopa (Aldomet)	20	

MULTI-SELECT

☐ Other, name(s) if known ..... ☐ Or not known
AHTOTH AHTOTHNM AHTNK

~~Now go to Question 13.~~

12. a) Have they been diagnosed with high blood pressure for the first time in this pregnancy? YES ☐ NO ☐ HTNEWYN

DYNAMIC BASED ON 12A

12. b) If 'yes', at what gestation were they diagnosed (to nearest week)? HTGESTWK ☐☐ Week(s) ☐ Not known HTGESTNK

DYNAMIC BASED ON 12A

12. c) If 'yes', what was the blood pressure at diagnosis (in mmHg)?
1st BP DIASYS1 ____/____ DIADIA1
2nd BP DIASYS2 ____/____ DIADIA2
3rd BP DIASYS3 ____/____ DIADIA3
☐ Not known DIABPNK

Participant ID: OPTIMUM - R ☐☐–☐☐☐

AHTCRYN

DYNAMIC BASED ON 12D

12. d) Are they currently taking blood pressure lowering medicatic YES ☐ NO ☐

12. e) If yes, how many blood pressure medications? ☐ 1 ☐ 2+ ☐ Not known

AHTDPNUM

12. f) If yes, what are the names of the medication(s)?
Please tick (all) those that **currently** taking (can refer to maternity notes). AHTDPNAM
Listed are common generic (brand) drugs used in pregnancy:

MULTI-SELECT

Labetolol (Trandate)	10	Nifedipine (Adalat)	14
Amlodipine (Istin)	12	Methyldopa (Aldomet)	20

AHTDPOTH ☐ Other, name(s) ..... AHTDPONM .....

13. a) Have they measured their own BP at home at **any** point in this pregnancy so far? YES ☐ NO ☐

HOMBPYN

DYNAMIC BASED ON 13A

13. b) If yes, how often do they measure it usually? Daily 4 ☐ Weekly 3 ☐ Monthly 2 ☐ Less 1 ☐

HOMBPFRQ

14. Have they had a diagnosis of pre-eclampsia (PE) or high blood pressure in a previous pregnancy? HTPEPP

No 0 ☐ PE 1 ☐ High BP 2 ☐ Not known 9 ☐ Not applicable 8 ☐

Your General Health

15. Do you have any of the following medical conditions?

	YES	NO
Diabetes type 1 DIABT1YN	☐	☐
Diabetes type 2 DIABT2YN	☐	☐
Chronic kidney/renal disease	☐	☐ CKDRENYN
Asthma ASTHMAYN	☐	☐

Research related questions

16. Are you currently involved in any other research study? CURRESYN YES ☐ NO ☐

If 'yes', what is the study name? CURRESSN ..... Not known ☐ CURRESNK

Or any details if name not known CURRESDT .....

.....

Participant ID: OPTIMUM - R ☐☐ – ☐☐☐

Booking and today's CLINIC blood pressure measurements TOBOOKYN

17. Please record any clinic blood pressure measurements that have been taken at booking and this baseline visit (from the maternity notes): today is booking visit? (please tick if 'yes') ☐

Date DD/MMM/YYYY	Gestation (wks + days)	1st BP (mmHg)	2nd BP (mmHg)	3rd BP (mmHg)
Booking BOOKDAT ☐☐/☐☐☐/20☐☐	BKGESTWK ☐☐ + ☐ BKGESTDY	BKSYS1 ____/____ BKDIA1	BKSYS2 ____/____ BKDIA2	BKSYS3 ____/____ BKDIA3
Today's clinic reading CLINDAT ☐☐/☐☐☐/20☐☐	CLGESTWK ☐☐ + ☐ CLGESTDY	CLSYS1 ____/____ CLDIA1	CLSYS2 ____/____ CLSYS2	CLSYS3 ____/____ CLDIA3

STUDY blood pressure readings

Do not start until the participant has been seated for 5 minutes and please use the study monitor.
Always use the arm indicated below and the same size cuff.

Please remind the participant that she should request to use the same arm, suitable cuff size and to have <u>three measurements</u> taken when clinicians are measuring her BP in clinic.

18. Arm used — RIGHT 1 | LEFT 2 — ARM

19. Cuff size used CUFFSIZE — Small 17-22cm 1 | Medium 22-32cm 2 | Large 32-42cm 3 | XLarge 32-52cm 4

20. BP reading

First reading	Second reading	Third reading
BLSYS1____/____ mmHg BLDIA1	BLSYS2____/____ mmHg BLDIA2	BLSYS3____/____ mmHg BLDIA3

21. **Tick here if participant is randomised to the <u>self-monitoring group</u>:** 2 RANDGRP
or tick here if '<u>usual care' group</u>: 1

BP monitor number (on base) _ _ _ _ _ _ _ _ _ BPMONID

22. **Please tick the one that applies:**
Participant has completed the questionnaires and they are attached? ☐ PCQATT
Participant has detached the questionnaires to complete at home? ☐ PCQHOME
If completing at home – please log in study diary and call if not received in 2 weeks, completing by telephone.

Completed by (must be on site delegat log): PRINT:.....

Signature:..... Date: .....

If found please post to: OPTIMUM-BP study, DPCHS, University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG or phone Dr Louise Pealing: Freephone XXXXXXXXXXX

Participant ID: OPTIMUM - R ☐☐ – ☐☐☐

This section is to be completed by the participant.

23. Here we would like to ask you about your thoughts and feelings relating to your health today.

A number of statements which people have used to describe their feelings are given below. Read each statement and then tick the most appropriate circle to the right of the statement to indicate how you **feel right now, at this moment**. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which best describes your present feelings.

	Not at all 0	Somewhat 1	Moderately 2	Very Much 3
I feel calm STAI1	○	○	○	○
I am tense STAI2	○	○	○	○
I feel upset STAI3	○	○	○	○
I feel relaxed STAI4	○	○	○	○
I feel content STAI5	○	○	○	○
I am worried STAI6	○	○	○	○

Participant ID: OPTIMUM - R ☐☐–☐☐☐

24. These are five statements about your general health today.

In each group below please tick the box next to the statement which best describes your health **today**.

Mobility: EQ5D0101 MISSING/AMBIGUOUS 9	
I have no problems in walking about	1
I have slight problems in walking about	2
I have moderate problems in walking about	3
I have severe problems in walking about	4
I am unable to walk about	5

Self-care: EQ5D0102 MISSING/AMBIGUOUS 9	
I have no problems washing or dressing myself	1
I have slight problems washing or dressing myself	2
I have moderate problems washing or dressing myself	3
I have severe problems washing or dressing myself	4
I am unable to wash or dress myself	5

Usual activities: (e.g. work, study, housework, family, leisure activities) EQ5D0103	
I have no problems doing my usual activities MISSING/AMBIGUOUS 9	1
I have slight problems doing my usual activities	2
I have moderate problems doing my usual activities	3
I have severe problems doing my usual activities	4
I am unable to do my usual activities	5

Pain/Discomfort: EQ5D0104 MISSING/AMBIGUOUS 9	
I have no pain or discomfort	1
I have slight pain or discomfort	2
I have moderate pain or discomfort	3
I have severe pain or discomfort	4
I have extreme pain or discomfort	5

Anxiety/Depression: EQ5D0105 MISSING/AMBIGUOUS 9	
I am not anxious or depressed	1
I am slightly anxious or depressed	2
I am moderately anxious or depressed	3
I am severely anxious or depressed	4
I am extremely anxious or depressed	5

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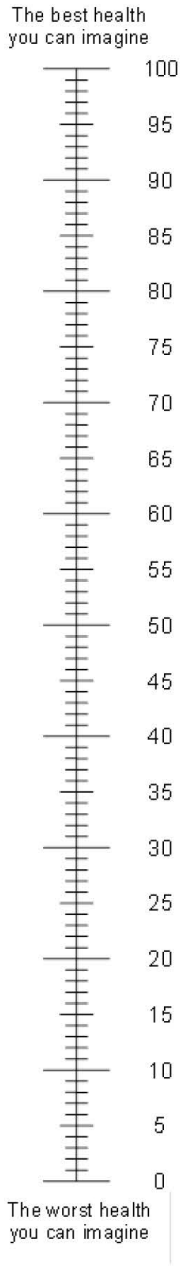
OPTIMUM-BP

Participant ID: OPTIMUM - R ☐☐ – ☐☐☐

25. We would like to know how good or bad your health is TODAY.

- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.



EQ5D0106

YOUR HEALTH TODAY = ☐

0 - 100
MISSING/
AMBIGUOUS 999

The questionnaire ends here if the participant is NOT taking any blood pressure lowering medication. If they are taking medication, please turn over.

Please send the completed questionnaire in the prepaid envelope to the below address:

If found please post to: OPTIMUM-BP study, DPCHS, University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG or phone Dr Louise Pealing: Freephone XXXXXXXXXXX

Participant ID: OPTIMUM - R ☐☐–☐☐☐

For participants taking blood pressure lowering medication at the baseline visit:

Taking blood pressure lowering medication? **YES** ☐ **NO** ☐ AHTMEDYN

26. **Here we would like to ask you about how you take your blood pressure medication.**
Read each statement and then tick the most appropriate circle to the right of the statement to indicate how you take your blood pressure medications. There are no right or wrong answers.

	Questions about using blood pressure medicines prescribed for you	1 ALWAYS	2 OFTEN	3 SOME-TIMES	4 RARELY	5 NEVER
M1	I forget to take my medicines MARSM1	o	o	o	o	o
M2	I alter the dose of my medicines MARSM2	o	o	o	o	o
M3	I stop taking my medicines for a while MARSM3	o	o	o	o	o
M4	I decide to miss out a dose MARSM4	o	o	o	o	o
M5	I take less than instructed MARSM5	o	o	o	o	o

27. **Here we would like to ask you about your thoughts and feelings about taking your blood pressure medication.** Read each statement and then tick the most appropriate circle to the right of the statement to indicate your thoughts about your blood pressure medications. There are no right or wrong answers.

STATEMENTS:	1 Strongly Agree	2 Agree	3 Uncertain	4 Disagree	5 Strongly disagree
a. My health, at present, depends on my blood pressure medication BMQA	o	o	o	o	o
b. Having to take blood pressure medication worries me BMQB	o	o	o	o	o
c. My life would be impossible without my blood pressure medication BMQC	o	o	o	o	o
d. Without my blood pressure medication I would be very ill BMQD	o	o	o	o	o
e. I sometimes worry about long-term effects of my blood pressure medication BMQE	o	o	o	o	o
f. My blood pressure medication is a mystery to me BMQF	o	o	o	o	o
g. My health in the future will depend on my blood pressure medication BMQG	o	o	o	o	o
h. My blood pressure medication disrupts my life BMQH	o	o	o	o	o
i. I sometimes worry about becoming too dependent on my blood pressure medication BMQI	o	o	o	o	o
j. My blood pressure medication protects me from becoming worse BMQJ	o	o	o	o	o

THIS IS THE END OF THE QUESTIONNAIRE - THANK YOU FOR COMPLETING IT

If found please post to: OPTIMUM-BP study, DPCHS, University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG or phone Dr Louise Pealing: Freephone XXXXXXXXXXX

APPENDIX 8: Statistical analysis plan

Primary Care Clinical Trials Unit

STATISTICAL ANALYSIS PLAN

OPTIMUM-BP

Blood pressure self-monitoring for the management of women during pregnancy with hypertension: a feasibility study

OPTIMUM-BP: Optimising Titration and Monitoring of Maternal Blood Pressure.

Ethics ref: 15/EM/0490

Version number and date: v1.0, 22/01/2018

Version History

Version:	Version Date:	Changes:
1.0	22/01/2018	Original

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1 INTRODUCTION

1.1 PREFACE

Trial Statisticians: Alecia Nickless, Ly-Mee Yu

Chief Investigator: Louise Pealing

Supervisors: Richard McManus, Lucy Chappell, Sue Ziebland

Trial Manager: Eleanor Temple

Trial Operations Director: Emma Ogburn

Data Managers: Sadie Kelly, David Watt, Christopher Lovekin

Trial Protocol: OPTIMUM-BP Protocol, date: 12/09/2016, v2.0

Ethics reference: 15/EM/0490

ISRCTN Trial Registration: 16018898

Statistical package to be used: Stata/MP2

1.2 PURPOSE AND SCOPE OF THE PLAN

This statistical analysis plan (SAP) will cover the main statistical analysis as stated in the protocol named above. The SAP will be agreed by the Trial Management Group (TMG) and signed off by the Chief Investigator (CI) and Trial Statisticians prior to database lock and data analysis. No interim analyses are planned for this feasibility trial.

This document details the proposed presentation and analysis for the main paper(s) and DPhil thesis reporting results of the OPTIMUM-BP trial. The results reported should follow the strategy set out here. Subsequent analyses of a more exploratory nature will not be bound by this strategy, though they are expected to follow the broad principles described here. The principles are not intended to curtail exploratory analyses (for e.g. to decide cut off points for categorisation of continuous variables, though as far as possible clinically relevant categories with sufficient data will be chosen), nor to prohibit accepted practices (e.g. data transformation prior to analysis), but they are intended to establish the rules that will be followed, as closely as possible, when analysing and reporting the trial.

The analysis strategy will be available on request when the principal papers are submitted for publication in a journal. Suggestions for subsequent analyses by journal editors or reviewers, will be considered carefully, and carried out as far as possible in line with the principles described here, and if reported, the source of the suggestion acknowledged.

Any deviations from the statistical analysis plan will be described and justified in the final report of the trial. The statistical analysis will be carried out by the Chief Investigator. The analysis will be validated by an independent statistician at the Primary Care Clinical Trials Unit.

More detailed health economic analysis and the qualitative ethnographic analysis are outside the scope of this statistical analysis plan.

The ICH Harmonised Tripartite Guideline: Statistical Principles for Clinical Trials E9 (5 February 1998)[1] was reviewed in producing this SAP.

1.3 TRIAL OVERVIEW

Raised blood pressure complicates about one in ten pregnancies and is associated with substantial morbidity and the risk of mortality for the mother and baby. High blood pressure can be present before or early on in pregnancy as pre-existing chronic hypertension, or it can present de-novo during the second half of pregnancy as gestational hypertension. Both of these hypertensive conditions increase the risk of pre-eclampsia, raised blood pressure with new urinary protein leak, a multisystem disorder unique to pregnancy, which can give rise to serious complications for mother and baby.

Both hypertension in pregnancy and pre-eclampsia can be asymptomatic in the early stages, and regular antenatal blood pressure and urinary protein measurement are used to detect and monitor these conditions. Despite increased monitoring for higher risk groups, women can develop significantly raised blood pressure and pre-eclampsia between antenatal clinic visits. When high blood pressure is detected, antihypertensive treatment may be initiated to help manage and control the condition with titration of medication depending on intermittent clinic blood pressure measurements. Home readings have the potential to increase blood pressure surveillance and provide a better estimate of underlying blood pressure which may in turn help clinicians to more appropriately titrate medication to improve blood pressure control. We would like to know if blood pressure self-monitoring (SMBP) could be used to improve blood pressure control for women with hypertension in pregnancy.

This pilot study has been set up to inform the planning of a large-scale multi-centre randomised controlled trial (RCT). We want to increase our experience of applying SMBP in the pregnant population with hypertension; to assess recruitment and retention potential; select the most appropriate primary and secondary outcome measures and to estimate effect size of the intervention; and to evaluate the trial processes and the acceptability of the intervention. The primary objective of the large-scale RCT would be to determine whether SMBP can improve BP control in pregnant women with hypertension.

Women recruited to the pilot study will be randomly assigned on a 2:1 basis to one of two groups: SMBP or usual care, respectively. Participants assigned to usual care will have their blood pressure monitored by their clinical teams at antenatal clinic visits, and management decisions made using these readings. Participants assigned to the SMBP group will use an automated home BP monitor to measure their BP daily and clinicians will be able to use the recorded home readings, in addition to

clinic readings, when making management decisions. The women in the chronic hypertension cohort will record their home BP readings in a study diary, and the gestational hypertension group will use telemonitoring in the form of texting or a study-specific App. All participants will be followed up to 12 weeks postnatal.

1.4 Objectives

Primary Objective:

- Feasibility of the study.

Secondary Objectives:

1. To investigate whether the use of SMBP in pregnant women with hypertension can improve blood pressure control.
2. To determine the relationship between self-monitored and professionally measured/clinic BP during pregnancy in women with hypertension (intervention group).
3. To explore antihypertensive medication adherence amongst pregnant women with hypertension comparing BP self-monitoring and usual care groups.
4. To determine the effect of SMBP on clinician antihypertensive medication prescribing.
5. To assess safety of an SMBP intervention in this context using maternal and perinatal outcomes.
6. To evaluate the effects of SMBP on health resource use.
7. To explore participant and clinician use and experience of SMBP in the study.

Objective 6 for the purposes of this SAP will include simple descriptive measures of health resource use. A more detailed health economic analysis is outside the scope of this SAP.

Objective 7 will be explored using participant questionnaires described further in this SAP, and using ethnographic methods which are outside the scope of this SAP.

Exploratory Analyses:

- To explore alternative measures for assessing BP control in this context.
- To present Observation Group baseline and delivery outcome data.

2 Trial Design

OPTIMUM-BP is a mixed methods multi-centre, open-label, parallel randomised controlled feasibility study with allocation concealment. Due to the nature of the intervention the participating women, clinicians and researchers cannot be masked to intervention. It compares self-monitoring of blood pressure (SMBP) to Usual Care (2:1 allocation) for the management of pregnancy hypertension.

We will aim to recruit 160 women; 80 women with chronic hypertension and 80 with gestational hypertension over a 2 year period.

Women with chronic hypertension, who are eligible but who decline to consent to inclusion in the randomised trial will be invited to join a parallel non-randomised (observational) arm of the study for additional exploratory analysis. Baseline and pregnancy outcome data will be collected for this Observational Group to assist assessment of generalisability and safety.

The OPTIMUM-BP protocol (referred to on page 4) describes the detailed trial design.

All results will be analysed on an intention-to-treat basis. If women are lost to follow-up, they will be included in their randomised group for all outcomes for which we have information. We will use a complete case analysis with no imputation for missing data.

2.1 TARGET POPULATION

Inclusion criteria:

- Women with **chronic hypertension** (defined as sustained diastolic BP≥90mmHg and/or systolic BP≥140 mmHg, measured in the standardised fashion, present at booking or before 20 weeks gestation, or receiving treatment outside pregnancy and/or at time of referral)
- Recruited at booking to 23+6 weeks gestation

OR

- Women with **gestational hypertension** (defined as sustained diastolic B≥90mmHg and/or systolic BP≥140 mmHg, measured in the standardised fashion, after 20 weeks gestation without the presence of proteinuria.
- Recruited at 20+0 to 37+6 weeks gestation

In both cases, additionally:

- Able to give informed written consent
- Willing to be randomised
- Viable singleton pregnancy
- Age ≥ 18 years

Exclusion criteria:

The woman may not enter the study if ANY of the following apply:

- Unwilling to self-monitor
- Insufficient understanding of the study
- Confirmed superimposed pre-eclampsia (as defined by the International Society for the Study of Hypertension in Pregnancy (ISSHP) 2014 statement) at time of enrolment.

Inclusion criteria are the same for women enrolling into the observational group, except they are not willing to be randomised.

2.2 SAMPLE SIZE

A formal sample size calculation is not required for this feasibility pilot study.

We will aim to recruit 80 women with chronic hypertension and 80 with gestational hypertension, with replacement for withdrawals if there is sufficient time to recruit new participants within the study time-line.

Sample size was based on recommendations by Teare et al[2], who suggest a sample size of at least 70 in order to be able to estimate the standard deviation of a normally distributed variable.

The final sample size was based on clinician experience of expected numbers of eligible patients and participant recruitment rates for similar studies at the study sites which could be recruited over the trial time-line.

2.3 RANDOMISATION AND BLINDING IN THE ANALYSIS STAGE

A secure web-based randomisation system has been provided by the University of Oxford Primary Care Clinical Trials Unit (Sortition v2.3).

The system will allow for the allocation of patients to two trial groups: self-monitoring or usual care on a 2:1 basis and for this allocation to be stratified according to recruitment site and hypertension group. A 2:1 ratio with enrichment for the intervention group was decided to provide increased experience with this intervention in this population and provide increased feasibility data for a large trial.

Group allocation is masked at randomisation but due to the nature of the intervention it is not possible to mask the participants, clinicians or researchers to the group allocation.

2.4 OUTCOME MEASURES

2.4.1 PRIMARY OUTCOMES

All measured at the end of the trial period:

- Recruitment rate is defined as the overall number of participants randomised per month. We will also calculate the overall proportion of those who were approached and eligible that were randomised.
- Loss to follow-up is defined as those for whom we do not have delivery outcomes as a proportion of the number of participants recruited and randomised.
- Withdrawal rate is calculated as the number of participants withdrawing consent for final notes review as a proportion of those recruited and randomised.

- Discontinuation of the self-monitoring intervention will be calculated as proportion of those recruited and randomised to the self-monitoring group who specifically withdraw from self-monitoring before delivery.

- Adherence and persistence with the BP self-monitoring protocol will be defined as proportion of intervention participants who complete no home monitoring, who complete at least one home BP measurement per week and the median number of readings per week (with interquartile range).

  In addition, we will present proportion of those in the control group recorded as using home BP monitoring during current pregnancy, as indicated from the medical notes.

In analyses using home BP data, prioritisation will follow the order: BP monitor data, App/text submitted data, BP diary data and we will report when each type of data are used or missing.

(See CONSORT Diagram (Appendix 2))

2.4.2 Secondary outcomes

This feasibility trial is not powered to detect differences between the treatment groups in the below secondary and exploratory outcomes. Therefore, only adjusted estimates of the treatment effects and the 95% confidence intervals will be reported from these analyses.

2.4.2.1 Blood Pressure Control

A range of different outcomes will be explored to best define and measure the concept of blood pressure control in the antenatal period. We will explore BP control using both study and clinic BP measurements.

For definitions of mean study and clinic BP measurements see Appendix III.

BP control measures will include:

Mean adjusted differences in between-group systolic and diastolic *study* blood pressures (using a mixed model). (See section 5.1)

Mean adjusted differences in between-group systolic and diastolic *clinic* blood pressures (using a mixed model).

Mean highest systolic *clinic* blood pressure between randomisation and delivery (using linear regression).

Time-weighted average systolic and diastolic *clinic* blood pressures (using an area under the curve analysis with the trapezium rule).

(See section 5.1)

2.4.2.2 DIFFERENCE BETWEEN HOME AND CLINIC BP READINGS

This analysis will explore the evidence for any 'white coat effect' or 'masked' effects in this population.

Self-monitored and clinic BP readings will be compared throughout pregnancy for all intervention group participants with both sets of readings for a given gestational week.

2.4.2.3 MEDICATION ADHERENCE AND BELIEFS

Data from the medication adherence (MARS) and medication belief (BMQ) questionnaires will be presented for three time points for all those taking antihypertensive medications and completing these questionnaires: baseline, visit 3 (28 weeks) and visit 4 (34 weeks gestation).

Medication adherence:
Scores for the self-reported Medication Adherence Report Scale questionnaire (the MARS-5 questionnaire[3]) will be presented as means and standard deviations for each group at each time point. See Appendix IV for scoring details.

Medication beliefs:
Scores for the Medication Beliefs Questionnaire (the 10 point BMQ questionnaire[4]) will be presented as means and standard deviations for each group at each time point. See Appendix IV for scoring details.

2.4.2.4 ANTIHYPERTENSIVE PRESCRIBING

Prescribed antihypertensive medications were recorded at baseline, follow-up (20, 28, 34 weeks gestation) and pre-delivery (via Notes Review).

Proportion of women taking antihypertensive medication at any point in the antenatal period, number of agents, and type of agents, will be presented for both groups.

To allow the comparison of the amount of different antihypertensive medications prescribed during the antenatal period, individual drug doses will be converted into Defined Daily Doses (DDD, as defined by the World Health Organisation for each antihypertensive medication prescribed[5], see Appendix III for more details).

2.4.2.5 SAFETY AND MATERNAL AND PERINATAL OUTCOMES

Descriptive data concerning maternal and perinatal outcomes for both groups will be reported.

Reporting of serious adverse events (SAEs) to the research team is to occur throughout the study if thought to be related to the research processes or intervention. The particular group being studied are high risk for serious pregnancy complications and several expected SAEs are reported amongst the secondary maternal/perinatal outcomes described above. Any SAEs not captured above will be tabulated by group.

2.4.2.6 HEALTH RESOURCE USE

Clinic attendance, Day/Maternity Assessment Unit (DAU/MAU) visits and admissions (for all cause) are collected at each antenatal study visit and in final Notes Review, including overall length of stay for mother and baby at time of delivery and any high-level maternal or neonatal care.

- Count data (total number of separate admissions)
- Binary data (total number of participants in each group with at least one maternal admission).

2.4.2.7 PATIENT EXPERIENCE

Data from the EQ-5D-5L (a five domain, five level) quality of life questionnaire will be compared at two time points (baseline and 6 weeks postnatal) for each group[6]. The EQ-5D-5L includes an overall visual analogue score (EQ-VAS).

Scores from the EQ-VAS and EQ-5D-5L Cross-Walk Index value will be presented as a mean and standard deviation for each group at each time point.

Scores from the Abbreviated State Trait Anxiety Inventory-6 score[7], will be compared at two time points (baseline and 6 weeks postnatal) for each group.

Little's questionnaire[8], will be used at the 6 week postnatal study visit to assess acceptability of the different methods of blood pressure monitoring (clinic and home monitoring). Scores from the questionnaire will be presented as median and interquartile range for each question, overall mean of all items and standard deviation for each group. See Appendix IV for scoring details.

2.4.3 EXPLORATORY ANALYSIS

<u>Alternative measures of blood pressure control:</u>

- Frequency of severe hypertension:
  SBP≥160 mmHg or DBP ≥110 mmHg (on or off treatment)

- Clinic blood pressure readings in target range:
  - On antihypertensive treatment: 150>SBP>100 mmHg and 100>DBP>70 mmHg
  - Off antihypertensive treatment: SBP<140 mmHg and DBP<90 mmHg

(For blood pressure threshold and time-in range analysis, see section 7)

Observation Group comparison:

The baseline demographic and clinical characteristics, antenatal clinic blood pressures and pregnancy outcomes for the Observation Group will be presented alongside similar data for the combined randomised groups.

3 ANALYSIS – GENERAL CONSIDERATIONS

3.1 DESCRIPTIVE STATISTICS

The analyses for this pilot study will be primarily descriptive and will not include any hypothesis testing or presentation of p-values for group comparisons.

Continuous variables will be presented as means with standard deviations (or medians with interquartile ranges if skewed) by treatment group. Binary and categorical variables will be reported as counts and percentages in each treatment group. Difference between groups will be calculated and described with 95% confidence intervals (CI) only and will not include significance tests with p-values.

3.2 CHARACTERISTICS OF PARTICIPANTS

Summary statistics of baseline demographic and clinical variables by treatment group will be assessed to ensure balance of these characteristics between the two randomised groups.

Frequencies and percentages will be reported for categorical variables, means and standard deviation will be reported for continuous variables if normally distributed, median and interquartile range if skewed. Number with missing data for each characteristic will be presented. No formal statistical testing will be applied to test for any difference between randomised groups with respect to the baseline characteristics.

The same baseline characteristics will also be reported for the observation group.

3.3 DEFINITION OF POPULATION FOR ANALYSIS

For the primary outcome (feasibility measures) the whole population will be analysed collectively and separately where described.

The analysis of secondary outcomes will be on an intention to treat (ITT) basis. That is, after randomisation, participants will be analysed according to their allocated intervention group irrespective of what they actually receive. The unit of analysis will be the woman and it will be a complete case analysis with no imputation for missing data.

We will explore any effect of loss to follow-up should this be significant.

3.4 POOLING OF INVESTIGATIONAL SITES

The investigation sites are as follows:

Oxford (John Radcliffe Hospital)

London (St Thomas' Hospital)

London (King's College Hospital) – only recruiting to the gestational hypertensive cohort

Wolverhampton (New Cross Hospital)

The randomisation will be stratified by site and results will be pooled across sites except for the recruitment rate outcomes which will also be broken down by site.

4 PRIMARY ANALYSIS

4.1 PRIMARY OUTCOME

The primary objective is to assess feasibility for a larger trial. The feasibility measures will be expressed as counts and percentages. There will be no formal hypothesis testing between randomised groups. The primary analysis will use measures at the end of the study.

Primary outcomes are descriptive and are defined in 2.4.1

(See CONSORT Diagram (Appendix III))

4.2 HANDLING MISSING DATA

The rate of missing data is highly relevant for a feasibility study, and the primary outcomes will capture and describe much of this.

We will not impute any missing data for any of the analyses specified in this SAP, but we will explore the assumptions of missing at random (MAR).

4.3 HANDLING OUTLIERS

A possible outlier for this study will be defined as a data-point at least three standard deviations from the mean of its distribution in the variable for a specific time-point.

For outliers that have not already been queried in data input and data cleaning, they will be queried for double-checking at the time of initial analyses.

5 SECONDARY ANALYSIS

5.1 SECONDARY OUTCOMES

Secondary outcomes have been grouped by variable type. Analysis will be conducted on all randomised participants and combining the two hypertensive groups: participants with chronic or gestational hypertension.

A range of generalised linear models have been outlined below dependent on variable type. The model assumptions will be explored by assessing the departure from normality using residual and diagnostic plots. If the assumptions seem to be violated, either a transformation to the data or non-parametric methods will be used.

5.1.1 BINARY OUTCOMES

Binary secondary outcomes (e.g. number of participants with at least one antenatal admission, perinatal outcomes) will be analysed by presenting the frequency and proportion in each study group. A logistic regression model will be fitted to the data with randomisation group, recruitment site and type of hypertension as covariates. Adjusted relative risks and 95% confidence intervals will be presented. The regression model might be unstable at low event rates. If the number of events is less than 20, the results from the model will be interpreted with caution.

5.1.2 REPEATED MEASURES OUTCOMES

Study and clinic systolic and diastolic blood pressures, MARS and BMQ questionnaire mean scores, and antihypertensive DDD will all be analysed using mixed effects linear regression models with repeated measures.

The linear mixed effect model with model the relevant outcome at different time points and include the covariates of randomisation group and time. The model will adjust for recruitment site, type of hypertension and baseline values, fitted as fixed effects with unstructured covariance. We will include up to a three-way interaction term into the models to enable the calculation of a treatment effect within each hypertensive cohort at a particular week of gestation. The difference in the adjusted means between the randomisation groups with 95% CI at each time point will be presented and interaction terms reported.

5.1.3 CONTINUOUS OUTCOMES

One value per participant (e.g. time-weighted mean clinic systolic or diastolic blood pressure between randomisation and delivery) will be analysed by presenting means and standard deviation by randomisation group. A linear regression model will be fitted with randomisation group as the fixed effect and adjusting for recruitment site, type of hypertension and baseline blood pressure. We will include an interaction term into the model to enable the calculation of a treatment effect within each hypertensive cohort.

Post-delivery scores on the EQ5D5L (using the cross-walk index value), VAS and STAI questionnaires will be analysed as above but adjusting for baseline questionnaire scores.

5.1.4 PERSISTENCE WITH SMBP

Persistence information will be plotted using Kaplan Meier and frequency plots.

5.1.5 COUNT OUTCOMES

Number of separate admissions and visits to clinic and DAU/MAU will be analysed presenting the event rate in each randomisation group. A Poisson model will be fitted to the data to compare between groups. The dependent variable is the number of admissions/visits while the explanatory variables will include randomisation group, recruitment site, type of hypertension and baseline blood pressure. We will include an interaction term into the model to enable the calculation of a treatment effect within each hypertensive cohort. The incidence rate ratio and 95% CI will be reported. If there is evidence of over-dispersion a negative binomial model will be explored.

5.1.6 COMPARING HOME AND CLINIC BP MEASUREMENTS

Self-monitored and clinic BP readings will be compared throughout pregnancy for all intervention group participants from both hypertension groups with both sets of readings for any given gestational week.

- The mean of each set of clinic readings in a given week (using all readings), will be compared with the mean of any home readings recorded by the participant in the preceding seven days. Mean data will be presented by gestational week for systolic and diastolic blood pressure for those participants that have both clinic and home BP readings in a given week.

- Bland Altman analysis of differences for paired measurements will be completed for 4 week gestational periods for both systolic and diastolic blood pressures.

6 SUBGROUP ANALYSES

Interaction terms will be included in the models as described above, to explore if there is a difference in the effect of the intervention between the two hypertension groups.

7 ADDITIONAL EXPLORATORY ANALYSIS

Exploratory blood pressure control analyses will include:

- Blood pressure readings above the threshold (as described in 2.4.3) will be explored using the Fischer's exact test to obtain empirical odds in both study groups, showing numbers in each group having at least one blood pressure reading over the specified threshold. We will also use a log linear model to analyse the count of exceedances obtained for each women, which will include an offset value for how many measurements they had in total, and this model with include fixed effects covariates for site, type of hypertension and baseline blood pressure.
- Time-in-BP -range (as described in 2.4.3) will be calculated for each participant using the method described by Rosendaal et al[9]. This derived time-in-range value will then be compared between study groups using a linear regression model adjusted for site,

hypertension group and baseline blood pressure, and with an interaction term between hypertension and randomisation group.

8 SAFETY ANALYSIS

8.1 ADVERSE EVENTS

See section 2.4.2.7

9 VALIDATION

The statistical analysis will be carried out by the Chief Investigator, but will be validated by an independent statistician at the Primary Care Clinic Trials Unit.

10 CHANGES TO THE PROTOCOL OR PREVIOUS VERSIONS OF SAP

Amendment no.	New SAP version no.	Date issued	Author(s) of changes	Details of changes made

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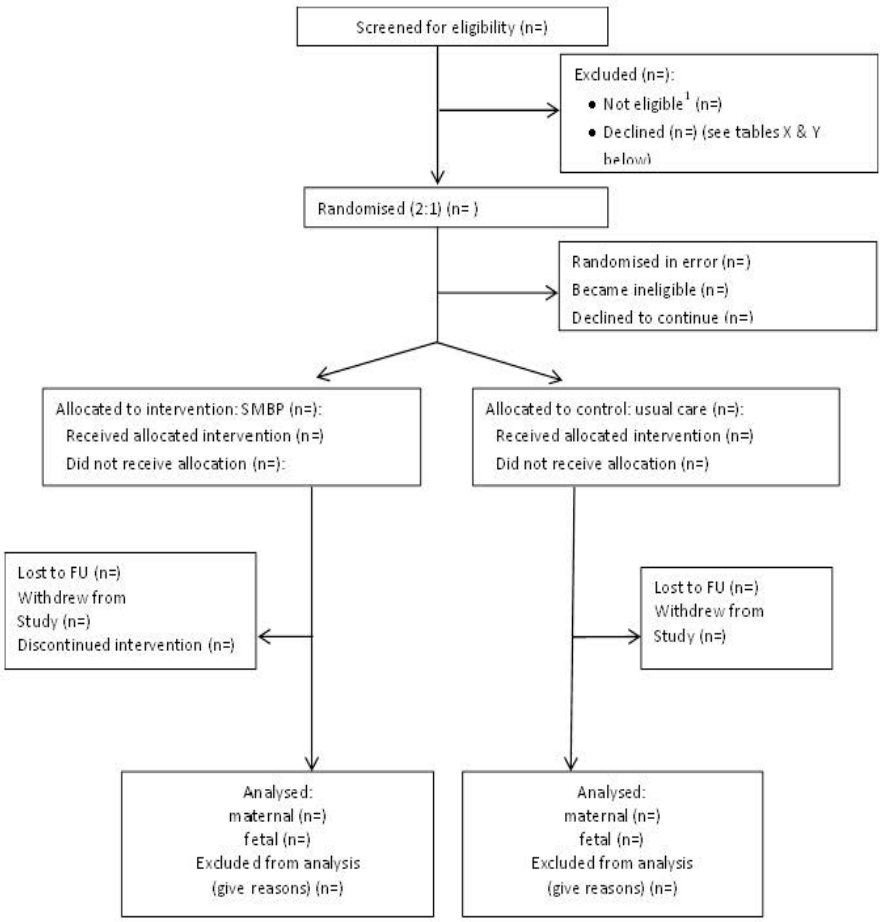
12 APPENDICES

12.1 APPENDIX I. SCHEDULE OF PROCEDURES

Procedures	Screening	Baseline (visit 1*)	20 wk (visit 2)	28 wk (visit 3)	34 wk (visit 4)	6 wk PN (visit 5)	Notes Review
Eligibility check	X						
Informed consent		X					
Demographics		X					
Medical history		X					
Document medications		X	X	X	X		X
Randomisation		X					
Study BP		X	X	X	X		
Clinic BP		Clinic blood pressure measurements will be taken throughout pregnancy and recorded at study visits and final notes review					
Adverse event assessment		Adverse events will be reported if thought related to the study processes and intervention and as outcomes in the notes review					
Download home BP monitor data			X	X	X	X	
Collect SMBP diary			X	X	X	X	
EQ-5D-5L & STAI-6		X				X	
MARS & BMQ questionnaires		X		X	X		
Little's questionnaire						X	

12.2 Appendix II. CONSORT flow diagram of trial participants



12.3 Appendix III. Definitions of Study and Clinic BP Measurements

Study Visit BP measurements:

- Study systolic blood pressure at each of the antenatal study visits 2-4 (mean of readings 2-3 at each visit).
- Study diastolic blood pressure at each of the antenatal study visits 2-4 (mean of readings 2-3 at each visit).

Clinic BP measurements:

- Clinic systolic blood pressure at each antenatal clinic/DAU visit (mean of all readings).
- Clinic diastolic blood pressure at each antenatal clinic/DAU visit (mean of all readings).

12.4 Appendix IV. Scoring of questionnaires and DDD

The MARS-5 consists of 5 common patterns of non-adherent behaviour that respondents score on a 5-point Likert scale (with 1 = always, 2 = often, 3 = sometimes, 4 = rarely, and 5 = never). The first statement of the MARS-5 questions patients about unintentional nonadherence (e.g., I forget to take them), whereas the other 4 statements question intentional nonadherence (e.g., I alter the dose). Scores are summed, and totals range from 5 to 25, with higher scores indicating higher self-reported adherence. Participants were asked to consider only their antihypertensive medication when completing the questionnaire.

The BMQ consists of a specific part which contains two five-item scales assessing patients' beliefs about the necessity of specific prescribed medication for controlling their disease and their concerns about potential adverse effects of taking it. Respondents indicate their degree of agreement with each statement on a five-point Likert scale, ranging from 1 'strongly disagree' to 5 'strongly agree'. Scores obtained for both scales are summed. Thus, total scores for the Necessity and Concerns Scales range from 5 to 25. Higher scores indicate stronger beliefs. A necessity–concerns differential score can be calculated as the difference between the necessity and the concerns scales, with a possible range of -20 to +20. This differential can be thought of as a cost–benefit analysis for each respondent, for whom costs (concerns) are weighed against their perceived benefits (necessity beliefs).

The Little's questionnaire has 13 items marked against a 5 point Likert scale (1=disagree strongly; 2=disagree; 3=disagree slightly; 4=unsure or not applicable; 5=agree slightly; 6=agree; 7=agree strongly).The 13 items are divided into 5 broad domains: 3 problem and 2 positive (disturbance and discomfort, self-consciousness, uncertainty, accuracy, control and efficiency). Scoring is reversed for the positive domains when summing for the total score.

To allow the comparison of the amount of different antihypertensive medications prescribed during the antenatal period, individual drug doses will be converted into Defined Daily Doses (DDD, as defined by the World Health Organisation for each antihypertensive medication prescribed[5]). Doses of antihypertensive will be assumed to be kept constant between trial data collection timepoints. Mean defined daily doses will be compared overall (for all antihypertensives prescribed) and for each antihypertensive class for the time that women receive treatment up until delivery.

APPENDIX 9: Publication of OPTIMUM-BP feasibility RCT

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A randomised controlled trial of blood pressure self-monitoring in the management of hypertensive pregnancy. OPTIMUM-BP: A feasibility trial

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ABSTRACT

Objective: To assess the feasibility of a blood pressure self-monitoring intervention for managing pregnancy hypertension.
Study design: OPTIMUM-BP was an unmasked randomised controlled trial comparing a self-monitoring of blood pressure (SMBP) intervention versus usual care for the management of pregnancy hypertension. Women with chronic (CH) or gestational hypertension (GH) from 4 UK centres were randomised (2:1) intervention to control. Self-monitoring involved daily home blood pressure (BP) measurements, with recording via study diary or telemonitoring. Clinicians were invited to use the home readings in clinical and antihypertensive titration decisions.
Main outcomes: The primary outcomes were recruitment, retention, adherence and persistence with the intervention.
Results: Women from four UK centres were randomised: 158/222 (71%) of those approached agreed, comprising: 86 women with chronic hypertension (55 SMBP, 31 control) and 72 with gestational hypertension (49 SMBP, 23 control) of whom outcome data were available from 154 (97%) and were included in the analysis. The median (IQR) number of days with home BP readings per week were 5.5 (3.1–6.5) for those with chronic hypertension and 6.1 (4.5–6.7) with gestational hypertension. Participants persisted with the intervention for 80% or more of their time from enrolment until delivery in 86% (43/50) and 76% (38/49) of those with chronic and gestational hypertension respectively. Recorded clinic and study BPs were similar for both groups.
Conclusions: This is the first randomised investigation of BP self-monitoring for the management of pregnancy hypertension and indicates that a large RCT would be feasible.

1. Introduction

Hypertensive disorders of pregnancy are common and associated with substantial maternal and perinatal morbidity and mortality [1,2]. Much of the research and clinical focus has previously been on the timely detection and effective management of preeclampsia and eclampsia. There has been conflicting evidence and limited guidance regarding managing non-proteinuric hypertension in pregnancy, with a recognition that severe hypertension is a risk factor for maternal stroke [3–5] but it is also necessary to seek to avoid possible iatrogenic risks of

Abbreviations: SMBP, self-monitoring of blood pressure; CH, chronic hypertension; GH, gestational hypertension

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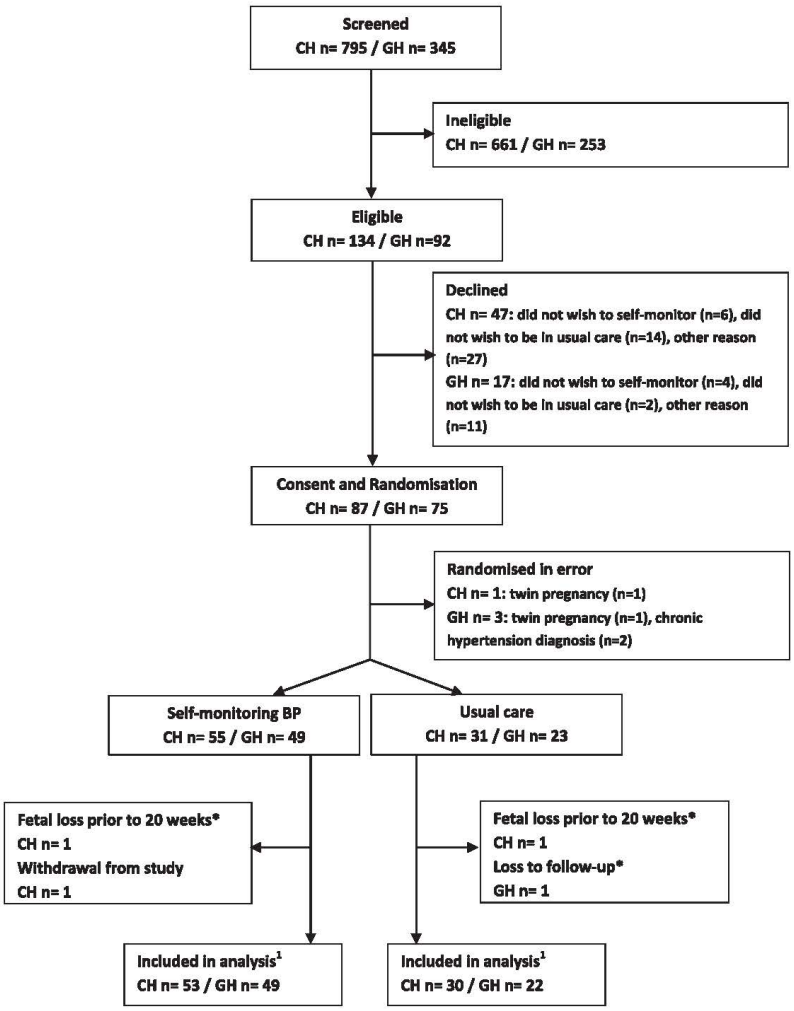

Fig. 1. OPTIMUM-BP CONSORT (Consolidated Standards of Reporting Trial) flowchart. *No data available after baseline.

controlling blood pressure (BP), such as reduced fetal growth. The recent Control of Hypertension in Pregnancy Study (CHIPS) showed that tight (diastolic target of 85 mmHg) versus less-tight control (diastolic target of 105 mmHg) of BP in hypertensive pregnancies was associated with a reduced incidence of maternal severe hypertension without a consequent increase in adverse perinatal outcomes, and a secondary analysis showed that severe hypertension was associated with multiple adverse maternal and perinatal outcomes independent of the development of preeclampsia [6,7]. However the optimal approach to obtaining BP control in pregnancy and therefore avoiding severe hypertension is uncertain. Currently, pregnant women with hypertensive disorders usually have more frequent clinic surveillance to monitor for any deterioration in BP, assessing for emerging preeclampsia and fetal complications associated with pregnancy hypertension [8]. Not only does this place a considerable burden on both the health service and importantly the woman herself, but deterioration may occur between clinic visits [9,10].

In the general adult population with chronic hypertension, evidence shows that BP self-management that includes self-monitoring and titration of antihypertensives leads to significantly improved BP control and higher patient satisfaction [11–14]. Previous small, mostly non-randomised studies of BP self-monitoring in the pregnant population [15–17] suggest a similar approach may be feasible and acceptable.

OPTIMUM-BP used a BP self-monitoring intervention developed from other self-monitoring BP trials [11,18] for use by pregnant women with hypertension. This trial was designed to study the feasibility and acceptability of a BP self-monitoring intervention in the management of hypertension in pregnancy. It aimed to inform the further development

Table 1
Demographic and clinical characteristics at enrolment of 158 pregnant women with hypertension included in the OPTIMUM-BP feasibility trial from December 2015 until December 2017.

Characteristic	Chronic Hypertension		Gestational Hypertension	
	Randomised to SMBP (n = 55)	Randomised to usual care (n = 31)	Randomised to SMBP (n = 49)	Randomised to usual care (n = 23)
Age in years*	35.9 (5.6)	35.5 (4.2)	33.4 (5.9)	34.2 (5.1)
Gestation at recruitment in weeks†	16.6 (12.9 to 20.1)	14.9 (13.0 to 20.0)	35.0 (32.4 to 36.1)	34.7 (32.1 to 36.4)
Body mass index* (kg/m^2)	31.0 (7.0)	31.9 (7.0)	29.5 (7.1)	27.6 (6.4)
Ethnicity				
White	27 (49%)	21 (68%)	37 (76%)	18 (78%)
Black	21 (38%)	8 (26%)	11 (22%)	4 (18%)
Asian	6 (11%)	2 (6%)	1 (2%)	1 (4%)
Other	1 (2%)	0 (0%)	0 (0%)	0 (0%)
Deprivation quintile‡				
1st – least deprived	18 (33%)	7 (23%)	13 (27%)	4 (17%)
2nd	13 (24%)	7 (23%)	10 (20%)	6 (26%)
3rd	7 (13%)	9 (29%)	7 (15%)	5 (22%)
4th	9 (16%)	6 (19%)	9 (18%)	3 (13%)
5th – most deprived	6 (10%)	2 (6%)	9 (18%)	3 (13%)
Unknown	2 (4%)	0 (0%)	1 (2%)	2 (9%)
Highest educational qualification				
Professional/Higher qualifications	36 (65%)	16 (52%)	37 (76%)	20 (87%)
School qualifications	15 (27%)	14 (45%)	9 (18%)	3 (13%)
No formal qualifications	3 (6%)	1 (3%)	1 (2%)	0 (0%)
Unknown	1 (2%)	0 (0%)	2 (4%)	0 (0%)
Smoking history				
Never smoked	39 (71%)	26 (84%)	40 (82%)	17 (74%)
Quit before pregnancy	9 (16%)	4 (13%)	8 (16%)	4 (18%)
Smoking during pregnancy	5 (9%)	0 (0%)	0 (0%)	1 (4%)
Not known	2 (4%)	1 (3%)	1 (2%)	1 (4%)
Other self-reported medical history**				
Diabetes type 1	0 (0%)	1 (3%)	0 (0%)	1 (4%)
Diabetes type 2	2 (4%)	3 (10%)	1 (2%)	0 (0%)
Chronic kidney disease	1 (2%)	1 (3%)	0 (0%)	0 (0%)
Asthma	7 (13%)	4 (13%)	5 (10%)	1 (4%)
Parity				
0	17 (31%)	9 (29%)	20 (41%)	14 (61%)
≥1	38 (69%)	22 (71%)	29 (59%)	9 (39%)
Diagnosis of preeclampsia or gestational hypertension in previous pregnancy	20 (53%)	16 (73%)	15 (52%)	5 (56%)
Proportion prescribed** antihypertensive medication at enrolment	40 (73%)	21 (68%)	30 (61%)	15 (65%)
*Blood pressure at enrolment in mmHg**				
Systolic	136.6 (13.8)	139.5 (13.1)	139.5 (14.0)	137.3 (1.3)
Diastolic	85.9 (10.1)	87.4 (11.5)	86.9 (9.9)	87.9 (8.0)
Previous SMBP in this pregnancy at least once	25 (45%)	16 (52%)	14 (29%)	5 (21%)

Abbreviations: CH: Chronic hypertension; GH: Gestational hypertension; SMBP: Self-monitoring blood pressure; BP: Blood pressure; SD: Standard deviation; N: Number; IQR: Interquartile range.

* Mean and SD.

† Median and interquartile range.

‡ Deprivation measured as Index of Multiple Deprivation score using Office of National Statistics for England data [24].

** Participants' self-reported medication history.

of the intervention and processes for use in a future large randomised controlled trial (RCT), to investigate the effectiveness of this intervention for blood pressure control during pregnancy.

2. Methods

OPTIMUM-BP was an unmasked randomised controlled clinical trial including pregnant women with chronic or gestational hypertension. The trial compared hypertensive management utilising clinic BP alone vs management supplemented by self-monitoring of BP. The study protocol and materials were approved by the UK Research Ethics Committee (15/EM/0490) and research and development approvals gained. All study participants provided written, informed consent. Trial registration: DOI 10.1186/ISRCTN16018898.

2.1. Participants

Pregnant women with hypertension were enrolled by study investigators from four National Health Service (NHS) maternity units in England. Eligibility criteria included women aged ≥18 years with a singleton pregnancy and with chronic or gestational hypertension, without preeclampsia. Women with chronic hypertension (treated or not) could have a prenatal diagnosis of hypertension or sustained BP readings ≥140 mmHg systolic and/or ≥90 mmHg diastolic before 20 weeks' gestation, and were recruited any time between booking and 23^{+6} weeks' gestation. Women with gestational hypertension, defined as sustained BP readings ≥140 mmHg systolic and/or ≥90 mmHg diastolic after 20 weeks' gestation and without proteinuria, were recruited between 20 and 37^{+6} weeks' gestation. Women were excluded if they were unwilling to self- monitor, had insufficient understanding of the study or had preeclampsia (as defined by the International Society for the Study of Hypertension in Pregnancy 2014 statement)

Table 2
Feasibility outcomes for 158 pregnant women with hypertension included in the OPTIMUM-BP feasibility trial from December 2015 until December 2017.

Overall recruitment	71% (158 randomised, 222 eligible*)		
Chronic hypertension recruitment	65% (86 randomised, 133 eligible*)		
Gestational hypertension recruitment	81% (72 randomised, 89 eligible*)		
Recruitment totals per centre n (%)	Total	CH	GH
Guy's and St Thomas' NHS Foundation Trust	68 (43%)	47 (55%)	21 (29%)
Oxford University Hospitals NHS Foundation Trust	51 (32%)	27 (31%)	24 (33%)
New Cross Hospital, Royal Wolverhampton NHS Trust	19 (12%)	12 (14%)	7 (10%)
King's College Hospital NHS Foundation Trust	20 (13%)	0 (0%)	20 (28%)
Overall recruitment rate per site per month	2.5 (158 randomised, cumulative 64 months recruitment period over four sites)		
Chronic hypertension recruitment rate per site per month	2.8 (86 randomised, 31 months recruiting)		
Gestational hypertension recruitment rate per site per month	2.2 (72 randomised, 33 months recruiting)		
Adherence with study visits	Total	SMBP	Usual Care
Chronic hypertension group	N = 83	N = 53	N = 30
Applicable antenatal study visits	89% (175/197)	88% (107/121)	90% (68/76)
6 weeks postnatal study visit	72% (60/83)	72% (38/53)	73% (22/30)
Gestational hypertension group	N = 71	N = 49	N = 22
Applicable antenatal study visits	83% (19/23)	77% (13/17)	100% (6/6)
6 weeks postnatal study visit	73% (52/71)	74% (36/49)	73% (16/22)
*Discontinuation with SMBP intervention***			
Chronic hypertension group	7% (4/55 originally randomised to SMBP)		
Gestational hypertension group	4% (2/49 originally randomised to SMBP)		
*Fidelity with assigned randomisation group****			
Chronic hypertension group	39% (12 started SMBP/31 randomised to usual care)		
Gestational hypertension group	17% (4 started SMBP/23 randomised to usual care)		
Adherence with SMBP protocol[α]			
Chronic hypertension group	N = 50		
Median (IQR) number of BP readings days per week[β]	5.5 (3.1 to 6.5)		
Median (IQR) number of monitor readings per day on days monitored[β]	2.2 (2.1 to 2.5)		
Gestational hypertension group[α]	N = 43		
Median (IQR) number of BP readings days per week[β]	6.1 (4.5 to 6.7)		
Median (IQR) number of monitor readings per day on days monitored[β]	2.9 (2.5 to 4.6)		

* Deducting 4 women who were found later not to be eligible (see Fig. 1).
** Participants who actively withdrew from SMBP and completed a study discontinuation form.
*** Proportion of usual care group starting SMBP with evidence of SMBP readings recorded in clinical notes.
[α] From women who supplied home data using BP monitor, App or BP diary data where available.
[β] Deducting any antenatal admission dates for a woman where she was not expected to self-monitor.

[19] at time of enrolment.

2.2. Procedures

Eligible and consented women completed a baseline assessment including questionnaires on quality of life scores (EQ-5D-5L) [20], measurement of anxiety (STAI-6) [21] and medication beliefs (BMQ) [22] and medication adherence (MARS) [23]. Members of the research team obtained study BP measurements and data on demographics, medical and obstetric history, current and past antihypertensive therapy and socioeconomic status (Index of Multiple Deprivation) [24]. Women were randomised, stratified for recruiting centre and type of hypertension, in permuted blocks of random size (2 or 4) in a 2:1 ratio to BP self-monitoring or usual care. Women randomised to the intervention also received all usual care, and no antenatal visits were removed from their schedule. The randomisation sequence was computer-generated, and secure web-based software was used to ensure allocation concealment, although due to the nature of the intervention, neither participants nor investigators or clinicians were masked. Outcome measurement was not masked. Study visit BP readings were taken with an automated, validated monitor to minimise bias.

Women allocated to usual care had their BP monitored by their local clinical team, and these BPs measured by healthcare professionals were used to inform care and decisions around antihypertensive medication. Women randomised to the intervention were additionally asked to measure their BP daily, at approximately the same time each day, using an automated BP monitor (Microlife WatchBP Home) validated in pregnancy and preeclampsia, after measuring and recording upper-arm diameter to select appropriate cuff size [25]. Participants were asked to take two readings, at least one minute apart, and to record the second in their study diary, or submit the reading using their mobile phone, via text or the study App (the App was available for the women with gestational hypertension only, during the latter phase of the study). The digitally reported readings were automatically transmitted to a secure server, which provided immediate automated responses. This telemonitoring service provided reminders when BP readings were overdue. The digital readings were available for use by the clinical team at follow-up appointments via the woman's App or the study website. Women recording their home readings in a diary were asked to bring their diary to their antenatal follow-up visits to share their readings with their clinical team. In addition to receiving training about how to best measure their BP and symptoms of pregnancy hypertensive disease, women were also provided with guidance about normal and out-of-range readings using an algorithm the study team had created based on the UK NICE Hypertension in Pregnancy guideline [8] (see Supplementary information 1 for study materials) and how and when to contact their local clinical team for out-of-range readings or symptoms. This same algorithm was used to generate the immediate responses provided through the telemonitoring system.

All women, depending on their gestation at recruitment, were asked to attend up to three antenatal study visits at 20, 28 and 32 weeks' gestation, and one six week postnatal face-to-face or telephone study visit. At these visits, BP measurement was taken by the study team using the Microlife WatchBP Home monitor. Delivery outcome data were collected from the maternity record within three months of delivery.

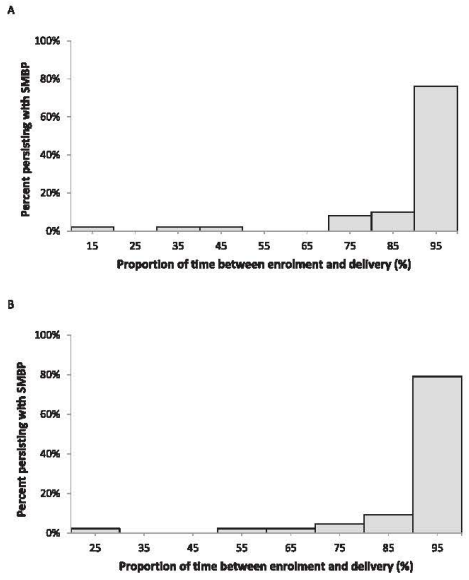

Fig. 2. Persistence with self-monitoring of blood pressure. A: Proportion of time women with chronic hypertension persisted with self-monitoring of blood pressure. Persistence of self-monitoring of BP (SMBP) for 50 women with chronic hypertension providing SMBP data. Of 53 randomised to SMBP: 4 formally discontinued from the intervention, 2 of whom still supplied home data, 2 who never started SMBP and 1 who did not formally discontinue but did not supply data. B: Proportion of time women with gestational hypertension persisted with self-monitoring of blood pressure. Persistence of self-monitoring of BP for 43 women with gestational hypertension providing SMBP data. Of 49 women randomised to SMBP: 2 formally discontinued from the intervention, 1 of who still supplied data, 1 who never started SMBP and 5 who did not formally discontinue but did not supply data.

Clinical teams at the study sites received update training on the standardised method for measuring BP [26] and were advised to record three readings at each antenatal follow-up visit. The average of all three clinic readings on any single occasion was taken as the clinic BP for that episode.

2.3. Analyses

The primary outcomes were for feasibility, measured by recruitment, discontinuation, and adherence and persistence with the self-monitoring protocol. Secondary outcomes included several measures of BP control (to best inform the design and analysis of a future large multi-site RCT), delivery outcomes and safety, health resource use, quality of life scores, antihypertensive prescribing behaviour and self-reported medication beliefs and adherence.

No formal sample size calculation was used but we aimed for a target sample size of 160, consistent with the feasibility design [approximately half with gestational hypertension and half with chronic hypertension] [27]. An intention to treat analysis was performed, with the woman as the unit of analysis using all available data, with no imputation for missing data. The statistical software Stata/SE version 14 was used for all analyses. Differences between randomisation groups are reported with 95% confidence intervals (95% CI), not including formal significance tests.

Analyses are reported separately by hypertension group due to the women having slight variance in the method for BP reporting (BP diarys for those with chronic hypertension and text/App for those with gestational hypertension) and also due to the later gestations of diagnosis and hence recruitment for those with gestational hypertension. Study and clinic BP were analysed using a linear mixed effects regression model with unstructured covariance. The model accounted for repeated measurements on the same participant by means of random effects and adjusted for site and study baseline BP as fixed effects, with interaction between randomisation group and categorical study visit for study BP or interaction between randomisation group and continuous quadratic time measured in weeks of gestation for clinic BP analyses, allowing the model to accommodate a mid-trimester BP dip. Study BP analysis for the group with gestational hypertension used a linear regression model, adjusted for recruiting centre and study baseline BP. A repeated measures model was not used for this group as there were insufficient study visit data due to their later gestations at enrolment into the study. (Further statistical analysis details are supplied in Supplementary information 2).

3. Results

Between December 2015 and December 2017, 1140 women were screened for trial eligibility (Fig. 1) of whom 226 were eligible and 162 provided written consent (target 160). Most women did not provide a reason for declining study enrolment, but the number of women stating they were declining due to specifically not wanting to be randomised to either intervention group were 15% (20/134) and 7% (6/92) for those with chronic and gestational hypertension respectively (details in Fig. 1). Four women were recruited in error [as ineligible] and excluded from further analysis leaving one hundred and fifty-eight women; for women with chronic hypertension: 55 were randomised to self-monitoring and 31 to usual care and for women with gestational hypertension: 49 were randomised to self-monitoring and 23 to usual care. Participants not included in the analysis of clinical outcomes were three with chronic hypertension (two for early miscarriages and one early withdrawal by clinician on medically unrelated grounds) and one with gestational hypertension (lost early to follow-up as emigrated).

Baseline characteristics were generally similar between the allocation groups (Table 1) for women with chronic and gestational hypertension, except within the group with chronic hypertension, where there were relative imbalances in ethnicity and previous diagnosis of a pregnancy hypertensive disorder (see Table 1). Overall, women identifying as a non-white ethnicity accounted for 35% (55/158) and the mean IMD score was 4.8 (SD 2.8) across groups (see Table 1 for details). Thirty-eight percent (60/158) had performed BP home monitoring at least once in the current pregnancy prior to enrolment, the majority of these from the group with chronic hypertension.

3.1. Feasibility outcomes

The main feasibility outcomes are described using the combined groups (i.e. all participants both chronic and gestational hypertension). The proportion of those eligible that were recruited was 71% (222 eligible, 158 randomised, see Table 2). The overall randomisation rate was 2.5 participants per site per month.

Formal discontinuation of self-monitoring of BP by women randomised to the intervention group was low, with a combined rate of 6% (6/104), three of whom still supplied some home BP monitoring data until discontinuation. None of these women withdrew consent for notes review follow-up. The 49 women with chronic hypertension who provided home readings reported BP measurements on a median of 5.5 days per week (IQR 3.1–6.5) and median of 2.2 readings per day (IQR 2.1–2.5). Three women (7%) from the intervention group provided no home readings at all (two who formally discontinued with intervention very early in follow-up and one who never supplied home

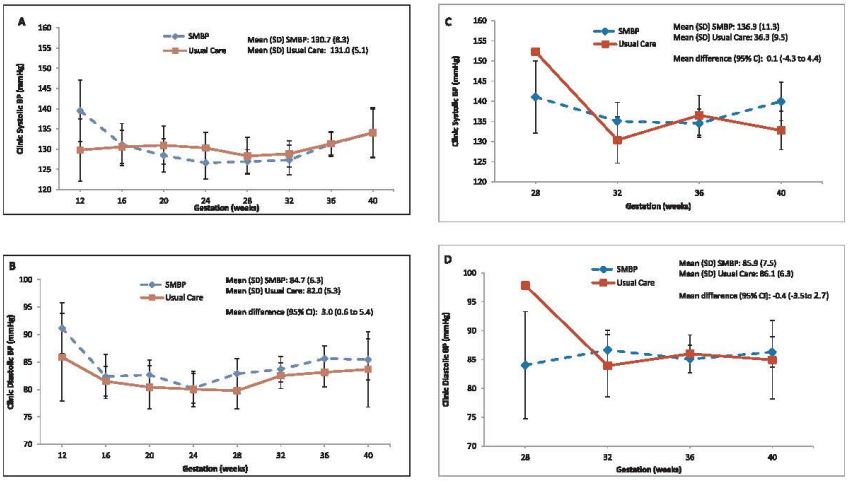

Fig. 3. A-D: Clinic blood pressure across gestation for (A-B) women with chronic hypertension and (C-D) women with gestational hypertension, by randomisation group. A. Mean clinic SBP across gestation in pregnant women with chronic hypertension. B. Mean clinic DBP across gestation in pregnant women with chronic hypertension. C. Mean clinic SBP across gestation in pregnant women with gestational hypertension. D. Mean clinic DBP across gestation in pregnant women with gestational hypertension. The number of participants with chronic hypertension (A &B): 10–13.9 weeks (n = 8 SMBP and 5 UC) 14–17.9 weeks (n = 23 SMBP and 16 UC) 18–21.9 weeks (n = 34 SMBP and 19 UC) 22–25.9 weeks (45 SMBP and 27 UC) 26–29.9 weeks (n = 44 SMBP, 28 UC), 30–33.9 weeks (n = 42 SMBP, 25 UC), 34–37.9 weeks (n = 44 SMBP, 28 UC), 38–41.9 weeks (n = 22 SMBP, 10 UC). The number of participants with gestational hypertension (C&D): 26–29.9 weeks (n = 6 SMBP, 1 UC), 30–33.9 weeks (n = 17 SMBP, 7 UC), 34–37.9 weeks (n = 44 SMBP, 20 UC), 38–41.9 weeks (n = 24 SMBP, 8 UC). SMBP: self-monitoring of blood pressure, UC: usual care.

data). The 43 women with gestational hypertension provided home readings on a median of 6.1 days per week (IQR 4.5–6.7) with a median of 2.9 readings per day (IQR 2.5–4.6). Six women (12%) from the gestational hypertension intervention group provided no home readings (one who formally discontinued with intervention very early and five who never supplied data). In terms of cross-over from control to some form of self-initiated BP self-monitoring, there was evidence of this in the maternity notes from 12/31 (39%) randomised to usual care from the chronic hypertension group, and four from the 23 (17%) from the gestational hypertension group.

There was high persistence with the self-monitoring intervention (see Fig. 2) with 86% (43/50 of those supplying home data) of women with chronic and 76% (38/49) of women with gestational hypertension providing home BP readings for 80% or more of their time from enrolment until delivery.

3.2. Clinical outcomes

The mean clinic systolic and diastolic BP profiles throughout pregnancy by allocation group are presented in Fig. 3A–D. For both the chronic and gestational hypertension groups, no difference was observed between intervention groups for any measures of systolic BP control for either study or clinic measurements (see Fig. 3A and C and Supplement Tables 1A-B). In terms of diastolic BP, there was no difference between groups for those with gestational hypertension but for chronic hypertension, diastolic BP was higher in the self-monitoring group compared to usual care (mean and time-weighted mean clinic diastolic BP) (Supplement Table 2A). A post-hoc sensitivity analysis excluding those readings taken in the maternity assessment unit subsequent to women reporting high home BP measurements, seeking to reduce possible detection bias between groups, had no discernible impact on the pattern of the original results.

No between-group differences were seen in mean defined daily dose, nor the mean number of antihypertensive medications (Supplement Tables 1A and B). Similarly, the medication adherence and beliefs about medication scores showed no difference between study groups (Supplement Tables 1A and B). Maternal and perinatal outcomes (Table 3) for women with chronic and gestational hypertension were also similar between groups.

3.3. Adverse events, quality of life and BP monitoring preference

There was one unrelated serious adverse event reported for a woman from the BP self-monitoring arm in the gestational hypertension group with a case of postnatal influenza.

No between-group differences were seen at baseline, or at six weeks postnatal in participants' mean self-reported overall five-domain EQ-5D-5L, visual analogue score (VAS) [20] or STAI-6 scores [21] in either hypertension group (see Supplemental Table 3). Assessment of participant BP monitoring preferences (from respondents to Little's "problem score" questionnaire undertaken postnatally [28]), indicated that clinic BP monitoring caused more anxiety than home monitoring (related to waiting around, worrying about knowing what the BP was), whereas home monitoring scored more highly on all three positive factors: feeling in control, good use of clinician time, worth the trouble to get accurate readings (see Supplemental Table 4). There was a lower overall 'problem score' for the home BP monitoring group compared with usual care clinic monitoring, for both chronic and gestational hypertension groups: mean difference score (95% CI) −0.3 (−0.5 to −0.02) and −0.7 (−0.9 to −0.4) respectively.

4. Discussion

This is the first randomised controlled trial looking at the feasibility of BP self-monitoring for the management of women with pregnancy hypertension. Recruitment, follow-up, and adherence with the

Table 3
Maternal and perinatal outcomes for 154 pregnant women with chronic and gestational hypertension included in the OPTIMUM-BP feasibility trial from December 2015 until December 2017.

Characteristic	Chronic Hypertension			Gestational Hypertension		
	SMBP Group N = 53	Usual Care Group N = 30	Adjusted[α] Odds Ratio or Difference in Mean/Median (95% CI)	SMBP Group N = 49	Usual Care Group N = 22	Adjusted[α] Odds Ratio or Difference in Mean/Median (95% CI)
Maternal outcomes						
Time between randomisation and delivery*, days	142 (34)	150 (32)		31 (24)	25 (17)	
Need for IV antihypertensive drugs week before delivery	5 (9%)	0 (0%)		0 (0%)	0 (0%)	
Onset of delivery:						
Spontaneous	3 (5%)	2 (7%)		6 (12%)	7 (32%)	
Induction	30 (57%)	22 (73%)		32 (66%)	7 (32%)	
Pre-labour caesarean section	20 (38%)	6 (20%)		11 (22%)	8 (36%)	
Indication for induction of labour/pre-labour caesarean section (all that apply):						
Preeclampsia	15 (28%)	2 (7%)		15 (31%)	8 (36%)	
Hypertension	12 (23%)	2 (7%)		4 (8%)	1 (5%)	
Fetal growth restriction	4 (8%)	3 (10%)		4 (8%)	2 (10%)	
Preeclampsia						
Total	19 (36%)	5 (17%)	2.9 (0.9 to 9.1)	19 (39%)	8 (36%)	1.1 (0.4 to 3.4)
Defined by new proteinuria only	5 (9%)	2 (7%)		8 (16%)	2 (9%)	
Other maternal organ dysfunction	10 (19%)	2 (7%)		9 (18%)	3 (14%)	
With fetal growth restriction	6 (11%)	2 (7%)		4 (8%)	4 (18%)	
Adverse maternal outcome[¥]	0 (0%)	1 (3%)		1 (2%)	1 (4%)	
Admitted to ITU	0 (0%)	0 (0%)		1 (2%)	0 (0%)	
Total admission nights[‡]	5 (3 to 8)	4 (2 to 5)		4 (3 to 6)	3 (2 to 6)	
Perinatal outcomes	N = 53	N = 30		N = 49	N = 22	
Gestation at delivery* (weeks)	36.9 (4.2)	37.9 (2.4)	−1.1 (-2.8 to 0.6)	38.0 (2.0)	37.6 (2.4)	0.4 (-0.7 to 1.5)
Preterm birth (< 34 weeks)	7 (13%)	2 (7%)	2.5 (0.5 to 13.7)	2 (4%)	2 (9%)	0.4 (0.1 to 3.2)
Mode of delivery, n (%)						
Spontaneous vaginal delivery	13 (25%)	15 (50%)		21 (43%)	9 (41%)	
Assisted vaginal delivery	1 (2%)	4 (13%)		4 (8%)	4 (18%)	
Emergency pre-labour caesarean section	15 (28%)	4 (13%)		4 (8%)	5 (23%)	
Emergency caesarean section in labour	10 (19%)	2 (7%)		11 (22%)	1 (4%)	
Elective pre-labour caesarean section	14 (26%)	5 (17%)		9 (18%)	3 (14%)	
Total with caesarean section, n (%)	39 (74%)	11 (37%)	4.9 (1.8 to 13.2)	25 (51%)	13 (59%)	1.4 (0.5 to 3.9)
Birth weight* (grams)	2808 (9 4 0)	3086 (6 2 8)	−300.2 (-690.7 to 90.2)	3061 (7 3 8)	3003 (8 5 1)	54.2 (-341.7 to 450.0)
Birth weight < 10th centile[†]	8 (15%)	1 (3%)	5.3 (0.6 to 45.8)	9 (18%)	4 (18%)	1.3 (0.3 to 5.4)
Birth weight < 3rd centile[†]	2 (4%)	1 (3%)		2 (4%)	0 (0%)	
Perinatal death:						
Stillbirth	2 (4%)	0 (0%)		0 (0%)	0 (0%)	
Neonatal death	1 (2%)	0 (0%)		0 (0%)	0 (0%)	
Admitted to neonatal unit	9 (17%)	4 (13%)	1.4 (0.4 to 5.3)	9 (18%)	2 (9%)	2.2 (0.4 to 11.5)
Total admission nights[‡ **]	3 (2 to 6)	2 (1 to 4)		2 (2 to 4)	3 (2 to 4)	

[¥] Adverse maternal outcome: eclampsia (1), intracranial haemorrhage or infarct (0), HELLP (haemolysis, elevated liver enzymes, low platelets) syndrome (0) or death (0).
[*] Mean and SD.
[†] Using intergrowth-21st, accessed https://www.intergrowth21.org.uk/.
[‡] Median and IQR.
[**] Does not contain data for the two stillbirths.
[α] Adjusted for study site and baseline clinic SBP.

intervention were much greater than average rates quoted for UK randomised trials [29]. Persistence with the self-monitoring intervention was high across both types of hypertension group and supports the hypothesis that self-monitoring is acceptable in this population. This is consistent with women reporting no differences in anxiety or quality of life scores between randomised groups, and indicating a greater preference with lower "problem scores" for BP self-monitoring versus usual clinic monitoring [28].

The study was not powered to detect a difference between randomisation groups for the secondary outcomes concerning BP control and delivery outcomes hence caution must be taken in drawing conclusions. Systolic BP in all groups and diastolic BP in gestational hypertension did not show any differences, although we saw a small and statistically significant increase in mean diastolic and time-weighted mean diastolic clinic BP for the group using self-monitoring versus usual care in women with chronic hypertension. The greater proportion of caesarean sections within the self-monitoring versus usual care group for women with chronic hypertension is likely to be a chance finding but there was a consistent trend for higher rates of pre-eclampsia, greater proportion born prematurely less than 34 weeks, reduced birth weight and greater proportion less than tenth centile for weight for this group. It seems unlikely that self-monitoring of BP increases adverse outcomes of this nature, particularly as our prescribing and medication adherence data did not reveal any difference between the randomisation groups. Chance imbalances in outcomes between randomisation groups are likely in feasibility trials with smaller sample sizes; we saw evidence for this within two known important predictors of perinatal outcome (ethnicity and previous pregnancy hypertensive disorder) within the group with chronic hypertension. The small numbers used for feasibility studies also preclude them being able to successfully minimise or adjust for all important confounders in the randomisation and analyses of such studies.

4.1. Previous literature

Previous studies in the non-pregnant population with hypertension have shown that self-monitoring accompanied with self-management produces improved BP control, is preferred by participants to usual care [11–13] and provided the impetus for this study. To our knowledge, the only previous randomised controlled trial of self-monitoring of BP in pregnancy included a general pregnant population rather than hypertensive women [30]. Observational and qualitative studies have reported increased satisfaction from self-monitoring but could not evaluate clinical effectiveness [31–33].

4.2. Strengths and limitations

The study benefited from being run across four NHS sites and recruiting from women with a range of ethnicities and socioeconomic and educational backgrounds, supporting the concept that BP self-monitoring is feasible and acceptable for a wide range of women whose pregnancies are complicated by hypertension. The high adherence and persistence with the self-monitoring intervention is reassuring given the high recruitment proportion of more than 70% of those eligible. The recruitment rate of 2.5 per site per month suggests that this is a feasible intervention to trial on a larger scale.

The trial was run pragmatically using clinic measurements in addition to study BP readings and has shown the feasibility of collecting and using routine clinical data. This is important in pregnancy where attendance at study visits is problematic and affected by later study entry and premature delivery (for example < 25% of those with gestational hypertension attended a study visit at 34/40 whereas all had clinic BP data). The rapidly dynamic nature of BP change in pregnancy is such that intermittent study visits less accurately portray underlying BP trends. Randomisation using allocation concealment limited selection bias. Although it was not possible to mask the participants or clinicians to randomisation group due to the nature of the intervention, providing additional reminders to clinical teams during site visits regarding best practice for BP measurement helped to limit detection bias.

While it is possible that there may be some inaccuracy of reporting BP readings by participating women, via text, study App or recorded in diarys, accuracy in similar studies has been shown to be high (94% identical and only 1% submitted at a different BP threshold) [34]. Accuracy of BP reporting is forming part of an exploratory analysis to be published.

The study detected evidence of cross-over between groups, (17–39% of our usual care group with gestational and chronic hypertension respectively taking up some form of home monitoring); however, the evidence from the non-pregnant hypertensive population has shown that informal self-monitoring alone has limited impact on BP control as opposed to self-monitoring combined with active intervention [11,12].

4.3. Clinical and research implications

In higher risk pregnancy, the motivation of pregnant women for greater involvement in their care, the need to provide effective sustainable health care pathways and the opportunities from real-time participant data collection are met in a BP self-monitoring intervention. This is the only published randomised study to date investigating the use of BP self-monitoring in a pregnant hypertensive population and shows that it is feasible and acceptable. Self-monitoring could be one way to achieve tighter BP control as shown to be beneficial in the general adult population [12] and the CHIPS study [7]. This provides the justification for further exploring the role of BP self-monitoring in hypertensive pregnancies.

5. Conclusion

BP self-monitoring for the management of hypertension during pregnancy is feasible and well tolerated by women when combined with clinic monitoring. A large scale randomised controlled trial powered to explore the effectiveness and cost-effectiveness of self-monitoring for improved BP control in hypertensive pregnancies is warranted.

Declaration of Competing Interest

The authors declare the following conflicts of interest: LM receives consultancy fees from Drayson Technologies.

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OPTIMUM Collaborators

Layla Lavallee at John Radcliffe Hospital, Oxford University Hospitals NHS Foundation Trust. Zoe Vowles at Guy's and St Thomas' NHS Foundation Trust. Nick Kametas and Polly Kay at King's College Hospital NHS Foundation Trust. David Churchill, Laura Gardiner and Katherine Cheshire at New Cross Hospital. The Royal Wolverhampton NHS Trust. Sue Ziebland from the Department of Primary Care, Oxford University and Marloes Franssen and David Watt from the Oxford Primary Care Clinical Trials Unit.

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Author contributions

The study was conceived by RM, LC and LP. The protocol was developed by LP, LC, KT and RM with the advice and support of all authors. The study was managed by ET and recruitment was led by HW and CC. The analysis plan and analysis were completed by LP with guidance from AN. The first draft of the paper was written by LP with RM, LC KT and subsequently edited and approved by all co-authors. All authors have read and approved the final manuscript.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.preghy.2019.09.018.

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APPENDIX 10: Publication of OPTIMUM-BP secondary analysis

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Adherence with blood pressure self-monitoring in women with pregnancy hypertension, and comparisons to clinic readings: A secondary analysis of OPTIMUM-BP

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ABSTRACT

Objectives: To assess adherence to self-monitoring of blood pressure (SMBP), and differences between SMBP and clinic readings, in a self-monitoring intervention for managing pregnancy hypertension.
Study design: OPTIMUM-BP was an unmasked randomised controlled clinical trial. 154 women with pregnancy hypertension from four maternity units in England were recruited and randomised to SMBP or usual care. This secondary analysis included 91 women randomised to self-monitoring who provided BP readings. Trial instructions were for daily SMBP.
Main outcome measures: Adherence was calculated as proportion of days on which SMBP readings were taken. Proportion of weeks in which at least 4 and at least 2 SMBP readings were taken was also calculated. Mean differences between clinic and SMBP measurements were calculated.
Results: Self-monitored BP data were available for 49 women with chronic hypertension and 42 women with gestational hypertension. Median percentage of days with SMBP readings was 77% (IQR 51, 89) in the chronic hypertension group and 85% (IQR 52, 95) in the gestational hypertension group. Adherence did not vary by different socio-demographic groups. Mean difference (95% CI) between clinic and SMBP for systolic BP was 0.99 mmHg (−1.44, 3.41; chronic hypertension) and 3.76 mmHg (0.75, 6.78; gestational hypertension) and for diastolic BP was 3.03 mmHg (0.93, 5.12; chronic hypertension) and 3.27 mmHg (0.56, 5.98; gestational hypertension).
Conclusions: Adherence to self-monitoring was good and differences between SMBP and clinic readings were small. These findings offer reassurance about the use of self-monitoring at a time when it is being increasingly implemented in maternity settings.

1. Introduction

Hypertension affects around 10% of pregnancies and is associated with adverse maternal and fetal outcomes [1–3]. High blood pressure (BP) can develop between antenatal appointments and may be asymptomatic until an advanced stage, and BP self-monitoring might allow for the earlier detection and improved management of pregnancy hypertension [3]. Other possible benefits of self-monitoring include a potential reduction in the need for clinic visits, reducing healthcare expense as well as being more convenient for women [4,5]. Studies in the non-pregnant population have shown that self-monitoring of blood pressure (SMBP) combined with self-titration of medication can be effective and lead to better blood pressure control than relying on clinic visits [6–8]. The recent COVID-19 pandemic has also highlighted the benefit and sometimes necessity of people being able to self-monitor in order to reduce their attendances at health services, and has led to more widespread use of SMBP in pregnancy, particularly in women with hypertension [9].

There is limited information on feasibility, adherence and outcomes of SMBP in the pregnant population which perhaps leads to reluctance of clinicians to trust women to monitor sufficiently or effectively [5,10]. In addition, there is insufficient evidence to date on whether there should

Abbreviations: SMBP, self-monitoring of blood pressure; CH, chronic hypertension; GH, gestational hypertension.

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2210-7789/© 2021 The Author(s). Published by Elsevier B.V. on behalf of International Society for the Study of Hypertension in Pregnancy. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

be differences between home and clinic thresholds used for diagnosis and management of pregnancy hypertension, as is the case for the general adult population [11,12].

OPTIMUM-BP was a randomised controlled trial which investigated the feasibility and acceptability of BP self-monitoring for the antenatal control of blood pressure in pregnant women with hypertension [13]. This is a secondary analysis of the results, with the aim of looking firstly at adherence and monitoring behaviour of women undertaking SMBP, and secondly at comparisons between SMBP and clinic readings.

2. Methods

2.1. Study design

OPTIMUM-BP was an unmasked randomised controlled clinical trial including pregnant women with chronic or gestational hypertension. Full details of study methodology are available in the main results paper [13]. Women from four maternity units in England were recruited and randomised to blood pressure self-monitoring or usual care between December 2015 and December 2017. BP was measured and data collected on demographics, medical and obstetric history, antihypertensive therapy and socio-economic status (including Index of Multiple Deprivation [14]).

Women allocated to usual care had their BP monitored by their local midwifery and obstetric teams. The average of up to three recorded clinic readings on any single occasion was taken as the clinic BP for that episode. Women randomised to the intervention were additionally asked to measure their BP daily, at approximately the same time, using an appropriately sized cuff with a validated automated BP monitor (Microlife WatchBP Home, validated in pregnancy and preeclampsia) [15]. Participants were asked to take two readings at least one minute apart, and to record the second in their study diary. In the gestational hypertension group, they also had the option to submit the reading via text or study app on their mobile phone. The digitally reported readings were automatically transmitted to a secure server, which provided immediate automated responses [13]. Women were provided with guidance about normal and out of range readings and an algorithm based on UK NICE Hypertension in Pregnancy Guidelines [16].

All women were also asked to attend up to three antenatal study visits at 20, 28 and 34 weeks' gestation, and one six week postnatal face to face or telephone study visit. BP measurement was taken by the study team at these visits using the same model of validated monitor [15].

The study protocol and materials were approved by a UK Research Ethics Committee (15/EM/0490) and research and development approvals gained. All study participants provided written, informed consent. Trial registration: ISRCTN16018898.

2.2. Inclusion in analysis

For this secondary analysis, 91 women who were randomised to self-monitoring and provided SMBP readings (diary, app or downloaded BP monitor data) were included. BP measurements with systolic BP (SBP) < 70 or > 260 mmHg or with diastolic BP (DBP) < 40 or > 260 mmHg were discarded as erroneous [17]. The chronic hypertension group and gestational hypertension group were analysed separately due to the differences in protocol.

2.3. Statistical analysis

2.3.1. Adherence

Adherence was calculated as the percentage of days enrolled in the study on which participants provided SMBP data. Further adherence variables were calculated as proportion of weeks that women provided at least 4 or at least 2 SMBP readings. Median adherence and quartiles were calculated. Differences in adherence (using the percentage of days SMBP data provided adherence variable) by demographic and pregnancy specific factors were then assessed using nonparametric tests of the equality of medians.

For subjects with downloaded monitor readings, each diary/app reading was compared with monitor readings, to calculate the proportion that were matched to one of the monitor readings and the proportion within 5 mmHg. The proportion of differences that impacted upon the 'action colour' (ie would have affected management per the trial alert algorithm, Table S1) was also calculated.

2.3.2. Clinic-SMBP differences

The mean difference with 95% confidence intervals was calculated between each clinic visit and the average SMBP readings for the seven days prior to that clinic. If the previous clinic visit was within the preceding 7 days, only the SMBP readings following the last clinic were included, to account for the fact that there may have been medication changes at the previous clinic. Where more than one source of blood pressure reading for a given woman was available, downloaded monitor readings were used in preference to app readings, which were used in preference to diary readings. As participants were told to ignore the first SMBP reading and to record the second, any first readings on a given occasion were excluded unless that was the only reading of the day; all other readings were included.

Two sensitivity analyses were done. The first used only SMBP readings taken on the same day as the clinic readings. The second used only the second SMBP reading, excluding any subsequent readings taken.

Mean (95% confidence intervals) SMBP and clinic BP readings were plotted by gestation for participants who had both SMBP and clinic BP data in the same week of pregnancy. Bland Altman plots were constructed to compare SMBP and clinic readings by BP level [18,19].

In the chronic hypertension group, mean clinic readings were also compared to mean study visit readings where blood pressure had been measured systematically three times and a mean taken of all three readings (at 28 and 34 weeks' gestation; insufficient numbers to look at the 20 week study visit). This was not done for the gestational hypertension group as the majority were recruited after 34 weeks (after the date of the last potential study visit).

All analyses were performed using STATA 16 (Stata-Corp, College Station, Texas, USA).

3. Results

3.1. Inclusion

Of the 154 women randomised in the OPTIMUM-BP study, 55 women with chronic hypertension and 49 women with gestational hypertension were randomised to self-monitoring. Of the 55 women with chronic hypertension, 2 were excluded due to early miscarriage or medical reasons, 1 lost to follow up, and 3 did not supply any self-monitoring data, leaving 49 (89%) women with chronic hypertension who provided SMBP data and were included in this analysis. Of the 49 women with gestational hypertension randomised to self-monitoring, 7 did not provide any SMBP data, leaving 42 (86%) women included in this analysis (Fig. 1). Demographic and clinical characteristics at enrolment of participants are shown in Table 1.

3.2. Adherence

In women with chronic hypertension the median percentage of days that SMBP readings were supplied was 77% (IQR 51–89). A median of 81% (IQR 71–96) of weeks included four or more SMBP readings, and a median of 94% (IQR 78–100) of weeks included two or more SMBP readings (Table 2). In the gestational hypertension group these figures were 85% (IQR 52–95), 80% (IQR 50–100) and 91% (IQR 80–100) respectively. Median interval between SMBP readings was 1 day (IQR 1–1) in both chronic and gestational hypertension groups compared to median interval between clinic readings of 8 days (IQR 7–13) in the

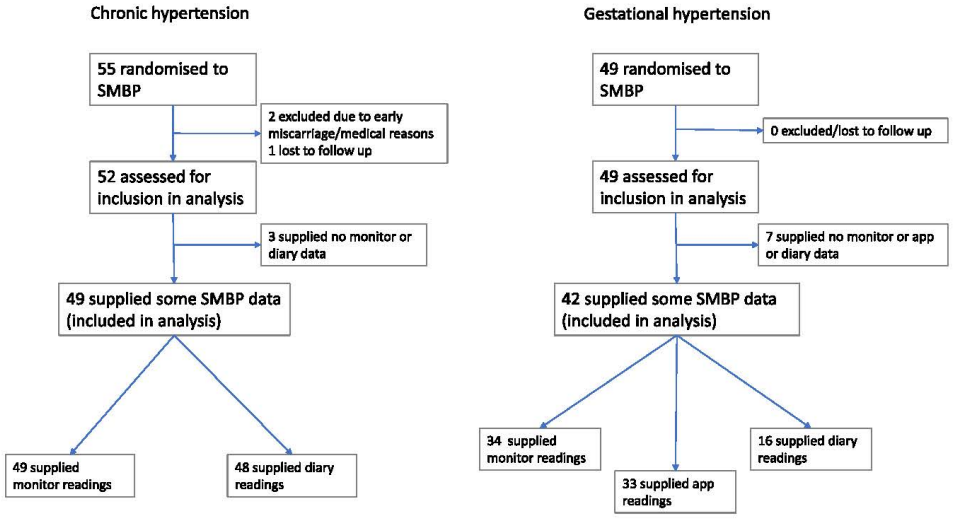

Fig. 1. Flow diagram of inclusion in analysis.

Table 1
Demographic and clinical characteristics at enrolment of pregnant women with hypertension who self-monitored blood pressure in the OPTIMUM-BP feasibility trial.

	Chronic Hypertension (n = 49)	Gestational Hypertension (n = 42)
Age (years), mean (SD)	36.0 (5.4)	32.9 (5.8)
Gestation at recruitment, median (IQR)	16.6 (13.0, 20.3)	34.6 (31.7, 36.0)
BMI (kg/m^2), mean (SD)	31.1 (6.4)	30.1 (7.2)
Ethnicity, n (%)		
White	25 (51)	31 (74)
Black	18 (37)	10 (24)
Asian	6 (12)	1 (2)
Most deprived deprivation quintile*, n(%)	17 (35)	13 (31)
Professional/Higher education, n(%)	34 (69)	32 (76)
Never smokers, n(%)	35 (71)	35 (83)
Other self-reported medical history, n (%)		
Diabetes type 2	2 (4)	1 (2)
Chronic kidney disease	1 (2)	0 (0)
Nulliparity, n(%)	16 (33)	19 (45)
Diagnosis of preeclampsia or gestational hypertension in previous pregnancy, n(%)	17 (35)	13 (31)
Proportion prescribed antihypertensive medication at enrolment, n(%)	36 (73)	26 (62)
Previous SMBP in this pregnancy at least once, n(%)	22 (45)	11 (26)

Abbreviations: SMBP: self-monitoring of blood pressure; SD: standard deviation; IQR: Interquartile range.
*Deprivation measured as Index of Multiple Deprivation score using Office of National Statistics for England data.

Table 2
Percentage of time that participants submitted SMBP readings (monitor or diary or app) between randomisation and delivery, and comparisons between monitor and diary/app readings.

	Chronic Hypertension (n = 49)	Gestational Hypertension (n = 42)
Adherence with SMBP		
Percent of days with SMBP readings, Median (IQR)	77 (51, 89)	85 (52, 95)
Percent of weeks with 4 + SMBP readings, Median (IQR)	81 (71 ,96)	80 (50, 100)
Percent of weeks with 2 + SMBP readings, Median (IQR)	94 (78, 100)	91 (80, 100)
Monitor vs diary/app readings*		
Diary/app reading matches a monitor reading exactly	88%	87%
Diary/app readings matches a monitor reading within 5 mmHg	95%	98%
Diary/app reading matches *second* monitor reading exactly	42%	39%
Diary/app readings matches *second* monitor reading within 5 mmHg	66%	58%

* In chronic hypertension group based on 3456 observations from 47 participants; in gestational hypertension group based on 419 observations from 27 participants

chronic hypertension group and 4.5 days (IQR 3.5–7) in the gestational hypertension group (Table S2).

When looking at possible factors associated with adherence, there was no evidence of difference by age, body mass index, ethnicity, education or smoking in the chronic or gestational hypertension group (Table 3). When considering pregnancy related factors, there was no evidence of difference in adherence by parity, previous hypertensive disorder of pregnancy, medication at enrolment, or previous self-monitoring in this pregnancy in either group. In the gestational hypertension group, there was some evidence of increased adherence in the group recruited at later gestation.

Table 3
Median adherence (percentage of days between randomisation and delivery that women used SMBP) by demographic and pregnancy specific factors.

Variable	Chronic Hypertension	p-value	Gestational Hypertension	p-value
Demographic factors				
Age				
20–34	82 (50, 94)	0.07	85 (70, 95)	0.9
35–44	71 (51, 89)		81 (33, 95)	
45+	71 (37, 76)			
BMI				
<30	75 (50, 88)	0.5	86 (73, 95)	0.8
30+	81 (51, 94)		71 (48, 94)	
Ethnicity				
White	83 (66, 94)	0.1	86 (48, 95)	0.2
Black	62 (23, 94)		69 (52, 91)	
Asian	76 (68, 79)		96 (96, 96)	
Education				
No formal qualifications	12 (5, 19)	0.3	10 (10, 10)	0.6
School qualifications	67 (36, 95)		88 (77, 95)	
Professional/Higher qualifications	79 (67, 89)		85 (50, 95)	
Smoking				
Current smoker	88 (64, 93)	0.6	10 (10, 10)	0.3
Current non-smoker	77 (50, 91)		86 (66, 95)	
Pregnancy specific factors				
Gestation at recruitment				
<15 weeks (CHTN)	78 (66, 94)	0.9	–	
>15 weeks (CHTN)	76 (50, 89)		–	
<32 weeks (GH)	–		48 (31, 71)	0.005
>32 weeks (GH)	–		90 (77, 96)	
Parity				
0	77 (67, 83)	0.6	85 (52, 96)	0.8
>1	81 (41, 94)		86 (48, 95)	
Previous HDP				
No	75 (50, 89)	0.8	79 (48, 92)	0.4
Yes	68 (41, 87)		91 (71, 94)	
Medicated at enrolment				
No	77 (32, 83)	0.8	81 (44, 95)	0.7
Yes	78 (54, 94)		86 (66, 95)	
Previous SMBP in this pregnancy				
No	78 (41, 89)	0.6	86 (52, 96)	0.7
Yes	76 (66, 89)		85 (47, 95)	

The median number of readings per day was 2 (IQR 2–2, range 0–17) in the chronic hypertension group and was 2 (IQR 2–4, range 0–25) in the gestational hypertension group.

When readings retrieved from monitor downloads were compared to those submitted in the diary on the same day, 3032/3456 (88%) of diary readings matched one of the monitor readings exactly, and 3282/3456 (95%) matched one of the monitor readings within 5 mmHg in the chronic hypertension group (Table 2). In the gestational hypertension group 365/419 (87%) of app/diary readings matched one of the monitor readings exactly, and 409/419 (98%) matched one of the monitor readings within 5 mmHg. When comparing the diary/app recorded reading with the second monitor reading specifically, 2270/3456 (66%) of the readings in the chronic hypertension group matched within 5 mmHg and 242/419 (58%) of the readings in the gestational hypertension group matched within 5 mmHg. In 316/3456 (9%) of the chronic hypertension diary readings and 34/419 (8%) of the gestational hypertension app/diary readings, these differences were associated with the monitor readings having a higher 'action colour,' ie would have affected automated prompts to action for the women compared to the diary/app reading (as shown in the Blood Pressure Threshold Algorithm, Table S1).

3.3. Clinic vs SMBP readings

Mean difference between clinic and SMBP readings was 0.99 mmHg (95% CI −1.44, 3.41) for SBP and 3.03 mmHg (0.93, 5.12) for DBP in the chronic hypertension group. In the gestational hypertension group the mean difference in SBP was 3.76 mmHg (0.75, 6.78) and in DBP was 3.27 mmHg (0.65, 5.98). Sensitivity analyses looking at including only the second reading of the day from monitor readings, and only including readings done on the same day as clinic, did not substantively change the results (Table S3).

The median of the differences between the maximum and minimum readings in clinic SBP taken on the same day was 10 mmHg (IQR 5.5, 15) and in DBP was 5 mmHg (IQR 2, 10).

SMBP and clinic readings plotted across different gestations were not suggestive of evidence of increasing differences between SMBP and clinic readings as gestation increased (Fig. 2). Considering clinic-SMBP differences by average blood pressure, Bland Altman plots showed some suggestion that at higher average BP readings there was more difference between SMBP and clinic (as evidenced by slightly more data points in the top right quarter of the plot, Fig. 3).

Results for differences between clinic and study visit blood pressures showed no evidence of difference (Table S4, Fig. S3).

4. Discussion

4.1. Main findings

This analysis of adherence to self-monitoring of blood pressure in pregnancy has shown that both chronic hypertension and gestational hypertension groups had good adherence with a low level of inaccurate reporting. There was some suggestion that the gestational hypertension group were more likely to do daily readings and take more readings each day, perhaps because they were monitoring for shorter durations and that hypertension diagnosis and monitoring was a new experience for them. An extension of this was the especially high levels of adherence in the subgroup of women with gestational hypertension who joined the study after 32 weeks' gestation, who would have only been monitoring for around five to six weeks. It was of interest that other than this subgroup, there was no evidence of differences in adherence by other demographic or pregnancy factors. However, around one in ten monitor readings were higher than those submitted, though these instances were observed infrequently across many women, rather than being clustered in certain individuals. This may have been due to reasons such as women additionally checking their BP prior to taking medication or following certain activities, over and above what was required within the self-monitoring instructions. Overall, differences between SMBP and clinic BP readings were small, with no variation by gestation, although there was some suggestion of greater differences at higher blood pressures as might be expected. These systolic/diastolic home-clinic BP differences (around 3/3 mmHg) were smaller than differences within same day clinic readings (around 10/5 mmHg), and so are unlikely to substantially impact on clinical management, within the wider interpretation of all BP readings. In the absence of data to suggest clinically significant differences between clinical and SMBP readings, this would support using the same thresholds for acting on SMBP readings as on clinic readings.

4.2. Strengths and limitations

A strength of this study is the detailed information recorded on BP self-monitoring practices in women with both chronic and gestational hypertension during pregnancy, with the use of a validated blood pressure monitor for pregnancy. Four centres participated (both teaching and general hospitals) with a multi-ethnic population albeit of higher than average education. This gives some reassurance for generalisability although the population was relatively small reflecting that

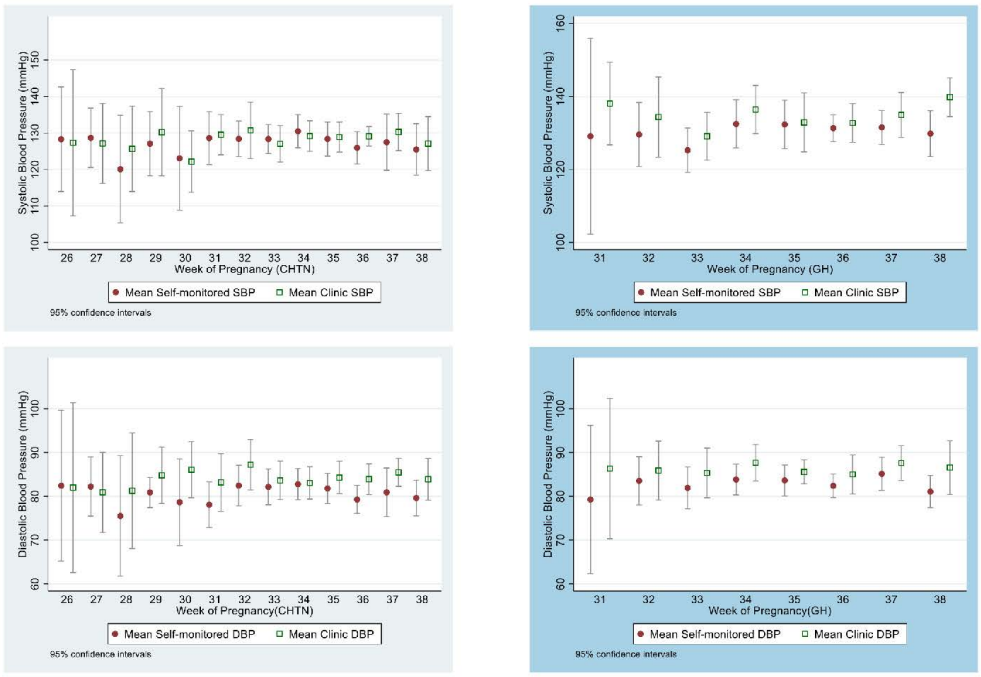

Fig. 2. Clinic and SMBP readings throughout pregnancy in chronic hypertension (left) and gestational hypertension (right) groups.

it comprised a feasibility study. This may have limited the power to detect differences between groups, particularly subgroups.

4.3. Previous literature

One other antenatal randomised controlled trial of SMBP during pregnancy has been done, which included low risk women rather than women with hypertension [20]. They undertook SMBP on a weekly basis, and results showed a mean number of missed weeks of BP measurements of 0.8 (SD 1.2). No comparisons between monitors and reported readings, or between SMBP and clinic readings were reported. In comparison, women in the current study managed at least two readings per week a median of 90% of the weeks that they were monitoring, although adherence dropped off compared to the daily readings requested.

A systematic review and individual patient data metanalysis assessing differences between clinic and SMBP readings in pregnancy found similarly small mean differences overall (1–2 mmHg)[11]. The subgroup analysis of women with hypertension in pregnancy showed bigger differences than seen here between clinic and SMBP readings, although heterogeneity was high and only 2 of the 7 studies used blood pressure monitors validated for use in pregnancy. A subsequent prospective observational study on a healthy normotensive pregnant population in Denmark, compared self-monitoring done at three discrete times in pregnancy for three days at a time [21]. Mean differences between clinic and SMBP measurements were 11 mmHg in SBP and 9 mmHg in DBP (i.e. higher in clinic than SMBP). The Bland–Altman plots showed increasing difference at higher BPs, similar to the analyses presented here, as well as in the wider adult population [22]. The bigger differences between SMBP and clinic measurements compared to the current study may reflect the shorter duration of monitoring that means women do not become so used to blood pressure monitoring. Another more recent cohort study comparing SMBP and clinic readings in women with hypertension in pregnancy in a UK maternity unit has also been reported [23]. Clinic readings were compared with a single home reading taken closest to the clinic measurement. Mean differences of 7.3 mmHg in SBP and 4.3 mmHg in DBP were seen (i.e. higher in clinic than SMBP), with slightly greater differences at earlier gestations and no clear variation by average BP viewed in Bland-Altman plots [23]. It is not clear why the differences between clinic and SMBP readings were lower in the analyses presented in this paper than in other studies looking at clinic-SMBP differences in pregnant populations with hypertension. Sample sizes were not large in this or the other previous studies, which is known to increase heterogeneity between studies, and larger studies evaluating differences would be beneficial. Another possible contributor is that the analysis in this paper used downloaded monitor readings where these were available, in preference to readings documented in participants' diaries or apps, whereas most of the studies compared above used self-reported SMBP readings when comparing to clinic readings, that were not independently checked.

4.4. Clinical and research implications

The findings of this analysis offer reassurance regarding adherence to self-monitoring in a pregnant population with hypertension, a finding not limited to particular subgroups of women. Generalisability of the results may have been limited by the fact that women consenting to join the study may be more motivated or accepting of the idea of self-monitoring. Some women may choose not to undertake SMBP when offered, or may discontinue once started, typically for reasons such as

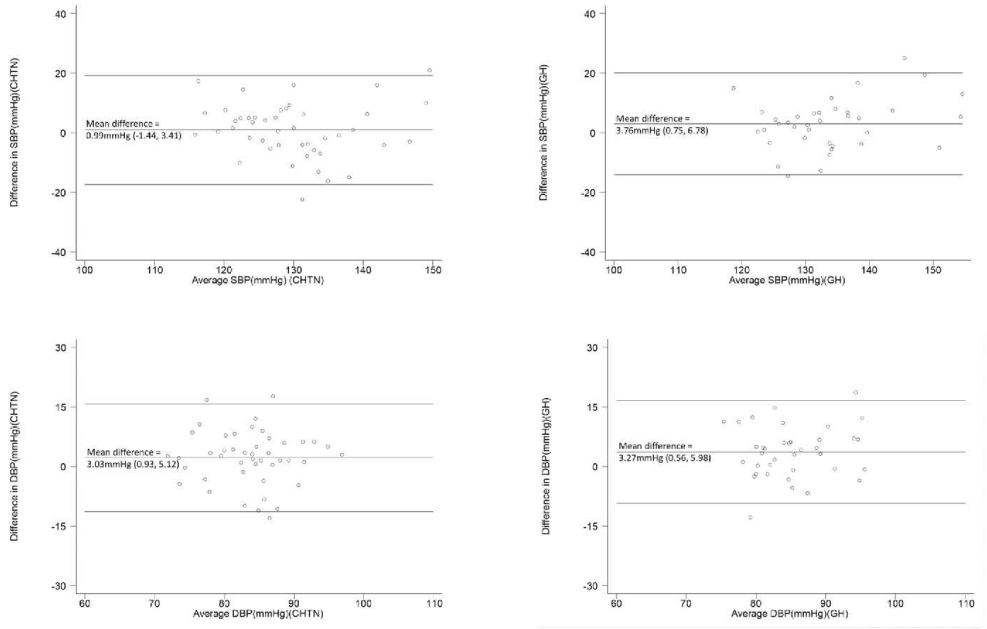

Fig. 3. Bland Altman plots showing difference between clinic and SMBP readings (in the 7 days preceding clinic) against mean blood pressure readings Middle line represents mean difference between clinic and SMBP blood pressure readings, outer lines represent the mean difference +/- 1.96 standard deviation (limits of agreement) Participants included where SMBP and clinic readings available from the same week (178 observations for 45 participants in chronic hypertension group; 103 observations from 37 participants in the gestational hypertension group 95% CIs adjusted for clustering by participant.

perceived lack of time or concern that the monitoring was increasing stress, but the majority are willing and motivated to monitor. Further work is needed to optimise equity of SMBP uptake across diverse groups of women, and to empower women to persist, through better understanding reasons for discontinuation. The differences seen between clinic and SMBP readings were less than has been reported in other studies of women with hypertension in pregnancy. Larger studies are needed to elucidate this question. The recent implementation of self-monitoring due to the COVID pandemic should also be seen as an opportunity to further evaluate self-monitoring practices in women with hypertension in pregnancy.

5. Conclusion

Adherence to self-monitoring in this population was good and differences between SMBP and clinic readings were small. These findings offer some reassurance about the use of self-monitoring at a time when it is being increasingly implemented in maternity settings.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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OPTIMUM Collaborators

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.

org/10.1016/j.preghy.2021.05.016.

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APPENDIX 11: Search strategy for SMBP in pregnancy literature

Systematic literature search for quantitative studies of SMBP in pregnancy

# ▲	Searches: e.g. Medline	Results
1	exp Hypertension, Pregnancy-Induced/	35690
2	(preeclampsia or preeclamptic or pre-eclampsia or pre-eclamptic).ti,ab.	30625
3	1 or 2	46536
4	Pregnancy/	861051
5	pregnancy complications/ or pregnancy complications, cardiovascular/	104388
6	Pregnant Women/	7858
7	Prenatal Care/	26691
8	Prenatal Diagnosis/	36652
9	(pregnancy* or pregnant).ti,ab.	454108
10	(prenatal or pre-natal or antenatal or ante-natal or prepartum or pre-partum or antepartum or ante-partum or prepartal or pre-partal or antepartal or ante-partal).ti,ab.	131000
11	(gestational or gestation).ti,ab.	199003
12	4 or 5 or 6 or 7 or 8 or 9 or 10 or 11	1046960
13	Blood Pressure/	271370
14	Hypertension/	230752
15	(blood pressure or bp).ti,ab.	409175
16	(hypertension or hypertensive).ti,ab.	416204
17	(normotension or normotensive).ti,ab.	35373
18	13 or 14 or 15 or 16 or 17	872258
19	12 and 18	46001
20	3 or 19	75781
21	(home* adj5 (determin* or monitor* or assess* or measure* or record*)).ti,ab.	37674
22	(home* and (determin* or monitor* or assess* or measure* or record*)).ti.	6552
23	(self* adj5 (determin* or monitor* or assess* or measure* or record*)).ti,ab.	102188
24	(self* and (determin* or monitor* or assess* or measure* or record*)).ti.	14980
25	(telemonitor* or tele-monitor* or (remote adj3 monitor*)).ti,ab.	4223
26	omron 705*.ti,ab.	63
27	omron 907*.ti,ab.	4
28	omron mit*.ti,ab.	5
29	omron m7*.ti,ab.	6
30	hem 705*.ti,ab.	44
31	hem 907*.ti,ab.	34
32	(microlife adj3 3bto*).ti,ab.	5
33	(microlife adj3 bp home).ti,ab.	0
34	microlife bp 3ac*.ti,ab.	5
35	(bp home adj3 (wristwatch or watch)).ti,ab.	0
36	dinamap 1846.ti,ab.	25
37	upper arm monitor*.ti,ab.	2
38	21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37	145719
39	20 and 38	606
40	3 or 12	1048297
41	Blood Pressure Monitoring, Ambulatory/	9592
42	Blood Pressure Determination/ and (Self Care/ or Home Care Services/)	570
43	(home adj (blood pressure or bp)).ti.	874
44	(self* adj (blood pressure or bp)).ti.	49
45	41 or 42 or 43 or 44	10286
46	40 and 45	353
47	39 or 46	859

Database:	Interface:	Coverage:	Date:	Hits
Cinahl	EBSCOHost	1982-present	07/01/2021	373
Cochrane Database of Systematic Reviews	Cochrane Library, Wiley	Issue 1 of 12, January 2021	07/01/2021	29
Cochrane Central Register of Controlled Trials	Cochrane Library, Wiley	Issue 1 of 12, January 2021	07/01/2021	339
Database of Abstracts of Reviews of Effects	Cochrane Library, Wiley	Issue 2 of 4, April 2015	04/07/2016	0
Embase	OvidSP	1974-present	07/01/2021	1005
Medion Database	http://www.mediondatabase.nl/	No longer available	04/07/2016	0
Medline (Ovid MEDLINE® Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE®) 1946 to present	OvidSP	1946-present	07/01/2021	859
PsycINFO	OvidSP	1806-present	07/01/2021	34
Science Citation Index, Social Science Citation Index and Conference Proceedings Citation Index - Science	Web of Science Core Collection, Thomson Reuters			660
Total:				3299
Duplicates:				935
Final Total:				2364
Unique results added since Jun 2016				743
Trial registers				
Clinicaltrials.gov	https://clinicaltrials.gov/ct2/home		04/07/2016	87
WHO ICTRP	http://apps.who.int/trialsearch/Default.aspx		04/07/2016	264

APPENDIX 12: Topic guide for interviews with pregnant women

OPTIMUM-BP

Interview Topic Guide for Patients

Preamble
I'm interested to know about how you came to be invited to take part in the OPTIMUM-BP study and your experiences: Examples....What information were you given and at what stage of your pregnancy were you invited? What was it like taking part? I'd like you to tell me your story with as much detail as possible. Then I might have some extra questions depending on what we've covered already. You may also refuse to answer any questions without explanation. The interview is expected to last between 30-60 minutes depending on what we discuss.
Establish verbal consent
I would like to stress that everything you say will be treated as completely confidential and you will remain anonymous in any report that may result from this research – we will remove any identifying information. This interview will be audio recorded so that it can be transcribed (written down in full) later. At any time during the interview we can stop the recorder if you wish. We will ask you to review the transcript to make sure you are happy with its content and you agree there are no identifying information.
Your pregnancy
What has your pregnancy been like? Was this your first pregnancy? Do you have any previous experience of high blood pressure or pre-eclampsia? Did you have any discussions with your GP about blood pressure or medications before your pregnancy? Can you describe your experience of antenatal care: who did you see, where and how often? How did you find the visits; are there any things you would have changed?
Recruitment, information and consent
What information were you given about the study? How well do you think it described the study? Did you feel the information was easy to understand and was there enough explanation? Which study group were you in? Why did you decide to take part? People take part in research for many different reasons eg....How did you feel? How easy was it to make up your mind? What did you think about the consent process? There is a lot of information in this about your data and legal rights – was this clear or did this concern you in any way?
Study experience
What was it like taking part in the study? How did you find the study visits? How did you find the questionnaires? How was the training to use the BP monitor? Was it sufficient and well explained? Would you change anything?
Opinions about BP self-monitoring

How did you feel about being asked to monitor your own BP at home? How did you find daily monitoring? Was it hard or easy to fit into your daily routine? How did you find using the diary to record your readings? Would you want to text or email your readings in the future? Did you get any high or low readings? How did these readings make you feel? Did you have to take any action? How was it trying to act on any of your readings, for e.g. who did you contact, was this easy, did you know how to contact for help? Did you get advice and were you happy or reassured with this or not? How do you think the self-monitoring affected your care – e.g. did you have to make more visits, did you have to travel much more, did it take up more or less time do you think? How did the self-monitoring make you feel? Did you feel more or less worried about your BP and general health? Did you find it reassuring or any other feelings? Did self-monitoring affect you in any other ways: did it make you think differently about you BP medication or what food you ate, or activities you did? Did you notice that BP readings reflected any symptoms you felt? Did you prefer having your blood pressure measured in clinic or doing it yourself – why? Overall what were your feelings about self-monitoring? What would you want for yourself in any future pregnancies? What would you advise to other pregnant women who are being offered self-monitoring?
Knowledge
What did you know about high blood pressure or pre-eclampsia before taking part in the study? Do you feel you know more now? How has having chronic hypertension in your pregnancy affected you? Did you know much about research before taking part in the study?
Looking back and forward
Looking back – how was it taking part? Was it what you expected? Would you recommend it to others? Do you think you might do BP self-monitoring outside pregnancy – why/why not?