Effect of self-monitoring of blood pressure on blood pressure control in pregnant individuals with chronic or gestational hypertension: the BUMP 2 randomized trial

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Word count: 3459
Short title: The BUMP2 trial
Date of revision: 11/03/2022

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Key Points (90 words)

Question: Does self-monitoring of blood pressure by individuals with hypertension in pregnancy lead to better clinic blood pressure control compared with usual antenatal care?

Findings: In this randomized clinical trial that included 850 pregnant individuals with chronic hypertension or gestational hypertension, use of self-monitoring of BP with telemonitoring resulted in an adjusted mean difference in clinic-based systolic blood pressure compared with usual care alone of + 0.03 mmHg for chronic hypertension and -0.03 mmHg for gestational hypertension. Neither difference was statistically significant.

Meaning: Among pregnant individuals with chronic or gestational hypertension, blood pressure self-monitoring with telemonitoring did not lead to improved clinic-based blood pressure control.

Abstract

Importance: Inadequate management of raised BP is a significant contributing factor to maternal deaths. The role of blood pressure self-monitoring in pregnancy in improving clinical outcomes for the woman and infant is unclear.

Objective: To evaluate the effect of blood pressure self-monitoring, compared with usual care alone, on blood pressure control and other related maternal and infant outcomes, in individuals with pregnancy hypertension.

Design, setting and participants: Unmasked, randomized clinical trial that recruited between November 2018 and September 2019 in 15 hospital maternity units in England. Individuals with chronic hypertension (enrolled up to 37 weeks' gestation) or with gestational hypertension (enrolled between 20 and 37 weeks gestation). Final follow-up was in May 2020.

Interventions: Participants were randomized to either blood pressure self-monitoring using a validated monitor and a secure telemonitoring system in addition to usual care (n=430) or to usual care alone (n=420). Usual care comprised blood pressure measured by health care professionals at regular antenatal clinics.

Main outcomes: The primary maternal outcome was the difference in mean systolic blood pressure recorded by health care professionals between randomization and birth.

Results: Among 454 participants with chronic hypertension (mean age 36 years, mean gestation at entry 20 weeks) and 396 with gestational hypertension (mean age 34 years, mean gestation at entry 33 weeks) who were randomized, primary outcome data were available from 444 (97.8%) and 377 (95.2%) respectively. In the chronic hypertension cohort, there was no statistically significant difference in mean systolic blood pressure for the self-monitoring groups vs the usual care group (133.8 mmHg vs 133.6 mmHg, respectively; adjusted mean difference, 0.03 mmHg; 95% CI -1.73 to 1.79) In the gestational hypertension cohort, there was also no significant difference in mean systolic blood pressure (137.6 mmHg compared with 137.2 mmHg; adjusted mean difference, -0.03mmHg; 95% CI -2.29 to 2.24). There were 8 serious adverse events in the self-monitoring group (4 in each cohort) and 3 in the usual care group (2 in chronic hypertension cohort and 1 in gestational hypertension cohort).

Conclusions and relevance: Among pregnant individuals with chronic or gestational hypertension, blood pressure self-monitoring with telemonitoring compared with usual care did not lead to significantly improved clinic-based blood pressure control.

Trial registration: Prospectively registered clinicaltrials.gov NCT03334149.

Key words: Pregnancy; hypertension; blood pressure; self-monitoring; pre-eclampsia; trial

Introduction

Elevated blood pressure (BP) in pregnancy has been estimated to have affected approximately 18 million pregnancies worldwide in 2019 and has been found to be a leading cause of maternal and perinatal mortality and morbidity.[1,2] Globally, an estimated 42,000 individuals die annually from the complications of pregnancy hypertension, around 14% of total maternal deaths.[3] Additionally approximately 15% of the 2.6 million stillbirths that occur globally each year are attributed to pregnancy hypertension disorders,[4,5,6] independently of the development of pre-eclampsia.[7]

Self-monitoring of blood pressure (SMBP), in which an individual measures their own BP outside of the clinical setting, is recommended and widely used for non-pregnant persons.[8] In non-pregnant individuals, SMBP in conjunction with co-interventions including telemonitoring is associated with better BP control.[9] In pregnancy, a pivotal component of antenatal care is regular BP measurement, particularly in pregnancy hypertension.[10] Regular measurement supports hypertension management to avoid adverse consequences for woman and infant. SMBP has the potential to engage and empower pregnant individuals in their own care, improve detection of raised BP between antenatal visits, reduce additional clinic visits, and allow management to be informed by multiple BP readings including those outside the clinic setting.

Studies of SMBP have documented use by 19% of pregnant individuals,[11] and although feasibility studies have shown that the intervention is acceptable for normotensive[12] and hypertensive[13] pregnant individuals, definitive evidence for effectiveness is lacking.[14] The Blood Pressure Monitoring in Hypertensive Pregnancy (BUMP2) trial aimed to evaluate the effect of SMBP in individuals with pregnancy hypertension on BP control (assessed as systolic BP measurements), alongside a linked trial assessing self-monitoring for the detection of raised BP in individuals with higher risk pregnancies.[15][*citation for BUMP1*]

Methods

Study design

The methods of the trial have been previously described.[16] The protocol and statistical analysis plan are included in Supplement 1 and Supplement 2, respectively, and are summarized here) Individuals entered this trial as new participants with chronic or gestational hypertension, or transitioned from the linked trial (which recruited individuals at increased risk of pregnancy hypertension), when they became hypertensive maintaining the original randomization. The trial was approved by the Research Ethics Committee (West Midlands - South Birmingham: ref 17/WM/0241), host institutions and Health Research Authority. All participants gave written informed consent before any trial procedures.

Study Population

Individuals aged 18 years or older were eligible if they had chronic hypertension (defined as sustained systolic BP ≥140 mmHg and/or diastolic BP ≥90 mmHg, present at booking or before 20 weeks' gestation, or receiving antihypertensive treatment outside pregnancy or at time of referral) and were recruited up to 37^{+0} weeks' gestation, or gestational hypertension (defined as sustained systolic BP ≥140 mmHg and/or diastolic BP ≥90 mmHg after 20 weeks' gestation), recruited at 20^{+0} to 37^{+0} weeks' gestation.[16] Individuals considered likely to deliver within 48 hours of eligibility assessment were excluded. Eligible individuals, willing and able to give informed consent, were recruited from secondary care in 15 UK maternity units.

Randomization and masking

Individuals who agreed to participate were randomized in a 1:1 ratio, either to SMBP or usual care. An independent statistician generated a randomization sequence list, using permutated varying blocks (sized 4 or 6) and stratified by recruitment site and parity, which was delivered online for use by researchers at each site (REDCap version 7.0.9). Individuals who developed hypertension during the linked trial [*citation to BUMP1*] migrated to this trial, staying in their original randomization group as suggested during

development work.[15,17] The intervention was not masked from participants, clinicians, or data collectors due to its nature.

Procedures

Participants in both groups were asked to follow usual antenatal pregnancy visits and care. Recruitment continued until end of September 2019 at which point the planned sample size had been achieved.

Self-monitoring

Participants randomized to SMBP were provided with a monitor validated in pregnancy and pre-eclampsia (Microlife WatchBP Home)[18] and a secure telemonitoring system using an app, with an optional paper diary.[15] Participants were asked to monitor their BP daily at a time convenient to them, sitting quietly prior to taking two readings 1 minute apart and submitting their second reading to the telemonitoring system. Raised readings triggered a request for a third reading which, if still raised, led to advice to contact their local maternity unit. Participants received reminders and weekly motivational messages developed iteratively with involvement of pregnant individuals.[17] Clinicians could access self-monitored BP readings via a web-based dashboard or directly via viewing the app on participants' phones. Midwives at each site received weekly summaries of participants' readings to allow audit and follow-up of those not responding to app messages.

Usual prenatal care

Usual prenatal care entailed pregnant individuals attending antenatal clinics as required, including BP measurement and, if needed, medication initiated or adjusted by their usual antenatal care team. Individuals randomized to usual care were not prevented from self-monitoring but did not receive the app or other advice regarding this. SMBP telemonitoring is not a routine part of maternity care in the UK.

Follow-up and questionnaires

All participants were followed-up at approximately 30 weeks' gestation (or 2 weeks after baseline if recruited after 30 weeks) and at 8 weeks after birth and asked to complete patient questionnaires: health-related quality of life (EuroQoL EQ-5D-5L questionnaire),[19] State Trait Anxiety Inventory short form-6 questionnaire,[20] modified brief Illness Perception Questionnaire,[21] and, in individuals recruited directly to the trial, medication adherence (MARS questionnaire).[22] A medical notes review was completed after primary discharge of the woman and newborn.

Protocol Amendments

There were no substantial changes to the published study design, methods, or outcomes after the start of the trial, other than the increase in sample size before the end of the trial allowing separate analysis of chronic and gestational hypertension as described below.

Outcomes

The primary outcome was the difference in mean systolic BP, defined as the mean of BP recorded by healthcare professionals in the clinical record from date of entry into the study plus one day, until date of delivery minus one day, between usual care and self-monitoring groups. Secondary clinical outcomes pre-specified in the Statistical Analysis Plan were: maternal outcomes: clinic-measured diastolic BP, systolic BP readings >140mmHg (measured by a healthcare professional), severe hypertension (systolic BP ≥160 mmHg and/or diastolic BP ≥110 mmHg),[16] serious maternal complications, onset of labour; perinatal outcomes: gestation at delivery, birthweight (including centiles), small for gestational age (<10th and <3rd centiles), neonatal unit admission, length of neonatal unit stay, stillbirths, early neonatal deaths, mode of delivery.[15] Patient-reported outcomes were quality of life (EuroQol EQ-5D-5L, 0 (worst) to +1 (best), minimally clinically important difference [MCID] 0.037)), anxiety ((STAI6, scaled to 100: lowest 0 (best) to highest 100 (worst), MCID 10), illness perception (least 6 to most 60 (reflects increasing confidence in ability to manage

hypertension, MCID not available), fidelity to the monitoring schedule and adherence as described above.[19,20,22,23] Full list available eTable 1.

In accordance with UK recommendations, self-reported ethnicity was recorded using standard descriptions.[24]

Sample size

The initial sample size calculation (based on chronic hypertension and gestational hypertension groups considered together) estimated that 256 per group would be sufficient to detect a 5 mmHg difference in systolic BP between groups at 90% power and 5% level of significance (2-sided), accounting for 15% attrition and a standard deviation of 16 mmHg, based on data from the previous feasibility study[12] and PELICAN[25] study. The sample size was calculated using NCSS PASS V.12.0. The planned sample size of 512 for direct recruitment into the trial was subsequently increased to 600 during the trial and prior to any analyses to retain power in the cohorts of individuals with chronic and gestational hypertension.

Statistical analysis

The primary analysis included all participants for whom data were available, according to the group to which participants were randomly allocated regardless of any subsequent deviation from protocol, i.e. all individuals recruited to the linked trial who become hypertensive and transitioned into the this trial, as well as those recruited *de novo* to this trial and this was taken into account in the models used (see below). Individuals recruited in late pregnancy, if they gave birth before any eligible BPs were recorded, were not included in the primary analysis since no data could be contributed. For all neonatal outcomes, the analysis excluded individuals with a pregnancy loss (for whatever cause) without a live birth before 24 weeks' gestation.

Although the trial initially planned to analyse all hypertensive categories together, publication of the OPTIMUM-BP trial[13] evaluating the feasibility of SMBP in individuals with hypertensive pregnancies demonstrated potential differences in BP characteristics, duration of intervention and effect size between individuals with chronic hypertension and gestational hypertension. It was therefore pre-specified before the end of recruitment that these groups would be analysed separately, and the sample size increased to allow for this.

The primary analysis compared mean systolic BPs between the intervention group and the control group using a linear mixed-effects model, adjusting for mean baseline systolic BP and parity (as a binary variable), and including a random effect for recruitment site to account for possible differences in practice between sites. The models assumed an unstructured variance covariance matrix between measurements from the same site. The model for the gestational hypertension cohort adjusted for the transition from the linked trial. Although, the model also implicitly accounted for data missing at random mechanism, we also explored any covariates that were related to missingness of the primary outcome and we adjusted these covariates to the model as a sensitivity analysis. Pre-specified sensitivity analyses were carried out as for the primary outcome, including combining the chronic hypertension and gestational hypertension cohorts in an individual patient data type analysis (i.e. all individuals in the trial regardless of hypertension diagnosis). Pre-specified subgroup analyses fitted these models with an interaction between treatment group and the subgroup of interest: parity, gestational age, previous self-monitoring in this pregnancy, deprivation, ethnicity, highest educational qualification.

Binary secondary outcomes were analysed using logistic mixed effects models, adjusting for parity and included site as a random effect. Treatment effects were described using odds ratios with 95% confidence intervals. Continuous secondary outcomes were analysed using linear mixed-effects models including a random intercept for each participant to account for the repeated measures (where applicable), as well as a random effect for site. Models used a similar approach to that taken for the primary outcomes. Adjusted

mean differences between randomized groups with 95% confidence intervals and p values were estimated at each time point. Continuous outcomes that did not fulfil normality assumption were analysed using quantile regression, adjusting for parity and site (as fixed effects). Perinatal outcomes included an adjustment for twin births. Categorical secondary outcomes were analysed descriptively. Findings for analyses of secondary endpoints should be interpreted as exploratory because of the potential for type I error due to multiple comparisons.

A *post hoc* analysis considered the prevalence of discordance between clinic and home measures of hypertension. An additional *post hoc* analysis assessed prescription of antihypertensives during the trial using defined daily doses.[26] There were no interim analyses. All analyses were performed using STATA SE version 16.1 (StataCorp). All analyses were 2 sided with a significance threshold of $p<0.05$.

Results

A total of 850 pregnant individuals with hypertension were randomized between November 2018 and September 2019, including; 600 pregnant individuals recruited directly and 250 individuals from the linked trial who developed hypertension and transitioned into this trial. A total of 430 individuals were allocated to SMBP and 420 individuals to usual care (Figure 1). The primary outcome was available for 416 (96.7%) participants in the SMBP group and 405 (96.4%) participants in the usual care group. The baseline characteristics were similar between the two allocation groups, across the chronic and gestational hypertension cohorts with groups balanced on stratification factors (Table 1, eTable 2 in Supplement 3). Individuals with chronic hypertension were recruited at 20 weeks, had a mean age of 36 years and 66% had self-monitored blood pressure previously in this pregnancy; those with gestational hypertension were recruited at 33 weeks, had a mean age of 34 years and 43% had self-monitored blood pressure previously in this pregnancy.

Primary Outcome

There was no significant difference in the mean systolic BP in those allocated to SMBP, in either the chronic or gestational hypertension groups (Table 2). In participants with chronic hypertension, the mean clinic systolic BP was 133.8 mmHg in the SMBP group compared with 133.6 mmHg in those with usual care (adjusted mean difference 0.03 mmHg; 95% CI -1.73 to 1.79). In participants with gestational hypertension, the mean systolic BP was 137.6 mmHg compared with 137.2 mmHg in those with usual care (adjusted mean difference -0.03 mmHg; 95% CI -2.29 to 2.24).

There was no effect on the primary outcome in prespecified sensitivity analyses, including combining chronic and gestational cohorts in an individual patient data type analysis (eTable 3 in Supplement 3). Similarly, in prespecified subgroup analyses within each hypertensive cohort there was no significant interaction for parity, gestational age at entry, previous self-measurement of BP in this pregnancy, deprivation score, ethnicity, highest educational qualification or baseline blood pressure including no significant difference in the gestational hypertension cohort only, for those transitioning from the linked trial (Figures 2 and 3). There was no significant interaction by hypertension cohort (eTable3 in Supplement 3).

Secondary Outcomes

In individuals with chronic hypertension, there was no significant difference in the majority of maternal and infant secondary outcomes, other than a lower proportion with spontaneous onset of labour: 12 participants (5%) in the SMBP group vs. 21 participants (10%) in the usual care group; adjusted odds ratio 0.52 (95% CI, 0.29 to 0.92) (Table 3). This may have related to a higher proportion of participants in the SMBP group being diagnosed with pre-eclampsia, though a lower proportion (not tested) of this group had one or more serious maternal complications (eTable 4 in Supplement 3). There was no significant difference in gestational age at birth, spontaneous vaginal births, or in any of the infant outcomes. There were three stillbirths in the cohort, one in the SMBP group and two in the usual care group.

In participants with gestational hypertension, there were also no significant differences in the maternal and infant secondary outcomes, other than a lower proportion of individuals with a spontaneous onset of labour: 30 individuals (15%) in the SMBP group versus 44 individuals (22%) in the usual care group; adjusted odds ratio 0.62 (95% CI, 0.39 to 0.99), though with no significant difference in the proportion with spontaneous vaginal births (Table 3). There was one stillbirth in the self-monitoring group and none in the usual care group. Other descriptive secondary outcomes are shown in eTable 4 in Supplement 3.

There were no significant differences in anxiety and adherence measures at baseline or follow-up (eTable 5 in Supplement 3). Individuals with chronic and gestational hypertension who were randomized to self-monitoring had significantly improved scores on the modified brief Illness Perception Questionnaire at both 30 weeks and postnatally compared with usual care (eTable 6a and b in Supplement 3). There were no significant differences in maternal health-related quality of life measured using EQ-5D-5L between the randomized groups in the main analysis and sensitivity analysis (eTables 7a and b in Supplement 3).

Adverse Events

There were no significant differences in adverse events or serious adverse events between the two groups (4 vs. 2 in chronic hypertension group and 4 vs. 1 in gestational hypertension group, by self-monitoring and usual care allocations respectively), and no serious adverse events related to intervention (eTable 8 in Supplement 3).

In assessment of fidelity to the intervention, only two participants (0.4%) exclusively used a paper diary; as these data were not directly comparable to that in the app, those readings were excluded. Using BP readings provided by participants via the app, those who were recruited directly to this trial at outset submitted readings on 62% of expected number of days (eTable 9 in Supplement 3). Participants who transitioned from the linked trial (and were asked to do more frequent BP measurement in this trial) self-monitored on 51% of the expected days (eTable 9 in Supplement 3).

Post hoc analyses

In a *post hoc* analysis of 430 participants allocated to SMBP and considering the whole period between randomization and delivery, 259 (60.2%) had high clinic and home BP readings, 107 (24.9%) had high clinic BP readings but all home readings normal, 24 (5.6%) had normal clinic but high home readings, and 36 (8.4%) had normal clinic and normal home BP readings throughout (with data from four women missing). Analyses of antihypertensive defined daily dose of proportions showed no significant difference between groups in medication dosing over time (eTable 10 in Supplement 3).

Discussion

Among pregnant individuals with chronic or gestational hypertension, SMBP with telemonitoring compared with usual care alone did not lead to significantly improved clinic-based BP control. These results were similar for all sub-groups including those with gestational hypertension, whether they were recruited directly into the trial or transitioned from the linked trial when they developed hypertension

The strengths of this trial include the intervention being developed iteratively with the input of pregnant individuals and behavioural change experts.[17] It was appropriately powered including separately for chronic and gestational hypertension, undertaken in multiple maternity units across England with diverse socio-demographic characteristics (including a substantial proportion from non-White racial and ethnic groups), with recruitment completed prior to the COVID-19 pandemic. The results may therefore be generalizable to populations beyond those in the study.

To our knowledge, this was the first adequately powered trial of SMBP in individuals with pregnancy hypertension. Three small-scale feasibility trials have previously been published; the first was an evaluation in 57 individuals with newly-diagnosed gestational hypertension in which it was concluded that home BP

monitoring was feasible and acceptable.[27] The second was a trial of revealed vs. concealed ambulatory home BP monitoring on a single occasion in 100 individuals with hypertension in late pregnancy, demonstrating feasibility and acceptability of ambulatory monitoring.[28] More recently, the feasibility trial for the current study in 158 individuals with chronic or gestational hypertension showed acceptability and prompted the separate analysis of gestational and chronic hypertension.[13] None of these studies were designed to address the effect of out-of-hospital monitoring on clinical or health resource outcomes.

A systematic review and individual patient data analysis examined SMBP in both men and non-pregnant women; participants were generally chosen on the basis of treated but poorly controlled hypertension with mean baseline BP readings commonly higher than 140 mmHg.[9] While the individual patient data results showing reduced BP associated with SMBP were similar for men and women, the populations were different to the current trial where mean baseline ~~individual patient data~~ blood pressure was in the normal range (including some participants initially not requiring treatment) reducing opportunities for intervention.

Despite reports of a white-coat effect in pregnancy from individual studies, a systematic review and individual patient data meta-analysis of 21 pregnancy studies reported a mean difference between self-monitoring and clinic systolic BPs of less than 1.2mmHg, suggesting that similar alert thresholds could be used for both settings.[29] In hypertensive individuals (based on a smaller number of lower-quality studies), a wider home-clinic difference was seen of 8-16mmHg. Almost 25% of participants in the current study recorded only normal BP at home despite raised clinic pressures suggesting a white coat effect and this might have diluted any effect of self-monitoring on BP control as measured in the clinic. There was no significant difference in prescription of antihypertensives between groups for individuals with either chronic or gestational hypertension suggesting that clinicians may have been treating based on clinic BP despite access to self-monitored BP data.

Limitations

This study has several limitations. First, there was uncertain use of SMBP by the usual care group during the trial. Participants reported self-monitoring prior to randomization (chronic hypertension [66%] and gestational hypertension [43%]) may have diluted the intervention effect, although only the intervention group had access to the study app. This is consistent with other findings that approximately 49% of hypertensive pregnant individuals self-monitor BP, often of their own initiative and without input from health care professionals.[11] Outside of pregnancy, such self-monitoring in the absence of other co-interventions has little effect.[9]

Second, although the app included reminders to monitor, clear instructions on when to contact the maternity unit with a raised BP, and a dashboard for clinicians, the intervention did not include other factors such as automated transfer of BP readings to the electronic health record, self-managed titration of antihypertensive medication, or lifestyle counselling that might have improved effectiveness. Third, training was undertaken for each site at the start of the trial. It is possible that repeated training throughout the trial might have improved the utilization of self-monitoring and reinforced optimal uptake.

Conclusions

Among pregnant individuals with chronic or gestational hypertension, SMBP with telemonitoring compared with usual care did not lead to significantly improved clinic-based BP control.

Authors' contributions

RM together with LC and KT, conceived and led the study, providing detailed supervision of all aspects throughout. LMY, LH, ORA, CC, MG, SG, JH, PL, CM, LM, JS, LT and LY provided senior expertise and leadership, contributing to designing the study, securing funding and supervising the conduct of the study. HW and CC led the research midwifery team with LL. LMY with UG, carried out the statistical analysis, and HC and ORA carried out the economic analysis. LY, LT and LH led the development of the intervention and supported its implementation with CV and MS. MF and GD with LE led trial implementation supervised by JA. MG was the key public contributor. LC wrote the first draft with RM, KT and UG. All authors commented on drafts of this paper. RM will act as guarantor and affirms that the manuscript is an honest, accurate, transparent, and full account of the trial. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Declaration of interests

RM has previously received BP monitors from Omron Healthcare for research purposes and is working with them on a telemonitoring system. LT is a Non-Executive Director & Director of R&D for Sensyne Health Plc. LM is a part-time employee and shareholder of Sensyne Health plc. All other authors declare no conflicts of interest.

The BP monitors for the BUMP trials were purchased from the manufacturer (Microlife) at commercial prices. The BUMP app has been developed into a commercial product in collaboration with Sensyne Health and provided free to the NHS during the coronavirus pandemic through free licencing from both University of Oxford and Sensyne Health.

Funding

This work was funded from a National Institute for Health Research (NIHR) Programme grant for applied research (RP-PG-1209-10051) and NIHR Professorships awarded to RM (NIHR-RP-R2-12-015) and LC (NIHR - RP-2014-05-019). RM and KT received funding from the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research (CLAHRC) now recommissioned as NIHR Applied Research Collaboration Oxford and Thames Valley (ARC-OxTV). LM received support from NIHR Oxford Biomedical Research Centre. LH is based in The Healthcare Improvement Studies Institute (THIS Institute), University of Cambridge. THIS Institute is supported by the Health Foundation, an independent charity committed to bringing about better health and healthcare for people in the UK. JS was supported by the

National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care South London (NIHR CLAHRC South London) at King's College Hospital NHS Foundation Trust, now recommissioned as NIHR Applied Research Collaboration South London. LY's research programme is partly supported by NIHR Applied Research Collaboration (ARC)-West, NIHR Health Protection Research Unit (HPRU) for Behavioural Science and Evaluation, and the NIHR Southampton Biomedical Research Centre (BRC). RM, JS, LMY and LC are NIHR Senior Investigators. Service support costs were administered through the NIHR Clinical Research Network. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and social care.

Role of the funder

The funders and sponsors of the study had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Access to data statement

UG and Dr. LMY had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Acknowledgements

We thank the independent Trial Steering Committee (all unpaid for this role): chair: Laura Magee MD (King's College London), members: Jim Thornton MB MD (University of Nottingham), John Norrie MSc (University of Edinburgh) and Tim Coleman MD (University of Nottingham) and the independent Data Monitoring Committee (all unpaid for this role): chair: Nigel Simpson MB ChB (University of Leeds), Julia Sanders PhD (Cardiff University) and Miliça Bucknall PhD (Keele University). We thank our PPI representatives; Margaret Glogowska, Jacqui Williams and Tricia Carver who supported the trial management and trial steering groups. We thank Lucy Curtin, for administrative support and Lucy Abel who did preparatory Health Economic work on the project. LC, LA and JW received compensation; all others listed did not.
The study would not have been possible without the contributions of participants, site research midwives and doctors. The BUMP investigators are listed separately.

Group Information: The BUMP2 Investigators are listed in Supplement 4.

Data sharing

See supplement 5

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Supplemental Content

Supplement 1 Trial Protocol

Supplement 2 Statistical analysis plan

Supplement 3 Supplementary tables and figures

Supplement 4 The BUMP investigators

Supplement 5 Data Sharing Statement

Figure 1: Eligibility, randomization, and data availability in a trial of self-monitoring for blood pressure control in pregnant individuals with hypertension (see separate file)

Figure 2: Sub-group analyses for mean systolic blood pressure in chronic hypertension group (see separate file)

Footnote for Figure 2:

Linear mixed-effects model of mean systolic blood pressure modelled against an interaction between randomised group and subgroup indicator, parity, and site. Level of significance=0.05

[a] Mean differences presented for self-monitoring versus usual care.

[b] The index of multiple deprivation is an assessment of deprivation based on a multiple weighted components including income, employment, education, health, crime, barriers to housing and services, and living environment. It is assessed at the postcode level. Scores below the median indicate higher deprivation than scores above the median.

[c] BP≥140/90mmHg means systolic and/or diastolic greater or equal to 140/90mmHg as measured by a professional.

Figure 3: Sub-group analyses for mean systolic blood pressure in gestational hypertension group (see separate file)

Footnote for Figure 3:

Linear mixed-effects model of mean systolic blood pressure modelled against an interaction between randomised group and subgroup indicator, parity, site and transfer from BUMP1. Level of significance=0.05

[a] Mean differences presented for self-monitoring versus usual care.

[b] The index of multiple deprivation is an assessment of deprivation based on a multiple weighted components including income, employment, education, health, crime, barriers to housing and services, and living environment. It is assessed at the postcode level. Scores below the median indicate higher deprivation than scores above the median.

[c] BP≥140/90mmHg means systolic and/or diastolic greater or equal to 140/90mmHg as measured by a professional.

583 Table 1: Baseline characteristics by randomized group

	Chronic hypertension		Gestational hypertension	
	Self-Monitoring	Usual Care	Self-Monitoring	Usual Care
	n=233	n=221	n=197	n=199
Age (years)	36.0 (5.4)	35.5 (5.8)	33.5 (6.1)	33.6 (5.6)
Gestation (weeks) at entry	18.6 (15.3 to 23.3)	18.3 (15.4 to 23.3)	34.3 (29.7 to 35.9)	33.9 (30.3 to 36.1)
Parity: no previous births	85 (36.5%)	77 (34.8%)	103 (52.3%)	101 (50.8%)
Body mass index (kg/m^2)	30.7 (26.7 to 34.7)	30.5 (26.3 to 35.8)	29.4 (24.8 to 35.1)	28.5 (25.0 to 35.4)
Index of multiple deprivation quintile[a]	n=229	n=218	n=196	n=196
1 (most deprived)	67 (29.3)	55 (25.2)	39 (19.9)	24 (12.2)
2	60 (26.2)	68 (31.2)	49 (25.0)	43 (21.9)
3	47 (20.5)	41 (18.8)	36 (18.4)	45 (23.0)
4	30 (13.1)	32 (14.7)	35 (17.9)	45 (23.0)
5 (least deprived)	25 (10.9)	22 (10.1)	37 (18.9)	39 (19.9)
Ethnicity[b]	n=228	n=220	n=196	n=199
Asian or Asian British	25 (10.7%)	25 (11.3%)	23 (11.7%)	25 (12.6%)
Black or Black British	70 (30.0%)	71 (32.1%)	17 (8.6%)	22 (11.1%)
Chinese	1 (0.4%)	1 (0.5%)	3 (1.5%)	2 (1.0%)
Mixed or Multiple ethnic groups	11 (4.7%)	11 (5.0%)	7 (3.6%)	11 (5.5%)
Other ethnic group	7 (3.0%)	4 (1.8%)	8 (4.1%)	4 (2.0%)
White	115 (49.4%)	109 (49.3%)	141 (71.6%)	137 (68.8%)
Current smoker	9 (3.9%)	9 (4.1%)	8 (4.1%)	5 (2.5%)
Highest education	n=226	n=218	n=196	n=199
Tertiary Education	113 (50.0)	105 (48.2)	88 (44.9)	102 (51.3)
Professional qualifications, n(%)	30 (13.3)	23 (10.6)	31 (15.8)	15 (7.5)
A-level or GCSE, n(%)	60 (26.6)	60 (27.5)	63 (32.1)	78 (39.2)
Vocational qualifications, n(%)	11 (4.9)	17 (7.8)	10 (5.1)	2 (1.0)
No formal qualifications, n(%)	12 (5.3)	13 (6.0)	4 (2.0)	2 (1.0)
Self-measured blood pressure in this pregnancy	146 (62.7%)	151 (68.3%)	82 (41.6%)	89 (44.7%)
Risk factors for hypertension				
Previous hypertensive disorder of pregnancy	86 (36.9%)	81 (36.7%)	62 (31.5%)	69 (34.7%)
Family history of pre-eclampsia	28 (12.0%)	26 (11.8%)	40 (20.3%)	34 (17.1%)
Autoimmune disease[c]	7 (3.0%)	4 (1.8%)	13 (6.6%)	13 (6.5%)
Diabetes (type 1 or type 2)	19 (8.2%)	15 (6.8%)	13 (6.6%)	12 (6.0%)
Twin pregnancy	7 (3.0%)	5 (2.3%)	14 (7.1%)	9 (4.5%)
Interval between pregnancies >10 years	13 (5.6%)	16 (7.2%)	7 (3.6%)	10 (5.0%)
Chronic kidney disease (any grade)	15 (6.4%)	14 (6.3%)	2 (1.0%)	8 (4.0%)
Blood pressure				
Mean systolic blood pressure at entry	133.8 (13.0)	134.4 (13.3)	135.1 (11.0)	133.1 (11.0)
Mean diastolic blood pressure at entry	83.7 (10.0)	84.9 (9.8)	85.6 (8.6)	85.0 (9.0)
On antihypertensive medication at 20 weeks' gestation	169 (72.5)	155 (70.1)	-	-

584 Data are n (%), mean (SD) or median (interquartile range).

585 [a] The index of multiple deprivation is an assessment of deprivation based on a multiple weighted components including
586 income, employment, education, health, crime, barriers to housing and services, and living environment. It is assessed
587 at the postcode level.

[b] Ethnicity self-attributed from standard UK classification. “Other” included any other ethnicity not listed above in which case participants were asked to specify (Chronic hypertension Self-monitoring: 2 not stated and one each of the following: Anglo-Arab, British Arab, Mauritian, Middle-East Iranian, Thai; Usual Care: 2 not stated and one each of the following: Japanese and Korean; Gestational hypertension Self-monitoring: 6 not stated and one each of the following: Myanmar and Turkish Kurdish; Usual Care: 3 not stated and one Myanmar)

[c] Any autoimmune disease (for example systemic lupus erythematosus or antiphospholipid syndrome)

Table 2: Primary outcome: Mean blood pressure for women with chronic hypertension and gestational hypertension

Chronic hypertension	Self-Monitoring	Usual Care	Adjusted mean difference (95% CI)	p value
Primary outcome available [b]	229 (98.3%)	215 (97.3%)		
Systolic blood pressure (mmHg)[c]	133.8 (10.3)	133.6 (11.1)	0.03 (-1.73 to 1.79)[a]	0.97
Diastolic blood pressure (mmHg)	84.0 (7.4)	84.3 (7.9)	-0.03 (-1.28 to 1.22)	0.96
Gestational hypertension	Self-Monitoring	Usual Care		
Primary outcome available [b]	187 (94.9%)	190 (95.5%)		
Systolic blood pressure (mmHg)	137.6 (12.1)	137.2 (10.8)	-0.03 (-2.29 to 2.24)[d]	0.98
Diastolic blood pressure (mmHg)	86.1 (7.8)	86.3 (7.7)	-0.35 (-1.77 to 1.06)	0.63

Data are n (%) or mean (SD). SBP: systolic blood pressure.

[a] Chronic Hypertension, self-monitoring vs. usual care; estimated from linear mixed effects model adjusting for mean baseline systolic blood pressure, parity and recruitment site. N=11 participants not included in the model due to missing baseline systolic blood pressure (n=7 from Self-monitoring, n=4 from Usual care).

[b] Individuals with missing primary outcomes (10 in the chronic hypertension self-monitoring group, 6 in the chronic hypertension usual care group, 10 in the gestational hypertension self-monitoring group, and 9 in the gestational hypertension usual care group) were not included in this analysis; no imputation was undertaken.

[c] Mean blood pressure was defined as the mean of the means of all systolic BP readings recorded by health care professionals, from post-entry into the study until up to one day before the date of delivery. No self-recorded BP was used.

[d] Gestational hypertension, self-monitoring vs. usual care; estimated from linear mixed effects model adjusting for mean baseline systolic blood pressure, parity, transfer from BUMP1 and recruitment site. N=6 participants not included in the model due to missing baseline systolic blood pressure (n=4 from Self-monitoring, n=2 from Usual care).

614 Table 3: Secondary outcomes for women with chronic and gestational hypertension

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	Self-Monitoring	Usual Care	(Unadjusted) Absolute risk differences (CI)	Adjusted effect measure (95% CI)[a]	p value
Chronic hypertension					
Maternal outcomes	n=233	n=221			
Number of blood pressure measurements	n=3079	n=2836			
Number (proportion) of days with systolic blood pressure >140 mmHg	1019 (33%)	987 (35%)	-0.02 (-0.04 to 0.01)	OR 0.93 (0.75 to 1.16)	0.51
Gestation at birth (weeks)	38.3 (37.0 to 39.1)	38.1 (37.1 to 39.0)	-	MedD 0.07 (-0.28 to 0.42)	0.69
Maternal outcomes for those with primary outcome only	n=229	n=215			
Severe hypertension[b]	51 (22%)	48 (22%)	0.02 (-0.05 to 0.10)	OR 1.00 (0.57 to 1.76)	0.99
Pre-eclampsia	44 (19%)	33 (15%)	0.04 (-0.03 to 0.11)	OR 1.31 (0.77 to 2.24)	0.32
Received a blood transfusion[c]	3 (1%)	11 (5%)	-0.04 (-0.07 to -0.01)	-	-
Maternal death[c]	0	0	-	-	-
Maternal outcomes for those delivering after 24 weeks	n=227	n=216			
Spontaneous onset of labour	12 (5%)	21 (10%)	-0.04 (-0.09 to 0.004)	OR 0.52 (0.29 to 0.93)	0.03
Infant outcomes (all births)	n=233	n=221			
Spontaneous vaginal birth	61 (26%)	71 (32%)	-0.06 (-0.14 to 0.02)	OR 0.76 (0.44 to 1.32)[d]	0.33
Stillbirths[c]	1 (0.4%)	2 (1%)	-	-	-
Infants <10th birthweight centile	31 (13%)	32 (14%)	-0.01 (-0.08 to 0.06)	OR 0.90 (0.52 to 1.55)[d]	0.71
Birthweight centile	49.9 (21.1 to 77.1)	43.5 (18.0 to 74.8)	-	MedD 7.28 (-2.94 to 17.50)[d]	0.16
Infant outcomes (live births only)	n=232	n=219			
Neonatal unit admission	48 (21%)	47 (21%)	-0.01 (-0.08 to 0.07)	OR 0.91 (0.65 to 1.28)	0.59
Early neonatal deaths	1 (0.4%)	0		-	-
Days of neonatal unit stay (for those admitted)	15.0 (4.0 to 34.0)	11.0 (3.0 to 33.0)	-	MedD 0.00 (-13.21 to 13.32)	> 0.99
Gestational hypertension	Self-Monitoring	Usual Care			
Maternal outcomes	n=197	n=199			
Number of blood pressure measurements	n=1430	n=1624			
Number (proportion) of days with systolic blood pressure >140 mmHg	602 (42%)	679 (42%)	0.01 (-0.3 to 0.04)	OR 1.15 (0.76 to 1.72)	0.51
Gestation at birth (weeks)	37.7 (36.3 to 39.0)	38.0 (36.9 to 39.1)	-	MedD -0.14 (-0.61 to 0.33)	0.55

Maternal outcomes for those with primary outcome only	n=187	n=190			
Severe hypertension[b]	38 (20%)	49 (26%)	-0.01 (-0.09 to 0.08)	OR 0.74 (0.40 to 1.35)	0.32
Pre-eclampsia	71 (38%)	63 (33%)	0.05 (-0.05 to 0.14)	OR 1.24 (0.80 to 1.93)	0.33
Received a blood transfusion[c]	12 (6%)	7 (4%)	0.03 (-0.17 to 0.01)	-	-
Maternal death[c]	0	0	-	-	-
Maternal outcomes for those delivering after 24 weeks	n=195	n=198			
Spontaneous onset of labour	31 (16%)	44 (22%)	-0.06 (-0.14 to 0.01)	OR 0.65 (0.39 to 1.07)	0.092
Infant outcomes (all births)	n=209	n=207			
Spontaneous vaginal birth	75 (36%)	89 (43%)	-0.07 (-0.17 to 0.02)	OR 0.74 (0.49 to 1.12)[d]	0.15
Stillbirths[c]	1 (0.5%)	0	-	-	-
Infants <10th birthweight centile	31 (15%)	30 (14%)	0.004 (-0.07 to 0.07)	OR 1.06 (0.60 to 1.89)[d]	0.83
Birthweight centile	51.3 (16.2 to 83.3)	45.4 (17.2 to 81.4)	-	MedD 3.31 (-5.64 to 12.26)[d]	0.47
Infant outcomes (live births only)	n=208	n=207			
Early neonatal deaths[c]	0	1 (0.5%)	-	-	-
Neonatal intensive care admission	56 (27%)	52 (25%)	0.02 (-0.07 to 0.10)	OR 1.07 (0.72 to 1.61)	0.73
Days of neonatal unit stay (for those admitted)	8.0 (3.0 to 22.0)	10.0 (4.0 to 25.0)	-	MedD -5.00 (-11.39 to 1.39)	0.12

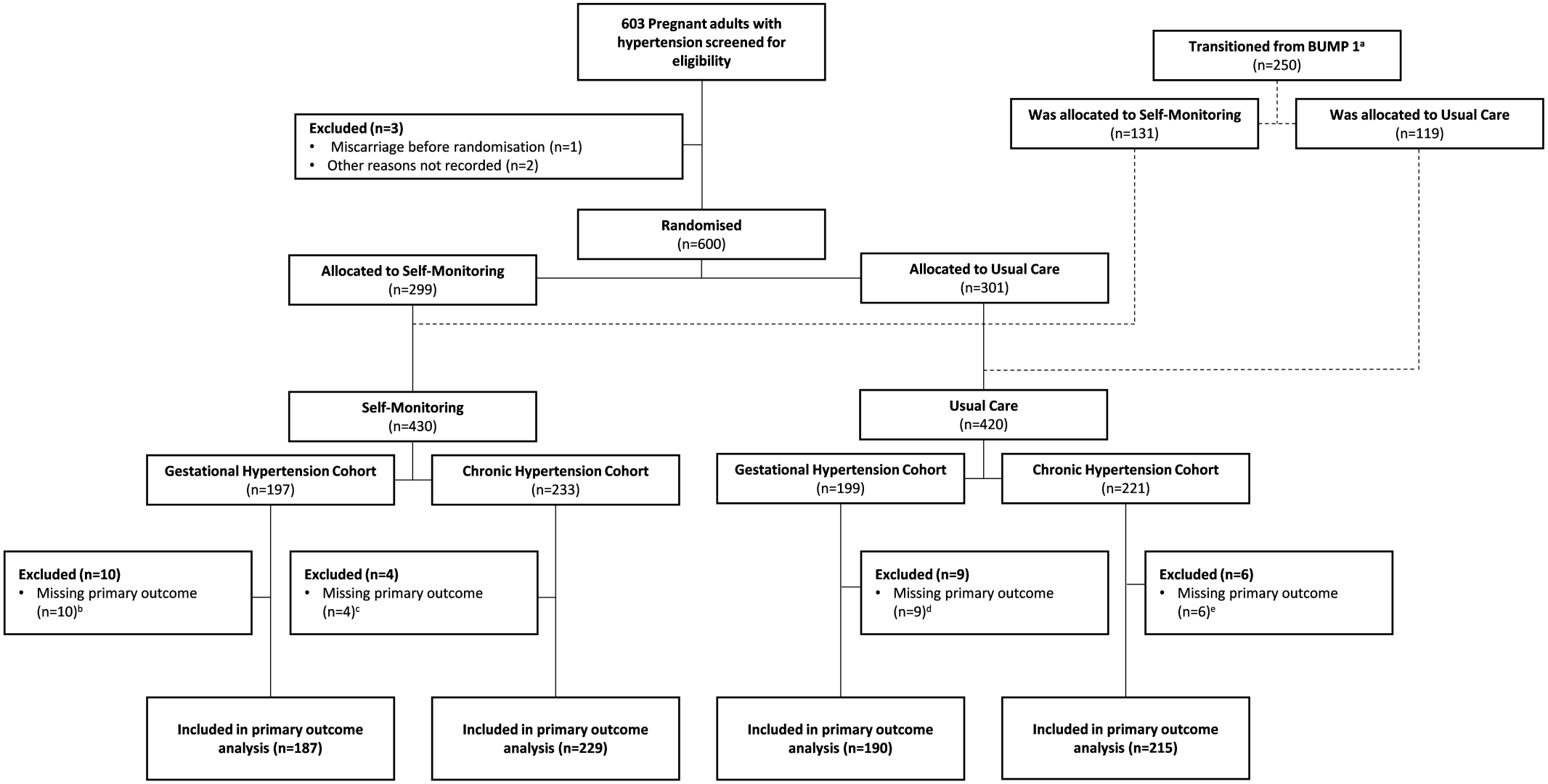
Data are n (%), mean (SD) or median (interquartile range). MD: mean difference; MedD: median difference; OR: odds ratio; All blood pressure measured by professionals.

[a] Self-monitoring vs. usual care; OR (95% CI) estimated from logistic mixed effects models adjusting for parity and recruitment site. For the gestational hypertension cohort only, transition from BUMP1; MedD (95% CI) estimated from quantile regression models adjusting for parity & recruitment site, and transition from BUMP1 for the gestational hypertension cohort only; MD (95% CI) estimated from linear mixed effects models adjusting for parity & recruitment site and for the gestational hypertension cohort only, transition from BUMP1

[b] Severe hypertension defined as systolic BP ≥160 mmHg and/or diastolic BP ≥110 mmHg),[16]

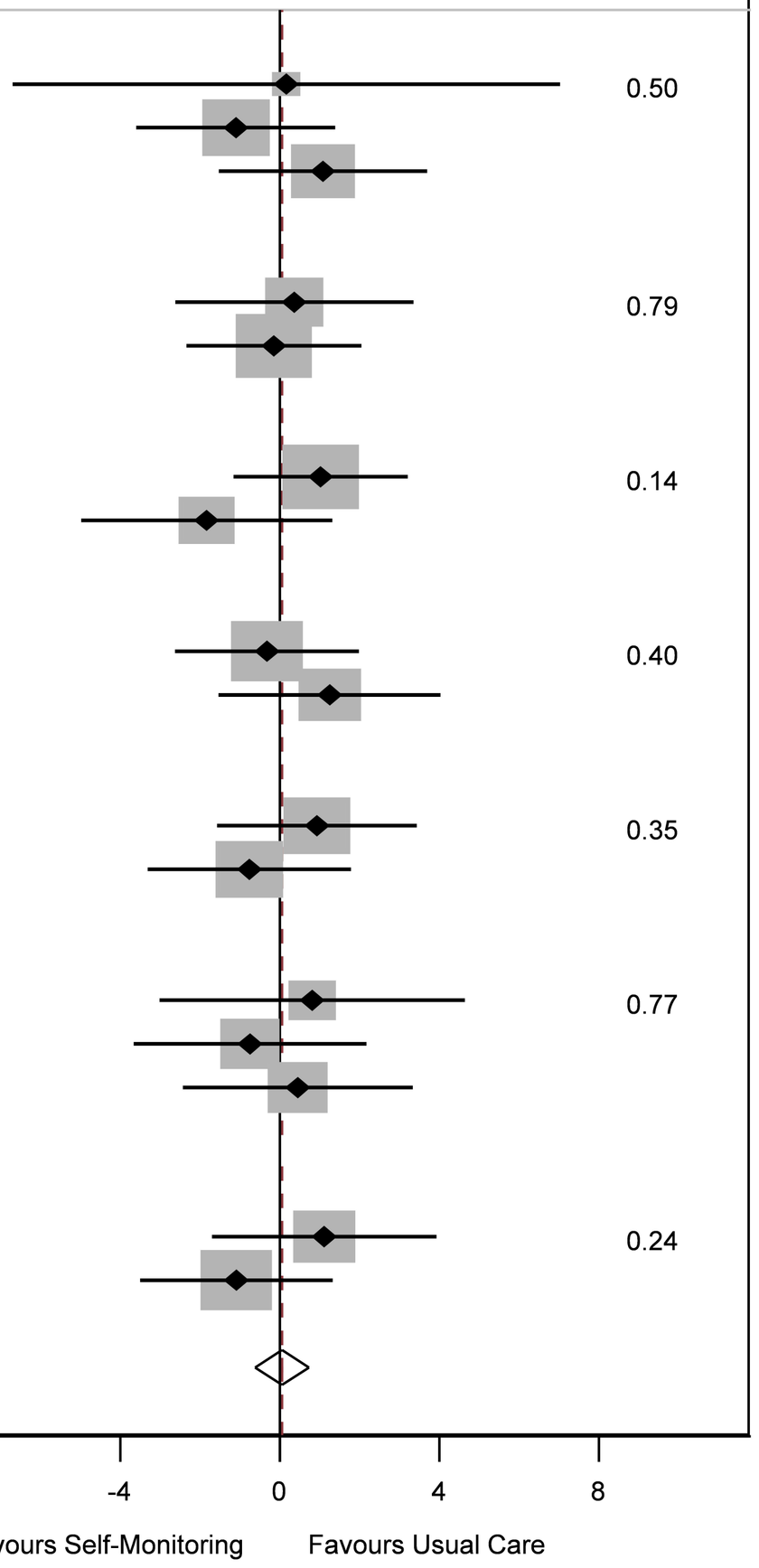
[c] The results are presented descriptively if less than 10% of the women/babies had an event and/or there are <5 events in any one cell.

[d] Models include an adjustment for twin birth



[a] The BUMP1 trial aimed to establish whether self-monitoring BP with telemonitoring in addition to usual care could lead to earlier detection of raised clinic BP compared to usual care during higher risk pregnancies. Pregnant individuals who developed hypertension during the linked BUMP1 trial migrated to this trial, staying in their original randomisation groups but changing to daily monitoring.
[b] Delivery 1-2 days after entering the trial and no primary outcome recorded (n=1); Delivery >2 days after entering the trial but before primary outcome was recorded (n=9).
[c] Delivery date not recorded so primary outcome could not be determined (n=2); Delivery >2 days after entering the trial but before primary outcome was recorded (n=2).
[d] Delivery date not recorded so primary outcome could not be determined (n=1); Delivery >2 days after entering the trial but before primary outcome was recorded (n=8).
[e] Delivery date not recorded so primary outcome could not be determined (n=4); Delivery >2 days after entering the trial but before primary outcome was recorded (n=2).

Subgroup	Self-Monitoring N	Self-Monitoring Mean (SD)	Usual Care N	Usual Care Mean (SD)	Mean Difference (95% CI)[a]	P value for Interaction
Gestation age at study entry						
<12 weeks	14	130.3(6.8)	14	128.4(7.2)	0.16 (-6.70, 7.03)	0.50
12 to 19+6 weeks	110	132.6(9.8)	110	133.8(11.5)	-1.10 (-3.60, 1.39)	
≥20 weeks	105	135.6(10.9)	91	134.2(10.9)	1.08 (-1.53, 3.69)	
Parity						
0	83	134.3(10.7)	75	133.8(11.9)	0.36 (-2.62, 3.35)	0.79
≥1	146	133.5(10.1)	140	133.5(10.6)	-0.15 (-2.34, 2.04)	
Measuring BP prior to randomization						
Yes	143	134.7(10.4)	148	133.5(11.1)	1.02 (-1.16, 3.21)	0.14
No	81	132.4(10.2)	64	134.0(11.4)	-1.84 (-4.98, 1.31)	
Deprivation score[b]						
≤Median	127	134.3(9.8)	125	134.4(12.0)	-0.32 (-2.63, 1.98)	0.40
>Median	98	133.5(10.9)	87	132.2(9.2)	1.25 (-1.54, 4.03)	
Ethnicity						
Other	110	135.0(10.2)	108	134.4(12.1)	0.93 (-1.58, 3.43)	0.35
White	114	132.9(10.4)	106	132.9(9.9)	-0.76 (-3.31, 1.79)	
Highest education						
Postgraduate or above	51	134.0(11.8)	47	133.1(9.4)	0.81 (-3.02, 4.64)	0.77
First degree or prof. qualification	88	133.2(9.0)	78	133.8(11.9)	-0.75 (-3.67, 2.17)	
A-level or equivalent, GCSE, O-Level or CSE, vocational qualifications or no formal qualifications	83	134.7(10.8)	87	133.9(11.4)	0.45 (-2.43, 3.33)	
Baseline BP (Post-hoc analysis)[c]						
≥140/90 mmHg	94	138.4(9.7)	89	137.1(11.0)	1.11 (-1.70, 3.93)	0.24
<140/90 mmHg	128	130.3(9.0)	122	131.2(10.5)	-1.09 (-3.50, 1.32)	
Overall					0.05 (-0.62, 0.73)	



Subgroup	Self-Monitoring N	Self-Monitoring Mean (SD)	Usual Care N	Usual Care Mean (SD)	Mean Difference (95% CI)[a]	P value for Interaction
Transitioned from BUMP 1						
Yes	123	137.1(11.7)	116	136.3(10.2)	0.20 (-2.62, 3.02)	0.79
No	64	138.6(12.7)	74	138.6(11.5)	-0.43 (-4.20, 3.34)	
Gestation age at study entry						
<34/40 weeks	89	138.6(12.8)	97	137.8(11.1)	0.49 (-2.73, 3.71)	0.72
≥34/40 weeks	98	136.7(11.3)	93	136.5(10.5)	-0.33 (-3.51, 2.85)	
Parity						
0	101	138.9(13.1)	97	137.9(10.5)	0.63 (-2.46, 3.73)	0.54
≥1	86	136.1(10.5)	93	136.5(11.1)	-0.77 (-4.07, 2.52)	
Measuring BP prior to randomization						
Yes	76	136.5(11.0)	84	138.2(10.4)	0.43 (-3.05, 3.90)	0.74
No	110	137.0(11.6)	105	136.5(11.0)	-0.36 (-3.35, 2.63)	
Deprivation score[b]						
≤Median	84	138.8(13.6)	68	137.6(10.4)	0.24 (-3.36, 3.85)	0.79
>Median	102	136.6(10.6)	119	136.9(11.2)	-0.40 (-3.35, 2.56)	
Ethnicity						
Other	51	140.8(14.2)	59	139.6(11.4)	0.41 (-3.77, 4.59)	0.86
White	135	136.4(11.0)	131	136.1(10.4)	-0.02 (-2.69, 2.64)	
Highest education						
Postgraduate or above	45	137.5(13.7)	50	135.6(11.3)	2.43 (-2.12, 6.98)	0.42
First degree or prof. qualification	68	138.4(12.2)	62	138.6(10.4)	-0.14 (-3.96, 3.67)	
A-level or equivalent, GCSE, O-Level or CSE, vocational qualifications or no formal qualifications	73	137.0(11.0)	78	137.1(10.8)	-1.47 (-5.04, 2.10)	
Baseline BP (Post-hoc analysis)[c]						
≥140/90 mmHg	93	138.4(12.5)	82	140.5(10.6)	-2.06 (-5.38, 1.27)	0.06
<140/90 mmHg	90	136.9(11.6)	106	134.6(10.3)	2.28 (-0.86, 5.42)	
Overall					0.02 (-0.78, 0.82)