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Effect of Self-monitoring of Blood Pressure on Blood Pressure Control in Pregnant Individuals With Chronic or Gestational Hypertension
The BUMP 2 Randomized Clinical Trial

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IMPORTANCE Inadequate management of elevated blood pressure is a significant contributing factor to maternal deaths. The role of blood pressure self-monitoring in pregnancy in improving clinical outcomes for the pregnant individual 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 Unblinded, 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 AND MEASURES 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 mm Hg vs 133.6 mm Hg, respectively; adjusted mean difference, 0.03 mm Hg [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 mm Hg compared with 137.2 mm Hg; adjusted mean difference, −0.03 mm Hg [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 the chronic hypertension cohort and 1 in the 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.

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Supplemental content

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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 annually die of 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,[4-6] independently of the development of preeclampsia.[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 nonpregnant persons.[8] In nonpregnant individuals, SMBP in conjunction with cointerventions, 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 the pregnant individual and infant. SMBP has the potential to engage and empower pregnant individuals in their own care, improve detection of elevated 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 pregnant individuals with normotension[12] and hypertension,[13] definitive evidence for effectiveness is lacking.[14] The Blood Pressure Monitoring in High Risk Pregnancy to Improve the Detection and Monitoring of Hypertension 2 (BUMP 2) 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 elevated BP in individuals with higher-risk pregnancies.[15,16]

Methods

Study Design

The methods of the trial have been previously described.[17] 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 developed hypertension 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 mm Hg and/or diastolic BP ≥90 mm Hg, present at book-

Key Points

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 blood pressure with telemonitoring resulted in an adjusted mean difference in clinic-based systolic blood pressure, compared with usual care alone, of 0.03 mm Hg for chronic hypertension and −0.03 mm Hg 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.

ing 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 mm Hg and/or diastolic BP ≥90 mm Hg after 20 weeks' gestation) and were recruited at 20 to 37 weeks' gestation.[17] 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 Blinding

Individuals who agreed to participate were randomized in a 1:1 ratio, either to SMBP or usual care (Figure 1). 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[16] migrated to this trial, staying in their original randomization group as suggested during development work.[15,18] The intervention was not blinded 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 preeclampsia (Microlife WatchBP Home)[19] 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 2 readings 1 minute apart and submitting their second reading to the telemonitoring system. Elevated readings triggered a request for a third reading, which, if still elevated, led to advice to contact their local maternity unit (eFigure in

Figure 1. Eligibility, Randomization, and Data Availability in a Trial of Self-monitoring for Blood Pressure Control in Pregnant Individuals With Hypertension
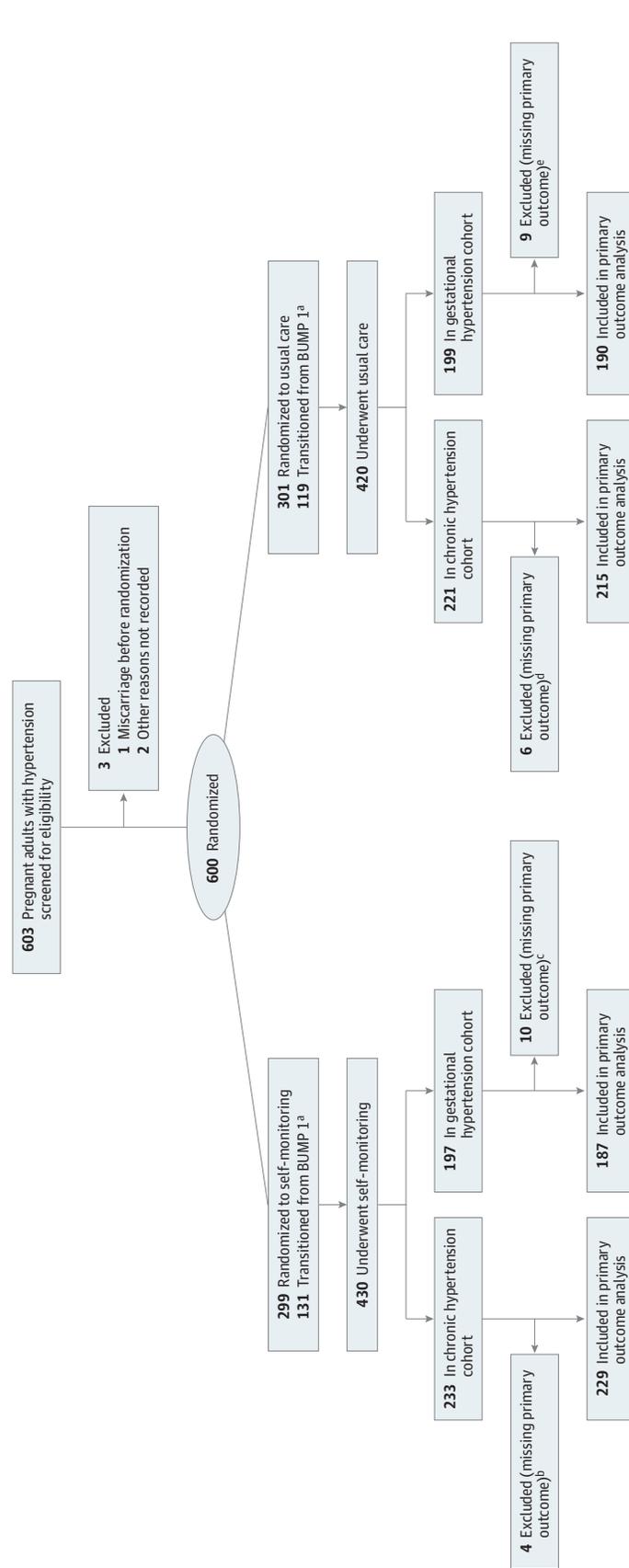
[a] The BUMP 1 trial aimed to establish whether self-monitoring blood pressure with telemonitoring in addition to usual care could lead to earlier detection of elevated clinic blood pressure, compared with usual care, during higher-risk pregnancies. A total of 250 pregnant individuals who developed gestational hypertension during the linked BUMP 1 trial migrated to this trial, staying in their original randomization groups but changing to daily monitoring.

[b] Delivery date not recorded so primary outcome could not be determined (n = 2); delivery more than 2 days after entering the trial but before primary outcome was recorded (n = 2).

[c] Delivery 1 to 2 days after entering the trial and no primary outcome recorded (n = 1); delivery more than 2 days after entering the trial but before primary outcome was recorded (n = 9).

[d] Delivery date not recorded so primary outcome could not be determined (n = 4); delivery more than 2 days after entering the trial but before primary outcome was recorded (n = 2).

[e] Delivery date not recorded so primary outcome could not be determined (n = 1); delivery more than 2 days after entering the trial but before primary outcome was recorded (n = 8).

Supplement 3). Participants received reminders and weekly motivational messages developed iteratively with involvement of pregnant individuals.[18] 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 5-level EQ5 version [EQ-5D-5L] questionnaire),[20] State-Trait Anxiety Inventory short form–6 questionnaire,[21] modified Brief Illness Perception Questionnaire,[22] and, among individuals recruited directly to the trial, medication adherence (Medication Adherence Report Scale questionnaire).[23] A medical notes review was completed after primary discharge of the participant 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 BPs recorded by health care professionals in the clinical record from date of entry into the study plus 1 day, until date of delivery minus 1 day, between usual care and self-monitoring groups. Secondary clinical outcomes prespecified in the statistical analysis plan were maternal outcomes, including clinic-measured diastolic BP, systolic BP readings greater than 140 mm Hg (measured by a health care professional), severe hypertension (systolic BP ≥160 mm Hg and/or diastolic BP ≥110 mm Hg),[17] serious maternal complications, and onset of labor, and perinatal outcomes, including gestation at delivery, birth weight (including centiles), small for gestational age (<10th and <3rd centiles), neonatal unit admission, length of neonatal unit stay, stillbirths, early neonatal deaths, and mode of delivery.[15] Patient-reported outcomes were quality of life (EQ-5D-5L score, 0 [worst] to 1 [best]; minimally clinically important difference [MCID], 0.037), anxiety (State-Trait Anxiety Inventory short form–6, 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]), and fidelity to the monitoring schedule and adherence as described above.[20,21,23,24] The full list is available eTable 1 in Supplement 3.

In accordance with UK recommendations, self-reported race and ethnicity was recorded using standard descriptions.[25]

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-mm Hg difference in systolic BP between groups at 90% power and 5% level of significance (2-sided), accounting for 15% attrition and an SD of 16 mm Hg, based on data from the previous feasibility study[12] and PELICAN[26] study. The sample size was calculated using NCSS PASS version 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, ie, all individuals recruited to the linked trial who developed hypertension and transitioned into 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 because 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 analyze 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, prespecified before the end of recruitment that these groups would be analyzed 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. Prespecified sensitivity analyses were carried out as

Table 1. Baseline Characteristics by Randomized Group

| | No. (%) | | | |
| | Chronic hypertension | | Gestational hypertension | |
Characteristic	Self-monitoring	Usual care	Self-monitoring	Usual care
No. of participants	233	221	197	199
Age, mean (SD), y	36.0 (5.4)	35.5 (5.8)	33.5 (6.1)	33.6 (5.6)
Gestation at entry, median (IQR), wk	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, median (IQR)[a]	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[b]				
No. of participants	229	218	196	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)
Race and ethnicity[c]				
No.	228	220	196	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)
White	115 (49.4)	109 (49.3)	141 (71.6)	137 (68.8)
Other	7 (3.0)	4 (1.8)	8 (4.1)	4 (2.0)
Current smoker	9 (3.9)	9 (4.1)	8 (4.1)	5 (2.5)
Highest education				
No. of participants	226	218	196	199
Tertiary education	113 (50.0)	105 (48.2)	88 (44.9)	102 (51.3)
Professional qualifications	30 (13.3)	23 (10.6)	31 (15.8)	15 (7.5)
A level or GCSE	60 (26.6)	60 (27.5)	63 (32.1)	78 (39.2)
Vocational qualifications	11 (4.9)	17 (7.8)	10 (5.1)	2 (1.0)
No formal qualifications	12 (5.3)	13 (6.0)	4 (2.0)	2 (1.0)
Risk factors for hypertension				
Previous hypertensive disorder of pregnancy	86 (36.9)	81 (36.7)	62 (31.5)	69 (34.7)
Family history of preeclampsia	28 (12.0)	26 (11.8)	40 (20.3)	34 (17.1)
Autoimmune disease[d]	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 y	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)
Self-measured blood pressure in this pregnancy	146 (62.7)	151 (68.3)	82 (41.6)	89 (44.7)
Mean blood pressure at entry, mean (SD), mm Hg				
Systolic	133.8 (13.0)	134.4 (13.3)	135.1 (11.0)	133.1 (11.0)
Diastolic	83.7 (10.0)	84.9 (9.8)	85.6 (8.6)	85.0 (9.0)
Receiving antihypertensive medication at 20 wk gestation	169 (72.5)	155 (70.1)		

Abbreviation: GCSE, General Certificate of Secondary Education.

[a] Calculated as weight in kilograms divided by height in meters squared.

[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.

[c] Race and ethnicity self-attributed from standard UK classification. The Other category included any other race or ethnicity not listed above in which case participants were asked to specify (chronic hypertension self-monitoring: 2 not stated and 1 each of the following: Anglo-Arab, British Arab, Mauritian, Middle East Iranian, Thai; usual care: 2 not stated and 1 each of the following: Japanese and Korean and gestational hypertension self-monitoring: 6 not stated and 1 each of the following: Myanmar and Turkish Kurdish; usual care: 3 not stated and 1 Myanmar). "Mixed" is the official term used during data collection.

[d] Any autoimmune disease (eg, systemic lupus erythematosus or antiphospholipid syndrome).

Table 2. Primary Outcome: Mean Blood Pressure for Participants With Chronic Hypertension and Gestational Hypertension

	Self-monitoring	Usual care	Adjusted mean difference (95% CI)	P value
Chronic hypertension				
Primary outcome available, No. (%)[a]	229 (98.3)	215 (97.3)		
Blood pressure, mean (SD), mm Hg				
Systolic[b]	133.8 (10.3)	133.6 (11.1)	0.03 (−1.73 to 1.79)[c]	.97
Diastolic	84.0 (7.4)	84.3 (7.9)	−0.03 (−1.28 to 1.22)	.96
Gestational hypertension				
Primary outcome available, No. (%)[a]	187 (94.9)	190 (95.5)		
Blood pressure, mean (SD), mm Hg				
Systolic	137.6 (12.1)	137.2 (10.8)	−0.03 (−2.29 to 2.24)[d]	.98
Diastolic	86.1 (7.8)	86.3 (7.7)	−0.35 (−1.77 to 1.06)	.63

[a] 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.

[b] Mean blood pressure was defined as the mean of the means of all systolic blood pressure readings recorded by health care professionals, from after entry into the study until up to 1 day before the date of delivery. No self-recorded blood pressure was used.

[c] Chronic hypertension, self-monitoring vs usual care; estimated from linear

mixed-effects model adjusting for mean baseline systolic blood pressure, parity, and recruitment site. Eleven participants not included in the model due to missing baseline systolic blood pressure reading (n = 7 from self-monitoring, n = 4 from usual care).

[d] Gestational hypertension, self-monitoring vs usual care; estimated from linear mixed-effects model adjusting for mean baseline systolic blood pressure, parity, transfer from BUMP 1, and recruitment site. Six participants not included in the model due to missing baseline systolic blood pressure reading (n = 4 from self-monitoring, n = 2 from usual care).

for the primary outcome, including combining the chronic hypertension and gestational hypertension cohorts in an individual patient data–type analysis (ie, all individuals in the trial regardless of hypertension diagnosis). Prespecified 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, race and ethnicity, and highest educational qualification.

Binary secondary outcomes were analyzed using logistic mixed-effects models, adjusting for parity, and included site as a random effect. Treatment effects were described using odds ratios with 95% CIs. Continuous secondary outcomes were analyzed 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% CIs and *P* values were estimated at each time point. Continuous outcomes that did not fulfil normality assumption were analyzed using quantile regression, adjusting for parity and site (as fixed effects). Perinatal outcomes included an adjustment for twin births. Categorical secondary outcomes were analyzed descriptively. Findings for analyses of secondary end points 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.[27] 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* < .05.
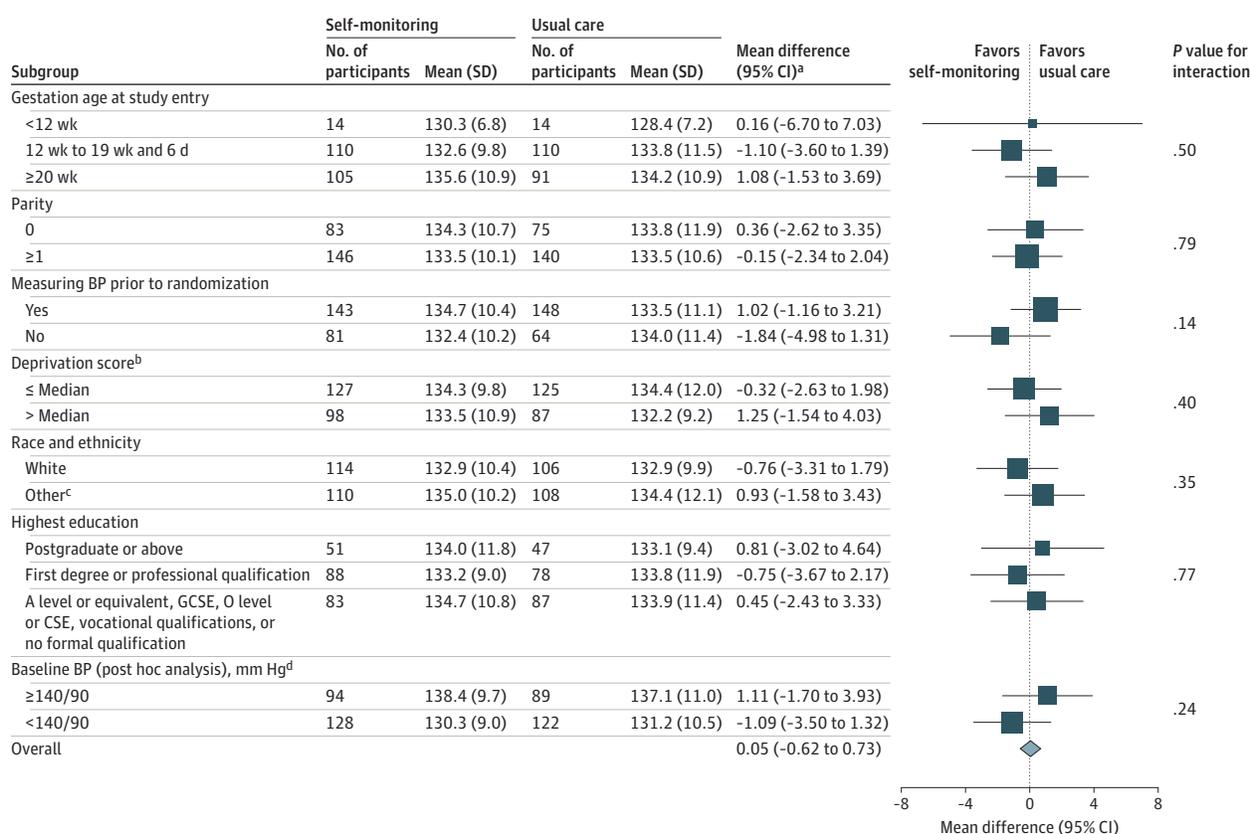
Results

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 participants (96.7%) in the SMBP group and 405 participants (96.4%) in the usual care group. The baseline characteristics were similar between the 2 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 BP previously in this pregnancy. Individuals with gestational hypertension were recruited at 33 weeks, had a mean age of 34 years, and 43% had self-monitored BP previously in this pregnancy.

Primary Outcome

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

Figure 2. Subgroup Analyses for Mean Systolic Blood Pressure (BP) in Chronic Hypertension Group

Subgroup	Self-monitoring		Usual care		Mean difference (95% CI)[a]	Favors self-monitoring / Favors usual care	P value for interaction
	No. of participants	Mean (SD)	No. of participants	Mean (SD)			
Gestation age at study entry							
<12 wk	14	130.3 (6.8)	14	128.4 (7.2)	0.16 (−6.70 to 7.03)		
12 wk to 19 wk and 6 d	110	132.6 (9.8)	110	133.8 (11.5)	−1.10 (−3.60 to 1.39)		.50
≥20 wk	105	135.6 (10.9)	91	134.2 (10.9)	1.08 (−1.53 to 3.69)		
Parity							
0	83	134.3 (10.7)	75	133.8 (11.9)	0.36 (−2.62 to 3.35)		.79
≥1	146	133.5 (10.1)	140	133.5 (10.6)	−0.15 (−2.34 to 2.04)		
Measuring BP prior to randomization							
Yes	143	134.7 (10.4)	148	133.5 (11.1)	1.02 (−1.16 to 3.21)		.14
No	81	132.4 (10.2)	64	134.0 (11.4)	−1.84 (−4.98 to 1.31)		
Deprivation score[b]							
≤ Median	127	134.3 (9.8)	125	134.4 (12.0)	−0.32 (−2.63 to 1.98)		.40
> Median	98	133.5 (10.9)	87	132.2 (9.2)	1.25 (−1.54 to 4.03)		
Race and ethnicity							
White	114	132.9 (10.4)	106	132.9 (9.9)	−0.76 (−3.31 to 1.79)		.35
Other[c]	110	135.0 (10.2)	108	134.4 (12.1)	0.93 (−1.58 to 3.43)		
Highest education							
Postgraduate or above	51	134.0 (11.8)	47	133.1 (9.4)	0.81 (−3.02 to 4.64)		
First degree or professional qualification	88	133.2 (9.0)	78	133.8 (11.9)	−0.75 (−3.67 to 2.17)		.77
A level or equivalent, GCSE, O level or CSE, vocational qualifications, or no formal qualification	83	134.7 (10.8)	87	133.9 (11.4)	0.45 (−2.43 to 3.33)		
Baseline BP (post hoc analysis), mm Hg[d]							
≥140/90	94	138.4 (9.7)	89	137.1 (11.0)	1.11 (−1.70 to 3.93)		.24
<140/90	128	130.3 (9.0)	122	131.2 (10.5)	−1.09 (−3.50 to 1.32)		
Overall					0.05 (−0.62 to 0.73)		

−8 −4 0 4 8
Mean difference (95% CI)

Linear mixed-effects model of mean systolic BP modeled against an interaction between randomized group and subgroup indicator, parity, and site. Level of significance = .05. A level indicates Advanced level; CSE, Certificate of Secondary Education; GCSE, General Certificate of Secondary Education; and O level, Ordinary level.

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

[b] The index of multiple deprivation is an assessment of deprivation based on 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] The Other category includes any other race or ethnicity not listed above, in which case participants were asked to specify.

[d] BP of 140/90 mm Hg or greater means systolic and/or diastolic BP greater or equal to 140/90 mm Hg as measured by a health care professional.

There was no effect on the primary outcome in prespecified sensitivity analyses, including combining chronic and gestational hypertension 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, race and ethnicity, highest educational qualification, or baseline BP level including no significant difference in the gestational hypertension cohort only for those transitioning from the linked trial (**Figure 2** and **Figure 3**). There was no significant interaction by hypertension cohort (eTable 3 in Supplement 3).
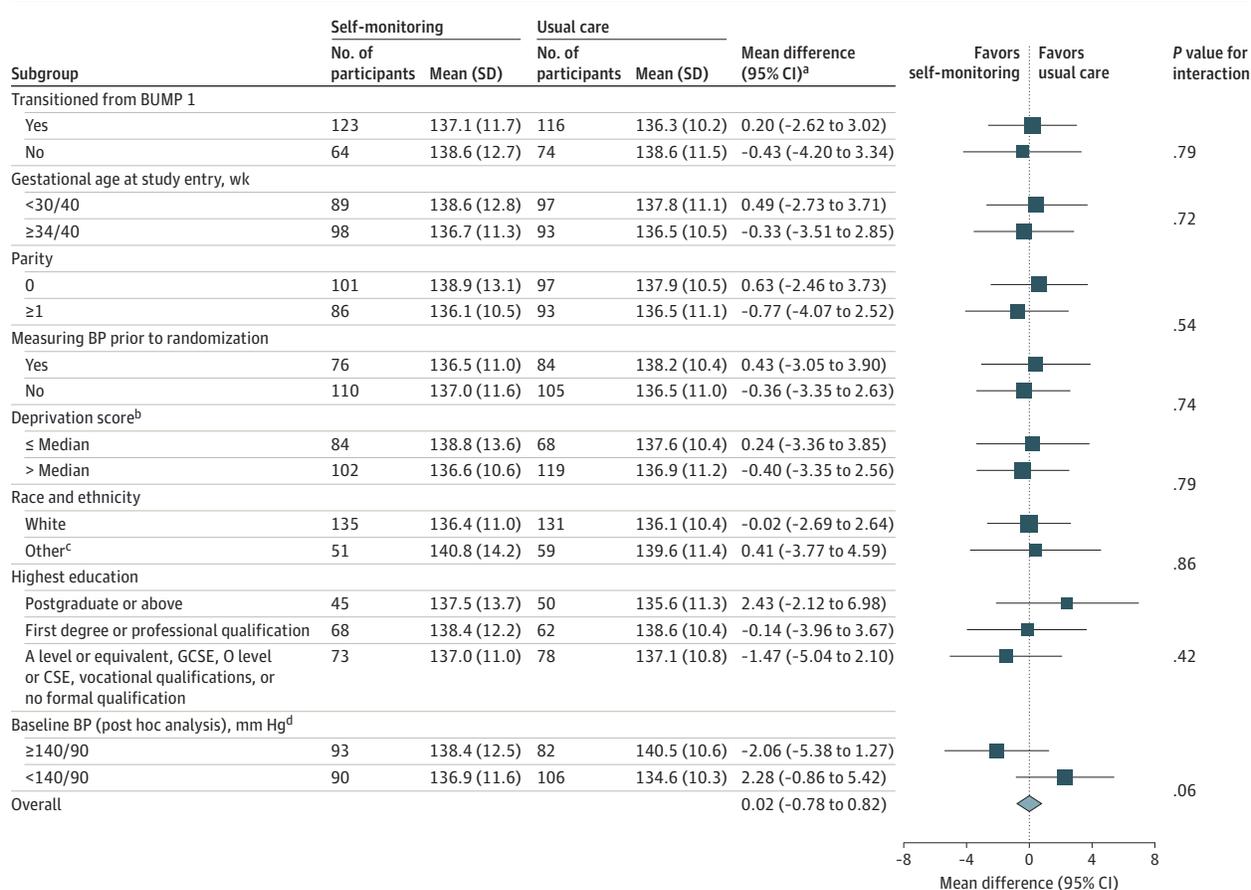
Secondary Outcomes
Among individuals with chronic hypertension, there was no significant difference in the majority of maternal and infant secondary outcomes, other than a lower proportion with spontaneous onset of labor: 12 participants (5%) in the SMBP group vs 21 participants (10%) in the usual care 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 preeclampsia, though a lower proportion (not tested) of this group had 1 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 3 stillbirths in the cohort: 1 in the SMBP group and 2 in the usual care group.

Among 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 labor: 31 individuals (16%) in the SMBP group vs 44 individuals (22%) in the usual care group (adjusted odds ratio, 0.65 [95% CI, 0.39 to 1.07]), though with no significant difference in the proportion with spontaneous vaginal births (Table 3). There was 1 stillbirth in the self-monitoring group and none in the usual care group.

Figure 3. Subgroup Analyses for Mean Systolic Blood Pressure (BP) in Gestational Hypertension Group

Subgroup	Self-monitoring		Usual care		Mean difference (95% CI)[a]	Favors self-monitoring / Favors usual care	P value for interaction
	No. of participants	Mean (SD)	No. of participants	Mean (SD)			
Transitioned from BUMP 1							
Yes	123	137.1 (11.7)	116	136.3 (10.2)	0.20 (-2.62 to 3.02)		
No	64	138.6 (12.7)	74	138.6 (11.5)	-0.43 (-4.20 to 3.34)		.79
Gestational age at study entry, wk							
<30/40	89	138.6 (12.8)	97	137.8 (11.1)	0.49 (-2.73 to 3.71)		
≥34/40	98	136.7 (11.3)	93	136.5 (10.5)	-0.33 (-3.51 to 2.85)		.72
Parity							
0	101	138.9 (13.1)	97	137.9 (10.5)	0.63 (-2.46 to 3.73)		
≥1	86	136.1 (10.5)	93	136.5 (11.1)	-0.77 (-4.07 to 2.52)		.54
Measuring BP prior to randomization							
Yes	76	136.5 (11.0)	84	138.2 (10.4)	0.43 (-3.05 to 3.90)		
No	110	137.0 (11.6)	105	136.5 (11.0)	-0.36 (-3.35 to 2.63)		.74
Deprivation score[b]							
≤ Median	84	138.8 (13.6)	68	137.6 (10.4)	0.24 (-3.36 to 3.85)		
> Median	102	136.6 (10.6)	119	136.9 (11.2)	-0.40 (-3.35 to 2.56)		.79
Race and ethnicity							
White	135	136.4 (11.0)	131	136.1 (10.4)	-0.02 (-2.69 to 2.64)		
Other[c]	51	140.8 (14.2)	59	139.6 (11.4)	0.41 (-3.77 to 4.59)		.86
Highest education							
Postgraduate or above	45	137.5 (13.7)	50	135.6 (11.3)	2.43 (-2.12 to 6.98)		
First degree or professional qualification	68	138.4 (12.2)	62	138.6 (10.4)	-0.14 (-3.96 to 3.67)		
A level or equivalent, GCSE, O level or CSE, vocational qualifications, or no formal qualification	73	137.0 (11.0)	78	137.1 (10.8)	-1.47 (-5.04 to 2.10)		.42
Baseline BP (post hoc analysis), mm Hg[d]							
≥140/90	93	138.4 (12.5)	82	140.5 (10.6)	-2.06 (-5.38 to 1.27)		
<140/90	90	136.9 (11.6)	106	134.6 (10.3)	2.28 (-0.86 to 5.42)		.06
Overall					0.02 (-0.78 to 0.82)		

Mean difference (95% CI) axis: -8 -4 0 4 8

Linear mixed-effects model of mean systolic BP modeled against an interaction between randomized group and subgroup indicator, parity, site, and transfer from BUMP 1. Level of significance = .05. A level indicates Advanced level; CSE, Certificate of Secondary Education; GCSE, General Certificate of Secondary Education; and O level, Ordinary level.

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

[b] The index of multiple deprivation is an assessment of deprivation based on 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] The Other category includes any other race or ethnicity not listed above, in which case participants were asked to specify.

[d] BP of 140/90 mm Hg or greater means systolic and/or diastolic blood pressure greater or equal to 140/90 mm Hg as measured by a health care professional.

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 or 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 6 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 (eTable 7 in Supplement 3).

Adverse Events

There were no significant differences in adverse events or serious adverse events between the 2 groups (serious adverse events: 4 vs 2 in the chronic hypertension group and 4 vs 1 in the 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 2 participants (0.4%) exclusively used a paper diary; because these data were not directly comparable with those 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 following transition) 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 entire period between randomization and

Table 3. Secondary Outcomes for Participants With Chronic and Gestational Hypertension

	No. (%)		Unadjusted absolute risk differences (95% CI)	Adjusted effect measure, OR (95% CI)[a]	P value
	Self-monitoring	Usual care			
Chronic hypertension					
Maternal outcomes, No.	233	221			
No. of blood pressure measurements[b]	3079	2836			
No. (proportion) of days with systolic blood pressure >140 mm Hg	1019 (33)	987 (35)	-0.02 (-0.04 to 0.01)	0.93 (0.75 to 1.16)	.51
Gestation at birth, median (IQR), wk	38.3 (37.0 to 39.1)	38.1 (37.1 to 39.0)		MedD, 0.07 (-0.28 to 0.42)	.69
Maternal outcomes for those with primary outcome only, No.	229	215			
Severe hypertension[c]	51 (22)	48 (22)	0.02 (-0.05 to 0.10)	1.00 (0.57 to 1.76)	.99
Preeclampsia	44 (19)	33 (15)	0.04 (-0.03 to 0.11)	1.31 (0.77 to 2.24)	.32
Received a blood transfusion[d]	3 (1)	11 (5)	-0.04 (-0.07 to -0.01)		
Maternal death[d]	0	0			
Maternal outcomes for those delivering after 24 wk, No.	227	216			
Spontaneous onset of labor	12 (5)	21 (10)	-0.04 (-0.09 to 0.004)	0.52 (0.29 to 0.93)	.03
Infant outcomes (all births), No.	233	221			
Spontaneous vaginal birth	61 (26)	71 (32)	-0.06 (-0.14 to 0.02)	0.76 (0.44 to 1.32)[e]	.33
Stillbirths[d]	1 (0.4)	2 (1)			
Infants <10th birth weight centile	31 (13)	32 (14)	-0.01 (-0.08 to 0.06)	0.90 (0.52 to 1.55)[e]	.71
Birth weight centile	49.9 (21.1 to 77.1)	43.5 (18.0 to 74.8)		MedD, 7.28 (-2.94 to 17.50)[e]	.16
Infant outcomes (live births only), No.	232	219			
Neonatal unit admission	48 (21)	47 (21)	-0.01 (-0.08 to 0.07)	0.91 (0.65 to 1.28)	.59
Early neonatal deaths	1 (0.4)	0			
Days of neonatal unit stay for those admitted, median (IQR)	15.0 (4.0 to 34.0)	11.0 (3.0 to 33.0)		MedD, 0 (-13.21 to 13.32)	>.99
Gestational hypertension					
Maternal outcomes, No.	197	199			
No. of blood pressure measurements[b]	1430	1624			
No. (proportion) of days with systolic blood pressure >140 mm Hg	602 (42)	679 (42)	0.01 (-0.3 to 0.04)	1.15 (0.76 to 1.72)	.51
Gestation at birth, median (IQR), wk	37.7 (36.3 to 39.0)	38.0 (36.9 to 39.1)		MedD, -0.14 (-0.61 to 0.33)	.55
Maternal outcomes for those with primary outcome only, No.	187	190			
Severe hypertension[c]	38 (20)	49 (26)	-0.01 (-0.09 to 0.08)	0.74 (0.40 to 1.35)	.32
Preeclampsia	71 (38)	63 (33)	0.05 (-0.05 to 0.14)	1.24 (0.80 to 1.93)	.33

(continued)

Table 3. Secondary Outcomes for Participants With Chronic and Gestational Hypertension (continued)

	No. (%)		Unadjusted absolute risk differences (95% CI)	Adjusted effect measure, OR (95% CI)[a]	P value
	Self-monitoring	Usual care			
Received a blood transfusion[d]	12 (6)	7 (4)	0.03 (−0.17 to 0.01)		
Maternal death[d]	0	0			
Maternal outcomes for those delivering after 24 wk, No.	195	198			
Spontaneous onset of labor	31 (16)	44 (22)	−0.06 (−0.14 to 0.01)	0.65 (0.39 to 1.07)	.09
Infant outcomes (all births), No.	209	207			
Spontaneous vaginal birth	75 (36)	89 (43)	−0.07 (−0.17 to 0.02)	0.74 (0.49 to 1.12)[e]	.15
Stillbirths[d]	1 (0.5)	0			
Infants <10th birth weight centile	31 (15)	30 (14)	0.004 (−0.07 to 0.07)	1.06 (0.60 to 1.89)[e]	.83
Birth weight centile, median (IQR)	51.3 (16.2 to 83.3)	45.4 (17.2 to 81.4)		MedD, 3.31 (−5.64 to 12.26)[d]	.47
Infant outcomes (live births only), No.	208	207			
Early neonatal deaths[d]	0	1 (0.5)			
Neonatal intensive care admission	56 (27)	52 (25)	0.02 (−0.07 to 0.10)	1.07 (0.72 to 1.61)	.73
Days of neonatal unit stay for those admitted, median (IQR)	8.0 (3.0 to 22.0)	10.0 (4.0 to 25.0)		MedD, −5.00 (−11.39 to 1.39)	.12

Abbreviations: MedD, median difference; OR, odds ratio.

[a] Self-monitoring vs usual care; OR (95% CI) was estimated from logistic mixed-effects models adjusting for parity and recruitment site. For the gestational hypertension cohort only, participants could transition from BUMP 1; MedD (95% CI) was estimated from quantile regression models adjusting for parity and recruitment site, and adjusting for transition from BUMP 1 for the gestational hypertension cohort only.

[b] All blood pressure measured by health care professionals.

[c] Severe hypertension defined as systolic blood pressure of 160 mm Hg or greater and/or diastolic blood pressure of 110 mm Hg or greater.[17]

[d] The results are presented descriptively if less than 10% of the participants/babies had an event and/or there are fewer than 5 events in any 1 cell.

[e] Models include an adjustment for twin birth.

delivery, 259 (60.2%) had high clinic and home BP readings, 107 (24.9%) had high clinic BP readings but all normal home readings, 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 4 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 subgroups 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 included the intervention being developed iteratively with the input of pregnant individuals and behavioral change experts.[18] It was appropriately powered including separately for chronic and gestational hypertension, undertaken in multiple maternity units across England with diverse sociodemographic 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.[28] 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.[29] 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 nonpregnant women; participants were generally chosen on the basis of treated but poorly controlled hypertension with mean baseline BP readings commonly higher than 140 mm Hg.[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 BP 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 1.2 mm Hg, suggesting that similar alert thresholds could be used for both settings.[30] Among individuals with hypertension (based on a smaller number of lower-quality studies), a wider home-clinic difference was seen of 8 to 16 mm Hg. Almost 25% of participants in the current study recorded only normal BP at home despite elevated 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 had several limitations. First, there was uncertain use of SMBP by the usual care group during the trial. Participants reporting 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 pregnant individuals with hypertension 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 cointerventions has little effect.[9]

Second, although the app included reminders to monitor, clear instructions on when to contact the maternity unit with an elevated BP reading, 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, BP self-monitoring with telemonitoring, compared with usual care, did not lead to significantly improved clinic-based BP control.

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