

## A randomised controlled trial of blood pressure self-monitoring in the management of hypertensive pregnancy. OPTIMUM-BP: A feasibility trial



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### ABSTRACT

**Objective:** To assess the feasibility of a blood pressure self-monitoring intervention for managing pregnancy hypertension.

**Study design:** OPTIMUM-BP was an unmasked randomised controlled trial comparing a self-monitoring of blood pressure (SMBP) intervention versus usual care for the management of pregnancy hypertension. Women with chronic (CH) or gestational hypertension (GH) from 4 UK centres were randomised (2:1) intervention to control. Self-monitoring involved daily home blood pressure (BP) measurements, with recording via study diary or telemonitoring. Clinicians were invited to use the home readings in clinical and antihypertensive titration decisions.

**Main outcomes:** The primary outcomes were recruitment, retention, adherence and persistence with the intervention.

**Results:** Women from four UK centres were randomised: 158/222 (71%) of those approached agreed, comprising: 86 women with chronic hypertension (55 SMBP, 31 control) and 72 with gestational hypertension (49 SMBP, 23 control) of whom outcome data were available from 154 (97%) and were included in the analysis. The median (IQR) number of days with home BP readings per week were 5.5 (3.1–6.5) for those with chronic hypertension and 6.1 (4.5–6.7) with gestational hypertension. Participants persisted with the intervention for 80% or more of their time from enrolment until delivery in 86% (43/50) and 76% (38/49) of those with chronic and gestational hypertension respectively. Recorded clinic and study BPs were similar for both groups.

**Conclusions:** This is the first randomised investigation of BP self-monitoring for the management of pregnancy hypertension and indicates that a large RCT would be feasible.

### 1. Introduction

Hypertensive disorders of pregnancy are common and associated with substantial maternal and perinatal morbidity and mortality [1,2]. Much of the research and clinical focus has previously been on the

timely detection and effective management of preeclampsia and eclampsia. There has been conflicting evidence and limited guidance regarding managing non-proteinuric hypertension in pregnancy, with a recognition that severe hypertension is a risk factor for maternal stroke [3–5] but it is also necessary to seek to avoid possible iatrogenic risks of

**Abbreviations:** SMBP, self-monitoring of blood pressure; CH, chronic hypertension; GH, gestational hypertension

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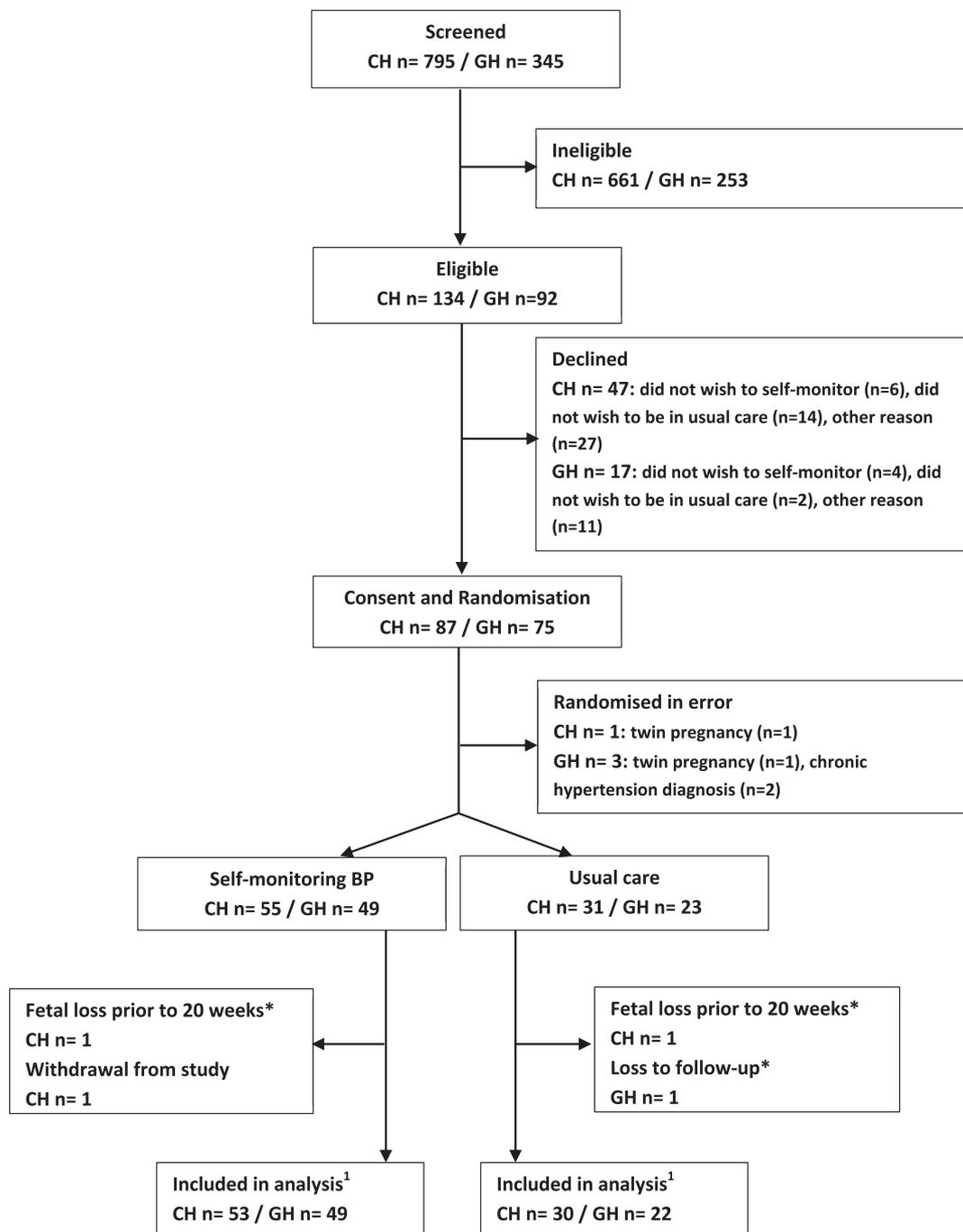


Fig. 1. OPTIMUM-BP CONSORT (Consolidated Standards of Reporting Trial) flowchart. \*No data available after baseline.

controlling blood pressure (BP), such as reduced fetal growth. The recent Control of Hypertension in Pregnancy Study (CHIPS) showed that tight (diastolic target of 85 mmHg) versus less-tight control (diastolic target of 105 mmHg) of BP in hypertensive pregnancies was associated with a reduced incidence of maternal severe hypertension without a consequent increase in adverse perinatal outcomes, and a secondary analysis showed that severe hypertension was associated with multiple adverse maternal and perinatal outcomes independent of the development of preeclampsia [6,7]. However the optimal approach to obtaining BP control in pregnancy and therefore avoiding severe hypertension is uncertain. Currently, pregnant women with hypertensive disorders usually have more frequent clinic surveillance to monitor for any deterioration in BP, assessing for emerging preeclampsia and fetal complications associated with pregnancy hypertension [8]. Not only

does this place a considerable burden on both the health service and importantly the woman herself, but deterioration may occur between clinic visits [9,10].

In the general adult population with chronic hypertension, evidence shows that BP self-management that includes self-monitoring and titration of antihypertensives leads to significantly improved BP control and higher patient satisfaction [11–14]. Previous small, mostly non-randomised studies of BP self-monitoring in the pregnant population [15–17] suggest a similar approach may be feasible and acceptable.

OPTIMUM-BP used a BP self-monitoring intervention developed from other self-monitoring BP trials [11,18] for use by pregnant women with hypertension. This trial was designed to study the feasibility and acceptability of a BP self-monitoring intervention in the management of hypertension in pregnancy. It aimed to inform the further development

**Table 1**

Demographic and clinical characteristics at enrolment of 158 pregnant women with hypertension included in the OPTIMUM-BP feasibility trial from December 2015 until December 2017.

| Characteristic   | Chronic Hypertension        |                                   | Gestational Hypertension    |                                   |
|--|-----------------------------|-----------------------------------|-----------------------------|-----------------------------------|
|  | Randomised to SMBP (n = 55) | Randomised to usual care (n = 31) | Randomised to SMBP (n = 49) | Randomised to usual care (n = 23) |
| Age in years*  | 35.9 (5.6)                  | 35.5 (4.2)                        | 33.4 (5.9)                  | 34.2 (5.1)                        |
| Gestation at recruitment in weeks <sup>†</sup>                               | 16.6<br>(12.9 to 20.1)      | 14.9<br>(13.0 to 20.0)            | 35.0<br>(32.4 to 36.1)      | 34.7<br>(32.1 to 36.4)            |
| Body mass index* (kg/m <sup>2</sup> )  | 31.0 (7.0)                  | 31.9 (7.0)                        | 29.5 (7.1)                  | 27.6 (6.4)                        |
| <b>Ethnicity</b>   |                             |                                   |                             |                                   |
| White  | 27 (49%)                    | 21 (68%)                          | 37 (76%)                    | 18 (78%)                          |
| Black  | 21 (38%)                    | 8 (26%)                           | 11 (22%)                    | 4 (18%)                           |
| Asian  | 6 (11%)                     | 2 (6%)                            | 1 (2%)                      | 1 (4%)                            |
| Other  | 1 (2%)                      | 0 (0%)                            | 0 (0%)                      | 0 (0%)                            |
| <b>Deprivation quintile<sup>‡</sup></b>                                      |                             |                                   |                             |                                   |
| 1st – least deprived   | 18 (33%)                    | 7 (23%)                           | 13 (27%)                    | 4 (17%)                           |
| 2nd  | 13 (24%)                    | 7 (23%)                           | 10 (20%)                    | 6 (26%)                           |
| 3rd  | 7 (13%)                     | 9 (29%)                           | 7 (15%)                     | 5 (22%)                           |
| 4th  | 9 (16%)                     | 6 (19%)                           | 9 (18%)                     | 3 (13%)                           |
| 5th – most deprived  | 6 (10%)                     | 2 (6%)                            | 9 (18%)                     | 3 (13%)                           |
| Unknown  | 2 (4%)                      | 0 (0%)                            | 1 (2%)                      | 2 (9%)                            |
| <b>Highest educational qualification</b>                                     |                             |                                   |                             |                                   |
| Professional/Higher qualifications   | 36 (65%)                    | 16 (52%)                          | 37 (76%)                    | 20 (87%)                          |
| School qualifications  | 15 (27%)                    | 14 (45%)                          | 9 (18%)                     | 3 (13%)                           |
| No formal qualifications   | 3 (6%)                      | 1 (3%)                            | 1 (2%)                      | 0 (0%)                            |
| Unknown  | 1 (2%)                      | 0 (0%)                            | 2 (4%)                      | 0 (0%)                            |
| <b>Smoking history</b>   |                             |                                   |                             |                                   |
| Never smoked   | 39 (71%)                    | 26 (84%)                          | 40 (82%)                    | 17 (74%)                          |
| Quit before pregnancy  | 9 (16%)                     | 4 (13%)                           | 8 (16%)                     | 4 (18%)                           |
| Smoking during pregnancy   | 5 (9%)                      | 0 (0%)                            | 0 (0%)                      | 1 (4%)                            |
| Not known  | 2 (4%)                      | 1 (3%)                            | 1 (2%)                      | 1 (4%)                            |
| <b>Other self-reported medical history<sup>4</sup></b>                       |                             |                                   |                             |                                   |
| Diabetes type 1  | 0 (0%)                      | 1 (3%)                            | 0 (0%)                      | 1 (4%)                            |
| Diabetes type 2  | 2 (4%)                      | 3 (10%)                           | 1 (2%)                      | 0 (0%)                            |
| Chronic kidney disease   | 1 (2%)                      | 1 (3%)                            | 0 (0%)                      | 0 (0%)                            |
| Asthma   | 7 (13%)                     | 4 (13%)                           | 5 (10%)                     | 1 (4%)                            |
| <b>Parity</b>  |                             |                                   |                             |                                   |
| 0  | 17 (31%)                    | 9 (29%)                           | 20 (41%)                    | 14 (61%)                          |
| ≥1   | 38 (69%)                    | 22 (71%)                          | 29 (59%)                    | 9 (39%)                           |
| Diagnosis of preeclampsia or gestational hypertension in previous pregnancy  | 20 (53%)                    | 16 (73%)                          | 15 (52%)                    | 5 (56%)                           |
| Proportion prescribed <sup>**</sup> antihypertensive medication at enrolment | 40 (73%)                    | 21 (68%)                          | 30 (61%)                    | 15 (65%)                          |
| <b>Blood pressure at enrolment in mmHg<sup>*</sup></b>                       |                             |                                   |                             |                                   |
| Systolic   | 136.6 (13.8)                | 139.5 (13.1)                      | 139.5 (14.0)                | 137.3 (1.3)                       |
| Diastolic  | 85.9 (10.1)                 | 87.4 (11.5)                       | 86.9 (9.9)                  | 87.9 (8.0)                        |
| Previous SMBP in this pregnancy at least once                                | 25 (45%)                    | 16 (52%)                          | 14 (29%)                    | 5 (21%)                           |

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

\* Mean and SD.

† Median and interquartile range.

‡ Deprivation measured as Index of Multiple Deprivation score using Office of National Statistics for England data [24].

\*\* Participants' self-reported medication history.

of the intervention and processes for use in a future large randomised controlled trial (RCT), to investigate the effectiveness of this intervention for blood pressure control during pregnancy.

## 2. Methods

OPTIMUM-BP was an unmasked randomised controlled clinical trial including pregnant women with chronic or gestational hypertension. The trial compared hypertensive management utilising clinic BP alone vs management supplemented by self-monitoring of BP. The study protocol and materials were approved by the UK Research Ethics Committee (15/EM/0490) and research and development approvals gained. All study participants provided written, informed consent. Trial registration: DOI 10.1186/ISRCTN16018898.

### 2.1. Participants

Pregnant women with hypertension were enrolled by study investigators from four National Health Service (NHS) maternity units in England. Eligibility criteria included women aged ≥18 years with a singleton pregnancy and with chronic or gestational hypertension, without preeclampsia. Women with chronic hypertension (treated or not) could have a prenatal diagnosis of hypertension or sustained BP readings ≥140 mmHg systolic and/or ≥90 mmHg diastolic before 20 weeks' gestation, and were recruited any time between booking and 23<sup>+6</sup> weeks' gestation. Women with gestational hypertension, defined as sustained BP readings ≥140 mmHg systolic and/or ≥90 mmHg diastolic after 20 weeks' gestation and without proteinuria, were recruited between 20 and 37<sup>+6</sup> weeks' gestation. Women were excluded if they were unwilling to self-monitor, had insufficient understanding of the study or had preeclampsia (as defined by the International Society for the Study of Hypertension in Pregnancy 2014 statement)

**Table 2**

Feasibility outcomes for 158 pregnant women with hypertension included in the OPTIMUM-BP feasibility trial from December 2015 until December 2017.

|  |   |               |             |
|--|---|---------------|-------------|
| Overall recruitment  | 71% (158 randomised, 222 eligible <sup>*</sup> )                              |               |             |
| Chronic hypertension recruitment   | 65% (86 randomised, 133 eligible <sup>*</sup> )                               |               |             |
| Gestational hypertension recruitment   | 81% (72 randomised, 89 eligible <sup>*</sup> )                                |               |             |
| Recruitment totals per centre n (%)  | Total   | CH            | GH          |
| Guy's and St Thomas' NHS Foundation Trust                                      | 68 (43%)  | 47 (55%)      | 21 (29%)    |
| Oxford University Hospitals NHS Foundation Trust                               | 51 (32%)  | 27 (31%)      | 24 (33%)    |
| New Cross Hospital, Royal Wolverhampton NHS Trust                              | 19 (12%)  | 12 (14%)      | 7 (10%)     |
| King's College Hospital NHS Foundation Trust                                   | 20 (13%)  | 0 (0%)        | 20 (28%)    |
| Overall recruitment rate per site per month                                    | 2.5 (158 randomised, cumulative 64 months recruitment period over four sites) |               |             |
| Chronic hypertension recruitment rate per site per month                       | 2.8 (86 randomised, 31 months recruiting)                                     |               |             |
| Gestational hypertension recruitment rate per site per month                   | 2.2 (72 randomised, 33 months recruiting)                                     |               |             |
| Adherence with study visits  | Total   | SMBP          | Usual Care  |
| Chronic hypertension group   | N = 83  | N = 53        | N = 30      |
| Applicable antenatal study visits  | 89% (175/197)   | 88% (107/121) | 90% (68/76) |
| 6 weeks postnatal study visit  | 72% (60/83)   | 72% (38/53)   | 73% (22/30) |
| Gestational hypertension group   | N = 71  | N = 49        | N = 22      |
| Applicable antenatal study visits  | 83% (19/23)   | 77% (13/17)   | 100% (6/6)  |
| 6 weeks postnatal study visit  | 73% (52/71)   | 74% (36/49)   | 73% (16/22) |
| <i>Discontinuation with SMBP intervention</i> <sup>**</sup>                    |   |               |             |
| Chronic hypertension group   | 7% (4/55 originally randomised to SMBP)                                       |               |             |
| Gestational hypertension group   | 4% (2/49 originally randomised to SMBP)                                       |               |             |
| <i>Fidelity with assigned randomisation group</i> <sup>***</sup>               |   |               |             |
| Chronic hypertension group   | 39% (12 started SMBP/31 randomised to usual care)                             |               |             |
| Gestational hypertension group   | 17% (4 started SMBP/23 randomised to usual care)                              |               |             |
| <i>Adherence with SMBP protocol</i> <sup>†</sup>                               |   |               |             |
| Chronic hypertension group   | N = 50  |               |             |
| Median (IQR) number of BP readings days per week <sup>‡</sup>                  | 5.5 (3.1 to 6.5)  |               |             |
| Median (IQR) number of monitor readings per day on days monitored <sup>‡</sup> | 2.2 (2.1 to 2.5)  |               |             |
| Gestational hypertension group <sup>‡</sup>                                    | N = 43  |               |             |
| Median (IQR) number of BP readings days per week <sup>‡</sup>                  | 6.1 (4.5 to 6.7)  |               |             |
| Median (IQR) number of monitor readings per day on days monitored <sup>‡</sup> | 2.9 (2.5 to 4.6)  |               |             |

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

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

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

<sup>‡</sup> From women who supplied home data using BP monitor, App or BP diary data where available.

<sup>†</sup> Deducting any antenatal admission dates for a woman where she was not expected to self-monitor.

[19] at time of enrolment.

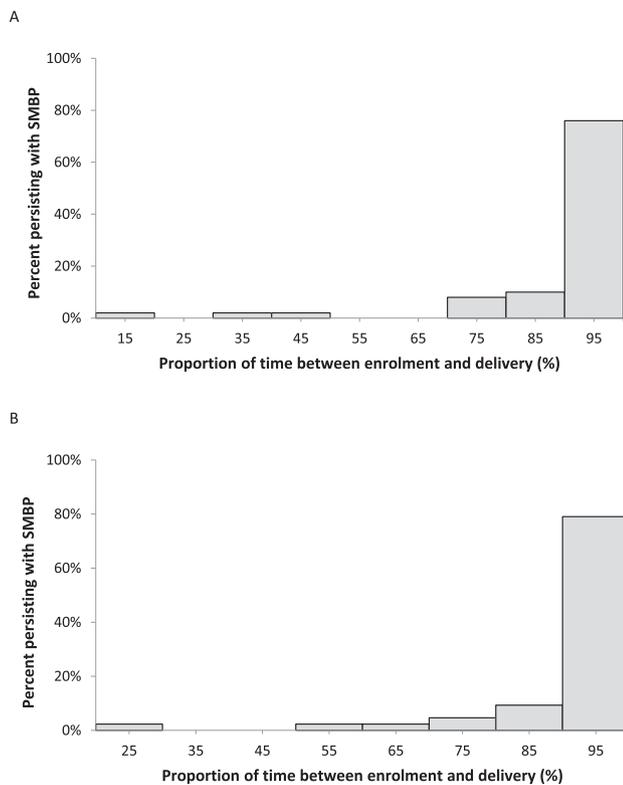
## 2.2. Procedures

Eligible and consented women completed a baseline assessment including questionnaires on quality of life scores (EQ-5D-5L) [20], measurement of anxiety (STAI-6) [21] and medication beliefs (BMQ) [22] and medication adherence (MARS) [23]. Members of the research team obtained study BP measurements and data on demographics, medical and obstetric history, current and past antihypertensive therapy and socioeconomic status (Index of Multiple Deprivation) [24]. Women were randomised, stratified for recruiting centre and type of hypertension, in permuted blocks of random size (2 or 4) in a 2:1 ratio to BP self-monitoring or usual care. Women randomised to the intervention also received all usual care, and no antenatal visits were removed from their schedule. The randomisation sequence was computer-generated, and secure web-based software was used to ensure allocation concealment, although due to the nature of the intervention, neither participants nor investigators or clinicians were masked. Outcome measurement was not masked. Study visit BP readings were taken with an automated, validated monitor to minimise bias.

Women allocated to usual care had their BP monitored by their local clinical team, and these BPs measured by healthcare professionals were used to inform care and decisions around antihypertensive medication. Women randomised to the intervention were additionally asked to measure their BP daily, at approximately the same time each day, using an automated BP monitor (Microlife WatchBP Home) validated in pregnancy and preeclampsia, after measuring and recording upper-arm

diameter to select appropriate cuff size [25]. Participants were asked to take two readings, at least one minute apart, and to record the second in their study diary, or submit the reading using their mobile phone, via text or the study App (the App was available for the women with gestational hypertension only, during the latter phase of the study). The digitally reported readings were automatically transmitted to a secure server, which provided immediate automated responses. This telemonitoring service provided reminders when BP readings were overdue. The digital readings were available for use by the clinical team at follow-up appointments via the woman's App or the study website. Women recording their home readings in a diary were asked to bring their diary to their antenatal follow-up visits to share their readings with their clinical team. In addition to receiving training about how to best measure their BP and symptoms of pregnancy hypertensive disease, women were also provided with guidance about normal and out-of-range readings using an algorithm the study team had created based on the UK NICE Hypertension in Pregnancy guideline [8] (see Supplementary information 1 for study materials) and how and when to contact their local clinical team for out-of-range readings or symptoms. This same algorithm was used to generate the immediate responses provided through the telemonitoring system.

All women, depending on their gestation at recruitment, were asked to attend up to three antenatal study visits at 20, 28 and 32 weeks' gestation, and one six week postnatal face-to-face or telephone study visit. At these visits, BP measurement was taken by the study team using the Microlife WatchBP Home monitor. Delivery outcome data were collected from the maternity record within three months of delivery.



**Fig. 2.** Persistence with self-monitoring of blood pressure. A: Proportion of time women with chronic hypertension persisted with self-monitoring of blood pressure. Persistence of self-monitoring of BP (SMBP) for 50 women with chronic hypertension providing SMBP data. Of 53 randomised to SMBP: 4 formally discontinued from the intervention, 2 of whom still supplied home data, 2 who never started SMBP and 1 who did not formally discontinue but did not supply data. B: Proportion of time women with gestational hypertension persisted with self-monitoring of blood pressure. Persistence of self-monitoring of BP for 43 women with gestational hypertension providing SMBP data. Of 49 women randomised to SMBP: 2 formally discontinued from the intervention, 1 of who still supplied data, 1 who never started SMBP and 5 who did not formally discontinue but did not supply data.

Clinical teams at the study sites received update training on the standardised method for measuring BP [26] and were advised to record three readings at each antenatal follow-up visit. The average of all three clinic readings on any single occasion was taken as the clinic BP for that episode.

### 2.3. Analyses

The primary outcomes were for feasibility, measured by recruitment, discontinuation, and adherence and persistence with the self-monitoring protocol. Secondary outcomes included several measures of BP control (to best inform the design and analysis of a future large multi-site RCT), delivery outcomes and safety, health resource use, quality of life scores, antihypertensive prescribing behaviour and self-reported medication beliefs and adherence.

No formal sample size calculation was used but we aimed for a target sample size of 160, consistent with the feasibility design [approximately half with gestational hypertension and half with chronic hypertension] [27]. An intention to treat analysis was performed, with the woman as the unit of analysis using all available data, with no imputation for missing data. The statistical software Stata/SE version 14 was used for all analyses. Differences between randomisation groups are reported with 95% confidence intervals (95% CI), not including formal significance tests.

Analyses are reported separately by hypertension group due to the women having slight variance in the method for BP reporting (BP diaries for those with chronic hypertension and text/App for those with gestational hypertension) and also due to the later gestations of diagnosis and hence recruitment for those with gestational hypertension. Study and clinic BP were analysed using a linear mixed effects regression model with unstructured covariance. The model accounted for repeated measurements on the same participant by means of random effects and adjusted for site and study baseline BP as fixed effects, with interaction between randomisation group and categorical study visit for study BP or interaction between randomisation group and continuous quadratic time measured in weeks of gestation for clinic BP analyses, allowing the model to accommodate a mid-trimester BP dip. Study BP analysis for the group with gestational hypertension used a linear regression model, adjusted for recruiting centre and study baseline BP. A repeated measures model was not used for this group as there were insufficient study visit data due to their later gestations at enrolment into the study. (Further statistical analysis details are supplied in [Supplementary information 2](#)).

### 3. Results

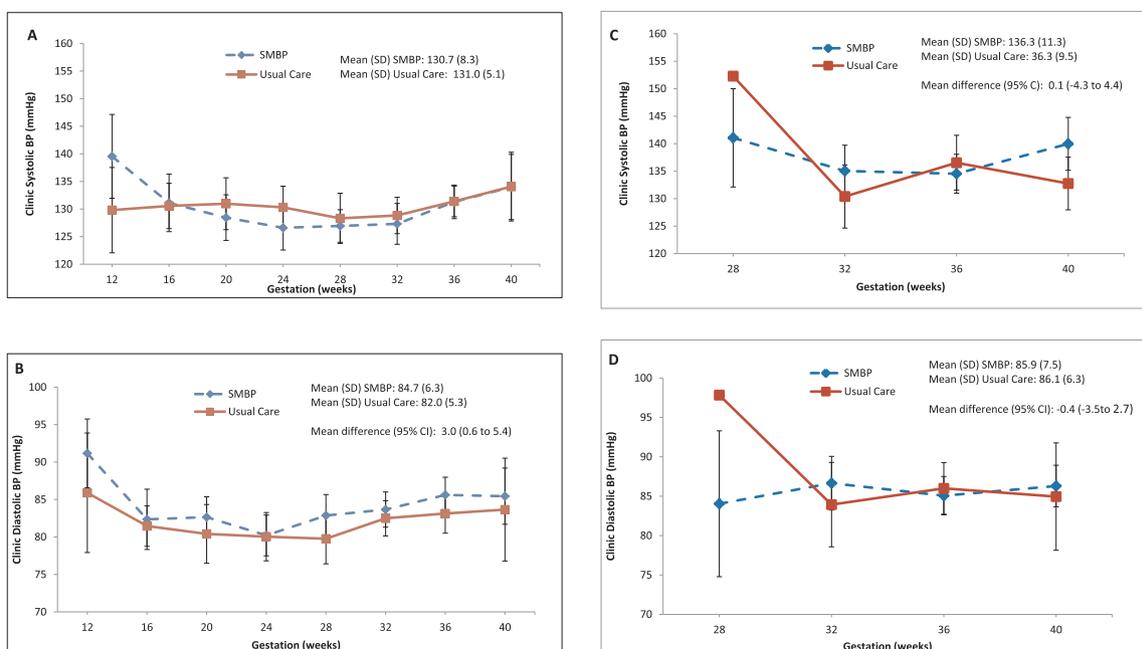
Between December 2015 and December 2017, 1140 women were screened for trial eligibility (Fig. 1) of whom 226 were eligible and 162 provided written consent (target 160). Most women did not provide a reason for declining study enrolment, but the number of women stating they were declining due to specifically not wanting to be randomised to either intervention group were 15% (20/134) and 7% (6/92) for those with chronic and gestational hypertension respectively (details in Fig. 1). Four women were recruited in error [as ineligible] and excluded from further analysis leaving one hundred and fifty-eight women; for women with chronic hypertension: 55 were randomised to self-monitoring and 31 to usual care and for women with gestational hypertension: 49 were randomised to self-monitoring and 23 to usual care. Participants not included in the analysis of clinical outcomes were three with chronic hypertension (two for early miscarriages and one early withdrawal by clinician on medically unrelated grounds) and one with gestational hypertension (lost early to follow-up as emigrated).

Baseline characteristics were generally similar between the allocation groups (Table 1) for women with chronic and gestational hypertension, except within the group with chronic hypertension, where there were relative imbalances in ethnicity and previous diagnosis of a pregnancy hypertensive disorder (see Table 1). Overall, women identifying as a non-white ethnicity accounted for 35% (55/158) and the mean IMD score was 4.8 (SD 2.8) across groups (see Table 1 for details). Thirty-eight percent (60/158) had performed BP home monitoring at least once in the current pregnancy prior to enrolment, the majority of these from the group with chronic hypertension.

#### 3.1. Feasibility outcomes

The main feasibility outcomes are described using the combined groups (i.e. all participants both chronic and gestational hypertension). The proportion of those eligible that were recruited was 71% (222 eligible, 158 randomised, see Table 2). The overall randomisation rate was 2.5 participants per site per month.

Formal discontinuation of self-monitoring of BP by women randomised to the intervention group was low, with a combined rate of 6% (6/104), three of whom still supplied some home BP monitoring data until discontinuation. None of these women withdrew consent for notes review follow-up. The 49 women with chronic hypertension who provided home readings reported BP measurements on a median of 5.5 days per week (IQR 3.1–6.5) and median of 2.2 readings per day (IQR 2.1–2.5). Three women (7%) from the intervention group provided no home readings at all (two who formally discontinued with intervention very early in follow-up and one who never supplied home



**Fig. 3.** A-D: Clinic blood pressure across gestation for (A-B) women with chronic hypertension and (C-D) women with gestational hypertension, by randomisation group. A. Mean clinic SBP across gestation in pregnant women with chronic hypertension. B. Mean clinic DBP across gestation in pregnant women with chronic hypertension. C. Mean clinic SBP across gestation in pregnant women with gestational hypertension. D. Mean clinic DBP across gestation in pregnant women with gestational hypertension. The number of participants with chronic hypertension (A & B): 10–13.9 weeks (n = 8 SMBP and 5 UC) 14–17.9 weeks (n = 23 SMBP and 16 UC) 18–21.9 weeks (n = 34 SMBP and 19 UC) 22–25.9 weeks (45 SMBP and 27 UC) 26–29.9 weeks (n = 44 SMBP, 28 UC), 30–33.9 weeks (n = 42 SMBP, 25 UC), 34–37.9 weeks (n = 44 SMBP, 28 UC), 38–41.9 weeks (n = 22 SMBP, 10 UC). The number of participants with gestational hypertension (C&D): 26–29.9 weeks (n = 6 SMBP, 1 UC), 30–33.9 weeks (n = 17 SMBP, 7 UC), 34–37.9 weeks (n = 44 SMBP, 20 UC), 38–41.9 weeks (n = 24 SMBP, 8 UC). SMBP: self-monitoring of blood pressure, UC: usual care.

data). The 43 women with gestational hypertension provided home readings on a median of 6.1 days per week (IQR 4.5–6.7) with a median of 2.9 readings per day (IQR 2.5–4.6). Six women (12%) from the gestational hypertension intervention group provided no home readings (one who formally discontinued with intervention very early and five who never supplied data). In terms of cross-over from control to some form of self-initiated BP self-monitoring, there was evidence of this in the maternity notes from 12/31 (39%) randomised to usual care from the chronic hypertension group, and four from the 23 (17%) from the gestational hypertension group.

There was high persistence with the self-monitoring intervention (see Fig. 2) with 86% (43/50 of those supplying home data) of women with chronic and 76% (38/49) of women with gestational hypertension providing home BP readings for 80% or more of their time from enrolment until delivery.

### 3.2. Clinical outcomes

The mean clinic systolic and diastolic BP profiles throughout pregnancy by allocation group are presented in Fig. 3A–D. For both the chronic and gestational hypertension groups, no difference was observed between intervention groups for any measures of systolic BP control for either study or clinic measurements (see Fig. 3A and C and Supplement Tables 1A–B). In terms of diastolic BP, there was no difference between groups for those with gestational hypertension but for chronic hypertension, diastolic BP was higher in the self-monitoring group compared to usual care (mean and time-weighted mean clinic diastolic BP) (Supplement Table 2A). A post-hoc sensitivity analysis excluding those readings taken in the maternity assessment unit subsequent to women reporting high home BP measurements, seeking to reduce possible detection bias between groups, had no discernible impact on the pattern of the original results.

No between-group differences were seen in mean defined daily

dose, nor the mean number of antihypertensive medications (Supplement Tables 1A and B). Similarly, the medication adherence and beliefs about medication scores showed no difference between study groups (Supplement Tables 1A and B). Maternal and perinatal outcomes (Table 3) for women with chronic and gestational hypertension were also similar between groups.

### 3.3. Adverse events, quality of life and BP monitoring preference

There was one unrelated serious adverse event reported for a woman from the BP self-monitoring arm in the gestational hypertension group with a case of postnatal influenza.

No between-group differences were seen at baseline, or at six weeks postnatal in participants' mean self-reported overall five-domain EQ-5D-5L, visual analogue score (VAS) [20] or STAI-6 scores [21] in either hypertension group (see Supplemental Table 3). Assessment of participant BP monitoring preferences (from respondents to Little's "problem score" questionnaire undertaken postnatally [28]), indicated that clinic BP monitoring caused more anxiety than home monitoring (related to waiting around, worrying about knowing what the BP was), whereas home monitoring scored more highly on all three positive factors: feeling in control, good use of clinician time, worth the trouble to get accurate readings (see Supplemental Table 4). There was a lower overall 'problem score' for the home BP monitoring group compared with usual care clinic monitoring, for both chronic and gestational hypertension groups: mean difference score (95% CI)  $-0.3$  ( $-0.5$  to  $-0.02$ ) and  $-0.7$  ( $-0.9$  to  $-0.4$ ) respectively.

## 4. Discussion

This is the first randomised controlled trial looking at the feasibility of BP self-monitoring for the management of women with pregnancy hypertension. Recruitment, follow-up, and adherence with the

**Table 3**

Maternal and perinatal outcomes for 154 pregnant women with chronic and gestational hypertension included in the OPTIMUM-BP feasibility trial from December 2015 until December 2017.

| Characteristic   | Chronic Hypertension |                            |   | Gestational Hypertension |                            |   |
|--|----------------------|----------------------------|---|--------------------------|----------------------------|---|
|  | SMBP Group<br>N = 53 | Usual Care Group<br>N = 30 | Adjusted <sup>ca</sup> Odds Ratio or Difference in Mean/Median (95% CI) | SMBP Group<br>N = 49     | Usual Care Group<br>N = 22 | Adjusted <sup>ca</sup> Odds Ratio or Difference in Mean/Median (95% CI) |
| <i>Maternal outcomes</i>   |                      |                            |   |                          |                            |   |
| Time between randomisation and delivery*, days   | 142 (34)             | 150 (32)                   |   | 31 (24)                  | 25 (17)                    |   |
| Need for IV antihypertensive drugs week before delivery                                  | 5 (9%)               | 0 (0%)                     |   | 0 (0%)                   | 0 (0%)                     |   |
| <i>Onset of delivery:</i>  |                      |                            |   |                          |                            |   |
| Spontaneous  | 3 (5%)               | 2 (7%)                     |   | 6 (12%)                  | 7 (32%)                    |   |
| Induction  | 30 (57%)             | 22 (73%)                   |   | 32 (66%)                 | 7 (32%)                    |   |
| Pre-labour caesarean section   | 20 (38%)             | 6 (20%)                    |   | 11 (22%)                 | 8 (36%)                    |   |
| <i>Indication for induction of labour/pre-labour caesarean section (all that apply):</i> |                      |                            |   |                          |                            |   |
| Preeclampsia   | 15 (28%)             | 2 (7%)                     |   | 15 (31%)                 | 8 (36%)                    |   |
| Hypertension   | 12 (23%)             | 2 (7%)                     |   | 4 (8%)                   | 1 (5%)                     |   |
| Fetal growth restriction   | 4 (8%)               | 3 (10%)                    |   | 4 (8%)                   | 2 (10%)                    |   |
| <i>Preeclampsia</i>  |                      |                            |   |                          |                            |   |
| Total  | 19 (36%)             | 5 (17%)                    | 2.9 (0.9 to 9.1)  | 19 (39%)                 | 8 (36%)                    | 1.1 (0.4 to 3.4)  |
| Defined by new proteinuria only  | 5 (9%)               | 2 (7%)                     |   | 8 (16%)                  | 2 (9%)                     |   |
| Other maternal organ dysfunction   | 10 (19%)             | 2 (7%)                     |   | 9 (18%)                  | 3 (14%)                    |   |
| With fetal growth restriction  | 6 (11%)              | 2 (7%)                     |   | 4 (8%)                   | 4 (18%)                    |   |
| Adverse maternal outcome <sup>‡</sup>  | 0 (0%)               | 1 (3%)                     |   | 1 (2%)                   | 1 (4%)                     |   |
| Admitted to ITU  | 0 (0%)               | 0 (0%)                     |   | 1 (2%)                   | 0 (0%)                     |   |
| Total admission nights <sup>§</sup>  | 5 (3 to 8)           | 4 (2 to 5)                 |   | 4 (3 to 6)               | 3 (2 to 6)                 |   |
| <i>Perinatal outcomes</i>  |                      |                            |   |                          |                            |   |
| Gestation at delivery* (weeks)   | 36.9 (4.2)           | 37.9 (2.4)                 | −1.1 (−2.8 to 0.6)  | 38.0 (2.0)               | 37.6 (2.4)                 | 0.4 (−0.7 to 1.5)   |
| Preterm birth (< 34 weeks)   | 7 (13%)              | 2 (7%)                     | 2.5 (0.5 to 13.7)   | 2 (4%)                   | 2 (9%)                     | 0.4 (0.1 to 3.2)  |
| <i>Mode of delivery, n (%)</i>   |                      |                            |   |                          |                            |   |
| Spontaneous vaginal delivery   | 13 (25%)             | 15 (50%)                   |   | 21 (43%)                 | 9 (41%)                    |   |
| Assisted vaginal delivery  | 1 (2%)               | 4 (13%)                    |   | 4 (8%)                   | 4 (18%)                    |   |
| Emergency pre-labour caesarean section   | 15 (28%)             | 4 (13%)                    |   | 4 (8%)                   | 5 (23%)                    |   |
| Emergency caesarean section in labour  | 10 (19%)             | 2 (7%)                     |   | 11 (22%)                 | 1 (4%)                     |   |
| Elective pre-labour caesarean section  | 14 (26%)             | 5 (17%)                    |   | 9 (18%)                  | 3 (14%)                    |   |
| Total with caesarean section, n (%)  | 39 (74%)             | 11 (37%)                   | 4.9 (1.8 to 13.2)   | 25 (51%)                 | 13 (59%)                   | 1.4 (0.5 to 3.9)  |
| Birth weight* (grams)  | 2808 (940)           | 3086 (628)                 | −300.2 (−690.7 to 90.2)   | 3061 (738)               | 3003 (851)                 | 54.2 (−341.7 to 450.0)  |
| Birth weight < 10th centile <sup>†</sup>   | 8 (15%)              | 1 (3%)                     | 5.3 (0.6 to 45.8)   | 9 (18%)                  | 4 (18%)                    | 1.3 (0.3 to 5.4)  |
| Birth weight < 3rd centile <sup>†</sup>  | 2 (4%)               | 1 (3%)                     |   | 2 (4%)                   | 0 (0%)                     |   |
| <i>Perinatal death:</i>  |                      |                            |   |                          |                            |   |
| Stillbirth   | 2 (4%)               | 0 (0%)                     |   | 0 (0%)                   | 0 (0%)                     |   |
| Neonatal death   | 1 (2%)               | 0 (0%)                     |   | 0 (0%)                   | 0 (0%)                     |   |
| Admitted to neonatal unit  | 9 (17%)              | 4 (13%)                    | 1.4 (0.4 to 5.3)  | 9 (18%)                  | 2 (9%)                     | 2.2 (0.4 to 11.5)   |
| Total admission nights <sup>§</sup> **   | 3 (2 to 6)           | 2 (1 to 4)                 |   | 2 (2 to 4)               | 3 (2 to 4)                 |   |

<sup>‡</sup> Adverse maternal outcome: eclampsia (1), intracranial haemorrhage or infarct (0), HELLP (haemolysis, elevated liver enzymes, low platelets) syndrome (0) or death (0).

\* Mean and SD.

<sup>†</sup> Using intergrowth-21st, accessed <https://www.intergrowth21.org.uk/>.

<sup>§</sup> Median and IQR.

\*\* Does not contain data for the two stillbirths.

<sup>ca</sup> Adjusted for study site and baseline clinic SBP.

intervention were much greater than average rates quoted for UK randomised trials [29]. Persistence with the self-monitoring intervention was high across both types of hypertension group and supports the hypothesis that self-monitoring is acceptable in this population. This is consistent with women reporting no differences in anxiety or quality of life scores between randomised groups, and indicating a greater preference with lower “problem scores” for BP self-monitoring versus usual clinic monitoring [28].

The study was not powered to detect a difference between randomisation groups for the secondary outcomes concerning BP control and delivery outcomes hence caution must be taken in drawing conclusions. Systolic BP in all groups and diastolic BP in gestational hypertension did not show any differences, although we saw a small and statistically significant increase in mean diastolic and time-weighted mean diastolic clinic BP for the group using self-monitoring versus usual care in women with chronic hypertension. The greater proportion of caesarean sections within the self-monitoring versus usual care group for women

with chronic hypertension is likely to be a chance finding but there was a consistent trend for higher rates of pre-eclampsia, greater proportion born prematurely less than 34 weeks, reduced birth weight and greater proportion less than tenth centile for weight for this group. It seems unlikely that self-monitoring of BP increases adverse outcomes of this nature, particularly as our prescribing and medication adherence data did not reveal any difference between the randomisation groups. Chance imbalances in outcomes between randomisation groups are likely in feasibility trials with smaller sample sizes; we saw evidence for this within two known important predictors of perinatal outcome (ethnicity and previous pregnancy hypertensive disorder) within the group with chronic hypertension. The small numbers used for feasibility studies also preclude them being able to successfully minimise or adjust for all important confounders in the randomisation and analyses of such studies.

#### 4.1. Previous literature

Previous studies in the non-pregnant population with hypertension have shown that self-monitoring accompanied with self-management produces improved BP control, is preferred by participants to usual care [11–13] and provided the impetus for this study. To our knowledge, the only previous randomised controlled trial of self-monitoring of BP in pregnancy included a general pregnant population rather than hypertensive women [30]. Observational and qualitative studies have reported increased satisfaction from self-monitoring but could not evaluate clinical effectiveness [31–33].

#### 4.2. Strengths and limitations

The study benefited from being run across four NHS sites and recruiting from women with a range of ethnicities and socioeconomic and educational backgrounds, supporting the concept that BP self-monitoring is feasible and acceptable for a wide range of women whose pregnancies are complicated by hypertension. The high adherence and persistence with the self-monitoring intervention is reassuring given the high recruitment proportion of more than 70% of those eligible. The recruitment rate of 2.5 per site per month suggests that this is a feasible intervention to trial on a larger scale.

The trial was run pragmatically using clinic measurements in addition to study BP readings and has shown the feasibility of collecting and using routine clinical data. This is important in pregnancy where attendance at study visits is problematic and affected by later study entry and premature delivery (for example < 25% of those with gestational hypertension attended a study visit at 34/40 whereas all had clinic BP data). The rapidly dynamic nature of BP change in pregnancy is such that intermittent study visits less accurately portray underlying BP trends. Randomisation using allocation concealment limited selection bias. Although it was not possible to mask the participants or clinicians to randomisation group due to the nature of the intervention, providing additional reminders to clinical teams during site visits regarding best practice for BP measurement helped to limit detection bias.

While it is possible that there may be some inaccuracy of reporting BP readings by participating women, via text, study App or recorded in diaries, accuracy in similar studies has been shown to be high (94% identical and only 1% submitted at a different BP threshold) [34]. Accuracy of BP reporting is forming part of an exploratory analysis to be published.

The study detected evidence of cross-over between groups, (17–39% of our usual care group with gestational and chronic hypertension respectively taking up some form of home monitoring); however, the evidence from the non-pregnant hypertensive population has shown that informal self-monitoring alone has limited impact on BP control as opposed to self-monitoring combined with active intervention [11,12].

#### 4.3. Clinical and research implications

In higher risk pregnancy, the motivation of pregnant women for greater involvement in their care, the need to provide effective sustainable health care pathways and the opportunities from real-time participant data collection are met in a BP self-monitoring intervention. This is the only published randomised study to date investigating the use of BP self-monitoring in a pregnant hypertensive population and shows that it is feasible and acceptable. Self-monitoring could be one way to achieve tighter BP control as shown to be beneficial in the general adult population [12] and the CHIPS study [7]. This provides the justification for further exploring the role of BP self-monitoring in hypertensive pregnancies.

## 5. Conclusion

BP self-monitoring for the management of hypertension during pregnancy is feasible and well tolerated by women when combined with clinic monitoring. A large scale randomised controlled trial powered to explore the effectiveness and cost-effectiveness of self-monitoring for improved BP control in hypertensive pregnancies is warranted.

### Declaration of Competing Interest

The authors declare the following conflicts of interest: LM receives consultancy fees from Drayson Technologies.

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### OPTIMUM Collaborators

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### Author contributions

The study was conceived by RM, LC and LP. The protocol was developed by LP, LC, KT and RM with the advice and support of all authors. The study was managed by ET and recruitment was led by HW and CC. The analysis plan and analysis were completed by LP with guidance from AN. The first draft of the paper was written by LP with RM, LC KT and subsequently edited and approved by all co-authors. All authors have read and approved the final manuscript.

### Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.preghy.2019.09.018>.

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