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1 Effect of self-monitoring of blood pressure on blood pressure control
2 in pregnant individuals with chronic or gestational hypertension: the
3 BUMP 2 randomized trial
4

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42 See Supplement for BUMP investigators

43
44

45 [Key Points \(90 words\)](#)

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

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

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

54

55

56 Abstract

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

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

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

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

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

72 Results: Among 454 participants with chronic hypertension (mean age 36 years, mean gestation at entry 20
73 weeks) and 396 with gestational hypertension (mean age 34 years, mean gestation at entry 33 weeks) who
74 were randomized, primary outcome data were available from 444 (97.8%) and 377 (95.2%) respectively. In
75 the chronic hypertension cohort, there was no statistically significant difference in mean systolic blood
76 pressure for the self-monitoring groups vs the usual care group (133.8 mmHg vs 133.6 mmHg, respectively;
77 adjusted mean difference, 0.03 mmHg; 95% CI -1.73 to 1.79) In the gestational hypertension cohort, there
78 was also no significant difference in mean systolic blood pressure (137.6 mmHg compared with 137.2 mmHg;
79 adjusted mean difference, -0.03mmHg; 95% CI -2.29 to 2.24). There were 8 serious adverse events in the
80 self-monitoring group (4 in each cohort) and 3 in the usual care group (2 in chronic hypertension cohort and
81 1 in gestational hypertension cohort).

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

85 Trial registration: Prospectively registered clinicaltrials.gov NCT03334149.

86

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

88 Introduction

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

95

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

104

105 Studies of SMBP have documented use by 19% of pregnant individuals,¹¹ and although feasibility studies
106 have shown that the intervention is acceptable for normotensive¹² and hypertensive¹³ pregnant individuals,
107 definitive evidence for effectiveness is lacking.¹⁴ The Blood Pressure Monitoring in Hypertensive Pregnancy
108 (BUMP2) trial aimed to evaluate the effect of SMBP in individuals with pregnancy hypertension on BP control
109 (assessed as systolic BP measurements), alongside a linked trial assessing self-monitoring for the detection of
110 raised BP in individuals with higher risk pregnancies.¹⁵ [citation for BUMP1]

111

112

113 Methods

114 Study design

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

122

123 Study Population

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

131

132 Randomization and masking

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

138 development work.^{15,17} The intervention was not masked from participants, clinicians, or data collectors due
139 to its nature.

140

141 *Procedures*

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

144

145 *Self-monitoring*

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

156

157 *Usual prenatal care*

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

162

163 *Follow-up and questionnaires*

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

170

171 *Protocol Amendments*

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

175

176 *Outcomes*

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

188 hypertension, MCID not available), fidelity to the monitoring schedule and adherence as described
189 above.^{19,20,22,23} Full list available eTable 1.

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

192

193 Sample size

194 The initial sample size calculation (based on chronic hypertension and gestational hypertension groups
195 considered together) estimated that 256 per group would be sufficient to detect a 5 mmHg difference in
196 systolic BP between groups at 90% power and 5% level of significance (2-sided), accounting for 15% attrition
197 and a standard deviation of 16 mmHg, based on data from the previous feasibility study¹² and PELICAN²⁵
198 study. The sample size was calculated using NCSS PASS V.12.0. The planned sample size of 512 for direct
199 recruitment into the trial was subsequently increased to 600 during the trial and prior to any analyses to
200 retain power in the cohorts of individuals with chronic and gestational hypertension.

201

202 Statistical analysis

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

211

212 Although the trial initially planned to analyse all hypertensive categories together, publication of the
213 OPTIMUM-BP trial¹³ evaluating the feasibility of SMBP in individuals with hypertensive pregnancies
214 demonstrated potential differences in BP characteristics, duration of intervention and effect size between
215 individuals with chronic hypertension and gestational hypertension. It was therefore pre-specified before
216 the end of recruitment that these groups would be analysed separately, and the sample size increased to
217 allow for this.

218

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

232

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

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

244

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

249

250

251 Results

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

263

264 Primary Outcome

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

271

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

279

280 *Secondary Outcomes*

281 In individuals with chronic hypertension, there was no significant difference in the majority of maternal and
282 infant secondary outcomes, other than a lower proportion with spontaneous onset of labour: 12 participants
283 (5%) in the SMBP group vs. 21 participants (10%) in the usual care group; adjusted odds ratio 0.52 (95% CI,
284 0.29 to 0.92) (Table 3). This may have related to a higher proportion of participants in the SMBP group being
285 diagnosed with pre-eclampsia, though a lower proportion (not tested) of this group had one or more serious
286 maternal complications (eTable 4 in Supplement 3). There was no significant difference in gestational age at
287 birth, spontaneous vaginal births, or in any of the infant outcomes. There were three stillbirths in the cohort,
288 one in the SMBP group and two in the usual care group.

289

290 In participants with gestational hypertension, there were also no significant differences in the maternal and
291 infant secondary outcomes, other than a lower proportion of individuals with a spontaneous onset of labour:
292 30 individuals (15%) in the SMBP group versus 44 individuals (22%) in the usual care group; adjusted odds
293 ratio 0.62 (95% CI, 0.39 to 0.99), though with no significant difference in the proportion with spontaneous
294 vaginal births (Table 3). There was one stillbirth in the self-monitoring group and none in the usual care
295 group. Other descriptive secondary outcomes are shown in eTable 4 in Supplement 3.

296

297 There were no significant differences in anxiety and adherence measures at baseline or follow-up (eTable 5
298 in Supplement 3). Individuals with chronic and gestational hypertension who were randomized to self-
299 monitoring had significantly improved scores on the modified brief Illness Perception Questionnaire at both
300 30 weeks and postnatally compared with usual care (eTable 6a and b in Supplement 3). There were no
301 significant differences in maternal health-related quality of life measured using EQ-5D-5L between the
302 randomized groups in the main analysis and sensitivity analysis (eTables 7a and b in Supplement 3).

303

304 *Adverse Events*

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

309

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

316

317 *Post hoc analyses*

318 In a *post hoc* analysis of 430 participants allocated to SMBP and considering the whole period between
319 randomization and delivery, 259 (60.2%) had high clinic and home BP readings, 107 (24.9%) had high clinic
320 BP readings but all home readings normal, 24 (5.6%) had normal clinic but high home readings, and 36
321 (8.4%) had normal clinic and normal home BP readings throughout (with data from four women missing).
322 Analyses of antihypertensive defined daily dose of proportions showed no significant difference between
323 groups in medication dosing over time (eTable 10 in Supplement 3).

324

325

326 Discussion

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

331

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

338

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

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

348

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

355

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

366

367 *Limitations*

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

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

381

382 *Conclusions*

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

385

386

387 *Authors' contributions*

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

398

399 *Declaration of interests*

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

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

408

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449 See supplement 5

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536 **Supplemental Content**

537 Supplement 1 Trial Protocol

538 Supplement 2 Statistical analysis plan

539 Supplement 3 Supplementary tables and figures

540 Supplement 4 The BUMP investigators

541 Supplement 5 Data Sharing Statement

542

543

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

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

550
551

552 Footnote for Figure 2:

553

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

556 ^a Mean differences presented for self-monitoring versus usual care.

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

561 ^c BP \geq 140/90mmHg means systolic and/or diastolic greater or equal to 140/90mmHg as measured by a
562 professional.

563
564

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

567
568

569 Footnote for Figure 3:

570

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

573 ^a Mean differences presented for self-monitoring versus usual care.

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

578 ^c BP \geq 140/90mmHg means systolic and/or diastolic greater or equal to 140/90mmHg as measured by a
579 professional.

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Table 1: Baseline characteristics by randomized group

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

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

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

588 ^b Ethnicity self-attributed from standard UK classification. "Other" included any other ethnicity not listed above in
589 which case participants were asked to specify (Chronic hypertension Self-monitoring: 2 not stated and one each of the
590 following: Anglo-Arab, British Arab, Mauritian, Middle-East Iranian, Thai; Usual Care: 2 not stated and one each of the
591 following: Japanese and Korean; Gestational hypertension Self-monitoring: 6 not stated and one each of the following:
592 Myanmar and Turkish Kurdish; Usual Care: 3 not stated and one Myanmar)
593 ^c Any autoimmune disease (for example systemic lupus erythematosus or antiphospholipid syndrome)
594

595 Table 2: Primary outcome: Mean blood pressure for women with chronic hypertension and
 596 gestational hypertension
 597

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

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

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

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

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

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

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

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

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

617

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

619 ^a Self-monitoring vs. usual care; OR (95% CI) estimated from logistic mixed effects models adjusting for parity and recruitment site. For the gestational hypertension cohort only,

620 transition from BUMP1; MedD (95% CI) estimated from quantile regression models adjusting for parity & recruitment site, and transition from BUMP1 for the gestational

621 hypertension cohort only; MD (95% CI) estimated from linear mixed effects models adjusting for parity & recruitment site and for the gestational hypertension cohort only, transition

622 from BUMP1

623 ^b Severe hypertension defined as systolic BP \geq 160 mmHg and/or diastolic BP \geq 110 mmHg),¹⁶

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

625 ^d Models include an adjustment for twin birth

626