

Effect of self-monitoring of blood pressure on diagnosis of hypertension during higher-risk pregnancy

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1 Effect of self-monitoring of blood pressure on diagnosis of hypertension during higher-risk
2 pregnancy: the BUMP 1 randomized trial

3

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35

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39

40 See Supplement for BUMP investigators

41 Key Points (88 words)

42 Question: Does self-monitoring of blood pressure by pregnant individuals at higher risk of pre-
43 eclampsia lead to earlier detection of pregnancy hypertension compared to usual antenatal care?

44 Findings: In this randomized clinical trial that included 2441 pregnant individuals at increased risk for
45 pre-eclampsia, use of self-monitoring of BP with telemonitoring compared with usual care resulted
46 in a mean time to clinic-based detection of hypertension of 104 vs 106 days, a difference that was
47 not statistically significant.

48 Meaning: Among pregnant individuals at higher risk of pre-eclampsia, blood pressure self-
49 monitoring with telemonitoring did not lead to earlier clinic-based detection of hypertension.

50

51 Abstract

52 Importance: Inadequate management of elevated BP is a significant contributing factor to maternal
53 deaths. Self-monitoring of blood pressure (BP) in the general population has been shown to improve
54 the diagnosis and management of hypertension, however little is known about its use in pregnancy.

55 Objective: To determine whether self-monitoring of BP in higher risk pregnancies leads to earlier
56 detection of pregnancy hypertension.

57 Design, setting and participants: Unmasked, randomised clinical trial that recruited between
58 November 2018 and October 2019. 2441 pregnant individuals at higher risk of pre-eclampsia were
59 recruited at 20 weeks' gestation from 15 hospital maternity units in England with final follow-up in
60 April 2020.

61 Interventions: Participating individuals were randomised to either BP self-monitoring with
62 telemonitoring (n=1223) plus usual care or usual antenatal care alone (n=1218) without access to
63 telemonitored BP.

64 Main Outcomes: The primary outcome was time to first recorded hypertension measured by a
65 healthcare professional.

66 Results: Among 2441 participants who were randomized (mean age, 33; median gestation 20
67 weeks), 2346 (96%) completed the trial. The time from randomisation to clinic recording of
68 hypertension was not significantly different between individuals in the self-monitoring group (mean
69 104 days) vs the usual care group (mean 106 days) (mean difference -1.6 days (95% confidence
70 intervals -8.1, 4.9, p = 0.6). Eighteen serious adverse events were reported during the trial with none
71 judged as related to the intervention: 12 (1%) in the self-monitoring group and 6 (0.5%) in those
72 receiving usual care.

73 Conclusions and relevance: Among pregnant individuals at higher risk of pre-eclampsia, blood
74 pressure self-monitoring with telemonitoring compared with usual care did not lead to significantly
75 earlier clinic-based detection of hypertension.

76 Trial Registration: ClinicalTrials.gov NCT03334149 <https://clinicaltrials.gov/ct2/show/NCT03334149>

77 Abstract Word Count: 273

78 Keywords: Pregnancy, Gestational Hypertension, Pre-eclampsia, Hypertension, Self-monitoring,

79 Blood Pressure, Telemonitoring, Clinical Trial.

80

81

82

83 INTRODUCTION

84 Raised blood pressure (BP) has been estimated to affect approximately 10% of pregnancies
85 worldwide and 18 million pregnancies worldwide in 2019.^{1,2} In the UK, inadequate management of
86 elevated BP has previously been reported as a significant contributing factor to maternal deaths.
87 Although maternal deaths related to high BP have reduced in the UK in recent years, pre-eclampsia
88 remains important due to its influence on maternal and perinatal outcomes.^{3,4} Individuals who are at
89 higher risk of pre-eclampsia, due to risk factors such as age, high body mass index, or existing
90 medical conditions may require more frequent monitoring.⁵ BP can increase rapidly in pregnancy
91 and hypertension may go undetected in between antenatal visits.⁶

92 Self-monitoring of blood pressure (SMBP), which involves an individual measuring their own BP
93 outside of the clinical setting, is now commonplace and effective at detecting and lowering BP in
94 adults with hypertension outside of pregnancy.⁷⁻⁹ Self-monitoring in pregnancy has been limited to
95 small and mostly non-randomized feasibility studies, often without validated BP monitors.^{10,11} Low
96 quality and heterogeneity limit the conclusions that can be drawn from such studies but initial
97 results suggest reduced morbidity and resource use, acceptability for individuals and their clinicians,
98 and feasibility.¹⁰⁻¹³

99 The Blood Pressure Monitoring in Higher Risk Pregnancy (BUMP1) trial aimed to establish whether
100 SMBP with telemonitoring in addition to usual care could lead to earlier detection of raised clinic BP
101 compared to usual care during higher risk pregnancies.

102

103

104 METHODS

105 *Study design*

106 The trial was an unmasked randomised clinical trial of SMBP in pregnancy for the detection of raised
107 BP. The methods of the trial and its development have been published previously and are
108 summarised below.^{14,15} The protocol and statistical analysis plan are available in Supplement 1 and
109 Supplement 2, respectively. The West Midlands - South Birmingham NHS Research Ethics
110 Committee: ref 17/WM/0241 provided ethical approval. All participants gave written informed
111 consent.

112

113 *Study Population*

114 Pregnant individuals at higher risk of pre-eclampsia were recruited by research midwives through
115 antenatal clinics in 15 secondary care maternity units between 16 and 24 weeks gestation between
116 November 2018 and September 2019. 'Higher risk' was defined by the relevant UK guidance at the
117 time and included one or more of the following risk factors for pregnancy hypertension⁵: age ≥ 40
118 years nulliparity pregnancy interval >10 years, family history pre-eclampsia, previous history pre-
119 eclampsia or gestational hypertension, body mass index ≥ 30 kg/m², chronic kidney disease (any CKD
120 stage), twin pregnancy, pre-pregnancy diabetes, autoimmune disease (for example systemic lupus
121 erythematosus or antiphospholipid syndrome). Individuals with a pre-existing diagnosis of
122 hypertension were excluded.

123 *Randomisation and masking*

124 Eligible individuals were randomised (1:1 ratio) to either usual care or usual care plus SMBP with
125 telemonitoring. The online randomisation sequence was generated by an independent statistician
126 using permuted varying block sizes of 4 or 6 and stratified by recruitment site and parity (0 vs ≥ 1).

127 Both participants and health care professionals were unmasked due to the nature of the
128 intervention.

129

130 *Procedures*

131 *Self-monitoring*

132 Participants randomised to SMBP continued with usual antenatal care and in addition were provided
133 with a validated automated monitor (Microlife WatchBP Home).¹⁶ They were given training and
134 written instructions for BP self-monitoring by the recruiting research midwife, then enrolled on a
135 mobile phone-based telemonitoring system with an optional paper diary.

136 Participants were asked to monitor their BP three times a week, taking two readings, submitting the
137 second to the study App manually. Raised readings triggered a request by the app for a third
138 reading, which if raised led to a request by the app for participants to contact their local maternity
139 unit [eFigure 3]. Initial contact was typically by telephone and subsequent arrangements for review
140 were at the discretion of the unit. BP thresholds were equivalent to clinic, based on pilot work and a
141 systematic review.^{13,17}

142 Each site received training on the trial and intervention from the study team. Clinicians had access to
143 a web-based dashboard and each site was sent a summary of their participants' results each week.
144 The app was designed to include a historic blood pressure data enabling participants to share their
145 results with clinicians via their mobile phone display.

146 Usual prenatal care consisted of pregnant individuals attending antenatal clinic as required (at least
147 seven times during an uncomplicated pregnancy)¹⁸ including having their BP measured by their

148 antenatal care team. They did not have access to the telemonitoring system and such systems were
149 not commonplace in the UK at the time of the study.

150 Protocol Amendments

151 The overall protocol was amended significantly on six occasions during the trial. Two amendments
152 affected the trial: adding the external pilot and then to continue recruitment until the accompanying
153 trial¹⁴ (same intervention in individuals with pregnancy hypertension) had finished recruitment
154 which had the effect of modestly increasing the sample size (from 2262 to 2441).

155 *Outcomes*

156 The primary outcome was difference in the time from randomisation to first recording of 'clinic
157 hypertension' between the randomised groups. Clinic hypertension was defined as sustained BP
158 $\geq 140/90$ mmHg [i.e. either raised systolic (SBP) or diastolic (DBP) blood pressure or both] recorded by
159 a healthcare professional in the clinical record in any setting up to the day before delivery.
160 'Sustained' was defined as at least two raised BP readings within one week (168 hours) with no
161 minimum time between readings, with the second reading date taken as date of diagnosis.⁵ Clinic
162 hypertension was additionally defined when either a recorded diagnosis of pre-eclampsia or
163 gestational hypertension or prescription of antihypertensive medication where those came before
164 recorded clinic hypertension. BP and other clinical data were extracted from the clinical record at
165 the end of each woman's participation in the trial. Prespecified subgroups were: eligible for aspirin
166 prophylaxis; gestational age at recruitment; parity; measuring BP prior to randomisation; deprivation
167 score; ethnicity; educational qualifications.

168 Secondary outcomes were both maternal (severe hypertension (systolic BP ≥ 160 mmHg and/or
169 diastolic BP ≥ 110 mmHg), serious maternal complications, onset of labour) and perinatal (stillbirth
170 and early neonatal death, gestation at delivery, mode of delivery, birth weight (including centiles),

171 small for gestational age (<10th and <3rd centiles), neonatal admissions). Patient reported outcomes
172 (illness perception (0 to 10, minimally clinically important difference [MCID] not available),¹⁹ anxiety
173 ((STAI6, scaled to 100 lowest 0 to highest 100, MCID 10),²⁰ maternal health-related quality of life
174 (EuroQol EQ-5D-5L, -0.594 (worst) to +1 (best), MCID 0.037))²¹ were captured by questionnaires at
175 baseline, 30 weeks gestation and 12 weeks postnatally [See eTable 1 for full list]. In accordance with
176 UK recommendations, self-reported ethnicity was recorded using standard descriptions derived from
177 those used by UK Office for National Statistics.²²

178 Post hoc analyses assessed fidelity of participants in the intervention group to the self-monitoring
179 regime as captured by the App and compared raised BP on self-monitoring to the reference standard
180 of raised BP on clinic measurements.

181 *Sample size*

182 An external pilot phase including 40 participants tested all trial procedures prior to the main trial
183 commencing. A sample size of 2262 (1131 per group) assuming a standard deviation (SD) of 40 days
184 was estimated to allow detection of an effect size of 12 days difference in time to detection of clinic
185 hypertension in pregnancy between self-monitoring and control groups, with 90% power, 5% level of
186 significance (2-sided) and assuming a 15% attrition rate. The sample size was determined via
187 simulation, using a bootstrapping method with replacement with parameters derived from pilot
188 work.¹³ Of the planned 2262 participants, 362 (16%) were expected to develop hypertension. A
189 statistical analysis plan was agreed prior to data lock (Supplement 2).

190 *Statistical analysis*

191 The primary analysis included all participants for whom data were available, according to the group
192 participants were randomly allocated to regardless of any subsequent deviation from protocol. The
193 primary outcome was analysed using a two-part “hurdle” model²³: first the model determined

194 whether the participants had a diagnosis of clinic hypertension using a probit model, assuming an
195 underlying latent distribution for the probability of having clinic hypertension. The second part
196 determined the time between randomisation and clinic hypertension conditional on having cleared
197 the hurdle. The pre-specified model adjusted for group, parity (0 or ≥ 1) as fixed effects, and site as
198 random effect. However, because the model would not converge, site was subsequently fitted as a
199 fixed effect. Sensitivity analyses included adjusting for baseline covariates that predicted
200 missingness, multiple imputation (100 imputations) of missing values, and including only raised BP
201 based on BP values (i.e. not clinical diagnoses or antihypertensive prescription). Prespecified
202 subgroups were investigated through fitting a subgroup by randomised group interaction term in the
203 model. Treatment effects of each subgroup and a test of interaction were obtained from the model.

204 Continuous secondary outcomes, such as birthweight and length of stay, were analysed by means of
205 regression method, adjusting for stratification factors. Binary secondary outcomes were analysed by
206 means of a log binomial model. Because of the potential for type I error due to multiple
207 comparisons, findings for analyses of secondary endpoints should be interpreted as exploratory.

208 Post hoc analyses were undertaken assessing intervention fidelity comparing app use to the protocol
209 of thrice weekly self-monitoring until BP rose to $\geq 135/85$ mmHg when participants were asked to
210 monitor daily until delivery or hypertension diagnosis. Recorded hypertension in clinic or by SMBP
211 was cross tabulated and the time between first raised SMBP and subsequent diagnosis of
212 hypertension assessed using similar methods to the primary outcome analysis (second part).

213 All analyses were performed using STATA SE version 16.1 (StataCorp) using a 5% threshold for
214 significance (2-sided).

215

216

217 RESULTS

218 Of 2458 potentially eligible pregnant individuals, 2441 were randomised to either BP self-monitoring
219 (n=1223, 50.1%) or usual care (n=1218, 49.9%) (in line with the randomisation algorithm) [Figure 1].

220 Four participants subsequently found to be ineligible after randomisation, were immediately
221 withdrawn from the trial and excluded from the analysis.

222 Primary outcome data were available from 2346/2437 participants (96%, 1171 self-monitoring, 1175
223 usual care) [Figure 1]. Baseline characteristics were well matched between groups with similar
224 demographics and risk factors for hypertension and pre-eclampsia [Table1]. Mean age was 33 years
225 old, mean gestation was 20 weeks, 950/2346 (39%) were of parity ≥ 1 , 1399/2346 (59%) had been
226 educated to at least degree level, 1801 (77%) were White British, 253 (11%) Asian or Asian British
227 and 187 (8%) Black or Black British. Mean BP recorded before randomisation was 114/69mmHg and
228 1146 (49%) had one major or two moderate risk factors for pre-eclampsia.⁵ Prior to randomisation,
229 639/2414 (27%) participants reported previously measuring their own BP (305 (25%) intervention
230 and 334 (28%) usual care).

231

232 *Primary Outcome*

233 Clinic hypertension was subsequently recorded for 363 (15.5%) of those randomised, of whom 102
234 (4%) had pre-eclampsia: 179 (15.3%) intervention group and 184 (15.7%) usual care [Table 2]. The
235 primary outcome (time to clinic hypertension defined from the clinical records) was not significantly
236 different between individuals who self-monitored or received usual prenatal care alone (mean 104.3
237 days vs 106.2 days respectively, mean difference -1.6 days (95% confidence interval -8.1, 4.9; p =
238 0.6)) [Table 2]. This was not materially affected by sensitivity analyses including adjustment for
239 missingness, multiple imputation or when clinic hypertension was restricted to evidence of raised
240 professionally recorded BP only (i.e. recorded diagnosis of gestational hypertension or prescription

241 of anti-hypertensive medications alone was excluded) [eTable 2 in Supplement 3]. The primary
242 outcome was not significantly different between randomised groups in most pre-specified
243 subgroups including aspirin eligibility, gestational age at recruitment, parity, previous experience of
244 self-monitoring, deprivation score, educational qualifications [eTable 3 and eFigure 1 and 2 in
245 Supplement 3]. There was a significant interaction for ethnicity but both individual group results
246 crossed unity.

247

248 *Secondary Outcomes*

249 *Maternal outcomes*

250 There was no statistically significant difference in the incidence of severe hypertension or in the
251 incidence of pre-eclampsia between the groups [Table 3].

252 The incidence of serious maternal complications was 15/1209 (1.2%) of those in the self-monitoring
253 group and 19/1209 (1.6%) of those receiving usual care; the pre-specified threshold of sufficient
254 events to undertake a formal statistical comparison was not met (2% or more) [Table 3]. No
255 participants in either group died.

256 There was no significant difference in the proportion with spontaneous onset of labour (482/1187,
257 41% self-monitoring vs 493/1181, 42% usual care; adjusted relative risk 0.97 (0.9, 1.1). Indications
258 for induction or pre-labour caesarean section are presented in eTable 4.

259 Anxiety (STAI6),²⁰ was not significantly different between groups at either 30 weeks' gestation or
260 postnatally [eTable 6 in Supplement 3]. Individuals in the self-monitoring group had significantly
261 improved scores on the modified brief Illness Perception Questionnaire at both 30 weeks and
262 postnatally [eTable 7 in Supplement 3].¹⁹ Participants' health-related quality of life based on index
263 scores derived from the EQ-5D-5L descriptive system²¹ was not significantly different between
264 groups at 30 weeks or at postnatal follow-up [eTable 8 in Supplement 3].

265

266 *Perinatal Outcomes*

267 The proportions of stillbirths and early neonatal deaths in both groups were not formally compared
268 due to low rates of occurrence. [Table 3]. Mean birthweight was 3247g in the self-monitoring group
269 and 3264g for usual care. Small for gestational age infant birthweight (<10th centile) was present in
270 104/1249 (8.3%) self-monitoring vs 87/1235 (7.0%) usual care; adjusted relative risk 1.2 (0.9, 1.5)
271 Median gestation at delivery was not different between groups (39 weeks) [Table 3]. There were no
272 significant differences in the proportions of either randomised groups that were admitted to a
273 neonatal unit or for subsequent length of stay [Table 3 and eTable 5]. Spontaneous vaginal delivery
274 occurred for (550 (43.7%) self-monitoring participants vs 527 (42.4%) usual care [eTable 5 in
275 Supplement 3].

276

277 *Adverse events*

278 Eighteen serious adverse events were reported during the trial with none judged as related to the
279 intervention by the supervising site principal investigator: 12 (1%) in the self-monitoring group (2
280 miscarriages 20-23⁺⁶/40, 5 still births, 2 neonatal deaths, 3 terminations for fetal abnormalities) and
281 6 (0.5%) in those receiving usual care (3 still births, 3 terminations due to fetal abnormalities (2) and
282 sepsis (1)).

283

284 *Post hoc outcomes*

285 In a post hoc analysis, fidelity to the intervention by individuals randomised to self-monitoring was
286 explored. Of the 1220 allocated to self-monitoring appropriately, 1198 self-monitored and 22 did
287 not. The vast majority of participants used the app (1196, 99.8%) with 23 (2.2%) also recording some
288 readings in a paper diary and 2 (0.2%) exclusively using a paper diary. Because data in the paper
289 diaries were not directly comparable to that in the App (for example in terms of recording of timing

290 of readings, repeat readings), those readings were excluded from further analysis. Participants
291 followed the protocol of monitoring three times per week until delivery or clinic hypertension 76.7%
292 of the time; if their SMBP rose to $\geq 135/85$ mmHg and they were asked to monitor daily until delivery
293 or hypertension diagnosis, this happened 71.7% of the time.

294 Of the 179 individuals with clinic hypertension in the intervention group, 131 (73%) had self-
295 monitored within a week of that diagnosis and 16 (9%) had no self-monitored readings at all [Table
296 4]. Of these, 109/179 (61%) individuals had a raised SMBP $\geq 140/90$ mmHg on the same day or before
297 the detection of clinic hypertension. The median time between first raised SMBP and a subsequent
298 diagnosis of hypertension was 29 days (interquartile range 7 to 72). Of those with a clinic diagnosis
299 of hypertension, 43/179 (24%) did not have a raised SMBP (indicating likely white coat hypertension)
300 at or before that time [Table 4].

301

302

303 DISCUSSION

304 In this randomized trial, SMBP from 20 weeks' gestation until delivery or development of
305 hypertension, in addition to usual care, did not lead to an earlier diagnosis of clinic hypertension,
306 defined on the basis of routinely recorded clinical data. There were no significant differences in
307 either maternal or perinatal outcomes or of serious adverse events. Of those individuals who self-
308 monitored BP in the trial who received a diagnosis of hypertension, the majority had self-monitored
309 within a week of diagnosis suggesting that these individuals would have had an opportunity to
310 detect hypertension at home.

311 To our knowledge, this was the largest randomised clinical trolled trial of blood pressure self-
312 monitoring in individuals with higher-risk pregnancy published to date and was powered to detect

313 clinically important differences between the groups.²⁴ The pragmatic trial design and broad inclusion
314 criteria make findings applicable to routine antenatal care. Participants randomised had appropriate
315 representation of ethnic minority ethnic groups but there was some evidence of over representation
316 of those with higher educational attainment in the trial overall. Follow-up was high with over 95% of
317 the primary outcome data available.

318 A recent systematic review found two randomised clinical trials involving self-monitoring in
319 antenatal care, one of which used self-monitoring as a screening test¹⁰: one UK-based group
320 randomised 80 low risk pregnant individuals to weekly self-monitoring with reduced routine
321 antenatal clinics and found that for individuals who self-monitored, overall clinic attendance was
322 reduced despite an increase in unscheduled care.²⁵ A French group randomised 57 individuals with
323 pregnancy hypertension without proteinuria between 18-36 weeks to self-monitor BP with or
324 without transmission of the measurements to their supervising clinicians and found no significant
325 difference between groups.²⁶ More recently, a US group randomised 300 low risk pregnant
326 individuals to remote monitoring with reduced clinics vs usual care. The individuals randomised to
327 remote care had reduced obstetric input but more nurse/midwife time was needed for providing
328 remote care.¹¹ Two other subsequent trials were not comparable.^{27 28} Two ongoing self-monitoring
329 trials, one in high risk pregnancies and one with a similar screening strategy to the current study
330 have not reported yet.^{29,30}

331 Self-monitoring of BP outside of pregnancy is already widespread and has a strong evidence
332 base.^{7,8,31} Prior to the current study there were few data regarding the prevalence of SMBP in
333 pregnancy, although the CHIPS study of different BP targets in pregnancy hypertension reported
334 38% of hypertensive pregnant individuals as self-monitoring.³² A survey undertaken in parallel to this
335 trial, but excluding those randomised found that in a sample of around 5500 pregnant individuals,
336 17% of those without hypertension and 49% of those with hypertension were self-monitoring, often
337 without clinician involvement.³³

338 *Limitations*

339 The study has several limitations. First, the trial was powered to detect a 12-day earlier presentation
340 with SMBP compared to clinic-based diagnosis, a difference that was considered to be clinically
341 relevant. Although very small differences cannot be ruled out, self-monitoring did not result in a
342 clinically important or statistically significant earlier presentation of hypertension. Second, the study
343 was not powered to detect differences in clinical outcomes. Third, the home readings for 26% of
344 individuals with a clinic-based primary outcome of hypertension were normal, so that these
345 participants could not have presented earlier on the basis of self-monitoring. Data on prognosis of
346 white coat hypertension remains sparse, particularly as to the relative effect of antihypertensive
347 therapy compared to true hypertension and therefore appropriate management strategies are
348 uncertain.³⁴

349 Fourth, 61% of those with hypertension in the intervention group had elevated home BP prior to or
350 concurrently with clinic BP and for these participants, SMBP rose approximately one month prior to
351 their clinic recorded hypertension. Participants received advice through the app to check such
352 readings with a midwife but there were no data regarding the response of participants and/or
353 clinicians to such readings. Linked qualitative work suggested that clinicians tend to favor clinic
354 readings in the case of discordance, perhaps explaining the observed lack of effect on the primary
355 outcome.³⁵

356 Fifth, 27% of randomised individuals had self-monitored prior to randomisation which might have
357 diluted any effect from the intervention. The study did not collect data regarding whether self-
358 monitoring continued later in pregnancy. However, other research suggests that at least half of
359 these participants may have continued to do self-monitoring without the knowledge of their clinical
360 team.³³ Outside of pregnancy, there is evidence that such monitoring (without clinical support) has
361 little effect on blood pressure.^{8,33}

362 Sixth, the threshold for hypertension diagnosis with SMBP in pregnancy is not established. In the
363 current study, the same BP threshold was used for home and clinic BP (140/90mmHg), although
364 participants were asked to increase the frequency of measurement once their pressure reached
365 135/85mmHg. This choice was made on the basis of a systematic review of BP measurement in
366 different settings, which suggested that self- and clinic monitored BP were equivalent in
367 normotensive pregnant individuals; it was also influenced by concerns from clinicians during the
368 development phase regarding over alerting.^{13,17} A lower threshold for home readings might have led
369 to a different result.

370 *Conclusions*

371 Among pregnant individuals at higher risk of pre-eclampsia, blood pressure self-monitoring with
372 telemonitoring compared with usual care did not lead to significantly earlier clinic-based detection
373 of hypertension.

374

375

376 [Figures and Tables](#)

377 Table 1: Baseline characteristics

378

379 Table 2: Primary Outcome

380

381 Table 3: Maternal and perinatal outcomes

382

383 Table 4: Self-monitoring vs clinic blood pressure for diagnosis of raised blood pressure

384

385 Figure 1: Flow through the trial

386 Eligibility, randomization, and data availability in a trial of self-monitoring for hypertension in
387 pregnant individuals at risk for pre-eclampsia.

388

389 **Supplemental Content**

390 Supplement 1 Trial Protocol

391 Supplement 2 Statistical Analysis Plan

392 Supplement 3 Supplementary tables and figures

393 Supplement 4 The BUMP investigators

394 Supplement 5 Data sharing statement

395

396

397 *Authors' contributions*

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

409

410 *Declaration of interests*

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

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

419

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465 References

- 466 1. Abalos E, Cuesta C, Grosso AL, Chou D, Say L. Global and regional estimates of preeclampsia
467 and eclampsia: a systematic review. *Eur J Obstet Gynecol Reprod Biol.* 2013;170(1):1-7.
- 468 2. Wang W, Xie X, Yuan T, et al. Epidemiological trends of maternal hypertensive disorders of
469 pregnancy at the global, regional, and national levels: a population-based study. *BMC*
470 *pregnancy and childbirth.* 2021;21(1):364.
- 471 3. Cantwell R, Clutton-Brock T, Cooper G, et al. Saving Mothers' Lives: Reviewing maternal
472 deaths to make motherhood safer: 2006-2008. The Eighth Report of the Confidential
473 Enquiries into Maternal Deaths in the United Kingdom. *BJOG : an international journal of*
474 *obstetrics and gynaecology.* 2011;118 Suppl 1:1-203.
- 475 4. Knight MB, K.;Tuffnell, D.;Shakespeare, J.;Kotnis, R.;Kenyon, S.;Kurinczuk, J.J. ;. *Saving Lives,*
476 *Improving Mothers' Care - Lessons learned to inform maternity care from the UK and Ireland*
477 *Confidential Enquiries into Maternal Deaths and Morbidity 2016-18.* Oxford: University of
478 Oxford;2020.
- 479 5. NICE. Hypertension in pregnancy: diagnosis and management (NICE Guideline 107). National
480 Institute for Health and Care Excellence. <https://www.nice.org.uk/guidance/cg107>.
481 Published 2010. Accessed February 8, 2022.
- 482 6. Douglas KA, Redman CW. Eclampsia in the United Kingdom. *BMJ.* 1994;309(6966):1395-
483 1400.
- 484 7. Hodgkinson JA, Lee MM, Milner S, et al. Accuracy of blood-pressure monitors owned by
485 patients with hypertension (ACCU-RATE study): a cross-sectional, observational study in
486 central England. *Br J Gen Pract.* 2020;70(697):e548-e554.
- 487 8. Tucker KL, Sheppard JP, Stevens R, et al. Self-monitoring of blood pressure in hypertension:
488 A systematic review and individual patient data meta-analysis. *PLoS Med.*
489 2017;14(9):e1002389.
- 490 9. Constanti M, Boffa R, Floyd CN, Wierzbicki AS, McManus RJ, Glover M. Options for the
491 diagnosis of high blood pressure in primary care: a systematic review and economic model. *J*
492 *Hum Hypertens.* 2021;35, 455–461
- 493 10. Kalafat E, Benlioglu C, Thilaganathan B, Khalil A. Home blood pressure monitoring in the
494 antenatal and postpartum period: A systematic review meta-analysis. *Pregnancy Hypertens.*
495 2020;19:44-51.
- 496 11. Butler Tobah YS, LeBlanc A, Branda ME, et al. Randomized comparison of a reduced-visit
497 prenatal care model enhanced with remote monitoring. *Am J Obstet Gynecol.*
498 2019;221(6):638 e631-638 e638.
- 499 12. Hinton L, Tucker KL, Greenfield SM, et al. Blood pressure self-monitoring in pregnancy
500 (BuMP) feasibility study; a qualitative analysis of women's experiences of self-monitoring.
501 *BMC pregnancy and childbirth.* 2017;17(1):427.
- 502 13. Tucker KL, Taylor KS, Crawford C, et al. Blood pressure self-monitoring in pregnancy:
503 examining feasibility in a prospective cohort study. *BMC pregnancy and childbirth.*
504 2017;17(1):442.
- 505 14. Dougall G, Franssen M, Tucker KL, et al. Blood pressure monitoring in high-risk pregnancy to
506 improve the detection and monitoring of hypertension (the BUMP 1 and 2 trials): protocol
507 for two linked randomised controlled trials. *BMJ Open.* 2020;10(1):e034593.
- 508 15. Band R, Hinton L, Tucker KL, et al. Intervention planning and modification of the BUMP
509 intervention: a digital intervention for the early detection of raised blood pressure in
510 pregnancy. *Pilot Feasibility Stud.* 2019;5:153.
- 511 16. Chung Y, de Greeff A, Shennan A. Validation and compliance of a home monitoring device in
512 pregnancy: microlife WatchBP home. *Hypertens Pregnancy.* 2009;28(3):348-359.

- 513 17. Tucker KL, Bankhead C, Hodgkinson J, et al. How Do Home and Clinic Blood Pressure
514 Readings Compare in Pregnancy? *Hypertension*. 2018;72(3):686-694.
- 515 18. NICE. Antenatal care for uncomplicated pregnancies (NICE Guideline 62). National Institute
516 for Health and Care Excellence. <https://www.nice.org.uk/guidance/cg62>. Published 2008.
517 Accessed February 8, 2022.
- 518 19. Broadbent E, Petrie KJ, Main J, Weinman J. The brief illness perception questionnaire. *J*
519 *Psychosom Res*. 2006;60(6):631-637.
- 520 20. Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the
521 Spielberger State-Trait Anxiety Inventory (STAI). *BrJ Clin Psychol*. 1992;31 (Pt 3):301-306.
- 522 21. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-
523 level version of EQ-5D (EQ-5D-5L). *Qual Life Res*. 2011;20(10):1727-1736.
- 524 22. Ethnic group, national identity and religion.
525 [https://www.ons.gov.uk/methodology/classificationsandstandards/measuringequality/ethnic](https://www.ons.gov.uk/methodology/classificationsandstandards/measuringequality/ethnicgroupnationalidentityandreligion)
526 [cgroupnationalidentityandreligion](https://www.ons.gov.uk/methodology/classificationsandstandards/measuringequality/ethnicgroupnationalidentityandreligion). Accessed January 28, 2022.
- 527 23. Cragg JG. Some Statistical Models for Limited Dependent Variables with Application to the
528 Demand for Durable Goods. *Econometrica*. 1971;39(5):829-844.
- 529 24. Tran K, Padwal R, Khan N, Wright MD, Chan WS. Home blood pressure monitoring in the
530 diagnosis and treatment of hypertension in pregnancy: a systematic review and meta-
531 analysis. *CMAJ Open*. 2021;9(2):E642-E650.
- 532 25. Ross-McGill H, Hewison J, Hirst J, et al. Antenatal home blood pressure monitoring: a pilot
533 randomised controlled trial. *BJOG : an international journal of obstetrics and gynaecology*.
534 2000;107(2):217-221.
- 535 26. Denolle T, Weber JL, Calvez C, et al. Diagnosis of white coat hypertension in pregnant
536 women with teletransmitted home blood pressure. *Hypertens Pregnancy*. 2008;27(3):305-
537 313.
- 538 27. Pealing LM, Tucker KL, Mackillop LH, et al. A randomised controlled trial of blood pressure
539 self-monitoring in the management of hypertensive pregnancy. OPTIMUM-BP: A feasibility
540 trial. *Pregnancy Hypertens*. 2019;18:141-149.
- 541 28. Holm L, Stucke-Brander T, Wagner S, et al. Automated blood pressure self-measurement
542 station compared to office blood pressure measurement for first trimester screening of pre-
543 eclampsia. *Health Informatics J*. 2019;25(4):1815-1824.
- 544 29. van den Heuvel JFM, Ganzevoort W, De Haan-Jebbink JM, et al. HOspital care versus
545 TELEmonitoring in high-risk pregnancy (HOTEL): study protocol for a multicentre non-
546 inferiority randomised controlled trial. *BMJ Open*. 2019;9(10):e031700.
- 547 30. Lanssens D, Thijs IM, Gyselaers W, consortium PI. Design of the Pregnancy REmote
548 MONitoring II study (PREMOM II): a multicenter, randomized controlled trial of remote
549 monitoring for gestational hypertensive disorders. *BMC pregnancy and childbirth*.
550 2020;20(1):626.
- 551 31. McManus RJ, Mant J, Franssen M, et al. Efficacy of self-monitored blood pressure, with or
552 without telemonitoring, for titration of antihypertensive medication (TASMINH4): an
553 unmasked randomised controlled trial. *Lancet*. 2018;391(10124):949-959.
- 554 32. Magee LA, von Dadelszen P, Rey E, et al. Less-tight versus tight control of hypertension in
555 pregnancy. *N Engl J Med*. 2015;372(5):407-417.
- 556 33. Tucker KL, Hodgkinson J, Wilson HM, et al. Current prevalence of self-monitoring of blood
557 pressure during pregnancy: the BUMP Survey. *J Hypertens*. 2021;39(5):994-1001.
- 558 34. Johnson S, Liu B, Kalafat E, Thilaganathan B, Khalil A. Maternal and Perinatal Outcomes of
559 White Coat Hypertension During Pregnancy: A Systematic Review and Meta-Analysis.
560 *Hypertension*. 2020;76(1):157-166.
- 561 35. Hinton L, Hodgkinson J, Tucker KL, et al. Exploring the potential for introducing home
562 monitoring of blood pressure during pregnancy into maternity care: current views and
563 experiences of staff-a qualitative study. *BMJ Open*. 2020;10(12):e037874.

- 564 36. Exploring the UK's Digital Divide. Office for National Statistics.
565 [https://www.ons.gov.uk/peoplepopulationandcommunity/householdcharacteristics/homein
567 ternetandsocialmediausage/articles/exploringtheuksdigitaldivide/2019-03-04](https://www.ons.gov.uk/peoplepopulationandcommunity/householdcharacteristics/homein
566 ternetandsocialmediausage/articles/exploringtheuksdigitaldivide/2019-03-04) Published
568 2019. Updated 04/03/2019. Accessed February 8, 2022.
569 37. van Hout B, Janssen MF, Feng YS, et al. Interim scoring for the EQ-5D-5L: mapping the EQ-
5D-5L to EQ-5D-3L value sets. *Value Health*. 2012;15(5):708-715.

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572 Table 1: baseline characteristics by randomised group

	Self-Monitoring	Usual Care
Characteristic	n=1220 ^a	n=1217 ^a
Age (years)	32.8 (5.7)	33.0 (5.6)
Gestation (weeks) at entry	20.3 (1.6)	20.3 (1.6)
Parity: no previous births	745 (61.1%)	742 (61.0%)
Body mass index (kg/m ²)	26.5 (22.7 to 32.1)	26.1 (22.6 to 32.4)
Index of multiple deprivation quintile ^b	n=1210	n=1211
1 (most deprived)	167 (13.8%)	170 (14.0%)
2	247 (20.4%)	239 (19.7%)
3	228 (18.8%)	258 (21.3%)
4	254 (21.0%)	244 (20.2%)
5 (least deprived)	314 (26.0%)	300 (24.8%)
Ethnicity ^c	n=1211	n=1007
Asian or Asian British	135 (11.1%)	118 (9.8%)
Black or Black British	88 (7.3%)	99 (8.2%)
Chinese	16 (1.3%)	11 (0.9%)
Mixed	55 (4.5%)	41 (3.4%)
Other	30 (2.5%)	24 (2.0%)
White (British, Irish, Other)	887 (73.3%)	914 (75.7%)
Current smoker	57 (4.7%)	59 (4.9%)
Highest education	n=1209	n=1201
Tertiary Education	715 (59.1%)	684 (57.0%)
Professional qualifications, n(%)	122 (10.1%)	120 (10.0%)
A-level or GCSE, n(%)	294 (24.3%)	335 (27.9%)
Vocational qualifications, n(%)	34 (2.8%)	32 (2.7%)
No formal qualifications, n(%)	44 (3.6%)	30 (2.5%)
Risk factors for hypertension		
Body mass index > 30 kg/m ²	444 (46.4%)	417 (34.3%)
Previous hypertensive disorder of pregnancy	199 (16.3%)	220 (18.1%)
Family history of pre-eclampsia	144 (11.8%)	133 (10.9%)
Autoimmune disease ^d	83 (6.8%)	81 (6.7%)
Pre-pregnancy Diabetes (type 1 or 2)	75 (6.2%)	67 (5.5%)
Twin pregnancy	73 (6.0%)	67 (5.5%)
Interval between pregnancies >10 years	34 (2.8%)	36 (3.0%)
Chronic kidney disease (any grade)	9 (0.7%)	14 (1.2%)
Blood pressure ^e	n=1161	n=1162
Mean SBP at entry	113.4 (12.8)	113.9 (12.3)
Mean DBP at entry	68.5 (9.0)	69.0 (9.0)
Health questionnaires	n=1202	n=1194
EQ-5D-5L Index Value ^f	0.88 (0.77 to 1.00)	0.85 (0.77 to 1.00)
	n=1201	n=1191
STAI-6 ^g	22.2 (5.6 to 33.3)	22.2 (5.6 to 33.3)

Self-monitoring prior to trial N, n (%)	n=1209	n=1205
	305 (25%)	334 (28%)

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

574 SBP: systolic blood pressure; DBP diastolic blood pressure.

575 ^a As shown in Figure 1, 1223 (self-monitoring) and 1218 (control) were randomised, however 3
576 intervention and 1 control participant were randomised in error and withdrawn immediately hence
577 data are presented here for the remaining 1220 and 1217 respectively. N as stated unless otherwise
578 specified.

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

582 ^c Ethnicity self-attributed from closed list based on standard UK classification. Mixed included those
583 self-identifying as mixed ethnicity (any combination). Other included any other ethnicity not listed
584 above in which case participants were asked to specify: Self-monitoring: Arab: 4, Japanese: 3, Latin
585 American: 2, Mauritian: 2, Brazilian: 1, Filipino: 1, Iraqi Kurdish: 1, Pacific Islander: 1, Tibetan
586 Burmese Origin: 1, Turkish Kurdish: 1, Vietnamese: 1, Middle Eastern: 1, None stated: 11.

587 Usual care arm: Latin American: 6, Arab: 3, Japanese: 2, Afghan: 1, Brazilian: 1, Filipino: 1, Iranian: 1,
588 Malaysian: 1, South East Asia: 1, South Korean: 1, Vietnamese: 1, None stated: 5.

589 ^d Any autoimmune disease for example systemic lupus erythematosus or antiphospholipid syndrome

590 ^e at last clinic visit prior to randomisation

591 ^f EQ-5D-5L: EuroQol instrument 5 Dimensions 5 levels (index value calculated from 5 domains:
592 mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Value calculated using
593 cross walk tool³⁷ range -0.3-1, higher is better quality of life).

594 ^g STAI: short form of stait-trait anxiety inventory (6 items range 6-24; scaled to be out of 100, higher
595 is more anxious).²⁰

596

597

598 Table 2: Primary outcome: time from randomisation to diagnosis of raised sustained blood pressure

	Self-Monitoring	Usual Care	Estimated effect [95% CI]	P value ^b
Participants with primary outcome data	1171	1175		
Clinic hypertension ^a	179 (15.3%)	184 (15.7%)	0.0% [-3% to 2%] ^c	0.75
Mean time to clinic hypertension (days)	104.3 (32.6) [n=179]	106.2 (32.0) [n=184]	-1.6 [-8.1 to 4.9] ^d	0.64
Median (interquartile range)	109 (90 to 127) [n=179]	115 (90 to 129) [n=184]		

599

600 Data are n (%) or mean (SD).

601 ^a Sustained raised blood pressure defined as two blood pressures $\geq 140/90$ mmHg within 168 hours or a
602 recorded diagnosis of pregnancy hypertension or prescription of an antihypertensive medication, whichever
603 came first.

604 ^b Self-monitoring versus usual care: threshold level of significance $p = 0.05$.

605 ^c Difference in percentage of having raised blood pressure modelled against randomised group, parity, and
606 site.

607 ^d Mean difference in days to clinic hypertension

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612 Table 3 Selected Secondary Maternal and Perinatal Outcomes by Randomised Group ^a

	Self-Monitoring	Usual Care	Adjusted absolute difference (95% CI) ^b	Adjusted risk ratio ^b (95% CI)	P value for treatment effect
MATERNAL					
Severe hypertension	69/1171 (6.0%)	57/1175 (4.9%)	1.09% [-0.94% to 3.12%]	1.22 [0.87 to 1.70]	0.25
Pre-eclampsia (N)	51/1209 (4.2%)	51/1209 (4.2%)	0.01% [-1.84% to 1.85%]	1.00 [0.66 to 1.51]	1.00
One or more serious maternal complications ^c	15/1209 (1.2%)	19/1209 (1.6%)	--	--	--
PERINATAL					
Median Gestation at delivery (IQR)	39.3 (38.1 to 40.4) <i>N=1190</i>	39.3 (38.0 to 40.4) <i>N=1185</i>	0.14 [-0.01 to 0.30] ^d	--	--
Stillbirth	5/1260 (0.4%)	3/1248 (0.2%)	--	--	--
Neonatal death within 7 days	2/1248 (0.2%)	0/1240	--	--	--
Small for gestational age (<10 th centile)	104/1249 (8.3%)	87/1235 (7.0%)	1.10% [-1.09% to 3.29%]	1.15 [0.87 to 1.53]	0.32
Infant admitted to neonatal intensive care	161/1248 (12.9%)	163/1240 (13.1%)	-0.64% [-3.34% to 2.05%]	0.95 [0.77 to 1.17]	0.63

613

614 ^a See tables e3 and e4 in Supplement 3 for additional maternal and perinatal outcomes615 ^b Statistical comparisons completed when >2% event rate: Self-monitoring versus usual care. Log-Poisson generalised linear mixed effects model with
616 robust standard errors adjusted for randomised arm, and parity as fixed effects; and site as a random effect. Level of significance p<0.05

617 ^c one or more from: Eclampsia, transient ischemic attack or stroke, HELLP syndrome (haemolysis, elevated liver enzymes, low platelets), liver involvement
618 (ALT or AST >70 U/L), pulmonary oedema, renal involvement (creatinine ≥ 90 mmol), haematological involvement (platelets $< \times 100^9$ /L).
619 ^d Estimated median difference (95% confidence interval) derived from quantile regression adjusted for randomised arm, parity and site.
620

621

622 Table 4: Self-monitoring vs clinic blood pressure for diagnosis of raised blood pressure

		Raised BP on any home readings ^b		
		Yes	No	Total
Raised BP on any health professional readings ^a	Yes	120	43	163
	No	240	651	891
	Total	360	694	1054

623

624 This table includes all 1054 women randomised to self-monitoring who had both health professional
625 and self-monitored blood pressures recorded

626 163 (15.5%) had clinic hypertension

627 43 (4.1%) had white coat hypertension (raised in clinic but not at home)

628 240 (22.8%) had masked hypertension (raised at home but not in clinic)

629 ^aTwo blood pressures $\geq 140/90$ mmHg from any community or hospital setting within 168 hours or a
630 new prescription of antihypertensive medication for raised blood pressure, whichever came first.

631 ^bFirst recording of $\geq 140/90$ mmHg on home blood pressure device.

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