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Extended Research Article

Optimising the monitoring and management of raised blood pressure including proteinuria testing during pregnancy: the BUMP research programme including 2 RCTs

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Scientific summary

Optimising the monitoring and management of raised blood pressure including proteinuria testing during pregnancy: the BUMP research programme including 2 RCTs

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Scientific summary

Background

Raised blood pressure (BP) affects 10% of pregnancies worldwide, of which around half develop pre-eclampsia, a leading cause of maternal and perinatal morbidity and mortality. Early detection of raised BP and/or proteinuria and subsequent management of pregnancy hypertension is therefore important and could be improved through self-monitoring whilst empowering women and allowing reduced antenatal visits. However, little evidence was available to guide the utilisation of self-monitoring in pregnancy.

Objectives

The overall aim of this programme was to evaluate whether self-monitoring of BP (SMBP) could improve the detection of raised BP during pregnancy, whether it was feasible for use in the titration of antihypertensive medication in pregnancy hypertension and whether women with raised BP in pregnancy could accurately test their urine for proteinuria, a key marker for pre-eclampsia. Linked qualitative and economic components examined patient and professional experiences of self-monitoring and responses to it along with cost-effectiveness within the trial and in the longer term.

Key research questions

WS1: Development

- What are the best self-monitoring interventions to use?
- How can SMBP and urine best integrate into current antenatal care pathways?

WS2: Blood pressure self-monitoring during pregnancy for anti-hypertensive titration

- Is titration of antihypertensive medication during and after pregnancy using self-monitoring feasible?
- What is the participant and professional experience of such monitoring and titration?

WS3: Self-monitoring to improve the detection and management of raised blood pressure in pregnancy

- What is current practice in BP self-monitoring in pregnancy?
- Can BP self-monitoring improve the detection and management of hypertension during pregnancy?
- How is BP self-monitoring in pregnancy implemented in daily life and routine clinical practice?
- Is BP self-monitoring in pregnancy cost-effective?

WS4: Self-monitoring of urinary protein in hypertensive pregnancy

- Can pregnant women with hypertension accurately self-monitor for proteinuria and could this detect pre-eclampsia earlier than usual care?
- Is self-monitoring of urine practical and acceptable to hypertensive pregnant women, their midwives and obstetricians?

WS5: Modelling of the potential long-term costs and consequences

- Is SMBP and protein in hypertensive pregnancy potentially cost-effective and what are the key parameters affecting this?

Methods

WS1: Development

Focus groups and interviews were undertaken with NHS staff (including obstetricians, community and hospital midwives). We worked iteratively with women talking through their experiences of prototypes of the self-monitoring app and trial materials (Band R, Hinton L, Tucker KL, Chappell LC, Crawford C, Franssen M, *et al.* Intervention planning and modification of the BUMP intervention: a digital intervention for the early detection of raised blood pressure in pregnancy. *Pilot Feasibility Stud* 2019;**5**:153. https://doi.org/10.1186/s40814-019-0537-z; Hinton L, Hodgkinson J, Tucker KL, Rozmovits L, Chappell L, Greenfield S, *et al.* Exploring the potential for introducing home monitoring of blood pressure during pregnancy into maternity care: current views and experiences of staff – a qualitative study. *BMJ Open* 2020;**10**:e037874. https://doi.org/10.1136/bmjopen-2020-037874).

WS2: Blood pressure self-monitoring during pregnancy for antihypertensive titration

The OPTIMUM feasibility trial

It was an unmasked randomised controlled trial (RCT) comparing a SMBP versus usual care for the management of pregnancy hypertension. Women with chronic (CH) or gestational hypertension (GH) from four UK centres were randomised (2 : 1) intervention to control. Primary outcomes were recruitment, retention, adherence and persistence with the intervention (Pealing LM, Tucker KL, Mackillop LH, Crawford C, Wilson H, Nickless A, *et al.*; OPTIMUM-BP Investigators. A randomised controlled trial of blood pressure self-monitoring in the management of hypertensive pregnancy. OPTIMUM-BP: a feasibility trial. *Pregnancy Hypertens* 2019;**18**:141–9. https://doi.org/10.1016/j.preghy.2019.09.018).

WS3: Self-monitoring to improve the detection and management of raised blood pressure in pregnancy

3.1 BUMP survey

Pregnant women from antenatal clinics in 16 hospitals in England were invited to complete a survey about SMBP.

3.2.1 The BUMP1 trial (Dougall G, Franssen M, Tucker KL, Yu L-M, Hinton L, Rivero-Arias O, *et al.* Blood pressure monitoring in high-risk pregnancy to improve the detection and monitoring of hypertension (the BUMP 1 and 2 trials): protocol for two linked randomised controlled trials. *BMJ Open* 2020;10:e034593. https://doi.org/10.1136/bmjopen-2019-034593)

It was a multicentre, RCT that recruited pregnant women at higher risk of pre-eclampsia at 20 weeks' gestation. Women were randomised to BP self-monitoring with telemonitoring and usual care or to usual care alone. The primary outcome was time to the first recorded raised BP taken by a healthcare professional (HCP). Trial registration: NCT03334149. Recruitment 2018–9. Final follow-up April 2020.

3.2.2 The BUMP2 trial

It was a multicentre, RCT that recruited women with CH and GH up to 37 weeks' gestation. Women were randomised to BP self-monitoring with telemonitoring and usual care or to usual care alone. The primary maternal outcome was the difference in mean systolic BP recorded by HCPs between study entry and childbirth. Analyses were by intention to treat (ITT) and stratified by CH or GH. Trial registration: NCT03334149. Recruitment 2018–19. Final follow-up May 2020.

3.3 BUMP trials qualitative process evaluation

In-depth interviews were carried out with 39 trial participants and 7 women who declined to take part in the trials to explore their experiences of self-monitoring BP or reasons for choosing not to. Twenty-one HCPs involved in women's care or in the administration of the trial were interviewed. Interviews were purposively sampled from study sites.
A planned ethnographic study was not feasible. Inductive and deductive thematic analysis was carried out on both qualitative data sets. Interviews were analysed using a coding frame that was developed from the research aims and incorporating additional themes that emerged from the data.

3.4 BUMP within-trial economic analyses

National Health Service (NHS) perspectives were used for both within trial cost–consequences analyses. Patient-level resource use data were extracted from clinical notes and costed and women's health-related quality of life was measured during the trials using the EuroQol EQ-5D-5L questionnaire, with responses converted to single index scores. Mean costs and EQ-5D-5L scores were computed and compared between trial arms. Within BUMP2, analyses were conducted separately for CH and GH cohorts.

WS4: Self-monitoring of urinary protein in hypertensive pregnancy

4.1 The UDIP study

It was a diagnostic accuracy study that recruited 345 pregnant women to self-test for urinary protein using visually read dipsticks. The primary reference test was protein–creatinine ratio (PCR) and secondary index tests included testing by antenatal HCPs and an automated colorimetric reader. Primary outcome measures were sensitivity and specificity.

4.2 UDIP qualitative study

In-depth interviews were carried out with 21 pregnant hypertensive or pre-eclamptic women who took part in the UDIP study, and 18 HCPs who had experience working in antenatal care. Five focus group totalling 15 participants were conducted with HCPs.

WS5: Modelling of the potential long-term costs and consequences

With no cost or effect differences observed overall or across pre-specified subgroups in the BUMP1 and BUMP2 trials, the need for long-term cost-effectiveness modelling was negated. Instead, model frameworks to facilitate future exploration of the potential long-term costs and effects of combining SMBP with BP management policies for the prevention of hypertension-related complications, were developed. The models cover the pregnancy pathway and a subsequent ten-year period to capture the risks, costs, and consequences of women developing cardiovascular disease. Model parameters are entered as distributions to enable probabilistic sensitivity analysis, and the frameworks facilitate results being presented for women with differing characteristics and for different intervention effect sizes.

Results

WS1: Development (Band R, Hinton L, Tucker KL, Chappell LC, Crawford C, Franssen M, et al. Intervention planning and modification of the BUMP intervention: a digital intervention for the early detection of raised blood pressure in pregnancy. Pilot Feasibility Stud 2019;5:153. https://doi.org/10.1186/s40814-019-0537-z; Hinton L, Hodgkinson J, Tucker KL, Rozmovits L, Chappell L, Greenfield S, et al. Exploring the potential for introducing home monitoring of blood pressure during pregnancy into maternity care: current views and experiences of staff – a qualitative study. BMJ Open 2020;10:e037874. https://doi.org/10.1136/bmjopen-2020-037874)

Focus groups and interviews were conducted with 147 NHS staff at seven different hospital sites. Areas identified as important included: providing clear patient information and supporting staff in decision-making in the context of discrepant readings. Analyses suggested that SMBP would be welcomed by HCPs, while also highlighting potential barriers. This work and iterative development with pregnant women supported the development of a pragmatic and workable trial with user-friendly materials and app.

WS2: Blood pressure self-monitoring during pregnancy for antihypertensive titration (Pealing LM, Tucker KL, Mackillop LH, Crawford C, Wilson H, Nickless A, et al.; OPTIMUM-BP Investigators. A randomised controlled trial of blood pressure self-monitoring in the management of hypertensive pregnancy. OPTIMUM-BP: a feasibility trial. Pregnancy Hypertens 2019;18:141–9. https://doi.org/10.1016/j.preghy.2019.09.018; Pealing L, Tucker KL, Fletcher B, Lawley E, Chappell LC, McManus RJ, Ziebland S. Perceptions and experiences of blood pressure self-monitoring during hypertensive

pregnancy: a qualitative analysis of women's and clinicians' experiences in the OPTIMUM-BP trial. Pregnancy Hypertens 2022;30:113–23. https://doi.org/10.1016/j.preghy.2022.09.006)

Women from four UK centres were randomised: 158/222 (71%) of those approached agreed, comprising 86 women with CH (55 SMBP, 31 control) and 72 with GH (49 SMBP, 23 control). Outcome data were available from 154 (97%). The median number of days with home BP readings per week was 5.5 [interquartile range (IQR) 3.1–6.5] for those with CH and 6.1 (4.5–6.7) with GH. Participating women persisted with the intervention for 80% time from enrolment until delivery. Recorded clinic and study BPs were similar for both groups.

Interviews showed that the women found SMBP feasible and acceptable and were highly motivated and proactive in their monitoring. They reported greater control and knowledge, which provided reassurance. Most women reported that they responded appropriately for out-of-range readings or symptoms.

WS3: Self-monitoring to improve the detection and management of raised blood pressure in pregnancy

3.1 The BUMP survey (Tucker KL, Hodgkinson J, Wilson HM, Crawford C, Stevens R, Lay-Flurrie S, *et al*. Current prevalence of self-monitoring of blood pressure during pregnancy: the BUMP survey. *J Hypertens* 2021;39:994–1001. https://doi.org/10.1097/HJH.0000000000002734)

Completed surveys were received from 5181/5555 pregnant women (93%). The analysis showed that 983/5181 (19%) were currently SMBP. Around half of those were hypertensive 189/389 (49%) and 794/4792 (17%) were normotensive. However, only 482/983 (49%) of those that monitored their BP reported sharing this information with their obstetric and midwifery team. Comparison to hospital demographic data suggested that respondents were broadly representative.[1]

3.2.1 The BUMP1 trial (Tucker KL, Mort S, Yu LM, Campbell H, Rivero-Arias O, Wilson HM, *et al*.; BUMP Investigators. Effect of self-monitoring of blood pressure on diagnosis of hypertension during higher-risk pregnancy: the BUMP 1 randomized clinical trial. *JAMA* 2022;327:1656–65. https://doi.org/10.1001/jama.2022.4712)

A total of 2441 women were randomised to BP self-monitoring plus usual care or usual care alone (n = 1218). Primary outcome data were available from 2346 (96%) women. Baseline characteristics were similar and 15.5% developed hypertension. Time to detection of clinic hypertension was not significantly different between groups: −1.6 days [95% confidence interval (CI) −8.1 to 4.9, p = 0.6]. There was no significant difference in the incidence of severe clinic hypertension [adjusted relative risk 1.2 (0.9 to 1.7), p = 0.3], in maternal and fetal outcomes, or serious adverse events. Most women who developed high BP had self-monitored their BP within a week of diagnosis (73%), and half had raised home BP readings prior to a clinic diagnosis.

3.2.2 The BUMP2 trial (Chappell LC, Tucker KL, Galal U, Yu L-M, Campbell H, Rivero-Arias O, *et al*.; BUMP 2 investigators. Effect of self-monitoring of blood pressure on blood pressure control in pregnant individuals with chronic or gestational hypertension: the BUMP 2 randomized clinical trial. *JAMA* 2022;327:1666–78. https://doi.org/10.1001/jama.2022.4726)

Eight hundred and fifty pregnant women (454 with CH, 396 with GH) were enrolled into the BUMP2 trial: 430 were randomly allocated to BP self-monitoring (primary outcome available on 416 (96.7%) women) and 420 women to usual care (primary outcome available on 405 (96.4%) women). There was no evidence of difference in the mean systolic BP in those allocated to BP self-monitoring, in either the CH cohort [mean standard deviation (SD) systolic BP: 133.8 (10.3) mmHg in the self-monitoring group compared to 133.6 (11.1) mmHg in those with usual care (adjusted mean difference 0.03; 95% CI −1.73 to 1.79)] or the GH cohort [mean (SD) systolic BP: 137.6 (12.1) mmHg compared to 137.2 (10.8) mmHg in those with usual care (adjusted mean difference −0.03; 95% CI −2.29 to 2.24)].

3.3 Qualitative process evaluation (Chisholm A, Tucker KL, Crawford C, Green M, Greenfield S, Hodgkinson J, *et al*. Self-monitoring blood pressure in pregnancy: evaluation of health professional experiences of the BUMP trials. *BMC Pregnancy Childbirth* 2024;35:88–95.https://doi.org/10.1016/j.preghy.2024.01.134)

The majority of trial participants interviewed had positive experiences of self-monitoring, reporting it was reassuring, acceptable, convenient and sometimes led to the earlier detection of hypertension. Having their own series of BP

readings could feel empowering but also introduced some uncertainty and new responsibility. Some women described delayed or selective reporting of high BP readings. Some women preferred not to self-monitor due to concerns about anxiety, fears of preoccupation with monitoring, low perceived risk of hypertension, or choosing to have an HCP present for BP measurement.

Women's accounts demonstrated that HCP engagement with BP self-monitoring varied.

Healthcare professionals largely trusted home readings from the validated monitors used. Most said such measurements positively affected their clinical encounters and professional roles, amplifying the information on which to base decisions and enriching their relationships with women. Some felt SMBP gave women new responsibilities that required additional support from HCPs.

3.4 BUMP within-trial economic analyses(Campbell HE, Chappell LC, McManus RJ, Tucker KL, Crawford C, Green M, Rivero-Arias O. Detection and control of pregnancy hypertension using self-monitoring of blood pressure with automated telemonitoring: cost analyses of the BUMP randomized trials. *Hypertension* 2024;81:887–96. https://doi.org/10.1161/HYPERTENSIONAHA.123.22059)

In BUMP1 and BUMP2, there were no significant differences between trial arms in EuroQol EQ-5D-5L scores at any time points. In both analyses, healthcare contacts and costs were also similar across resource use categories in each trial arm. In BUMP1, mean (standard error) total healthcare costs with SMBP and with usual care were £7200 (£323) and £7063 (£245) respectively, mean difference (95% CI), £151 (–£633 to £936). For the BUMP 2 chronic hypertension cohort, corresponding figures were £13,384 (£1230), £12,614 (£1081), and £323 (–£2904 to £3549) and for the gestational hypertension cohort were £11,456 (£901), £11,145 (£959), and £41 (–£2486 to £2567).

WS4: Self-monitoring of urinary protein in hypertensive pregnancy

WS4.1 UDIP (Jakubowski BE, Stevens R, Wilson H, Lavallee L, Brittain L, Crawford C, *et al*. Cross-sectional diagnostic accuracy study of self-testing for proteinuria during hypertensive pregnancies: the UDIP study. *BJOG* 2022;129:2142–8. https://doi.org/10.1111/1471-0528.17180)

Hypertensive pregnant women were recruited: 335/345 (97%) had sufficient data to be included in the analysis of whom 118 (35.2%) had a positive PCR. Self-testing had a sensitivity of 0.71 [95% CI 0.62 to 0.79] and a specificity of 0.89 [95% CI 0.84 to 0.92] compared to PCR. Sensitivity and specificity of testing by HCPs and the colorimetric reader were similar: sensitivity 0.73 (95% CI 0.64 to 0.80) and 0.78 (95% CI 0.69 to 0.85) respectively; specificity 0.88 (95% CI 0.82 to 0.92) and 0.83 (95% CI 0.78 to 0.88) respectively.

WS4.2 UDIP qualitative

Associated qualitative work found that self-testing was acceptable to pregnant women and HCPs, and could provide an opportunity for pregnant women to be more involved in their care.

WS5: Modelling of the potential long-term costs and consequences

The model frameworks developed provide a facility for exploration of the potential cost-effectiveness of future SMBP-guided interventions for different cohorts of women affected by pregnancy hypertension and for differing levels of intervention effectiveness.

We present no definitive cost-effectiveness results, instead running a series of hypothetical scenarios to illustrate the capabilities of the models. For example, simulating a hypothetical scenario in which a new SMBP-guided intervention could reduce the risk of a pregnant women developing pre-eclampsia by 10%, the modelling suggested that long-term cost-effectiveness could potentially vary between hypertensive pregnant women and women at risk of pregnancy hypertension. This is because hypertensive women face a greater likelihood of developing associated complications both during and following pregnancy, in turn suggesting a greater absolute level of benefit from a 10% reduction in complications via the mechanism of better BP control. Such hypotheses would of course require empirical testing in practice.

Conclusions

WS1: Development

The BUMP intervention was developed and user tested for implementation in higher risk and hypertensive pregnant women in the BUMP trials.

WS2: Blood pressure self-monitoring during pregnancy for antihypertensives titration – pilot trial

This randomised feasibility trial of BP self-monitoring during hypertensive pregnancy indicated that a large RCT would be acceptable and feasible.

WS3: Self-monitoring to improve the detection and management of raised blood pressure in pregnancy

WS3.1: BUMP survey

Healthcare professionals should be aware that many women are choosing to self-monitor their BP. They are advised to enquire about this proactively and consider providing information on BP monitoring in pregnancy.

WS3.2.1: BUMP1 trial

Self-monitoring of BP during higher risk pregnancy appears to be safe. However, it did not improve the detection of hypertension when used alongside usual care. Self-monitoring did provide prior notice of hypertension in many women suggesting it could be useful. Not all women will want to self-monitor meaning that an individualised approach will be needed. Further work is needed to assess the place of SMBP, for example, in remote consultations or alongside self-management.

WS3.2.2: BUMP2 trial

Blood pressure self-monitoring in pregnancy hypertension was not associated with a change in BP control, as assessed by clinic systolic BP, but appears to be safe, without evidence of harm or unintended deleterious effects on pregnancy outcomes. Not all women will want to self-monitor meaning that an individualised approach will be needed. Furthermore, the addition of further components of self-management may be required in order to achieve improvements in BP control and other pregnancy outcomes.

WS3.3: Process evaluation

The majority of women and HCPs involved in the trial found SMBP enhanced their experiences of the clinical encounter and the HCP–woman relationship. However, not all women found self-care helpful. Furthermore, selective or delayed reporting of raised readings, along with the pursuit of normal readings, and HCPs' variable engagement with home readings could have impacted the performance of the BUMP intervention. SMBP by women in the usual care arm may have affected evidence for the intervention's effectiveness in identifying or managing hypertension.

WS3.4: Economic analysis

The SMBP intervention as evaluated in the BUMP trials was not associated with changes in health-related quality of life or healthcare resource use or with, pregnancy hypertension. When coupled with findings that SMBP is both safe and acceptable to individuals, this is reassuring for healthcare providers upon whom the recent coronavirus pandemic forced a rapid, widespread and unplanned roll out of this technology.

WS4: Self-monitoring of urinary protein in hypertensive pregnancy

Pregnant women visually read a dipstick for urinary protein with similar accuracy to antenatal HCPs (4.1). Self-testing, including a potential home testing regime, was acceptable to both HCPs and pregnant women (4.2). Self-testing therefore opens the possibility to monitor or screen for proteinuria with similar accuracy, but greater frequency, at home than through health service appointments.

WS5: Modelling of the potential long-term costs and consequences

Model frameworks have been developed to explore the potential cost-effectiveness of future interventions that work to act upon SMBP readings and improve the detection and management of hypertension in pregnancy.

Recommendations for research

Future research should:

1. Evaluate the feasibility, effectiveness and cost-effectiveness of novel interventions with self-monitoring within clinical pathways which act on raised self-monitored BP in women at risk of hypertension in pregnancy.
2. Evaluate the effectiveness and cost-effectiveness of self-monitored BP plus novel interventions designed to result in professional action in the light of raised self-monitored BP readings in hypertensive pregnant women.
3. Assess the impact of combining SMBP with self-testing of proteinuria as part of an intervention to detect worsening hypertension and/or proteinuria in women at risk of pre-eclampsia.
4. Examine the prevalence of white coat hypertension in pregnancy and its effect on outcomes, specifically whether women with normal home BP can be safely managed on their home pressures.
5. Explore how home readings alter professional roles and how they could be used within a shared decision-making model,
6. Explore the views of women and HCPs on using self-monitoring to replace some elements of usual care.
7. Explore how self-monitoring can support positive changes in the relationships between pregnant women and their HCPs.
8. Assess educational and support needs for women around hypertension in pregnancy.

Study registration

This study is registered as Current Controlled Trials ISRCTN16018898.

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