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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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Abstract

Background: Raised blood pressure affects 10% of pregnancies worldwide, of which around half develop pre-eclampsia including proteinuria, causing maternal and perinatal morbidity and mortality.

Objectives: To develop and test interventions for self-monitoring of blood pressure designed to improve the detection and management of hypertension in pregnancy. Additionally, to test the accuracy of self-testing of urine for protein, a key marker of pre-eclampsia.

Design and methods: Development phase, a pilot trial, two large randomised controlled trials of self-monitoring of blood pressure interventions with integrated economic evaluations, linked qualitative work, a large survey and a diagnostic accuracy study of self-testing for proteinuria, and finally economic modelling.

Setting and participants: Antenatal clinics in 16 English hospitals. Participants were pregnant women and antenatal healthcare professionals.

Patient and public involvement: Comprehensive involvement from initial development through to dissemination, with collaboration from both individuals and relevant charities and organisations.

Interventions: Self-monitoring of blood pressure supported by app to improve the detection (BUMP1) and management (BUMP2) of raised blood pressure in pregnancy (WS3.2.1 and 2). Proteinuria self-testing by pregnant hypertensive women (UDIP, WS4).

Main outcome measures: Qualitative data informed the development of the BUMP App and trial (WS1). Feasibility of self-monitoring of blood pressure in hypertensive pregnancy (recruitment, retention, adherence and intervention persistence) (WS2). Prevalence of self-monitoring of blood pressure during pregnancy (WS3.1). Time to diagnosis of hypertension defined in routinely recorded clinical data (BUMP1, WS3.2.1) and difference in mean systolic blood pressure recorded by healthcare professionals between randomisation and birth (BUMP2, WS3.2.2). WS3.3 and 4.2 evaluated experiences with the trial and UDIP respectively using inductive and deductive thematic analysis. Within-trial cost–consequence analysis and long-term cost-effectiveness modelling (WS3.4 and WS5). Proteinuria testing accuracy (WS4.1).

Results: *WS1*: Areas important to staff included providing clear patient information and supporting them in decision-making in the context of discrepant readings. The intervention was optimised iteratively with pregnant women.

WS2: A feasibility trial showed that the self-monitoring of blood pressure intervention was feasible and acceptable.

WS3.1: Data from a survey of 5181 women showed that 19% of pregnant women were currently self-monitoring blood pressure but only 482/983 (49%) shared this information with healthcare professionals.

WS3.2.1: Self-monitoring of blood pressure in addition to usual care did not lead to an earlier diagnosis of clinic hypertension in routinely recorded clinical data with no evidence of differences in maternal or perinatal outcomes or serious adverse events (BUMP1).

WS3.2.2: Self-monitoring of blood pressure in pregnancy hypertension did not improve clinic blood pressure control, with no difference in maternal or perinatal outcomes or serious adverse events (BUMP2).

WS3.3: Self-monitoring was generally accepted by women and professionals with differences in views of which blood pressure data to give precedence. Women found self-monitoring empowering, provided health professionals considered home readings in their management. On occasion self-monitoring proved unsettling due to uncertainty.

WS3.4: Within trial economic analyses revealed no significant difference in overall total costs between trial arms in either BUMP1 or BUMP2. Women's health-related quality of life (EQ-5D-5L) was similar between groups in both trials.

WS4: Self-testing for proteinuria had a sensitivity of 0.71 (95% confidence interval 0.62 to 0.79) and a specificity of 0.89 (95% confidence interval 0.84 to 0.92) compared to laboratory protein–creatinine ratio testing and this was not clinically or statistically different when compared to healthcare professionals or a colorimetric monitor (UDIP, WS4.1). Self-testing was generally acceptable (WS4.2).

WS5: Model frameworks capable of facilitating exploration of the long-term cost-effectiveness of combining self-monitoring of blood pressure with blood pressure treatment and management policies were developed for use in future research projects in the area.

Implementation: Self-monitoring was rapidly and widely implemented during the pandemic but has yet to become fully embedded in clinical pathways.

Limitations: Self-monitoring of blood pressure by women in the control groups; difficulties in testing self-monitoring of blood pressure in clinical pathways in the absence of evidence or accepted treatment thresholds; process evaluation suggested women and professionals privileged different information.

Conclusions: Self-monitoring of blood pressure during higher risk or hypertensive pregnancy was feasible, acceptable, safe, and no more expensive, but did not improve the detection of hypertension or blood pressure control in those with hypertension when used alongside usual care. During the programme, self-monitoring of blood pressure entered common practice in pregnancy, a process accelerated by the pandemic. Pregnant women can read a dipstick for urinary protein with similar accuracy to healthcare professionals or colorimetric testing, and find this acceptable, suggesting that self-testing could be included in clinical pathways.

Future work: Future trials of interventions including self-monitoring of blood pressure should test strategies in the context of novel clinical pathways.

Study registration: This study is registered as Current Controlled Trials ISRCTN16018898.

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Contents

Glossary

Chronic or essential hypertension Hypertension predating pregnancy or presenting before 20 weeks without pre-eclampsia.

Gestational hypertension Hypertension presenting in pregnancy at 20 weeks or later without pre-eclampsia.

Hypertension Sustained high blood pressure measured by a professional ≥ 140 mmHg and/or 90 mmHg, or a clinical label of hypertension accompanied by antihypertensive treatment.

Pre-eclampsia Hypertension plus proteinuria and/or multiorgan changes (ISSHP definition).

Proteinuria Protein in the urine.

Raised blood pressure Blood pressure measured by a professional ≥ 140 mmHg and/or 90 mmHg.

White coat hypertension Where blood pressure measured in a clinic setting is raised but when measured at home or on ambulatory monitoring, it is normal.

List of abbreviations

APEC	action on pre-eclampsia
BP	blood pressure
CH	chronic hypertension
CLAHRC	Collaborations for Leadership and Applied Health Research and Care
GH	gestational hypertension
GP	general practitioner
HCP	healthcare professional
IQR	interquartile range
ISSHP	International Society for the Study of Hypertension in Pregnancy
ITT	intention to treat
PCR	protein–creatinine ratio
PPI	patient and public involvement
QALYs	quality-adjusted life-years
RCT	randomised controlled trial
SMBP	self-monitoring of blood pressure
UDIP	diagnostic accuracy study of self-testing for proteinuria during hypertensive pregnancies
WS	workstream

Plain language summary

Background and aims

Home monitoring of blood pressure supports the management of raised blood pressure (hypertension) in the general population, but little was known about its use in pregnancy. Similarly, little was known regarding self-testing for protein in the urine, a marker of pre-eclampsia which is a serious condition linked to hypertension in pregnancy.

The BUMP programme aimed to develop and test blood pressure home monitoring and protein self-testing to see if these could improve the detection of raised blood pressure and/or proteinuria and management of hypertension in pregnancy.

Findings

Focus groups and interviews with healthcare professionals and development work (designing the intervention) with pregnant women supported the development of a user-friendly app, trial design and materials.

A survey identified that one in five of pregnant women currently home monitor blood pressure, increasing to half of those with hypertension, though did not share these readings with healthcare professionals.

The BUMP trials recruited more than 3000 women at higher risk of pre-eclampsia, or those with raised blood pressure. Participating women were randomly allocated to either usual care or usual care plus self-monitoring of blood pressure.

Home monitoring of blood pressure did not result in earlier recording of hypertension in clinic. Over half of the women diagnosed with hypertension had raised blood pressure at home. For women with high blood pressure, home monitoring did not improve blood pressure control. Home monitoring of blood pressure was safe and engagement was high, with the majority of women continuing home monitoring throughout pregnancy. No differences in costs or quality of life were found.

Pregnant women self-tested for urinary protein with similar accuracy to healthcare professionals and were happy to test finding it, convenient and reassuring. Staff found home readings valuable, although some were less willing to incorporate them into antenatal care.

Conclusions

Home monitoring of blood pressure during higher risk or hypertensive pregnancy was acceptable, safe, and no more expensive than usual care alone but it did not improve the detection of hypertension or blood pressure control in those with hypertension when used alongside usual care. Self-testing of urine for protein could support remote care of hypertensive women.

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.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research programme (NIHR award ref: RP-PG-0614-20005) and is published in full in *Programme Grants for Applied Research*; Vol. 14, No. 3. See the NIHR Funding and Awards website for further award information.

Research summary

The programme consisted of five workstreams (WSs). Due to additional funding via NIHR Professorships, WS3 was completed prior to WS2 and is therefore reported in order for continuity reasons (and the original numbering has been reversed).

The key research questions were

WS1: Development

- What are the best self-monitoring interventions to use?
- How can self-monitoring of BP (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

- WS3.1: What is current practice in BP self-monitoring in pregnancy?
- WS3.2.1 and WS3.2.2: Can BP self-monitoring improve the detection and management of hypertension during pregnancy?
- WS3.3: How is BP self-monitoring in pregnancy implemented in daily life and routine clinical practice?
- WS3.4 Is BP self-monitoring in pregnancy cost-effective?

WS4: Self-monitoring of urinary protein in hypertensive pregnancy

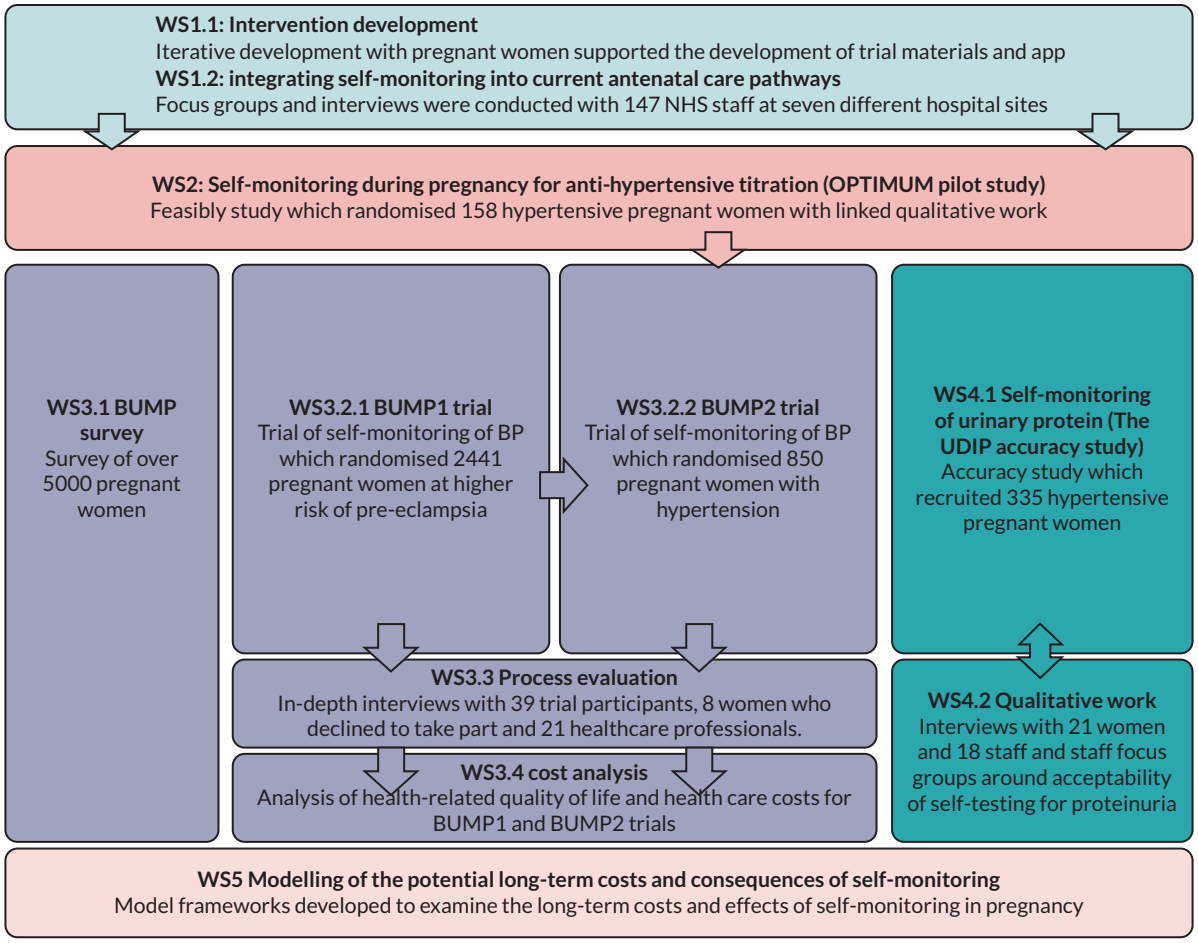
- WS4.1: Can pregnant women with hypertension accurately self-monitor for proteinuria and could this detect pre-eclampsia earlier than usual care?
- WS4.2: Is self-monitoring of urine practical and acceptable to hypertensive pregnant women, their midwives and obstetricians?

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

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

Synopsis

The programme was composed of five WSs which are described below:



This programme of work concerned the management raised blood pressure (BP) in pregnancy, along with the detection of proteinuria, specifically investigation the role of self-monitoring of both BP and proteinuria. It was arranged in five WSs as outlined in the diagram. Overall, it aimed 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. 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.

The first WS concerned intervention development building on our previous NIHR-funded work in the BUMP pilot study and the TASMINH series of trials.

WS1: Intervention development[1,2]

Introduction

Raised BP is a common problem in pregnancy. Our pilot work suggested that, with support from midwives and doctors, it is possible for women to monitor BP and urine safely, potentially identifying problems earlier and controlling BP better.

Aim

To develop and fine-tune comprehensive self-monitoring interventions, ensuring they were user-friendly and could be integrated into care pathways.

Methods

Focus groups and interviews with NHS staff (including obstetricians, community and hospital midwives) and 'think aloud interviews' with pregnant women. Patient and public involvement (PPI) representatives contributed to intervention development.

Patient and public involvement

Patient and public involvement co-investigators assisted in study design, interpretation of results and dissemination.

Results

Focus groups and interviews were conducted with 144 NHS staff (obstetricians, community and hospital midwives, general practitioners, trainees, pharmacists and healthcare assistants) at seven different hospital sites. Analysis suggested that SMBP would be welcomed by staff, while highlighting potential barriers. Feedback from pregnant women identified changes required to make patient-facing materials more motivating and helpful. Training regarding the intervention to deliver at site initiation visits was developed.

Discussion

Qualitative findings informed trial and intervention design to improve acceptability and feasibility for staff and patients.

Recommendations for future research

The impact of SMBP on maternity services could be profound. Future research should explore how it can support positive changes in the relationships between women and their healthcare professionals (HCPs).

There were no changes to study design or analysis.

Publications

Lavallee L, Tucker K and McManus R. Pregnant women are doing it for themselves – self-monitoring of blood pressure in pregnancy. *Br J Midwifery* 2018;**26**. https://doi.org/10.12968/bjom.2018.26.7.451

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 Studies* 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. http://dx.doi.org/10.1136/bmjopen-2020-037874

Presentations

This work was presented at the NIIHR School for Primary Care Showcase in September 2017.

Following on from the intervention development, co-funding from both the NIHR Research Professorship awarded to Prof Richard McManus and from NIHR Oxford Collaborations for Leadership and Applied Health Research and Care (CLAHRC), allowed WS3 in the original application to be brought forward and hence it is presented in reverse order (i.e. as WS2). WS2 as presented here included the OPTIMUM-BP trial which tested the self-monitoring intervention developed in WS1 in women with hypertension in pregnancy, both de novo (GH) and those with long-term hypertension (CH).

WS2: A randomised controlled trial of blood pressure self-monitoring in the management of hypertensive pregnancy. OPTIMUM-BP[3,4]

Aim

To test the feasibility of SMBP to guide the management of hypertensive pregnancy.

Methods

OPTIMUM-BP was an unmasked RCT comparing a SMBP intervention 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. Self-monitoring involved daily home BP measurements, with recording via study diary or telemonitoring.

Patient and public involvement

PPI support was provided by women with a history of pregnancy hypertension who advised on trial materials and intervention.

Main outcomes

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

Results

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

Qualitative findings

Interviews with hypertensive pregnant women taking part in the study found that the women found SMBP feasible and acceptable and were highly motivated and proactive in their monitoring, reporting greater control and knowledge, which provided reassurance. Several women from the control group reported SMBP. Observations in the clinic suggested that self-monitoring worked best within close working relationships and persistence was driven by a perceived need to safeguard the pregnancy. Most women reported that they responded appropriately for out-of-range readings or symptoms.

Conclusions

This was the first randomised investigation of BP self-monitoring for the management of pregnancy hypertension and indicated that a large RCT would be feasible.

Recommendations for future research

An adequately powered trial of self-monitoring in pregnancy hypertension for the control of BP is feasible and should be undertaken (see below).

Changes to the study design

Through additional funding from the Oxford CLAHRC and an NIHR Professorship, this study completed earlier than initially planned which meant to that the substantive trial could also be completed within the programme (WS2.2.2). This was approved by the programme grant panel at the time of the checkpoint report. A planned ethnographic study was not feasible.

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Publications

Pealing LM, Tucker KL, Mackillop LH, Crawford C, Wilson H, Nickless A, *et al*. A randomised controlled trial of blood pressure self-monitoring in the management of hypertensive pregnancy. OPTIMUM-BP: a feasibility trial. *Pregnancy Hypertension* 2019;**18**:141–9. https://doi.org/10.1016/j.preghy.2019.09.018

Bowen L, Pealing L, Tucker KL, McManus RJ and Chappell LC. Adherence with blood pressure self-monitoring in women with pregnancy hypertension, and comparisons to clinic readings: a secondary analysis of OPTIMUM-BP. *Pregnancy Hypertension* 2021;**25**:65–74. https://doi.org/10.1016/j.preghy.2021.05.016

Pealing LM, Tucker KL, Fletcher B, Lawley E, Chappell LC, McManus RJ and Ziebland S. Perceptions and experiences of blood pressure self-monitoring during hypertensive pregnancy: a qualitative analysis of women's experiences in the OPTIMUM-BP trial. *Pregnancy Hypertension* 2022;**30**:1113–23. https://doi.org/10.1016/j.preghy.2022.09.006

Presentations

This work was presented at International Society for the Study of Hypertension in Pregnancy (ISSHP) annual conference in 2018.

WS3 formed the main body of the programme and included the largest survey to date of SMBP in pregnancy, two substantive trials (BUMP1 and 2) and accompanying process evaluation and within trial economic analyses.

The BUMP survey (3.1) aimed to understand SMBP habits in women during pregnancy, both with and without hypertension.

WS3: The BUMP survey, trials and process evaluations

The BUMP survey[5]

Aim
To provide a better understanding of the current prevalence of, and attitudes to, SMBP (BP) during pregnancy.

Methods
Pregnant women from antenatal clinics at 16 hospitals in England were invited to complete a survey about self-monitoring of BP in pregnancy.

Patient and public involvement
PPI representatives supported the development of the survey, interpretation of the results and dissemination.

Outcome measures
The primary outcome was the proportion of women who undertook BP self-monitoring. Secondary outcomes included the self-monitoring schedules and how women interacted with clinicians regarding SMBP. Population characteristics including risk factors for pre-eclampsia, ethnicity and deprivation level were considered.

Results
Overall, 5181 completed surveys were received (93% response rate). Comparison to hospital demographic data indicated that these women were representative of the UK population. Overall, 983/5181 (19%) of women were currently self-monitoring their BP, comprising of hypertensive women 189/389 (49%) and normotensive women 794/4792 (17%). Only around half [482/983 (49%)] of those who self-monitored reported ever sharing this information with their antenatal care team.

Conclusion
Healthcare professionals should be aware that many women are choosing to monitor their BP at home. Professionals should enquire about this proactively and consider providing better support for self-monitoring in pregnancy. Extrapolated nationwide, around 125,000 pregnant women would be currently monitoring their or own BP in the UK, yet only half of these women may communicate their home BP to their obstetric and midwifery care teams.

Recommendations for future research
Trials of interventions in or to detect hypertensive pregnancy should routinely ask about SMBP.

There were no changes to study design or analysis for the BUMP survey.

Publication
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 Hypertension* 2020;**39**:994–1001. https://doi.org/10.1097/hjh.0000000000002734

Presentations
This work was presented at the Action on Pre-eclampsia (APEC) expert meeting in 2020.

The next part of WS2 included two large RCTs [BUMP1 (3.2.1) and BUMP2 (3.2.2)] along with linked qualitative work (3.3) and embedded economic analysis (3.4). The four parts of WS3 are presented consecutively but in reality were undertaken in parallel.

Self-monitoring to improve the detection and management of raised blood pressure in pregnancy (The BUMP1 and BUMP2 RCTs)[6–8]

Changes to study design

Due to additional funding the programme was able to be more ambitious running the planned screening trial (BUMP1) and additionally a properly powered trial of titration of self-monitoring in hypertension in pregnancy (BUMP2). This extension of the initially proposed work was approved by the programme steering group and the NIHR PGfAR team in 2017.

The BUMP1 trial concerned women at risk of hypertension in pregnancy and aimed to assess the place of self-monitoring in the detection of raised BP during pregnancy.

Self-monitoring of blood pressure in women with higher risk pregnancies: the BUMP1 multicentre randomised controlled trial[6]

Background

SMBP in the general adult population supports the diagnosis and management of hypertension.

Aim

To evaluate whether SMBP during higher-risk pregnancy improves the detection of hypertension in pregnancy.

Methods

This multicentre RCT 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 trial was prospectively registered with the clinicaltrials.gov registry, NCT03334149.

Patient and public involvement

Patient and public involvement reps among the co-investigators and drawn from women attending hypertension clinics in Oxford and London assisted in study design, interpretation of results and dissemination.

Outcomes

The primary outcome was time to the first recorded raised BP taken by a HCP.

Results

A total of 2441 women were randomised to BP self-monitoring (n = 1223) or usual care (n = 1218). Primary outcome data were available from 2346 (96%) women. Baseline characteristics were similar and 15.5% developed hypertension. Time to clinical detection of raised BP was not significantly different between groups, giving a difference of −1.6 days (−8.1 to 4.9, p = 0.6). There was no significant difference in the incidence of severe hypertension [adjusted relative risk 1.2 (0.9 to 1.7), p = 0.3], in maternal and fetal outcomes, or in Serious Adverse Events. Most of the women who developed hypertension had self-monitored their BP within a week of diagnosis (73%), and half had raised home BP readings prior to a clinic diagnosis.

Conclusions

Self-monitoring of BP during higher risk pregnancy appears to be safe, but did not change the timing of diagnosis of hypertension when used alongside usual care. Further work is needed to assess the place of SMBP, for example in remote consultations or alongside self-management.

Recommendations for future research

Future research should evaluate co-interventions with self-monitoring within clinical pathways, which act on raised self-monitored BP in women at risk of hypertension in pregnancy. It should also 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 using these BP readings.

The BUMP2 trial included women who had got a diagnosis of hypertension in pregnancy. This included those with pre-existing hypertension (CH) and those who developed it (GH). It considered whether the addition of self-monitoring over and above usual antenatal care improved BP control prior to delivery.

Blood pressure monitoring in pregnant women with hypertension for improving blood pressure control: the BUMP2 randomised controlled trial[7]

Background
The role of BP self-monitoring in pregnancy in improving clinical outcomes for the woman and infant is unclear.

Aim
To evaluate the effect of BP self-monitoring, compared with usual care, on BP control, and other related maternal and infant outcomes, in women with pregnancy hypertension.

Methods
In this parallel-group, non-masked, multicentre, RCT in 15 UK maternity units, BP self-monitoring using a validated monitor and a secure telemonitoring system was compared with usual care, using individual randomisation in women with CH (enrolled up to 37 weeks' gestation) or GH (enrolled between 20 and 37 weeks' gestation or transferring from the BUMP1 trial following development of hypertension). The trial was prospectively registered with the clinicaltrials.gov registry, NCT03334149.

Patient and public involvement
PPI reps among the co-investigators and drawn from women attending hypertension clinics in Oxford and London assisted in study design, interpretation of results and dissemination.

Outcomes
The primary maternal outcome was the difference in mean systolic BP recorded by HCPs between randomisation and birth, between usual care and self-monitoring groups. Analyses were by ITT and stratified by CH or GH.

Results
Between 22 November 2017 and 18 February 2020, 850 pregnant women (454 with CH, 396 with GH) were enrolled into the BUMP2 trial: 430 women 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 (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% confidence interval (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)].

Conclusions
Blood pressure self-monitoring in pregnancy hypertension is 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. Addition of further components of self-management may be required in order to achieve improvements in BP control and other pregnancy outcomes.

Recommendations for future research
Future research should assess the impact of self-monitored BP plus co-interventions designed to result in professional action in the light of raised self-monitored BP on BP control in hypertensive pregnant women.

Publications

Dougall G, Franssen M, Tucker KL, Yu L, 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**:232020. https://doi.org/10.1136/bmjopen-2019-034593

Chappell L, Tucker KL, Galal U, Yu L, Campbell H, Rivero-Arias O, *et al*. Blood pressure monitoring in pregnant women with hypertension for improving blood pressure control (BUMP2): a randomised clinical trial. *JAMA*. 2022;**327**:1666–78. https://doi.org/10.1001/jama.2022.4726

Tucker KL, Mort S, Yu L-M, Campbell H, Rivero-Arias O, Wilson HM, *et al*. Randomised controlled trial of self-monitoring of blood pressure during higher risk pregnancy: the BUMP1 trial. *JAMA* 2022;**327**:1656–65. https://doi.org/10.1001/jama.2022.4712. Erratum in: *JAMA*. 2022;**328**:217.

Presentations

This work was presented at The European Society of Hypertension annual meeting 2021, the Society for Academic Primary Care in 2021, the ISSHP in 2021, the American Heart Association conference; Hypertension 2021 and at the APEC expert day 2021.

Alongside the two trials was an integrated qualitative process evaluation which included both women and their HCPs:

Qualitative process evaluation[9]

Background

The qualitative research in the BUMP trials aimed to understand the experiences and perspectives of women who self-monitored their BP in the BUMP1 and BUMP2 trials, and those of HCPs involved in providing antenatal care to these women and/or in the administration of the trial. It also explored the perspectives of women who declined to participate in the trials.

Methods

In-depth interviews were carried out with 39 trial participants and eight women who declined to take part in the trial to explore their experiences of SMBP or reasons for choosing not to. Twenty-one HCPs were interviewed. 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. Interviews were undertaken by an experienced qualitative researcher and overseen by LH, a senior social scientist. Neither are clinically trained although the emerging analysis and interpretations were discussed with the wider study team who were a mix of research scientists and clinicians.

Patient and public involvement

PPI co-investigators assisted in study design, interpretation of results and dissemination.

Results

The majority of trial participants had positive experiences of SMBP, reporting that self-monitored BP in pregnancy was reassuring, acceptable, convenient and sometimes led to the earlier detection of hypertension. Having a series of BP readings could feel empowering but also introduced some uncertainty and new responsibility. Some women preferred not to self-monitor due to concerns about anxiety management, fears of preoccupation with monitoring, low perceived risk of hypertension, or choosing to have a HCP present for BP measurement. Selective or delayed reporting of raised readings, along with the pursuit of normal 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.

Healthcare professionals largely trusted self-monitored readings from validated BP monitors. Most said self-monitored readings positively affected their clinical encounters and professional roles, adding to the information on which to base decisions and enriching their relationships with women. Some HCPs felt women's responsibility to decide on the timing of monitoring and whether to act on self-monitored readings was burdensome for women, and required additional support from HCPs. Some HCPs would have liked to adjust the thresholds for women with conditions such as renal disease or CH.

Conclusions

The majority of women and HCPs involved in the trial found SMBP enhanced their experiences of the clinical encounter and the HCP–woman relationship. High levels of SMBP in the pregnant population may have made the impacts of the trial intervention difficult to isolate.

Recommendations for future research

Future research could explore how home readings alter professional roles and how they could be used within a shared decision-making model, and the views of women and HCPs on using self-monitoring to replace some elements of usual care.

There were no changes to study design or analysis for the qualitative work linked to the BUMP trials.

Publications

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. *Pregnancy Hypertension* 2024 March 1;**35**:88–95. https://doi.org/10.1016/j.preghy.2024.01.134

Chisholm A, Tucker KL, Crawford C, Green M, Greenfield S, Hodgkinson J, *et al.* (2024) Self-monitoring blood pressure in pregnancy: evaluation of women's experiences of the BUMP trials. *BMC Pregnancy Childbirth* 2024 November 28;**24**:800. https://doi.org/10.1186/s12884-024-06972-4

Presentations

This work was presented at the APEC expert day 2021.

Within trial economic analyses[10]

Background

The BUMP1 and BUMP2 trials were designed with integrated economic evaluations, conducted from an NHS perspective, to assess the costs and consequences of adding SMBP to usual antenatal care.

Methods

In each trial, health-related quality of life was measured at various time points using the EuroQoL EQ-5D-5L questionnaire, with responses converted into single index scores. Clinical notes review identified participant-level data on antenatal contacts, inpatient care during and after delivery, and infant inpatient care. Unit costs from established sources were applied to these data. Mean (SD) costs and EQ-5D-5L scores were computed for each trial arm and comparisons between arms were made using mean differences and 95% CIs. Within BUMP2, analyses were conducted separately for CH and GH cohorts.

Patient and public involvement

PPI co-investigators assisted in study design, interpretation of results and dissemination.

Results

In BUMP1 and BUMP2, there were no significant differences between trial arms in EuroQol EQ-5D-5L scores at any time points. Given the null findings across the other health outcomes in both trials, we did not proceed to the estimation of quality adjusted life-years (QALYs). In both analyses, healthcare contacts and costs were 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 BUMP2 CH cohort, corresponding figures were £13,384 (£1230), £12,614 (£1081) and £323 (–£2904 to £3549) and for the GH cohort were £11,456 (£901), £11,145 (£959) and £41 (–£2486 to £2567).

Conclusions

The SMBP intervention as evaluated in the BUMP trials was not associated with changes in healthcare resource use or costs for individuals at risk of, or with, pregnancy hypertension. When coupled with findings from WS3.2 that SMBP was 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.

There were no changes in study design.

Recommendations for future research

Aligned with WS3.2, future research studies assessing the impact of combining SMBP with co-interventions designed to result in professional action in the light of raised readings, should be designed with economist input to ensure a comprehensive assessment of cost-effectiveness can be made.

Publications

The EQ-5D-5L data collected for the economic analysis were published alongside the trials' clinical and patient reported outcomes – see Self-monitoring of blood pressure in women with higher risk pregnancies: the BUMP1 multicentre randomised controlled trial and Blood pressure monitoring in pregnant women with hypertension for improving blood pressure control: the BUMP2 randomised controlled trial. The analysis of resource use and cost was published separately in the following publication:

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

Presentations

Nil to date.

Alongside the work on SMBP, WS4 concerned self-monitoring of urinary protein. This is important because development of proteinuria during pregnancy alongside hypertension is a sign of pre-eclampsia. Prior to this work, little was known regarding the ability of pregnant women to accurately detect proteinuria and how that compared to health professionals or colorimetric readers in terms of test performance. WS4 comprised a test accuracy study with integrated qualitative work. During the original application process, we were advised to reduce the amount of qualitative work. Co-funding from the Primary Care Research Trust (PCRT) allowed the research associate employed for this WS to undertake a DPhil (PhD) alongside the programme and as part of this to add an additional comparison arm (colorimetric reader used by a health professional) as well as to increase the qualitative work from 5 to 21 women interviewed and from 10 HCP interviews to 18 plus an additional five focus groups.

WS4: Self-monitoring of urinary protein in hypertensive pregnancy

Cross-sectional diagnostic accuracy study of self-testing for proteinuria during hypertensive pregnancies: the UDIP study[11]

Aim

To determine the accuracy of self-testing for proteinuria during pregnancy.

Methods

Diagnostic accuracy study: Pregnant women recruited from antenatal clinics, maternity assessment units, and inpatient wards at three hospital sites, self-tested for urinary protein using visually read dipsticks, samples were then sent for laboratory estimation of the spot protein–creatinine ratio (PCR) (primary reference test). Secondary index tests included testing by antenatal HCPs and an automated colorimetric reader.

Main outcome measures

Sensitivity, specificity, negative predictive value, positive predictive value and likelihood ratios were calculated for self-testing (primary index test) along with HCPs and colorimetric testing compared to the primary reference (PCR ≥ 30 mg/mmol).

Patient and public involvement

Study progress and results were fed back to the PPI representatives on the programme steering committee at regular intervals.

Results

Three hundred and thirty-five out of 345 (97%) had sufficient data to be included in the analysis, of whom 118 had proteinuria by 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.

Conclusion

Pregnant women can visually read a dipstick for urinary protein with similar accuracy to antenatal HCPs. Automated colorimetric testing was not significantly different, in contrast to some previous studies. Self-testing has the potential to form part of a self-monitoring regime in pregnancy.

Recommendations for future research

Self-testing of urine should be evaluated as part of an intervention to detect proteinuria in women at risk of pre-eclampsia.

There were no changes to study design other than to add a third comparator to the reference standard namely use of a colorimetric reader in addition to manual reading by pregnant women and HCPs.

Publication

Jakubowski B, 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

Presentations

This work was presented at the APEC expert day 2021 and at the Royal College of Obstetricians annual academic meeting in 2020.

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The UDIP qualitative study[12]

Background

The qualitative work from the UDIP study aimed to understand HCPs and pregnant women's views of the UDIP study, a potential home-based self-testing regime, and how self-testing could be integrated into antenatal care and pregnant women's lives.

Methods

In-depth interviews were carried out with 21 pregnant women who took part in the UDIP study. An additional 18 interviews were carried out with HCPs, and five focus groups with 15 participants were also conducted with HCPs. Interviews and focus groups were undertaken by a research associate (Bethany Jakubowski), and overseen by Lisa Hinton, a senior social scientist. Neither are clinically trained; however, the analysis and the interpretation of the data were regularly discussed with the wider study team, primarily Lisa Hinton, Katherine Tucker, Richard McManus, Lucy Chappell, as much of this study made up Bethany Jakubowski's DPhil thesis.

Patient and public involvement

Study design and findings were regularly discussed with PPI representatives on the programme steering committee.

Results

The majority of HCPs and pregnant women who took part in this study found self-testing to be an acceptable intervention in antenatal care. Home-based self-testing has the potential to empower patients and give them a chance to be more involved in their care. There were practical barriers to consider for implementation, such as interpreting the dipstick correctly and understanding proteinuria within the wider context of pre-eclampsia. These barriers could be overcome with patient education and training. Further exploration of the potential of a home-based self-testing regime revealed there were other barriers to successful implementation, such as paternalistic attitudes in HCPs and patient anxiety relating to the burden of treatment.

Conclusions

Healthcare professionals and pregnant women who took part in the UDIP study found self-testing to be an acceptable intervention in antenatal care, and home-based self-testing regime has the potential to improve patient involvement in care.

Recommendations for future research

Further qualitative work is needed to explore the lived experience of a home-based self-testing regime, and the potential burden of treatment this creates for patients. Further work is also needed to explore the barriers to integrating self-testing into usual care, and the impact on HCP's workload.

As previously described, the qualitative aspects of the UDIP study were enhanced over and above that commissioned by co-funding from the PCRT allowing additional interviews with both women and health professionals plus additional health professional focus groups. BJ was awarded a DPhil and is now undertaking postdoctoral research in women's health at Kings College London.

Publication

Jakubowski BE, Tucker KL, Lavallee L, Wilson H, Mackillop L, Chappell LC, *et al*. Participatory surveillance and candidacy: a discourse analysis of views on self-testing for proteinuria in pregnancy. *Qual Health Res* 2024;**35**:863–75. https://doi.org/10.1177/10497323241274270

Presentations

This work was presented at the APEC expert day 2021 and at the Royal College of Obstetricians annual academic meeting in 2020.

The final WS was health economic modelling of the impact of SMBP during pregnancy. Originally this included self-monitoring to detect hypertension in pregnancy and was expanded to include self-monitoring in hypertensive pregnancies. Due to a lack of superiority of self-monitoring in WS2.2.1 or 2 in either primary outcome or costs, the modelling in WS5 was adapted to develop model frameworks for use in future research. Specifically, the model frameworks will be used in the NIHR HTA Giant Panda study (NIHR128721, ISRCTN12792616) which is comparing different treatments for pregnancy hypertension.

WS5: Modelling of the potential long-term costs and consequences of novel self-monitoring interventions

Background/aim

To develop model frameworks to allow an exploration of the potential long-term costs and effects of future interventions combining SMBP with targeted BP management policies for the prevention of hypertension-related complications.

Methods

Two model frameworks were constructed; the first focused upon women at risk of developing pregnancy hypertension (as per BUMP1), and the second upon women with existing pregnancy hypertension (as per BUMP2). The model structures were informed by expert clinical opinion and the published literature. Modelled pregnancy pathways included the complications of pregnancy hypertension (e.g. pre-eclampsia and stroke) and key affected pregnancy outcomes. The augmented risks of developing CH and cardiovascular disease following pregnancy hypertension and pre-eclampsia were simulated using a Markov model over a 10-year period. Health outcomes were expressed as quality-adjusted life-years (QALYs).

Event probabilities and associated costs and utility scores were informed by the BUMP trials and the published literature and were entered as distributions to enable probabilistic sensitivity analysis. When run, the models facilitate an estimation of mean costs and maternal QALYs and can be used to generate these estimates for a range of different hypothesised intervention effect sizes and different cohorts of women with varying ages and comorbidities.

Patient and public involvement

PPI representatives amongst the co-investigators and drawn from women attending hypertension clinics in Oxford and London assisted in study design, interpretation of results and dissemination.

Results

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

We present no definitive cost-effectiveness results, but do illustrate the capacity of the frameworks to accept and respond to modifications in parameter values such as the baseline characteristics of women (e.g. risk factors and comorbidities) and to explore intervention treatment effects of varying magnitudes. 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 women with pregnancy hypertension and women at risk of 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

Model frameworks have been developed that can be used to explore the potential long-term cost-effectiveness of future interventions that add novel targeted BP management policies to SMBP during pregnancy.

Changes to study design

The original aim of WP5 was to develop an early economic model to assess the potential long-term costs and consequences of SMBP during pregnancy, however, and given that there were no significant differences in costs and effects overall or for any pre-specified subgroups in either the BUMP1 or BUMP2 trials, we developed two modelling frameworks that can be used to explore potential value for money of any intervention in this area in future research.

Recommendations for future research

Given the implications of pregnancy hypertension for long-term cardiovascular disease risk, and the likelihood that future research will seek to determine whether combining SMBP with interventions that act upon raised home BP readings (e.g. self-titration of medication) can improve the health outcomes of pregnant women, there is likely to be an increased demand for long-term model frameworks such as those presented here. With this mind, future research ought to continue to refine and improve these frameworks, with a particular focus upon using follow-up outcome data from trial participants to validate their predicted long-term outcomes.

Publication

Campbell HE, Chappell LC, McManus RJ, Tucker KL, Rivero-Arias O, for the BUMP Investigators. Frameworks for modelling the potential longer-term costs and consequences of self-monitoring of blood pressure (SMBP) during pregnancy. URL: https://ora.ox.ac.uk/objects/uuid:32a0962d-9b4d-4b7c-81ea-e9235fe0b022 (accessed 8 November 2024).

The following sections detail PPI in the programme, along with reflections and limitations. Finally, the combined conclusions from the programme are summarised before the publications list, acknowledgements and other end pieces.

Patient and public involvement and engagement within the BUMP programme

Aim

Patients and public representatives were involved throughout the programme of work to ensure the trials and studies completed were relevant to and accessible to women and their families.

Methods

Planning the research

Patients and public representatives were involved in the development of this project from the start and had input on every aspect of programme development. The application was developed with women who had lived experience of pre-eclampsia and white coat hypertension and was additionally discussed with patient groups at Oxford and Birmingham. Our PPI representatives helped to write the Plain language summary.

Conducting the research

Two PPI representatives with experience of pre-eclampsia joined all-investigators meetings and a separate representative joined the programme steering group. The research team made efforts to avoid jargon and to develop an inclusive and supportive culture in meetings with open discussion. Meetings always included time to ask our PPI representatives for their views and/or questions to ensure that their voices were heard.

Pregnant women were also consulted via representation in each of the WSs to ensure that each element of the research remained user-focused and relevant. Documents such as patient information sheets, interview topic guides and lay summaries were always checked with PPI representatives before being used and were particularly helpful in making sure materials were understandable.

MG joined the research group as a co-investigator in the first year of the programme in his role as chief executive of 'Action on Pre-eclampsia', the relevant national charity. Action on Pre-eclampsia has supported the research group in many ways, including putting research updates or advertisement for recruitment in their newsletters and including the research team presentations in their midwife training and expert days every year.

Outcomes of patient and public participation

Blood pressure monitoring in pregnancy was initially identified as an important topic by the research group in collaboration with our PPI members and by Mothers in Research Agenda Setting and this supported the original development of this programme of work.

Our intervention development itself and the design of the main trials were supported by our PPI. PPI members had input on all aspects, including recruitment, where they were able to suggest the most suitable timing of approach, locations, and who should approach potential participants. They highlighted what they thought would be important information around hypertension in pregnancy, about taking part in the study, and how this should be presented appropriately and interestingly in information leaflets and advertisements. PPI members tested and commented on patient facing documents to ensure they were appropriate for potential participants and participants.

Our PPI told us about the competing priorities during this time of their lives and that participating women were likely to consider the baby's health a priority (over their own). They told us what information had been lacking for them and what information could support the experience of women and therefore study recruitment and retention. This included

the need for regular contact from the study team throughout their involvement, providing motivation and reassurance it was useful to take part. When preparing patient-facing documents, they supported us by having input on readability, language and what was most likely to be key information.

The continuous support and input from our PPI representatives led to the development of well-accepted interventions and easy-to-access trial and study documents that, in turn supported recruitment and acceptance of the interventions being tested. Working with groups across the UK supported diverse representation and all ethnic groups were well-represented within the research.

Interpreting findings

The involvement with APEC during this programme has supported access to the relevant community of researchers, clinicians and the public. This has been particularly important in raising the profile of the research and dissemination of our findings, including newsletters, web blogs and presentations at the APEC training and Expert days. Our PPI representatives were co-authors on several publications from the programme, particularly having input around readability and interpretation of the findings.

Discussion and conclusions

Working with patient and public representatives has supported the development of user-friendly interventions and studies. This in turn supported recruitment (over and above planned) within the grant. Close links to the relevant charity APEC and close support from their Chief Executive Marcus Green has had a central role in the development, delivery and dissemination of this research programme.

Reflections and critical perspective

Including PPI at every stage of this programme of work has underpinned the successful delivery of research and dissemination. The active inclusion of minority and seldom-heard groups has meant that these results are generalisable. We plan to further develop the breadth of involvement in the future and we will continue to work with APEC and other community groups specific to ensure the ongoing appropriateness of our research to the whole population. Going forward we plan to improve how we assess and record PPI involvement and impact, using tools such as an impact log that will enable us to better report and feedback to our PPI representatives.

Reflections on what was and what was not successful in the programme

This programme has successfully brought together a multidisciplinary group of methodologists and clinicians to deliver the largest ever trials of SMBP in pregnancy along with the largest study of self-testing for proteinuria. All were delivered on time and within budget and in BUMP1 and 2, two trials rather than the originally proposed single trial were completed.

The interventions, carefully developed in our first WS, were acceptable to large numbers of women who maintained adherence throughout. An inclusive and diverse approach to recruitment was used resulting in at least 25% non-White participants, rising to 50% in the CH group of BUMP2.

Qualitative process evaluations, delivered alongside the quantitative work, showed high levels of acceptability from both women and their HCPs for self-testing of all types. They also gave insight into the different privileging of clinic and self-monitored BP by women and their clinicians. Future work may well find self-monitoring easier to include in care pathways as professionals become more used to dealing with the results and this is important in the context of so many women already choosing to self-monitor. Furthermore, it is pleasing that the programme was able to directly inform the rapid roll-out of remote BP monitoring for women at higher risk of pre-eclampsia in April 2020, in light of the pandemic, with a management algorithm directly borrowed from the BUMP trials. One hundred and forty-five maternity units nationally received validated BP monitors from NHS England and the majority implemented their use in daily practice.

Limitations relating to the method or execution of the research

Self-monitoring research brings a number of challenges as well as the potential for success. Compared with other interventions, it is not usually possible to mask participants from the intervention and hence contamination is a potential issue. While clinicians could in theory have had self-monitored BP withheld, this was not felt to be acceptable or ethical when explored in the development work and data from outside pregnancy suggest that self-monitoring alone has little impact. Women clearly expressed views that self-monitoring represented their 'real' BP and this might have led to a reluctance to increase medication in the light of raised clinic readings or even self-titration.

Self-monitoring of blood pressure is now widespread outside of pregnancy and monitors are freely available for purchase at modest cost and are easy to use. Half way through our trials, the extent of ongoing monitoring without the knowledge of health professionals became apparent through the survey work undertaken within the programme but again development work and experience suggested that it would not be appropriate to try to withhold self-monitoring in the control group.

However, clinicians' decisions remained largely driven by clinic measurement and the programme was less successful at ensuring integration of SMBP into practice with clinic readings.

Planned economic modelling was affected by the neutral trial results but the framework developed within the programme will be useful for ongoing work including the HTA Giant Panda trial which several of the BUMP co-investigators are also working on.

Equality and diversity

This programme has successfully recruited a diverse population of women reflecting both the population in this age group (where ethnic minority people make up around 22% of the population) and the increased prevalence of people from ethnic minorities in those suffering from pregnancy hypertension: In BUMP1, 25% of women were from a non-White ethnic group and in BUMP2 the figures were 30% (GH) and 50% (CH). In the linked qualitative work overall, 26% were from a non-White ethnic group overall and in the CH group 46% were from a non-White ethnicity. Similarly in the proteinuria work, 45% of participants were drawn from an ethnic minority population. This was despite not translating our research materials in the light of data that women of child-bearing age in the UK have high levels of English literacy. Furthermore, it should be noted that we did not collect ethnicity data on our patient representatives. In terms of gender, we did not specifically collect data regarding this. We have referred to women in this report and in the published papers for BUMP1 and 2 and UDIP we have in addition referred to pregnant people reflecting emerging guidance in this area. Further study relating to intersectionality and how this might impact self-monitoring in minority ethnic and/or socially deprived populations, and clinical engagement, is warranted.

Impact and learning

This programme has successfully developed and trialled two interventions addressing SMBP in pregnancy both for monitoring women at higher risk and with pregnancy hypertension. We have shown that while such interventions are feasible on a wide scale, they do not lead to earlier diagnosis of hypertension or better BP control. However, self-monitoring in addition to usual care did not increase costs and was not associated with any evidence of harm or unexpected consequences. Most women and HCPs were supportive in qualitative work. Despite good adherence to the interventions, self-monitoring did not change outcomes which perhaps reflects differences between women and their health professionals in the weight they attached to self-monitored BP. This in turn appeared to be due to a lack of evidence of how self-monitored BP should be incorporated into decision making, especially when readings were divergent from those made in the clinic. Such issues are inevitable when doing research in a novel area. The finding that at least a third of all clinic readings in BUMP2 were above 140/90 mmHg, suggests an intervention which could optimise antihypertensive prescribing is still needed.

In terms of self-testing for proteinuria, the UDIP study showed that women could do this as accurately as health professionals and with similar results to the automated readers that are recommended in guidelines but used less commonly in practice. Overall accuracy in the context of a one-off test is probably insufficient, despite this underpinning usual care; however, repeated testing in the home environment would be predicted to overcome this. This suggests that future interventions could combine SMBP with self-testing for proteinuria alongside co-interventions designed to support professional action in the light of such monitoring.

In the meantime, women have voted with their feet and the majority are now self-monitoring in the context of pregnancy hypertension, around half without professional recommendation. The pandemic has led to widespread implementation with NHS England providing 16,000 monitors to maternity units in April 2020. Evaluation of this rapid adoption was outside of this programme but suggests care pathways have already started to change.

Recommendations for future research

The BUMP trials were the first large scale evaluations of the impact of SMBP on the management of women with or at risk of hypertension in pregnancy. Many areas of interest still remain and these are outlined below. A key issue remains integrating novel interventions such as self-monitoring into care pathways during trials.

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.

Implications for practice and any lessons learnt

The emergence of the coronavirus pandemic in early 2020 meant that SMBP and urine were implemented into practice on a much wider scale than anticipated. This was against a background, as shown here, of a significant minority of women already choosing to measure their own BP while pregnant. This programme of work has shown similar results compared to usual care from SMBP either in the detection of hypertension in higher-risk pregnancy or in the control of BP in women with diagnosed hypertension. A large survey demonstrated that many women were already self-monitoring, particularly in the context of hypertension.

Importantly, women accepted self-monitoring for proteinuria and did so with similar accuracy to HCPs or automated readers. This type of self-monitoring therefore creates an opportunity to check for proteinuria with greater frequency than is achieved through appointments with health professionals, potentially leading to early detection with resulting improvements in patient safety.

The pandemic brought about widespread implementation and adoption of self-monitoring of both BP and proteinuria as an infection control mechanism and this has continued in many centres.

Overall, this work does not provide evidence for widespread implementation of SMBP *in preference* to standard clinic monitoring but does suggest that self-monitoring could be safely used as an option for women for whom clinic attendance is not possible. On this basis, since the programme completed, there have been efforts to implement self-monitoring more widely in the NHS. Further work should now assess whether different novel self-monitoring-based interventions could positively affect outcomes.

Additional information

CRediT contribution statement

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Other contributions

Ly-Mee Yu (https://orcid.org/0000-0003-0331-7364): Trial design, Statistical and trial methodology, Statistical analyses, and contribution to manuscript.

Acknowledgements

The BUMP research team

The authors acknowledge colleagues past and present in the wider BUMP research team including Ms Carole Crawford, Dr Marloes Franssen, Dr Greig Dougall, Lazarina Engonidou, Prof. Carl Heneghan (all Nuffield Department of Primary Care, University of Oxford, UK), Mauro Santos, Carmelo Velardo (Institute of Biomedical Engineering, Department of Engineering Science, University of Oxford, UK). Prof. Khalid Khan was an original co-investigator but moved away from Queen Mary University of London during the programme and so stepped down. PPI representatives: Margaret Glogowska, Jacqui Williams and Tricia Carver.

Data-sharing statement

Requests for access to data should be addressed to the corresponding author or to the data custodian (information.guardian@phc.ox.ac.uk). Access to anonymised data may be granted following review.

Ethics statement

Ethical approval was obtained as follows:

Development work (WS1): Ethical approval was given by a sub-committee of the South Central – Oxford C Research Ethics on 06 July 2016 (ref.: 16/SC/036).

OPTIMUM (WS2): The study was approved by the East Midlands – Nottingham 2 Research Ethics Committee (15/EM/0490) on the 28 October 2015.

BUMP survey (WS3.1): Ethical approval was provided by the South West-Cornwall and Plymouth Research Ethics Committee (17/SW/0296) on 15 December 2017.

BUMP trials including process evaluation and health economic data (WS3.2–4): Ethical approval was gained from the West Midlands – South Birmingham NHS Research Ethics Committee: ref. 17/WM/0241.

UDIP accuracy study (WS4): Ethical approval was provided by Yorkshire and the Humber – Leeds East Research Ethics Committee (18/YH/0208).

Information governance statement

The University of Oxford and partners in this research are committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679.

Under the Data Protection legislation, The University of Oxford is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: www.phc.ox.ac.uk/intranet/information-governance

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/KHGB9944.

Primary conflicts of interest: Richard J McManus has received BP monitors for research use from Omron and is working with them to develop a telemonitoring system for use in primary care. He receives no personal payment for this work. Richard J McManus has received funding from an NIHR professorship (NIHR-RP-R2-12-015) and the NIHR CLAHRC now recommissioned as NIHR Applied Research Collaboration Oxford and Thames Valley (ARC-OxTV) and was a member of HTA Clinical Evaluation and Trials Committee. Lucy C Chappell is the Chief Executive Officer for National Institute for Health Research (since August 2021). Lucy C Chappell has received funding from an NIHR professorship (NIHR-RP-2014-05-019). Katherine L Tucker has received funding from the NIHR CLAHRC now recommissioned as NIHR Applied Research Collaboration Oxford and Thames Valley (ARC-OxTV). Lucy C Chappell was a member of HTA Remit and Competitiveness Group, EME Strategy Advisory Committee, HTA Post-Funding Committee teleconference, HTA Funding Committee Policy Group, HTA Clinical Evaluation and Trials Committee, HTA Programme Oversight committee and COVID-19 Reviewing. Lisa Hinton was employed at the THIS Institute is supported by the Health Foundation, an independent charity committed to bringing about better health and health care for people in the UK. Lisa Hinton was a member of HS&DR Commissioned Associate Board Member and HS&DR Associate Board Member. Jane Sandall was a member of HS&DR Commissioned Board Members and HS&DR Commissioned R&R Sub board and is Head of Maternity and Midwifery Research NHSE&I. Oliver Rivero-Arias is a member of the EuroQol group. Paul Leeson is supported by the NIHR Oxford Biomedical Research Centre. Lucy H Mackillop is supported by the NIHR Oxford Biomedical Research Centre and was a part-time employee and shareholder of Sensyne Health plc. Lionel Tarassenko is supported by the NIHR Oxford Biomedical Research Centre and was a Director of Sensyne Health plc.

Lucy Yardley was a member of HTA Antimicrobial Resistance Themed call board, HTA Efficient Study Designs-2 and PHR Research Funding Board. Ly-Mee Yu was a member of HTA Efficient Study design-2.

Editorial note

This report includes all pregnant people including pregnant women and pregnant people who do not identify as women. We take an additive approach in this statement while maintaining women-centred language as recommended by the Royal College of Obstetrics and Gynaecology and the Royal College of Midwives and have referred to pregnant women throughout.

Copyright and credit statement

Publications

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 Studies* 2019;**5**:153. https://doi.org/10.1186/s40814-019-0537-z

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