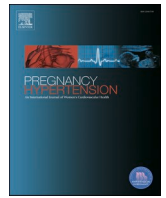




Contents lists available at ScienceDirect

# Pregnancy Hypertension: An International Journal of Women's Cardiovascular Health

journal homepage: [www.elsevier.com/locate/preghy](http://www.elsevier.com/locate/preghy)

## Implementation of a novel shared decision-making intervention in women with chronic hypertension in pregnancy: multiple-site multiple-method investigation

Rebecca Whybrow<sup>a,\*</sup>, Jane Sandall<sup>a</sup>, Joanna Girling<sup>b</sup>, Heather Brown<sup>c</sup>, Paul T Seed<sup>a</sup>, Marcus Green<sup>d</sup>, Sarah Findlay<sup>e</sup>, Louise Webster<sup>b</sup>, Lucy C Chappell<sup>a</sup>

<sup>a</sup> Department of Women and Children's Health, King's College London, St Thomas' Hospital, London, UK

<sup>b</sup> Women's Services, Chelsea and Westminster Hospital NHS Foundation Trust, London, UK

<sup>c</sup> Women's Services, Brighton and Sussex Universities Hospital Trust, East Sussex, UK

<sup>d</sup> Action on Pre-eclampsia, Evesham, Worcestershire, UK

<sup>e</sup> Lay Representative, UK

### ARTICLE INFO

#### Keywords:

Pregnancy  
Hypertension  
Chronic hypertension  
Antihypertensive  
Shared decision-making  
Patient decision aid

### ABSTRACT

**Background:** Many women with chronic hypertension are conflicted about antihypertensive medication during pregnancy and some are non-adherent to prescribed medication.

**Objectives:** Codesign, implement and evaluate a novel shared decision-making (SDM) intervention for use with pregnant women with chronic hypertension.

**Setting and participants:** Pregnant women with chronic hypertension and their principal healthcare professionals (obstetricians, midwives, and physicians), at three National Health Service hospital trusts with different models of care.

**Main outcome measures:** The RE-AIM framework guided the evaluation. Primary: Decisional conflict scale, medication intention survey and women's acceptability. Secondary: Healthcare professionals' acceptability and the barriers and facilitators to SDM implementation with pregnant women with chronic hypertension.

**Results:** Fifty women participated. Nearly half (46 %; n = 23) of women were from Black and Asian backgrounds. The SDM intervention was effective at reducing decisional conflict (mean reduction from baseline 42 %, 95 % CI 35–49, p ≤ 0.05). In 36 women (72 %), the reduction was of clinical importance. 24 women (48 %) were uncertain about or planned not to take antihypertensives prior to the SDM intervention, compared to two women (4 %) after the intervention. The intervention was acceptable to women and healthcare professionals. 10 of 14 healthcare professionals felt that the in-consultation aid facilitated SDM in current antenatal contexts, a similar proportion (10/14) felt the length of consultations hindered SDM.

**Conclusion:** A novel codesigned SDM intervention reduced decisional conflict and increased women's intention to take antihypertensive agents during pregnancy. This intervention could be adopted into practice for women making pregnancy decisions where there is uncertainty around the medication management option.

### 1. Introduction

Women with chronic hypertension make up about 2 % of the pregnant population, and with changes in pregnancy demographics that include increases in maternal age and rates of obesity, this proportion is rising [1–3]. Women with chronic hypertension are at greater risk of developing severe hypertension and pre-eclampsia than normotensive women or those with gestational hypertension [1]. These women also

have a higher risk of stillbirth compared to women with gestational hypertension [4]; in those who develop severe hypertension, approximately half of their infants will be admitted to the neonatal unit [5]. Although treating hypertension in pregnancy reduces the incidence of severe hypertension, there remains uncertainty whether treatment of mild and moderate hypertension in pregnancy improves other health outcomes (such as pre-eclampsia), and there is a paucity of data from long term follow-up of children whose mothers took antihypertensive

\* Corresponding author.

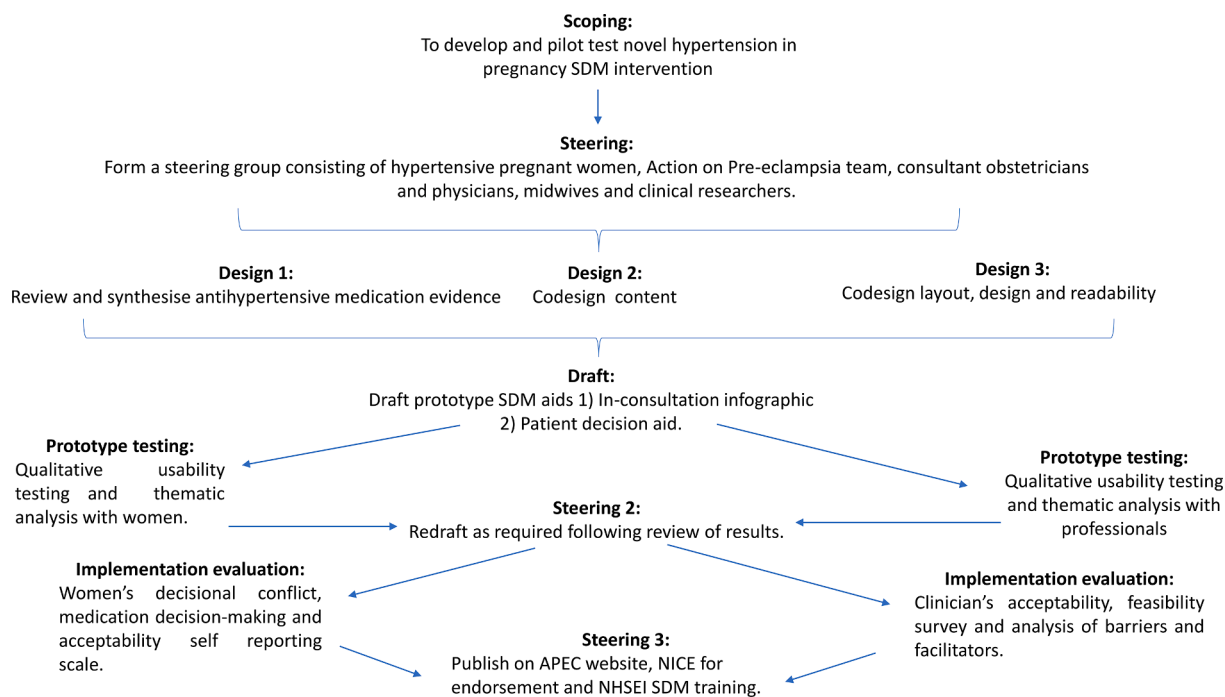
E-mail address: [Rebecca.whybrow@kcl.ac.uk](mailto:Rebecca.whybrow@kcl.ac.uk) (R. Whybrow).

<https://doi.org/10.1016/j.preghy.2022.09.007>

Received 30 March 2022; Received in revised form 7 September 2022; Accepted 15 September 2022

Available online 20 September 2022

2210-7789/© 2022 The Authors. Published by Elsevier B.V. on behalf of International Society for the Study of Hypertension in Pregnancy. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).



**Fig. 1.** Development process for patient decision aids adapted for the chronic hypertension in pregnancy decision aids included within the novel shared decision-making intervention development and testing programme.

medication in pregnancy [6,7]. Hypertension in pregnancy is commonly treated with antihypertensives in line with national guidance [8]. However, recent research identified clinical variation in the management of chronic hypertension in pregnancy across different English hospitals [9]. Furthermore, there was variation in women's experience of the management of hypertension in pregnancy, with three-quarters of women experiencing internal conflict regarding their antihypertensive prescription which was mediated by concerns about the safety of the medication, side-effects of medication and health beliefs about hypertension [9]. Just under half of these women were non-adherent to their antihypertensive medication, a finding supported by other studies involving patient observational and survey data [10–13].

Shared decision-making (SDM) is a branch of personalised care and support planning usually adopted when there is uncertainty regarding the best treatment option. Clinicians and patients share the best available evidence so that patients are supported to consider management options to achieve informed preferences [14]. In maternity services, the term 'shared decision-making' is sometimes replaced with 'informed decision-making' because it is felt to more accurately reflect the autonomy women have in their decision-making [15]. However, across the UK National Health Service, the term 'shared decision-making' continues to be routinely used [16]. The adoption of SDM in the management of hypertension in pregnancy is recommended in National Guidelines [8] and there is a body of evidence that demonstrates it improves patient experience, reduces clinical variation and can improve health outcomes in people with chronic conditions [17]. Nevertheless, SDM is not routinely implemented in antenatal care for women with chronic hypertension [18,19]. This study sought to codesign and implement a novel SDM intervention with the aim of reducing decisional conflict, and supporting informed decision-making, in women with chronic hypertension who were making decisions about antihypertensive treatment in pregnancy. The SDM intervention was underpinned by the Theory of Planned Behaviour. Through this lens it is understood that engagement in SDM is determined by three variables: (1) attitude—that is, the degree to which both the healthcare professional and woman have a favourable or unfavourable opinion of SDM; (2) subjective norm—that is, a person's beliefs about whether peers and people of importance

think that he or she should engage in SDM; and (3) perceived behavioural control—that is, the perceived ability to perform SDM and to deal with anticipated obstacles [20].

## 2. Methods

The Chronic Hypertension in pregnancy iMplementatION study (CHAMPION) is a multiple-method investigation (consisting of focus groups, qualitative interviews and surveys that include validated scales [21–23]) into the codesign and implementation of a novel SDM intervention for women with chronic hypertension in pregnancy. Codesign methodology was adopted as it is the application of user-centric research and service/systems development approaches to solve a particular problem [24]. Development and implementation occurred between May 2018 and May 2021. The objectives of this study were, for women with chronic hypertension in pregnancy, to:

- Codesign a novel SDM intervention for use in usual antenatal care.
- Describe implementation of SDM into routine care in three different NHS Trusts.
- Evaluate the impact of novel SDM intervention implementation using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework [25].

### 2.1. Research Ethics approval

Ethical approval for the CHAMPION study was provided by the National Research Ethics Service (17/LO/2041).

### 2.2. Development of the chronic hypertension in pregnancy SDM intervention

The 'Systematic Patient Decision Aid Development Process' [26] is an iterative model that systemises the development and evaluation of SDM interventions. The model was used through this study (Fig. 1) and can be categorised into two phases: 1) the development phase, which

**Table 1**  
RE-AIM evaluation measures.

RE-AIM item	Measure
Reach	The absolute number, proportion, and representation of women willing to participate in the study was recorded by the research team.
Effectiveness	The impact of the intervention on individuals was assessed using the following measures. Decisional conflict was measured pre- and post-intervention (on the same day or at the next appointment up to four weeks later) using a ten item, self-report scale [21] (score ranging from 0 to 100 % decisional conflict), with scores above 37.5 indicative of decision delay and below 25 indicative of decision implementation. Interaction tests were used to look for differences in effect in different sub-groups (gestation at time of intervention, parity, ethnicity, and hospital trust). Antihypertensive decision-making was assessed by asking women which antihypertensive they preferred as part of the pre- and post-decisional conflict validated self-reporting tool [21]. Acceptability, appropriateness, and feasibility were measured in women using a survey. Women were asked which decision aids they used and how likely they were to recommend the intervention using the 'friends and family' test framework. The survey also included questions about the clarity and content of the intervention using a five-point Likert scale. A free text box was included within the acceptability survey [22]. Acceptability, appropriateness, and feasibility were measured in healthcare professionals using a validated implementation outcomes scale [23] (1–5); with one being low and five being high levels of acceptability.
Adoption	The absolute number of antenatal clinics who were willing to take part in the study.
Implementation	Clinical observations of fidelity could not be carried out because of COVID-19 restriction. Instead, women indicated which tools of they had used as part of their decision-making process. In addition, the barriers and facilitators influencing health professionals adoption of SDM was carried out using the qualitative survey questions in the Ottawa validated survey [37]. Responses were coded and thematically analysed to understand the most frequently cited barriers and facilitators to SDM implementation.

included designing and testing prototypes, and phase 2) the evaluative phase which included implementing and evaluating the SDM intervention.

### 2.3. Phase one. The development phase

To design the decision-aid prototypes focus group methodology was adopted (Supplementary Table 1 contained within Supplementary File 1) [27]; to test the prototypes iterative qualitative usability testing and content analysis was performed (Supplementary Table 2 contained within Supplementary File 1) [28]. The steering group agreed the final iteration to be implemented and evaluated (Supplementary File 1).

**Phase two. Implementation and evaluation** The implementation of the novel hypertension SDM intervention was informed by previous research of the barriers and facilitators to SDM in the NHS that identified the following implementation facilitators: (1) preparation of the woman; (2) staff training; (3) development of brief support tools; (4) availability of tools, and (5) support from senior staff and inclusion in clinical guidelines [14]. In addition to the tools, our intervention therefore included a brief pre-recorded presentation for healthcare professionals on the principles of SDM and an overview of the tools, designed to be undertaken at a time preferable for the professionals. To ensure the programme had senior level support, the lead obstetrician for chronic hypertension in pregnancy at each unit agreed to champion the novel intervention. The decision aids were submitted to the NICE Guidelines for endorsement based on compliance with the 'international patient decision aid standards' which was granted prior to implementation. The final SDM tools can be accessed through the patient support group website: <https://action-on-pre-eclampsia.org.uk/public-area/high-blood-pressure-in-pregnancy/> and through the tools and resources section of the National Institute for Health and Care Excellence Hypertension In Pregnancy Guideline: <https://www.nice.org.uk/guidance/ng133/resources/endorsed-resource-high-blood-pressure-in-pregnancy-decision-aid-and-infographic-6958842157>.

**Table 2**  
Demographics of women and results of the decisional conflict scale used to evaluate the novel SDM interventions.

Women's demographics	n = 50 (%)
<b>Ethnicity</b>	
Asian	13 (26)
Black	10 (20)
White Other	9 (18)
White British	15 (30)
Any other	3 (6)
<b>Parity at booking</b>	
0	29 (58)
1	9 (18)
2	8 (16)
3	4 (8)
<b>Age (years)</b>	
20–34	31 (62)
35–39	15 (30)
40–49	4 (8)
<b>Interpreter required</b>	
No	45 (90)
Yes	5 (10)
<b>NHS Trust</b>	
NHS Trust 1	29 (58)
NHS Trust 2	10 (20)
NHS Trust 3	11 (22)
<b>Decisional conflict scale</b>	
<b>Score (%) (SD)</b>	
Decisional conflict scale score	
Pre-mean	50 (27)
Post-mean	8 (10)
Mean difference	42 (95 % CI, 49–35, p= <0.05)
Uncertainty sub score	
Pre-mean	56 (41)
Post-mean	7 (14)
Mean difference	49 (95 % CI, 61–37, p= <0.05)
Informed sub score	
Pre-mean	66 (34)
Post-mean	6 (16)
Mean difference	60 (95 % CI, 70–50, p= <0.05)
Values clarity score	
Pre-mean	47 (42)
Post-mean	10 (17)
Mean difference	37 (95 % CI, 48–26, p= <0.05)
Support score	
Pre-mean	34 (28)
Post-mean	9 (17)
Mean difference	25 (95 % CI, 32–18, p= <0.05)

Confidence interval (CI).

[uk/public-area/high-blood-pressure-in-pregnancy/](https://www.nice.org.uk/guidance/ng133/resources/endorsed-resource-high-blood-pressure-in-pregnancy-decision-aid-and-infographic-6958842157) and through the tools and resources section of the National Institute for Health and Care Excellence Hypertension In Pregnancy Guideline: <https://www.nice.org.uk/guidance/ng133/resources/endorsed-resource-high-blood-pressure-in-pregnancy-decision-aid-and-infographic-6958842157>.

Implementation of the SDM intervention occurred between September 2020 and May 2021 at three NHS Trusts with varied, but typical configurations of services for pregnant women with hypertension in the UK. Hospital Trust 1 was a tertiary city centre hospital with a newly formed specialist service that included consultant obstetricians and midwives who provided antenatal and intrapartum care to women with chronic hypertension within a specialist clinic; Hospital Trust 2 was a suburban district general hospital with a consultant-led antenatal clinic with antenatal midwives alongside providing care to women with a variety of pre-existing medical conditions; Hospital Trust 3 had a tertiary hospital with a joint obstetric and physician led clinic for women with pre-existing medical conditions and a caseload community-based midwifery team. Healthcare professionals caring for women with chronic hypertension were purposively sampled and emailed the SDM presentation. Women were recruited to the study from the antenatal clinics at any gestation. Pre-intervention surveys took place in a private space within the antenatal clinics (Supplementary File 2). Women were given the patient decision aids and asked to read them before their

appointment. Infographics were also available on the desk in the clinic rooms. Obstetricians and midwives were asked to discuss antihypertensive options within their scope of practice using the infographics and support the women to reach informed decisions about their medication at a clinically appropriate time. The post-intervention survey for women was carried out up to four weeks following the antenatal appointment (Supplementary File 2).

Evaluation of the intervention was underpinned by the RE-AIM framework developed to improve the adoption and sustainable implementation of evidence-based interventions in a wide range of health, public health, educational, community, and other settings [25]. Its key dimensions are reach and effectiveness (individual level), adoption and implementation (staff, setting, system, or policy/other levels), and maintenance (both individual and staff/setting/system/policy levels); although maintenance was not assessed in this study (Table 1) [25]. Primary outcome: In pregnant women with chronic hypertension effectiveness was measured using the validated Ottawa decisional conflict self-report scale [21]. Decisional conflict was measured pre- and post intervention (on the same day or at the next appointment up to four weeks later) using a ten item validated scale covering four sub scales: decisional certainty, values clarity, information needs, and support with a total score ranging from 0 to 100 % decisional conflict, with scores above 37.5 indicative of decision delay and below 25 indicative of decision implementation (Supplementary File 2). Interaction tests were used to look for differences in effect in different sub-groups (gestation at time of intervention, parity, ethnicity, and hospital trust). The post intervention healthcare professional survey can be found in Supplementary File 3.

A sample size of 50 was chosen; to ensure we had an adequate sample to ascertain the effectiveness of the intervention to reduce decisional conflict we performed a power calculation. The calculation based on a depression in pregnancy decision aid study with geographical similarities to our study, reporting a mean pre-intervention decisional conflict baseline score of 53.2 % falling to post-intervention score of 32.2 %, with a standard deviation (SD) of 11.5 and 16.4 [29]. To calculate the SD of the difference, we conservatively chose a correlation of 0.4. This

allowed us to estimate the SD of the difference as being at most 15.82 using standard formulae. Using the Stata command power, we estimated we would have a sufficient sample size with nine participants (90 % power), but we recruited a higher number across three trusts to increase generalisability. A target of twelve healthcare professionals' surveys was determined by variation in profession, level of experience and NHS Trust, and then guided by data saturation.

### 3. Results

#### 3.1. Reach

Fifty-two pregnant women were approached to take part in the SDM intervention implementation and evaluation phase, of whom fifty consented to participate. The women in the study were broadly representative of the national hypertensive pregnancy population with 46 % (n = 23) of respondents from Black and Asian backgrounds and 38 % (n = 19) aged 35 and over and 10 % (n = 5) required interpreting services (Table 2). Women were recruited from all three Trusts (29, 10 and 11 women), with Trust 1 recruiting more women because of a higher proportion of hypertensive women in their pregnancy population compared to Trust 2 and Trust 3 [9].

#### 3.2. Effectiveness

Of the fifty women recruited to the study, 92 % (n = 46) completed the acceptability survey [22]. All but one woman would recommend the intervention to friends and family. Overall, both the infographic and booklet were considered clear and informative. Fourteen healthcare professionals (7 midwives and 7 doctors) were purposively recruited to implementation and evaluation phase of the study from the three participating hospital Trusts. The intervention was found to be acceptable (4.5/5), appropriate (4.4/5) and feasible (4.4/5) by these professionals [23].

All fifty pregnant women with chronic hypertension completed the ten-item decisional conflict self-reported scale [21] prior to and after

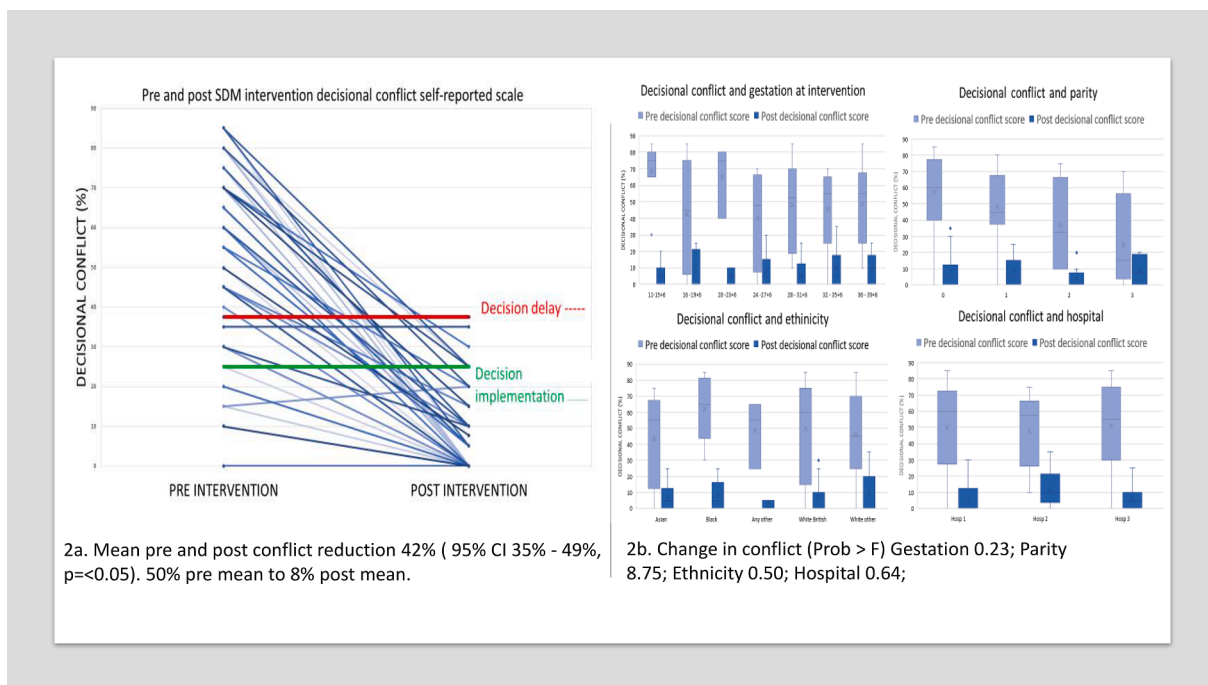


Fig. 2. Pre- and post-decisional conflict score in women with chronic hypertension in pregnancy exposed to the novel SDM intervention as part of usual care. 2b. Box-Whisker Plot of pre- and post-decisional conflict score in women with chronic hypertension in pregnancy exposed to the novel SDM intervention as part of usual care analysed by a. gestation b. parity c. ethnicity d. hospital trust.

their antenatal appointment (47/50 immediately after their consultation and 3/50 at their subsequent antenatal appointment). The mean conflict reduction was 42 % (95 % CI 35–49,  $p \leq 0.05$ ), from a mean of 50 % (SD 27) before to 8 % (SD 10) after the intervention (Table 2). In total, forty-eight women (96 %) experienced post-intervention reductions in decisional conflict, one had no change in score and the remaining woman had a 5 % increase in conflict score but remained with a score below 25 %. Prior to appointment, forty-two women (84 %) were conflicted about antihypertensive use in pregnancy (score above 37.5 %). In thirty-six (72 %) women, the reductions were of clinical importance (a pre-specified reduction from above 37.5 % to below 25 %) (Fig. 2a) [21]. The women who received an antenatal consultation that included the infographic, but chose not to read the pre-consultation aid, had clinically significant reductions in decisional conflict in 8 of 9 cases. The remaining woman had no change in her conflict score. There were post-intervention reductions across all four sub-scales: decisional certainty, values clarity and information needs, and support scores (Table 2) [21].

The results were consistent across all sub-groups except parity; mean difference in decisional conflict effect reduced in line with increasing parity (Fig. 2b). Medication intention was recorded pre- and post-intervention to monitor whether the aid was balanced. Reductions in clinical variation were identified following exposure to the intervention; of 24 (45 %) women who reported they had ‘uncertainty’ about their antihypertensive medication or that they preferred ‘no treatment’ for their hypertension, all became certain about their antihypertensive choice (Table 3). In all but 2 (4 %) women, anti-hypertensive treatment was preferred following exposure to the SDM intervention.

### 3.3. Adoption and implementation

All three NHS Trusts adopted the SDM intervention into their antenatal clinics; they also chose to adopt it into other settings that included the antenatal ward and the day assessment unit for women with chronic hypertension. All fifty women used at least one of the SDM tools, 92 % ( $n = 46$ ) reported using the in-consultation aid as intended and 74 % ( $n = 37$ ) using the patient decision aid as intended. Three women reported not reading the booklet because it was not available in their language but used the infographic with an interpreter and healthcare professional instead.

All fourteen healthcare professionals returned the free text survey response questions. Midwives and doctors felt that consultation time was a barrier to the implementation of SDM (10/14). Some healthcare professionals identified an absence of more extensive SDM training as a potential barrier to implementation (4/14), but midwives also wanted more training on hypertension in pregnancy (4/7). One obstetrician

**Table 3**

Pre- and post-antihypertensive choice in pregnant women with chronic hypertension exposed to the implementation of novel SDM interventions as part of usual antenatal care.

Medication	Pre-intervention antihypertensive decision $n = 50$ (%)	Post-intervention antihypertensive decision $N = 50$ (%)	Change in pre-decision intention following decision aid
Labetalol	14 (28)	21 (42)	–
Methyldopa	2 (4)	7 (14)	–
Nifedipine	8 (16)	15 (30)	–
Other	4 (8)	3 (6)	–
Unsure	15 (30)	0 (0)	14/15 chose treatment
No treatment	9 (18)	2 (4)	8/9 chose treatment
Missing answer	4 (8)	4 (8)	–

Sum of medication choices greater than 50 as some women chose more than one medication.

thought there needed to be a change in culture, and not just training, to ensure adoption of antenatal antihypertensive SDM. In addition, healthcare professionals reported current antenatal care pathways were a barrier to implementing SDM as women require follow up consultations with obstetricians and midwives at times when they feel they need to revisit decision-making (6/14).

Healthcare professionals felt in-consultation aids and patient decision aids facilitated SDM in current antenatal contexts (10/14). Women could be empowered to engage in SDM and hypertension care planning through implementation of in-consultation aids and through conversations with their professionals (10/14). Professionals reported that multi-lingual aids and interpreters were important facilitators of SDM in women with chronic hypertension (8/14). Midwives (6/7) also recognised the importance of working within a multi-professional team when providing care for women with hypertension (Fig. 3).

## 4. Discussion

This novel SDM intervention significantly reduced the decisional conflict of women with hypertension in pregnancy. For most women this was a clinically important reduction that enabled them to make easier decisions about antihypertensive uptake in pregnancy. Women who did not read the pre-consultation patient decision aid but did use the in-consultation infographic with a professional who had received brief training on SDM also had clinically important reductions in decisional conflict. The novel SDM intervention led to an increase in women reporting to take antihypertensive medication and may therefore also improve outcomes in this group of women, warranting future investigation. The benefits of the intervention were found across the sub-groups. However, the mean difference in decisional conflict effect reduced in line with increasing parity as multiparous women had on average lower pre-intervention decisional conflict scores, possibly because of prior positive pregnancy outcomes. Whilst healthcare professionals felt the duration of consultations may hinder SDM, the in-consultation aid facilitated SDM in current antenatal contexts. In addition, healthcare professionals considered that women needed access to decisional support materials in their own languages where feasible, and to have access to interpreters to further facilitate SDM.

### 4.1. Strengths

Just under half of all the women recruited to the study were either Black or Asian ethnicity and importantly were representative of the wider chronic hypertension in pregnancy population. The study also included women who did not speak English as a first language and required interpreter services making the findings relevant to this group of women too. The application of the theory of planned behaviour, along with a codesign approach to the ‘process development model’ and the use of validated SDM scales and surveys strengthens the study’s findings.

### 4.2. Limitations

Due to COVID-19 hospital restrictions the research team were unable to carry out observations of the tools being used within the antenatal appointments and therefore could not directly assess fidelity. A small number of senior healthcare professionals at the NHS Trusts implementing the novel SDM intervention were members of the development steering group. Trainee doctors and midwives who completed acceptability surveys might therefore have viewed the intervention more positively. Future research could build on this study by randomising participants, exploring medication adherence, and understanding in more detail the mechanisms of action.

### 4.3. Implications for policy makers

Personalised care and support planning in pregnant women with

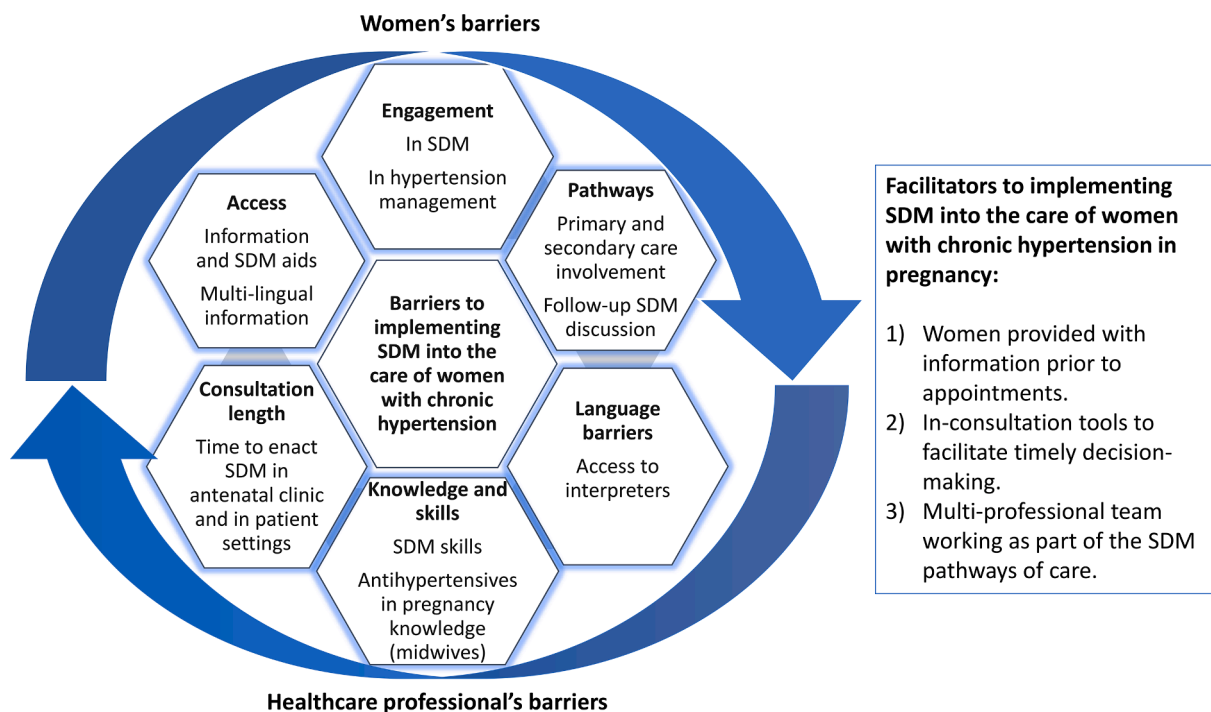


Fig. 3. Healthcare professionals' perceptions of the barriers and facilitators to implementing SDM in women with chronic hypertension in pregnancy.

hypertension should include the adoption of a SDM approach for the management of hypertension. Pregnant women with hypertension may have high levels of decisional conflict in relation to antihypertensive use in pregnancy. This is not unexpected as there is a general societal belief that medication should be avoided in pregnancy coupled with a lack of research into the long term safety of antihypertensives [30]. Previous research has shown many women are not provided with information about the safety of the medications or offered a choice of antihypertensive based on individual requirements [9]. The baseline decisional conflict scores in this study were in line with recent research into decision aid use for antenatal antidepressant medication decisions carried out in similar NHS settings [29]. Notably, the mean difference reductions of 42 % in this study were on average greater than the reduction of 21 % reported in the antenatal antidepressant decision aid study [29], and in other studies of pregnancy-related patient decision aids [31]. A recent in-consultation SDM intervention for women making birth choices following a previous caesarean section saw a 16 % reduction in decisional conflict [32].

Successful development and implementation of this novel intervention can be understood through the lens of the theory of planned behaviour that describes behaviour to be dependent on intention mediated by attitude, subjective norm, and perceived behavioural control [24]. The novel SDM intervention addressed intention to participate in SDM through women's access to information, staff training, brief conversation aids, availability of tools, support from senior staff and inclusion in clinical guidelines. This study adds to the limited evidence base on codesign. Codesign with women with chronic hypertension in pregnancy and healthcare professionals who provide care for these women is likely to have resulted in more positive attitudes towards the SDM intervention, enhanced the perception of the importance of implementing SDM and improved the behavioural control over the intervention by reducing potential obstacles during the design phase.

Nevertheless, healthcare professionals were asked to identify barriers to the implementation of SDM in this group of women and frequently they described the importance of having pathways that integrated and facilitated SDM. This included ensuring an integrated multi-professional model of care as well as developing pathways that

allow women time to revisit decisions as necessary. The system itself must be responsive to individual needs and enable personalised care and support planning to occur. Similar findings were reported in recent research carried out in cancer patients. It found that decision making was an ongoing and unpredictable process with many decision moments, which often came unannounced. The adoption of SDM was therefore influenced as much by service design as it was by the consultation discussions [33]. Finally, although healthcare professionals thought longer consultations would support SDM, the use of in-consultation aids and patient decision aids facilitated SDM in current antenatal care contexts. Professionals also wanted better access to translators to facilitate in-consultation SDM to non-English speaking women with hypertension. This is of particular importance to the pregnant hypertensive populations which is made up of a disproportionate number of women from Black and South Asian communities [34,35] some of whom may require interpreting services. These women have proportionally more stillbirths and maternal deaths compared to White women [35], resulting in the UK national maternal mortality review (MBRRACE) recommendations to provide interpreters to women who require them [36]. Future research may include understanding whether the implementation of the novel intervention results in improved medication adherence and health outcomes.

## 5. Conclusion

A novel codesigned SDM intervention that sought to address the three components of the theory of planned behaviour (attitude, subjective norm, and perceived behavioural control) significantly reduced conflict and increased women's intention to take antihypertensives during pregnancy complicated by hypertension. It is acceptable to women and professionals alike. This model could be adopted into practice for women making other pregnancy decisions where there is uncertainty around medication choices.

## 6. Exclusive submission statement

The following manuscript, implementation of a novel shared

decision-making intervention in women with chronic hypertension in pregnancy: multiple-site multiple-method investigation, is being exclusively submitted to Pregnancy Hypertension.

## 7. Disclaimers

The views expressed are those of the author[s] and not necessarily those of the NIHR or the Department of Health and Social Care.

## CRediT authorship contribution statement

**Rebecca Whybrow:** Conceptualization, Methodology, Formal analysis, Investigation, Writing, Visualization, Project administration. **Jane Sandall:** Conceptualization, Methodology, Formal analysis, Writing – review & editing, Supervision, Funding acquisition. **Joanna Girling:** Investigation, Resources, Writing – review & editing. **Heather Brown:** Investigation, Resources, Writing – review & editing. **Paul T Seed:** Formal analysis, Visualization, Writing – review & editing. **Marcus Green:** Resources, Visualization, Writing – review & editing. **Sarah Findlay:** Visualization, Writing – review & editing. **Louise Webster:** Formal analysis, Writing – review & editing, Supervision. **Lucy C Chappell:** Conceptualization, Methodology, Formal analysis, Writing – review & editing, Supervision, Funding acquisition.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Acknowledgements:

This work was supported by the National Institute for Health Research (Research Professorship RP-2014-05-019) and by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care South London (NIHR CLAHRC South London) at King's College Hospital NHS Foundation Trust. Jane Sandall is an NIHR Senior Investigator and is supported by the National Institute for Health Research (NIHR) Applied Research Collaboration South London (NIHR ARC South London) at King's College Hospital NHS Foundation Trust. Paul T Seed and Louise M Webster are partly funded by Tommy's (Registered charity no. 1060508) and Paul T Seed was funded by CLAHRC South London (NIHR).

## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.preghy.2022.09.007>.

## References

- [1] K. Bramham, B. Parnell, C. Nelson-Piercy, et al., Chronic hypertension and pregnancy outcomes: systematic review and meta-analysis, *BMJ: Br. Med. J.* 348 (2014), g2301, <https://doi.org/10.1136/bmj.g2301>.
- [2] E.W. Seely, J. Ecker, Clinical practice. Chronic hypertension in pregnancy, *N. Engl. J. Med.* 365 (5) (2011) 439–446, <https://doi.org/10.1056/NEJMcp0804872> [published Online First: 2011/08/05].
- [3] Modder J FK. Management of Women with Obesity in Pregnancy. CMA/RCOG Joint Guideline, 2010.
- [4] V. Flenady, L. Koopmans, P. Middleton, et al., Major risk factors for stillbirth in high-income countries: a systematic review and meta-analysis, *Lancet* 377 (9774) (2011) 1331–1340, [https://doi.org/10.1016/S0140-6736\(10\)62233-7](https://doi.org/10.1016/S0140-6736(10)62233-7) [published Online First: 2011/04/19].
- [5] L.A. Magee, P. von Dadelszen, J. Singer, et al., The CHIPS randomized controlled trial (control of hypertension in pregnancy study): is severe hypertension just an elevated blood pressure? *Hypertension* 68 (5) (2016) 1153–1159, <https://doi.org/10.1161/HYPERTENSIONAHA.116.07862> [published Online First: 2016/09/14].
- [6] E. Abalos, L. Duley, D.W. Steyn, et al., Antihypertensive drug therapy for mild to moderate hypertension during pregnancy, *Cochrane Database Syst. Rev.* (10) (2018) CD002252, <https://doi.org/10.1002/14651858.CD002252.pub4> [published Online First: 2018/10/03].
- [7] L.A. Magee, P. von Dadelszen, E. Rey, et al., Less-tight versus tight control of hypertension in pregnancy, *N. Engl. J. Med.* 372 (5) (2015) 407–417, <https://doi.org/10.1056/NEJMoa1404595>.
- [8] NICE. Hypertension in pregnancy: diagnosis and management NICE guideline [NG133]: National Institute for Health and Care Excellence, 2019.
- [9] R. Whybrow, L. Webster, J. Girling, et al., Implementation of national antenatal hypertension guidelines: a multicentre multiple methods study, *BMJ Open* 10 (10) (2020) e035762.
- [10] L. Webster, E. Myers Jenny, C. Nelson-Piercy, et al., Labetalol versus nifedipine as antihypertensive treatment for chronic hypertension in pregnancy, *Hypertension* 70 (5) (2017) 915–922, <https://doi.org/10.1161/HYPERTENSIONAHA.117.09972>.
- [11] A. Lupattelli, O. Spigset, H. Nordeng, Adherence to medication for chronic disorders during pregnancy: results from a multinational study, *Int. J. Clin. Pharm.* 36 (1) (2014) 145–153, <https://doi.org/10.1007/s11096-013-9864-y>.
- [12] D. Matsui, Adherence with drug therapy in pregnancy, *Obstet. Gynecol. Int.* 2012 (2012) 5, <https://doi.org/10.1155/2012/796590>.
- [13] A. Helou, K. Stewart, J. George, Adherence to anti-hypertensive medication in pregnancy, *Pregnancy Hypertension* 25 (2021) 230–324, <https://doi.org/10.1016/j.preghy.2021.06.002>.
- [14] G. Elwyn, S. Laitner, A. Coulter, et al., Implementing shared decision making in the NHS, *BMJ* 341 (2010), <https://doi.org/10.1136/bmj.c5146>.
- [15] NHSEI. Personalised care and support planning guidance. Guidance for local maternity systems. In: Programme MT, ed., 2021.
- [16] NICE. Shared decision making NG197: National Institute for Health and Care Excellence, 2021.
- [17] A.C.A. Coulter. Making shared decision-making a reality. No decision about me without me. King's Fund, 2011.
- [18] E.G.E. Mathijssen, J.E. Vriezekolk, C.D. Popa, et al., Shared decision making in routine clinical care of patients with rheumatoid arthritis: an assessment of audio-recorded consultations, *Ann. Rheum. Dis.* 79 (2) (2020) 170–215, <https://doi.org/10.1136/annrheumdis-2019-216137>.
- [19] S. Murray, M. Augustyniak, J.E. Murase, et al., Barriers to shared decision-making with women of reproductive age affected by a chronic inflammatory disease: a mixed-methods needs assessment of dermatologists and rheumatologists, *BMJ Open* 11 (6) (2021) e043960, <https://doi.org/10.1136/bmjopen-2020-043960>.
- [20] I. Ajzen, The theory of planned behavior, *Organ. Behav. Hum. Decis. Process.* 50 (2) (1991) 179–211, [https://doi.org/10.1016/0749-5978\(91\)90020-T](https://doi.org/10.1016/0749-5978(91)90020-T).
- [21] A.M. O'Connor, Validation of a decisional conflict scale, *Med. Decis. Making* 15 (1) (1995) 25–30, <https://doi.org/10.1177/0272989x9501500105>.
- [22] G.M. Sullivan, A.R. Artino Jr., Analyzing and interpreting data from likert-type scales, *J. Grad. Med. Educ.* 5 (4) (2013) 541–542, <https://doi.org/10.4300/jgme-5-4-18> [published Online First: 2014/01/24].
- [23] B.J. Weiner, C.C. Lewis, C. Stanick, et al., Psychometric assessment of three newly developed implementation outcome measures, *Implementation Sci: IS* 12 (1) (2017) 108, <https://doi.org/10.1186/s13012-017-0635-3> [published Online First: 2017/08/31].
- [24] T. Greenhalgh, C. Jackson, S. Shaw, et al., Achieving research impact through co-creation in community-based health services: literature review and case study, *Milbank Quart.* 94 (2) (2016) 392–429, <https://doi.org/10.1111/1468-0009.12197>.
- [25] J.S. Holtrop, P.A. Estabrooks, B. Gaglio, et al., Understanding and applying the RE-AIM framework: clarifications and resources, *J. Clin. Transl. Sci.* 5 (1) (2021) e126, <https://doi.org/10.1017/cts.2021.789> [published Online First: 2021/05/14].
- [26] A. Coulter, D. Stilwell, J. Kryworuchko, et al., A systematic development process for patient decision aids, *BMC Med. Inf. Decis. Making* 13 (2) (2013) S2, <https://doi.org/10.1186/1472-6947-13-S2-S2>.
- [27] J. Kitzinger, Qualitative research: introducing focus groups, *BMJ* 311 (7000) (1995) 299–302, <https://doi.org/10.1136/bmj.311.7000.299>.
- [28] N. Bansback, J.A. Chiu, R. Carruthers, et al., Development and usability testing of a patient decision aid for newly diagnosed relapsing multiple sclerosis patients, *BMC Neurol* 19 (1) (2019) 173, <https://doi.org/10.1186/s12883-019-1382-7> [published Online First: 2019/07/20].
- [29] H. Khalifeh, E. Molyneaux, R. Brauer, et al., Patient decision aids for antidepressant use in pregnancy: a pilot randomised controlled trial in the UK, *BJGP Open* 3 (4) (2019) (no pagination)(1666).
- [30] C. Fitton, M.F.C. Steiner, L. Aucott, In-utero exposure to antihypertensive medication and neonatal and child health outcomes: a systematic review, *J. Hypertens.* (2017).
- [31] A.J. Poprzeczny, K. Stocking, M. Showell, et al., Patient decision aids to facilitate shared decision making in obstetrics and gynecology: a systematic review and meta-analysis, *Obstet. Gynecol.* 135 (2) (2020) 444–451.
- [32] F. Hadizadeh-Talasz, F. Ghoreyshi, F. Mohammadzadeh, et al., Effect of shared decision making on mode of delivery and decisional conflict and regret in pregnant

- women with previous cesarean section: a randomized clinical trial, *BMC Pregnancy Childbirth* 21 (1) (2021) 144, <https://doi.org/10.1186/s12884-021-03615-w>.
- [33] I.P.M. Griffioen, J.A.C. Rietjens, M. Melles, et al., The bigger picture of shared decision making: a service design perspective using the care path of locally advanced pancreatic cancer as a case, *Cancer Med.* 10 (17) (2021) 5907–5916, <https://doi.org/10.1002/cam4.4145>.
- [34] B.T. Bateman, K.F. Huybrechts, M.A. Fischer, et al., Chronic hypertension in pregnancy and the risk of congenital malformations: a cohort study, *Am. J. Obstet. Gynecol.* 212 (3) (2015) 337e1–437e14, <https://doi.org/10.1016/j.ajog.2014.09.031> [published Online First: 2014/09/28].
- [35] L.C. Chappell, S. Enye, P. Seed, et al., Adverse perinatal outcomes and risk factors for preeclampsia in women with chronic hypertension: a prospective study, *Hypertension* 51 (4) (2008) 1002–1009, <https://doi.org/10.1161/hypertensionaha.107.107565> [published Online First: 2008/02/09].
- [36] M. Knight, K. Bunch, D. Tuffnell, J. Shakespeare, R. Kotnis, S. Kenyon, J.J. Kurinczuk (Eds.). *Saving Lives, Improving Mothers' Care Lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2016-18*. In: *Maternal NaICORP*, ed., 2020.
- [37] F. Légaré, S. Ratté, K. Gravel, et al., Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions, *Patient Educ. Couns.* 73 (3) (2008) 526–535, <https://doi.org/10.1016/j.pec.2008.07.018>.