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Women's views and postpartum follow-up in the CHIPS Trial (Control of Hypertension in Pregnancy Study)

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ABSTRACT

Objective: To compare women's views about blood pressure (BP) control in CHIPS (Control of Hypertension In Pregnancy Study) (NCT01192412).
Design: Quantitative and qualitative analysis of questionnaire responses.
Setting: International randomised trial (94 sites, 15 countries).
Population/sample: 911 (92.9%) women randomised to 'tight' (target diastolic blood pressure, 85 mmHg) or 'less tight' (target diastolic blood pressure, 100 mmHg) who completed questionnaires.
Methods: A questionnaire was administered at ~6–12 weeks postpartum regarding post-discharge morbidity and views about trial participation. Questionnaires were administered by the site co-ordinator, and contact was made by phone, home or clinic visit; rarely, data was collected from medical records. Quantitative analyses were Chi-square or Fisher's exact test for categorical variables, mixed effects multinomial logistic regression to adjust for confounders, and $p < 0.001$ for statistical significance. NVivo software was used for thematic analysis of women's views.
Main outcome measures: Satisfaction, measured as willingness to have the same treatment in another pregnancy or recommend that treatment to a friend.
Results: Among the 533 women in 'tight' ($N = 265$) vs. 'less tight' ($N = 268$) control who provided comments for qualitative analysis, women in 'tight' (vs. 'less tight') control made fewer positive comments about the amount of medication taken (5 vs. 28 women, respectively) and intensity of BP monitoring (7 vs. 17, respectively). However, this did not translate into less willingness to either have the same treatment in another pregnancy (434, 95.8% vs. 423, 92.4%, respectively; $p = 0.14$) or recommend that treatment to a friend (435, 96.0% and 428, 93.4%, respectively; $p = 0.17$). Importantly, although

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satisfaction remained high among women with an adverse outcome, those in 'tight' control who suffered an adverse outcome (vs. those who did not) were not consistently less satisfied, whereas this was not the case among women in 'less tight' control among whom satisfaction was consistently lower for the CHIPS primary outcome ($p < 0.001$), severe hypertension ($p \leq 0.01$), and pre-eclampsia ($p < 0.001$).
Conclusions: Women in 'tight' (vs. 'less tight') control were equally satisfied with their care, and more so in the face of adverse perinatal or maternal outcomes.

Introduction

The CHIPS Trial (Control of Hypertension In Pregnancy Study) was an international randomised trial of 'less tight' [target diastolic blood pressure (dBP) of 100 mmHg] vs. 'tight' control (target dBP of 85 mmHg) of non-severe non-proteinuric hypertension in pregnancy [1]. 'Less tight' (vs. 'tight') control was associated with no benefit or harm to the baby, in terms of the primary outcome of perinatal loss or high level neonatal care for >48 h (31.4% vs. 30.7%), or the secondary outcome of serious maternal complications (3.7% vs. 2.0%). However, 'less tight' (vs. 'tight') control was associated with maternal risk, in terms of more severe hypertension (40.6% vs. 27.5%, $p < 0.0001$), platelet count $<100 \times 10^9$/L (4.3% vs. 1.6%, $p < 0.05$), and elevated liver enzymes with symptoms (4.3% vs. 1.8%, $p < 0.05$). Although 'less tight' control did not significantly decrease rates of birth weight <10th centile (16.1% vs. 19.8%), the differential rate of 3.7% may be interpreted by some clinicians to be of potential clinical importance.

On balance, 'tight' control of non-severe pre-existing or gestational hypertension in pregnancy appears to be the prudent clinical approach. If a negative impact on fetal growth were true, there was no evidence that this translated into a negative effect on death or illness for the baby, as reflected by the CHIPS primary outcome for which the trial was adequately powered. However, as pregnant women are known to be reluctant to take medication in pregnancy, clinicians may be reluctant to prescribe 'tight'.

After a closed-meeting presentation of the CHIPS results to investigators, more of them indicated that they would recommend 'tight' control (32, 45.7%) rather than 'less tight' control (6, 8.6%), but a significant number (30, 42.9%) were undecided and indicated that they would seek women's views before making their recommendation.

In order to further inform clinicians about 'tight' (vs. 'less tight') control, we extend the findings of the main trial by exploring the views of women who were assigned to each type of BP control and completed a postpartum questionnaire.

Materials and methods

CHIPS was a pragmatic, open, multicentre, international RCT (ISRCTN 71416914; NCT01192412) [1]. It was approved by the Research Ethics Board at the University of British Columbia as the co-ordinating centre and at all study sites.

The protocol is available on-line at nejm.org. In brief, women at 14^{+0}–33^{+6} weeks gestation with non-proteinuric pre-existing or gestational hypertension, office diastolic BP (dBP) 90–105 mmHg (or 85–105 mmHg if on antihypertensives) and a live fetus were randomised to 'less tight' control (target dBP 100 mmHg) or 'tight' (target dBP 85 mmHg). The composite primary outcome was pregnancy loss or high level neonatal care for >48 h in the first 28 days of life, and the secondary outcome, serious maternal complications before 6 weeks postpartum. Outcomes were compared between groups using logistic regression adjusted for key prognostic factors.

This report is focussed on information collected by site co-ordinators who were not responsible for direct patient care and who had health sciences backgrounds and CHIPS-specific training. Co-ordinators administered a structured postpartum questionnaire designed to: (i) collect information about potential post-discharge maternal or neonatal morbidities in the 6 weeks following birth for the mother, or 28 days of life for the baby, whichever was later, that may contribute to the primary or secondary outcomes; and (ii) explore maternal views about trial participation. The questionnaire was completed by contacting all CHIPS participants at 6–12 weeks postpartum (or 36 weeks corrected gestational age for preterm babies, whichever was later), by telephone, home or clinic visit, as appropriate for the centres; if this was not possible, the co-ordinator contacted the woman's medical practitioner and/or reviewed medical records in order to inform the primary and secondary outcomes (but not the satisfaction component of the questionnaire).

Women's views about trial participation were explored by two standard questions: willingness to have the same treatment again in a future pregnancy, and willingness to recommend the same treatment to a friend) [2,3]. Women were invited to provide comments after each question, as well as any other additional comments that they wished to share. All responses were recorded by co-ordinators at the time of interview, and subsequently entered verbatim in English into the study database for analysis.

Quantitative analysis of the questionnaire was by Chi-square or Fisher's exact test as appropriate for categorical variables, with $p < 0.001$ considered to be statistically significant as specified a priori by the CHIPS protocol.

Using mixed effects multinomial logistic regression, we simultaneously estimate the odds ratio (OR) of 'definitely yes' vs. 'probably/definitely not' and 'probably yes' vs. 'probably/definitely not' for 'less tight' vs. 'tight' control. The p value is against the alternative hypothesis that at least one of these ORs is not equal to 1. In the first analysis as in the primary CHIPS analysis [1], we adjusted for hypertension type, previous severe hypertension, use of any antihypertensive therapy at randomisation, gestational diabetes, weeks of gestation at randomisation, and centre (as random effect). In an additional analysis, we also adjusted for ethnicity, region, and perinatal mortality ratio of the recruiting country to account for potential cultural differences in women's views.

NVivo qualitative research software (Version 10, 2012, QSR International, Doncaster Victoria, Australia) was used to organise, analyse, and interpret women's free text responses. A thematic analysis approach was used for this study. This method is frequently used to identify patterns in large data sets so that relevant patterns can be explored in-depth [4]. Data were coded and stored as nodes that were subsequently used to explore similar and disparate themes that either were specified a priori or emerged during analysis (Panel 1). The first stage of analysis included a 'start list' of codes; these initial themes reflected the expected responses. Subsequently, themes were added, combined and split to better represent the respondents' views that did not reasonably fit into an a priori thematic category. All data were coded by one researcher (MV), a public health researcher with extensive experience in qualitative analyses specifically within the hypertensive disorders of pregnancy. Thematic categories were reviewed by study

Themes defined *a priori*	Data-driven themes	FINAL THEMES USED
Process of care		
Increased attention from health care providers		Extra health care provider attention
Better quality care		Quality care
Medication/treatment provided*		Quality of treatment
Research processes		
	Comments about research staff	Comments about research staff
Participating in research to help others		Play role in research & help others
	Learning opportunity	Learning opportunity
	Quality of study	Quality of study
Required extra work		Amount of work required
	Importance of research	Importance of research
Drivers of decision-making		
Felt reassured/worried		Feelings of safety (+) or worry (-)
Safety		
Medication/treatment provided*		Amount of medication
Being in control of blood pressure level		Blood pressure level
	Increased BP monitoring	Increased BP monitoring
Outcomes		
Maternal outcomes		Maternal outcomes
Infant outcomes		Infant outcomes
Other		
Any / no problems		Any / no problems
Depends on pregnancy		Planning for future pregnancies
Not applicable		
Don't know		Don't know

**This theme was divided into 'quality of treatment' and 'amount of medication'.*

Panel 1. A priori and data driven theme categories for analysis of maternal responses to CHIPS postpartum questionnaire.

investigators (LAM, PvD) who provided input on coding and themes. Respondents were classified to allow for analysis of the qualitative findings according to: allocation to 'less tight' or 'tight' BP control, response to each of the maternal satisfaction questions, and occurrence of each of the following adverse outcomes: primary perinatal, secondary maternal, severe maternal hypertension, pre-eclampsia, delivery at <34 weeks, and delivery at <37 weeks.

Results

There were 987 women randomised in CHIPS to 'less tight' ($N = 497$) or 'tight' control ($N = 490$) and included in the analyses [1]. For the 981 women with data for the primary and secondary outcomes (493 in 'less tight' and 488 in 'tight' control), an additional 10 (5 vs. 5, respectively) were lost to follow-up for the postpartum questionnaire after delivery, resulting in completed postpartum questionnaires for maternal and neonatal morbidity for 971 (99.0%) women (Table 1). The primary perinatal outcome (perinatal loss or high level neonatal care for >48 h) was informed by the postpartum questionnaire in 25 (8.2%) babies (15/150 in 'tight' and 10/155 in 'less tight') and the secondary maternal outcome in 5 (17.9%) women (4/10 in 'tight' and 1/18 in 'less tight').

Postpartum questionnaires were completed by mothers at a median of about 8 weeks postpartum. Most questionnaires were completed by telephone interview. In 60 (6.2%) women (30 in 'less tight' and 30 in 'tight' control), questionnaires were completed entirely by use of medical records, 52 because they were not contactable, and 8 because of stillbirth or neonatal death that made the co-ordinators uncomfortable contacting the women (Table S2). As such, there were 911 postpartum questionnaires (from 92.9% of women in the primary analysis) with data informative for the maternal satisfaction and views analyses presented in this paper.

Table 1
Postpartum questionnaire completion for the 981 women in CHIPS (N (%) women or median [IQR], as appropriate).

	'Less tight' control $N = 493$	'Tight' control $N = 488$	p[a]
Respondents by any method	488 (99.0%)	483 (99.0%)	1.00
Missing	5	5	
Time after delivery questionnaire completed (week)	8.29 [6.57; 11.57]	8.00 [6.71; 10.57]	0.55
Method of questionnaire completion[b]			
Telephone	309 (62.7%)	287 (58.8%)	0.21
Personal interview	158 (32.0%)	166 (34.0%)	0.51
Information obtained (in whole or part) from medical records or maternity care provider	43 (8.7%)	41 (8.4%)	0.86
Missing	5	5	

[a] Using Chi-square.
[b] Responses are not mutually exclusive.

Table 2
Women's views about participation in CHIPS for 911 respondents to maternal satisfaction questions (*N* (%) women).

	'Less tight' control (*N* = 458)	'Tight' control (*N* = 453)	Unadjusted analysis	Adjusted analyses	
			p^a	p^b	p^c
Women willing to have the same treatment in another pregnancy					
Respondents (*N* women)	454 (99.1%)	452 (99.8%)			
Provided no answer	4 (0.9%)	1 (0.2%)			
Definitely yes	309 (67.5%)	307 (67.8%)	0.18	0.15	0.14
Probably yes	114 (24.9%)	127 (28.0%)			
Probably NOT	22 (4.8%)	15 (3.3%)			
Definitely NOT	9 (2.0%)	3 (0.7%)			
Provided further comments for qualitative analysis	268/454 (59.0%)	265/452 (58.6%)			
Would recommend the same treatment to a friend					
Respondents (*N* women)	455 (99.3%)	453 (100%)			
Provided no answer	3 (0.7%)	0			
Definitely yes	296 (64.6%)	281 (62.0%)	0.27	0.17	0.17
Probably yes	132 (28.8%)	154 (34.0%)			
Probably NOT	24 (5.2%)	16 (3.5%)			
Definitely NOT	3 (0.7%)	2 (0.4%)			
Provided further comments for qualitative analysis	207/455 (45.5%)	213/453 (47.0%)			
Respondents to one/both questions who chose to accept the invitation to provide other comments	241/455 (53.0%)	219/453 (48.3%)			

[a] Using Fisher's exact test.
[b] Adjusted for hypertension type, previous severe hypertension, use of antihypertensive therapy at randomisation (yes/no), gestational diabetes at randomisation, weeks of gestation at randomisation, and centre (as random effect) as in the main CHIPS adjusted analysis [1].
[c] Adjusted for hypertension type, previous severe hypertension, use of antihypertensive therapy at randomisation (yes/no), gestational diabetes at randomisation, weeks of gestation at randomisation, and centre (as random effect) as in the main CHIPS adjusted analysis [1]. In addition to ethnicity, region and perinatal mortality ratio of the recruiting country to account for potential cultural differences in women's views.

Maternal satisfaction with care

Table 2 presents the women's views about their participation the CHIPS Trial, from 911 respondents to the maternal satisfaction questionnaire. Just over half of the women (i.e., 268/455 in 'less tight' and 265/453 in 'tight' control) provided additional qualitative comments. The vast majority of women in 'tight' (and 'less tight') control were satisfied with their care, as measured by willingness to either have the same treatment in another pregnancy and highlighted in grey in Table 2 (92.4% in 'less tight' vs. 95.8% in 'tight' control) or recommend the same treatment to a friend (93.4% vs. 96.0%, respectively).

Table 3 presents responses according to trial outcomes for all but the CHIPS secondary outcome for which there were too few events (*N* = 28) to allow for meaningful interpretation. Overall, more than 80% of women reported being satisfied with their care, regardless of their allocated group or pregnancy outcome; however, women in 'less tight' control with an adverse outcome (vs. those without) appeared to be less satisfied than women in 'tight' control who had an adverse outcome (vs. those without). Among women who received 'less tight' control, those with an adverse outcome (vs. those without) were significantly less satisfied (according to willingness to have the same treatment in a future pregnancy and recommend treatment to a friend) for all outcomes other than birth weight <10th centile. Among women in 'tight 'control, women with an adverse outcome (vs. those without) were less willing to have the same treatment in a future pregnancy for the CHIPS primary outcome and pre-eclampsia, but satisfaction measured by recommending treatment to a friend was not significant for any outcome.

Qualitative analyses according to 'less tight' vs. 'tight' control and satisfaction with care

Following completion of the closed-ended questions; just over half of women provided additional general comments following the first, 'willingness' question, and just under half commented following the second 'recommend to a friend' question (Table 2). The final list of 18 themes used for qualitative analysis included five themes driven by the data, four in research processes (i.e., comments about research staff, learning opportunity, quality of study, and importance of research) and one in drivers of decision-making (i.e., increased BP monitoring) (Panel 1).

Table 4 presents women's themes according to 'less tight' vs. 'tight' control. Within each treatment group, responses according to whether women were willing to have the same treatment in a future pregnancy (as a measure of satisfaction), and then whether the comments were positive (e.g., worry) or negative (e.g., reassurance) within that theme are presented in Table S3. (Responses for the satisfaction question of 'would recommend treatment to a friend' were similar and are presented in Appendix Table S4.) In 'tight' (and 'less tight') control groups, most themes were commented on positively. Women's statements usually related to processes of care (especially extra health care provider care and quality of care), and less frequently, to 'drivers of decision-making', followed by research-processes and outcomes.

With regards to process of care, comments reflected the importance of one-to-one personalised attention (e.g., "**kept a close eye on me throughout my pregnancy**", 'less tight') and the feeling that the quality of care was better due to participation in the trial (e.g., "**because I seemed to be looked after better**", 'tight'). With regards to the themes related to delivery of care and how the research was conducted, women expressed that the trial enabled them and their families to learn from the experience, as research staff answered questions and explained the condition and procedures thoroughly (e.g., "**everything was explained to me, I understood everything**", 'tight' control). The information led some women to become more involved in their health (e.g., "**made me more involved/compliant with my BP management**", 'tight' control).

With regards to 'drivers of clinical decision-making', women in 'tight' control felt safe (e.g., "**I feel more reassured about my health, my pregnancy, and my baby"**, 'tight') and positively about the BP level achieved, as did women in 'less tight 'control (e.g., "**my mind was at ease about not taking anything and that I was safe on the trial**", 'less tight'; "**I felt that my blood pressure was well controlled**", 'less tight'). Women in 'tight' (vs. 'less tight') control

Table 3
Satisfaction by outcome among women in 'less tight' ($N=488$) vs. 'tight' control ($N=483$).[a]

Theme	'Less Tight' control ($N=488$)			'Tight' control ($N=483$)		
	Adverse outcome	No adverse outcome	p	Adverse outcome	No adverse outcome	p[b]
CHIPS primary outcome	$N=151$	$N=337$		$N=148$	$N=335$	
Willing to have treatment in future pregnancy			**0.005***			**0.02***
Yes	126 (83.4%)	305 (90.5%)		127 (85.8%)	308 (91.9%)	
No	17 (11.3%)	15 (4.5%)		10 (6.8%)	8 (2.4%)	
Missing	8	17		11	19	
Recommend treatment to a friend			**0.002***			0.41
Yes	127 (84.1%)	309 (91.7%)		130 (87.8%)	306 (91.3%)	
No	16 (10.1%)	12(3.6%)		7 (7.5%)	11 (5.4%)	
Missing	8	16		11	18	
Birth weight <10th centile	$N=77$	$N=411$		$N=95$	$N=388$	
Willing to have treatment in future pregnancy			0.37			0.14
Yes	68 (88.3%)	363 (88.3%)		83 (87.3%)	352 (90.7%)	
No	7 (9.1%)	25 (6.1%)		6 (6.3%)	12 (3.1%)	
Missing	2	23		6	24	
Recommend treatment to a friend			0.43			0.39
Yes	69 (89.6%)	367 (89.3%)		85 (89.5%)	351 (90.5%)	
No	6 (7.8%)	22 (5.3%)		5 (5.3%)	13 (3.4%)	
Missing	2	22		5	24	
Severe hypertension	$N=197$	$N=291$		$N=131$	$N=352$	
Willing to have treatment in future pregnancy			**0.004***			0.08
Yes	170 (86.3%)	261 (89.7%)		113 (86.3%)	322 (91.5%)	
No	21 (10.6%)	11 (3.8%)		8 (6.2%)	10 (2.8%)	
Missing	6	19		10	20	
Recommend treatment to a friend			**0.01***			0.93
Yes	173 (87.8%)	263 (90.4%)		117 (89.3%)	319 (90.6%)	
No	18 (9.1%)	10 (3.4%)		5 (3.8%)	13 (3.7%)	
Missing	6	18		9	20	
Pre-eclampsia	$N=237$	$N=251$		$N=221$	$N=262$	
Willing to have treatment in future pregnancy			**0.0005***			**0.03***
Yes	200 (84.4%)	231 (92.0%)		193 (87.3%)	242 (92.4%)	
No	25 (10.5%)	7 (2.8%)		13 (5.9%)	5 (1.9%)	
Missing	12	13		15	15	
Recommend treatment to a friend			**0.0002***			0.92
Yes	202 (85.2%)	234 (93.2%)		199 (90.0%)	237 (90.5%)	
No	23 (9.7%)	5 (2.0%)		8 (3.6%)	10 (3.8%)	
Missing	12	12		14	15	

[a] Satisfaction was explored according to whether women were willing to have the same treatment in a future pregnancy (yes/no), or recommend the same treatment to a friend in her pregnancy (yes/no).
[b] p value by Chi-square or Fisher's Exact Test, as appropriate.
* These results were significant with a p-value.

Table 4
Theme categories mentioned by women when asked about willingness to have the same treatment in another pregnancy.[a]

Theme	'Less tight' ($N=268$)		'Tight' ($N=265$)	
	Pos	Neg	Pos	Neg
Process of care				
Extra health care provider attention	63	1	60	1
Quality care	60	2	55	0
Quality of treatment	17	5	16	3
Research processes				
Comments about research staff	20	1	21	0
Play role in research & help others[b]	23	0	16	0
Learning opportunity[b]	11	0	26	0
Quality of study	14	1	14	0
Amount of work required	11	4	16	3
Importance of research[b]	2	0	3	0
Drivers of decision-making				
Feelings of safety (+) or worry (−)	23	5	22	3
Amount of medication	28	8	5	9
Blood pressure level achieved	11	14	11	6
Increased BP monitoring	17	1	7	1
Outcomes				
Maternal outcomes	24	10	33	6
Infant outcomes	4	0	13	3
Other				
Any/no problems	14	0	11	0
Planning for future pregnancies[c]	8	0	7	0
Don't know[c]	3	0	6	0

[a] Results are presented according to randomised group ('less tight' vs. 'tight' control), willingness to have the same treatment in another pregnancy ('yes' or 'no'), and whether the comments made were positive or negative.
[b] These themes are positive by their nature.
[c] These themes are neither positive nor negative in nature.

did appear to make fewer positive comments about the amount of medication taken (5 vs. 28, respectively) and the level of BP monitoring (7 vs. 17, respectively), but more positive comments regarding outcomes for both mother (33 vs. 24, respectively) and baby (13 vs. 4, respectively).

Most negative comments were made by women who were not willing to have the same treatment again in a future pregnancy or recommend that treatment to a friend (Table S3). Women were worried about having taken too much medication in 'tight' control (e.g., "**did not like having high doses of medication**") or too little medication in 'less tight' control (e.g., "**being off meds made her feel anxious and concerned** *[about]* **stroke or heart attack**"). Women in 'tight' control may have less frequently expressed concerns about BP level achieved (under drivers of clinical decision-making), and outcomes compared with women in 'less tight' control, as illustrated by comments such as, "**I cannot have less tight control in the future as my last pregnancy was difficult in terms of blood pressure management**" ('less tight'), and "**[I] was not happy with having an abruption, wondering if being in less tight group contributed"** ('less tight').

Comment

Summary of results

In CHIPS, more than 90% of women in both 'tight' and 'less tight' control groups expressed satisfaction as reflected by a willingness to have the same treatment in a future pregnancy or recommend that treatment to a friend. Additional comments revealed that women in both BP control groups had a positive research experience and high regard for the quality of care received. This finding likely reflects the high quality of care provided to women as part of the CHIPS Trial.

In 'tight 'control, satisfaction remained high among women with an adverse outcome, even in comparison with women without an adverse outcome; this was not consistently true among women in 'less tight' control. Qualitative analysis of comments supported these findings, despite women in 'tight' control making fewer positive comments about the amount of medication received or the level of BP monitoring. This would suggest that preferences to limit medication use and monitoring are not the primary drivers of satisfaction overall or with outcomes. Nevertheless, some women in both groups reported anxieties related to treatment of their BP during pregnancy, highlighting the importance of psychological support in pregnancy and postpartum.

Strengths and weaknesses

Strengths of this study include its large numbers, randomisation to 'less tight' vs. 'tight' BP control (such that the two groups of women should have differed only by the type of BP control that they received), high response rate, and inclusion of open-ended questions that allowed participants to describe their feelings and explain their responses. Also, the qualitative and quantitative findings are from the same individuals, so the former results can be used to support the latter.

Weaknesses include that the postpartum questionnaire was administered by the CHIPS trial co-ordinators to whom respondents knew from data collection throughout the trial; although women may have felt uncomfortable expressing negative feelings regarding their treatment, the co-ordinators were not in charge of their care. There were small numbers of women in some thematic groups, making inferences difficult. Given the number of countries involved ($N = 15$) and languages ($N = 9$), it was not possible to either explore responses by region/country of recruitment or conduct the thematic analysis first in the original language which may have avoided potential error introduced by translation followed by thematic analysis in English. Satisfaction may have been best explored using scales rather than by asking about willingness to have the same treatment again or recommend it to a friend, but CHIPS was a large, international trial, and issues of language, culture and cost influenced our decision to go with simplicity. Postpartum questionnaires were not completed for 8/25 women who suffered perinatal losses; in this minority of cases, study co-ordinators did not feel comfortable contacting participants (as outlined in the CHIPS protocol) to explore satisfaction of the CHIPS Trial. Although we respected their views, and the number of women affected was small, our decision may have skewed the results. Finally, the views presented here may not be generalisable to hypertensive pregnant women in general.

Comparison with the published literature

Our data from the main CHIPS Trial document similar satisfaction rates to those reported by women who participated in the CHIPS Pilot Trial, in which more than 90% of women were satisfied with their BP management and care, regardless of allocation to 'less tight' or 'tight' BP control [5]. This was true despite being very involved in management of their BP, as in the main CHIPS Trial; women were expected to know the dBP goal to which they had been randomised, and to carry a diary in which all BP measurements were to be recorded. Our data from the main CHIPS Trial go further by collecting and qualitatively analysing additional comments that women were invited to provide. Comments from women assigned to 'tight' (or 'less tight') control most commonly related favourably to process of care. This is consistent with knowledge that women's involvement in their care, the quality of the caregiver–patient relationship, and the amount of support from caregivers all influence women's evaluation of care, regardless of setting [6,7]. We were unable to identify additional published literature on women's views about their BP management per se, in distinction to their preferences for home BP measurement [8], outpatient (vs. inpatient) care [9], and adequate information about prognosis [10]. These studies indicate the preference for outpatient monitoring, similar to the care provided for the majority of women in CHIPS (i.e., 84.0% vs. 83.2% in 'less tight' vs. 'tight' control, respectively) [8,9]. However, numerous studies exploring patient satisfaction in RCTs have reported similar drivers in willingness to participate: personal clinical benefit, a duty to help others, the importance of contributing to research, increased specialist attention, learning, a good rapport with the research team, clinical reassurance, and perceptions of treatment [11–13].

A stakeholder analysis would be ideal to seek the views of clinicians regarding 'tight' and 'less tight' control of BP, taking into account primary and secondary analyses of CHIPS data, including those of women's views.

Conclusion

This qualitative study extends the findings of the main CHIPS Trial by detailing the individual experiences of women who received 'less tight' and 'tight 'control. Women in 'tight' control were satisfied with their care, even in the face of adverse outcomes. Clinicians prescribing 'tight' BP control in pregnancy should feel reassured by this information.

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Authors' contribution

All named authors contributed to the design of the project, its execution and analysis, and the writing and revision of the manuscript.

Ethical approval

The CHIPS Trial was approved by the Research Ethics Board at the University of British Columbia as the Co-ordinating Centre (H08-00882) and at all study sites.

Conflict of interest

Dr. von Dadelszen reports receiving consulting fees and in-kind support of research from Alere International related to pre-eclampsia and fetal growth restriction through the provision of Triage PlGF cartridges.

Dr. Helewa reports grants from CIHR-Factors associated with inadequate prenatal care, grants from CIHR-Reducing inequities in access to and use of prenatal care in the Winnipeg Health Region through Health System improvement, grants from CIHR-Quality of prenatal care questionnaire development, grants from CIHR-Effect of Folic Acid supplementation in pregnancy on preeclampsia Folic Acid Clinical Trial (FACT), outside the submitted work. Dr. Magee reports grants from Canadian Institutes of Health Research, during the conduct of the study; personal fees from Bill & Melinda Gates Foundation, outside the submitted work. Jennifer Menzies reports grants, personal fees and non-financial support from CIHR, during the conduct of the study. No other potential conflict of interest relevant to this article was reported.

This manuscript is dedicated to the memory of our dear friend and colleague, Dr. Andrée Gruslin.

Acknowledgements

We sincerely thank all of the women who gave of themselves by participating in CHIPS. This manuscript is dedicated to the memory of our dear friend and colleague, Dr. Andrée Gruslin.

We thank the 987 women who participated in CHIPS.

Appendix A

Table S1
CHIPS Study Group.

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Adjudication Committee: Laura A. Magee (Chair), Elizabeth Asztalos, Kellie Murphy, Evelyne Rey, Peter von Dadelszen
Data Safety Monitoring Board: Michael B. Bracken (Chair), Patricia Crowley, Lelia Duley, Richard Ehrenkranz, Kevin Thorpe
Data programmers and analysts: Sunny Chan, Michael Shi, Shelley Yu
Collaborators: The number of women recruited in each country and centre is specified in brackets.
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(*Continued*)

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Appendix B. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.ejogrb.2016.07.509.

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