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Synopsis

Timing of birth to improve outcomes in chronic or gestational hypertension: the WILL RCT

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Abstract

Background: For women with chronic or gestational hypertension who remain well, early term birth (at 37–38 weeks' gestation) may reduce maternal complications, caesareans and stillbirths, but it may increase neonatal morbidity compared with expectant care. Expectant care may increase costs. There are no high-quality data to guide care, which currently involves maternal–fetal surveillance and intervention for maternal or fetal compromise, which may be rapid or unexpected.

Objective: To investigate optimal timing of birth for women with chronic or gestational hypertension who reach term and remain well.

Design: Pragmatic, unmasked, multicentre randomised trial with a health economic analysis.

Setting: Fifty United Kingdom hospitals.

Participants: Inclusion: maternal age ≥ 16 years, chronic or gestational hypertension, singleton pregnancy, live fetus, 36^{+0}–37^{+6} weeks' gestation and able to give documented informed consent. Exclusion: contraindication to either trial arm (e.g. pre-eclampsia), blood pressure ≥ 160/110 mmHg until controlled, major fetal anomaly anticipated to require neonatal care unit admission or participation in another timed birth trial.

Interventions: Planned early term birth at 38^{+0-3} weeks' (intervention) or 'usual care at term' (control, revised from 'expectant care until at least 40^{+0} weeks', August 2022).

Main outcome measures: Maternal coprimary: composite of 'poor maternal outcome' (severe hypertension, maternal death or maternal morbidity and superiority hypothesis).

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Neonatal coprimary: neonatal care unit admission ≥ 4 hours (non-inferiority hypothesis). Each coprimary is measured until primary hospital discharge or 28 days post birth (whichever is earlier).
Key secondary: caesarean birth.
Randomisation: 1 : 1 ratio, minimised for key prognostic variables: site, hypertension type and prior caesarean.
Blinding: It was not possible to mask care providers or participants to the intervention. For the coprimary maternal outcome, there was local site principal investigator/delegate sign-off based on review, masked to allocated group, of primary case notes.
Results: From 2019 to 2022, 403 participants were randomised (37% of target 1080) to intervention (*n* = 201) or control (*n* = 202). The funder stopped the trial during the coronavirus disease discovered in 2019 pandemic for delayed recruitment. In the intervention (vs. control) group, birth was a median of 0.9 weeks earlier (38.4, interquartile range 38.3–38.6 vs. 39.3, interquartile range 38.7–39.9 weeks). There was no evidence of a difference in 'poor maternal outcome' (13% vs. 12%, respectively; adjusted risk ratio 1.16, 95% confidence interval 0.72 to 1.87). For 'neonatal care unit admission ≥ 4 hours', the intervention was considered to be non-inferior to control, as the adjusted risk difference, 95% confidence interval upper bound did not cross the 8% pre-specified non-inferiority margin (7% vs. 7%, respectively; adjusted risk difference 0.003, 95% confidence interval −0.05 to +0.06), although event rates were lower than estimated. There was no evidence of a difference in caesarean (29% vs. 36%, respectively; adjusted risk ratio 0.81, 95% confidence interval 0.61 to 1.08).
Limitations: Recruitment was 37% of the anticipated sample size (as above).
Conclusions: Despite being unable to recruit to target in this study, we observed that most women with chronic or gestational hypertension required labour induction and planned birth at 38^{0-3} weeks (vs. usual care), which resulted in birth an average of 6 days earlier and there were no differences in poor maternal outcome or neonatal morbidity. Our findings provide reassurance about planned birth at 38^{0-3} weeks as a clinical option for these women.
Future work: An individual participant data meta-analysis is planned to address whether the intervention (vs. control) reduces caesarean; low adverse event rates would make unfeasible mounting another randomised trial.
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A plain language summary of this synopsis is available on the NIHR Journals Library Website https://doi.org/10.3310/AAVV3131.

Introduction

Clinical background

In the UK, up to 55,000 pregnancies/year are complicated by chronic hypertension (diagnosed before pregnancy or at < 20 weeks' gestation) or gestational hypertension (diagnosed at ≥ 20 weeks), and half of these women will reach term gestational age. Observational data suggest that delivery between 38^{+0} and 39^{+6} weeks may optimise outcomes for the baby by minimising stillbirth that rises in incidence with advancing gestational age at term (dark blue line, *Figure 1*),[1] but it may also increase neonatal morbidity (light blue line, *Figure 1*) and costs, related primarily to the cost of maternal and fetal surveillance during expectant care and possibly increased caesarean deliveries that are greater than the costs of labour induction.[2,3] However, observational studies are confounded by indication for delivery, so it is not possible to estimate with any certainty the impact of different gestations of delivery on perinatal outcomes. Also, the impact of planned delivery at term (i.e. at 37^{+0}–41^{+6} weeks) on maternal morbidity or caesarean could not be assessed.

Also, of note, are two reviews of trials for induction at term in non-hypertensive pregnancies. Induction was associated with a reduction in caesareans, stillbirth and neonatal death and morbidity.[4,5] There was no negative impact of induction on maternal death, operative delivery or postpartum haemorrhage (PPH). In a recent trial of 6106 low-risk nulliparous women at term, induction at 39 weeks was associated with fewer caesareans and a reduction in the development of a maternal hypertensive disorder, without an increase in perinatal mortality/morbidity.[6] Also, in a large randomised controlled trial (RCT), induction (vs. expectant care) was associated with more reassurance, less worry and no perception of a decrease in maternal control during birth.[7] Limited non-RCT data suggest that following induction, maternal pain is similar and satisfaction is high.[8]

There are no definitive trials that have established how best to manage women with chronic or gestational hypertension who reach 37 weeks and require delivery at term. There are only limited relevant data from five trials (1819 women) in the 2017 Cochrane review.[9] The vast majority of women in prior trials either had proteinuric pre-eclampsia or were randomised at earlier or later gestational ages than we proposed (or both).

Variation in guidelines and practice supports equipoise. The National Institute for Health and Care Excellence (NICE, 2019) advises that timing of birth for women with chronic or gestational hypertension 'be agreed upon with

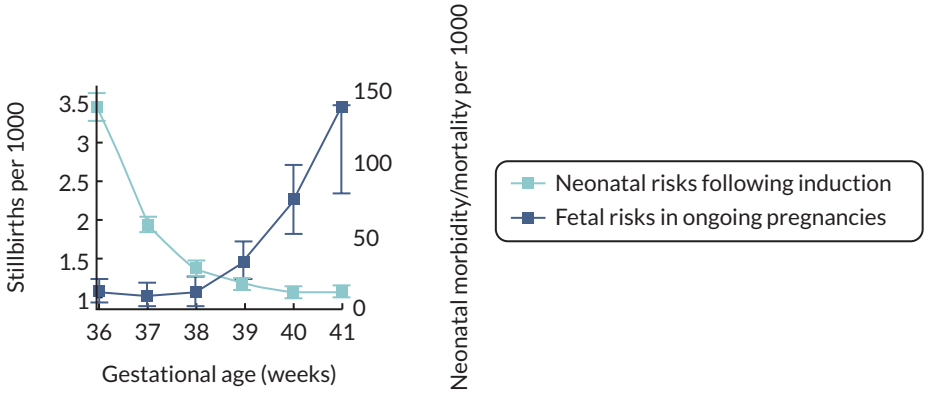

FIGURE 1 Neonatal risks following induction and fetal risks in ongoing pregnancies between 36 and 41 weeks' gestation. Reproduced with permission from Hutcheon *et al.*[1] This is an Open Access article distributed under the terms of the Creative Commons Attribution Licence, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited. The figure includes minor additions and formatting changes to the original text.

the woman'.[10] Current care at term involves maternal and fetal surveillance and intervention for maternal morbidity or fetal compromise, either of which may be rapid or unexpected. Practice varies widely.

Trial rationale

The When to Induce Labour to Limit risk in pregnancy hypertension (WILL) Trial aimed to address the optimal timing of delivery for women with chronic or gestational hypertension, who reached term gestational age and were otherwise well. The study provides data for women to make informed choices about maternal and perinatal risk and for the NHS to plan services. We anticipate receptiveness to the WILL results, as induction is a familiar intervention and earlier delivery rates have been successfully implemented for women with pre-eclampsia at term.[11,12]

Participant population

The trial targeted women with either chronic or gestational hypertension who remained well without pre-eclampsia at term gestational age. Women were consented from 36^{+0} to 37^{+6} weeks when they presented for routine care but were not randomised until 37^{+0-6} weeks to minimise inclusion of women who delivered spontaneously or developed an indication for delivery before this time.

Clinical research questions

1. Does planned early term delivery at 38^{+0} to 38^{+3} weeks' gestation, compared with usual care at term, in pregnant women with chronic or gestational hypertension that develops by 37^{+6} weeks' gestation reduce a composite of 'poor maternal outcome' without unduly increasing neonatal care unit admission for ≥ 4 hours, measured to hospital discharge or 28 days after delivery (whichever is earlier)?
2. What is the impact of planned early term delivery at 38^{+0} to 38^{+3} weeks, compared with usual care at term, in pregnant women with chronic or gestational hypertension that develops by 37^{+6} weeks on maternal and neonatal clinical outcomes and cost–consequence outcomes from an NHS perspective?

Methods for data collection and analysis

Full details of the proposed study have been published previously.[13]

In this pragmatic, two-arm, parallel-group, open-label, multicentre, RCT carried out in 50 maternity units in the UK, we compared planned early term birth at 38^{+0-3} weeks (intervention) with 'usual care at term' (control, revised from 'expectant care until at least 40^{+0} weeks', August 2022) in women with chronic or gestational hypertension at term.

The maternal coprimary outcome was a composite of 'poor maternal outcome' (severe hypertension, maternal death or maternal morbidity) with a superiority hypothesis. The neonatal coprimary outcome was neonatal care unit admission for ≥ 4 hours with a non-inferiority hypothesis. Each coprimary outcome was measured until primary hospital discharge or 28 days post birth (whichever was earlier). A key secondary outcome was caesarean birth. Other secondary outcomes, measured over the same time frame as the coprimary outcomes, included instrumental birth, the components of the maternal coprimary outcome, pre-eclampsia, elevated liver enzymes, platelet count $< 100 \times 10^9$/l, sepsis, PPH, potential cointerventions, maternal intensive care unit admission, maternal satisfaction, other fetal/neonatal outcomes and healthcare resource use. Other secondary outcomes measured at 6 weeks postpartum by post-discharge maternal questionnaire included: infection of the caesarean wound, episiotomy or vaginal tear (as applicable); poor maternal outcome (assessed as one or more of the components of the maternal coprimary outcome) (as assessed post

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discharge after birth by maternal questionnaire). Details are given in the published protocol, and definitions are provided in *Report Supplementary Material 3*.[13] We included all maternal and fetal/newborn outcomes in the hypertensive pregnancy core outcome set,[14] with the exception of neonatal seizures.

Maternal satisfaction was assessed by the Childbirth Experience Questionnaire (CEQ1), which has been validated for use in the UK.[15]

The trial was prospectively registered with the International Standard Randomised Controlled Trial Number (ISRCTN) registry (ISRCTN77258279).

Sample size and statistical analysis

We estimated that a sample size of 1080 women (540/group) was required to detect an absolute risk reduction of 8% in the rate of poor maternal outcome from a control group rate of 25% (unpublished data),[16] with 90% power at an alpha level of 0.05 (superiority hypothesis). For the neonatal coprimary outcome, we estimated that this sample size would have 88% power to detect a non-inferiority margin of 8%, assuming a control group rate of 23%, and would have 90% power to detect a 10% decrease in caesarean,[17] assuming a control group rate of 45%. No adjustment was made for loss to follow-up or dropouts.

A comprehensive statistical analysis plan (see *Report Supplementary Material 1*) was developed and any amendments were made before any analyses. These were undertaken according to this plan. Participants were analysed using the intention-to-treat principle (irrespective of adherence with the treatment protocol).

Coprimary outcomes were analysed using mixed-effects logistic regression, adjusted for hypertension type and prior caesarean, as fixed effects (when convergence was possible) and recruiting centre as a random effect. Adjusted risk ratios (aRRs) and adjusted risk differences (aRDs) with 95% confidence intervals (CIs) were calculated by marginal standardisation for covariate adjustment.[18] For the neonatal coprimary outcome, non-inferiority was based on the upper limit of the 95% CI in relation to our non-inferiority margin of 8%. Binary secondary outcomes were analysed as per primary outcomes. Continuous outcomes were analysed using mixed-effects linear regression to generate adjusted mean differences and 95% CIs.

Pre-planned subgroup analyses were limited to coprimary outcomes and were undertaken on variables used in the minimisation algorithm, except for recruiting centre and ethnicity, body mass index, prior severe hypertension (index pregnancy) or any of the following at randomisation: antihypertensive therapy, gestational diabetes mellitus or smoking.

Sensitivity analyses limited to coprimary and key secondary outcomes were to assess the impact of missing data, further adjust for baseline characteristics, exclude women and babies if birth in the intervention arm was before 38^{0-3} weeks and in the control group before 39^{+0} weeks, assess heterogeneity of treatment effect due to the change to usual care (control arm) and assess the impact on the neonatal coprimary outcome of stillbirths or neonatal deaths before neonatal unit admission. Unadjusted differences in medians (and corresponding 95% CI) were performed using bootstrapping methods (repetitions = 1000, seed = 123,456). Complier average causal effect analyses were not performed due to analytical difficulties in applying the standardisation approach.

The primary economic analysis was a cost–consequence analysis from an NHS perspective comparing intervention and control management strategies. All resource use was valued with unit cost data (2020–1 prices) obtained from NHS Reference Costs.[19] Overall mean costs and measures of their variance were calculated for outpatient visits, hospital admissions, tests of maternal or fetal well-being, maternity care and neonatal care for both groups. Mean differences in costs were calculated using regression analysis, with bootstrapped bias-corrected 95% CIs (1000 samples) (see *Report Supplementary Material 2*). There were no deviations from the original plan.

Enrolment and randomisation

Among 50 participating sites with a median of 4976 births annually (interquartile range 3400–5800 births annually), 46 sites consented at least one woman between 3 June 2019 and 19 December 2022, with a pause after the internal pilot trial (from 20 March to 5 July 2020) due to the coronavirus disease discovered in 2019 (COVID-19) pandemic. *Figure 2* shows that of the 2822 screened, 1030 women were identified as eligible, of whom 432 (47%) consented to participate and 582 (57%) declined. Of 432 women who consented, 403 were randomised, 201 to intervention and 202 to control. There were two protocol deviations in women in the control group: one woman had a planned timed birth, and another was randomised on the training site; both were analysed in their randomised group.

Both groups were similar at trial entry. On average, women were just over 30 years of age, with slightly more than 20% from ethnic minority groups and over half with a body mass index ≥ 30 kg/m^2. Approximately, half of women

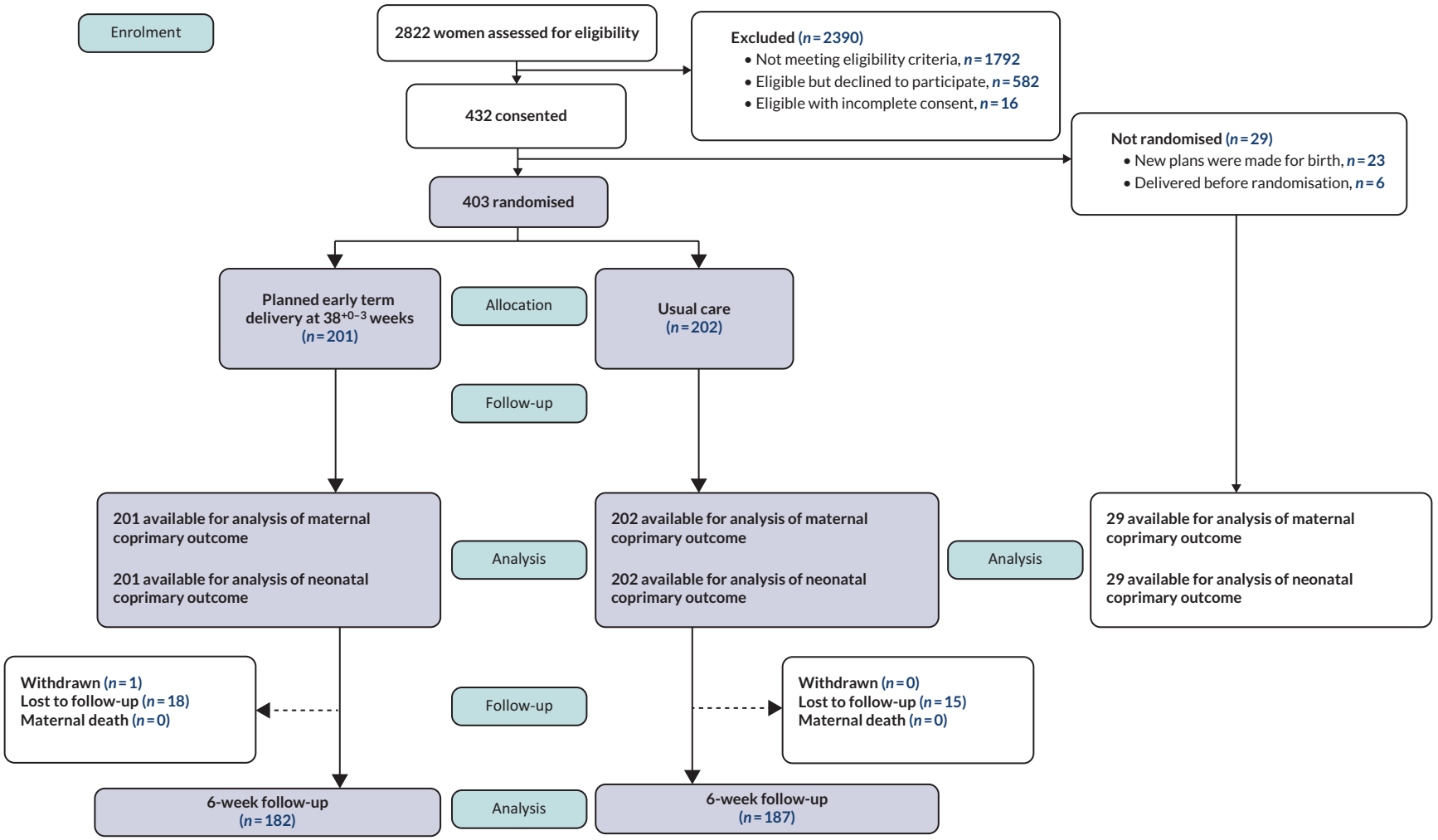

FIGURE 2 Consolidated Standards of Reporting Trials diagram.

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had chronic hypertension. Among 209 parous women (52%), approximately one-sixth had a prior caesarean. The gestational age at randomisation was just over 37 weeks. Most women were on antihypertensive medication at enrolment – usually one agent, usually labetalol. Blood pressure (BP) was < 140/90 mmHg in approximately 75% of participants.

Adherence and birth initiation

Adherence to recommended timing of birth was over 90% in the intervention group; non-adherence was most often due to busy hospital induction or theatre schedules. Throughout the trial, median gestational age at initiation of birth was monitored in both groups and reported to individual centres. Gestational ages at both initiation of birth and actual birth were a median of 0.9 (95% CI 0.7 to 1.0) weeks earlier in the intervention (vs. control) group. Initiation of birth was a median of 0.3 weeks before actual birth in each group. A minority (22%) of women in the control group went into spontaneous labour; most were induced (69%) or had an elective caesarean (9%).

Results summary

Coprimary and key secondary outcomes

We found no evidence of a difference in the maternal coprimary ('poor maternal') outcome between the intervention and control groups: 13% versus 12%, respectively; aRR 1.16, 95% CI 0.72 to 1.87; aRD 0.02, 95% CI −0.05 to 0.09. The lower limit of the aRD 95% CI did not include the pre-specified effect size of an 8% point reduction. Receipt of transfusion (of any blood product), as a component of the composite outcome, occurred significantly more often in the intervention group (9/201, 4.5%) versus the control group (2/202, 1.0%), but the 95% CI reflected high levels of uncertainty due to low event rates (aRR 4.68, 95% CI 1.05 to 20.84). All transfusions were postpartum, but there was no evidence of a between-group difference in PPH (see *Other outcomes* below).

For high-level neonatal care ≥ 4 hours, the intervention group was considered to be non-inferior to the control group, as the upper bound of the 95% CI of the aRD did not cross the pre-specified non-inferiority margin of 8% (7% vs. 7%, aRD 0.003, 95% CI −0.05 to 0.06); however, observed event rates were lower than estimated. There were no stillbirths or neonatal deaths. High-level neonatal care was required most commonly for suspected/confirmed infection, respiratory disease or 'poor condition' at birth.

For each coprimary outcome, there was no evidence of heterogeneity of treatment effect for any subgroups. Sensitivity analyses produced similar results.

The risk of the key secondary outcome of caesarean birth was 29% in the intervention group compared with 36% in the control group (aRR 0.81, 95% CI 0.61 to 1.08). While this was not statistically significant, the aRD and 95% CI (−0.07, 95% CI −0.16 to 0.02) included the pre-specified minimal clinically important difference of 10%. The trend towards a difference in caesarean was due to caesarean in labour (following spontaneous onset or induction). The indication for caesarean in the intervention group was most often as dictated by the study protocol, and in the control group, it was based on maternal or fetal indications.

Key publications arising from the trial are listed in *Table 1*.

Other outcomes

For the woman, the incidence of pre-eclampsia was lower in the intervention (28%) versus control (38%) group (aRR 0.74, 95% CI 0.56 to 0.98), diagnosed before or after birth. There was no evidence of between-group differences in PPH, sepsis or intensive therapy unit admission. For the baby, the incidence of respiratory problems was similar between intervention and control groups, whether defined as an indication for high-level neonatal care for ≥ 4 hours (2% vs. 4%, respectively), as that requiring oxygen or positive pressure ventilation (3% vs. 5%, respectively), clinically (3% vs. 5%, respectively) or according to an

TABLE 1 Research papers being synthesised in the synopsis

Primary analysis of the trial including the health economic analysis Determining optimal timing of birth for women with chronic or gestational hypertension at term: The WILL (When to Induce Labour to Limit risk in pregnancy hypertension) randomised trial. *PLOS Med* 2024 November 26;**21**:e1004481. https://doi.org/10.1371/journal.pmed.1004481. PMID: 39591427
Women's childbirth experiences in the WILL randomised trial (When to Induce Labour to Limit Risk in Pregnancy Hypertension): a mixed methods analysis. https://obgyn.onlinelibrary.wiley.com/doi/10.1111/1471-0528.18257.
Experiences of conducting effective patient and public involvement and engagement (PPIE) by the WILL Trial (When to Induce Labour to Limit risk in pregnancy hypertension) Management Team www.researchsquare.com/article/rs-5326038/v1. https://doi.org/10.21203/rs.3.rs-5326038/v1

abnormal chest X-ray (one infant in each group). There was no other evidence of between-group differences in other neonatal outcomes, including establishing breastfeeding or its exclusivity.

Antihypertensive therapy was taken less often in the intervention versus control groups before and after birth; most women took only one agent, most frequently labetalol followed by nifedipine, even postpartum.

There was less monitoring of well-being in the intervention versus control groups, with regard to pre-eclampsia blood or urine testing, obstetric outpatient visits by midwives or in the office/clinic, medical/day/maternal assessment unit or emergency department or fetal cardiotocography or ultrasound. These contributed to lower absolute rates of resource use and costs overall, from an NHS perspective, for care of women in the intervention (£6659.57 ± 1871.63) versus control (£7067.37 ± 2350.80) group (i.e. −£407.80, 95% CI −793.47 to + 39.55; $p = 0.054$), with significantly lower costs in the intervention versus control group for outpatient visits (−£235.32, 95% CI −309.45 to −154.13; $p < 0.001$) and tests of maternal and fetal well-being specifically (−£102.84, 95% CI −136.65 to −67.78; $p < 0.001$).

Childbirth Experience Questionnaire

The CEQ1 was completed by 357 (88.5%) participants, 177 (88.1%) in the intervention group and 180 (93.1%) in the control group. In a complete-case analysis for the intervention versus control group, there were no significant differences in CEQ1 scores overall (3.1 ± 0.4 in the intervention vs. 3.1 ± 0.4 in the control group; aRD 0.06, 95% CI −0.03 to 0.14) or for each domain of childbirth experience. Of note, the scores for 'professional support' were particularly high.

Discussion/interpretation

Principal findings and achievements per project outcome

For women with chronic or gestational hypertension who reach term and remain well, we found that the planned early term birth at 38^{+0-3} weeks versus usual care at term resulted in birth an average of 6 days earlier, although almost 70% of women in the usual care at term group still required labour induction. Planned early term birth at 38^{+0-3} weeks resulted in low rates of adverse maternal and perinatal coprimary outcomes, with no evidence of differences in our coprimary or key secondary outcomes compared with usual care at term. The 95% CI around our comparative estimate for the maternal coprimary outcome (5% point reduction in risk and up to 9% point increase in risk) excludes our target difference of 8% reduction in risk. The 95% CI around our comparative estimate for the neonatal coprimary outcome (5% reduction in risk up to 6% increase in risk) excludes our target non-inferiority margin of 8% increase in risk. It is worth noting that both of the control outcome rates were lower than anticipated, demonstrating that women and babies overall had better outcomes than we initially anticipated.

Also, we found that planned early term birth (vs. usual care at term) did not increase caesarean birth, with the 95% CI from the comparative estimate (16% point reduction in risk and up to a 2% point increase in risk), including a 10% reduction in risk, set as the minimally clinically important difference a priori. There was a reduction in pre-eclampsia (defined broadly) for the woman, with no evidence of increased respiratory or other health problems for the baby. Women were equally satisfied with their care. However, many aspects of healthcare utilisation (monitoring of maternal and fetal well-being and obstetric outpatient visits) and their associated costs were lower in the planned early term birth (vs. usual care at term) group, and the direction of costs overall favoured planned early term birth.

Comparison with the literature

Our findings are consistent with observational data, suggesting that the optimal timing of birth for women with chronic or gestational hypertension at term is from 38^{+0} to 39^{+6} weeks' gestation.[1,2] Our finding of a (non-significant) reduction in caesarean associated with planned early term birth is consistent with the Hypertension and Preeclampsia Intervention Trial at Term (HYPITAT) trial[17] as well as many other trials of induction for other indications.[5,20] While we did observe an increase in transfusion associated with planned early term birth (vs. usual care), the 95% CI from the aRD ranged from 0.1% to 8.0% increased risk, reflecting the uncertainty in this estimate. There was no evidence of an increase in PPH, consistent with systematic reviews of either labour induction for any indication (vs. expectant care) at term,[21] or labour induction for women with any hypertensive disorder of pregnancy (HDP), including those with chronic or gestational hypertension.[22]

There is little prior randomised trial literature to guide the timing of birth for women with chronic or gestational hypertension at term. Most trials enrolled women with pre-eclampsia and have dominated traditional and individual participant data meta-analyses of timed birth for women with any HDP.[9,22–24] While four trials have included at least some women who would have met WILL eligibility criteria (at least 340 participants), only one excluded women with pre-eclampsia.[25] That trial was small ($N = 102$), not prospectively registered and found no differences in a

composite of maternal or neonatal mortality or morbidity or caesarean. There is one ongoing trial (250 women) in India of timed birth at 38 weeks (vs. 40 weeks) for mild gestational hypertension (CTRI/2022/06/043028, recruitment anticipated to end in 2024).

Contribution to existing knowledge

The WILL trial demonstrated that the rate of maternal and neonatal morbidities at term gestational age is very low for women with chronic or gestational hypertension. This may be due to WILL being undertaken in an era of good BP control, with national guidelines in England recommending a target BP ≤ 135/85 mmHg since June 2019,[10] when WILL recruitment began. The majority of women in WILL were taking antihypertensive therapy at enrolment and had BP < 140/90 mmHg. Improved maternal outcomes are consistent with the reduction in severe hypertension and maternal end-organ complications that define pre-eclampsia (particularly thrombocytopaenia and elevated liver enzymes) as seen with BP control in the seminal Control of Hypertension In Pregnancy Study and the Chronic Hypertension And Pregnancy trials.[16,26] A recent retrospective cohort study of women with chronic hypertension controlled with antihypertensive therapy demonstrated that maternal and perinatal outcome rates were low and similar between planned early term birth (particularly at 38 weeks) and ongoing expectant care.[27]

Our healthcare utilisation and economic findings are similar to those of the HYPITAT trial, in which earlier birth was associated with a shorter duration of (and lower incidence of) maternal and fetal surveillance and lower associated costs.[3]

Future work should address whether planned early term birth in women with chronic or gestational hypertension reduces caesarean; an individual participant data meta-analysis is planned, as it would be difficult to justify mounting another randomised trial, given our findings, with low adverse event (AE) rates affecting feasibility.

Strengths and limitations

Strengths

The trial utilised the Clinical Research Network which is a UK established health service-based research strategy designed to aid participant recruitment into clinical research and is embedded within the NHS infrastructure. WILL recruited from a geographically representative range of sites in England and Wales, with two sites in Scotland, managed in a 'real-world' setting in NHS maternity units and benefited from national midwifery leadership. The trial directly addresses a top research priority in the Inducing Labour NICE Guidance.[28] The intervention reflects real-world practice and the outcomes mirror the core outcome set for pregnancy hypertension.

All aspects of the trial were fully remote. Remote consent was introduced in response to COVID-19 restrictions in the UK; however, randomisation and follow-up were designed to be achieved remotely throughout. WILL's use of a third-party text messaging service to facilitate return of the patient-reported 6-week postpartum questionnaire proved to be very successful with a return rate of > 87%.

A strength of the trial was its generalisability to real-world care of women with chronic or gestational hypertension through inclusion of women with comorbidities, including gestational diabetes, particularly given the shared underlying risk factors for pregnancy hypertension and comorbidity, including obesity and advanced maternal age. Of particular note, the trial was reviewed independently by the 'SupporTing Recruitment and retention Improvements for Diverse Ethnicities' (STRIDE) programme, UK, and was found to exceed expectations for having a diverse study population.[29]

Limitations

The control arm of WILL was changed from expectant care until at least 40 weeks to usual care during the recruitment phase of the trial in response to a gradual change in practice driven by the publication of the A Randomised Trial of Induction vs Expectant Management (ARRIVE) trial results,[6] drafted NICE Inducing Labour guidance and COVID-19-fuelled enthusiasm for shorter hospital stays – further detailed in the *Reflections: challenges and changes* section.

Recruitment was halted abruptly and earlier than planned as WILL was identified as a trial significantly behind recruitment targets during the National Institute for Health and Care Research (NIHR) Research Reset, a process which was designed to reduce the size of the NIHR portfolio following national research delays due to COVID-19. This meant that the trial achieved 37% of the target sample size despite indications that recruitment was improving following resolution of all lockdowns.

Take-home messages

The WILL trial results indicate that for women with chronic or gestational hypertension whose BP is controlled, who have reached term and remain well, most (78%) women managed expectantly will require iatrogenic birth for clinical need prior to the onset of spontaneous labour. While the likelihood that planned early birth is harmful for the baby is low, such a management strategy may be beneficial

for the mother; planned early term birth is associated with a lower risk of progression to pre-eclampsia, albeit being potentially associated with a smaller, increased risk of transfusion. The potential reduction in caesarean may appeal to women, and the associated reduction in healthcare utilisation and health system costs may prompt some units to recommend planned early term birth to these women. Thus, it appears on balance that planned early term birth at 38^{+0-3} weeks is the preferred clinical option.

Reflections: challenges and changes

The end of the pilot phase (March 2020) coincided with the start of COVID-19 restrictions in the UK. In response, all site activity was paused until July 2020, when a phased reopening of sites began. Not all sites were able to reopen following this pause, and those that did were operating at reduced capacity within research departments. COVID-19 continued to pose problems for the NHS and WILL throughout the main phase of the trial and had a significant impact on recruitment rates at all sites.

Acting on site feedback, the ARRIVE trial, and the challenges of recruiting in the current clinical environment, the trial team changed the nature of the control arm from 'expectant care from at least 40 weeks' to 'usual care at term'. This was further prompted by a change in clinical practice since the COVID-19 pandemic, resulting in clinicians and women declining WILL, as they did not wish to delay booking induction or elective caesarean until at least 40 weeks should this be the woman's allocated treatment. We believe that there were three determinants of this:

1. Influence by the circulation, in May 2021, of the draft NICE 'Inducing Labour' guidelines in which clinicians were advised to 'consider induction of labour from 39^{+0} weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications associated with continued pregnancy …', with examples including women of Black, Asian or other minority ethnic backgrounds. No recommendation was made specifically about women with chronic or gestational hypertension, although this recommendation would apply to women eligible for WILL. This draft recommendation was removed in its entirety from the final NICE guidance (NG207) issued on 4 November 2021;[28] however, as is NICE practice, this change was not highlighted and some maternity providers are not even aware that this 39-week recommendation has been removed.
2. The publication of the ARRIVE trial (2018) which reported favourable effects of labour induction at 39^{+0-4} weeks (vs. expectant care) among low-risk nulliparous women.[6]
3. The COVID-19 pandemic fuelled enthusiasm for shorter hospital stays and elective caesarean. Also, the latter are anticipated to increase as NHS England has recently suggested that targets minimising elective caesarean rates (to maximise vaginal births) should be replaced by individualised assessment to reduce adverse outcomes.[30] As the upper limit of acceptability (for women and clinicians) for booking elective caesareans was 39^{+5} weeks at many sites, these women were not considered for WILL if they were not willing to delay caesarean to 40^{+0} weeks should they be randomised to the expectant (not usual) care arm.

It is important to highlight the implications of the Ockenden report on the question that WILL was seeking to answer.[30] Ockenden highlighted the danger of avoiding intervention on principle. The report has led to the lifting of caesarean targets without regard for the indications. As such, Ockenden supports intervention to reduce adverse outcomes in general, consistent with the aim of the WILL trial specifically.

Engagement with partners and stakeholders

Institutional capacity-strengthening strategies included regular site teleconferences as a forum to engage with local principal investigators and site staff, monthly newsletters that often included training pages or frequently asked questions on themes of interest in the field of pregnancy hypertension, refresher training for staff at sites and registration for the NIHR Associate Principal Investigator (API) scheme in which 16 APIs registered (7 completed the scheme, 4 withdrew before completion and 5 were unable to complete due to early trial closure). Some patient-facing documents were translated into the most common languages of our target population (informed by feedback via site surveys), which included voice-over animations in Urdu, Bengali and Punjabi, and written information in Polish, thus improving local capacity to recruit from a diverse population. A productive patient and public involvement and engagement (PPIE) group was convened, details of which can be found in the *Patient and public involvement* section.

Patient and public involvement

Aim of patient and public involvement and engagement input

The aim of our PPIE was to ensure that all aspects of the study were informed by the voices of pregnant women (and their wider families) to maximise the benefits of the study results.

Methods of patient and public involvement and engagement input

We worked with PPIE representatives from grant preparation through to dissemination. We included representatives from a range of perspectives, including the relevant patient support groups, Action on Pre-eclampsia (APEC) and Stillbirth and Neonatal Death Charity (Sands, Janet Scott, co-applicant), and people and families with lived experience of pregnancy hypertension. These perspectives were included during research design, development of participant information resources, research management and troubleshooting (as members of the Co-Investigator Group and Trial Steering Committee), interpretation of the data and writing and dissemination of the findings.

A lay PPIE group, consisting of seven members of the public with personal or close relative lived experience was convened. This PPIE group contributed to the design and development of an infographic to aid recruitment discussions between research staff and potential participants, the primary focus of which was to empower and educate women about the complications associated with hypertension in pregnancy; research staff at sites had provided feedback to explain that this was often a barrier to recruitment. Our experiences of setting up the lay PPIE group are reported in full detail .

Results of patient and public involvement input

Engagement with our PPIE group provided important insights into barriers to recruitment. They expressed opinions on the trial patient-facing materials with particular emphasis on inclusivity of all ethnicities and genders. As a result of these discussions, we learned that perceptions of labour and birth vary across communities, with a negative perception of induction and caesarean being common in some ethnic groups, possibly impacting on the recruitment of people in these communities. The majority of the PPIE group expressed opinions that trial materials should be inclusive of trans and non-binary communities. As a result of this, the infographic that they designed used gender-neutral language and inclusive images throughout. The PPIE group proposed wording with regard to explaining risks for women with hypertension in pregnancy, including rates of stillbirth; however, the Research Ethics Committee (REC) considered their wording to be too harsh and preferred a softer approach. As the trial ended early, we were unable to assess the impact on recruitment of the use of the infographic.

Discussion of patient and public involvement input

We were not able to fully evaluate the impact of the lay PPIE group, as they came into effect towards the end of the recruitment period when we had not anticipated that the trial was to be stopped early.

Reflections and critical perspective

Our PPIE group spent considerable time giving input into a coproduced infographic covering the risks of chronic or gestational hypertension at term. Nevertheless, the REC insisted on changes to language to make the information 'less scary'. We were unsuccessful in arguing for the voice of the PPIE group, but we were a little dismayed that they could be over-ridden in this way. In the end, to avoid further delays, we made the changes that the REC requested.

Our PPIE funding was for direct participant reimbursement rather than a PPIE co-lead. As the funding culture changed just after this, it was, at times, challenging to request assistance from APEC for participant PPIE group recruitment, although the chief executive officer of APEC was an active attendee at the coinvestigator group meetings and was available for input on documents, strategies, etc. This serves to reinforce the importance of a funded PPIE Lead, as is now standard practice.

Many members of the PPI group were recruited from 'People in Research'; however, other sources of recruitment could have been considered in order to maximise the diversity of PPIE experiences. The trial team worked to achieve full consensus regarding decisions whenever possible, but when there was an unresolved difference of opinion, decisions were made via a majority vote. This left one individual feeling that they had not been heard.

Equality, diversity and inclusion

The study enrolled 403 pregnant women from 50 maternity units with a wide geographical diversity in the UK; 21.5% of women were from non-White ethnic minority groups (following Office for National Statistics ethnic group descriptors). This meets or exceeds the 19% non-White ethnicity of the UK population, as would be anticipated in a hypertensive population. STRIDE (University of Aberdeen)[29] independently reviewed the WILL trial regarding diversity and found that our population matches or exceeds their recommendations for the proportions of Black and Asian women required for the trial results to be truly generalisable in the UK.

Consideration of the disease burden, epidemiology, presentation and outcomes in the population groups and any differences in the application of existing preventative, screening or diagnostic strategies and treatments

The WILL aimed to recruit all-comers with hypertension in pregnancy. Women with comorbidities were not excluded from the trial, evidenced by the number of people recruited to the trial with a range of comorbidities such as diabetes and renal disease. We recruited a diverse population (as above), and we should note that the November 2021 NICE labour induction guidelines make no recommendation that ethnicity should play any role in determining timing of birth despite ethnic minority (and particularly, Black ethnicity) women being at higher risk of stillbirth.[28]

Generalisability and transferability of evidence

As above, WILL recruited a study population from across the UK that was representative of the UK population. Labour induction is an intervention available to all women in the UK and, in fact, available worldwide through low-cost mechanical means (i.e. balloon catheters). We evaluated all outcomes in the core data set for hypertensive pregnancy, with the exception of neonatal seizures.

Participant representation

The trial was designed with ease of study participation in mind. Remote processes were inbuilt throughout, including consent, randomisation and follow-up, to reduce participant burden. The recruitment window was planned at a time when participants would be seen routinely in antenatal clinics.

The trial's inclusive approach to recruitment and enrolment is in keeping with the wider pregnancy population characteristics and suggests that our research teams enabled participation of a diverse group of women and that our findings are generalisable. Patient recruitment materials were translated into Polish, Urdu, Bengali and Punjabi, as these languages were identified as most commonly spoken within our recruiting centres, in order to optimise participation of underserved groups. In addition, the PPIE group, containing members from diverse backgrounds, discussed issues affecting recruitment among people from seven minority ethnic backgrounds, including perceived stigma among some communities around induction of labour and caesarean section. This knowledge was implemented in the development of a patient-facing infographic designed to be inclusive of all ethnic groups and genders. Patients who were not confident with reading English were encouraged to use friends and family to help them complete the two questionnaires in the trial.

All trial participants provided consent for their mobile phone number to be used as a follow-up mechanism and will be sent a text with a brief summary of the trial results, and they were advised that when published, the final results of the trial will be available on the Birmingham Clinical Trials Unit trial website.

Participant data

We examined whether the effect of the intervention (vs. control) differed according to various baseline characteristics, including ethnicity; no effect was seen, although such subgroup analyses are invariably underpowered.

Reflections on your research team and wider involvement

The research team consisted of people from a wide range of experiences and expertise in global obstetric and neonatal healthcare settings, midwifery, clinical trials methodology, statistics and trial management. Junior members of the team were given opportunities for career advancement, including promotion and authorship.

Impact and learning

Based on the findings of the WILL trial, it appears on balance that planned early term birth at 38^{+0-3} weeks is the preferred clinical option. When BP is controlled and women with chronic or gestational hypertension remain well at term, most (78%) women who were managed expectantly will require iatrogenic birth for clinical need prior to the onset of spontaneous labour. While the likelihood that planned early birth is harmful for the baby is low, such a management strategy may be beneficial for the mother. The potential reduction in caesarean may appeal to women, and there is an associated reduction in healthcare utilisation and health system costs.

Implications for decision-makers

The WILL trial results provide data for informed decision-making about timing of birth in women with chronic or gestational hypertension who reach term gestational age and are otherwise well. The WILL trial findings will also assist health systems in planning services for these women.

Research recommendations

Future work should address whether planned early term birth in women with chronic or gestational hypertension reduces caesarean; an individual participant data meta-analysis is

This synopsis should be referenced as follows:
Kirkham K, Gkini E, Moakes C, Tohill S, Hutcheon JA, Singer J, *et al.* Timing of birth to improve outcomes in chronic or gestational hypertension: the WILL RCT. *Health Technol Assess* 2026;**30**(2). https://doi.org/10.3310/AAVV3131

planned to address caesarean birth, in addition to adverse maternal and fetal/newborn outcomes, as it would be difficult to justify mounting another randomised trial, given our findings, with low AE rates affecting feasibility.

Also, future work should address the impact (if any) of the intervention on longer-term paediatric outcomes, such as growth and development. Consent for linkage of trial records with relevant routinely collected records was granted by > 90% of participants. The team is planning to make an application to NHS Digital for relevant records.

Conclusions

The WILL trial results indicate that for women with chronic or gestational hypertension whose BP is controlled, who have reached term and remain well, most (78%) women managed expectantly will require iatrogenic birth for clinical need prior to the onset of spontaneous labour. While the likelihood is low that planned early birth is harmful for the baby, such a management strategy may be beneficial for women. Planned early term birth is associated with a clinically important, lower risk of progression to pre-eclampsia, albeit potentially being associated with a smaller, increased risk of transfusion; this stands alone as an intervention that could reduce the risk of progression to pre-eclampsia at term in women with chronic or gestational hypertension, similar to the development of de novo pre-eclampsia in the ARRIVE trial of timed birth at term for low-risk nulliparous women.[6] The potential reduction in caesarean may appeal to women, and the associated reduction in healthcare utilisation and some health system costs may prompt some units to recommend planned early term birth to these women.

Given the low rates of adverse outcomes in WILL due to good BP control, it would appear unfeasible to mount another trial to address the research question posed by WILL. As such, on balance, planned early term birth at 38^{+0-3} weeks (compared with usual care at term) may be the preferred clinical option. The WILL trial results provide data for women to make informed choices about maternal and perinatal risk and health systems to plan services for pregnancies with chronic or gestational hypertension at term.

Additional information

CRediT contribution statement

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Ruth Evans: Data curation.

Sean Cole: Data curation.

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Tracy Roberts: Funding acquisition, Methodology, Supervision, Writing – editing and reviewing.

Janet Scott: Funding acquisition, Writing – editing and reviewing.

Laura Price: Methodology.

Patient data statement

On the informed consent form, participants were asked for their permission to link study data collected about them and their babies with other routinely collected health, educational or social data in order to learn more about the impact of different planned timing of delivery on long-term health for women with high blood pressure in a term pregnancy. They were also asked if they would be willing to be contacted in the future about other studies requiring collection of new data and tracking their or their babies' long-term health and development and progress of their child (subject to additional funding).

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

Ethics approval for this study (18/LO/2033) was obtained from the NHS Health Research Authority by the London Fulham Research Ethics Committee on 10 January 2018.

Information governance statement

The University of Birmingham is 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 cosponsor Kings College London (KCL) and Guys and St Thomas' Foundation Trust (GSTT) act as the Data Controller; the University of Birmingham is the Data Processor. The University of Birmingham processes personal data in accordance with KCL/GSTT instructions. You can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for KCL's Data Protection Officer here: www.kcl.ac.uk/research/research-environment/rgei/research-ethics/use-of-personal-data-in-research.

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/AAVV3131.

Primary conflicts of interest: See submitted Conflict of Interest forms. Jon Dorling reports membership on the HTA MNCH Panel (1 March 2013–31 May 2018), HTA Efficient Study Designs -ox 2 (1 November 2015–31 July 2016), HTA General Committee (1 August 2016–4 May 2018) and the following NIHR grant funding award IDs: 17/86/06, NIHR134216, 17/94/31, NIHR152188, NIHR204885. Pollyanna Hardy reports membership on the HTA Commissioning Committee (15 September 2020–3 November 2024). Peter von Dadelszen reports membership on the Global HPSR Committee (18 February 2020–18 February 2025).

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 report.

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Trial registration

This trial is registered as Current Controlled Trials ISRCTN77258279.

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Award publications

This synopsis provided an overview of the research award *WILL (When to Induce Labour to Limit risk in pregnancy hypertension) - a multicentre, randomised controlled trial*.

Other articles published as part of this thread are:

Magee L, Kirkham K, Tohill S, Gkini E, Moakes C, Dorling J, *et al*. Determining optimal timing of birth for women with chronic or gestational hypertension at term: The WILL (When to Induce Labour to Limit risk in pregnancy hypertension) randomised trial. *PLOS Med* 2024;**21**:e1004481. https://doi.org/10.1371/journal.pmed.1004481

Tohill S, Kirkham K, Gkini E, Moakes C, Silverio S, Horgan G, *et al*. Women's childbirth experiences in the WILL randomised trial (When to Induce Labour to Limit risk in pregnancy hypertension): a mixed methods analysis. *BJOG* 2025;**132**;1426–37. https://doi.org/10.1111/1471-0528.18257

For more information about this research, please view the award page (www.fundingawards.nihr.ac.uk/award/16/167/123).

Additional outputs

von Dadelszen P, Tohill S, Wade J, Hutcheon JA, Scott J, Green M, *et al*.; the WILL Pilot Trial Study Group. Labor induction information leaflets – Do women receive evidence-based information about the benefits and harms of labor induction? *Front Glob Womens Health* 2022;**3**:936770. https://doi.org/10.3389/fgwh.2022.936770

Magee LA, Tohill S, Kirkham K, Evans R, Gkini E, Moakes CA, *et al*.; the WILL Trial Study Group. WILL (When to Induce Labour to Limit risk in pregnancy hypertension): a multicentre randomised controlled trial – adaptations to deliver a timing-of-birth trial during the COVID-19 international pandemic. *Trials* 2022;**23**:884. https://doi.org/10.1186/s13063-022-06834-4

Kirkham K, Tohill S, Hutcheon JA, Dorling J, Gkini E, Moakes C, *et al*.; The WILL Trial Study Group. WILL (When to induce labour to limit risk in pregnancy hypertension): Protocol for a multicentre randomised trial. *Pregnancy Hypertens* 2023;32:35–42. https://doi.org/10.1016/j.preghy.2023.03.002

The following was still under review when this synopsis was published. The following preprint version is available for the reader; please be aware this may not have been peer reviewed:

Kirkham K, Tohill S, Wade J, Stubbs C, von Dadelszen P, Richards A, *et al*. Experiences of conducting effective patient and public involvement and engagement (PPIE) by the WILL Trial (When to Induce Labour to Limit risk in pregnancy hypertension) Management Team. *Research Square* 2025. https://doi.org/10.21203/rs.3.rs-5326038/v1

About this synopsis

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List of supplementary materials

Report Supplementary Material 1
Statistical Analysis Plan

Report Supplementary Material 2
Health Economics Analysis Plan

Report Supplementary Material 3
Secondary outcomes: maternal, fetal/neonatal, and health economic

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/AAVV3131).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

The supplementary materials (which include but are not limited to related publications, patient information leaflets and questionnaires) are provided to support and contextualise the publication. Every effort has been made to obtain the necessary permissions for reproduction, to credit original sources appropriately, and to respect copyright requirements. However, despite our diligence, we acknowledge the possibility of unintentional omissions or errors and we welcome notifications of any concerns regarding copyright or permissions.

List of abbreviations

AE	adverse event
APEC	Action on Pre-eclampsia Charity
API	Associate Principal Investigator
ARRIVE	A Randomised Trial of Induction vs Expectant Management
BP	blood pressure
CEQ1	Childbirth Experience Questionnaire
HDP	hypertensive disorder of pregnancy
ISRCTN	International Standard Randomised Controlled Trial Number
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
PPH	postpartum haemorrhage
PPIE	patient and public involvement and engagement
RCT	randomised controlled trial
REC	Research Ethics Committee
STRIDE	SupporTing Recruitment and retention Improvements for Diverse Ethnicities

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