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Participant Information Sheet

When to Induce Labour to Limit risk in pregnancy hypertension –

a multicentre, randomised controlled trial (WILL)

Version 6.0 25th May 2022

1. Invitation

We would like to invite you to take part in our research study called WILL in which this hospital is taking part. The study is entirely voluntary, you do not have to take part. Before you decide, we would like you to understand why the research is being done and what it will involve for you. A member of our research team will go through this information sheet with you and answer any questions you may have. Please feel free to talk to your obstetrician, midwife, family and friends about the study.

2. What is the purpose of this study?

The **WILL** study is looking to enrol women who have high blood pressure (hypertension) during their pregnancy. High blood pressure increases the risk of harm to the mother and to her baby, and the **WILL** trial is being conducted to see at how many weeks of pregnancy it is best to give birth in order to minimise this risk as much as possible.

In the UK, up to 55,000 pregnant women each year have high blood pressure during their pregnancies. Some doctors opt for early planned birth at term (at 37-38 weeks) because this may reduce stillbirth, complications for the mother, and possibly needing a Caesarean birth. However, early planned birth at term may also cause harm, including newborn health problems such as breathing or other difficulties that may require the baby be cared for in a neonatal unit.

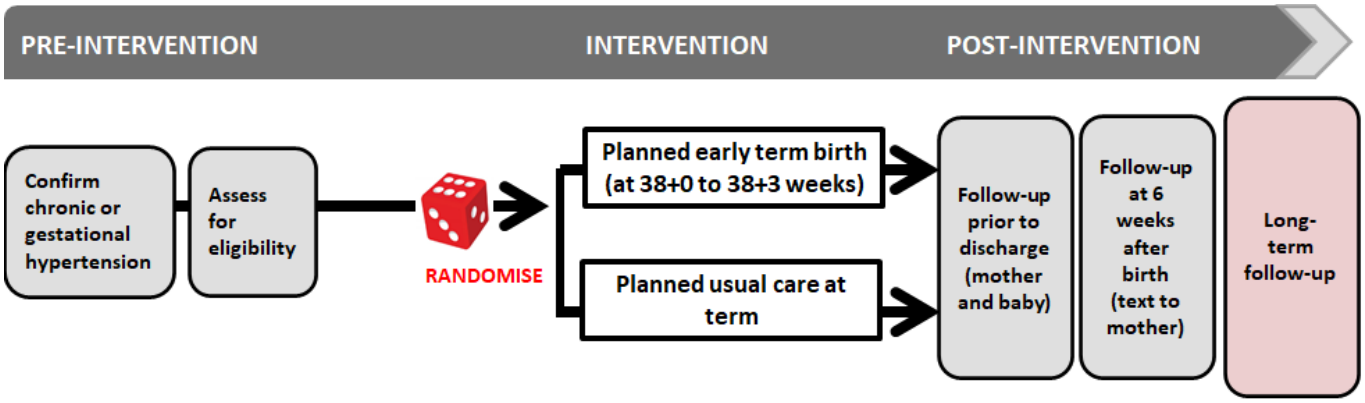
The WILL study is looking at the outcomes experienced by 1,080 pregnant women with high blood pressure who have been pregnant for at least 36 to 37 weeks to see if giving birth to their baby between 38 weeks plus zero days to 38 weeks plus 3 days is better for the mother and her baby than receiving the routine usual care

provided at your hospital. Currently, there is no conclusive evidence to say which timing of birth is best. Different doctors do different things, and this is why we are doing the **WILL** study.

3. Why have I been asked to take part?

You have been invited to take part because you have high blood pressure in your pregnancy and are nearing 'term' gestational age (defined as 37-42 weeks). If your doctors felt that one timing of birth approach would be better for you or your baby then they would not have invited you to take part in the **WILL** study.

4. What would taking part involve?



If you decide to take part in the **WILL** study, we will need a consent form that records your agreement to take part in this study and to have information about you and your baby (including the birth and postnatal care in hospital) shared confidentially with the research team at the University of Birmingham who are running the **WILL** study. The consent form must be signed, either by you in person, by you in discussion with research staff by phone or video (in which case you will then send the consent back to the hospital), or by the research staff in discussion with you by phone or video (in which case you will be sent a copy).

Once the consent form is signed, details about you and your pregnancy will be put into a computer which will randomly choose for you one of two timing of birth groups:

- **Planned early term birth**: In this group, your baby's birth will be planned for between 38 weeks plus zero days and 38 weeks plus three days, by induction of labour (or elective Caesarean if that is already your plan for birth).

- **Usual care at term**: In this group, you will be monitored according to the routine NHS antenatal care at your hospital. Unless you go into spontaneous labour, or you develop a problem that means you need to give birth beforehand, the timing of your baby's birth will be decided between you and your doctor. This may involve induction of labour or elective Caesarean if that is already your plan for birth.

Your midwives and doctors will discuss with you the details of labour induction (or elective Caesarean if that is already your plan for birth), and its benefits and risks.

Neither you nor your health care team can decide which timing of birth group you will be in. All other aspects of your care will be the same as if you decided that you did not want to take part in the **WILL** study. Your health care team can change your planned timing of birth if they think that there is a clinical need for you to give birth at a different time.

Most of the information that is needed about you and your baby will be collected directly from your medical notes and data routinely collected on NHS and central government databases. There are also two questionnaires to complete:

- Before you leave hospital, you will be asked to complete a questionnaire about your experience of childbirth. If you are unable to complete it before leaving hospital, this can be posted back to the research team or completed with the assistance of the research midwife, either over the phone or face-to-face at a postnatal visit.
- Six weeks after you have had your baby, we will ask you to answer a few brief questions about any health problems that you or your baby may have had since leaving hospital. These questions will be sent to you via text message by a private company (Textlocal). We will link your responses with other data through your study number, so your identity remains confidential.

The answers that you provide will help health care staff and researchers get a fuller picture of your birth and postnatal experiences. Also, we will ask for your permission to link your and your baby's health records with other routinely collected health, educational, or social data, to learn more about the impact of different timings of birth in women with high blood pressure at term.

Finally, the consent form will also ask for your permission to be contacted in the future if we wish to collect more information about how you are doing and how your child is developing. By giving your permission to be contacted in the future, you are not committing yourself to taking part in a new follow-up study.

5. What are the possible benefits of taking part?

Currently, women with high blood pressure who reach term gestational age can be induced at 38 or more weeks. We do not know which timing of birth will have the best possible outcomes for mothers and babies.

The potential benefits of planned early birth at term relate to reducing risks to you and your unborn baby.

Giving birth at 38 weeks (vs. a later gestational age) may decrease the risk of the baby not growing very well or stillbirth (which occurs in less than 1% of such babies) and health problems for mothers, such as separation of the placenta from the wall of the womb (in about 2% of women) or development of 'pre-eclampsia' (a dangerous form of high blood pressure that accounts for most complications that occur in 4% of women). It is also possible that giving birth at 38 weeks (vs. a later gestational age) may decrease the 45% chance of needing a Caesarean birth.

It is also possible that you and your baby may not gain any personal benefit at all from taking part in the WILL study. However, the trial will provide valuable information to decide which timing is best in order to minimise the risk that women (and their babies) in the future may experience as a result of having high blood pressure in pregnancy, at term.

6. What are the possible disadvantages and risks of taking part?

The risks of planned early birth at term relate to the newborn.

Giving birth at 38 weeks (vs. a later gestational age) may increase the risk of newborn health problems (particularly breathing problems) that may require special neonatal care. Also, it may be that up to 1% more children born at 38 weeks (instead of later) will require special educational support (such as for dyslexia).

In summary, no one knows which timing of birth approach is best to minimise harm to the mother with high blood pressure at term and her child. National guidance in the UK recommends that timing of birth for pregnant women with high blood pressure "be agreed upon with the woman." Please be assured that your clinical team will always work in the best interests of you and your baby.

7. Who is organising and funding the research?

The WILL study is being funded by the National Institute for Health Research (Ref: 16/167/123).

The WILL study is being sponsored by Kings College London (KCL), co-sponsored by Guy's and St. Thomas' NHS Foundation Trust (GSTT), and managed by the University of Birmingham's Clinical Trials Unit.

No one involved in the trial is being paid to recruit women into the study and women are not paid to take part either.

8. How have patients and the public been involved in this study?

The design of the WILL study has been guided by a survey of women with experience of high blood pressure in pregnancy, and prior patient/public involvement as part of a number of projects; these include the Royal College of Obstetricians and Gynaecologists' (RCOG's) 'Each Baby Counts' initiative and the national review of fetal and newborn deaths in the UK, Action on Pre-eclampsia (APEC) and Sands, the UK's leading pre-eclampsia and stillbirth charities. We have a patient representative on the WILL Trial Management Group and Trial Steering Committee that oversee the project. These lay representatives inform all aspects of the trial, including study design, materials, and procedures.

9. Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee (REC) to protect your safety, rights, well-being and dignity. This study has been approved by the Fulham Research Ethics Committee and the Research & Development (R&D) department for each hospital involved.

10. Will my taking part in this study be kept confidential?

Yes - all information collected in the study will remain strictly confidential in the same way as your other medical records.

King's College London (KCL) and Guy's and St Thomas' NHS Foundation Trust (GSTFT) will be using information from you and your baby's medical records in order to undertake this study and will act as the data managers. They are responsible for looking after your information, using it properly and keeping identifiable information about you for 25 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to

manage your information in specific ways so that the research is reliable and accurate. You can find out more about how we use your information at https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research.aspx.

[NHS/other site] will collect information from [you and/or your medical records] for this research study in accordance with our instructions. [NHS site] will use your name, NHS number and contact details (including email address, telephone number) to contact you, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. [NHS site] will pass these details to KCL, GSTFT and Birmingham University along with the information collected from you and your baby's medical records. Individuals from KCL, GSTFT and Birmingham University and regulatory organisations may look at your medical and research records to check the accuracy of the research study.. The only people who will have access to information that identifies you are those who need to contact you to answer any questions about your or your baby's participation in the WILL study or to audit data collection. The people who analyse the information will not be able to identify you.

All information collected will be securely stored at KCL, GSTT and at study sites for 25 years.

We would like your permission to keep the information we have collected about you and your baby, as we may be interested in this information to assess your long-term health and the development of your child, by linking-up your and your child's (or both) WILL trial data with routinely-collected health, educational, or social data stored at central UK NHS bodies, such as NHS Digital, without contacting you further. To do this linking-up, we will send the central NHS bodies your and your baby's NHS number, date of birth, and sex; these central bodies will link your details to their data and send this information back to the WILL study team. If we need further information that is not in the routinely-collected information at NHS Digital, we would like permission to recontact you to find out if anything related to the birth has affected other health outcomes. Also, we would contact your child when s/he is 16 years of age to ensure that they are happy to continue having their information used in our research.

If you agree to take part, you will be assigned a unique study number. The answers you give will be linked to this study number and not your name. In routine communication between your hospital and the WILL Trial Office, you will only be identified by your study number, last four digits of your NHS number and your

month and year of birth. All individuals who have access to your information have a duty of confidentiality to you.

Your mobile number will be shared with the company, Textlocal, so they can send you the questionnaire 6 weeks after birth. Your details will be encrypted. Textlocal will not use your data for any other purpose. Once your responses have been transferred to the study database, Textlocal will securely delete all of your data.

From time to time, we may be asked to share the data we have collected with researchers running other studies so that they can answer other important questions about timing of birth. These studies may be at universities, NHS organisations or companies involved in health research and may be in this country or abroad. Any such request to share information will only be granted if the necessary procedures and approvals are in place. This information will not identify you or your baby and will only be used for the purpose of health research. It cannot be used to contact you or to affect your care.

11. Involvement of General Practitioner

With your permission, we will write to your GP practice to let them know that you are taking part in the **WILL** study. Your GP will not be able to access your answers or any of the information we hold on file about you.

If we are unable to contact you by post, telephone, email or text after your leave hospital, we may contact your GP for their assistance in gathering a few important details about any health problems that you or your baby may have had.

12. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [insert Principal Investigator name, telephone number and e-mail address]. If you remain unhappy and wish to complain formally, you can do this through the Patients Advice and Liaison Service (PALS) on [add local PALS details]

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against GSTFT and/or KCL but you may have to pay your legal costs. The normal NHS complaints processes will still be available to you (if appropriate).

13. What if I change my mind and no longer want to take part?

You are free to withdraw from the study at any time and you do not have to give a reason why you have changed your mind. Deciding to withdraw from the study will not change the standard of care received by you or your baby.

You can withdraw your consent to our processing of your and your baby's data at any time. If you withdraw from the study, we will clarify with you whether we can use your stored data, whether we can collect any new data from your and your baby's medical notes, and whether we can link your stored data to other NHS or central government bodies for measuring long-term outcomes. If you do not let the study staff or trial office know of the type of withdrawal you want, then we will assume that we can process your and your baby's information in this way. We will also assume that you do not want the study office to contact you in the future.

In the unlikely event that you lose the capacity to consent during the study you will be withdrawn, and we will use any data already collected.

Under the provisions of the General Data Protection Regulation (GDPR) 2018, you have the right to know what information the Trials Office holds about you. If you wish to view this information, or find more about how we use this information, please contact Legal Services at the address below. Please note that a small fee may be payable to retrieve this information.

Legal Services, University of Birmingham, Edgbaston, Birmingham, B15 2TT

14. What happens if new information becomes available?

Sometimes new information becomes available about timing of birth whilst a study is running. If this happens with WILL, then a member of the research team will contact you to tell you about this.

If your doctor is happy for you to continue in the WILL study, you will decide whether you wish to continue, and you may be asked to re-sign a consent form. If you decide not to carry on in the WILL study, you will continue to receive normal NHS maternity care.

If your doctor or a member of the research team considers that you should withdraw from the WILL study then they will explain the reasons why to you and arrange for your standard clinical care to continue.

15. What happens when the research study stops?

Once you have given birth, you will receive the same follow-up and care from your hospital health care team and GP as if you had not taken part in this study.

16. What will happen to the results of the research study?

The results of the WILL study will be published in medical journals and presented at specialist meetings and conferences. Women who take part in this study will be sent a summary of the findings as well as a link that will allow them to access the results of the trial *via* the trial website. No individual participants or their baby will be identifiable in any results or publications.

17. Do you have any further questions?

Having read this information sheet, we hope you will choose to take part in the WILL Study. If you have questions about the study now or later, feel free to ask your obstetrician or midwife, or the person at your hospital who is looking after the WILL Study. Their name and telephone number are at the end of this document.

If you require any general information about research, the UK Clinical Research Collaboration has produced a useful guide entitled, 'Understanding Clinical Trials'. This can be downloaded from their website: www.ukcrn.org.uk. If you require specific information about the research project, please either contact any of the WILL staff listed below or visit our website: www.birmingham.ac.uk/WILL. Only the clinical staff looking after you can give you advice about your pregnancy and the birth options that may be available to you.

Thank you for taking the time to read this leaflet about the WILL trial.

Contact Information

If you would like to speak to someone about the study, please contact:

< Contact Name > <Job Title>

<Telephone and/or E-mail>

Support can also be found through the NHS Patient Advisory and Liaison Service (PALS) or equivalent.

Tel: <insert local PALS contact number(s)>

Email: <insert local PALS email address>