



WILL Trial

ISSUE 19

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Contact the WILL Team

Any queries?

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Christmas is coming!!



December's all about mince pies and starry nights
Christmas decorations, trees and lights
However we are able to spend Christmas this year
Let's hope it brings all of us much festive cheer!



We wish you all a Merry Christmas and a Happy New Year!

Site and participant update

As of the 30th November 2020, we have **22** sites open and **121** randomised participants! **14** of those were in November, equalling our previous highest month of January 2020.

This month, we also saw our **108th** randomised participant (representing **10%** of our target) - **Leicester Royal Infirmary** being the ones to get the lucky number!

Congratulations this month goes to the following sites:

Croydon University Hospital for consenting & randomising **4** participants. **Leicester Royal Infirmary** for consenting **2** & randomising **3** participants. **St Marys Hospital Manchester** and **University Hospital of Wales Cardiff** for consenting & randomising **2** participants each. **St Marys Maternity Unit Poole, Singleton Hospital** and **St Michaels Hospital Bristol** for consenting & randomising **1** participant each. Also to **Sunderland Royal Hospital** for consenting **1** participant to WILL.

Thank you! *for all your hard work!*

Adherence to trial

We recently compiled our first report of adherence to the timing of birth according to allocated trial group. In order to measure the effects of the interventions, there needs to be at least 1 week's separation of birth between groups. So far, we are very pleased to let you know that this has been achieved. Thank you for keeping WILL on track!

WILL Twitter account



We hope that you like reading our tweets!

If you haven't already, please follow our account **@WILLTrial** and give the tweets a 'like' to help spread the word about WILL.

You could receive a tweet like the one here: a hand picked photo, gif, or picture for every woman you randomise to WILL!

Database: Six-week questionnaire

The WILL team may inform you that a participant has not answered any of the text messages from Textlocal, and ask you to phone the participant. If the woman answers the questions this way, please can you leave the following question unanswered:

Q: Did the woman indicate that she would prefer to answer these questions with a member of the research team?

We will know how you completed the form based on the question at the end, which asks how the questionnaire was completed: *by woman with research team, from woman's GP records, or unable to complete.*

WILL team Christmas availability

Katie and Ruth: both on leave from the 21st December—4th January.

Sue is off for a week starting 21st December, and Julie off for a week starting 28th December. One of us will always be available if needed.

Please NOTE: Sue & Julie do not have access to the WILL inbox (that will be checked, but intermittently). As such, please use our individual emails or give us a phone call.



Guy's and St Thomas'
NHS Foundation Trust

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Successful Recruitment

We asked the research midwives at some of our top-recruiting sites to share their secrets about how WILL is going so well there. This month we are focusing on the South sites **Croydon University Hospital** and **St Mary's Maternity Unit Poole**:

TOP TIPS



Croydon team: Research Midwife Geraldine Upson and PI Dr Bini Ajay

How did you initially get the word out to clinical staff about WILL at your hospital when you first opened/re-opened?

Do you do anything on an ongoing basis to

- Create an eligibility card to raise awareness of the study, and distribute contact mobile numbers and email address of research team. Distribute the cards in essential areas: Triage/DAU/ANC/ community teams.
- Visit each area within hospital to make staff aware, and speak Consultants/Registrars and HCAs (as the staff who record BP).
- Find a lovely engaged PI, like we have!
 - Run a research session at mandatory training & doctors' induction.
- Send emails about the study to all of the doctors & midwives in relevant areas.
- Put WILL trial information on general staff maternity and antenatal Facebook pages.
- When a woman is recruited and her consultant wasn't involved, brief him/her via email to let them know what is happening, and what the study is about, particularly that the timing of birth plan should not be adjusted unless there is a clinical need.

- Screen mainly from DAU/Triage and ANC Diabetic clinic.
- Check electronic records for hypertensive women attending and make every effort to see eligible women.
- Check the Day Assessment Diary every week.
- Undertake the HTA sFlt/PIGF ratio test QIP and use your results database.
- Do a joint PANCovid/WILL screen at daily antenatal rounds, as a screening tool every 1-2 weeks.

Where do you screen for potential participants?

How often do you screen

Why do you think that recruitment to WILL is going so well at your site?

Can you provide at least 3 top tips to help other WILL

- Make introductions to new staff & doctors, including student midwives.
- Log eligible women early as you can follow up several times when they attend for other appointments.
- Have open communication with women to understand their needs and get to know them.
- Work closely with your PI. The PI here is excellent: enthusiastic & always available to answer queries.
 - Get involved with whoever sets up home BP monitoring & with the DAU lead midwife as they build up relationships with women who may be eligible for WILL.
- Bribery! Our clinic staff are extra-motivated if we bring them refined carbs. Maoam chews and M&S biscuits work wonders!
- Multitask - If you are running more than one study/QIP/audit with similar eligibility criteria or are working in an area where you will find potential participants, merge your searches rather than doing them individually.
- Maintain a strong presence in antenatal clinic. The support workers and midwives are good at

• I often give out the PIS leaflet at 28-30 weeks. Prior to this, I may have given out the WILL Introductory Pamphlet. I try and see the women logged at 34-36 weeks, often when attending DAU/ANC.

• I try to see women prior to their appointments to see if they are interested, as often, women are given a date/mode of delivery, especially at 36 weeks.

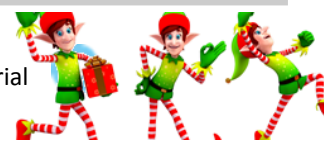
• We have found it more efficient to approach women when they are 36/40 and to recruit them when they are 37/40, so we can randomise them at the same time. We have wasted a lot of time in the past talking to women who were potentially eligible at 28-35/40, but by the time they are 36/40, they are ineligible.

At what gestation is WILL discussed with potential women? Is it discussed as part of their options for birth, or as something separate?

Helpful Hints



Poole team: Research Midwives Susara Blunden and Steph Grigsby and PI Dr Latha Vinayakarao



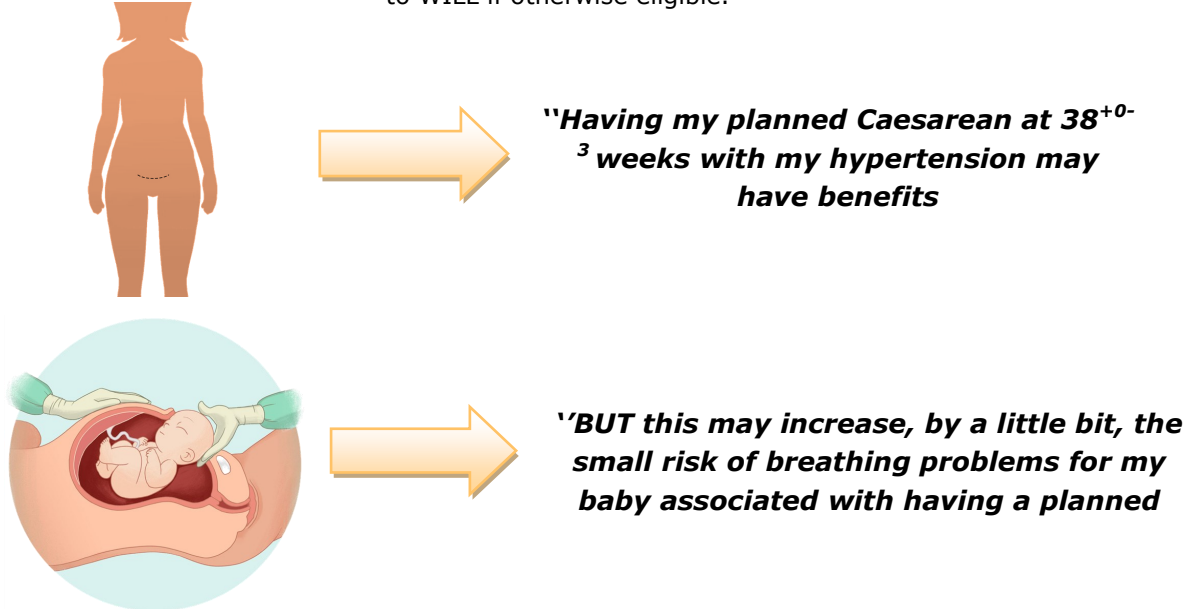
WILL Training page

Information on this page will help you with any discussions you have with women and doctors/midwives caring for them about WILL. We will feature a different topic each month. This month is:

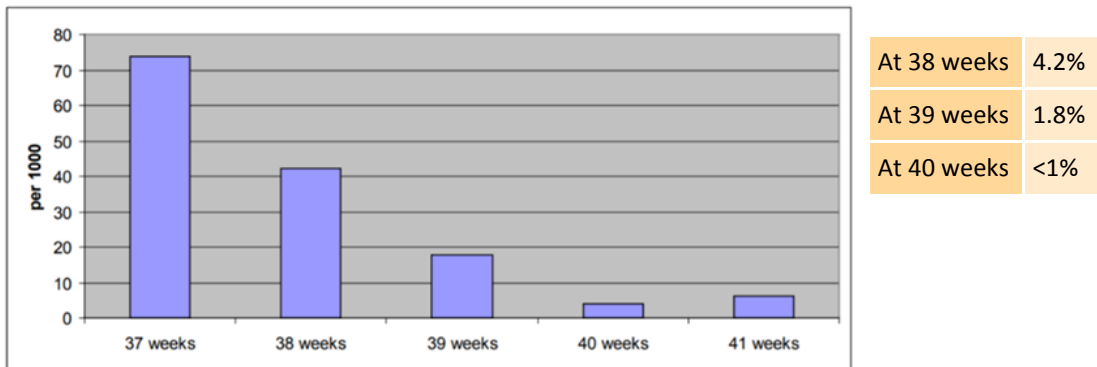
Elective Caesarean

Women with planned Caesareans are eligible for WILL.

Many women will have their elective Caesarean booked for 39⁺⁰⁻⁵. However, as long as the woman and doctor are happy for her to have her Caesarean at either 38⁺⁰⁻³ or at 40 weeks or more, then she can be randomised to WILL if otherwise eligible.



Neonatal respiratory morbidity is slightly more common at 38 weeks than 39 weeks, and at 39 weeks compared with 40 weeks, as shown in the Table and Figure, below, from NICE guidance. (The Figure shows respiratory morbidity per 1000 Caesareans before labour.)



True or False?

Q: NICE guidelines for Caesarean birth recommend administration of antenatal corticosteroids for elective Caesarean until 38⁺⁶ weeks?

A: True. However, there is between-hospital variation in the implementation of this guideline. Some sites give steroids before elective Caesarean only until 34⁺⁶, while others do so until 37⁺⁶ weeks or 38⁺⁶ weeks.

(The reluctance of some sites to prescribe steroids after 34 weeks relates to a high number needed to treat to prevent one case of respiratory morbidity, as well as the potential for steroids to do harm.)

Topic for next newsletter: Pre-eclampsia





Emails and links:

Nhs.net email:
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WILL team at BCTU:
will@trials.bham.ac.uk

Website:
www.birmingham.ac.uk/WILL

Database:
Trials.bham.ac.uk/WILL

Test database:
Trials.bham.ac.uk/WILLTest



The WILL Team: who to contact

WILL at BCTU:

Randomisation challenges or telephone randomisation

Supplies/merchandise

SAE reporting

Database administrative issues, e.g. passwords

Payments for participants

Data queries

WILL Lead RMs:

Recruitment questions (eligibility, screening, etc.)

Clinical & protocol questions

Data form completion (including adjudication of maternal outcome page)

Data queries

Help talking to clinical staff



WILL monthly recruitment table
Total as of 30th November 2020

C=Consented/ R=Randomised

	Jun-Dec 2019	Jan-Jun 2020*	July 2020	Aug 2020	Sept 2020	Oct 2020	Nov 2020	Total
	(C/R)	(C/R)	(C/R)	(C/R)	(C/R)	(C/R)	(C/R)	(C/R)
Croydon University Hospital	3/3	6/6	1/1	0/0	1/1	2/2	4/4	17/17
St Mary's Maternity Unit Poole	4/4	6/6	0/0	2/1	1/1	1/1	2/1	16/14
Leicester Royal Infirmary	5/5	1/1	†	0/0	0/0	5/4	2/3	13/13
James Cook University Hospital	5/5	3/2			0/0	3/2	0/0	11/9
Liverpool Women's Hospital	6/6	1/1	2/2	0/0	1/1	0/0	0/0	10/10
St Mary's Manchester	4/4	3/3			0/0	0/0	2/2	9/9
Leeds Teaching Hospitals	7/6	2/2	0/0	0/0	0/0	0/0	0/0	9/8
Bradford Royal Infirmary	0/0	4/4	0/0	0/0	2/2	0/0		6/6
Nottingham Queens Medical Centre	4/3	1/1		††	0/0	0/0	0/0	5/4
West Middlesex Hospital	3/3	1/1				0/0	0/0	4/4
St. Thomas' Hospital	3/3	1/1	0/0	0/0	0/0	0/0	0/0	4/4
Princess Anne Southampton	1/1	2/2		0/0	1/1	0/0	0/0	4/4
Royal United Hospital Bath	1/1	1/1	0/0	1/1	1/1	0/0	0/0	4/4
Singleton Hospital Swansea	1/1	2/2	0/0	0/0	0/0	0/0	1/1	4/4
North West Anglia NHS Foundation Trust	1/1	2/2	**	**	**	**	**	3/3
Birmingham Women's Hospital	1/1	1/0		1/1	0/0	0/0	0/0	3/2
Nottingham City Hospital	2/0	1/1		††	0/0	0/0	0/0	3/1
University Hospital of Wales Cardiff					0/0	0/0	2/2	2/2
York Teaching Hospital	1/1	0/0						1/1
Kingston Hospital						1/1	0/0	1/1
St Michael's Hospital Bristol					•	0/0	1/1	1/1
Sunderland Royal Hospital	0/0	0/0			0/0	0/0	1/0	1/0
Great Western Hospital						0/0	0/0	0/0
Airedale General Hospital							0/0	0/0
Royal Berkshire Hospital							0/0	0/0
Total (C/R)	52/48	38/36	3/3	4/3	7/7	12/10	15/14	131/121

*The trial was paused from 20 Mar to 7 Jul 2020 for COVID-19

† Restarted 31 Jul 2020 ** Unable to restart WILL following COVID-19 pandemic

†† Restarted 27th Aug 2020 • Opened end of September 2020

WILL Trial Newsletter

Website: www.birmingham.ac.uk/WILL



Twitter: @WillTrial

