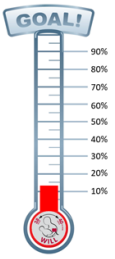
WILL Trial

ISSUE 23

APRIL 2021

Happy Easter to you all!
Hope you enjoy eating lots of chocolate. 'WILL easter egg hunt' - can you find the 10 eggs that we've hidden in this edition?

Site and participant update



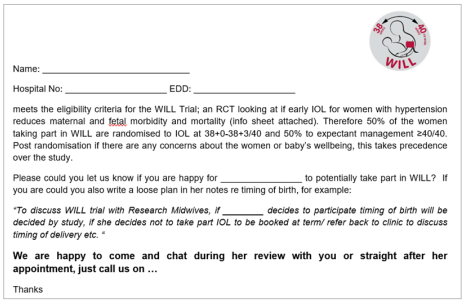
As of the 31st March 2021, we have **23** sites open and **149** randomised participants! **7** of those were in March.

Congratulations to **Croydon University Hospital** for consenting and randomising **2** participants, and to **Cwm Taf Morgannwg University Health Board, James Cook University Hospital, Great Western Hospital, Princess Anne Hospital** and **St Mary's Maternity Unit** for consenting and randomising **1** participant each. Thank you everyone!

We are currently at 13.8% of our overall target for randomised women. Every participant will inch us ever closer to our goal of answering the important research question of WILL. Thank you for continuing to work hard for each one!

Poole: WILL clinic note

On our last teleconference, one of the Research Midwives at Poole kindly shared with us a note that they put on the front of a woman's maternity notes to highlight to her doctor that she may be eligible for WILL. It is working really well and the site was happy for us to share their example. Please contact us if you would like us to email you this note electronically to use.



Name: _____

Hospital No: _____ EDD: _____

meets the eligibility criteria for the WILL Trial; an RCT looking at if early IOL for women with hypertension reduces maternal and fetal morbidity and mortality (info sheet attached). Therefore 50% of the women taking part in WILL are randomised to IOL at 38+0-38+3/40 and 50% to expectant management ≥40/40. Post randomisation if there are any concerns about the women or baby's wellbeing, this takes precedence over the study.

Please could you let us know if you are happy for _____ to potentially take part in WILL? If you are could you also write a loose plan in her notes re timing of birth, for example:

"To discuss WILL trial with Research Midwives, if _____ decides to participate timing of birth will be decided by study, if she decides not to take part IOL to be booked at term/ refer back to clinic to discuss timing of delivery etc. "

We are happy to come and chat during her review with you or straight after her appointment, just call us on …

Thanks

Database

WILL Data Query Management demonstration (link)

Ruth has put together a short video demonstrating how to address data queries (click green link above). This link will also be added to any data query emails you receive. If you have experience of completing WILL data queries, you may want to skip to the section: *Manage Queries* at 5mins 11secs.

Screening form

• When updating, remember to change the date of screening, click '*calculate GA'*, check if any responses need to be amended and update the completion details (date and name). If updating the form retrospectively, please update it as if you were completing it at the time when you were first aware that the woman was ineligible or declined.

• If the woman is ineligible and this is addressed elsewhere in the inclusion/exclusion checklists, there is no need to repeat this ineligibility in the '*Contraindication to either one of the trial arms'.*
For example, if the answer to singleton pregnancy in the inclusion section is 'No', you don't need to also tick 'Yes' in the 'Contraindication…' section.

• If selecting '*Care-provider does not want woman to participate'* please consider if this is due to one of the options listed and could be ticked instead, rather than the care-provider is not supportive of the study/research. If the latter, please document the reason in the CRF notes box.

All forms

• Please could you remember to tick the question *'Please confirm all above items have been considered and that only those ticked apply'* wherever you see this.

The data completion rate has been excellent, so a very big thank you for all your hard work with the outcomes!

Contact the WILL Team

Any queries?

Please contact us:

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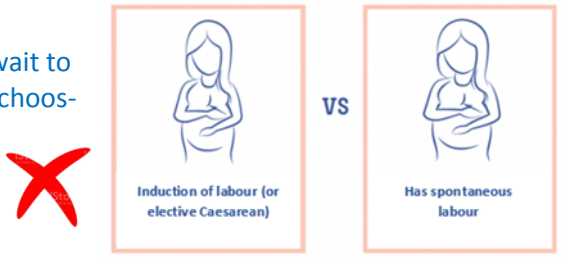
WILL Training page

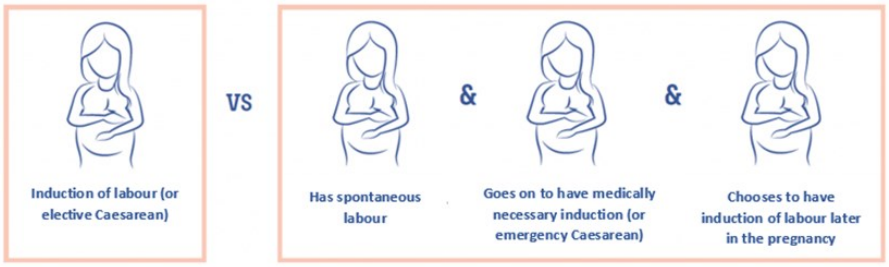
Information on this page will help you with any discussions you have with women and doctors/midwives caring for them about WILL.

We will feature a different topic each month. This month is:

Induction of labour vs spontaneous labour

Women who decline participation in WILL because they would like to wait to go into spontaneous labour (rather than be induced) are, in reality not choosing between the two...





...The choice is actually between **induced labour** and **expectant care.**

If women consent to take part in WILL, induction of labour and expectant care are the two options to which they will be randomly assigned. The 'expectant care' group may result in **any** of the above outcomes.

Although we do not know what will happen for each woman, we do know that:

⇒ Induction of labour (compared with expectant care) reduces the risk of Caesarean delivery by ≈10%, and specifically in high-risk pregnancies (such as those of women in WILL) and at term gestational age (as in WILL) [2,3].

⇒ As induction is associated with an increase in vaginal births overall, it is not surprising that some of the additional vaginal births will be operative (such as Ventouse or forceps), based on data from low-risk women induced at or beyond term [1].

1. Middleton P, Shepherd E, Crowther CA. Induction of labour for improving birth outcomes for women at or beyond term. Cochrane Database Syst Rev 2018;5:CD004945. doi: 10.1002/14651858.CD004945.pub4.
2. Mishanina E, Rogozinska E, Thatthi T, Uddin-Khan R, Khan KS, Meads C. Use of labour induction and risk of cesarean delivery: a systematic review and meta-analysis. CMAJ 2014;186(9):665-73
3. Boulvain M, Stan C, Irion O. Membrane sweeping for induction of labour. Cochrane Database Syst Rev 2005; (1):CD000451

Any direct comparisons between induced and spontaneous labour may be misleading. However, in discussions with women, we can describe the differences between induced labour and spontaneous labour if it were to happen during expectant care:

⇒ The active phase of induced and spontaneous labour is the same. The differences between induced and spontaneous labour are during the latent phase of labour. Active labour is the same, in nature, duration, and outcome [4-6].

⇒ In induced labour, it usually takes 1-2 days for women to progress into active labour. In spontaneous labour, the duration of the latent phase varies, however on average it is ≈20 hours among primiparous women and ≈10-12 hours among parous women.

⇒ You will note from the adherence report, that to date in WILL, the gestational age at delivery is only 0.1 weeks after the gestational age at initiation of delivery in both the planned early term birth and expectant care arms of the trial.

4. Vahratian A, Zhang J, Troendle JF, et al. Labor progression and risk of cesarean delivery in electively induced nulliparas. Obstet Gynecol 2005; 105:698
5. Hoffman MK, Vahratian A, Sciscione AC, et al. Comparison of labor progression between induced and nonin-duced multiparous women. Obstet Gynecol 2006; 107:102
6. Janakiraman V, Ecker J, Kaimal AJ. Comparing the second stage in induced and spontaneous labor. Obstet Gynecol 2010; 116:606.

Let us know if there are any topics you would like covered in the WILL training page

Emails and links:

Nhs.net email:
gst-tr.willtrial@nhs.net

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 tele-phone 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 31st March 2021
C=Consented/ R=Randomised

	Jun-Dec 2019 (C/R)	Jan-Jun 2020* (C/R)	July-Dec 2020 (C/R)	Jan 2021 (C/R)	Feb 2021 (C/R)	March 2021 (C/R)	Total (C/R)
Croydon University Hospital	3/3	6/6	10/9	1/1	1/1	2/2	**23/22**
St Mary's Maternity Unit Poole	4/4	6/6	8/6	1/1	1/1	1/1	**21/19**
Leicester Royal Infirmary	5/5	1/1	7/7	4/4	0/0	0/0	**17/17**
James Cook University Hospital	5/5	3/2	3/2	0/0	0/0	1/1	**12/10**
Leeds Teaching Hospitals	7/6	2/2	1/1	1/1	0/0	0/0	**11/10**
Liverpool Women's Hospital	6/6	1/1	3/3	0/0	0/0	0/0	**10/10**
St Mary's Manchester	4/4	3/3	2/2	0/0	ǂ	ǂ	**9/9**
Bradford Royal Infirmary	0/0	4/4	2/2 ǂ	ǂ	ǂ	ǂ	**6/6**
Singleton Hospital Swansea	1/1	2/2	2/2	0/0	0/0	0/0	**5/5**
Nottingham QMC	4/3	1/1	0/0	ǂ	ǂ	ǂ	**5/4**
West Middlesex Hospital	3/3	1/1	0/0	0/0	0/0	0/0	**4/4**
St. Thomas' Hospital	3/3	1/1	0/0	ǂ	0/0	0/0	**4/4**
Princess Anne Southampton	1/1	2/2	1/1	0/0	0/0	1/1	**5/5**
Royal United Hospital Bath	1/1	1/1	2/2	ǂ	0/0	0/0	**4/4**
University Hospital of Wales			3/3	1/0	0/0	0/0	**4/3**
North West Anglia NHS FT	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	ǂ	ǂ	ǂ	**3/1**
Sunderland Royal Hospital	0/0	0/0	2/2	0/0	1/1	0/0	**3/3**
Great Western Hospital			0/0	2/1	0/0	1/1	**3/2**
York Teaching Hospital	1/1	0/0	0/0 ǂ	ǂ	ǂ	ǂ	**1/1**
Kingston Hospital			1/1	0/0	0/0	0/0	**1/1**
St Michael's Hospital Bristol			1/1	0/0	1/1	0/0	**2/2**
Cwm Taf Morgannwg UHB					1/1	1/1	**2/2**
Airedale General Hospital			0/0	0/0	0/0	0/0	**0/0**
Royal Berkshire Hospital			0/0	0/0	0/0	0/0	**0/0**
Western Sussex Hospitals			0/0	0/0	ǂ	ǂ	**0/0**
Kings College Hospital Trust					0/0	0/0	**0/0**
New Cross Hospital					0/0	0/0	**0/0**
Southend University Hospital					0/0	0/0	**0/0**
Total (C/R)	**52/48**	**38/36**	**49/45**	**10/8**	**5/5**	**7/7**	**161/149**

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

*** Unable to restart WILL following COVID-19 pandemic*

ǂ Paused to WILL due to COVID-19 pandemic