



Contact the WILL Team

Any queries?

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WILL Trial

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The month of bonfire and fireworks might be different this year, but WILL is beginning to 'rocket' again as we celebrate our best month since re-opening.

Site and participant update



A very big welcome to new sites **Great Western Hospital, Swindon** and **Kingston Hospital**! We now have **21** sites open and continue to welcome back pilot sites and prepare for new sites coming on board very soon.

As of the 31st October 2020, we had **107** randomised participants! **10** of those were randomised in October. We have had a great month and congratulations to the teams at the following sites for consenting and randomising an amazing number of participants this month:

Leicester Royal Infirmary: 5 consented and **4** randomised, **James Cook University Hospital: 3** consented and **2** randomised, **Croydon University Hospital: 2** consented and **2** randomised, **St Marys Maternity Unit, Poole Hospital: 1** consented and **1** randomised and **Kingston Hospital: 1** consented and **1** randomised (only 6 days after opening to WILL - a fantastic start!!)

Thank you everyone for all your hard work screening for potential participants. Keep up the great work.

Milestone reached!

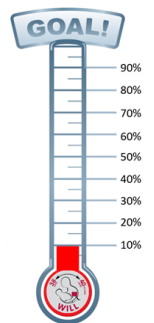
This month we celebrated reaching a big WILL milestone:

St Marys Maternity Unit, Poole randomised our 100th randomised participant. We hope that you enjoyed your gift.

Our next milestone will be our **108th participant** = **10%** of our grand total - we are very nearly there!

A massive thank you to all of our sites that are helping us reach these targets and to all the women for taking part in WILL.

We couldn't do this without your continued support and interest.



Lets keep aiming for at least
1 randomised participant per site per month.

Keep 'thinking WILL'!

- W: Where** are hypertensive women being seen - face to face, virtual appointment's?
- I: Information** can be given at any gestation & sent out if women not seen in person.
- L: Link** up with your clinical teams who are seeing women with hypertension.
- L: Let** us know if we can help you with anything.

Completed Consent Forms

As Ruth is spending a little more time at BCTU, you can now send completed consent forms in the post. However, you can still continue to scan and email them to our secure WILL nhs.net email account: gst-tr.willtrial@nhs.net

Reminder: Please can you write the **participant's study number** at the top of both pages of the consent form.

WILL Training page

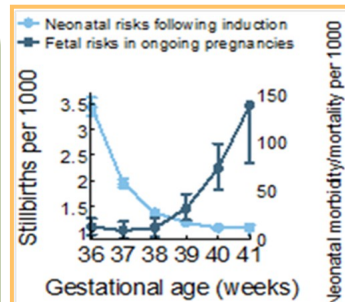
This month we had planned to focus on Elective Caesareans, but instead have decided to look back at some important events that took place in October:



Baby Loss Awareness Week (9-15th Oct UK) and Pregnancy and Infant Loss Remembrance Day (15th Oct US/Canada)...

Chronic hypertension increases the risk of stillbirth and neonatal death with advancing gestational age at term. <https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1111/j.1471-0528.2010.02754.x>

The WILL trial is helping to improve outcomes for women with pregnancy hypertension and their babies, by asking if planned birth at 38 weeks is better than waiting until at least 40 weeks? Answering this important research question will help reduce pregnancy loss.



Early term birth (at 37-38 weeks) may reduce stillbirth, as shown in the figure (dark blue line), for women with chronic hypertension. However, we need to make sure that we do not time birth too early, because we want to avoid an increase in neonatal health problems (light blue line). [BJOG 2011;118(1):49-54]. This is why the planned early term delivery group is at 38 weeks.

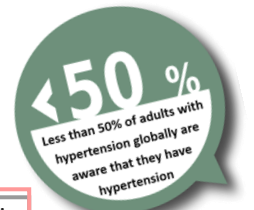
Stillbirth risk for babies of mothers with chronic or gestation hypertension :

- is increased to 1/1000 by 36 weeks
- which is the same risk of stillbirth as in low-risk women at 41+ weeks when IOL is



And...World Hypertension Day (17th Oct)

- ⇒ Aims to increase awareness of high blood pressure in all populations around the world.
- ⇒ Highlights the importance of hypertension to cardiovascular disease risk.

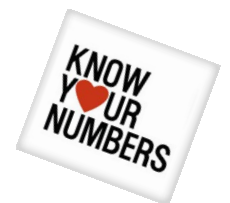


Risks for pregnant women:

For women with gestational hypertension, the progression to pre-eclampsia is associated with an increased risk of chronic hypertension, as well as cardiovascular disease (such as stroke and myocardial infarction).

It is not known whether these risks are further magnified for women with chronic hypertension, by the development of superimposed pre-eclampsia.

As women with high blood pressure in pregnancy are at increased risk of long-term hypertension, having their blood pressure measured regularly is key to making sure women stay as healthy as possible.



Why is WILL important?

The WILL trial is studying whether planned early term birth (at 38+0-3 weeks) vs. expectant care at term (until at least 40+0 weeks) may decrease progression to pre-eclampsia and other maternal complications.

Topic for next newsletter: ... Elective Caesarean





Emails and links:

Nhs.net email:
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WILL team at BCTU:
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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 31st October 2020

C=Consented/ R=Randomised

	Jun-Dec 2019 (C/R)	Jan-Jun 2020* (C/R)	July 2020 (C/R)	Aug 2020 (C/R)	Sept 2020 (C/R)	Oct 2020 (C/R)	Total (C/R)
St Mary's Maternity Unit Poole	4/4	6/6	0/0	2/1	1/1	1/1	14/13
Croydon University Hospital	3/3	6/6	1/1	0/0	1/1	2/2	13/13
Leicester Royal Infirmary	5/5	1/1	†	0/0	0/0	5/4	11/10
James Cook University Hospital	5/5	3/2			0/0	3/2	11/9
Liverpool Women's Hospital	6/6	1/1	2/2	0/0	1/1	0/0	10/10
Leeds Teaching Hospitals	7/6	2/2	0/0	0/0	0/0	0/0	9/8
St Mary's Manchester	4/4	3/3			0/0	0/0	7/7
Bradford Royal Infirmary	0/0	4/4	0/0	0/0	2/2	0/0	6/6
Nottingham Queens Medical	4/3	1/1		††	0/0	0/0	5/4
West Middlesex Hospital	3/3	1/1				0/0	4/4
St. Thomas' Hospital	3/3	1/1	0/0	0/0	0/0	0/0	4/4
Princess Anne Southampton	1/1	2/2		0/0	1/1	0/0	4/4
Royal United Hospital Bath	1/1	1/1	0/0	1/1	1/1	0/0	4/4
Singleton Hospital Swansea	1/1	2/2	0/0	0/0	0/0	0/0	3/3
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	3/2
Nottingham City Hospital	2/0	1/1		††	0/0	0/0	3/1
York Teaching Hospital	1/1	0/0					1/1
Kingston Hospital						1/1	1/1
Sunderland Royal Hospital	0/0	0/0			0/0	0/0	0/0
University Hospital of Wales					0/0	0/0	0/0
St Michael's Hospital Bristol					•	0/0	0/0
Great Western Hospital						0/0	0/0
Total (C/R)	52/48	38/36	3/3	4/3	7/7	12/10	116/107

*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