



Contact the WILL Team

Any queries?

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WILL Trial

ISSUE 30

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It's Nearly Christmas!!

December is all about mince pies, cosy nights in, hot chocolate, marshmallows, Christmas markets, Christmas decorations, trees and lights, festive cheer and maybe even snow.

This year is even more special as we can spend time with family and friends.

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

Site and participant update:

As of the 30th November 2021, we have **40** sites actively open to recruitment, and we have **247** randomised participants! **17** of those were in November.

Welcome to **University College London Hospital, Royal Bolton Hospital, University Hospital North Durham** and **East Surrey Hospital** our newest sites to join us.

What an amazing month. Congratulations and thank you to the following sites:

St Mary's Maternity Unit Poole for consenting and randomising an amazing **6** participants.

Kingston Hospital, King's Mill Hospital and Southend University Hospital for consenting and randomising **2** participants each.

Croydon University Hospital, Leicester Royal Infirmary, Great Western Hospital for consenting and randomising **1** participant each.

Chesterfield Royal Hospital for consenting and randomising their **1st** participant.

St Mary's Manchester for consenting **1** participant.

Royal Berkshire Hospital for randomising **1** participant.

November: Best month for recruitment so far

Our previous best month was 15 randomised participants and we ended November with **17** randomised. This is fantastic. Keep up the brilliant work. Maybe December will be our best month ever? What a great way to end the year!



Extension to end of recruitment: July 2023

WILL has officially been granted additional funding for an 18-month extension by NIHR Health Technology Assessment program. Recruitment will now end in July 2023 with the end of the trial in January 2024. This extension is a reflection of the hard work and commitment you have all given to WILL to answer the important question of When to Induce Labour to Limit risk in pregnancy hypertension. So it is full steam ahead and we look forward to working with you all, welcoming new sites and seeing many more recruits in the next 18 months. Official confirmation will be sent out to sites.

Please do not hesitate to contact Katie (WILL Trial Manager) for further information.

NIHR Associate PI Scheme: WILL already has a couple of Associate PIs that have signed up for this scheme. Do you know of any doctors, midwives or nurses for whom research is not their main role that would be interested? There is a time commitment of 6 months and support from the PI is required, as they would work alongside the Associate PI so that they gain experience. Eligibility can be checked on the website. If interested, discuss with your PI, and find more information here:

<https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040>

Lead Research Midwife: update - Julie Wade:

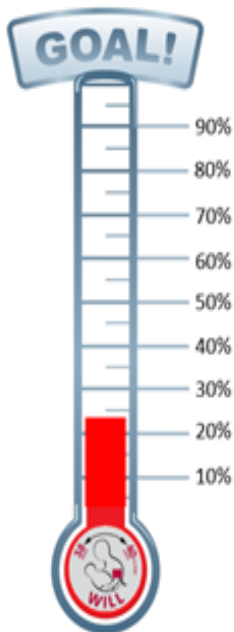
Sadly for WILL, Julie is leaving us to take on new leadership responsibilities at GSTT. It has been great working with Julie and we wish her lots of luck in her new role. Thank you for the time that you have spent with us on WILL and we will all miss you. Don't forget to keep in touch.

Sue will continue to support all of the WILL sites.





WILL is currently at
22.7% of our
randomised target.



Database: 6 week Questionnaire - 1st text message

To ensure that the first text message is sent 6 weeks after birth please could you:

- Check that the correct mobile number is entered on the **Baseline Form**
- Complete the **Delivery, Maternal Outcome** and **Neonatal forms** as soon as possible after birth

To date, we are pleased to let you know that the return rate for the 6 week questionnaire has increased from 78% to 81%, so keep up the great work.

Thank you.

Maternal Outcome form: verification sign off

Thank you to sites for completing the verification sign off section on the maternal outcome page. Sometimes sites do struggle to get a member of their team to verify data on this form. We hope that these tips/reminders are helpful:

In which sections of the form does data need verifying?:

- only the **abnormal laboratory tests** and **maternal complications** sections.

Who can verify data?:

- A member of your team that is masked to the arm the participant was allocated to and has not been involved in her care.
- Can be a research nurse, research midwife, Doctor, trials/research assistant, member of the R&D department who meet the following criteria:
 - GCP trained and have a signed and dated CV.
 - Named on the delegation and training logs. (this can be just for task 'I')
 - Trained in checking medical notes against CRF data (onsite training).
 - Trained to log onto the WILL database:
 - to open a Maternal Outcomes form
 - check the data in the *Abnormal laboratory results* and *Maternal complications* sections
 - complete the sign off section to confirm the data is accurate

Top Tip:

Try to get as many members of your team that you can on the delegation log with the duty 'I' - '**Maternal Outcomes review and sign-off**'.

Staff with just task 'I' do not need to have protocol training or full database training, just training in carrying out that specific task.

Make a cup of tea, have a break and enjoy!

WILL Wordsearch

R	A	S	T	N	M	A	T	E	R	N	A	L	O
A	T	Y	N	T	O	N	T	T	N	O	Y	N	N
N	T	N	E	O	N	A	T	A	L	D	Y	N	H
N	N	N	O	I	S	N	E	T	R	E	P	Y	H
I	Y	A	G	Y	B	A	B	I	N	N	I	N	N
R	E	Y	H	A	A	H	N	P	S	T	C	N	T
A	N	S	O	B	S	T	T	P	A	S	R	S	N
N	N	I	F	T	I	R	N	N	N	L	Y	A	H
D	M	G	O	I	N	I	N	I	T	N	S	N	A
O	F	I	I	I	C	B	S	B	A	O	R	A	V
M	Y	T	I	F	S	A	M	T	S	I	R	H	C
I	B	I	N	A	T	I	V	I	T	Y	T	A	N
S	M	T	Y	N	T	S	D	G	N	S	I	E	N
E	T	N	D	E	M	H	S	R	Y	A	C	A	A

SANTA
MATERNAL
BABY
HYPERTENSION
BIRTH
NATIVITY
GIFTS
RANDOMISE
NEONATAL
CHRISTMAS



WILL Training page

NICE IOL guideline and the WILL trial



3

The new 2021 Inducing Labour guidelines (ng207) were released on 4 November 2021: (<https://www.nice.org.uk/guidance/ng207/resources/inducing-labour-pdf-66143719773637>).

These guidelines emphasise the importance of the research question addressed by WILL, and the lack of evidence to support optimal timing of birth at term gestational age.

The WILL trial aims to evaluate, among pregnant women with chronic or gestational hypertension that develops by 37⁺⁶ weeks, the clinical effectiveness and cost-consequences of two different timing of delivery strategies:

- Planned early term delivery at 38⁺⁰ to 38⁺³ weeks
- Expectant care at term until at least 40⁺⁰ weeks

The guideline makes **7 key research recommendations**, two of which are addressed by WILL for women with chronic or gestational hypertension at term gestational age:



RESEARCH RECOMMENDATIONS:

#1 "Prevention of prolonged pregnancy: At what gestational age should induction of labour be offered in the subgroups of women who may be more likely to experience adverse outcomes if pregnancy continues?"

#2: "Based on individual patient data meta-analysis, what is the optimal timing of induction of labour?"

There is also **NO specific mention of guidance for women with pregnancy hypertension** or specifically, women with chronic or gestational hypertension near term – the population of interest for the WILL trial.



There are **benefits to trial participation** that extend beyond the potential benefits of the intervention, including improved outcomes, compared with non-participants. Also, in WILL as in other trials in pregnancy, the management strategy is high-quality and peer-reviewed, and the outcomes closely-tracked. These are being adjudicated, will be analysed rigorously, and potential subgroups of women who may benefit more (or least) examined.

Thank you for your support of this important NIHR-funded trial!

Feedback: Please could you provide us with any feedback on the information in this training page regarding the NICE IOL guideline and WILL? Does it help you with talking to women and doctors about WILL?

We can chat about this information during our next teleconference too.

Please email any feedback to wiltrial@bham.ac.uk



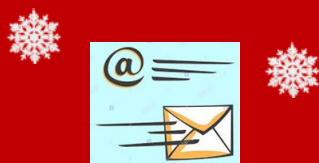
WILL monthly recruitment table

Total as of 30th November 2021

C=Consented/ R=Randomised



	Jun-Dec 2019	Jan-Dec 2020 *	Jan-June 2021	July-Oct 2021	Nov 2021	Total (C/R)
St Mary's Maternity Unit Poole	4/4	14/12	4/4	3/3	6/6	31/29
Croydon University Hospital	3/3	16/15	6/6	1/1	1/1	27/26
Leicester Royal Infirmary	5/5	8/8	5/5	4/4	1/1	23/23
St Mary's Manchester	4/4	5/5	2/2 †	4/4	1/0	16/15
Leeds Teaching Hospitals	7/6	3/3	2/2	2/2	0/0	14/13
Liverpool Women's Hospital	6/6	4/4	1/1	1/1	0/0	12/12
James Cook University Hospital	5/5	6/4	2/2	0/0	0/0	13/11
Bradford Royal Infirmary	0/0	6/6 †	1/1 †	2/2	0/0	9/9
Western Sussex Hospitals		0/0	3/2 †	5/6	0/0	8/8
Sunderland Royal Hospital	0/0	2/2	4/4	1/1	0/0	7/7
Singleton Hospital Swansea	1/1	4/4	1/1	1/1	0/0	7/7
Kings College Hospital Trust			3/3	4/4	0/0	7/7
Great Western Hospital		0/0	5/4	1/1	1/1	7/6
Princess Anne Southampton	1/1	3/3	2/2	0/0	0/0	6/6
Kingston Hospital		1/1	1/1	2/2	2/2	6/6
Royal United Hospital Bath	1/1	3/3	0/0 †	2/1	0/0	6/5
West Middlesex Hospital	3/3	1/1	0/0	1/1	0/0	5/5
Royal Berkshire Hospital		0/0	0/0 †	5/4	0/1	5/5
Birmingham Women's Hospital	1/1	2/1	1/1	2/1	0/0	6/4
University Hospital of Wales		3/3	2/1	0/0	0/0	5/4
Nottingham QMC	4/3	1/1	0/0 †	0/0	0/0	5/4
New Cross Hospital			3/2	2/2	0/0	5/4
St. Thomas' Hospital	3/3	1/1	0/0 †	0/0 †	0/0 †	4/4
Cwm Taf Morgannwg UHB			4/4	0/0	0/0	4/4
Kings Mill Hospital				2/2	2/2	4/4
Nottingham City Hospital	2/0	1/1	1/0 †	1/2	0/0	5/3
Southend University Hospital			2/1	1/0	2/2	5/3
North West Anglia NHS FT	1/1	2/2 **	**	**	**	3/3
St Michael's Hospital Bristol		1/1	2/2	0/0	0/0	3/3
St George's Hospital				2/2	0/0	2/2
York Teaching Hospital	1/1	0/0 †	0/0 †	0/0	0/0	1/1
Airedale General Hospital		0/0	0/0	1/1	0/0	1/1
Royal Cornwall Hospital				1/1	0/0	1/1
Royal Victoria Infirmary			0/0	1/1	0/0	1/1
Chesterfield Royal Hospital				0/0	1/1	1/1
Northumbria Hospital				0/0	0/0	0/0
Royal Oldham Hospital				0/0	0/0	0/0
University College London Hospitals						0/0
Royal Bolton Hospital						0/0
University Hospital North Durham						0/0
East Surrey Hospital						0/0
Total (C/R)	52/48	87/81	57/51	52/50	17/17	265/247



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 telephone randomisation

Supplies/merchandise

SAE reporting

Database administrative issues, e.g. passwords

Payments for participants

Data queries

WILL Lead RM:

Recruitment questions (eligibility, screening, etc.)

Clinical & protocol questions

Data form completion (including adjudication of maternal outcome page)

Data queries

Help talking to clinical staff

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

** Unable to restart WILL following COVID-19 pandemic

† Paused to WILL at some point during this time due to COVID-19 pandemic

Website: www.birmingham.ac.uk/WILL

Twitter: @WillTrial

