



# WILL Trial



ISSUE 36 AND 37

JUNE / JULY 2022

Contact the WILL Team

Any queries?  
Please contact us:

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Welcome to the June/July edition of the WILL Newsletter.

**Happy July - flowers blooming, holidays coming; summer is here!**

## Site and participant update:

As of the 30th June 2022, we have **43** sites actively open to recruitment.  
We currently have **329** randomised participants!  
**13** of those were in May and **12** in June.

Congratulations and thank you to the following sites:



	May	June
Leicester Royal Infirmary	1 consented and 1 randomised	
St Mary's Manchester	3 consented and 3 randomised	<b>Fantastic!</b>
Leeds Teaching Hospitals	1 consented and 1 randomised	1 consented and 1 randomised
Bradford Royal Infirmary	1 consented	
Western Sussex Hospitals	1 consented and 1 randomised	
Sunderland Royal Hospital		1 consented and 1 randomised
Princess Anne Southampton	<b>THANK YOU!</b>	1 consented and 1 randomised
Kings Mill Hospital	1 consented and 1 randomised	1 consented and 1 randomised
Nottingham QMC		1 consented and 1 randomised
Chesterfield Royal Hospital	1 randomised	1 consented and 1 randomised
Royal Cornwall Hospital	1 consented and 1 randomised	1 consented and 1 randomised
Northumbria Hospital		<b>1st</b> consented and randomised
University College London Hospitals	<b>GREAT JOB!</b>	1 consented and 1 randomised
University Hospital North Durham	<b>1st</b> consented and randomised	
East Surrey Hospital	1 consented and 1 randomised	2 consented and 1 randomised
The QE Hospital Kings Lynn	<b>1st and 2nd</b> participant →	2 consented and 2 randomised
University Hospital Wishaw		<b>1st</b> consented and randomised
Singleton Hospital	<b>BRILLIANT!</b>	1 consented and 1 randomised



to  
University Hospital North  
Tees  
that is now open to WILL.

**Target Milestone Reached: 30% of our randomised target**

Congratulations to King's Mill Hospital for randomising our 324<sup>th</sup> Participant and helping us reach our target milestone of 30% of the overall target. Hope you enjoyed your thank you gift. A massive THANK YOU to all sites for helping us reach this target.

## Amendment approved to change the:

**Expectant care arm from 'at least 40<sup>+0</sup> weeks to 'Usual Care at term'**

Substantial amendment 03 has now been approved for this change to the control arm. We feel that this amendment is important to WILL due to the change in clinical practice for women with pregnancy hypertension, since the trial began. Thank you for your feedback and helping us to make the right changes to the arm. We hope that this will be great for all sites in recruiting potential women to WILL.

**Next steps before amendment can be implemented at sites:**

- Amendment paperwork will be sent to site R&D departments for local approval.
- Once site approvals are in place and relevant documents have been received back the amendment can then be implemented.

**Remember:**

**WILL is an important trial for women with hypertension in pregnancy and remains the #1 research priority highlighted in the 2021 NICE Inducing Labour guidelines (NG207).**





### Emails and links:

Nhs.net email:  
[gst-tr.willtrial@nhs.net](mailto:gst-tr.willtrial@nhs.net)

WILL team at BCTU:  
[will@trials.bham.ac.uk](mailto:will@trials.bham.ac.uk)

Website:  
[www.birmingham.ac.uk/WILL](http://www.birmingham.ac.uk/WILL)

Database:  
[Trials.bham.ac.uk/WILL](http://Trials.bham.ac.uk/WILL)

Test database:  
[Trials.bham.ac.uk/WILLtest](http://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:

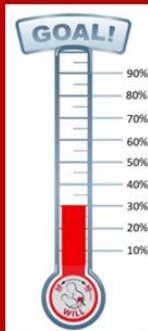
Recruitment questions (eligibility, screening, etc.)

Clinical & protocol questions

Data form completion (including adjudication of maternal outcome page)

Data queries

Help talking to clinical staff



## Relaunch teleconferences: 21st June and 4th July

We have held our first 'relaunch' teleconference to discuss the change to the expectant care arm. Our second teleconference will be on 4th July at 1-2pm. Slides and recording from the teleconferences will also be sent out to all sites. Please get in touch if you have any questions.



## Usual care at term: Guidance sheet

We have developed a 'WILL Guidance Sheet: Usual care at term' that explains the arm. We hope that you will find this useful explaining the arm to women. The guidance has been sent out to you as a separate document.

## Introductory Pamphlet: other languages

We have developed 3 videos of the pamphlet in: **Punjabi, Bengali & Urdu.**



The link to these can be sent to a potential participants to watch or added to your Trust website/research section if possible for potential women to access. If women were interested in taking part in WILL, you would need to use your hospital translation service to discuss further, obtain consent and randomise.

Bengali Voice Over link - [https://youtu.be/hwA9QB\\_hn9E](https://youtu.be/hwA9QB_hn9E)

Punjabi Voice Over link - <https://youtu.be/DzMQpmtxK68>

Urdu Voice Over link - <https://youtu.be/efkunhhCG6M>

## New Data Manager

Greetings everyone! My name is Sean Cole, I am the new Data Manager for WILL. Thank you to the team for already making me feel so welcome.



Please do not hesitate to get in touch as I am happy to help.

You will be able to contact me Monday - Friday:

9am - 5pm

Tel: 0121 415 9111

Email: [will@trials.bham.ac.uk](mailto:will@trials.bham.ac.uk) or [s.cole@bham.ac.uk](mailto:s.cole@bham.ac.uk)

## Database: Completion of data forms/queries

**Thank you** so much to all sites for completing the forms on the database in a timely manner. In **September**, our stats team will be carrying out a statistical analysis of **all** data. We are aiming to have the data as complete as possible by the **1st September**. Sean and Katie will be sending out emails with lists of queries and forms that need completing. Please get in touch if you need any help with queries raised.



**Please let us know if you cannot respond to queries before 1st September.**

## How to check for queries

**WILL Data Query Management demonstration:** 09 March 2021 at 19:56:51 ([panopto.eu](https://panopto.eu))



The link above will take you to you a short video demonstrating how to address data queries (click green link above). If you have experience of completing WILL data queries, you may want to skip to the section: **Manage Queries** at 5mins 11secs.

There are two processes for addressing queries: **EDIT & SAVE** and **MANAGE QUERIES**.

• **Manage Queries Process** : If you are **confirming that data entered is correct** use the Manage Queries process:  
Don't forget to:

- add a comment (ie: this is correct),
- add initials,
- change the query status to **Pending Resolution**
- click **Save**.

• **Edit and Save:** If you are **correcting or adding data on form itself**, there is no need to go through the Manage Queries process. Once complete all you need to do is save the form. The query status will automatically change to **Pending Resolution**. (after you log out of the database)

## Completed Consent Forms

Remember that completed consent forms can be sent to BCTU in the post, using the pre-paid stickers in your site file, or you can scan and email them to our secure WILL nhs.net email account: [gst-tr.willtrial@nhs.net](mailto:gst-tr.willtrial@nhs.net)

If sent via email, please ensure that it is from an **nhs.net** email account.

<b>WILL monthly recruitment table</b> <b>Total as of 30th June 2022</b> C=Consented/ R=Randomised										
<small>Key to recruitment table:            *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</small>										3
	Jun-Dec 2019	Jan-Dec 2020 *	Jan-Dec 2021	Jan 2022	Feb 2022	March 2022	Apr 2022	May 2022	June 2022	Total (C/R)
St Mary's Maternity Unit Poole	4/4	14/12	14/13	1/2	0/0	4/3	0/0	0/0	0/0	37/34
Croydon University Hospital	3/3	16/15	8/8	0/0	1/1	1/0	0/1	0/0	0/0	29/28
Leicester Royal Infirmary	5/5	8/8	11/11	4/4	0/0	0/0	0/0	1/1	0/0	29/29
St Mary's Manchester	4/4	5/5	7/6 †	0/0	1/1	3/3	0/0	3/3	0/0	23/22
Leeds Teaching Hospitals	7/6	3/3	4/4	0/0	0/0	0/0	0/0	1/1	1/1	16/15
James Cook University Hospital	5/5	6/4	2/2	1/1	0/0	0/0	0/0	0/0	0/0	14/12
Liverpool Women's Hospital	6/6	4/4	2/2	0/0	0/0	0/0	0/0	0/0	0/0	12/12
Bradford Royal Infirmary	0/0	6/6 †	4/4 †	0/0	0/0	2/2	0/0	1/0	0/0	13/12
Western Sussex Hospitals		0/0	9/8 †	1/2	0/0	0/0	1/1	1/1	0/0	12/12
Singleton Hospital Swansea	1/1	4/4	2/2	1/1	1/1	1/1	0/0	0/0	1/1	11/11
Great Western Hospital		0/0	9/8	0/0	0/0	2/2	0/0	0/0	0/0	11/10
Sunderland Royal Hospital	0/0	2/2	5/5	0/0	0/0	0/0	0/0	0/0	1/1	8/8
Princess Anne Southampton	1/1	3/3	2/2	0/0	1/1	0/0	0/0	0/0	1/1	8/8
Kings Mill Hospital			4/4	2/2	0/0	0/0	0/0	1/1	1/1	8/8
Nottingham QMC	4/3	1/1	0/0 †	0/0	1/1	1/1	0/0	0/0	1/1	8/7
East Surrey Hospital			0/0	0/0	1/1	2/1	2/2	1/1	2/1	8/6
Kings College Hospital Trust			7/7	0/0	0/0	0/0	0/0	0/0	0/0	7/7
Kingston Hospital		1/1	6/6	0/0	0/0	0/0	0/0	0/0	0/0	7/7
Chesterfield Royal Hospital			2/2	0/0	2/2	1/1	1/0	0/1	1/1	7/7
Birmingham Women's Hospital	1/1	2/1	4/3	0/0 †	0/0 †	0/0	0/0	0/0	0/0	7/5
Cwm Taf Morgannwg UHB			5/5	0/0	0/0	1/1	0/0	0/0	0/0	6/6
Royal United Hospital Bath	1/1	3/3	2/1 †	0/0	0/0	0/0	0/0	0/0	0/0	6/5
Royal Berkshire Hospital		0/0	5/5 †	0/0	0/0	1/0	0/0	0/0	0/0	6/5
University Hospital of Wales		3/3	2/1	0/0	0/0	0/0	1/1	0/0	0/0	6/5
Southend University Hospital			5/3	0/0	1/1	0/0	0/0	0/0	0/0	6/4
West Middlesex Hospital	3/3	1/1	1/1	0/0	0/0	0/0	0/0	0/0	0/0	5/5
St Michael's Hospital Bristol		1/1	2/2	0/0	0/0	0/0	2/2	0/0	0/0	5/5
New Cross Hospital			5/4	0/0	0/0	0/0	0/0	0/0	0/0	5/4
Nottingham City Hospital	2/0	1/1	2/2 †	0/0	0/0	0/0	0/0	0/0	0/0	5/3
St. Thomas' Hospital	3/3	1/1	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	4/4
North West Anglia NHS FT	1/1	2/2 **	**	**	**	**	**	**	**	3/3
St George's Hospital			2/2	0/0	0/0	1/1	0/0	0/0	0/0	3/3
Royal Victoria Infirmary			1/1	1/1	0/0	0/0	1/1	0/0	0/0	3/3
Royal Cornwall Hospital			1/1	0/0	0/0	0/0	0/0	1/1	1/1	3/3
University College London Hospitals			0/0	0/0	1/1	0/0	0/0	0/0	1/1	2/2
Kings Lynn								2/2	0/0	2/2
York Teaching Hospital	1/1	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	1/1
Airedale General Hospital		0/0	1/1	0/0	0/0	0/0	0/0	0/0	0/0	1/1
Glangwili Hospital			0/0	0/0	1/1	0/0	0/0	0/0	0/0	1/1
Walsall Manor Hospital				0/0	0/0	1/1	0/0	0/0	0/0	1/1
Royal Oldham Hospital			0/0	0/0	0/0	0/0	1/1	0/0	0/0	1/1
Northumbria Hospital			0/0	0/0	0/0	0/0	0/0	0/0	1/1	1/1
University Hospital North Durham			0/0	0/0	0/0	0/0	0/0	1/1	0/0	1/1
University Hospital Wishaw								0/0	1/1	1/1
Royal Bolton Hospital			0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Raigmore Hospital								0/0	0/0	0/0
Northwick Park Hospital								0/0	0/0	0/0
<b>Total (C/R)</b>	<b>52/48</b>	<b>87/81</b>	<b>136/126</b>	<b>11/13</b>	<b>11/11</b>	<b>21/17</b>	<b>9/9</b>	<b>13/13</b>	<b>13/12</b>	<b>353/330</b>