



Contact the WILL Team

Any queries?
Please contact us:

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WILL Trial

ISSUE 35

MAY 2022



The month of May brings warmer weather (hopefully), bank holidays, blooming flowers, and the fresh beginnings of summer. The month is known for love and success. We **love** working with you all and let's keep making WILL a **success**.

Site and participant update:

As of the 30th April 2022, we have **44** sites actively open to recruitment. We currently have **305** randomised participants! **9** of those were in April.

Congratulations and thank you to the following sites:

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

St Michael's Hospital Bristol for consenting and randomising **2** participants.

Croydon University Hospital for randomising 1 participant.

Western Sussex Hospitals, University Hospital of Wales & Royal Victoria Infirmary for consenting and randomising **1** participant each.

Chesterfield Royal Hospital for consenting 1 participant. Good luck when randomising

Welcome to Raigmore Hospital—NHS Highland that are now open to WILL. Our second Scottish site!



Congratulations to East Surrey Hospital for consenting and randomising **2** participants but also our **300th** Randomised Participant

Hope you enjoyed your treats



THANK YOU!

Changing the expectant care arm from 'at least 40⁺'

WILL is submitting a proposal to NIHR, to change the control arm from "expectant care at term from at least 40⁺ weeks" to "**Usual care at term**", in response to a change in practice since the trial began, as emphasised by feedback from sites. We will keep you posted!

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). This change will keep the trial relevant. Keep up the fantastic work.

Database: Maternal Outcome form - updates: Proteinuria:

We have added the following definition of **Proteinuria** to consider when answering:

Did the woman develop proteinuria between consent and birth? Only select **yes** if the definition below is met.

≥2+ by dipstick, ≥30mg/mmol by spot protein:creatinine ratio, or ≥0.3g/d by 24hr urine collection

Example scenarios for when to enter data or not:

- Urinary dipstick **negative/trace or +1** AND **34mg/mmol** of spot protein:creatinine ratio (PrCr) – **enter data (because the spot PCR was ≥30mg/mmol)**
- **negative/trace or +1** and **no** to other questions – **do not enter (because definition of proteinuria was not satisfied in the first place)**
- **+2** or more and **no** to other questions – **enter data (woman had proteinuria)**
- **+2** or more AND **34mg/mmol** of spot PrCr – **enter data**
- **34mg/mmol** of spot PrCr and **no** to other questions – **enter data**

You will also be able to add spot protein:creatinine ratio results of <30mg/mmol—only enter if other answers are **yes** and meet the definition of proteinuria.

PI sign off: Abnormal laboratory tests and Maternal complications sections:

It now states that '**This data will need verifying by the PI or delegate who has not been involved in the woman's care.**' We have taken out '**medically-qualified delegate**'. This is the same in the form completion details and verification section.

Verification role: we have created a new role on the database for staff whose **only** role is to verify data. They will **only** have access to the Maternal Outcome & Post-partum Management form to be able to verify data and enter information in the sign off section.





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:

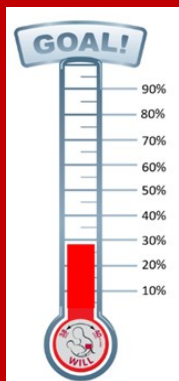
Recruitment questions (eligibility, screening, etc.)

Clinical & protocol questions

Data form completion (including adjudication of maternal outcome page)

Data queries

Help talking to clinical staff



Currently at 28.1%

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

WILL monthly recruitment table								
Total as of 30th April 2022								
C=Consented/ R=Randomised								
	Jun-Dec 2019	Jan-Dec 2020 *	Jan-Dec 2021	Jan 2022	Feb 2022	March 2022	Apr 2022	Total (C/R)
St Mary's Maternity Unit Poole	4/4	14/12	14/13	1/2	0/0	4/3	0/0	37/34
Croydon University Hospital	3/3	16/15	8/8	0/0	1/1	1/0	0/1	29/29
Leicester Royal Infirmary	5/5	8/8	11/11	4/4	0/0	0/0	0/0	28/28
St Mary's Manchester	4/4	5/5	7/6 †	0/0	1/1	3/3	0/0	20/19
Leeds Teaching Hospitals	7/6	3/3	4/4	0/0	0/0	0/0	0/0	14/13
James Cook University Hospital	5/5	6/4	2/2	1/1	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	12/12
Bradford Royal Infirmary	0/0	6/6 †	4/4 †	0/0	0/0	2/2	0/0	12/12
Western Sussex Hospitals		0/0	9/8 †	1/2	0/0	0/0	1/1	11/11
Great Western Hospital		0/0	9/8	0/0	0/0	2/2	0/0	11/10
Singleton Hospital Swansea	1/1	4/4	2/2	1/1	1/1	1/1	0/0	10/10
Sunderland Royal Hospital	0/0	2/2	5/5	0/0	0/0	0/0	0/0	7/7
Kings College Hospital Trust			7/7	0/0	0/0	0/0	0/0	7/7
Kingston Hospital		1/1	6/6	0/0	0/0	0/0	0/0	7/7
Princess Anne Southampton	1/1	3/3	2/2	0/0	1/1	0/0	0/0	7/7
Nottingham QMC	4/3	1/1	0/0 †	0/0	1/1	1/1	0/0	7/6
Birmingham Women's Hospital	1/1	2/1	4/3	0/0 †	0/0 †	0/0	0/0	7/5
Kings Mill Hospital			4/4	2/2	0/0	0/0	0/0	6/6
Cwm Taf Morgannwg UHB			5/5	0/0	0/0	1/1	0/0	6/6
Royal United Hospital Bath	1/1	3/3	2/1 †	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	6/5
University Hospital of Wales		3/3	2/1	0/0	0/0	0/0	1/1	6/5
Chesterfield Royal Hospital			2/2	0/0	2/2	1/1	1/0	6/5
Southend University Hospital			5/3	0/0	1/1	0/0	0/0	6/4
West Middlesex Hospital	3/3	1/1	1/1	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	5/5
New Cross Hospital			5/4	0/0	0/0	0/0	0/0	5/4
East Surrey Hospital			0/0	0/0	1/1	2/1	2/2	5/4
Nottingham City Hospital	2/0	1/1	2/2 †	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 †	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	3/3
Royal Victoria Infirmary			1/1	1/1	0/0	0/0	1/1	3/3
York Teaching Hospital	1/1	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	1/1
Royal Cornwall Hospital			1/1	0/0	0/0	0/0	0/0	1/1
University College London Hospitals			0/0	0/0	1/1	0/0	0/0	1/1
Glangwili Hospital			0/0	0/0	1/1	0/0	0/0	1/1
Walsall Manor Hospital				0/0	0/0	1/1	0/0	1/1
Royal Oldham Hospital			0/0	0/0	0/0	0/0	1/1	1/1
Northumbria Hospital			0/0	0/0	0/0	0/0	0/0	0/0
Royal Bolton Hospital			0/0	0/0	0/0	0/0	0/0	0/0
University Hospital North Durham			0/0	0/0	0/0	0/0	0/0	0/0
Kings Lynn								0/0
University Hospital Wishaw								0/0
Raigmore Hospital								0/0
Total (C/R)	52/48	87/81	136/126	11/13	11/11	21/17	9/9	327/305