



WILL Trial

ISSUE 25

JUNE 2021



Contact the WILL Team

Any queries?

Please contact us:

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Welcome to the June edition of the WILL newsletter.

Wimbledon starting, strawberries & cream, and hopefully lots of sunshine to look forward to this month!

Site and participant update

As of the 31st May 2021, we have **28** sites open and **170** randomised participants! **11** of those were in May (with **9** women consented). Congratulations to:

Sunderland Hospital: consented & randomised **2** women, & randomised a **3rd**. Amazing!

New Cross Hospital: consented & randomised their **1st** & **2nd** participants - fantastic!

Great Western Hospital & Princess Anne Hospital: randomised **1** participant each.

Croydon University Hospital, Kings College Hospital, Leicester Royal Infirmary and St Mary's Maternity Unit: consented and randomised **1** participant each.

And ending the month on a high, **St Michael's Hospital:** consented **1** participant.

We also welcome **Royal Victoria Infirmary** who have joined the WILL team this month and has now opened to recruitment!



Target milestones:

Congratulations to Princess Anne Hospital for randomising participant **162**, which represents **15%** of our overall target. Hope you enjoyed your gift!

thank
you
all

Exclusion criteria/Contraindication to trial arm

You will see on the database if you answer **Yes** to the question 'Contraindication to either one of the trial arms', a list of possible reasons will appear, such as:

- Evidence of pre-eclampsia
- GDM with poor glycaemic control
- GDM on insulin
- GDM on oral hypoglycaemic agent
- Planned elective Caesarean
- Chronic kidney disease
- Obesity (BMI ≥ 30 kg/m²)
- Care-provider does not want woman to participate



Please note: these reasons are **not** exclusions for WILL. However, they may be perceived to be by some doctors. For example, a woman with GDM on medication is **eligible** for WILL, but her doctor may think there will be an increased risk if she were randomised to the expectant care at term group of the trial.

The training pages on the WILL website may be useful in discussions you have with women or their doctors/midwives. Including women with these conditions into the trial will inform results that can help to guide their care.

<https://www.birmingham.ac.uk/research/bctu/trials/womens/will/investigators/training/training-page.aspx>

Amendment:

The relevant paperwork for this approved amendment has been sent to you. Please can you forward your R&D/R&I approval to will@trials.bham.ac.uk by the **21st June 2021**, after which time we will assume that the amendment has been implemented at your site.

World Pre-eclampsia Day: 22nd May

#ActEarlyScreenEarly



Visit APEC's website for events happening around world pre-eclampsia day. Their e-learning course **Hypertensive disorders of pregnancy** has been recently updated and carries CPD accreditation. It is designed for midwives, doctors and professionals caring for women with pregnancy hypertension:

<https://action-on-pre-eclampsia.org.uk/learning/>



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 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 May 2021

2

C=Consented/ R=Randomised

	Jun-Dec 2019 (C/R)	Jan-Dec 2020 * (C/R)	Jan 2021 (C/R)	Feb 2021 (C/R)	March 2021 (C/R)	April 2021 (C/R)	May 2021 (C/R)	Total (C/R)
Croydon University Hospital	3/3	16/15	1/1	1/1	2/2	0/0	1/1	24/23
St Mary's Maternity Unit Poole	4/4	14/12	1/1	1/1	1/1	0/0	1/1	22/20
Leicester Royal Infirmary	5/5	8/8	4/4	0/0	0/0	0/0	1/1	18/18
James Cook University Hospital	5/5	6/4	0/0	0/0	1/1	1/1	0/0	13/11
Leeds Teaching Hospitals	7/6	3/3	1/1	0/0	0/0	0/0	0/0	11/10
Liverpool Women's Hospital	6/6	4/4	0/0	0/0	0/0	0/0	0/0	10/10
St Mary's Manchester	4/4	5/5	0/0	†	†	†	†	9/9
Bradford Royal Infirmary	0/0	6/6 †	†	†	†	†	0/0	6/6
Singleton Hospital Swansea	1/1	4/4	0/0	0/0	0/0	1/1	0/0	6/6
Princess Anne Southampton	1/1	3/3	0/0	0/0	1/1	1/0	0/1	6/6
Sunderland Royal Hospital	0/0	2/2	0/0	1/1	0/0	1/0	2/3	6/6
University Hospital of Wales		3/3	1/0	0/0	0/0	1/1	0/0	5/4
Nottingham QMC	4/3	1/1	†	†	†	†	0/0	5/4
West Middlesex Hospital	3/3	1/1	0/0	0/0	0/0	0/0	0/0	4/4
St. Thomas' Hospital	3/3	1/1	†	0/0	0/0	0/0	0/0	4/4
Royal United Hospital Bath	1/1	3/3	†	0/0	0/0	0/0	0/0	4/4
Birmingham Women's Hospital	1/1	2/1	0/0	0/0	0/0	1/1	0/0	4/3
Great Western Hospital		0/0	2/1	0/0	1/1	1/0	0/1	4/3
North West Anglia NHS FT	1/1	2/2 **	**	**	**	**	**	3/3
Cwm Taf Morgannwg UHB				1/1	1/1	1/1	0/0	3/3
Nottingham City Hospital	2/0	1/1	†	†	†	†	0/0	3/1
Kingston Hospital		1/1	0/0	0/0	0/0	1/1	0/0	2/2
St Michael's Hospital Bristol		1/1	0/0	1/1	0/0	0/0	1/0	3/2
Kings College Hospital Trust				0/0	0/0	2/2	1/1	3/3
Western Sussex Hospitals		0/0	0/0	†	†	2/2	0/0	2/2
York Teaching Hospital	1/1	0/0 †	†	†	†	†	†	1/1
Airedale General Hospital		0/0	0/0	0/0	0/0	0/0	0/0	0/0
Royal Berkshire Hospital		0/0	†	†	†	†	0/0	0/0
New Cross Hospital				0/0	0/0	0/0	2/2	2/2
Southend University Hospital				0/0	0/0	0/0	0/0	0/0
Royal Victoria Infirmary								0/0
Total (C/R)	52/48	87/81	10/8	5/5	7/7	13/10	9/11	183/170

*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 due to COVID-19 pandemic

WILL Trial Newsletter



Website: www.birmingham.ac.uk/WILL

Twitter: @WillTrial

