



WILL Trial



ISSUE 28

SEPTEMBER / OCTOBER 2021

Contact the WILL Team

Any queries?
Please contact us:

Professor Laura A. Magee
Chief Investigator
Laura.A.Magee@kcl.ac.uk

Sue Tohill (North)
Lead Research Midwife
Sue.Tohill@kcl.ac.uk
Mob: 07773970879

Julie Wade (South)
Lead Research Midwife
Julie.Wade@kcl.ac.uk
Mob: 07970338451

Katie Kirkham
Senior Trial Manager
WILL@trials.bham.ac.uk
Tel: 0121 415 9109
Temp no. 07974715467

Ruth Evans
Data Manager
WILL@trials.bham.ac.uk
Tel: 0121 415 9111

Clive Stubbs
Team Leader
WILL@trials.bham.ac.uk
Tel: 0121 415 9117

Birmingham
Clinical Trials Unit (BCTU)
Institute of
Applied Health Research
Public Health Building
University of Birmingham
Edgbaston, Birmingham
B15 2TT
Tel: 0121 415 9109

Hope you're all ready to embrace the change of season but still enjoying the last of the summer with some warm sunny September days.

Site and participant update: August & September

As of the 30th September 2021, we have **34** sites actively open to recruitment, and we have **215** randomised participants! **9** of those were in August and **13** in September.

Welcome to **Kings Mill Hospital, Royal Cornwall Hospital, Chesterfield Royal Hospital, and St George's Hospital**; our newest sites to join us.

Congratulations and thank you to the following sites:

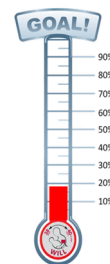
	August	September
Leicester Royal Infirmary	2 consented and 1 randomised	1 consented and 2 randomised
Royal Berkshire Hospital	2 consented and 1 randomised	1 consented and 2 randomised
Western Sussex Hospitals	1 consented and 1 randomised	1 consented and 1 randomised
Royal United Hospital	1 consented and 1 randomised	1 consented
Leeds Teaching Hospitals	2 consented and 2 randomised	
King's College Hospital	1 consented and 1 randomised	
Great Western Hospital	1 consented and 1 randomised	
Bradford Royal Infirmary	1 consented and 1 randomised	
New Cross Hospital	1 consented	
St Mary's Hospital Manchester		2 consented and 2 randomised
Sunderland Royal Hospital		1 consented and 1 randomised
Croydon University Hospital		1 consented and 1 randomised
West Middlesex		1 consented and 1 randomised
Airedale General Hospital		1 consented and 1 randomised
Kingston Hospital		1 consented and 1 randomised
Royal Cornwall Hospital		1 consented and 1 randomised
St Georges Hospital		1 consented



Monthly recruitment and milestones:

We are currently at **19%** of both the consented and randomised targets.

Next milestones: **20% of targets**
216th randomised participant & **235th** consented participant
A prize for the site(s) that reach these.



Extension to end of recruitment: July 2023

We are waiting for confirmation from our funder to extend the trial by 18 months, meaning that the recruitment end-date is anticipated to be **July 2023**, and the end of the trial will be January 2024. As soon as we have received confirmation, we will be back in touch. In the meantime, please can you inform your R&D department, PI and team lead and do not hesitate to contact Katie (WILL Trial Manager) for further information.

Database: Maternal Outcome Form/verification

Please, could you check if you have any maternal outcome forms that need data verified by the PI or delegate? To date, we are pleased that over **70%** of data on these forms have been verified, and it would be great if we increase this number as this is our primary outcome. **Thank you!** Please let us know if you are having problems finding someone to verify data. *Remember:* The only sections that need data verified are: **abnormal laboratory tests** and **maternal complications** sections.

NOTE: The person you ask to review and verify the data should not have been involved in the care of the woman and be masked to the arm to which she was allocated.





New Sites

We are looking for new sites to join WILL to help us to answer this important research question for women with chronic or gestational hypertension.

Do you know of any sites that might be interested?

Please can you let them know about WILL or pass on their details so that we can contact them.

Thank you.

WILL PPI group

Do you know of any women that would like to join our WILL PPI group?

Please ask if you can pass on their details to us so that we can get in touch or ask them to contact us directly.



WILL Language Survey:

Following discussion during SIVs and our recent teleconference (SLIDO poll), we would like to find out from sites which non-English languages are most commonly spoken by women who you may approach to take part in WILL. We are considering first translating the Introductory Pamphlet, so that the basic information about WILL can be provided to potential women to read.



We recently sent a link to complete a '**WILL Language Survey**' so that we can prioritise languages first. We will feedback the findings of this survey and the next steps. We value your opinion in translating this pamphlet, so thank you for completing it:

https://www.smartsurvey.co.uk/s/WILL_language_survey_FINAL/

Remote Consent:

We are improving our remote consent process based on feedback from sites and updating the flowchart in the '**Guidance on taking remote informed consent**' document, which will be sent to you shortly once approved by the REC. The amendments are:

Method 1 - 'signing the consent form':

If a woman is unable to sign the consent form with a pen, she can now type her initials and name in the word version of the ICF and send the completed ICF back by email. (Please file a copy of the email sent by the woman with her completed ICF in your ISF).

Method 2- 'witness':

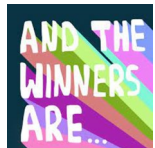
The 'witness' now does not need to be GCP-trained or named on the Delegation Log.

Examples of who could be a witness are: administrative assistant, midwife, HCA, nurse, research nurse, or doctor. It is best if the witness is Trust staff as they are bound by Trust confidentiality rules.

QUIZ winners:

Congratulations to **Kings College London & Leicester Royal Infirmary** for winning prizes for last month's newsletter quiz. Hope you enjoy your gifts which will be with you soon.

Thank you to everyone that took the time to complete our WILL quiz. We hope that you found it fun!



WILL Research Midwife Update: Julie Wade

Congratulations to Julie who has started a 6 month secondment as team leader with the clinical research team at GSTT. Julie will still be working on WILL but until February 2022 she will **only** be working: **Monday** and **Thursdays**. Sue will cover the days that Julie is not working so please do not hesitate to contact her or a member of the WILL team.

Associate PI Scheme

WILL is participating in the NIHR Associate PI scheme. The scheme links clinical staff who aren't research active/research aware with a study PI at the same site for 6 months.

The aims of the scheme are:

- To make research a routine part of clinical training.
- To develop doctors, nurses, and allied health professionals to be PIs of the future.
- To recognise and promote doctor, nurse and allied health professional engagement in NIHR portfolio research in a consistent manner.

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

Join the virtual launch event on the **3rd November** to learn more: <https://www.eventbrite.com/e/associate-pi-scheme-launch-event-registration-registration-173495268017>

www.eventbrite.com/e/associate-pi-scheme-launch-event-registration-registration-173495268017

NICE: Updated guidance - Induction of Labour

This 2021 updated guideline (currently draft) highlights the need for research into timing of birth for conditions associated with increased maternal and perinatal risk at term, such as women with chronic or gestational hypertension. Therefore, the WILL trial is really important for these women.



Summary of guideline that supports WILL:

- No specific guidance for what GA women with chronic or gestational hypertension should be induced
- "uncomplicated singleton pregnancies should be offered induction at 41 weeks..."
- "more research should be done to establish at what GA induction of labour should be offered in the groups of women who may be more likely to experience adverse outcomes if their pregnancy continues."





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 30th September 2021

C=Consented/ R=Randomised

	Jun-Dec 2019 (C/R)	Jan-Dec 2020 * (C/R)	Jan-June 2021 (C/R)	July 2021 (C/R)	Aug 2021 (C/R)	Sept 2021 (C/R)	Total (C/R)
Croydon University Hospital	3/3	16/15	6/6	0/0	0/0	1/1	26/25
St Mary's Maternity Unit Poole	4/4	14/12	4/4	1/1	0/0	0/0	23/21
Leicester Royal Infirmary	5/5	8/8	5/5	0/0	2/1	1/2	21/21
St Mary's Manchester	4/4	5/5	2/2 †	2/2	0/0	2/2	15/15
Leeds Teaching Hospitals	7/6	3/3	2/2	0/0	2/2	0/0	14/13
James Cook University Hospital	5/5	6/4	2/2	0/0	0/0	0/0	13/11
Liverpool Women's Hospital	6/6	4/4	1/1	1/1	0/0	0/0	12/12
Bradford Royal Infirmary	0/0	6/6 †	1/1 †	0/0	1/1	0/0	8/8
Sunderland Royal Hospital	0/0	2/2	4/4	0/0	0/0	1/1	7/7
Singleton Hospital Swansea	1/1	4/4	1/1	0/0	0/0	0/0	6/6
Princess Anne Southampton	1/1	3/3	2/2	0/0	0/0	0/0	6/6
Western Sussex Hospitals		0/0	3/2 †	1/2	1/1	1/1	6/6
Great Western Hospital		0/0	5/4	0/0	1/1	0/0	6/5
Royal United Hospital Bath	1/1	3/3	0/0 †	0/0	1/1	1/0	6/5
Birmingham Women's Hospital	1/1	2/1	1/1	2/1	0/0	0/0	6/4
West Middlesex Hospital	3/3	1/1	0/0	0/0	0/0	1/1	5/5
Kings College Hospital Trust			3/3	1/1	1/1	0/0	5/5
University Hospital of Wales		3/3	2/1	0/0	0/0	0/0	5/4
Nottingham QMC	4/3	1/1	0/0 †	0/0	0/0	0/0	5/4
Nottingham City Hospital	2/0	1/1	1/0 †	1/2	0/0	0/0	5/3
St. Thomas' Hospital	3/3	1/1	0/0 †	0/0 †	0/0 †	0/0 †	4/4
Cwm Taf Morgannwg UHB			4/4	0/0	0/0	0/0	4/4
Royal Berkshire Hospital		0/0	0/0 †	1/1	2/1	1/2	4/4
New Cross Hospital			3/2	0/1	1/0	0/0	4/3
North West Anglia NHS FT	1/1	2/2 **	**	**	**	**	3/3
St Michael's Hospital Bristol		1/1	2/2	0/0	0/0	0/0	3/3
Kingston Hospital		1/1	1/1	1/1	0/0	1/1	4/4
Southend University Hospital			2/1	1/0	0/0	0/0	3/1
York Teaching Hospital	1/1	0/0 †	0/0 †	0/0	0/0	0/0	1/1
Airedale General Hospital		0/0	0/0	0/0	0/0	1/1	1/1
Royal Cornwall Hospital					0/0	1/1	1/1
Royal Victoria Infirmary			0/0	0/0	0/0	0/0	0/0
Northumbria Emergency Specialist Hospital				0/0	0/0	0/0	0/0
Royal Oldham Hospital					0/0	0/0	0/0
Kings Mill Hospital					0/0	0/0	0/0
Chesterfield Royal Hospital					0/0	0/0	0/0
St George's Hospital						1/0	1/0
Total (C/R)	52/48	87/81	57/51	12/13	12/9	13/13	233/215

*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

