WILL Trial

ISSUE 20

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Contact the WILL Team

Any queries?

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Welcome 2021!

We hope that you all managed to have a lovely Christmas and Happy New Year!

Site and participant update

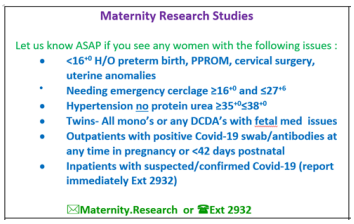
As of the 31st December 2020, we have **23** sites open and **129** randomised participants! **8** of those were in December.

Congratulations to **Sunderland Royal Hospital** for consenting **1** and randomising **2** participants and to **St Marys Maternity Unit Poole for consenting and randomising 2** participants. Also well done to **Singleton Hospital Swansea, Leeds Teaching Hospitals** and **University Hospital of Wales, Cardiff** for consenting and randomising **1** participant each. And thank you to **Croydon University Hospital** for consenting **2** participants and randomising **1** participant to WILL. Great work all!

We look forward to welcoming new sites to WILL during 2021!

Trial update

We know that 2021 has not had the start that we all were hoping for. However, WILL is still **open** and we hope that you can continue to keep working with us during the difficult time ahead. If you are facing any difficulties, please keep us updated. We are always happy to provide support if we can.


Maternity Research Studies

Let us know ASAP if you see any women with the following issues :

- <16+0 H/O preterm birth, PPROM, cervical surgery, uterine anomalies
- Needing emergency cerclage ≥16+0 and ≤27+6
- Hypertension no protein urea ≥35+0≤38+0
- Twins- All mono's or any DCDA's with fetal med issues
- Outpatients with positive Covid-19 swab/antibodies at any time in pregnancy or <42 days postnatal
- Inpatients with suspected/confirmed Covid-19 (report immediately Ext 2932)

✉Maternity.Research or ☎Ext 2932

Information cards: Poole Hospital

During our recent teleconference, research midwives Susara and Steph from St Mary's Maternity Unit Poole, spoke about how they have developed some pocket-sized information cards for clinical staff to remind them to contact the research team if they see a woman with any of the issues listed.

These cards are working very well as they are one of WILL's top-recruiting sites!

They have kindly shared it in case other sites would like to adapt it to their hospital and use something similar. Thank you!

Monitoring visits

We recently carried out our first monitoring visit with St Mary's Maternity Unit Poole Hospital. It went really well. We needed to conduct this remotely and we had offered the site a variety of options to do this:

1. Provide the central WILL team with electronic access to check participant notes.
2. Send redacted notes and information requested to the secure WILL email address.
3. Screenshare or show source data to the camera during a video call

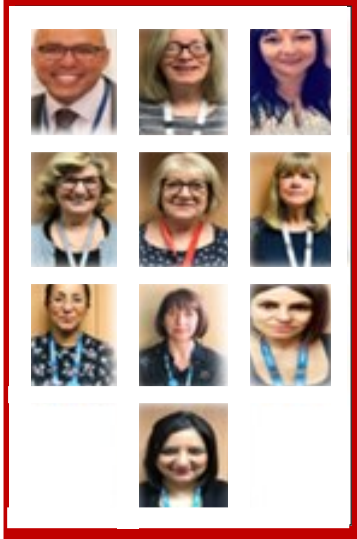
The site chose option 2, which was followed by a video call to discuss any points that had been raised. Thank you to Steph and Susara for being so accommodating with our first remote visit, and for providing valuable feedback.

Successful Recruitment

We asked the research midwives at some of our top-recruiting sites to share their secrets about how WILL is going so well there. This month we are focusing on one of the Midlands sites: **Leicester Royal Infirmary**

The Research team:

L-R, Claire Dodd , PI Cornelia Wiesender , Mark Finny ,Andrea Goodlife.



L-R Tommy Moussa, Molly Patterson, Sharon Bates, Sharon Raper, Gina Mulheron, Pat Amos, Rupa Modi, Bev Cowlishaw, Magda Kierenkowska, Mamta Joshi.

Helpful Hints

How did you initially get the word out to clinical staff about WILL at your hospital when you first opened/re-opened?

Do you do anything on an ongoing basis to keep WILL fresh in their

- We hold regular ***Tea Trolley Teaching sessions***: The team visit clinical areas and chats with staff whilst offering much-needed tea and biscuits (see photo on left)
- E-mails
- Word of mouth

- We have a dedicated hypertension clinic where all women with hypertension are seen.
- 2 of our research midwives are also experienced specialist hypertension midwives
- Fantastic team work, both research team and clinical.

Why do you think that recruitment to WILL is going so well at your site?

Can you provide at least 3 reasons why to help other WILL sites?

Do you have a home BP monitoring service? If so, how have you been able to use this to help identify potential participants?

- Yes, we have a very well-established (over 20 years) home BP monitoring service for women, both antenatally and postnatally. This has helped us identify suitable/potential women for WILL.

- We have talked to some women as early as 25 weeks regarding the study, just so that it's in their mind.

At what gestation is WILL discussed with potential

Have you faced any particular challenges or barriers to running WILL and if so, how have you

- We don't have any particular challenges. We get asked 'if slots for inductions are available' but we explain to people that we would be inducing these women anyway, it's just slightly earlier.

- Yes, we have used the telephone consent (3 times). It is absolutely fine, just make sure you have plenty of time, as does take longer than a face-to-face consent process.

Have you used the remote consent methods? If so which method have you used? Any feedback?

What do you enjoy most about working on the WILL trial?

- The support, the organisational set-up, easy-to-access team. I (Claire) personally really enjoy any hypertension studies as it is my area of interest.

WILL Training page

Information on this page will help you with any discussions you have with women and doctors/midwives caring for them about WILL.

We will feature a different topic each month. This month is:

Pre-eclampsia and 'suspected pre-eclampsia'

'Suspected pre-eclampsia' is only a working diagnosis, like 'suspected sepsis'.

Women with high blood pressure are at an increased risk of developing pre-eclampsia. Around 2-8% of pregnancies are affected by pre-eclampsia.

When and why is the term '**suspected pre-eclampsia'** used by clinicians?

- It is often used when women present with one/more of the symptoms or signs characteristic of pre-eclampsia, but there is not a definite diagnosis until tests are carried out to confirm or not.
- It is also used to describe normotensive women who present with a headache or fetal growth restriction and as such encompasses:
    - deteriorating chronic hypertension;
    - new/deteriorating gestational hypertension;
    - pre-eclampsia (defined by proteinuria);
    - pre-eclampsia (without proteinuria but with one/more other manifestations); or
    - any of the end-organ manifestations of pre-eclampsia (including proteinuria) that occur in a normotensive woman.

It is important to remember that **'suspected pre-eclampsia'** is a working diagnosis and following initial clinical evaluation and investigations, clinicians need to decide and document in the medical notes whether a woman has pre-eclampsia or not, in order to guide her care effectively. The clinician should be able to make a decision about whether or not pre-eclampsia is present within 24-48 hr of presentation.

APEC's e-learning course ***Hypertensive disorders of pregnancy*** has been recently updated and carries CPD accreditation. It is designed for midwives, doctors and healthcare professionals caring for women with pregnancy hypertension.

True or False?

Q: A woman is eligible to participate in WILL even if it is written in the notes 'suspected pre-eclampsia'?

A: False, she will not be eligible to take part until a diagnosis of pre-eclampsia is ruled out and a diagnosis of chronic or gestational hypertension is decided upon and documented as such.

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 tele-phone 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 December 2020

C=Consented/ R=Randomised

	Jun - Dec 2019 (C/R)	Jan-Jun 2020* (C/R)	July -Dec 2020 (C/R)	Total (C/R)
Croydon University Hospital	3/3	6/6	10/9	**19/18**
St Mary's Maternity Unit Poole	4/4	6/6	8/6	**18/16**
Leicester Royal Infirmary	5/5	1/1	7/7	**13/13**
James Cook University Hospital	5/5	3/2	3/2	**11/9**
Liverpool Women's Hospital	6/6	1/1	3/3	**10/10**
Leeds Teaching Hospitals	7/6	2/2	1/1	**10/9**
St Mary's Manchester	4/4	3/3	2/2	**9/9**
Bradford Royal Infirmary	0/0	4/4	2/2 ǂ	**6/6**
Singleton Hospital Swansea	1/1	2/2	2/2	**5/5**
Nottingham Queens Medical Centre	4/3	1/1	0/0	**5/4**
West Middlesex Hospital	3/3	1/1	0/0	**4/4**
St. Thomas' Hospital	3/3	1/1	0/0	**4/4**
Princess Anne Southampton	1/1	2/2	1/1	**4/4**
Royal United Hospital Bath	1/1	1/1	2/2	**4/4**
North West Anglia NHS Foundation Trust	1/1	2/2	**	**3/3**
University Hospital of Wales Cardiff			3/3	**3/3**
Birmingham Women's Hospital	1/1	1/0	1/1	**3/2**
Nottingham City Hospital	2/0	1/1	0/0	**3/1**
Sunderland Royal Hospital	0/0	0/0	2/2	**2/2**
York Teaching Hospital	1/1	0/0	0/0 ǂ	**1/1**
Kingston Hospital			1/1	**1/1**
St Michael's Hospital Bristol			1/1	**1/1**
Great Western Hospital			0/0	**0/0**
Airedale General Hospital			0/0	**0/0**
Royal Berkshire Hospital			0/0	**0/0**
Western Sussex Hospitals			0/0	**0/0**
Total (C/R)	**52/48**	**38/36**	**49/45**	**139/129**

**The trial was paused from 20 Mar to 7 Jul 2020 for COVID-19*
*** Unable to restart WILL following COVID-19 pandemic*
ǂ Still paused to WILL following COVID-19 pandemic