



Contact the WILL Team

Any queries?

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WILL Trial



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Welcome to the 10th edition of the WILL newsletter. It is the month of **love** and we are **loving** the number of participants that you have all randomised to WILL so far!

Recruitment update for January

As of 31st January 2020, we had **62** women randomised in WILL! **14** of these participants were in January. Participation in WILL is increasing month by month! This has been a great month. Lets keep up this amazing work!

Congratulations to **Bradford Royal Infirmary** for randomising their **1st** participant to WILL. So well deserved. Thank you!



And the gold star for top site this month goes to **Croydon University Hospital** who have randomised a fantastic **4** women!

Well done also to the teams at **Leeds Teaching Hospitals, Princess Anne Hospital, Southampton, Leicester Royal Infirmary, North West Anglia Trust** and **James Cook Hospital, Middlesborough** who have all randomised **1** woman each this month.

And big thank you to **St Mary's Hospital, Manchester** and **St Mary's Maternity Unit, Poole** for randomising **2** women each in January.

Thanks also to **Birmingham Women's Hospital** for consenting **1** woman this month.

You've all done amazingly! Look out for your gift for your January participants—our little way of saying thank you. We hope you liked your gifts for participants in December.

Recruitment target: pilot phase

We have now reached over half of our pilot phase target of 110 participants, which we need by the end of March 2020.

We need all of your support and efforts to continue to We can do it!

Remember to keep aiming to recruit **at least 1 participant** each site.

thank you! **get us there. a month** at



New WILL Trial Manager Katie

Hello to all the WILL Teams, I'd like to introduce myself: I'm Katie Kirkham, the new Senior Trial Manager for WILL (covering maternity leave for Kiran Sunner). I will be taking the reins from Lisa Leighton and would like to thank her for looking after the trial.

I am a registered nurse and have been working in clinical trials for over 6 years now. I am really looking forward to working with you

'Spotlight' on Leicester Royal Infirmary ²

Tea Trolley teaching



We visited Leicester Royal Infirmary on the 17th January and heard all about their 'Tea Trolley' teaching sessions that they do to promote research in their unit. Armed with tea and biscuits (see photo on left) the research team visits clinical areas and chats with staff. What a great way to promote research!

Hypertension midwife: Claire Dodd



Claire (pictured left) has worked as a specialist midwife in hypertension at University Hospitals Leicester (UHL) for the last 21 years. We asked Claire to tell us more about her exciting role:



'My role involves overseeing all women with hypertension during pregnancy, either in clinics or on the wards, ordering tests, checking results, arranging monitoring etc. We have a very well-established (over 20 years) home blood pressure monitoring service for women both antenatally and postnatally. Myself and my colleague, Andrea, also run a midwifery-led debriefing clinic 8-12 weeks postnatally for any woman who has had severe pre-eclampsia, delivered before 34 weeks or required magnesium sulphate.'

Midwifery research team at UHL:

Our model is quite unique in that all the team are part clinical and part research. Most of the team work one or two days a week on research as well as their clinical commitments. I only work 2 days a month as a research midwife. But I have found that this combined role has been extremely beneficial to recruitment for the WILL trial as I am able to identify suitable women from quite an early gestation. Being able to talk to these women about the study early gives them plenty of opportunity for questions and then decide if the study is right for them'.



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



Please keep providing feedback about what is going well and any comments that you have



Please don't hesitate to contact us if you need anything.

Database: Completing eCRFs

'Reconfirmation of Eligibility and Randomisation' form for women that cannot or do not want to be randomised

- Some women who consent to take part in WILL will not be able to be randomised once they reach 37⁺⁰ - 37⁺⁶ weeks as the clinical need for delivery develops. While this is uncommon (<10% of women to date), it is anticipated. Also, some women may change their minds, something that has not happened to date in WILL.
- Please **remember** that you still need to complete this form above, which can be opened by clicking on the 'Patient' then 'Randomise patient' tab.
- **This form must be completed before 38 weeks**, as currently the form on the database will no longer be available once this gestation is reached. **Please get in touch with us if you need to fill in the form but no longer have access.**



'Delivery' form

One of the indications for delivery offered in the WILL database is '**maternal hypertension not controlled by maximal therapy**'.

While there is no agreed definition of 'maximal therapy', in common clinical practice, this would usually mean **three** antihypertensive agents in high doses. It would not mean one agent, even in high dose. We recognise that this may not be straightforward, so if you have any questions, please do not hesitate to give us a call.

Amending Data:

- If you need to amend any data on a CRF, please check if the form is 'locked'.
- If the form is 'locked', please contact BCTU to request an 'unlock'.
- If you change/amend data before the form is unlocked, it will appear that changes have been made, but the form will not save the changes that have been made.

FAQs

Q: : What happens if a woman becomes hypertensive and is eligible for WILL, but then she becomes normotensive again without medication? Is there an option to re-screen on the Screening and Consent form?



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 Research Midwives (Sue & Julie)

Recruitment questions (eligibility, screening, etc.)

Clinical questions/protocol questions

Data form completion (including adjudication of maternal outcome page)

Data queries

Help with talking to clinical staff



WILL monthly recruitment table

Total as of 31st January 2020

C=Consented/ R=Randomised

	Jun - Dec 2019 (C/R)	Jan 2020 (C/R)	Total (C/R)
Leeds Teaching Hospitals	7/6	1/1	8/7
Croydon University Hospital	3/3	4/4	7/7
Liverpool Women's Hospital	6/6	0/0	6/6
Leicester Royal Infirmary	5/5	1/1	6/6
St Mary's Manchester	4/4	2/2	6/6
St Mary's Maternity Unit Poole	4/4	2/2	6/6
James Cook University Hospital	5/5	1/1	6/6
Nottingham Queens Medical Centre	4/3	0/0	4/3
St. Thomas' Hospital	3/3	0/0	3/3
West Middlesex Hospital	3/3	0/0	3/3
Princess Anne Southampton	1/1	1/1	2/2
North West Anglia NHS Foundation Trust	1/1	1/1	2/2
Birmingham Women's Hospital	1/1	1/0	2/1
Bradford Royal Infirmary	0/0	1/1	1/1
York Teaching Hospital	1/1	0/0	1/1
Singleton Hospital Swansea	1/1	0/0	1/1
Royal United Hospital Bath	1/1	0/0	1/1
Nottingham City Hospital	2/0	0/0	2/0
Sunderland Royal Hospital	0/0	0/0	0/0
Total (C/R)	52/48	15/14	67/62

January has been our best month yet, thanks to all of you working so hard! Keep up the fantastic work for February!

