



Contact the WILL Team

Any queries?

Please contact us:

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WILL Trial



ISSUE 15

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Welcome to the 15th edition of the newsletter
We are very pleased to announce that:

WILL has officially re-opened!!



Site update

We are happy to report that to date, we have **9** of our pilot sites open: **Croydon University Hospital, Liverpool Women's Hospital, St. Thomas' Hospital, Leeds Teaching Hospitals, Singleton Hospital, Royal United Hospital Bath, St Mary's Maternity Unit Poole, Bradford Royal Infirmary and Leicester Royal Infirmary.** Several more sites are close to re-opening too. It is great to be back working with all of you again.

We understand completely that some sites are not currently in a position to re-open, due to continued work pressures and COVID-19 restrictions. Please keep in touch and let us know when you are ready to restart. We will get you running again as soon as possible.

Participant update



We have already randomised **3** women to WILL in July! A **HUGE THANK YOU** to the teams at **Croydon University Hospital** for consenting and randomising **1** woman, and to **Liverpool Women's Hospital** for consenting and randomising **2** woman this month. This is amazing!!

Remote Consent: approval granted

In our new virtual care world, women are having fewer face-to-face appointments for maternity care. This will have an impact on opportunities to talk about WILL to potential participants and receive informed consent. We have been in active discussion about how to undertake these activities remotely.

We are pleased to announce that when face-to-face consent is not possible due to COVID-19 restrictions, our sponsor has approved the use of two remote consent methods. You will have received the document, '**Guidance on taking Remote Informed Consent**' which was recently emailed out to sites along with email/cover letters associated with exchange of information with these women. The guidance sheet explains the step-by-step instructions for sending women WILL information and obtaining remote consent.

Both methods can only be performed by a research midwife or doctor on the delegation log, and each involves the same conversation that you would have face-to-face with the women, but instead, the conversation is conducted over the telephone or by video.

- **Method 1:** Participant signs the consent form and emails a photo of it back to you.
- **Method 2:** Site Staff signs on behalf of Participant (used if the participant is unable to immediately return a signed ICF to site as in method 1)

We have had our 1st remotely consented participant!!

Just prior to sending out this newsletter we had our **1st participant consented remotely** at **Royal United Hospital Bath**. Thank you for being so willing to give this a go.



All went really well and we hope that other sites will take the opportunity to consent women in this way if you are not seeing them at face to face appointments. Please do not hesitate to contact us if you have any questions.



Emails and links:

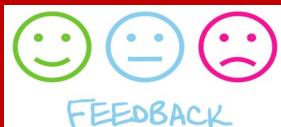
Nhs.net email:
gst-tr.willtrial@nhs.net

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.

Returning completed consent forms

Reminder: Please can you scan and email them to the secure WILL email address - gst-tr.willtrial@nhs.net - until further notice. We will update you as to when you can post them to us once BCTU re-opens.

Site 'refresher' training

'Refresher Training'

We held our first 'WILL refresher training' sessions via Zoom, on 13th and 27th July for all existing sites. We had a great turn-out. Thank you to all who could join us. If you weren't able to attend either of these sessions, you can watch the recording of the 1st session by copying and pasting this url into your browser...

https://bham-ac-uk.zoom.us/rec/share/7tVlcKzetTxJb8_G1hvkZ5Q-N7bJT6a82nVP-gIPzh40cztDgh5qDAE9hfOuaCTK

... and then entering the **password: 9v@2l8*q**

Alternatively, we can arrange some further refresher training at a time suitable to you; just contact Katie, Julie or Sue or email will@trials.bham.ac.uk.

Remote SIVs: New sites

As we are unable to visit sites at present, we plan to arrange remote SIVs. It is hoped that more than one site will be able to join us on each of the dates with an opportunity for individual site discussions after the SIV date, if needed.

Dates for our first remote SIVs via Zoom conferencing are confirmed as:



Thursday 27th August 1-4pm

&

Friday 4th September 1-4pm

Invites have been sent out and for those of you who 'accept' this invitation, we will be in touch to ask you to fill out a pre-SIV questionnaire. Electronic Investigator Site Files are being prepared and will be sent to you prior to the SIV.

As a minimum we will need the PI and at least one research midwife present for the SIV.

For all staff who will work on WILL at your site, please can you send us the following:

- Name
- Role
- Work email address
- CV – current, signed and dated
- GCP certificate – current

Database access: Please can you let us know which staff will require access to the database so that accounts on the **WILL training database** can be set up before the SIV. Access to the WILL Live Database will be given with Green Light.



Database training: This will be provided during the SIV, to members of your research team who require database access.

If you can't make these dates or you are not yet ready for your SIV, don't worry! We will send out more dates in the coming months, as our plan is to hold these remote SIVs on a regular basis each month.

We look forward to e-meeting you soon!

Teleconferences

Our monthly teleconference calls are back! We hope you will be able to join us. An invite has been sent out for our first teleconference since re-opening, which will be held on: **Monday 24th August at 1pm - 1.30pm**

Contacting the WILL team



RUTH: Working 9.15-17.00. Email WILL@trials.bham.ac.uk. If urgent, call **0121 293 8435**.

KATIE: Email k.i.kirkham@bham.ac.uk or call **07974715467** (response times may be longer than usual).

WILL research midwives, Julie & Sue: are both now back working on WILL 4 days/week.



WILL Training page

Welcome to the first 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.

Complications of Chronic and Gestational Hypertension

Did you know that women with chronic or gestational hypertension are at high risk of the following complications?

Pre-eclampsia

Will occur in up to:

- ≈25% of women with **chronic hypertension**
- ≈35% of those with **gestational hypertension** when it develops before term

Serious health problems

Will occur in ≈2% of women, including:

- * Blood transfusion
- * Fits (eclampsia)
- * Stroke
- * Long-term, double the risk of heart disease

Care in a neonatal unit

≈25% of these women will have babies admitted to a neonatal unit



Severe hypertension

Will occur in up to ≈40% of women

Stillbirth

- Risk is increased by 36 weeks (to 1/1000)
- This is the same risk as in low-risk women at 41+ weeks when labour induction is recommended

Birth by Caesarean

Around 45% of women with chronic or gestational hypertension will need to have a Caesarean birth

Remember: Severe hypertension and pre-eclampsia can develop quickly, and without symptoms, which is why these women need to be closely monitored during expectant care.

True or False?

Q: To be eligible for the WILL trial, women need to have an elevated blood pressure or be on antihypertensive medication at the time of consent?

A: False. Women are eligible for WILL if they have a *diagnosis* of chronic or gestational hypertension. Blood pressure can typically change during pregnancy, so please still consider these women for the trial.

Let us know if you found this page useful and if there are any topics you would like us to cover.

Topic for next newsletter: GESTATIONAL DIABETES MELLITUS (GDM)



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

87
randomised



WILL monthly recruitment table

Total as of 31st July 2020

C=Consented/ R=Randomised

	Jun-Dec 2019 (C/R)	Jan-Jun* 2020 (C/R)	July 2020 (C/R)	Total (C/R)
Croydon University Hospital	3/3	6/6	1/1	10/10
St Mary's Maternity Unit Poole	4/4	6/6	0/0	10/10
Liverpool Women's Hospital	6/6	1/1	2/2	9/9
Leeds Teaching Hospitals	7/6	2/2	0/0	9/8
James Cook University Hospital	5/5	3/2		8/7
St Mary's Manchester	4/4	3/3		7/7
Leicester Royal Infirmary	5/5	1/1	†	6/6
Nottingham Queens Medical Centre	4/3	1/1		5/4
West Middlesex Hospital	3/3	1/1		4/4
St. Thomas' Hospital	3/3	1/1	0/0	4/4
Bradford Royal Infirmary	0/0	4/4	0/0	4/4
Princess Anne Southampton	1/1	2/2		3/3
North West Anglia NHS Foundation Trust	1/1	2/2	**	3/3
Singleton Hospital Swansea	1/1	2/2	0/0	3/3
Royal United Hospital Bath	1/1	1/1	0/0	2/2
Birmingham Women's Hospital	1/1	1/0		2/1
York Teaching Hospital	1/1	0/0		1/1
Nottingham City Hospital	2/0	1/1		3/1
Sunderland Royal Hospital	0/0	0/0		0/0
Total (C/R)	52/48	38/36	3/3	93/87

*The trial was paused from 20 Mar to 7 Jul 2020 for COVID-19.

† Restarted 31 Jul 2020. **Unable to restart WILL following COVID-19 pandemic.

**Thank you to all sites for your enthusiasm, hard work & support.
We look forward to more sites opening soon & many more WILL participants this year!**

