

**Contact the WILL Team** 

Any queries?

Please contact us:

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# **WILL Trial**



ISSUE 10

JANUARY 2020

#### **Happy New Year!**

Welcome to 2020! We hope you had a brilliant Christmas and Happy New Year to you all! We're excited to see what the new year will bring. We look forward to working with you all this year, having more participants taking part in WILL and welcoming new sites joining us on WILL (following the pilot phase).

#### **Recruitment update for December**

As of 31st December 2019, we had **48 women randomised** in WILL! **11** of these participants were in December. Participation in WILL is increasing month by month!

Congratulations to all at **Singleton Hospital, Swansea** who had their **1st randomised** participant. This is brilliant!!

Also in December: James Cook University Hospital had a fantastic 3 participants consented, St Thomas' Hospital 1, Leeds Teaching Hospital 2, Croydon University Hospital 2, Leicester Royal Infirmary 1, and St Mary's Maternity Unit Poole 1.

Nottingham City Hospital also consented 1 woman too.

Look out for your gift that will arrive shortly. Thank you!

### Recruitment target: pilot phase

We need to keep up this amazing work so that we reach our 110 participants by the end of our pilot phase, March 2020, so that we can continue into the main phase.

Lets continue to keep aiming to recruit <u>at least 1 participant a month</u> at each site.

Remember:

- Make every contact with potential women count
- Don't forget to follow up potential women when they reach  $36^{+0}$   $37^{+6}$  weeks
- Look out for your reminder email when women reach 35 weeks
- Find out the gestational age at which first approaching for WILL works best at your site
- Maintain excellent communication with clinical areas so potential women are referred
- Call the WILL team to confirm eligibility



## **Certificates of recognition**

You should have, or will receive shortly, 'Certificates of Recognition' that you can use to thank staff for their hard work and support with recruitment to WILL. These individuals may be doctors, midwives, maternity support workers or other members of the clinical, research, or administrative

teams. These certificates are good to evidence feedback for revalidation and appraisals!



UNIVERSITY<sup>OF</sup> BIRMINGHAM











#### It's twins!

We are pleased to announce that Kiran (WILL Senior Trial Manager) gave birth to two beautiful twin boys in November. Mum and babies are doing well.



#### **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



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

#### **PARROT-2**

December saw the launch of the PARROT-2 trial which is looking at the role of repeat **placental growth factor** (**PIGF**) testing for women with suspected pre-eclampsia who remain undelivered. NICE guidelines recommends a PIGF test for all women with suspected preterm preeclampsia from 20-34+6 weeks gestation. Women taking part in PARROT-2 will then be randomised to either <u>revealed</u> or <u>concealed</u> repeat PIGF testing.

Some sites that are involved in WILL may also be participating in this study. We anticipate that the trials will work well alongside each other.

When considering a woman for PARROT-2, remember that she may still be eligible for WILL too, depending on the result of the PIGF. If the result of the PIGF is normal, pre eclampsia may be ruled out and gestational hypertension could be diagnosed, which would make the woman potentially eligible for WILL.

### **Database**

#### **Completion of eCRFs and data queries**

Thank you for entering data for participants in a timely manner. Please continue to do so, especially as this will ensure that the six week questionnaire will be sent out on time.

This will also mean that at the end of the pilot phase of the trial, we have a complete data set for analysis of the pilot study.

Continue to regularly check for overdue forms and data queries on forms that have been saved:

- Identify forms for completion on the homepage of the database and view report.
- Identify forms that have queries raised on them via the 'Letters and Report' menu and select 'DCF management report' and then either 'Overdue DCF queries' or 'Active DCF queries'.

#### 'WILL of the week'

The research team at Royal United Hospital in Bath run a 'WILL of the week'. They put up a poster of a different 'Will' all around the maternity unit to help engage and remind the clinical staff of WILL. Christmas week starred Will Ferrell as Buddy in ELF.



# WILL of the week: Week 14 SANTA S. CHINGE WILL of the week: Week 14 SANTA S. CHINGE The Will Ferrell or correct The Will serve or the week of the

#### WILL word search

For some light relief after the excesses of Christmas and New Year, we thought you might find this a bit of fun. Enjoy!

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#### **FAQs**

Q: Is a woman still eligible for the WILL trial if she has a PIGF between 12-99, or sFlt-1/PIGF 39-84 (i.e. a value between normal and abnormal)?

A: This PIGF result will not rule out pre eclampsia, please check with the woman's obstetrician as to her diagnosis. If any uncertainty, please wait until the diagnosis is clearer. Women who have pre eclampsia are not eligible for WILL. However, if the doctor is happy to confirm that diagnosis is gestational hypertension and not pre eclampsia, then she may still be eligible for the trial.







# 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





## WILL monthly recruitment table Total as of 31st December 2019

(shaded area is prior to site opening)

C=Consented/ R=Randomised

	Jun 19	Jul 19	Aug 19	Sept 19	Oct 19	Nov 19	Dec 19	Total
	(C/R)	(C/R)	(C/R)	(C/R)	(C/R)	(C/R)	(C/R)	(C/R)
Leeds Teaching Hospitals	0/0	1/1	1/1	1/1	1/0	2/1	1/2	7/6
St. Thomas' Hospital	0/0	0/0	0/0	1/1	1/1	0/0	1/1	3/3
West Middlesex Hospital	0/0	0/0	1/1	1/1	0/0	1/1	0/0	3/3
Birmingham Women's Hospital	0/0	0/0	0/0	1/1	0/0	0/0	0/0	1/1
Liverpool Women's Hospital	0/0	2/2	0/0	1/1	1/1	2/2	0/0	6/6
Bradford Royal Infirmary	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Princess Anne Southampton		0/0	0/0	0/0	0/0	1/1	0/0	1/1
Croydon University Hospital		0/0	0/0	0/0	1/1	0/0	2/2	3/3
Nottingham City Hospital		0/0	0/0	1/0	1/0	0/0	0/0	2/0
Nottingham Queens Medical Centre		0/0	0/0	0/0	1/1	2/2	1/0	4/3
Leicester Royal Infirmary		0/0	0/0	0/0	3/2	1/2	1/1	5/5
St Mary's Manchester		0/0	3/3	1/1	0/0	0/0	0/0	4/4
St Mary's Maternity Unit Poole			2/2	1/1	0/0	0/0	1/1	4/4
Norfolk and Norwich University Hospital			0/0	0/0	0/0	0/0	0/0	0/0
York Teaching Hospital			0/0	0/0	1/1	0/0	0/0	1/1
Singleton Hospital Swansea			0/0	0/0	0/0	0/0	1/1	1/1
North West Anglia NHS Founda- tion Trust				0/0	1/1	0/0	0/0	1/1
Royal United Hospital Bath				0/0	1/1	0/0	0/0	1/1
James Cook University Hospital					1/1	1/1	3/3	5/5
Sunderland Royal Hospital					0/0	0/0	0/0	0/0
Total (C/R)	0/0	3/3	7/7	8/7	13/ 10	10/ 10	11/ 11	52/ 48

What a great start to the WILL trial 2019 has been! Here's to an even better 2020!

**WILL Trial Newsletter** 



