



Contact the WILL Team

Any queries?

Please contact us:

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WILL Trial

ISSUE 12



MARCH 2020

Welcome to the 12th edition of the WILL newsletter.

We're looking forward to a month of daffodils, changing the clocks for longer days, and celebrating the arrival of Spring!

Recruitment update for February

As of the 29th February 2020, we had **71** women randomised in WILL! **9** of these participants were in February.

Congratulations to the teams at; **Leeds Teaching Hospital, Croydon University Hospital, St Mary's Manchester, James Cook University Hospital, St Mary's Maternity Unit, Poole, Bradford Royal Infirmary, Singleton Hospital Swansea, Royal United Hospital, Bath and West Middlesex Hospital** for consenting and randomising **1** participant each to WILL.

Thanks also to **James Cook University Hospital** and **St Mary's Maternity Unit, Poole** for consenting a further **1** woman each this month.

Look out for your gift for your February participants to say thank you for all your hard work.

Recruitment target: pilot phase

As we now move into the last month of the pilot phase, lets MARCH onwards and have a final BIG push to help us reach our pilot recruitment target.

M: make every contact with potential women count

A: approach all potential women and aim to recruit **at least 1 participant a month**

R: randomise!

C: consent! And call the WILL team to confirm eligibility if you need to

H: keep looking out for women with hypertension



Main Phase: Plan

Sue and Julie have been contacting some potential sites to invite them to join the main phase of WILL. The aim is to run seamlessly from the pilot into the main phase of the trial. While NIHR must officially approve the transition from pilot to main phase of the trial, we need to be ready for an April start when such an approval is received.

The WILL trial will be rolled out to further sites in a staggered process so please bear with us, and look out for an email or a phone call soon. Sue will continue to support sites in the Midlands and North and Julie sites in the South.

So far, the following SIVs have been arranged: **New Cross Hospital, Wolverhampton** - 24th March, **Royal Bolton Hospital** - 3rd April, **Kingston Hospital** - 7th April, **St Michaels' Hospital Bristol** - 30th April.

If you have any questions or want to know when you may be contacted about the main phase, please do not hesitate to get in touch.

Bradford - 'hug in a mug' to say Thank You

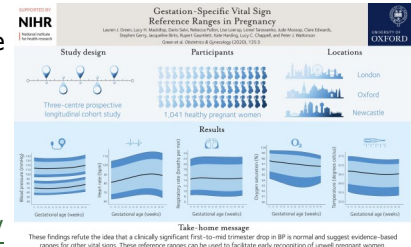
Bradford posted these pictures on Twitter to thank Vicky (clinical midwife) with a 'Hug in a Mug' and a 'WILL Certificate of Recognition' for helping with the WILL trial. The important message in the tweet was as follows: 'Clinical and Clinical research teams working hand in hand is essential to enable us to offer opportunities to our women'.

We think that this is a great way of thanking your clinical teams for their help with WILL!

Research corner:

Gestation-Specific Vital Sign Reference Ranges in Pregnancy

Findings from a recent study which set out to estimate normal ranges for maternal vital signs in pregnancy have refuted the idea that a clinically significant drop in BP in first-to-mid trimester is normal. The multicentre study, which included data from over 1000 women, found that this did not happen, but that there was a rise in BP towards the end of pregnancy.



<https://journals.lww.com/greenjournal/Abstract/publishahead/Gestation-Specific-Vital-Sign-Reference-Ranges-in.97472.aspx>

Sending us completed trial documents

NHS.net WILL email account: gst-tr.willtrial@nhs.net

⇒ Please use this email account to send any trial related documents that contain *patient identifiable data* such as **Consent Forms** (these can also still be returned by using a WILL FREEPOST envelope). Any information sent to this email address must only be sent from a similarly secure email account.

General WILL trial email account: will@trials.bham.ac.uk

⇒ Please use this email account to send any *non patient identifiable documents*, such as **Delegation Logs, CVs, Training Logs and other trial documents** (or these can also be can be posted to the BCTU Trial Office).

Database: Updating screening page

When updating a screening page, please remember to:

- Select an audit reason
- Update the screening date and recalculate the GA by clicking on the calculate GA tab
- Check and amend questions on this page as necessary
- Enter your name at the bottom of the page and enter a new date for form completion
- Save the form

SAE, Protocol Deviation or Withdrawal?

Please contact us if you think that you have had an SAE, Protocol deviation or a trial withdrawal so that we can guide you to complete the correct form, if necessary.

If you are unable to contact the WILL team before completing, please let us know as soon as possible that this form has been started/completed on the database so we can assist.

Randomised participants payments

Invoices for payments will be processed on a quarterly basis: April, July, October and January.

Please can you send your invoices to Katie at k.i.kirkham@bham.ac.uk or the WILL email address will@trials.bham.ac.uk



FAQs

Q: What is the minimum amount of data/forms that needs completing on the database to be able to randomise a participant?

A: The following forms need completing to be able to randomise a participant: Screening & Consent form and Reconfirmation of Eligibility & Randomisation form. (The Baseline form can be completed later when you have more time.)



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.

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

71



WILL monthly recruitment table

Total as of 29th February 2020

C=Consented/ R=Randomised

	Jun - Dec 2019 (C/R)	Jan 2020 (C/R)	Feb 2020 (C/R)	Total (C/R)
Leeds Teaching Hospitals	7/6	1/1	1/1	9/8
Croydon University Hospital	3/3	4/4	1/1	8/8
St Mary's Maternity Unit Poole	4/4	2/2	2/1	8/7
James Cook University Hospital	5/5	1/1	2/1	8/7
St Mary's Manchester	4/4	2/2	1/1	7/7
Liverpool Women's Hospital	6/6	0/0	0/0	6/6
Leicester Royal Infirmary	5/5	1/1	0/0	6/6
West Middlesex Hospital	3/3	0/0	1/1	4/4
Nottingham Queens Medical Centre	4/3	0/0	0/0	4/3
St. Thomas' Hospital	3/3	0/0	0/0	3/3
Princess Anne Southampton	1/1	1/1	0/0	2/2
North West Anglia NHS Foundation Trust	1/1	1/1	0/0	2/2
Bradford Royal Infirmary	0/0	1/1	1/1	2/2
Singleton Hospital Swansea	1/1	0/0	1/1	2/2
Royal United Hospital Bath	1/1	0/0	1/1	2/2
Birmingham Women's Hospital	1/1	1/0	0/0	2/1
York Teaching Hospital	1/1	0/0	0/0	1/1
Nottingham City Hospital	2/0	0/0	0/0	2/0
Sunderland Royal Hospital	0/0	0/0	0/0	0/0
Total (C/R)	52/48	15/14	11/9	78/71

**Thank you for all of your hard work and efforts so far.
Lets make March our best month yet - keep up the great work!**

