WILL Trial

ISSUE 26

JULY 2021

Happy July - flowers blooming, holidays coming; summer is here!

Site and participant update

As of the 30th June 2021, we have **30** sites open and **180** randomised participants! **10** of those were in June (with **13** women consented). Congratulations and thank you to:

Southend University Hospital: consented & randomised their **1st** participant and consented a **2nd** - fantastic!

St Mary's Hospital, Manchester: consented & randomised **2** women in 1 week - brilliant!

St Michael's Hospital: randomised **1** participant, and **New Cross Hospital**, **Western Sussex Hospitals** and **Nottingham City Hospital**: consented **1** participant each.

Liverpool Women's Hospital, Leeds Teaching Hospitals, Croydon University Hospital, Bradford Royal Infirmary, Cwm Taf Morgannwg UHB and **Great Western Hospital:** consented & randomised **1** participant each.

We also welcome **Northumbria Specialist Emergency Care Hospital** who have just joined the WILL team!

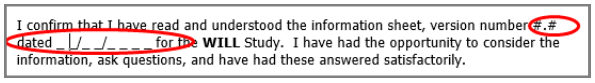
New approved documents now implemented

From the 21st June 2021, Substantial Amendment 02 was implemented at **all** WILL sites. Please can you check that you are now using the new approved Protocol (V3.0).

If you haven't done so already please could you send us the following:

- signed PI signature page of *WILL Trial Protocol v3.0*
- signed acknowledgement form for *Version Control Tracker v7.0*
- localised versions of *PIS v5.0*, *Introductory Pamphlet v2.0* and *Consent Form v4.0*.

* Please ensure the version number and date of the PIS is added to the consent form if not already on there.


I confirm that I have read and understood the information sheet, version number #.# dated __/__/____ for the **WILL** Study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.

We are happy to localise and/or print copies of the new documents for you if needed.

Extra support for WILL through CRN

Following the COVID-19 pandemic, WILL has been identified by the NIHR as a trial eligible for enhanced recovery support from the CRN. We are currently exploring what support will be available to us. This may include support for sites from Agile Research Delivery staff in local CRNs. Please can you let us know:

⇒ If you have Agile Research Midwives/Nurses within your CRN?

⇒ How could your LCRN best support you?

Did you wear Red?

#Red4Research Day took place on Friday 18th June 2021 with the aim to get as many people as possible wearing **red** to show their support and appreciation for all those taking part, undertaking and supporting COVID-19 research. We loved seeing all your photos on twitter!

Research corner:

Giant PANDA Trial: Pregnancy **AN**tihypertensive **D**rugs: which **A**gent is best?

birmingham.ac.uk/research/bctu/trials/womens/giantpanda

The aim of this study is to find out which antihypertensive medication is better for women with hypertension in pregnancy: labetolol vs nifedipine. The trial is now open and plans to recruit 2,300 women with hypertension from 50 participating hospital sites. It is anticipated that some of these sites will also be taking part in WILL.

Women can take part in WILL and Giant PANDA so please continue to consider these women for participation.

The more women who participate, the more that we will learn and improve care.

Contact the WILL Team

Any queries? Please contact us:

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Guidance for interpreting the adherence reports

Please NOTE:

- The report uses data from the 31 March 2021 report, as it is easier to understand a real example.
- The report is automated, so weeks are rounded to one decimal place. 'Table 0' aids interpretation.
- Each report has two tables that report the same information except for the time frame that they cover. Table 1 includes all women randomised to the trial to date, and Table 2 only includes women randomised in the last quarter (so that we can see the impact of any recent changes).

Table 0: Translating gestational age

Weeks (decimal)	Weeks+days
38.1	38+1
38.3	38+2
38.4	38+3
38.6	38+4
38.7	38+5
38.9	38+6

We hope to see **at least a one week separation** between groups in GA at initiation of birth and in particular, GA at delivery. To achieve this, we need to *aim* for a larger difference, which is why the interventions describe an almost two-week difference in GA at initiation of birth.

Table 1: Adherence and gestational age by trial allocation group (using 31 MAR 2021 data)

	Planned early term birth at 38+0 to 38+3 weeks		***Planned expectant care at term until at least 40+0 weeks***	
Adherent	N=74	74 women were randomised	75	75 women were randomised
Yes	66 (91.7%)	72/74 women randomised have given birth. 66/72 (91.7%) were adherent. 6/72 (8.3%) were non-adherent.	63 (90.0%)	70/75 women randomised have given birth. 63/70 (90.0%) were adherent. 7/70 (10.0%) were non-adherent.
No	6 (8.3%)		7 (10.0%)	
GA at initiation of birth (wks)				
	N=71	1 of 72 women who have delivered had spontaneous onset of labour and was not included in this calculation of GA at initiation of birth.	51	19 of 70 women who have delivered had spontaneous onset of labour and were not included in this calculation of GA at initiation of birth.
Median	38.1	Of 71 women who had labour induction or no labour (Caesarean before labour), the median GA at initiation of birth was 38.1 weeks (38+1 weeks). The median is the middle value of the data, so 50% (or half) of these women had a GA at initiation of birth of **38.1 weeks or more** and the other 50% had a GA at initiation of birth of **38.1 weeks or less**.	39.0	Of 51 women who had labour induction or no labour (Caesarean before labour), the median GA at initiation of birth was 39.0 weeks (39+0 weeks). The median is the middle value of the data, so 50% (or half) of these women had a GA at initiation of birth of **39.0 weeks or more** and the other 50% had a GA at initiation of birth of **39.0 weeks or less**.
Interquartile range (IQR)	[38.0, 38.3]	IQR represents the middle 50% of the data. This means that if we exclude the 25% of women with the smallest GA at initiation of birth and the 25% with the highest, the remaining 50% of women had GA at initiation of birth between 38.0 and 38.3 weeks.	[38.7, 39.9]	IQR represents the middle 50% of the data. This means that if we exclude the 25% of women with the smallest GA at initiation of birth and the 25% with the highest, the remaining 50% of women had GA at initiation of birth between 38.7 and 39.9 weeks.
Spontaneous onset of labour		1 woman had a spontaneous onset of labour.	19	19 women had a spontaneous onset of labour .
GA at birth (wks)				
n	72	72 of the 74 women had given birth.	70	70 of the 75 women had given birth.
Median	38.4	See above interpretation of median.	39.4	See above interpretation of median.
IQR	[38.2, 38.6]	See above for interpretation of IQR.	[38.9, 40.0]	See above for interpretation of IQR.

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 30th June 2021
C=Consented/ R=Randomised

	Jun-Dec 2019 (C/R)	Jan-Dec 2020 * (C/R)	Jan-June 2021 (C/R)	Total (C/R)
Croydon University Hospital	3/3	16/15	6/6	**25/24**
St Mary's Maternity Unit Poole	4/4	14/12	4/4	**22/20**
Leicester Royal Infirmary	5/5	8/8	5/5	**18/18**
James Cook University Hospital	5/5	6/4	2/2	**13/11**
Leeds Teaching Hospitals	7/6	3/3	2/2	**12/11**
Liverpool Women's Hospital	6/6	4/4	1/1	**11/11**
St Mary's Manchester	4/4	5/5	2/2 ǂ	**11/11**
Bradford Royal Infirmary	0/0	6/6 ǂ	1/1 ǂ	**7/7**
Singleton Hospital Swansea	1/1	4/4	1/1	**6/6**
Princess Anne Southampton	1/1	3/3	2/2	**6/6**
Sunderland Royal Hospital	0/0	2/2	4/4	**6/6**
University Hospital of Wales		3/3	2/1	**5/4**
Nottingham QMC	4/3	1/1	0/0 ǂ	**5/4**
Great Western Hospital		0/0	5/4	**5/4**
West Middlesex Hospital	3/3	1/1	0/0	**4/4**
St. Thomas' Hospital	3/3	1/1	0/0 ǂ	**4/4**
Royal United Hospital Bath	1/1	3/3	0/0 ǂ	**4/4**
Cwm Taf Morgannwg UHB			4/4	**4/4**
Birmingham Women's Hospital	1/1	2/1	1/1	**4/3**
North West Anglia NHS FT	1/1	2/2 **	**	**3/3**
St Michael's Hospital Bristol		1/1	2/2	**3/3**
Kings College Hospital Trust			3/3	**3/3**
Western Sussex Hospitals		0/0	3/2 ǂ	**3/2**
New Cross Hospital			3/2	**3/2**
Kingston Hospital		1/1	1/1	**2/2**
Nottingham City Hospital	2/0	1/1	1/0 ǂ	**4/1**
Southend University Hospital			2/1	**2/1**
York Teaching Hospital	1/1	0/0 ǂ	0/0 ǂ	**1/1**
Airedale General Hospital		0/0	0/0	**0/0**
Royal Berkshire Hospital		0/0	0/0 ǂ	**0/0**
Royal Victoria Infirmary			0/0	**0/0**
Total (C/R)	**52/48**	**87/81**	**57/51**	**196/180**

**The trial was paused from 20 Mar to 7 Jul 2020 for COVID-19*
*** Unable to restart WILL following COVID-19 pandemic*
ǂ Paused to WILL at some point during this time due to COVID-19 pandemic