



WILL Trial



ISSUE 38 AND 39

AUGUST / SEPTEMBER 2022

Contact the WILL Team

Any queries?
Please contact us:

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Welcome to the August/September edition of the WILL Newsletter.

Site and participant update:

As of the 31st August 2022, we have **41** sites actively open to recruitment. We currently have **353** randomised participants! **14** of those were in July and **9** in August.

Congratulations and thank you to the following sites:



	July	August
St Mary's Maternity Unit, Poole	4 consented and 4 randomised	1 consented and 1 randomised
Leicester Royal Infirmary	2 consented and 2 randomised	1 consented
University College London Hospitals	2 consented and 2 randomised	1 consented and 1 randomised
St Mary's Manchester	1 consented and 1 randomised	
Western Sussex Hospitals	1 consented and 1 randomised	
Kings College Hospital London	1 consented and 1 randomised	
Royal Berkshire Hospital	1 consented and 1 randomised	
Kings Mill Hospital	1 consented and 1 randomised	
Royal Oldham Hospital	1 consented and 1 randomised	
University College London Hospitals	2 consented and 2 randomised	
James Cook University Hospital		1 consented and 1 randomised
Croydon University Hospital		1 consented and 1 randomised
Sunderland Royal Hospital		1 consented and 1 randomised
Princess Anne Hospital		1 consented and 1 randomised
Chesterfield Royal Hospital		1 consented and 1 randomised
Northwick Park Hospital		1 consented
University Hospital North Tees		1 consented and 1 randomised
Liverpool Women's Hospital		1 consented
Leeds Teaching Hospitals		1 consented and 1 randomised



@NHS.net email: emailing completed consent forms



Please remember that if scanning and emailing us completed consent forms you can **only** send them to the WILL NHS.net email account: gst-tr.willtrial@nhs.net from your NHS.net email.

Please **do not** send from or to any other email account. This is to ensure that they are sent and received securely.

You can also post them to the WILL trial office using the pre-paid stickers that are in your site file.

Teleconference: 13th September 1-2pm via Teams

Our next teleconference is on Tuesday 13th September 1–2pm. It is a great opportunity to chat about recruitment with the WILL team and sites, how the change to Usual Care arm is going and answer any questions that you may have. We will also show you the new WILL merchandise, which you may find useful to relaunch WILL at your site.



The invite has been sent out but please get in touch if you need this to be resent.

Hope you can join us.
Look forward to seeing you then.

'Usual care at term'

Implemented at ALL sites

Substantial Amendment 03 to change the arm from 'Expectant care at term (from at least 40⁺⁰ weeks)' to '**Usual care at term**' has now been implemented at **all** WILL sites.

This change was made based on your feedback that clinical care had changed since WILL opened in 2019, and that clinicians and women may be reluctant to go up to 40⁺⁰ and were routinely inducing birth **from 39⁺⁰ weeks**.

We hope that this change will be make it easier to recruit potential women to WILL, including women with co-morbidities and planned Caesarean sections.

What is 'Usual Care at Term'?

This is based on standard NHS practice.

This will reflect how birth would normally have been planned if the woman were not taking part in WILL.

Birth should be initiated:

after 39⁺⁰ weeks
without a
clinical need



Ideally, after 39⁺³ weeks
to ensure a 1 week difference
between the trial arms



Q: Can IOL be booked <39⁺⁰ weeks?

A: Yes: However, if there is no clinical need, please consider booking **from 39⁺⁰ wks**.

If women in the usual care arm are booked for initiation of birth (or planned Caesarean section) at <39⁺⁰ weeks, without a clinical need, then the difference in GA at birth between trial groups would be similar, and the trial will not answer the research question posed by WILL.

As sites told us that 'usual care' for these women was that birth is initiated after 39⁺⁰, then ideally, we would like to see birth initiated on or after this gestation (unless there is a clinical need).

WILL Guidance Sheet: 'Usual care at term'

We have developed this sheet to help explain the usual care arm. We hope that you also find this guidance useful explaining the arm to women. Please let us know if you identify how we could make improvements.

Already screened women early in their pregnancy? Have they had older versions of the Introductory Pamphlet/PIS to read? What do you need to do?

- Contact the potential participant and give her updated leaflets to read. These can be sent to her remotely.
- Give her time to read the new versions and answer any questions that she may have.
- Document discussion and version of information in medical notes.

T: together we can make WILL a success and help answer this important question.
Thank you for your continued support

H: we think that the change to 'usual care at term' will **help** with recruitment

I: the **Introductory** pamphlet is also available as YouTube videos in Punjabi, Urdu and Bengali

N: **new** merchandise will be sent out to you soon to help promote/relaunch WILL at sites

K: **keep** screening for potential women early in their pregnancy, **keep** up the fantastic work

W: **when** and **where** are potential women being seen? Consider other clinical areas such as community, diabetes clinics. Remember all of the process for **WILL** can be done remotely.

I: give out/email/post **information** as early as you can so that they have plenty of time to read about WILL.

L: **Laura** is happy to chat at doctors, audit, research meetings to help promote WILL, talk about the arms and answer any questions. **Let** us know if we can help arrange a suitable date/time at your site.

L: **lastly**, enjoy working on WILL as much as we enjoy working with you all.

THINK WILL



Remember:
WILL is an important trial for women with hypertension in pregnancy and remains the #1 research priority highlighted in the 2021 NICE Inducing Labour guidelines (NG207).





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 telephone randomisation

Supplies/merchandise

SAE reporting

Database administrative issues, e.g. passwords

Payments for participants

Data queries

WILL Lead RM:

Recruitment questions (eligibility, screening, etc.)

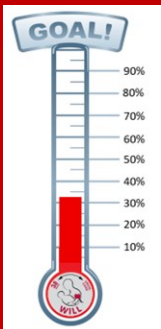
Clinical & protocol questions

Data form completion (including adjudication of maternal outcome page)

Data queries

Help talking to clinical staff

Currently at 32.6%



Database:

Completion of data forms/queries

Thank you so much to all sites for completing the forms on the database in a timely manner and for completing data queries so that the data is ready for our stats team to carry out an interim statistical analysis of **all** data.

Updates: Screening Form:

Calculating Gestational Age (GA)

The 'calculate GA' tab has now been removed. The GA is calculated by the **screening date and EDD** so once these have been entered the GA will be automatically calculated on the form.

Rescreening: when updating the screening form remember to enter a new screening date so that the GA is updated.

Please note: Once you have entered a new screening date and you are **not** making any other changes on the form you need to click anywhere on the form for the GA to update **before** clicking save. Once the form is saved please check that the correct GA is on the form.

Exclusion Criteria: contraindication to either trial arm

We have moved the list of responses to the question:

Contraindication (s) to either one of the trial arms?.

Previously, if 'yes' was selected there was a list of possible conditions to choose from that appeared to be contraindications. However, for WILL **only** evidence of pre-eclampsia is an exclusion. Now if the response is 'Yes' only:

'Evidence of pre-eclampsia' and 'other' will appear as options to select.

If 'other' is selected: Please specify from the list. Remember, for WILL we do **NOT** see these conditions as contraindications for all women but may reflect legitimate reasons why this women may not be suitable for WILL. As they may be *perceived* to be by some doctors, we would like to collect this information.

Screening and consent dates to match:

When a participant has consented please remember to check and amend the screening date, as this must be the same date as the consent date.

If the dates do not match an alert will appear before the form can be saved. When changing the date to match the consent date (and nothing else on the form) please remember to click anywhere on the form so that the GA is recalculated before saving.



Reminder emails to contact potential participant:

Reminder emails will now be sent out at **35 and 37 weeks** (rather than 32 and 35 weeks) for women that have been screened and eligible to take part.

If her eligibility status has changed and she is no longer potentially eligible, please update this on the WILL database

Steps for updating the screening form:

1. Open the form and select an Audit Reason from the dropdown list.
2. Change the date of screening to the date that you re-screened (even if before today).
3. Amend answers to questions on the form, as necessary.
4. Change the 'Date of form completion' to today's date. [For more details on updating the screening form, please refer to the WILL Trial Handbook, Section 5, p.3.]

Version of consent form:

Don't forget to select the new version of the Consent Form: **Version 5.0** from the drop down list.

* 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.



WILL monthly recruitment table										Key to recruitment table:					
Total as of 31st August 2022										C=Consented/ R=Randomised			** Unable to restart WILL following COVID-19 pandemic † Paused at some point during this time due to COVID-19 pandemic †† site has now closed		
	Jun-Dec 2019	Jan-Dec 2020 *	Jan-Dec 2021	Jan 2022	Feb 2022	March 2022	Apr 2022	May 2022	June 2022	July 2022	Aug 2022	4Total (C/R)			
St Mary's Maternity Unit Poole	4/4	14/12	14/13	1/2	0/0	4/3	0/0	0/0	0/0	4/4	1/1	42/39			
Leicester Royal Infirmary	5/5	8/8	11/11	4/4	0/0	0/0	0/0	1/1	0/0	2/2	1/0	32/31			
Croydon University Hospital	3/3	16/15	8/8	0/0	1/1	1/0	0/1	0/0	0/0	0/0	1/1	30/29			
St Mary's Manchester	4/4	5/5	7/6 †	0/0	1/1	3/3	0/0	3/3	0/0	1/1	0/0	24/23			
Leeds Teaching Hospitals	7/6	3/3	4/4	0/0	0/0	0/0	0/0	1/1	1/1	0/0	1/1	17/16			
James Cook University Hospital	5/5	6/4	2/2	1/1	0/0	0/0	0/0	0/0	0/0	0/0	1/1	15/13			
Liverpool Women's Hospital	6/6	4/4	2/2	0/0	0/0	0/0	0/0	0/0	0/0	0/0	1/0	13/12			
Bradford Royal Infirmary	0/0	6/6 †	4/4 †	0/0	0/0	2/2	0/0	1/0	0/0	0/0	0/0	13/12			
Western Sussex Hospitals		0/0	9/8 †	1/2	0/0	0/0	1/1	1/1	0/0	1/1	0/0	13/13			
Singleton Hospital Swansea	1/1	4/4	2/2	1/1	1/1	1/1	0/0	0/0	1/1	0/0	0/0	11/11			
Great Western Hospital		0/0	9/8	0/0	0/0	2/2	0/0	0/0	0/0	0/0	0/0	11/10			
Sunderland Royal Hospital	0/0	2/2	5/5	0/0	0/0	0/0	0/0	0/0	1/1	0/0	1/1	9/9			
Princess Anne Southampton	1/1	3/3	2/2	0/0	1/1	0/0	0/0	0/0	1/1	0/0	1/1	9/9			
Kings Mill Hospital			4/4	2/2	0/0	0/0	0/0	1/1	1/1	1/1	0/0	9/9			
Chesterfield Royal Hospital			2/2	0/0	2/2	1/1	1/0	0/1	1/1	0/0	1/1	8/8			
Kings College Hospital Trust			7/7	0/0	0/0	0/0	0/0	0/0	0/0	1/1	0/0	8/8			
Nottingham QMC	4/3	1/1	0/0 †	0/0	1/1	1/1	0/0	0/0	1/1	0/0	0/0	8/7			
East Surrey Hospital			0/0	0/0	1/1	2/1	2/2	1/1	2/1	0/0	0/0	8/6			
Kingston Hospital		1/1	6/6	0/0	0/0	0/0	0/0	0/0	0/0	††	††	7/7			
Royal Berkshire Hospital		0/0	5/5 †	0/0	0/0	1/0	0/0	0/0	0/0	1/1	0/0	7/6			
Birmingham Women's Hospital	1/1	2/1	4/3	0/0 †	0/0 †	0/0	0/0	0/0	0/0	0/0	0/0	7/5			
Cwm Taf Morgannwg UHB			5/5	0/0	0/0	1/1	0/0	0/0	0/0	0/0	0/0	6/6			
Royal United Hospital Bath	1/1	3/3	2/1 †	0/0	0/0	0/0	0/0	0/0	0/0	0/0	††	6/5			
University Hospital of Wales		3/3	2/1	0/0	0/0	0/0	1/1	0/0	0/0	0/0	0/0	6/5			
Southend University Hospital			5/3	0/0	1/1	0/0	0/0	0/0	0/0	0/0	0/0	6/4			
West Middlesex Hospital	3/3	1/1	1/1	0/0	0/0	0/0	0/0	0/0	0/0	0/0	††	5/5			
St Michael's Hospital Bristol		1/1	2/2	0/0	0/0	0/0	2/2	0/0	0/0	0/0	0/0	5/5			
University College London Hospitals			0/0	0/0	1/1	0/0	0/0	0/0	1/1	2/2	1/1	5/5			
New Cross Hospital			5/4	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	5/4			
Nottingham City Hospital	2/0	1/1	2/2 †	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	5/3			
St. Thomas' Hospital	3/3	1/1	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	4/4			
North West Anglia NHS FT	1/1	2/2 **	**	**	**	**	**	**	**	**	**	3/3			
St George's Hospital			2/2	0/0	0/0	1/1	0/0	0/0	0/0	0/0	0/0	3/3			
Royal Victoria Infirmary			1/1	1/1	0/0	0/0	1/1	0/0	0/0	0/0	0/0	3/3			
Royal Cornwall Hospital			1/1	0/0	0/0	0/0	0/0	1/1	1/1	0/0	0/0	3/3			
QE Hospital Kings Lynn								2/2	0/0	0/0	0/0	2/2			
Royal Oldham Hospital			0/0	0/0	0/0	0/0	1/1	0/0	0/0	1/1	0/0	2/2			
York Teaching Hospital	1/1	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	0/0 †	1/1			
Airedale General Hospital		0/0	1/1	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	1/1			
Glangwili Hospital			0/0	0/0	1/1	0/0	0/0	0/0	0/0	0/0	0/0	1/1			
Walsall Manor Hospital				0/0	0/0	1/1	0/0	0/0	0/0	0/0	0/0	1/1			
Northumbria Hospital			0/0	0/0	0/0	0/0	0/0	0/0	1/1	0/0	0/0	1/1			
University Hospital North Durham			0/0	0/0	0/0	0/0	0/0	1/1	0/0	0/0	0/0	1/1			
University Hospital Wishaw							0/0	0/0	1/1	0/0	0/0	1/1			
University Hospital of North Tees										0/0	1/1	1/1			
Northwick Park Hospital									0/0	0/0	1/0	1/0			
Royal Bolton Hospital			0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	††	0/0			
Raigmore Hospital									0/0	0/0	0/0	0/0			
Total (C/R)	52/48	87/81	136/126	11/13	11/11	21/17	9/9	13/13	13/12	14/14	12/9	379/353			