



Contact the WILL Team

Any queries?

Please contact us:

Professor Laura A. Magee  
Chief Investigator  
Laura.A.Magee@kcl.ac.uk

Sue Tohill (North)  
Lead Research Midwife  
Sue.Tohill@kcl.ac.uk

Julie Wade (South)  
Lead Research Midwife  
Julie.Wade@kcl.ac.uk  
Mob: 07970338451

Katie Kirkham  
Senior Trial Manager  
WILL@trials.bham.ac.uk  
Tel: 0121 415 9109  
Temp no. 07974715467

Ruth Evans  
Data Manager  
WILL@trials.bham.ac.uk  
Tel: 0121 415 9111  
Temp no. 0121 293 8435

Clive Stubbs  
Team Leader  
WILL@trials.bham.ac.uk  
Tel: 0121 415 9117

Birmingham  
Clinical Trials Unit (BCTU)  
Institute of  
Applied Health Research  
Public Health Building  
University of Birmingham  
Edgbaston, Birmingham  
B15 2TT

# WILL Trial

ISSUE 17

OCTOBER 2020



Autumn is officially here - a time of pumpkin carving, running through fallen leaves, and getting your cosy jumpers out!

## Site and participant update

A very big welcome to the **University Hospital of Wales, Cardiff** and **St Michael's Hospital, Bristol** who are our first main phase sites now open to recruitment!

We are very happy to have you join the WILL team.

We now have **18** sites open and continue to welcome back pilot sites as well as preparing for new sites coming on board very soon.

As of the 30th September 2020, we had **97** randomised participants! **7** of those were randomised in September.

Congratulations to the team at **Bradford Royal Infirmary** for consenting and randomising **2** participants this month! Well done also to the teams at **Croydon University Hospital, Princess Anne Hospital Southampton, St Mary's Maternity Unit Poole, Royal United Hospital Bath** and **Liverpool Women's Hospital** for consenting and randomising **1** participant each. Thank you everyone for all your hard work and efforts.

This month, we celebrated our **100th consented participant!** **Princess Anne Hospital Southampton** were the team to hit this fantastic milestone (and we hope you enjoyed your gift); however, we are thankful to ALL of our sites and the women who have taken part for helping us achieve this.

Please help us reach the **100th randomised participant**

Keep screening - it could be your site that gets a thank you gift!

## WILL Introductory Pamphlet & PIS

### At what gestation do you offer these to women?

- **WILL Introductory Pamphlet:** at any gestation to introduce WILL offered when consent can be taken, as it is an initial, more 'digestible' document.
- **WILL PIS (Patient Information Sheet):** at any gestation, if interested in taking part or would like more information.

Please remember that:

- The **PIS** must have been read before women consent to WILL.
- You can send women information if you do not see them in person. We have a Sponsor-approved form of words for you to use by email which may be more convenient.

## WILL Public Patient Involvement (PPI) group



# 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. This month is:

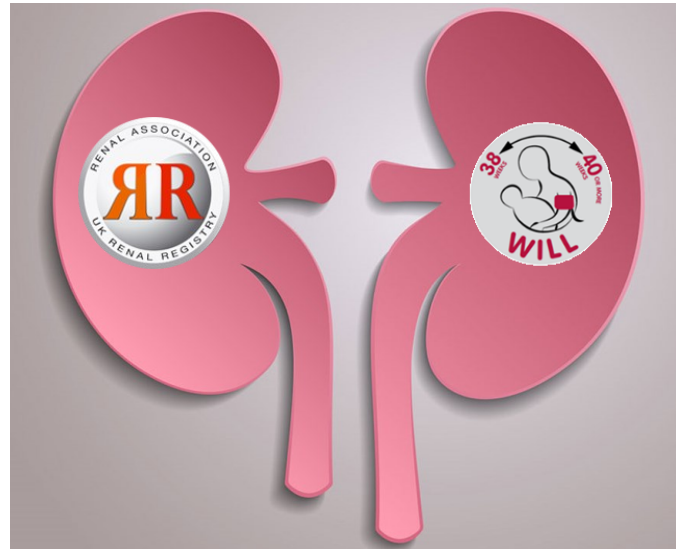
## Chronic Kidney Disease (CKD) ...

### The National Registry of Rare Kidney Diseases (RaDaR)

This is a Renal Association initiative designed to pull together information from patients with certain rare kidney conditions, such as CKD in pregnancy.

[www.rarerrenal.org](http://www.rarerrenal.org)

For more information about CKD in pregnancy



**RaDaR supports participation of women with CKD in WILL.**

These women are eligible for inclusion in WILL as long as they have no evidence of superimposed pre-eclampsia and meet other inclusion/exclusion criteria.



## and ... High Body Mass Index (BMI)

**Underweight**  
below 18.5

**Healthy Weight**  
between 18.5 and 24.9

**Overweight**  
between 25 and 29.9

**Obese**  
between 30 and 39.9

Around 1:5 (20%) of pregnant women have a BMI of 30 or above at the beginning of their pregnancy.

When is the best time to give birth to my baby?

To date there are no RCT's to guide timing of birth for women with high body mass index...

There is one trial that will be starting soon in Denmark.



Two large observational studies have associated planned early term birth with a reduced incidence of Caesarean...

1. Leonard SA, Carmichael SL, Main EK, Lyell DJ, Abrams B. *Risk of severe maternal morbidity in relation to pre-pregnancy body mass index: Roles of maternal co-morbidities and caesarean birth.* Paediatr Perinat Epidemiol 2019. doi: 10.1111/ppe.12555.
2. Palatnik A, Kominiarek MA. *Outcomes of elective induction of labor versus expectant management among obese women at ≥39 Weeks.* Am J Perinatol 2019. doi: 10.1055/s-0039-1688471.

BMI is a planned subgroup analysis in WILL:

**Please consider inclusion to WILL for this group of women so results can also guide their care.**





**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 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 September 2020**

C=Consented/ R=Randomised

	Jun-Dec 2019 (C/R)	Jan-Jun 2020* (C/R)	July 2020 (C/R)	Aug 2020 (C/R)	Sept 2020 (C/R)	Total (C/R)
St Mary's Maternity Unit Poole	4/4	6/6	0/0	2/1	1/1	<b>13/12</b>
Croydon University Hospital	3/3	6/6	1/1	0/0	1/1	<b>11/11</b>
Liverpool Women's Hospital	6/6	1/1	2/2	0/0	1/1	<b>10/10</b>
Leeds Teaching Hospitals	7/6	2/2	0/0	0/0	0/0	<b>9/8</b>
James Cook University Hospital	5/5	3/2			0/0	<b>8/7</b>
St Mary's Manchester	4/4	3/3			0/0	<b>7/7</b>
Leicester Royal Infirmary	5/5	1/1	†	0/0	0/0	<b>6/6</b>
Bradford Royal Infirmary	0/0	4/4	0/0	0/0	2/2	<b>6/6</b>
Nottingham Queens Medical Centre	4/3	1/1		††	0/0	<b>5/4</b>
West Middlesex Hospital	3/3	1/1				<b>4/4</b>
St. Thomas' Hospital	3/3	1/1	0/0	0/0	0/0	<b>4/4</b>
Princess Anne Southampton	1/1	2/2		0/0	1/1	<b>4/4</b>
Royal United Hospital Bath	1/1	1/1	0/0	1/1	1/1	<b>4/4</b>
Singleton Hospital Swansea	1/1	2/2	0/0	0/0	0/0	<b>3/3</b>
North West Anglia NHS Foundation Trust	1/1	2/2	**	**	**	<b>3/3</b>
Birmingham Women's Hospital	1/1	1/0		1/1	0/0	<b>3/2</b>
Nottingham City Hospital	2/0	1/1		††	0/0	<b>3/1</b>
York Teaching Hospital	1/1	0/0				<b>1/1</b>
Sunderland Royal Hospital	0/0	0/0			0/0	<b>0/0</b>
University Hospital of Wales Cardiff					•	
St Michael's Hospital Bristol					•	
<b>Total (C/R)</b>	<b>52/48</b>	<b>38/36</b>	<b>3/3</b>	<b>4/3</b>	<b>7/7</b>	<b>104/97</b>

\*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

†† Restarted 27th Aug 2020 • Opened end of September 2020

