



# WILL Trial



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## Contact the WILL Team

Any queries?

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Welcome to the May edition of the WILL newsletter.  
A month of flowers blooming and the sun starting to shine!

## Site and participant update

As of the 30th April 2021, we have **25** sites open and **159** randomised participants! **10** of those were in April (with 13 women consented). Congratulations to:

**Kings College London** and **Western Sussex Hospitals** for consenting and randomising their **1st** and days later, another! This is fantastic: **2** participants each.

**University Hospital of Wales, Cwm Taf Morgannwg UHB, Singleton Hospital, Kingston Hospital, Birmingham Women's Hospital** and **James Cook University Hospital** for consenting and randomising **1** participant each.

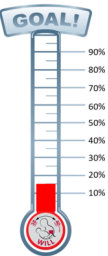
**Sunderland Hospital, Great Western Hospital** and **Princess Anne Hospital** for consenting **1** participant each, good luck when randomising.

Thank you everyone!



**Target milestones:** We are currently at **14.7%** of our overall target for randomised women. Our next milestone is **15% - 162 randomised participants**. With only **3** more participants needed, can we do this in the 1st week of May?

A gift will be sent to the site that randomises number 162!



## Database: completing CRFs

**Screening form:** When updating the screening form, please remember to **update the date of screening** to the date that you re-screened (even if you don't update the form on that day).

### Delivery form: Failed Induction of Labour

If a woman has a failed IOL and requires a Caesarean (before labour), please complete the form so that the information entered captures the IOL and birth details:

- **Details of birth:** Onset of labour - select 'Induced' and select all methods used
- **Mode of birth:** select 'Caesarean before labour' and select the reason

### Maternal and Fetal Surveillance form: recording virtual visits

Please can you record virtual visits as if the participant were attending a face-to-face appointment? Please could you also write in the **CRF notes box** at the bottom of the page:

- Number of virtual visits
- Dates of virtual visits

## Inclusion Criteria: confirmation of 'Live Fetus' at consent

On the day of consent (in-person or remote), please ensure that there is documentation of 'live fetus':



- **In-person consent:** CTG, Scan, FHR documented in notes.
- **Remote consent:** check if there were any concerns regarding the fetal heart at the last face-to-face appointment **and** that she is happy with her baby's movements.

## WILL Trial team email accounts:

Please use our secure NHS.Net email address to send **confidential/patient identifiable** information; such as completed consent forms: [gst-tr.WILLtrial@nhs.net](mailto:gst-tr.WILLtrial@nhs.net).

**Non confidential** and **non patient identifiable** information, e.g. delegation logs, training logs, data queries, daily emails should be sent to: [WILL@trials.bham.ac.uk](mailto:WILL@trials.bham.ac.uk).

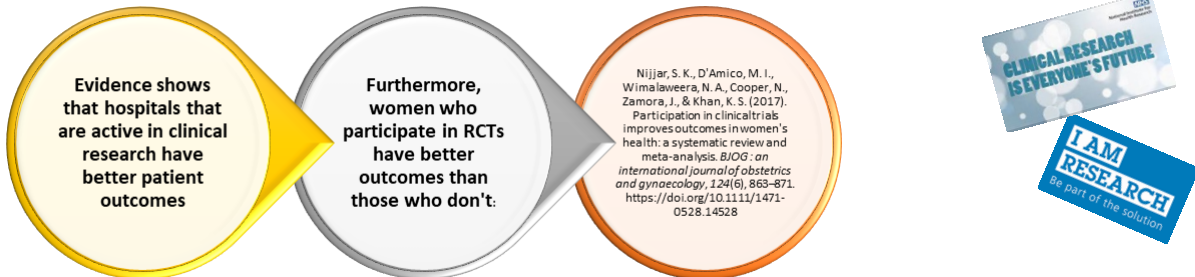
Information on this page will help you with any discussions you have with women and doctors/midwives caring for them about WILL.

We will feature a different topic each month. This month is:

## Women who decline taking part in research

There are a number of women who decline participation in WILL because they do not want to take part in research.

Why, and how can we overcome this barrier?



A study carried out by Southampton researchers looked at why women chose not to take part in clinical trials.

A **lack of trust** in medical research was the key finding.

Strategies to help remove the barriers identified were suggested:

- ▶ **Building Trust**
  - 'Get to know the team' - photos of the research team members and short written profiles could be displayed in waiting rooms.
  - Displaying testimonials from previous participants in the research areas would help reassure women about the safety of the study as well as highlighting the benefits of taking part.
  - Develop an online Trial guide available on the research website that has reviews, recommendations, and testimonials from previous trial participants.
- ▶ **Increasing self-efficacy**
  - Support women to find their own ways around the barriers to participation. Training for health care professionals which focuses on an empowering approach to communication may be useful. (The WILL team suggest health coaching at: <https://www.betterconversation.co.uk>, for example)
- ▶ **Practical considerations**
  - Many women may be concerned about demands on their busy lives, so highlighting that the trial would not make unreasonable demands on them or their time may be beneficial.
- ▶ **Advertising earlier**
  - Information could be provided earlier in the pregnancy and be more widely advertised, for example in local GP surgeries or by midwives.
- ▶ **Offering incentives and benefits**
  - The study should offer sufficient benefits to make the inconvenience of taking part worthwhile. As well as any more immediate personal benefits, this may be something as simple as emphasising the value of the study to society.

Strömmer S, Lawrence W, Rose T, Vogel C, Watson D, Bottell J N, Parmenter J, Harvey N C, Cooper C, Inskip H, Baird J, Barker M, Improving recruitment to clinical trials during pregnancy: A mixed methods investigation, *Social Science & Medicine*, Vol. 200, 2018, Pages 73-82. <https://doi.org/10.1016/j.socscimed.2018.01.014>. (<https://www.sciencedirect.com/science/article/pii/S0277953618300145>)

You might also want to direct women to the NIHR website and the section on **'Why should I take part?'** <https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-take-part-in-a-study.htm>

- To improve health and social care for others, as well as giving hope for future generations.
- To learn more about their condition.
- To be more closely and regularly monitored.
- To try a new treatment or device.
- To help researchers learn important new information.





**Emails and links:**

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gst-tr.willtrial@nhs.net

WILL team at BCTU:  
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Website:  
www.birmingham.ac.uk/WILL

Database:  
www.Trials.bham.ac.uk/WILL

Test database:  
www.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**

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**Total as of 30th April 2021**

C=Consented/ R=Randomised

	Jun-Dec 2019 (C/R)	Jan-Dec 2020 (C/R)	Jan 2021 (C/R)	Feb 2021 (C/R)	March 2021 (C/R)	April 2021 (C/R)	Total (C/R)
Croydon University Hospital	3/3	16/15	1/1	1/1	2/2	0/0	<b>23/22</b>
St Mary's Maternity Unit Poole	4/4	14/12	1/1	1/1	1/1	0/0	<b>21/19</b>
Leicester Royal Infirmary	5/5	8/8	4/4	0/0	0/0	0/0	<b>17/17</b>
James Cook University Hospital	5/5	6/4	0/0	0/0	1/1	1/1	<b>13/11</b>
Leeds Teaching Hospitals	7/6	3/3	1/1	0/0	0/0	0/0	<b>11/10</b>
Liverpool Women's Hospital	6/6	4/4	0/0	0/0	0/0	0/0	<b>10/10</b>
St Mary's Manchester	4/4	5/5	0/0	†	†	†	<b>9/9</b>
Bradford Royal Infirmary	0/0	6/6 †	†	†	†	†	<b>6/6</b>
Singleton Hospital Swansea	1/1	4/4	0/0	0/0	0/0	1/1	<b>6/6</b>
Princess Anne Southampton	1/1	3/3	0/0	0/0	1/1	1/0	<b>6/5</b>
Nottingham QMC	4/3	1/1	†	†	†	†	<b>5/4</b>
University Hospital of Wales		3/3	1/0	0/0	0/0	1/1	<b>5/4</b>
West Middlesex Hospital	3/3	1/1	0/0	0/0	0/0	0/0	<b>4/4</b>
St. Thomas' Hospital	3/3	1/1	†	0/0	0/0	0/0	<b>4/4</b>
Royal United Hospital Bath	1/1	3/3	†	0/0	0/0	0/0	<b>4/4</b>
Birmingham Women's Hospital	1/1	2/1	0/0	0/0	0/0	1/1	<b>4/3</b>
Sunderland Royal Hospital	0/0	2/2	0/0	1/1	0/0	1/0	<b>4/3</b>
Great Western Hospital		0/0	2/1	0/0	1/1	1/0	<b>4/2</b>
North West Anglia NHS FT	1/1	2/2 **	**	**	**	**	<b>3/3</b>
Cwm Taf Morgannwg UHB				1/1	1/1	1/1	<b>3/3</b>
Nottingham City Hospital	2/0	1/1	†	†	†	†	<b>3/1</b>
Kingston Hospital		1/1	0/0	0/0	0/0	1/1	<b>2/2</b>
St Michael's Hospital Bristol		1/1	0/0	1/1	0/0	0/0	<b>2/2</b>
Kings College Hospital Trust				0/0	0/0	2/2	<b>2/2</b>
Western Sussex Hospitals		0/0	0/0	†	†	2/2	<b>2/2</b>
York Teaching Hospital	1/1	0/0 †	†	†	†	†	<b>1/1</b>
Airedale General Hospital		0/0	0/0	0/0	0/0	0/0	<b>0/0</b>
Royal Berkshire Hospital		0/0	0/0	0/0	0/0	0/0	<b>0/0</b>
New Cross Hospital				0/0	0/0	0/0	<b>0/0</b>
Southend University Hospital				0/0	0/0	0/0	<b>0/0</b>
<b>Total (C/R)</b>	<b>52/48</b>	<b>87/81</b>	<b>10/8</b>	<b>5/5</b>	<b>7/7</b>	<b>13/10</b>	<b>174/159</b>

\*The trial was paused from 20 Mar to 7 Jul 2020 for COVID-19

\*\* Unable to restart WILL following COVID-19 pandemic

† Paused to WILL due to COVID-19 pandemic

**WILL Trial Newsletter**

Website: [www.birmingham.ac.uk/WILL](http://www.birmingham.ac.uk/WILL)



Twitter: @WillTrial

