WILL Trial

ISSUE 16 SEPTEMBER 2020

September marks the change of seasons and new beginnings.

We are excited to embark upon a new chapter of WILL and welcome new sites!

Site update

We are pleased to say that we now have **13** of our pilot sites open:
Croydon University Hospital, Liverpool Women's Hospital, St. Thomas' Hospital, Leeds Teaching Hospitals, Singleton Hospital, Royal United Hospital Bath, St Mary's Maternity Unit Poole, Bradford Royal Infirmary, Leicester Royal Infirmary, Birmingham Women's Hospital, Princess Anne Hospital, Southampton, Nottingham City Hospital and **Queens Medical Centre, Nottingham**

Participant update

As of 31st August 2020, we had **90** randomised participants, **3** of whom were randomised in August.

Congratulations to the teams at **Birmingham Women's Hospital** and **Royal United Hospital Bath** for randomising and consenting **1** participant each, and to the team at **St Mary's Maternity Unit, Poole** for randomising **1** participants and consenting **2** participant this month!

so much for all your hard work!

SIVs for new sites

We delivered our first group remote SIV and database training via videoconferencing on the 27th August, attended by **4** new sites. Thank you to all who were able to join. It was great to meet you all virtually!

We will be holding SIVs regularly each month and our confirmed dates for September are:

Friday 4th September 1-4pm
Tuesday 15th September 1-4pm
Monday 28th September 1-4pm

Please let us know if you can join us on any of these dates and we will send you further details, a pre-SIV questionnaire to complete and your Investigator Site Files.

Please, could the PI and at least one research midwife be present for the SIV?

Database:

6 Week Questionnaire: Text messages

Please can you complete the following eCRFs as soon as you can following birth:

- **Delivery**, **Neonatal** and **Maternal Outcome & Postpartum Management** forms

Until **ALL** of these forms are completed, the text message will **not** be sent out.

Reconfirmation of Eligibility & Randomisation' form: Women who cannot be randomised

Please remember that you still need to complete this form for **ALL** consented women via the **'Patient'** then '**Randomise patient'** tab, even if they cannot be randomised when they reach 37^{+0} - 37^{+6} weeks.

Reasons that women cannot be randomised include:

- *There is a clinical need for birth before 40+0 weeks; or*
- *They give birth spontaneously.*

Please do not hesitate to get in touch if you need any help to fill out this form.

Contact the WILL Team

Any queries?
Please contact us:

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WILL Training page

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

We will feature a different topic each month.

Gestational Diabetes Mellitus (GDM)

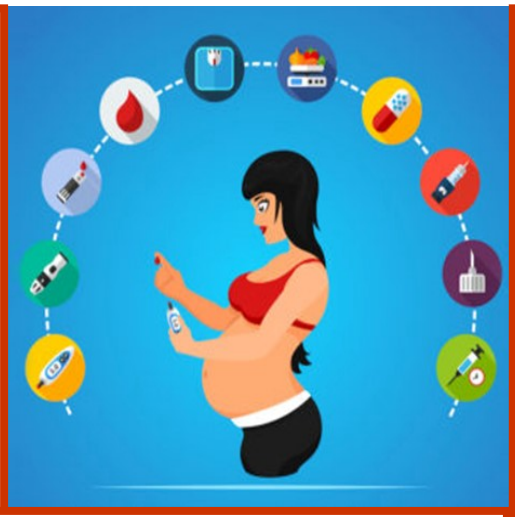
Did you know that women with GDM are eligible for WILL?

The doctors caring for these women need to be willing to follow the timing of birth allocated by randomisation for WILL. The issue is usually the willingness for a woman with GDM to continue her pregnancy until at least 40^{+0} weeks.

NICE guidance

(NG3, 2015) recommends that women with **'uncomplicated GDM'** give birth no later than 40^{+6} weeks.

- NICE does not define '**uncomplicated GDM'** or specify if this relates to the absence of co-morbidities such as hypertension.
- However, it is widely interpreted to mean GDM without one or more of the following: oral hypoglycaemic or insulin therapy, poor glycaemic control, and/or a macrosomic fetus.



Evidence

There are no high-quality data to guide timing of birth in GDM.

- Two trials (525 women) have examined planned early term birth (at 38^{+0} to 39^{+6} weeks) vs. expectant care (until at least 40 weeks) for women with GDM (regardless of management). They failed to reveal differences in major maternal or perinatal outcomes. *ł
- One trial (100 women with insulin-treated GDM) found that induction was associated with more neonatal hypoglycaemia. ł
- A decision analytic model for women with diet-controlled GDM, suggested that planned birth at 38 weeks may optimise outcomes by minimising perinatal death and neonatal morbidity. **

WILL and GDM:

- There are no ongoing trials that will inform practice in the UK.
- In clinical practice, timing of birth is currently individualised.
- The WILL Team regards all women with GDM as eligible, given the lack of adequate evidence on optimal timing of birth.
- GDM (by treatment type) is a planned subgroup in WILL, and randomisation of these women will provide information for all of us to help guide care in the NHS.

* Alberico S, Erenbourg A, Hod M, Yogev Y, Hadar E, Neri F, Ronfani L, Maso G; GINEXMAL Group. Immediate delivery or expectant management in gestational diabetes at term: the GINEXMAL randomised controlled trial. BJOG. 2017;124(4):669-677

ł Worda K, Bancher-Todesca D, Husslein P, Worda C, Leipold H. Randomized controlled trial of induction at 38 weeks versus 40 weeks gestation on maternal and infant outcomes in women with insulin-controlled gestational diabetes. Wien Klin Wochenschr. 2017;129(17-18):618-624

** Niu B, Lee VR, Cheng YW, Frias AE, Nicholson JM, Caughey AB. What is the optimal gestational age for women with gestational diabetes type A1 to deliver? Am J Obstet Gynecol 2014;211 (4):418.e1-6

True or False?

Q: A woman with Type 1 or Type 2 diabetes can take part in WILL?

A: True: If these women can continue their pregnancy until at least 40^{+0} weeks, they are eligible for WILL.

Outcomes for this group of women in WILL will further our knowledge about how to best care for women with diabetes.

Topic for next newsletter: ...Other co-morbidities: Chronic kidney disease and High BMI

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 31st August 2020

C=Consented/ R=Randomised

	Jun-Dec 2019 (C/R)	Jan-Jun* 2020 (C/R)	July 2020 (C/R)	Aug 2020 (C/R)	Total (C/R)
St Mary's Maternity Unit Poole	4/4	6/6	0/0	2/1	**12/11**
Croydon University Hospital	3/3	6/6	1/1	0/0	**10/10**
Liverpool Women's Hospital	6/6	1/1	2/2	0/0	**9/9**
Leeds Teaching Hospitals	7/6	2/2	0/0	0/0	**9/8**
James Cook University Hospital	5/5	3/2			**8/7**
St Mary's Manchester	4/4	3/3			**7/7**
Leicester Royal Infirmary	5/5	1/1	ǂ	0/0	**6/6**
Nottingham Queens Medical Centre	4/3	1/1		ǂǂ	**5/4**
West Middlesex Hospital	3/3	1/1			**4/4**
St. Thomas' Hospital	3/3	1/1	0/0	0/0	**4/4**
Bradford Royal Infirmary	0/0	4/4	0/0	0/0	**4/4**
Princess Anne Southampton	1/1	2/2		0/0	**3/3**
North West Anglia NHS Foundation Trust	1/1	2/2	**	**	**3/3**
Singleton Hospital Swansea	1/1	2/2	0/0	0/0	**3/3**
Royal United Hospital Bath	1/1	1/1	0/0	1/1	**3/3**
Birmingham Women's Hospital	1/1	1/0		1/1	**3/2**
Nottingham City Hospital	2/0	1/1		ǂǂ	**3/1**
York Teaching Hospital	1/1	0/0			**1/1**
Sunderland Royal Hospital	0/0	0/0			**0/0**
Total (C/R)	**52/48**	**38/36**	**3/3**	**4/3**	**97/90**

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

*ǂ Restarted 31 Jul 2020 ** Unable to restart WILL following COVID-19 pandemic*
ǂǂ Restarted 27th Aug 2020.