



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
Tel: 0207 8365454
EXT: 89548
Mob: 07773970879

Julie Wade (South)
Lead Research Midwife
Julie.Wade@kcl.ac.uk
Tel: 0207 8365454
EXT: 89548
Mob: 07970338451

Katie Kirkham
Senior Trial Manager
WILL@trials.bham.ac.uk
Tel: 0121 415 9109

Ruth Evans
Data Manager
WILL@trials.bham.ac.uk
Tel: 0121 415 9111

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
Tel: 0121 415 9109**

WILL Trial

ISSUE 13



APRIL 2020

Welcome to the 13th edition of the WILL newsletter.

Clocks have gone forward, nights are getting lighter, Spring has arrived, the sun is beginning to shine and Easter was glorious! We hope that you managed to buy your Easter eggs as chocolate can help to boost your mood and make you feel happy—something that we all need right now.



It is a very surreal time for everyone, not being able to go out other than to work, or shop for essential items, but not see friends and family.

WILL is PAUSED due to COVID-19

On the 24th March in response to the COVID-19 pandemic, we took the decision to PAUSE WILL. The most important justification for this was to allow all of us to focus on clinical care and facilitate deployment of research staff working on WILL to clinical duties, or COVID-19-related research.

We aim to resume WILL as soon as possible, when elective work resumes in the NHS. This may be as late as September 2020, but we will be reassessing this monthly and will keep you updated.

THANK YOU for all of your hard work and commitment so far on WILL.



Contacting the WILL team

The WILL team is still around to help you if you have any questions. Please note that as BCTU is currently closed, the contact details/working times have changed slightly for Katie and Ruth:



Ruth: Working 9.15–17.00: will@trials.bham.ac.uk and if urgent you can call on **0121 293 8435**.

Katie: You can contact via email: K.I.kirkham@bham.ac.uk or on **07974715467**; however, response times may be longer than usual.

WILL research midwives: Update

Julie: has been redeployed full-time to support clinical care.

Sue: at present will be working to support clinical care and WILL.

Until Julie is back with us, Sue will be available to support **all** of the WILL sites.

Recruitment update for March

As of the **20th March 2020**, we had **90** women consented and **84** women randomised in WILL!! It looked like March was on track to be our best month ever as when we paused WILL, we already had **13** participants so far!

It was fantastic that **St Mary's Maternity Unit, Poole** consented **2** and randomised **3** participants and **Bradford Royal Infirmary** consented and randomised **2** participants.

Congratulations also to the teams at; **Croydon University Hospital, Liverpool Women's Hospital, Queens Medical Centre and City Hospital Nottingham, St Thomas' Hospital, Princess Anne, Southampton, North West Anglia NHS Foundation Trust, Singleton Hospital Swansea** for consenting and randomising **1** participant each to WILL.

This is amazing, THANK YOU to you all.

We will be sending out gifts for your February and March participants as soon as





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



Please keep providing feedback about what is going well and any comments that you have



Please don't hesitate to contact us if you need anything.

WILL Participants:

Women who have not yet delivered in either arm:

Please can you help to ensure that women taking part in WILL who have not yet delivered still carry on with their participation, whether they are in the planned early term delivery arm or planned expectant care arm.

- Once these women are delivered, please can you complete outcome data ASAP?
- Please still report any SAEs, trial withdrawals or protocol deviations if they occur for relevant participants. The WILL team will see them and be in touch.
- Don't forget to let us know if you are having any difficulties due to staffing levels so that we can provide support.

****Please note that whilst WILL is paused, 'Randomisation' has been locked on the database, but all other data input is still active and you can resolve queries.****

Database:

During this time, Ruth and Katie will be checking through all of the data that have been entered on the database. We understand fully that you may find it difficult to complete data outcomes or check and respond to any queries raised. However, if you are able to, please could you:

- Check and complete any outstanding data for all participants (including women who could not be randomised).
- Check for and respond to any data queries that have been raised.



Research staff availability at sites:

Please keep in touch if you can and let us know how you are doing. It will be great to hear from you.

If possible, please could you let us know the names of your research team members who are still available and any new contact details?

This information will ensure that the WILL team contact you at convenient times during this phase of WILL.

Main phase: new plan

Once we know when we can re-open WILL at our existing pilot sites and at new sites, we will be in touch. Our plan for reopening sites is:

Existing pilot sites: We will arrange to deliver 'WILL refresher training' to all of our existing sites via conference facilities such as Zoom, telephone conference call or if needed, at a site visit.

New sites: It is hoped that we can start arranging our first SIV visits in September/October this year. As we have had to postpone some SIV visits, we aim to rearrange these first with those sites and then to start contacting other sites to arrange SIV dates.

We will keep you updated and Sue and Julie will be in contact as soon as they can. If you have any questions, please do not hesitate to get in touch.

Site 'remote' monitoring visits:

Katie is currently unable to visit sites that have had 5 or more participants to carry out an onsite monitoring visit. Therefore, she is looking at ways of monitoring as much data as possible remotely. She will be in touch with you shortly.

Randomised participants payments

Just to remind you that invoices for payments will be processed on a quarterly basis, in April, July, October and January. Please send any outstanding invoices to Katie at k.i.kirkham@bham.ac.uk or the WILL email address will@trials.bham.ac.uk



A message to you all:



From all of the WILL team we **THANK YOU** so much for all of your support and commitment on WILL so far. We look forward to working with you all again and welcoming new sites to our WILL team. **Please keep safe and well.**



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 Research Midwives (Sue & Julie)

Recruitment questions (eligibility, screening, etc.)

Clinical questions/protocol questions

Data form completion (including adjudication of maternal outcome page)

Data queries

Help with talking to clinical staff

84



WILL monthly recruitment table

Total as of 31st March 2020

C=Consented/ R=Randomised

	Jun - Dec 2019 (C/R)	Jan 2020 (C/R)	Feb 2020 (C/R)	March 2020 (C/R)	Total (C/R)
St Mary's Maternity Unit Poole	4/4	2/2	2/1	2/3	10/10
Croydon University Hospital	3/3	4/4	1/1	1/1	9/9
Leeds Teaching Hospitals	7/6	1/1	1/1	0/0	9/8
James Cook University Hospital	5/5	1/1	2/1	0/0	8/7
St Mary's Manchester	4/4	2/2	1/1	0/0	7/7
Liverpool Women's Hospital	6/6	0/0	0/0	1/1	7/7
Leicester Royal Infirmary	5/5	1/1	0/0	0/0	6/6
Nottingham Queens Medical Centre	4/3	0/0	0/0	1/1	5/4
West Middlesex Hospital	3/3	0/0	1/1	0/0	4/4
St. Thomas' Hospital	3/3	0/0	0/0	1/1	4/4
Bradford Royal Infirmary	0/0	1/1	1/1	2/2	4/4
Princess Anne Southampton	1/1	1/1	0/0	1/1	3/3
North West Anglia NHS Foundation Trust	1/1	1/1	0/0	1/1	3/3
Singleton Hospital Swansea	1/1	0/0	1/1	1/1	3/3
Nottingham City Hospital	2/0	0/0	0/0	1/1	3/1
Royal United Hospital Bath	1/1	0/0	1/1	0/0	2/2
Birmingham Women's Hospital	1/1	1/0	0/0	0/0	2/1
York Teaching Hospital	1/1	0/0	0/0	0/0	1/1
Sunderland Royal Hospital	0/0	0/0	0/0	0/0	0/0
Total (C/R)	52/48	15/14	11/9	12/13	90/84

Please take care of yourselves

