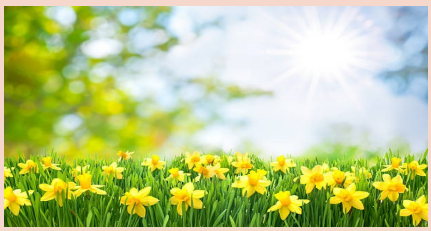


WILL Trial

ISSUE 2

MAY 2019

Hello and welcome to our second edition of the WILL Trial Newsletter. We hope that you all had a wonderful Easter bank holiday, and managed to enjoy the lovely weather.

We are thrilled with the high levels of interest in participating in WILL.

Our first three pilot sites are now ready to open to recruitment, so we should have recruits to report in June!.

Monthly teleconference

We plan to hold monthly teleconferences to discuss challenges and successes at trial sites. Our first call will be on Wednesday, 12th June from 13:30 to 14:30. An invitation will be sent to you shortly.

We are looking forward to hearing your views and knowing how best we can support you in the WILL trial. Please let us know about any days or times that work particularly well or poorly for you so that we can ensure that we select a range of days and times that will allow all to join at some point.

Website and database

We are pleased to inform you that the WILL website is now live! Please find the link via https://www.birmingham.ac.uk/will. The website will be updated on a regular basis, and will include Pilot sites, newsletters, recruitment figures and more. Please take a look and let us know your thoughts.

Arranging induction of labour

We are aware that many of you will be dealing with busy labour induction lists that may make challenging booking inductions for women in WILL who are randomised to planned early term delivery at 38+0 – 38+3 weeks.

Tips:

- Try to randomise women as close to 37+0 weeks as possible so that you have plenty of time to book an induction should the woman be randomised to planned early term delivery
- Try to book inductions as close as possible to 38+0 weeks in case the induction must be delayed because of other priorities on the delivery suite.

Keep us updated of any issues that you keep having so that we can provide support.

Contact the WILL Team

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 836554
EXT: 89548
Mobile tbc

Julie Wade (South)
Lead Research Midwife
Julie.Wade@kcl.ac.uk
Tel: 0207 836554
EXT: 89548
Mobile tbc

Kiran Sunner
Senior Trial Manager
WILL@trials.bham.ac.uk
Tel: 0121 4145 9109

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

Mary Nulty
Senior Data Manager
WILL@trials.bham.ac.uk
Tel: 0121 414 9011

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

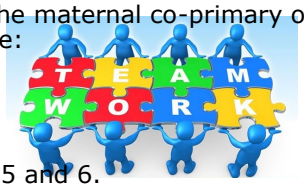
Site initiation visits (SIVs)

We have had the pleasure of conducting SIVs at the following sites:

- St Thomas' Hospital, London
- Leeds Hospitals
- Bradford Royal Infirmary
- Liverpool Women's Hospital
- Croydon University Hospital
- West Middlesex University Hospital
- Nottingham Hospitals
- Birmingham Women's Hospital

Maternal outcome sign-off

We have had great discussions about 'masked' sign-off for the maternal co-primary outcome (Form 6). Some logical questions being asked of us are:



Why are we doing it this way?
We need a completely unbiased assessment.
What data need to be verified?

Only source data for 'yes' responses to questions in Section 5 and 6.

Who can sign off and how?

Your PI or delegate, including a research midwife/ nurse who is named on the Delegation Log.
The individual must be both masked to the woman's group allocation, and not have been involved in her care or consented and/or randomised her to WILL. Simply print or photocopy the pages of the relevant medical notes that confirm the 'yes' response(s) (in Sections 5 and/or 6), redact any identifying information. The individual can then logon to the WILL database and confirm that the outcome occurred (nor not).

Remember we can help, so please contact us. We understand that each site will find a different solution to adjudication, and we will provide you with all the support that you need.

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

FAQs

Q: Doctors often don't commit to writing a diagnosis in medical notes – e.g., they might write: ?PIH, ?Pre-eclampsia. How should we check and confirm eligibility? Does the diagnosis need to be clearly documented in the notes?

A: Yes, this should be documented. Similar terms may be used such as 'essential hypertension' and 'pregnancy-induced hypertension' (PIH). If a woman's type of pregnancy hypertension is not clear from her notes, please check with the woman's clinician. It could be for example that s/he is planning to test placental growth factor (PlGF) before committing to a diagnosis. If there is any uncertainty, please delay recruitment until things are clearer, as a diagnosis of pre-eclampsia is an indication for birth and the woman would not be eligible for WILL.

Q: Is the inclusion criterion for gestational hypertension based on just one reading of elevated BP on or after 20 weeks' gestation?

A: Yes. WILL is a pragmatic trial and the protocol is based on NICE guidance for diagnosis and all aspects of care other than timing of birth. NICE does not specify that BP must be elevated (i.e. systolic BP of 140mmHg or more and/or diastolic BP of 90mmHg or more) on repeat measurement, although this is good clinical practice.

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