



Contact the WILL Team

Any queries?

Please contact us:

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WILL Trial

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Welcome back to WILL! We hope that you and your families have been keeping well during the pandemic, and that life at home and work is beginning to get back to normal.

WILL: update on 'restarting'

Whilst WILL recruitment has been paused since the 24th March due to the COVID-19 pandemic, we have all been busy. Thank you to all of you for completing follow-up for the women who were active in WILL when it paused.

The central team has been working with NIHR on the post-pilot review. We have received the good news that WILL has been given permission to proceed to the main phase! Also, our Recovery Plan for post-COVID-19 recruitment has also been approved.

Currently, our sponsor is preparing to issue approval to re-open and it has been great hearing from several of you at WILL sites, asking when you can start recruiting to WILL again. Your enthusiasm was very helpful to us in this process. Thank you for keeping in touch.

As soon as we have a date to re-open, we will let you know!

Thank you for completing the following to prepare for re-opening:

- 'Site viability assessment questionnaire'
- Data queries, inputting outcome data
- Sending updated CVs, GCP certificates and training logs if there have been any changes with your teams.

If you have not yet completed the 'Site viability assessment questionnaire, please can you send back to us as soon as you can.



Post COVID-19 Restart Checklist

BCTU will be sending out a 'Post-COVID-19 local Site Restart Checklist' to complete once sites indicate that they are ready to resume recruitment.

Main phase: 'restart' plan

Existing pilot sites: We will deliver 'WILL refresher training' to all existing sites via conference facilities, such as video or telephone conference calls.

New sites: We hope to start our first SIVs in Sept/Oct this year. We aim to prioritise re-scheduling SIVs with the sites that we had to postpone due to the pandemic, and will then start contacting other sites to arrange dates. These can also be offered virtually depending on sites preferences. Sue, Julie and Katie will be in contact as soon as they can to find out when might be convenient for you.

THANK YOU so much for your continued support and we really do look forward to working with you again and welcoming new sites to the WILL family!



Contacting the WILL team

RUTH: Working 9.15-17.00. Email WILL@trials.bham.ac.uk. If urgent, call 0121 293 8435.

KATIE: Email k.i.kirkham@bham.ac.uk or call 07974715467 (response times may be longer than usual).

WILL research midwives JULIE and SUE: are both now back working on WILL 4 days a week.



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 database:

Ruth and Katie have been checking through all data entered. We understand that you may have found it difficult to complete data outcomes or check and respond to queries raised during this time. However, if you are now 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.



Maternal outcome form: verifying data

Please could you check if you have any maternal outcome forms that need data to be verified by the PI/delegate. If you are not sure, Ruth can send you an email with these details. Remember, that the only sections on this form that need the data to be verified are:

Abnormal laboratory tests and maternal complications sections

Completing this form:

- There will be a prompt to let you know if data need adjudication.
- Once you have completed this form with initial data, tick the '**Submit and lock CRF**' box at the bottom of the form before saving it.
- At present, it will not be possible for the PI/PI-delegate to complete their section unless the form has been locked.

Remember that the person you ask to review and sign off should **not** have been involved in the care of the woman and should be masked to the arm to which she was allocated.

Let us know if you do not have a member of your team who is named on the delegation log and can do this task.

Please give the PI/delegate the information that they need to check and verify the data entered in the relevant sections of this form. It may be useful to do this with them or suggest that they arrange to have support for this from Ruth.

Process for PI or PI delegate:

Log on, open the form for editing from the Assessments list, and select an **Audit Reason** from the dropdown list at the top of the form.

Then follow these steps to complete the verification sign-off section:

- a) Check and confirm that you have verified the data entered in the 2 sections
- b) Enter your name
- c) Enter the password you use to log on to the WILL database.
- d) Then click on **Sign**; you should get a message saying your password has been recognised
- e) Enter the date
- f) Click on **Save**

Feel free to call us at the time of verifying data if you would like any help with entering the information or saving the form.



It is generally easier for us to assist with database issues as you encounter them, when you are logged in to the database so please call Ruth, Sue or Julie who will be happy to help you.

6 week postpartum questionnaire:

This questionnaire is sent to participants by Textlocal. Reminder texts are sent at 7, 21 and 28 days. BCTU will contact you after the 28 day text reminder to ask if you would contact the woman. The questionnaire can be completed over the phone with her at a time that is convenient.

If you are unable to contact the woman please could you obtain the information for the 6 week questionnaire from her GP, checking first that she indicated that she consented to contact with the GP for additional information on her Informed Consent Form.

