TARDIS – Working Practice Document, No. 09

Title: Day 90 Follow Up

THE DAY 90 FOLLOW-UP IS TO BE CONDUCTED BY AN APPOINTED INDIVIDUAL FROM THE NATIONAL COORDINATING CENTRE WHO HAS NOT RANDOMISED, TREATED OR OTHERWISE BEEN IN CONTACT WITH THE PATIENT, IN THE INTEREST OF IMPARTIALITY.

1. On a weekly basis, login to the TARDIS Trial Website (https://nottingham.ac.uk/~nszwww/tardis/tardistrialdb/tardis_login.php) and access the Day 90 Follow Up records. From here you will be able to print a copy of the Day 90 follow up form and enter the data collected.

For every patient enrolled into TARDIS within your country, ensure that you have received a corresponding copy of the Baseline Data Fax Sheet containing the patient's, GP's, and next of kin's contact details. These details should be provided to you from the recruiting centre shortly after a patient is randomised. If patient contact details have not been received you will need to contact the recruiting centre to request them. On receipt of the Baseline Data Fax Sheet, check and ensure the information is complete. The UK Day 90 follow up coordinator will require a copy of the patient's details to add to the patient database.

2. At 90 days after randomisation the patient will be due their scheduled telephone follow up. In preparation, one week prior to the follow up date, check you have all the paper work for the patient in question. Look up the patient's hospital records to ascertain the disposition of the patient, i.e. is the patient still alive, an inpatient, transferred to another hospital or has been discharged home. If this is not possible or the information is not current, the patient's General Practitioner/family doctor should be contacted. It is extremely important to carry out these checks to ensure that the patient is still living in order to avoid causing distress to the relatives.

3. On contacting the patient, determine if the patient is deemed fit to undertake the Day 90 Follow Up. If the patient is able to complete the follow up:
    i. First explain that you are from the TARDIS trial they participated in. If the patient has issues with you verifying where you are calling from then you can provide a phone number from the institutional switchboard for the patient to call (see appendix). This number can be found on the institutional website and therefore acting as verification.

ii. Follow the scripted form to ensure that all questions are answered and data collected.
iii. Date and sign the completed form ensuring that any/all errors are crossed out with a single line, initialled and dated accordingly. Under no circumstances should incorrect entries be erased/blotted out.
iv. Enter the answers as soon as possible onto the web-based forms at https://nottingham.ac.uk/~nszwww/tardis/tardistrialdb/tardis_login.php using your password to access the site and the PIN number to submit the data.

4. Every attempt should be made to obtain the answers from the patient rather than the carer. This may be more difficult but results in better quality data. If the patient is deemed unfit to undertake the 90 day follow up assessment:
    i. The patients Carer may be requested to help complete the assessment. The carer may be a family member, friend, care staff or Ward Nurse. NOTE: Where the Carer conveys the patient's answers, then it is deemed that the patient answered the questions e.g. the patient has difficulty hearing and requires a carer repeats question and responses between the assessor and patient. Where the Carer answers the questions on behalf of the patient, then it is deemed the Carer answers the questions e.g. the patient is unable to communicate with the follow up coordinator or carer their response to the follow up questions.
    ii. Complete the assessment using the scripted form and ensure that all appropriate questions are answered. If the Carer is completing the follow up on behalf of the patient the Cognitive Assessments and Zung Depression Rating Scale is not applicable and will not be completed.
    iii. Date and sign the completed form making sure that any and all errors are crossed out, initialled and dated accordingly. Under no circumstances should incorrect entries be erased/blotted out.
    iv. Enter the answers as soon as possible onto the web-based forms at https://nottingham.ac.uk/~nszwww/tardis/tardistrialdb/tardis_login.php using password to access the site and PIN number to submit the data.

5. If the patient does not have a telephone contact, and all avenues have been exhausted to obtain contact details, including asking the recruiting centre to help secure it, the postal version of the Day 90 Follow Up assessment form should be sent to the patient or carer.

6. If the patient has died during the 90 days from randomisation then please obtain information regarding cause and date of death. This information should then be entered onto the web-based forms.

7. If considerable effort has been made to contact the patient and carer by telephone and post with no success then a patient may be recorded as "Lost to follow-up – no mRS obtained". If a Doctor at the GP surgery has seen the patient recently, then a mRS questionnaire can be issued to the Dr the patient saw. This will obtain the mRS score, which can then be added to the database as 'lost to follow-up mRS obtained from doctor'. This is a last resort as it is very important to record an outcome for all patients. Please see the SOP for finding missing patients.

   PLEASE CONTACT THE INTERNATIONAL COORDINATING CENTRE BEFORE CONSIDERING ANY PATIENT LOST TO FOLLOW UP.

8. File away all the Day 90 follow up assessment forms separately to patient contact details

9. Please contact the TARDIS Trial Office by email (tardis@nottingham.ac.uk) or by telephone (+44 (0) 115 8231770) with any queries.

Appendix:

1. University of Nottingham switchboard – 0115 951 51 51