**PhEAST – Working Practice Document**

**Title: Day 90, 180 and 365 Follow Up, No. 006**

**The day-90, day-180 and day-365 follow-ups are to be conducted by an appointed, and delegated, coordinator from the national coordinating centre. This coordinator should be blinded to participants’ treatment allocation, in the interest of impartiality.**

**Review which follow-ups are due**

On a weekly basis, login to Redcap and export all participant enrolment data to excel. From there, see which follow ups need completing and on what dates.

**Participant Data**

For every participant enrolled into PhEAST, ensure that you have received a copy of their patient contact details and next of kin’s (NoK) contact details. It is the responsibility of the trial manager to request sites to upload this contact information, should this be forgotten. These details should be uploaded by the recruiting centre shortly after the participant is randomised, if possible. The contact details will then be entered onto Adara database in readiness for making contact at day 90, 180 and 365.

**The telephone follow up will be conducted at 90, 180 and 385 (±7) days after randomisation. As follows:**

1. One week before the follow due date, confirm that all contact details are available on the secure vault. If there are missing fields, the trial manager will contact the local site and request the missing information to be uploaded.
2. Prior to the day 90, 180 or 365 (±7) day follow-up, contact the participants’ GP practice and confirm their vital status (dead or alive). If the GP is able to confirm, check that the contact details for the participant and NoK remain current (*note: some GPs may not provide this extra information, or request they be contacted via secure email to retrieve this information*).
3. If it has been confirmed by the GP practice that the participant is deceased, collect the date of death (if the GP is willing to provide this information). Do not make any contact with the NoK if the participant has deceased. The day 90, 180 or 365 CRFs in the database should be updated with the information provided by the GP practice. The completed submission should then be printed off and filed in the locked allocated filing cabinet.
4. Once confirmed that the participant is living, and you have made contact, introduce yourself with your full name, your job title and that you are representing the PhEAST study, based at the University of Nottingham. You may need to remind the participant and/or NoK about the trial and when they entered the trial and at which hospital. If the patient has issues with you verifying where you are calling from, then you can provide the telephone number for the University of Nottingham switchboard for the patient to call (0115 951 5151) in order for them to be put back through to yourself or the stroke trials office.
5. Confirm the participant’s full name. If the participant is unable to communicate, the carer may need to support or respond to the day 90, 180 or 365 questions. Make every effort to gain the responses from the participant if possible.
6. Follow the day 90, 180 or 365 follow-up assessment (as applicable). There is a script for the speech and language assessments (see appendix 1).
7. Once the follow-up assessment has been completed, print off the electronically collected assessment (retain paper CRF), and store in the allocated locked filing cabinet.

**Carer/Nok Data collection**

The participant should respond to all questions wherever possible. However, if the participant does not have capacity to undertake their follow up assessment; or if communication is not possible; or if the patient has declined the follow-up but given consent to contact a carer/NoK:

1. The patient’s carer may be requested to help complete the assessment. The carer may be a family member; friend; member of care staff; or hospital staff (if an inpatient).
2. **NOTE**: Where the carer conveys the participant responses, then it is deemed that the participant responded to the questions e.g. the participant has hearing difficulty or dysphasia and requires a carer to channel the responses.

1. Where the carer answers the questions on behalf of the participant, then it is deemed that the carer answered the questions e.g. the patient is unable to communicate their responses to the follow-up questions to either the Follow-up Coordinator or carer.

**Postal Data collection**

A postal day-90, 180 or 365 follow-up assessment may be sent to the patient/carer, via post or e-mail if:

1. The patient/carer does not have a telephone contact number and all avenues have been exhausted to obtain contact details (including: asking the recruiting centre; the patient’s GP practice; and/or Data Quality).
2. Telephone contact with the patient/carer, has not been possible after multiple attempts.
3. The patient/carer has specifically requested that they would prefer to complete a written follow-up.
4. Once the assessment has been returned, submit the data on the trial website and stored as above.

**Lost to Follow up**

1. **Note:** Lost to follow up is the final and very last option when completing a follow up. All avenues of contacting the participant, carers, GP and other health care professionals such as community nurses, participant pharmacies, data quality, local site principle investigator, nurses and other multidisciplinary team professionals will have been exhausted.
2. Before marking any participant ‘Lost to Follow up’ the Chief Investigator will be informed, and a discussion will take place at the TMC. The discussion and outcome will be minuted.

1. The local recruiting site will be informed, and any training issues addressed.

**Appendix 1:**

**Follow-up Telephone Script for swallowing outcome measures.**

1. Do you consider yourself/\*name of participant\* to have swallowing difficulties?

Yes/no

1. Are you currently under the care of a speech and language therapist?

Yes/no

1. a) Do you/\*name of participant\* have a feeding tube in place?

Yes

No (proceed to question 4)

b) Is it a tube directly into the stomach through the wall of the tummy, or does it go through the nose into the stomach?

Direct -PEG/RIG

Nose – NGT

c) Do you/does \*name of participant\* take all your/their food and drink through the tube?

Yes – both (proceed to question 8)

No – has some food through the mouth (proceed to question 6)

No – has some drinks through the mouth (proceed to question 5, do not ask question 6)

No – has some food and drink through the mouth (proceed to question 5)

No – has most food and drink through the mouth (proceed to question 4)

1. When the speech and language therapist last saw you/\*name of participant\*, did they recommend any modifications or strategies for drinks or food?

Yes – both (ask questions 4 and 5)

Yes – drinks only (ask only question 4)

Yes – food only (ask only question 5)

No (proceed to question 6)

1. a) Did the speech and language therapist advise to use thickener in your/\*name of participant\*’s drinks?

Yes (ask 4b)

No (proceed to 4e)

b) Did the speech and language therapist describe a specific ‘level’ to thicken your drinks?

Yes (level 0 thin/ level 1 slightly thick/ level 2 mildly thick/ level 3 moderately thick/ level 4 extremely thick)

No/I don’t know (proceed to 4d)

c) Do you/Does \*name of participant\* follow the recommended level for thickened drinks?

Yes (proceed to question 5)

No (proceed to 4d)

d) i) How many scoops of thickener do you put in a drink of 200mls (approx. a standard tea mug)?

\_\_\_\_\_

 ii) What is the brand and name of the thickener you use?

\_\_\_\_\_

e) Did the speech and language therapist advise of the following strategies to help with drinking?

i) Someone should help you/\*name of participant\* with drinking e.g holding the cup/spoon during drinking – yes/no

ii) Someone should supervise you/\*name of participant\* during drinking – yes/no

iii) Using a teaspoon to drink – yes/no

iv) Taking one sip at a time – yes/no

v) Using a specialist cup e.g. valved release/ spouted beaker/ weighted cup

vi) Drinking a limited amount at one time e.g. 100mls – yes/no if yes, specify \_\_\_\_\_\_\_\_

vii) Tucking chin down during swallow – yes/no

viii) Turning/tilting the head during swallow – yes/no if yes, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_

ix) Supraglottic swallow (baring down before and during the swallow, may also suggest breathing out after swallowing) – yes/no if yes, specify \_\_\_\_\_\_\_\_

x) Keeping food and drink separate – yes/no

xi) Doing a second (or more) swallow for each mouthful – yes/no

xii) Other, please specify \_\_\_\_\_\_\_\_

1. a) Did the speech and language therapist advise a specific level to describe your/\*name of participant\*’s food preparation?

Yes (level 3 liquidised, level 4 puree/ level 5 minced and moist/ level 6 soft and bite-sized/ level 7 easy chew/ level 7 regular)

No (proceed to 5c)

b) Do you/Does \*name of participant\* follow the recommended level for modified food?

Yes (proceed to question 6)

No (proceed to 5c)

c) How would you describe the type of food you can safely eat?

i) Do you avoid crumbly, stringy, chewy foods or mixed consistencies e.g. cereal with milk – Yes/no

ii) Does meat need to be very tender and in small pieces? - Yes/no

iii) Do you only eat minced meat and vegetables that are soft and already mashed up? – yes/no

iv) Do you mash up the food before eating? – yes/no

v) Do you blend the food to a smooth consistency that holds its shape e.g. mousse? – yes/no

vi) Do you blend the food to a liquid consistency e.g. soup with no lumps or smoothy? – yes/no

d) Did the speech and language therapist advise of the following strategies to help with eating?

i) Someone should help you/\*name of participant\* with eating e.g holding the spoon/fork during eating – yes/no

ii) Someone should supervise you/\*name of participant\* during eating – yes/no

iii) Using a teaspoon to eat – yes/no

iv) Eating a limited amount at one time e.g. a specific number of teaspoons/ small meals – yes/no if yes, specify \_\_\_\_\_\_\_

v) Keeping food and drink separate – yes/no

vi) Doing a second (or more) swallow for each mouthful – yes/no

vii) Taking a sip of drink after each mouthful – yes/no

viii) Tucking your chin to your chest when you swallow – yes/no

ix) Turning or tilting your head when you swallow – yes/no

x) other please specify \_\_\_\_

1. Do you have any further comments on your/\*name of participant\*’s swallowing?

\_\_\_\_\_\_\_\_\_\_\_\_\_

**Scoring Guide**

**DSRS**

NOTE:

Supervision score of 3 is always chosen when a patient has an NG or PEG/RIG tube but is having some food or drink through the mouth

For Fluids look at the questions highlighted in yellow

For Diet look at questions highlighted in blue

For Supervision look at questions highlighted in green

Questions highlighted in purple give information for multiple categories

**Tube feeding:**

If the participant is having all food and drink through the tube then score 4 for each category, i.e. 4,4,4. (FOIS = 1, FSS =4/5 depending on tube type).

If the participant is having no more than 15 teaspoons of drinks and/or food total in one day, this is counted as “minimal oral trials”. This is scored with 4 for Fluids and Diet but 3 for supervision, i.e. 4,4,3. (FOIS = 2, FSS = 4/5 depending on tube type).

If the participant is having more than 15 teaspoons of food/drink but still needs some of their nutrition/hydration through the tube, then this is counted as “consistent oral trials”. For this you can score according to the level of modification in Fluids and Diet, but still always score 3 for supervision, e.g. it could be 4,3,3, or 2,3,3 depending on what kind of food and drink is being taken. (FOIS =3, FSS = 4/5 depending on tube type).

See the guide table below– remember this only accounts for people who need a feeding tube (PEG/RIG/NGT):

|  |  |  |
| --- | --- | --- |
| Fluids | Diet | DSRS score |
| No drinks through the mouth | No food through the mouth | 4,4,4 = 12 |
| No drinks through the mouth | Less than 15 tspns of food in a day | 4,4,3 =11 |
| Less than 15 tspns of drink in a day | No food through the mouth | 4,4,3 = 11 |
| 5 tspns of water twice a day | 5 tspns of yogurt once a day | 4,4,3 = 11 |
| 5 tspns of level 2 fluids 3 times a day | 5 tspns of level 4 diet 3 times a day | 1,3,3 = 7 |
| 100mls of level 1 fluids 4 times a day | 1/2 dinner plate of level 4 diet each meal | 1,3,3 = 7 |

**Fluids:**

If a level is given, match it to the level on the table.

If the level isn’t known and number of scoops is given (check that this is for 200mls (best estimate)) check against the table below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Thickener brand | Thickener name | Number of scoops | Corresponding level | DSRS fluid score |
| Nutricia | Nutilis Clear | 1 scoop2 scoops3 scoops7 scoops | Level 1Level 2 Level 3Level 4 | 1123 |
| Nestle | Resource Thicken up Clear | 1 scoop2 scoops3 scoops8 scoops | Level 1Level 2 Level 3Level 4 | 1123 |
| Fresenius | Thick and Easy Clear | 1 scoop2 scoops3 scoops6 scoops | Level 1Level 2 Level 3Level 4 | 1123 |
| Fresenius | Thick and Easy Original | 5 scoops6 scoops7 scoops8 scoops | Level 1Level 2 Level 3Level 4 | 1123 |

**Diet:**

If a level is given, match it to the level on the table. Note that a level 3 diet (which is unlikely to come up) would be scored as a diet score of 3.

If the level is not known and a description is given, check against the table below (if no given to all questions in 6c this would indicate a level 7 regular diet DSRS Diet 0):

|  |  |  |
| --- | --- | --- |
| Question with yes response (6c) | Corresponding level | DSRS Diet score |
| i) | Level 7 easy chew | 1 |
| ii) | Level 6 soft and bite sized | 2 |
| iii) | Level 5 minced and moist | 3 |
| iv) | Level 5 minced and moist | 3 |
| v)  | Level 4 puree | 3 |
| vi) | Level 3 liquidised | 3 |

**Supervision:**

If the participant needs help with eating and/or drinking – score a 2 for supervision

If the participant does not need help with eating and/or drinking but does need supervision – score a 1 for supervision.

**Remember that if the participant has a feeding tube this might affect the supervision score – see the feeding tube section.**

**Scoring Guide**

**FOIS**

For Fluids look at the questions highlighted in yellow

For Diet look at questions highlighted in blue

Questions highlighted in purple give information for multiple categories

The FOIS score only considers fluids up to level 3. If a participant does not have a feeding tube you only need to look at the Diet questions (blue)

If the participant is having all food and drink through the tube then this is scored as nothing by mouth FOIS 1. (DSRS = 12, FSS =4/5 depending on tube type).

If the participant is having no more than 15 teaspoons of drinks/food (combined if both) in one day this is scored as “minimal oral trials” FOIS 2 (DSRS = 11, FSS = 4/5 depending on tube type).

If the participant is having more than 15 teaspoons of food/drink but still has most of their nutrition/hydration through the tube, then this is counted as “consistent amount trials FOIS 3 (DSRS = varies but always supervision of 3, FSS = 4/5 depending on tube type).

See the guide table below:

|  |  |  |
| --- | --- | --- |
| FOIS score | Fluids | Diet |
| 1 | No drinks through the mouth | No food through the mouth |
| 2 | No drinks through the mouth | Less than 15 tspns of food in a day |
| 2 | Less than 15 tspns of drink in a day | No food through the mouth |
| 2 | 5 tspns of water twice a day | 5 tspns of yogurt once a day |
| 3 | 5 tspns of level 2 fluids 3 times a day | 5 tspns of level 4 diet 3 times a day |
| 3 | 100mls of level 1 fluids 4 times a day | 1/2 dinner plate of level 4 diet each meal |
| 4 | N/A | Level 5 minced and moist, level 4 puree diet or Level 3 liquidised diet – yes to 6c) v/vi |
| 5 | N/A  | Level 6 soft and bite sized – yes to 6c)ii/iii/iv |
| 6 | N/A | Level 7 easy chew diet – yes to 6c)i  |
| 7 | N/A | Level 7 regular diet – no modifications to food. |

**Scoring Guide**

**Feeding Status Scale (FSS)**

|  |
| --- |
| Table 1. The Feeding Status Scale.  |
| Intake route | Score | Level | Includes | Excludes |
|         Oral | 1 | Normal | * Regular oral diet (L7/L7 easy chew).
* Normal oral fluids (L0).
* Non-oral feeding route may be in situ but is not required to maintain nutrition.
 | * Tastes/oral trials of selected diet/fluids.
* Managing some oral intake but requires non-oral supplementation to maintain nutrition.
 |
| 2  | Soft | * Modified oral diet (L6 or below).
* Oral fluids – normal or modified (L0-L4).
* Non-oral feeding route may be in situ but is not required to maintain nutrition.
 | * Tastes/oral trials of selected diet/fluids.
* Managing some oral intake but requires non-oral supplementation to maintain nutrition.
 |
|                Non-oral | 3 | NGT | * Nasogastric tube feeding required to maintain nutrition.
* May receive oral fluids – normal or modified (Lo-L4).
* May receive tastes/oral trials of diet.
 | * Awaiting NGT placement/tube removed.
* Meeting nutritional requirements through oral intake.
 |
| 4 | PEG | * Percutaneous endoscopic gastrostomy feeding required to maintain nutrition.
* May receive oral fluids – normal or modified (Lo-L4).
* May receive tastes/oral trials of diet.
 | * Awaiting PEG placement.
* Meeting nutritional requirements through oral intake.
 |
| 5 | IV/Subcut fluids | * Non-oral supplemented fluid intake.
* May receive oral fluids – normal or modified (Lo-L4).
* May receive tastes/oral trials of diet.
 | * Meeting nutritional requirements through oral intake.
* Other route of non-oral feeding in situ.
 |
| 6 | Nothing | * May receive tastes/free water protocol for comfort.
* May be awaiting placement of PEG/NGT.
 | * Meeting nutritional requirements through oral intake.
* Non-oral feeding in situ.
 |
|   | 7 | Death |   |   |

At follow-up you will not score 5 or 6 as the participant will be out of hospital.

The table explains how to score each level.

If the participant reports no ongoing difficulties and no modifications, then score 1.

If they do not have a feeding tube but still require any modifications, then score 2.

If they have a feeding tube (regardless of whether they are having something through the mouth as well), then score 3 for NGT and 4 for PEG/RIG.