

General Update



I hope all our research teams have had a lovely summer and you all managed to see some sun!

Recruitment is still going strong and we have 73 patients who have been randomised in to the AMBER study. This is fantastic as we are ahead of our predicted recruitment. The funders and the data monitoring committee both congratulated us on the recruitment so we would like to pass this **THANKS ON TO EACH AND EVERYONE OF YOU INVOLVED IN AMBER!**

We have 11 sites up and running in the UK with only one final site left to open, Edinburgh (Site visit planned for the 10th September).

Monthly Nurse Teleconference

The last monthly teleconference was scheduled for 22nd July. We only had one person dial in to this and I wondered if you could feedback to the AMBER study office if you find these sessions useful. Please put Thursday 17th September 1-2pm in to your diary for the next TC. If this does not suit, please let us know as we would like to try and arrange a session that would suit the majority.

Clarification regarding supra-pubic catheters.

One of the studies exclusion criteria states “contraindications to abdominal massage”. We would like to clarify those patients with supra- pubic catheters should not be included into the AMBER study. We are updating the screening CRF to include this and will circulate new forms when this change has been made. In addition we have added a question to the CRF about anal irrigation. We were going to add this to the nurse assessment form but decided it was best to capture this at the screening phase in order that patients can be given the time (if they have just started using anal irrigation) before randomisation if required.

Any additional information on anal irrigation should still be collected during any follow up call under the section “changes in bowel habits”

Massage Training

We would again just like to re-inforce how **IMPORTANT** it is to demonstrate the massage strokes to the patient and let them feel the pressure and sensation of the different strokes. This should be done for the patients who are doing self-led massage and carer given massage. If any of the research team trained to perform the massage feel they would like a refresher course or need any tips or advice, please do let us know. Doreen would be more than happy to come and give a refresher training session.

In addition, I previously asked if you could feedback to the AMBER office your thoughts on recruiting patients who are severely disabled and/or have poor dexterity. Please after reading this, can you email AMBER@gcu.ac.uk and let us know if you are approaching these patients, if they are declining to take part or if you are not approaching these patients due to the fact that they are too disabled to do the massage? It would be really useful to know this information and we have a Trial Steering Committee meeting on the 10th August – it would be great to feedback findings to the committee.

Patients randomised to control arm.

If the patient says they are already familiar with the MS Essentials Booklet, can you still go over the main points and ask them if there is anything that they would like explained further.

% of stool

| Description of Stool (see Bristol Stool Chart at end of the form) What percentage of time is your stool: | 100% | 75% | 50% | 25% | 0% |
|--|--------------------------|--------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| Like pellets/hard lumps | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Sausage shaped, but lumpy | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Like a sausage but with cracks at its surface | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Like a sausage or snake, smooth on its surface | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Soft blobs with clear cup edge | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Fluffy pieces with ragged edges, a mushy stool | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Watery, no solid pieces | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

If a patient reports a % of stool higher or lower than one of the 5 categories shown opposite, please stick to the categories stated and tick the option that is closest to what the patient reports, e.g. if the patients say 40%, mark 50%.

Completing severity of symptoms – Page 5 of Nurse Assessment CRF

It has come to our attention that the severity of symptoms section on page 5 of the Nurse assessment CRF may not be as clear as it could be for completing. Please see below; the first column should be completed if the answer is none; 2nd column is mild, 3rd is moderate and 4th is severe. For example, in the completed section below the patient has mild visual problems, mild cognitive and mild bowel symptoms (not none). Please can you make sure you are completing this correctly? If you think you have been completing this section wrong please let us know and we can amend this.

| Severity of symptoms | As of to-day | NONE | MILD | MODERATE | SEVERE | | | |
|----------------------|--------------------------|------|-------------------------------------|----------|-------------------------------------|----------|--------------------------|--------|
| Visual problems | <input type="checkbox"/> | None | <input checked="" type="checkbox"/> | Mild | <input type="checkbox"/> | Moderate | <input type="checkbox"/> | Severe |
| Pain | <input type="checkbox"/> | None | <input type="checkbox"/> | Mild | <input checked="" type="checkbox"/> | Moderate | <input type="checkbox"/> | Severe |
| Spasm | <input type="checkbox"/> | None | <input type="checkbox"/> | Mild | <input checked="" type="checkbox"/> | Moderate | <input type="checkbox"/> | Severe |
| Mobility | <input type="checkbox"/> | None | <input type="checkbox"/> | Mild | <input checked="" type="checkbox"/> | Moderate | <input type="checkbox"/> | Severe |
| Cognitive | <input type="checkbox"/> | None | <input checked="" type="checkbox"/> | Mild | <input type="checkbox"/> | Moderate | <input type="checkbox"/> | Severe |
| Depression | <input type="checkbox"/> | None | <input type="checkbox"/> | Mild | <input checked="" type="checkbox"/> | Moderate | <input type="checkbox"/> | Severe |
| Fatigue | <input type="checkbox"/> | None | <input type="checkbox"/> | Mild | <input checked="" type="checkbox"/> | Moderate | <input type="checkbox"/> | Severe |
| Bladder | <input type="checkbox"/> | None | <input type="checkbox"/> | Mild | <input checked="" type="checkbox"/> | Moderate | <input type="checkbox"/> | Severe |
| Bowel | <input type="checkbox"/> | None | <input checked="" type="checkbox"/> | Mild | <input type="checkbox"/> | Moderate | <input type="checkbox"/> | Severe |

Bowel diaries

In general, the bowel diaries are being completed really well. As stated before, please review the bowel diary the patient has completed at the baseline appointment. If sections are not completed, please advise them that they should have a response in each box even if this is zero or none for when they complete the weekly diaries (weeks 1-6).

24 week follow –ups

We are at the stage on the study where some sites have patients at the 24 week follow up stage. Please refer to the “Nurse visit guide” for a full detailed description of what you need to do at these follow ups. In addition the AMBER office will email you when you have a patient due the 24 week follow up. Please note that all AEs should be resolved or ticked as ongoing and all con-meds should be ticked as ongoing at the end of the study or a date entered for “stop date”. Both these updated forms need to be sent after the 24 week follow up with the rest of the completed paperwork.

PLEASE REMEMBER TO ADD THE STUDY ID TO ALL OF THE PATIENTS FOLLOW UP PACK PAPERWORK BEFORE THEY TAKE THIS HOME WITH THEM AT THE BASELINE VISIT