NURSE STUDY VISIT GUIDE
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Document Version History

Version	Version Date	Significant Changes
1.0	16th December 2014	
2.0	5th February 2015	Added to section 7: Bristol stool chart needs to be sent to the sites with the appointment letter and pre-baseline bowel diary.
3.0	26th February 2015	Amended details on what sites have to send to AMBER study office at baseline and for the follow up calls to allow timely data entry.

1. Investigator Site Files

You will be provided with **3** lever Arch AMBER study Investigator Site files (ISF).

File 1 will contain a copy of all the relevant study documents (protocol, PIL and consents etc) and all other required paperwork for regulatory requirements (approval letters etc) The study office will send any amended versions of documents and a copy needs to be put in this file

File 2 will be filing of all the completed patient study Case Report Forms (CRFs) consents, and any other patient paperwork related to the AMBER study. Originals **MUST ALWAYS** be kept in the ISF. Copies should be made and sent to the AMBER study office or should be faxed using details below.

AMBER Study Office (K212)
NMAHP Research Unit
Buchanan House, Level 2
Glasgow Caledonian University
Cowcaddens Road
Glasgow
G40BA

Fax: 0141 331 8101

File 3 will contain copies of all the relevent stationary required for the study. Study packs will also be included and will be made up by the AMBER study office.

2. Site Initiation Visits

Prior to each site being "open" to recruitment the Trial Manager (TM) and/or the CI will attend the site for a **site initiation visit**. All study staff who will be working on the AMBER study should attend. All aspects of the study will be covered and there will be the option for a refresher massage training session. If sites have not attended a training day the nurses who will be delivering the intervention MUST attend the massage training on this visit.

The TM will complete a site initiation report following this visit. Once all relevant sections have been completed (this includes confirmation of all approvals in place) the site will officially be open to recruitment by the TM confirming this via email.

3. Case Report Forms (CRF) and Study Questionnaires

For a list of all the study CRFs and Questionnaires to be completed in the AMBER study please see Appendix 1

4. Study Database and Randomisation system

For information on the AMBER study Randomisation system. Please read the user guide for the Trust Randomisation system **(Also in section 7 of the ISF)**

The TM will provide database training to the sites for entering the screening form to the database. This is the only data entry that the sites have to fulfil.

5. Recruiting patients

a) Patients can be recruited either in clinic or by sending out an **"AMBER Recruitment pack"** to patients who have been screened from notes or a clinic list.

b) The **"AMBER Recruitment pack"** contains:

- Patient information Leaflet (General Amber study PIL)
- Letter of Introduction
- Expression of Interest form
- Reply paid envelope (to site)

c) Before giving this pack to potential participants or sending out in the post, the research nurse must add the participant ID to the Expression of Interest form.

d) The participant ID is a 6 digit ID. The first 3 letters indicate the site and the last 3 should be sequential numbers 001, 002 etc. For example the Southern General Hospital code is SGH thus participant IDs will be SGH001, SGH002, SGH003 etc. The TM will provide the site abbreviation code prior to recruiting.

e) All patients who have been sent a pack/approached in clinic should be added to the AMBER study screening log.

f) This screening log should be sent to the AMBER trial office by fax at the start of each month.

6. Return of "Expression of Interest Form"

a) Patients who are interested in the study will post back the expression of interest form (to the site who originally approached the patient) in a reply paid envelope.

b) The research nurse should telephone the patient and complete the Screening CRF.

c) The research nurse should enter the screening CRF to the study database. This is the only data entry to the AMBER study database that the sites have to complete.

d) The research nurse should arrange an appointment for the participant to come in for their baseline visit. This is either an additional clinic visit for the participant or should be combined with the participant's usual clinical visit if possible.

e) The Research nurse should update the screening log.

PLEASE NOTE * TRAVEL EXPENSES ARE VERY LIMTED FOR THE AMBER STUDY****

7. Completion of the Bowel Diary 7 days before the appointment date

The research nurse must post out the 7 day bowel diary to the participant for them to complete before their baseline appointment date. A Bristol Stool chart should be included with this bowel diary. The research nurse must take into account the hospital internal mail and make sure this is posted out in plenty of time that the participant receives this at least 7 days prior to the baseline appointment. There is a template cover letter to be posted with this bowel diary (and Bristol stool chart). The research nurse needs to add to this letter the start date (DAY 1) of when participants should start completing the 7 day bowel diary.
DAY 7 OF THE BOWEL DIARY IS THE DAY BEFORE THE APPOIINTMENT DATE (thus the Appointment date is then day 1 of the next 7 day bowel diary).

8. Baseline Appointment

a) On the day of the baseline appointment the research nurse should welcome the participant and answer any further questions they may have on the study.

b) The research nurse should consent the participant. Make sure the Participants ID is written on the consent form. The research nurse should make 4 copies of the consent form. One copy should be given to the participant. One copy should be filed in the patient notes along with a copy of the PIL. One copy should be filed in the ISF and one copy sent to the TM (fax or scan and email to the AMBER study office – details on page 2 of this guide).

c) The research nurse should also write in the patient notes that the patient has been consented to the trial and add a copy of the PIL to the notes also (there are specific a4 copies of the PIL for filing).

d) The research nurse should collect the bowel diary from the participant and check that this has been completed correctly. If the patient has forgot to bring the bowel diary along with them, ask if they can complete a new diary in clinic if they can remember the information. If this is too difficult, please give them a pre-paid envelope and ask them to post the completed diary back to the site. Participants can still be randomised.

e) After consent, the research nurse should randomise the patient. For detailed guidance on how to randomise using the Trust randomisation system, please refer to the user guide provided. The site staff and AMBER study office will receive email notification when a patient is randomised. This email should be printed and filed in the ISF or if stored electronically a file note should state where these are filed.

PLEASE NOTE * The research nurse should have the screening form in front of them or access to the database where the screening data was entered as the randomisation system asks the level of disability for that participant (3 options; Unaided, Aided walking or Wheelchair)*****

f) The research nurse should complete the nurse assessment form (first part of the AMBER CRF) once the patient is randomised. The AMBER CRF booklet contains the following: nurse assessment form, 6 weekly follow up CRFs, Conmed CRF, AE CRF,24 week CRF, completion of study CRF)

g) If participant is randomised to the intervention arm the research nurse, who is fully trained to deliver the intervention, will show the patient the massage DVD and deliver the massage to the patient and the carer. There is also a video for patients who will do self-massage. The research nurse will also advise on better general bowel management using the MS Society booklet. It is expected to take approximately 30 minutes for this part of the study however sites can feedback to the TM how long their first few baseline appointments take. This information will be really useful to feedback to sites coming on board.

h) If the participant is randomised to standard care the research nurse will go through the standard advice on how best to care for their bowel using the MS Society Booklet. No massage training will be given. This appointment will take 20-30 minutes less than the participants in the intervention arm.

i) The patient should complete the AMBER study questionnaire booklet as part of the baseline visit. If the participant **does not** have time to complete in clinic, they can be taken home with them. **However this is a last resort!!** If this happens the research nurse **must do** the following:

- Write "completed at home" on the questionnaires.
- Add the participant ID to the questionnaires before the patient takes them home.
- Give the participant a reply paid envelope to the AMBER study office.
- Email the TM to say that participant xxx has taken the questionnaires home to complete. In this way the TM can track the return of the questionnaires in order to keep compliance of complete date high.

j) If the participant completes the questionnaires in clinic, the research nurse should make a copy of these before sending back to the AMBER study office. Originals should be filed in the ISF (part 2).

k) The research nurse should complete the patient telephone appointment card with the agreed dates and times of when the patient will be contacted for their weekly follow up calls.

l) The research nurse will give the participant the "**AMBER study <u>follow up pack</u>**" to take away with them. The packs will be provided by the AMBER study office and should contain:

- Guide for participants
- MS Booklet on bowel dysfunction
- Laminated Bristol Stool chart (to use with bowel diaries)
- Telephone appointment card
- 6 x weekly Patient Resource Questionnaires
- 6 week questionnaire booklet
- Pre-paid envelope

If participant is in the **massage group** the research nurse should add the following to the pack:

- 6 x weekly Massage bowel diaries
- Massage Training DVD
- Quick Reference Guide – Abdominal Massage
- Patient Information Leaflet for Abdominal Massage

- Abdominal Massage Training manual

If participant is in the standard care group (**no massage**) the research nurse should put the following into the pack;

- 6 x weekly bowel diaries

m) At the end of the study baseline visit the research nurse should send the following paperwork to the AMBER trial office by **fax or scan and email or post:**

1. Consent
2. Bowel Diary (completed for 7 days before baseline appointment)
3. Nurse assessment form (up to page 11 in the CRF booklet)
4. Cone med form (if applicable, Page 30 of the CRF booklet)
5. Baseline Quality of Life Questionnaire.

n) All original paperwork should be filed in the ISF (Folder 2).

o) Research nurse should send a letter (including the general AMBER study PIL) to the participants GP. File a copy of this letter in the patient's notes.

9. Follow up Telephone calls (weeks 1-6)

a) Research nurse will contact patient at agreed time and complete the telephone call CRF.

b) The patient should be asked about any adverse events at this call. Complete the adverse event form and SAE form if applicable.

c) At the 6 week call, remind patient to complete the questionnaires and that the completed questionnaires should be sent to the AMBER trial office in the prepaid envelope provided.

p) After each call is completed the research nurse should send paperwork to the AMBER trial office by **fax or scan and email or post**

d) After completion all paperwork should be filed in the AMBER patient file.

10. 24 week Follow up

a) AMBER study office will send out the bowel diary, patient resource questionnaire and questionnaire booklet to the patient at the 24 week time point (a £5 voucher will be sent to the participant also).

b) AMBER Trial Office will send an email to site staff during the last week of each month with a list of patients at the 24 week time-point who are due to be contacted in the subsequent month.

c) The research nurse will complete the 24 week follow up call and complete a "completion of study" form (see also section 11).

d) The patient should be asked about any adverse events at this call. Complete the adverse event form and SAE form if applicable.

e) The research nurse should send all paperwork to the AMBER trial office

****PLEASE NOTE** YOU CAN SEND STUDY PAPERWORK TO US BY FAX OR BY EMAIL OR BY POST.**
**** Patient identifiable information CAN ONLY BE SENT BY FAX.**
If POSTING, please take a copy and keep the original at site.

11. Completion of Study form

a) The completion of study CRF should be completed either at the end of the study (where the patient has completed the 24 week follow up call) or if a patient no longer continues in trial (either through patient withdrawal, clinician withdrawal, lost to follow up, death).

b) The research nurse should send a copy of this CRF to the AMBER study office. Details should also be written into patient notes with details of this CRF – ie either that patient has now completed involvement of the study or that they have withdrawn.

c) If a participant wants to withdraw from the study, we are very keen to know the reason why for the process evaluation part of the AMBER study. The research nurse should determine if the patient has been selected for the interview sub-study prior to completion of this form by contacting the TM. If they are taking part in the interview sub-study please use the script below when speaking to the participant.

"We are sorry that you are no longer going to continue in the study but we would like your permission to tell the interview researchers about this. We think that we can learn a lot from people who withdraw from studies about ways that we could have improved things. No-one will try to persuade you to continue, we simply want to have a short telephone interview with you to find out your views and any suggestions that you might have that would improve things in the future. You can, of course, change your mind at any time and will be under no obligation to do anything at all if you do"

12. Interviews for Process Evaluation

12.1 Patient Interviews:

If a patient has indicated that they want to take part in the interview sub-study the sites will not have any additional work to do for this. This will be managed by the AMBER study office.

12.2 Staff Interviews

The PI and a member of staff trained on the intervention will be interviewed from each site. Chosen staff will be given an information leaflet and asked to sign a consent form. Staff will be telephoned twice – one at inception of the intervention and again at end of trial recruitment. The interviews will explore barriers, facilitators and contexts of implementation and will last approximately 30-40 minutes.

12.3 Process tracking questionnaires

A questionnaire will also be sent to sites for completion at 6 monthly intervals to track implementation of the intervention arm of the trial.

12.4 Fidelity Calls

Over the course of the Trial, 2 telephone follow up calls will be recorded at each site. The AMBER study office will provide all the recording equipment for this.

13. Amendments for the AMBER study

13.1 Protocol Amendments.

The TM will inform sites of any changes to the protocol. The PI must sign a protocol sign off sheet for any new version released.

13.2 Amendments of study paperwork

The TM will circulate any new and updated version of the study paperwork. Sites will be asked to sign and send back a receipt for this new paperwork and confirm that this change has been implemented to all study members at that site.

14. Delegation Log

Please notify the Trial Manager with any new staff who will be working on the AMBER study. They must be added to the delegation log and signed off by the PI before they work on the study. Signed and dated CVs and a copy of GCP certificates should be sent to the Trial Manager.

Appendix 1: AMBER STUDY CASE REPORT FORMS (CRF 02, 05-08 and 10 are combined in one booklet for the research nurse to complete)

CRF No	CRF NAME	When to be completed
01	AMBER SCREENING VISIT	Research Nurse Completes over the phone when Patient returns the "expression of interest form"
02	AMBER NURSE ASSESSMENT	Research Nurse to complete at baseline patient visit after consent and randomisation
03	AMBER BOWEL DIARY	To be completed 7 days prior to the baseline visit and weekly (by participant) in weeks 1-6 if participant randomised to standard care (No Massage). Participant completes these.
04	AMBER BOWEL & MASSAGE DIARY	To be completed weekly (by participant) in weeks 1-6 if participant is randomised to intervention (massage)
05	AMBER TELEPHONE RECORD (weeks 1-6)	To be completed by Research nurse weekly during weeks 1-6
06	AMBER TELEPHONE RECORD (weeks 24)	To be completed by Research nurse at week 24.
07	ConMeds	To be completed by the research nurse at the baseline visit and to be updated with information collected during all follow up calls (weeks 1-6 and week 24)
08	AMBER AE LOG	To be completed by the research nurse during all follow up calls (weeks 1-6 and week 24) – if applicable
09	AMBER SAE Form	To be completed by the research nurse during all follow up calls (weeks 1-6 and week 24) – if applicable. The PI must review and sign all SAE forms
10	AMBER COMPLETION OF STUDY	To be completed for every patient when their involvement in the study is complete. This may be at 24 weeks or sooner if the participant withdraws.
11	Ano-rectal CRF (London only)	Only to be completed in London site (at baseline and at 24 weeks)

AMBER study Questionnaires (QU 01-05 are combined as one questionnaire booklet)

Questionnaire No	Questionnaire Name	When Completed
01	AMBER CONSTIPATION SCORING SYSTEM	Baseline Visit and at 6 and 24 weeks
02	AMBER NEUROGENIC BOWEL DYSFUNCTION	Baseline Visit and at 6 and 24 weeks
03	AMBER QUALIVEEN BLADDER QS	Baseline Visit and at 6 and 24 weeks
04	Eq-5D	Baseline Visit and at 6 and 24 weeks
05	PR0M NEW BOWEL	Baseline Visit and at 6 and 24 weeks
06	AMBER PATIENT RESOURCE QUESTIONNAIRE	Weekly during weeks 1-6, and week 12, 18 and 24.