

### General Update

It has been a very busy few months for AMBER and here we are already in December – 11 months of recruiting and we have 121 participants randomised (79 to go!). This is FANTASTIC – Well done to every single person involved in the study!

We also presented the study at the Annual MS Trust conference. Kirsteen Goodman attended this conference and presented a poster which resulted in a lot of interest and good feedback about the study which was great to hear!

This edition of the AMBER updates will focus on some anomalies we have found on reaching the 24 week follow up of the study and some tips to maximise data return and therefore study integrity. We will also detail what to do if a patient wants to withdraw from completing some of the paperwork.

### **24 week follow ups!!**

**The 24 week data collection is crucial to the study so we need to try and maximise as many complete follow ups as possible!**

As you know, we will contact you when a participant is due the 24 week follow up. We will also highlight to you if a participant has not returned any follow up paperwork at this stage. You should ask the participant about this missing data as part of the 24 week follow up call to determine if they have sent this back to us or not. Please update the AMBER office on the outcome of this by documenting this in the 24 week follow up call CRF.

In addition, please ask the participant if they have received the 24 week pack (final bowel diary, QoL Qu booklet and patient resource form) during this call. If they say they have NOT received this pack, please alert the AMBER office. It may have got lost in the post and we can send another one out to them. Also please check their address.

If you can't reach a participant for this 24 week follow up call, please bring this to the attention of the AMBER office (call or email).

If during this final call the participant states they do not want to complete the end of study paperwork, please explain to them that this is the **final** stage of the study and ask if they would complete the **Neurogenic Bowel Dysfunction Score (NBDS)**. This is on page 17 of the Qu booklet. They can either complete this Qu only and return in the pre-paid envelope or offer to complete this over the phone with them and send this back to us. Please remember this is a last resort, we really need them to complete all the outcomes.

Please send the 24 week paperwork to us as soon as this is completed. Any adverse events should be closed off before sending the AE form back. Each item on the con-med form should either be ticked as on-going or a stop date entered.

### Jan 2016 - Jun2016

In the New Year we will only have **6 months of recruitment** left as recruitment ends on the 30<sup>th</sup> June 2016. If any sites are worried they will have any problems reaching their specified targets, please do get in touch the AMBER team sooner rather than later. Recruitment to the trial has been exceptional but to meet our goal of 200 participants we need each research site to meet their targets. **We are here to help if you need us to!**

### Completion of study form and patient withdrawals

The completion of study form is either completed at the end of the 24 week follow up call or if a patient withdraws or is lost to follow up etc.

It is important **we are** notified as soon as possible of any participants who informs you they want to withdraw, or if they are lost to follow up. If a patient withdraws you should tick all possible options and also give a reason in the other box. Please see the example below. This is extremely useful for us to know and the Data Monitoring Committee need to review. Please send us this information as soon as you become aware of this.

In addition when completing this form at the end of the study, please make sure EVERY question is answered.

If subject did not complete, give reason:	PLEASE TICK
Subject Lost to Follow Up	
Adverse Event (If SAE please make sure SAE form is completed)	
Protocol Non-Compliance	
Patient withdrew (more than one option may be ticked)	
Patient withdrew from having follow-up intervention phone calls	<input checked="" type="checkbox"/>
Patient withdrew from completing further questionnaires	<input checked="" type="checkbox"/>
Patient withdrew consent for the trial to use existing trial data	
Death	
Other (please specify): <b>Patient became unwell and felt that it was too much (Example)</b>	

### Training to standard care participants at study end

Thank you to those sites who have informed us that they aim to get the controls back to train them on the massage technique - this is great! We send participants in the control group the URL to the web-link to the training videos and we have recently uploaded the additional training material the intervention group get (same username and password used as the AMBER videos). Thank you to Sarah at Salford who suggested this. It would be great to get some feedback from sites to let us know how this training is received.

### Christmas and AMBER

The AMBER study office will be closed from 5pm on the 22<sup>nd</sup> Dec until Tuesday 5<sup>th</sup> Jan 2016 (Monday 4<sup>th</sup> is a bank holiday in Scotland) but we will be accessing the AMBER email over this period so please get in touch if there are any issues.

Thank you to all who let me know how you will cover the Christmas period at your sites. For those of you who have follow ups due w/c 21<sup>st</sup> and 28<sup>th</sup> December I will be in touch before we close. If you have any problems completing any of the follow up calls over these 2 weeks please let the AMBER team know and we can help.

**MERRY CHRISTMAS TO EVERYONE! THE AMBER TEAM HOPES YOU ALL HAVE A GREAT HOLIDAY PERIOD!!!**