AMBER Protocol Summary

Neurogenic bowel dysfunction (NBD: constipation and/or faecal incontinence) is common in people with multiple sclerosis (MS) and is rated as the most severe impact of their disease/injury, above wheelchair dependence. Despite this, current treatment options are limited, poorly evaluated and complex.

This research aims to find out whether abdominal massage can help improve the symptoms of NBD in these patients. A small study has already shown that it is possible for patients or carers to perform abdominal massage and in some cases this helped the patient with their symptoms. A larger study is now required to confirm the results one way or another.

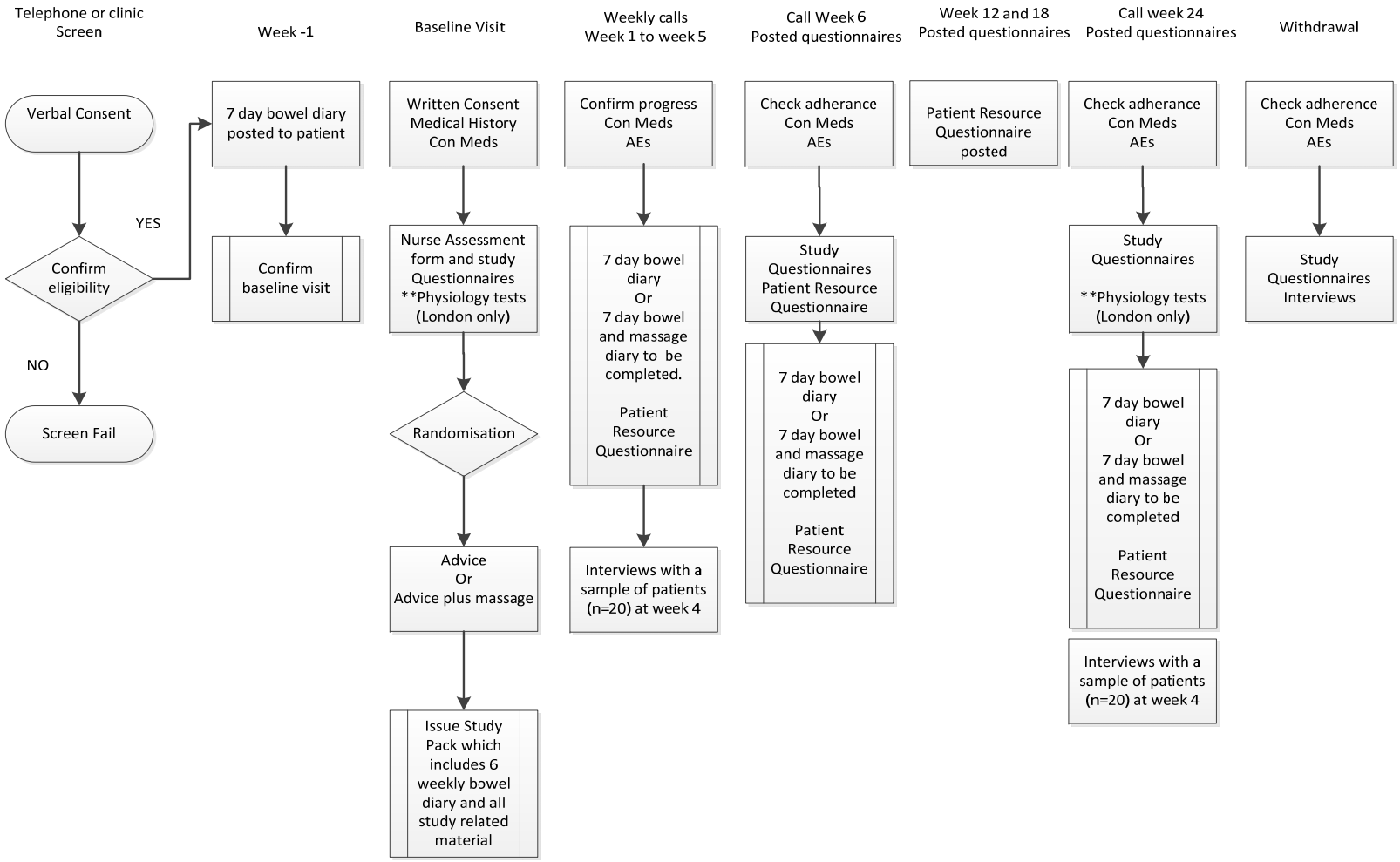
Patients with Multiple Sclerosis who attend one of the participating study centres who are bothered by constipation and or faecal incontinence will be asked to take part if they fit the other requirements for the trial. Those who agree to take part will be allocated at random to one of two groups, one will receive advice on the management of bowel dysfunction (called optimised bowel care), and the other will receive the same advice and will be taught how to do the abdominal massage (called abdominal massage and optimised bowel care). Both groups will visit a specialist nurse for 1 additional hour after their normal clinical appointment, or at an agreed time, to receive optimised bowel care advice. The patients in the intervention group +/or their carers will receive training on abdominal massage and a DVD/copy of demonstration of the massage for home use. All patients will also be called weekly for 6 weeks to discuss their bowel care.

We will measure the results of treatment after 6 and 24 weeks. We are primarily interested in whether patients in the intervention group (receiving optimized bowel care & abdominal massage) have had more of an improvement in their NBD symptoms at 24 weeks after they start the study that the control group (receiving optimized bowel care only). We also want to find out how bad the constipation and bowel symptoms are, how much this affects their life and if they have any problems with their bladder. We will also measure the costs of the treatments and any costs to the patient and their family, and balance these against any benefits of the intervention treatment.

During the trial we will assess how well the optimized bowel care and abdominal massage training was delivered by speaking with nurses and listening to recordings of some of the telephone calls. We will talk to the patients to find how they perceive the treatment they received and how they got on during the treatment period and once the treatment finished. We will explore how the treatment delivery and patient's perceptions impact on the patients NBD symptoms.

We have worked out from previous research that if 200 patients take part and most complete the trial, we will have enough data to successfully compare the treatments to find out if one is better than the other. Individual participation will be entirely voluntary and we do not believe there are any risks associated with taking part.

AMBER Participant Pathway



** AMBER study office sends out questionnaires at 12, 18 and 24 weeks.AMBER Summary May 2015

AMBER study office provide the site will all stationary packs