# Abdominal massage for neurogenic bowel dysfunction in people with multiple sclerosis

This CRF booklet contains the following:

- Nurse assessment CRF
- Telephone follow up CRF (weeks 1-6)
- Conmed CRF
- Adverse Event CRF
- Telephone follow up CRF (week 24)
- Completion of study CRF

**This form should be completed at the Participant's Baseline Visit.**

**Use page 2 of this form to keep a note of patient appointment and telephone call dates and times.**

**Please fax this form to the AMBER study office on completion and file original in the AMBER ISF.**

| **PATIENT DETAILS** | |
|---|---|
| Name | |
| Address | |
| Date of Birth | D D - M M M - Y Y Y Y |
| CHI or NHS Hospital number | |
| GP Name and address | |
| Occupation (If retired, please state previous occupation) | |
| Hobbies (active) | |

| **CONTACT DETAILS Preferred telephone number** | |
|---|---|
| Tel Home | |
| Tel Work | |
| Tel Mobile | |
| Permission to leave a message | ☐ YES ☐ NO |
| Preferred time | |

**Complete the appointment record with the participant with an agreed date and time to do the weekly telephone calls. Copy the agreed appointment details onto the patient's telephone appointment card for them to take away.**

| **APPOINTMENT RECORD** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Has the participant been contacted regarding baseline visit? | | | | | | | | ☐ YES ☐ NO |
| | Date and Time | Attended/ completed | | Cancelled | | Rescheduled | | |
| Dates | | YES | NO | YES | NO | YES | NO | Reason for Non Attendance/cancellation |
| Baseline Visit | | | | | | | | |
| Week 1 Call | | | | | | | | |
| Week 2 Call | | | | | | | | |
| Week 3 Call | | | | | | | | |
| Week 4 Call | | | | | | | | |
| Week 5 Call | | | | | | | | |
| Week 6 Call | | | | | | | | |
| Week 24 Call | | | | | | | | |
| Withdrawal | | | | | | | | |
| Rearranged appointments: | | | | | | | | |
| Additional contact/appointments – reasons: | | | | | | | | |

Date of Visit D D - M M M - Y Y Y Y

Has informed consent been given? ☐ YES ☐ NO

Patient randomised to Abdominal Massage ☐

Patient randomised to Advice ☐

| **1. DEMOGRAPHICS** | |
|---|---|
| Date of Birth | D D - M M M - Y Y Y Y |
| Gender | ☐ Male ☐ Female |
| Height | ☐ . ☐ ☐ m |
| Weight | ☐ ☐ ☐ . ☐ Kg |
| BMI (calculated by OpenClinica) | |

| 2. MULTIPLE SCLEROSIS | |
|---|---|
| **Year of diagnosis** | Y Y Y Y |
| **Method of Diagnosis** | ☐ MRI ☐ Lumber Puncture |
| **Type of MS** | ☐ Benign<br>☐ Relapsing Remitting<br>☐ Secondary Progressive<br>☐ Primary Progressive |
| **Severity of symptoms** | As of to-day |
| Visual problems | ☐ None ☐ Mild ☐ Moderate ☐ Severe |
| Pain | ☐ None ☐ Mild ☐ Moderate ☐ Severe |
| Spasm | ☐ None ☐ Mild ☐ Moderate ☐ Severe |
| Mobility | ☐ None ☐ Mild ☐ Moderate ☐ Severe |
| Cognitive | ☐ None ☐ Mild ☐ Moderate ☐ Severe |
| Depression | ☐ None ☐ Mild ☐ Moderate ☐ Severe |
| Fatigue | ☐ None ☐ Mild ☐ Moderate ☐ Severe |
| Bladder | ☐ None ☐ Mild ☐ Moderate ☐ Severe |
| Bowel | ☐ None ☐ Mild ☐ Moderate ☐ Severe |
| **Mobility** | Tick one option |
| Unaided | ☐ Distance limited to 500m or more: score 4.0<br>☐ Distance limited to 300m: score 4.5<br>☐ Distance limited to 200m: score 5.0<br>☐ Distance limited to 100m or less: score 5.5 |
| Aided | ☐ Intermittent or unilateral assistance required to walk 100m: score 6.0<br>☐ Constant bilateral assistance required to walk 20m: score 6.5<br>☐ Few steps, restricted to wheelchair, transfers independently: score 7.0<br>☐ Transfers with assistance; may require motorized wheelchair: score 7.5<br>☐ Essentially restricted to bed or chair: score 8.0 |

| **Additional Information** | |
|---|---|
| Can the participant undertake the massage themselves? | ☐ YES ☐ NO |
| Has the participant someone who can perform the massage for them? | ☐ YES ☐ NO |

| **3. BOWEL SYMPTOMS** | |
|---|---|
| **When did the problems with the bowel start?** | ☐ < 1 year<br>☐ 1-2 years<br>☐ 2-5 years<br>☐ 5-10 years<br>☐ > 10 years |
| **Do you have any pain associated with constipation?** | ☐ YES ☐ NO |
| **Do you experience bloating?** | ☐ YES ☐ NO |
| **Do you experience faecal incontinence as well?** | ☐ YES ☐ NO |
| **If yes, how often?** | ☐ More than once a day<br>☐ Daily<br>☐ 2-4 times a week<br>☐ Once a week<br>☐ Once a fortnight<br>☐ Other (please state)<br>__________________________ |

## 3. BOWEL SYMPTOMS cont.

**Severity**

1. How often do you go to the toilet and successfully open your bowels/pass a stool?

- ☐ More than once a day
- ☐ Daily
- ☐ 2-4 times a week
- ☐ Once a week
- ☐ Once a fortnight
- ☐ Other (please state)

______________________________

2. Description of Stool (see Bristol Stool Chart at end of the form) What percentage of time is your stool:

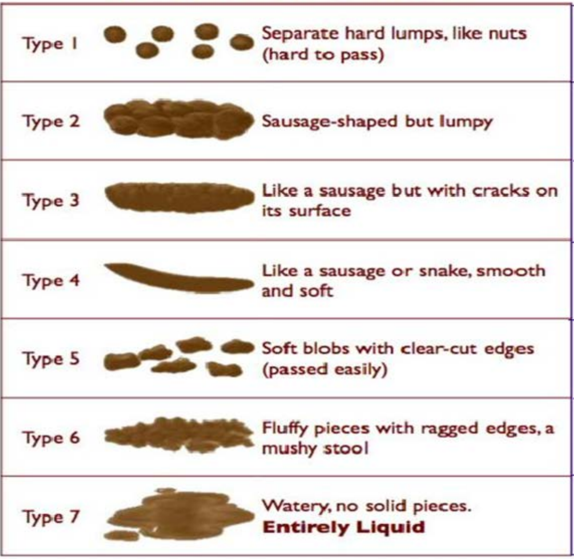
| | 100% | 75% | 50% | 25% | 0% |
|---|---|---|---|---|---|
| 1. Like pellets/hard lumps | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2. Sausage shaped, but lumpy | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3. Like a sausage but with cracks at its surface | ☐ | ☐ | ☐ | ☐ | ☐ |
| 4. Like a sausage or snake, smooth on its surface | ☐ | ☐ | ☐ | ☐ | ☐ |
| 5. Soft blobs with clear cup edge | ☐ | ☐ | ☐ | ☐ | ☐ |
| 6. Fluffy pieces with ragged edges, a mushy stool | ☐ | ☐ | ☐ | ☐ | ☐ |
| 7. Watery, no solid pieces | ☐ | ☐ | ☐ | ☐ | ☐ |

3. Do you have to strain to pass stool?

- ☐ All the time
- ☐ ¾ of the time
- ☐ ½ of the time
- ☐ ¼ of the time
- ☐ Never

## 3. BOWEL SYMPTOMS cont.

| Question | Response |
| --- | --- |
| 4. Do you use digital stimulation to help to pass a stool? | ☐ All the time<br>☐ ¾ of the time<br>☐ ½ of the time<br>☐ ¼ of the time<br>☐ Never |
| 5. Do you feel you empty your bowels, or do you feel a sensation of incomplete emptying? | ☐ All the time<br>☐ ¾ of the time<br>☐ ½ of the time<br>☐ ¼ of the time<br>☐ Never |
| 6. Do you feel there is something stopping you passing a stool? | ☐ All the time<br>☐ ¾ of the time<br>☐ ½ of the time<br>☐ ¼ of the time<br>☐ Never |


Bristol Stool Chart

| | |
|---|---|
| Type 1 | Separate hard lumps, like nuts (hard to pass) |
| Type 2 | Sausage-shaped but lumpy |
| Type 3 | Like a sausage but with cracks on its surface |
| Type 4 | Like a sausage or snake, smooth and soft |
| Type 5 | Soft blobs with clear-cut edges (passed easily) |
| Type 6 | Fluffy pieces with ragged edges, a mushy stool |
| Type 7 | Watery, no solid pieces. **Entirely Liquid** |

## 4. ASSESSMENT/TREATMENT/PLAN

| **Treatment/advice given** | | If yes, provide details |
|---|---|---|
| Has the participant been supplied with MS Society's Bowel book | ☐ YES ☐ NO | |
| Have the contents been discussed? | ☐ YES ☐ NO | |
| Has advice been given on: | | |
| Fluid intake | ☐ YES ☐ NO | |
| Defaecation position | ☐ YES ☐ NO | |
| Diet | ☐ YES ☐ NO | |
| Exercise | ☐ YES ☐ NO | |
| **Additional Comments/Advice** | | |

## 5. ABDOMINAL EXAMINATION

**(Please only complete if patient is in intervention arm of the study)**

**The participant should be lying supine and comfortably supported with their abdomen exposed**

| | |
|---|---|
| **Does the participant have any of the following on their abdomen?** | |
| Scars | ☐ YES ☐ NO |
| Open wounds | ☐ YES ☐ NO |
| Skin rash | ☐ YES ☐ NO |
| Hernia | ☐ YES ☐ NO |
| Lumps | ☐ YES ☐ NO |
| **Upon Palpation is there any ….** | |
| Tenderness | ☐ YES ☐ NO |
| Full bowel | ☐ YES ☐ NO |

## 6. ABDOMINAL MASSAGE

**(Please only complete if patient is in intervention arm of the study)**

| | |
|---|---|
| **Indicate whether the following has been given/discussed:** | |
| Participant training manual provided | ☐ YES ☐ NO |
| DVD showing abdominal massage | ☐ YES ☐ NO |
| Benefits of abdominal massage discussed | ☐ YES ☐ NO |
| Time of day the massage should be undertaken | ☐ YES ☐ NO |
| Repeated number of days per week | ☐ YES ☐ NO |
| Is the participant positioned comfortably? | ☐ YES ☐ NO |
| Has care been taken to minimise embarrassment? | ☐ YES ☐ NO |
| General hygiene been observed e.g. wash hands? | ☐ YES ☐ NO |
| Massage demonstrated: | ☐ YES ☐ NO |
| Stroking | ☐ YES ☐ NO |
| Effleurage | ☐ YES ☐ NO |

| **6. ABDOMINAL MASSAGE continued (Please only complete if patient is in intervention arm of the study)** | |
|---|---|
| (Massage demonstrated cont.) | |
| Kneading | ☐ YES ☐ NO |
| Vibration | ☐ YES ☐ NO |
| **Participant reactions** | |
| Relaxed | ☐ YES ☐ NO |
| Uncomfortable | ☐ YES ☐ NO |
| Did carer practise massage? | ☐ YES ☐ NO |
| Was there discussion on stance? | ☐ YES ☐ NO |
| Was there discussion on pressure? | ☐ YES ☐ NO |
| Is patient doing self-massage | ☐ YES ☐ NO |
| Was this practised | ☐ YES ☐ NO |
| **Discussion re: possible response** | |
| Flatus? | ☐ YES ☐ NO |
| Cramps? | ☐ YES ☐ NO |
| Tummy noises? | ☐ YES ☐ NO |
| Was the DVD watched? | ☐ YES ☐ NO |
| Contact details for telephone support provided? | ☐ YES ☐ NO |
| If it was appropriate to omit any part of the core content please give details | |
| If it was appropriate to add to any part of the core content please give details | |
| Any other comments? | |

DATA ENTERED ON DATABASE (SIGN & DATE)

D D - M M M - Y Y Y Y

| Participant ID | | | | | | | **TELEPHONE RECORD WEEKS 1-6** |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

| **TIMEPOINT** | **PLEASE CIRCLE** | | | | | | |
|---|---|---|---|---|---|---|---|
| Weeks from baseline visit | 1 | 2 | 3 | 4 | 5 | 6 | Withdrawal |

Was telephone call completed? ☐ YES ☐ NO

If NO please give reason:
*[and do not complete the rest of the form]*

Date of call D D - M M M - Y Y Y Y

Advice only ☐
Massage ☐

| **Telephone calls – Researcher should ask the participant the following questions and clearly explain to participant that they should answer each question in relation to the last 7 days.** | | |
|---|---|---|
| Have you changed your diet? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your fluid intake? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your defaecation position? | ☐ YES ☐ NO | If yes, how? |
| Are you taking more exercise? | ☐ YES ☐ NO | If yes, how? |
| Have your changed any medication? *If yes, record in Concomitant Medication Log* | ☐ YES ☐ NO | |
| Have you changed your use of laxatives (i.e those not prescribed by GP)? | ☐ YES ☐ NO | If yes, how? |

| **Telephone calls cont.** | |
| --- | --- |
| Has there been any change in your bowel habits? | ☐ YES ☐ NO |
| If yes, indicate how below | |
| More often | ☐ YES ☐ NO |
| Less time spent | ☐ YES ☐ NO |
| Less hard | ☐ YES ☐ NO |
| Other (specify) | ☐ YES ☐ NO |
| General discussion on any of these points | |
| Have you completed the diary this week. | ☐ YES ☐ NO |
| Have you completed the Patient Resource Questionnaire this week. | ☐ YES ☐ NO |
| Have there been any adverse events?<br>*If yes complete AE form and SAE if applicable* | ☐ YES ☐ NO |
| Additional Information | |

| **Telephone calls cont.** | |
|---|---|
| Are there going to be any change of address/contact information prior to your next study call/appointment? If yes, please detail. | ☐ YES ☐ NO |

| **Telephone calls cont. (massage participants only)** | |
|---|---|
| Did you administer the massage yourself? | ☐ YES ☐ NO |
| Did a carer administer the massage? | ☐ YES ☐ NO |
| What position was the massage administered (Lying, semi-lying, sitting) | ☐ Lying ☐ Semi-lying ☐ Sitting |
| Time of day administered (Morning, afternoon, evening) | ☐ Morning ☐ Afternoon ☐ Evening |
| Additional information. | |

DATA ENTERED ON DATABASE (SIGN & DATE)

D D - M M M - Y Y Y Y

| Participant ID | AMBER Abdominal Massage for Bowel Dysfunction Effectiveness Research | TELEPHONE RECORD WEEKS 1-6 |
|---|---|---|

| TIMEPOINT | PLEASE CIRCLE | | | | | |
|---|---|---|---|---|---|---|
| Weeks from baseline visit | 1 | 2 | 3 | 4 | 5 | 6 | Withdrawal |

Was telephone call completed? ☐ YES ☐ NO

If NO please give reason:
*[and do not complete the rest of the form]*

Date of call D D - M M M - Y Y Y Y

Advice only ☐
Massage ☐

| **Telephone calls – Researcher should ask the participant the following questions and clearly explain to participant that they should answer each question in relation to the last 7 days.** | | |
|---|---|---|
| Have you changed your diet? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your fluid intake? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your defaecation position? | ☐ YES ☐ NO | If yes, how? |
| Are you taking more exercise? | ☐ YES ☐ NO | If yes, how? |
| Have your changed any medication? *If yes, record in Concomitant Medication Log* | ☐ YES ☐ NO | |
| Have you changed your use of laxatives (i.e those not prescribed by GP)? | ☐ YES ☐ NO | If yes, how? |

| **Telephone calls cont.** | |
|---|---|
| Has there been any change in your bowel habits? | ☐ YES ☐ NO |
| If yes, indicate how below | |
| More often | ☐ YES ☐ NO |
| Less time spent | ☐ YES ☐ NO |
| Less hard | ☐ YES ☐ NO |
| Other (specify) | ☐ YES ☐ NO |
| General discussion on any of these points | |
| Have you completed the diary this week. | ☐ YES ☐ NO |
| Have you completed the Patient Resource Questionnaire this week. | ☐ YES ☐ NO |
| Have there been any adverse events?<br>*If yes complete AE form and SAE if applicable* | ☐ YES ☐ NO |
| Additional Information | |

| **Telephone calls cont.** | |
|---|---|
| Are there going to be any change of address/contact information prior to your next study call/appointment? If yes, please detail. | ☐ YES ☐ NO |

| **Telephone calls cont. (massage participants only)** | |
|---|---|
| Did you administer the massage yourself? | ☐ YES ☐ NO |
| Did a carer administer the massage? | ☐ YES ☐ NO |
| What position was the massage administered (Lying, semi-lying, sitting) | ☐ Lying ☐ Semi-lying ☐ Sitting |
| Time of day administered (Morning, afternoon, evening) | ☐ Morning ☐ Afternoon ☐ Evening |
| Additional information. | |

DATA ENTERED ON DATABASE (SIGN & DATE)

D D - M M M - Y Y Y Y

| Participant ID | AMBER Abdominal Massage for Bowel Dysfunction Effectiveness Research | TELEPHONE RECORD WEEKS 1-6 |
|---|---|---|
| ☐☐☐☐☐☐ | | |

| TIMEPOINT | PLEASE CIRCLE | | | | | |
|---|---|---|---|---|---|---|
| Weeks from baseline visit | 1 | 2 | 3 | 4 | 5 | 6 | Withdrawal |

Was telephone call completed? ☐ YES ☐ NO

If NO please give reason:
*[and do not complete the rest of the form]*

Date of call D D - M M M - Y Y Y Y

Advice only ☐
Massage ☐

| Telephone calls – Researcher should ask the participant the following questions and clearly explain to participant that they should answer each question in relation to the last 7 days. | | |
|---|---|---|
| Have you changed your diet? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your fluid intake? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your defaecation position? | ☐ YES ☐ NO | If yes, how? |
| Are you taking more exercise? | ☐ YES ☐ NO | If yes, how? |
| Have your changed any medication? *If yes, record in Concomitant Medication Log* | ☐ YES ☐ NO | |
| Have you changed your use of laxatives (i.e those not prescribed by GP)? | ☐ YES ☐ NO | If yes, how? |

| Telephone calls cont. | |
|---|---|
| Has there been any change in your bowel habits? | ☐ YES ☐ NO |
| If yes, indicate how below | |
| More often | ☐ YES ☐ NO |
| Less time spent | ☐ YES ☐ NO |
| Less hard | ☐ YES ☐ NO |
| Other (specify) | ☐ YES ☐ NO |
| General discussion on any of these points | |
| Have you completed the diary this week. | ☐ YES ☐ NO |
| Have you completed the Patient Resource Questionnaire this week. | ☐ YES ☐ NO |
| Have there been any adverse events?<br>*If yes complete AE form and SAE if applicable* | ☐ YES ☐ NO |
| Additional Information | |

| Telephone calls cont. | |
|---|---|
| Are there going to be any change of address/contact information prior to your next study call/appointment? If yes, please detail. | ☐ YES ☐ NO |

| Telephone calls cont. (massage participants only) | |
|---|---|
| Did you administer the massage yourself? | ☐ YES ☐ NO |
| Did a carer administer the massage? | ☐ YES ☐ NO |
| What position was the massage administered (Lying, semi-lying, sitting) | ☐ Lying ☐ Semi-lying ☐ Sitting |
| Time of day administered (Morning, afternoon, evening) | ☐ Morning ☐ Afternoon ☐ Evening |
| Additional information. | |

DATA ENTERED ON DATABASE (SIGN & DATE)

D D - M M M - Y Y Y Y

| Participant ID | AMBER | TELEPHONE RECORD WEEKS 1-6 |
|---|---|---|
| | | |

| TIMEPOINT | PLEASE CIRCLE | | | | | |
|---|---|---|---|---|---|---|
| Weeks from baseline visit | 1 | 2 | 3 | 4 | 5 | 6 | Withdrawal |

Was telephone call completed? ☐ YES ☐ NO

If NO please give reason:
*[and do not complete the rest of the form]*

Date of call D D - M M M - Y Y Y Y

Advice only ☐
Massage ☐

| Telephone calls – Researcher should ask the participant the following questions and clearly explain to participant that they should answer each question in relation to the last 7 days. | | |
|---|---|---|
| Have you changed your diet? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your fluid intake? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your defaecation position? | ☐ YES ☐ NO | If yes, how? |
| Are you taking more exercise? | ☐ YES ☐ NO | If yes, how? |
| Have your changed any medication? *If yes, record in Concomitant Medication Log* | ☐ YES ☐ NO | |
| Have you changed your use of laxatives (i.e those not prescribed by GP)? | ☐ YES ☐ NO | If yes, how? |

| **Telephone calls cont.** | |
|---|---|
| Has there been any change in your bowel habits? | ☐ YES ☐ NO |
| If yes, indicate how below | |
| More often | ☐ YES ☐ NO |
| Less time spent | ☐ YES ☐ NO |
| Less hard | ☐ YES ☐ NO |
| Other (specify) | ☐ YES ☐ NO |
| General discussion on any of these points | |
| Have you completed the diary this week. | ☐ YES ☐ NO |
| Have you completed the Patient Resource Questionnaire this week. | ☐ YES ☐ NO |
| Have there been any adverse events?<br>*If yes complete AE form and SAE if applicable* | ☐ YES ☐ NO |
| Additional Information | |

| Telephone calls cont. | |
| --- | --- |
| Are there going to be any change of address/contact information prior to your next study call/appointment? If yes, please detail. | ☐ YES ☐ NO |

| Telephone calls cont. (massage participants only) | |
| --- | --- |
| Did you administer the massage yourself? | ☐ YES ☐ NO |
| Did a carer administer the massage? | ☐ YES ☐ NO |
| What position was the massage administered (Lying, semi-lying, sitting) | ☐ Lying ☐ Semi-lying ☐ Sitting |
| Time of day administered (Morning, afternoon, evening) | ☐ Morning ☐ Afternoon ☐ Evening |
| Additional information. | |

DATA ENTERED ON DATABASE (SIGN & DATE)

D D - M M M - Y Y Y Y

| Participant ID | AMBER Abdominal Massage for Bowel Dysfunction Effectiveness Research | TELEPHONE RECORD WEEKS 1-6 |
|---|---|---|
| | | | | | | | | |

| TIMEPOINT | PLEASE CIRCLE | | | | | |
|---|---|---|---|---|---|---|
| Weeks from baseline visit | 1 | 2 | 3 | 4 | 5 | 6 | Withdrawal |

Was telephone call completed? ☐ YES ☐ NO

If NO please give reason:
*[and do not complete the rest of the form]*

Date of call D D - M M M - Y Y Y Y

Advice only ☐
Massage ☐

| **Telephone calls – Researcher should ask the participant the following questions and clearly explain to participant that they should answer each question in relation to the last 7 days.** | | |
|---|---|---|
| Have you changed your diet? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your fluid intake? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your defaecation position? | ☐ YES ☐ NO | If yes, how? |
| Are you taking more exercise? | ☐ YES ☐ NO | If yes, how? |
| Have your changed any medication? *If yes, record in Concomitant Medication Log* | ☐ YES ☐ NO | |
| Have you changed your use of laxatives (i.e those not prescribed by GP)? | ☐ YES ☐ NO | If yes, how? |

| Telephone calls cont. | |
|---|---|
| Has there been any change in your bowel habits? | ☐ YES ☐ NO |
| If yes, indicate how below<br>More often<br>Less time spent<br>Less hard<br>Other (specify) | <br>☐ YES ☐ NO<br>☐ YES ☐ NO<br>☐ YES ☐ NO<br>☐ YES ☐ NO |
| General discussion on any of these points | |
| Have you completed the diary this week. | ☐ YES ☐ NO |
| Have you completed the Patient Resource Questionnaire this week. | ☐ YES ☐ NO |
| Have there been any adverse events?<br>*If yes complete AE form and SAE if applicable* | ☐ YES ☐ NO |
| Additional Information | |

| Telephone calls cont. | |
|---|---|
| Are there going to be any change of address/contact information prior to your next study call/appointment? If yes, please detail. | ☐ YES ☐ NO |

| Telephone calls cont. (massage participants only) | |
|---|---|
| Did you administer the massage yourself? | ☐ YES ☐ NO |
| Did a carer administer the massage? | ☐ YES ☐ NO |
| What position was the massage administered (Lying, semi-lying, sitting) | ☐ Lying ☐ Semi-lying ☐ Sitting |
| Time of day administered (Morning, afternoon, evening) | ☐ Morning ☐ Afternoon ☐ Evening |
| Additional information. | |

DATA ENTERED ON DATABASE (SIGN & DATE)

D D - M M M - Y Y Y Y

| Participant ID | | | | | | AMBER Abdominal Massage for Bowel Dysfunction Effectiveness Research | **TELEPHONE RECORD WEEKS 1-6** |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

| **TIMEPOINT** | **PLEASE CIRCLE** | | | | | | |
|---|---|---|---|---|---|---|---|
| Weeks from baseline visit | 1 | 2 | 3 | 4 | 5 | 6 | Withdrawal |

Was telephone call completed? ☐ YES ☐ NO

If NO please give reason:
*[and do not complete the rest of the form]*

Date of call D D - M M M - Y Y Y Y

Advice only ☐
Massage ☐

| **Telephone calls – Researcher should ask the participant the following questions and clearly explain to participant that they should answer each question in relation to the last 7 days.** | | |
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| Have you changed your fluid intake? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your defaecation position? | ☐ YES ☐ NO | If yes, how? |
| Are you taking more exercise? | ☐ YES ☐ NO | If yes, how? |
| Have your changed any medication? *If yes, record in Concomitant Medication Log* | ☐ YES ☐ NO | |
| Have you changed your use of laxatives (i.e those not prescribed by GP)? | ☐ YES ☐ NO | If yes, how? |

| Telephone calls cont. | |
|---|---|
| Has there been any change in your bowel habits? | ☐ YES ☐ NO |
| If yes, indicate how below<br>More often<br>Less time spent<br>Less hard<br>Other (specify) | <br>☐ YES ☐ NO<br>☐ YES ☐ NO<br>☐ YES ☐ NO<br>☐ YES ☐ NO |
| General discussion on any of these points | |
| Have you completed the diary this week. | ☐ YES ☐ NO |
| Have you completed the Patient Resource Questionnaire this week. | ☐ YES ☐ NO |
| Have there been any adverse events?<br>*If yes complete AE form and SAE if applicable* | ☐ YES ☐ NO |
| Additional Information | |

| Telephone calls cont. | |
|---|---|
| Are there going to be any change of address/contact information prior to your next study call/appointment? If yes, please detail. | ☐ YES ☐ NO |

| Telephone calls cont. (massage participants only) | |
|---|---|
| Did you administer the massage yourself? | ☐ YES ☐ NO |
| Did a carer administer the massage? | ☐ YES ☐ NO |
| What position was the massage administered (Lying, semi-lying, sitting) | ☐ Lying ☐ Semi-lying ☐ Sitting |
| Time of day administered (Morning, afternoon, evening) | ☐ Morning ☐ Afternoon ☐ Evening |
| Additional information. | |

DATA ENTERED ON DATABASE (SIGN & DATE)

D D - M M M - Y Y Y Y

| Participant ID | | | | | |
|---|---|---|---|---|---|
| | | | | | |

AMBER Abdominal Massage for Bowel Dysfunction Effectiveness Research

## CONCOMITANT MEDICATIONS LOG

| Name of Drug[1] | Reason Prescribed | Dose | Units[2] | Frequency[3] | Route of Admin[4] state if other | Tick (✓) if on-going at start of study or enter Start Date | Tick (✓) if on-going at end of study or enter Date stopped or Dose changed |
|---|---|---|---|---|---|---|---|
| | | | | | | __/__/____ or ☐ | __/__/____ or ☐ |
| | | | | | | __/__/____ or ☐ | __/__/____ or ☐ |
| | | | | | | __/__/____ or ☐ | __/__/____ or ☐ |
| | | | | | | __/__/____ or ☐ | __/__/____ or ☐ |
| | | | | | | __/__/____ or ☐ | __/__/____ or ☐ |
| | | | | | | __/__/____ or ☐ | __/__/____ or ☐ |

[1]*All Laxatives used by participant should be added to this form*
[2]*Units: µg, mg, g, mL, IU, tablet, capsule, puff, other (specify)*
[3]*Frequency: Once Daily, Twice per day, 3 times per day, 4 times per day, Every week, Every 2 weeks, Every month, As needed (PRN), Other (specify)*
[4]*Route of Administration: 1. Oral 2. Subcutaneous 3. Intramuscular 4. Intravenous 5. Rectal 6. Topical 7. Inhaled 8. Other*

| **Signature** | | **Date** | D | D | M | M | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|---|

| Participant ID | | | | | | AMBER Abdominal Massage for Bowel Dysfunction Effectiveness Research | ADVERSE EVENTS LOG |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

| **Description of adverse event** (provide additional information on notes pages if required) | **Date of onset** DD/MM/YYYY | **Date reported to Investigator /team** DD/MM/YYYY | **Severity** 1. Mild 2. Moderate 3. Severe | **Causality** 1. Unrelated 2. Possible 3. Probable 4. Definite | **Action taken – please list all that apply** 1. None 2. Hospitalisation 3. Intervention stopped 4. Intervention reduced 5. Intervention interrupted 6. Con Meds commenced * 7. Other (specify) | **Outcome** 1. Recovered 2. Ongoing 3. Disability or incapacity 4. Death 5. Unknown | **Is this a Serious AE?** **YES** or NO** | **Date resolved** (Enter date resolved or tick if ongoing at end of study) DD/MM/YYYY | **PI Signature and Date** DD/MM/YYYY |
|---|---|---|---|---|---|---|---|---|---|
| | __/__/____ | __/__/____ | | | | | | __/__/____ or ☐ | __/__/____ |
| | __/__/____ | __/__/____ | | | | | | __/__/____ or ☐ | __/__/____ |
| | __/__/____ | __/__/____ | | | | | | __/__/____ or ☐ | __/__/____ |
| | __/__/____ | __/__/____ | | | | | | __/__/____ or ☐ | __/__/____ |
| | __/__/____ | __/__/____ | | | | | | __/__/____ or ☐ | __/__/____ |
| | __/__/____ | __/__/____ | | | | | | __/__/____ or ☐ | __/__/____ |

* Record on Con Meds Log
** If adverse event meets criteria for a serious adverse event (SAE), please submit an online SAE report within 24 hours of becoming aware of the event

| Participant ID | AMBER | 24 WEEK TELEPHONE RECORD |
|---|---|---|
| | | |

Was telephone call completed? ☐ YES ☐ NO

If NO please give reason:
*[and do not complete the rest of the form]*

Date of call D D - M M M - Y Y Y Y

Advice only ☐
Massage ☐

| **Telephone calls – Researcher should ask the participant the following questions and clearly explain to participant that they should answer each question in relation to the last 7 days.** | | |
|---|---|---|
| Have you changed your diet? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your fluid intake? | ☐ YES ☐ NO | If yes, how? |
| Have you changed your defaecation position? | ☐ YES ☐ NO | If yes, how? |
| Are you taking more exercise? | ☐ YES ☐ NO | If yes, how? |
| Have your changed any medication? *If yes, record in Concomitant Medication Log* | ☐ YES ☐ NO | |
| Have you changed your use of laxatives (i.e those not prescribed by GP)? | ☐ YES ☐ NO | If yes, how? |

| **Telephone calls cont.** | |
|---|---|
| Has there been any change in your bowel habits? | ☐ YES ☐ NO |
| If yes, indicate how below<br>More often<br>Less time spent<br>Less hard<br>Other (specify) | <br>☐ YES ☐ NO<br>☐ YES ☐ NO<br>☐ YES ☐ NO<br>☐ YES ☐ NO |
| General discussion on any of these points | |
| Have you completed the bowel diary this week | ☐ YES ☐ NO |
| Have you completed the Patient Resource Questionnaire this week? | ☐ YES ☐ NO |
| Have there been any adverse events?<br>*If yes complete AE form and SAE if applicable* | ☐ YES ☐ NO |
| Have you had a change in your MS?<br>(If YES, please give details) | ☐ YES ☐ NO<br>Details: |

| **Telephone calls cont. (massage participants only)** | |
|---|---|
| Have you continued the massage? | ☐ YES ☐ NO |
| **If NO why not?**<br>No benefit<br>Burden on carer<br>Too difficult | <br>☐ YES ☐ NO<br>☐ YES ☐ NO<br>☐ YES ☐ NO |
| **If YES**<br>How often?<br>Self or Carer massage?<br>Have you felt a benefit? | <br>-------------------------------------------------- (indicate frequency)<br>☐ Self ☐ Carer<br>☐ YES ☐ NO |

DATA ENTERED ON DATABASE (SIGN & DATE)

D D - M M M - Y Y Y Y

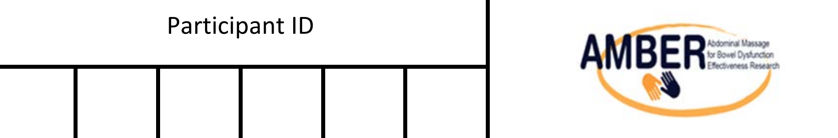
## COMPLETION OF STUDY FORM

| **Completion of Study** | **PLEASE CIRCLE** | |
|---|---|---|
| Did the participant complete the study? | Yes | No |

Date of completion/early withdrawal D D - M M M - Y Y Y Y

| **Change notified at: (please circle one)** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Baseline visit | Call 1 | Call 2 | Call 3 | Call 4 | Call 5 | Call 6 | Indicated in 6 week follow-up | Indicated in 24 week follow-up |

| **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 | |
| Patient withdrew from completing further questionnaires | |
| Patient withdrew consent for the trial to use existing trial data | |
| Death | |
| Other (please specify) | |



| Participant ID | | | | | | AMBER | COMPLETION OF STUDY FORM |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

| Follow-up | PLEASE CIRCLE | |
|---|---|---|
| Is there any follow-up required? | Yes | No |
| If yes, please specify | | |

| Protocol | PLEASE CIRCLE | |
|---|---|---|
| Were there any deviations from protocol?<br>(If Yes ensure Deviation Log is complete) | Yes | No |

| Signature (Information added to study database) | |
|---|---|
| | |
| PRINT NAME | SIGNATURE |
| D D - M M M - Y Y Y Y | |