Standalone Document 2

AMBER Case Report Forms (CRF's)

Includes:

- Screening form
- Anorectal CRF
- Baseline CRF
- Weekly telephone CRF (weeks 1-6)
- Adverse Event CRF
- Medication CRF
- Week 24 telephone call CRF
- Completion of Study CRF

Participant ID							SCREENING VISIT

SCREENING To be completed by the researcher to assess eligibility. Once completed enter this information to the study database.	
Date of Visit/call	D D – M M M – Y Y Y Y

INCLUSION CRITERIA	**PLEASE TICK**	
	YES	**NO**
1. Participant is male or female over the age of 18 years		
2. Participant has a diagnosis of MS (in a stable phase, ie no MS relapse for 3 months)		
3. Participant has had no major change of medication for 1 month eg introduction of disease modifying medications		
4. Participant is bothered by their bowel dysfunction		
5. Participant has not used abdominal massage for at least 2 months		

EXCLUSION CRITERIA	**PLEASE TICK**	
	YES	**NO**
1. Participant is unable to undertake the massage themselves or does not have a carer willing to do it		
2. Participant is unable to understand the study processes / give informed consent		
3. Participant has contraindications to abdominal massage (specify)		
History of abdominal/pelvic cancer		
History of hernia, hiatus, inguinal or umbilical		
Rectal prolapse		
Inflammatory bowel disease		
Past history of volvulus of bowel		
Pregnancy		
Supra-pubic catheter		
Do you have any recent abdominal scars, abdominal wounds or skin disorders that may make abdominal massage uncomfortable		

Red flags include

- Recent sudden and severe changes in bowel habits
- Rectal bleeding

If there are any red flags please contact the PI

Participant ID							SCREENING VISIT

ELIGIBILITY	PLEASE TICK	
	YES	NO
Is the patient eligible		
Randomisation Information required. Please tick one box regarding the patient's mobility.		
Walking unaided (EDSS score less than 6)		
Aided (EDSS score of 6 or 7)		
Wheelchair bound (EDSS score of 8)		
<u>* Researcher Please Note</u> ***The answer to the above question is required for the randomisation of the patient. Please ensure you have this form or access to the study database at the participants baseline visit.**		

Additional Screening information (Note this is not an exclusion criterion). If patients have just started using anal irrigation wait for at least a month before randomisation.	PLEASE TICK	
	YES	NO
Does the patient use anal irrigation?		
If YES, how often?		

Signature (Screener)	
PRINT NAME	SIGNATURE OF SCREENER
D D – M M M – Y Y Y Y	

Signature (Information added to study database)	
PRINT NAME	SIGNATURE OF SCREENER
D D – M M M – Y Y Y Y	

Participant ID						AMBER Abdominal Massage for Bowel Dysfunction Effectiveness Research	ANO-RECTAL PHYSIOLOGY FORM

Ano-Rectal Physiology Form	
Date of test	D D – M M M – Y Y Y Y
Timepoint	☐ Baseline ☐ 24 weeks
Parity	☐ no. of children born
Duration of symptoms pre-injury/diagnosis	☐ years
Symptoms	
Faecal incontinence	☐ YES ☐ NO
Difficult evacuation	☐ YES ☐ NO
Infrequent emptying	☐ YES ☐ NO
Abdominal pain	☐ YES ☐ NO
Bloating	☐ YES ☐ NO
Other (Specify if YES)	☐ YES ☐ NO
Transit study	☐ YES ☐ NO
Markers R colon	☐ n
Markers L colon	☐ n
Markers recto-sigmoid	☐ n
Total markers	☐ n
Please tick appropriate box for speed of transit	☐ SLOW ☐ NORMAL

Participant ID							ANO-RECTAL PHYSIOLOGY FORM

Ano-Rectal Physiology Form cont.	
Physiology measurements completed	YES NO
Anal electrosens	mA
Rectal electrosens	mA
Balloon threshold vol	ml
Balloon urge vol	ml
Balloon max tolerated vol	ml
Barostat rectal compliance	mmHg/ml
RAIR latency	msec
RAIR duration	msec
Anal rest pr	mmHg
Anal squeeze pr	mmHg
Wexner-total	

Signature (Tester)	
PRINT NAME	SIGNATURE OF TESTER

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

Participant ID							NURSE ASSESSMENT FORM

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)	

Participant ID						AMBER	NURSE ASSESSMENT FORM

2. MULTIPLE SCLEROSIS

Year of diagnosis	Y Y Y Y
Method of Diagnosis	☐ MRI ☐ Lumber Puncture
Type of MS	☐ Benign ☐ Relapsing Remitting ☐ Secondary Progressive ☐ 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 ☐ Distance limited to 300m: score 4.5 ☐ Distance limited to 200m: score 5.0 ☐ Distance limited to 100m or less: score 5.5
Aided	☐ Intermittent or unilateral assistance required to walk 100m: score 6.0 ☐ Constant bilateral assistance required to walk 20m: score 6.5 ☐ Few steps, restricted to wheelchair, transfers independently: score 7.0 ☐ Transfers with assistance; may require motorized wheelchair: score 7.5 ☐ Essentially restricted to bed or chair: score 8.0

Participant ID							NURSE ASSESSMENT FORM

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 ☐ 1-2 years ☐ 2-5 years ☐ 5-10 years ☐ > 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 ☐ Daily ☐ 2-4 times a week ☐ Once a week ☐ Once a fortnight ☐ Other (please state) _____

Participant ID							NURSE ASSESSMENT FORM

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

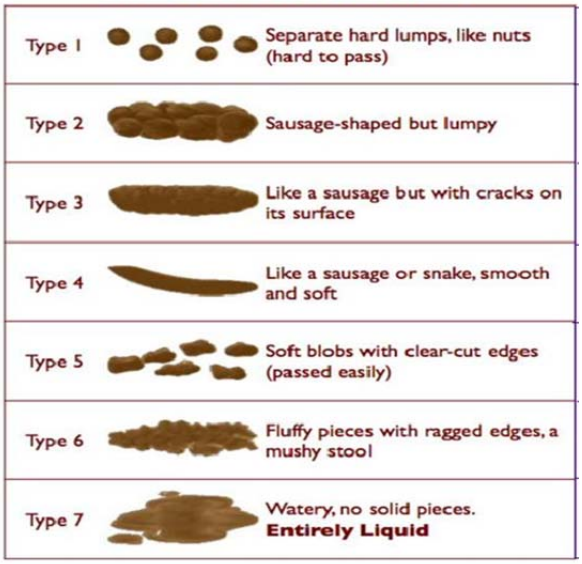
Participant ID						AMBER Abdominal Massage for Bowel Dysfunction Effectiveness Research	NURSE ASSESSMENT FORM

3. BOWEL SYMPTOMS cont.

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

Participant ID						AMBER Abdominal Massage for Bowel Dysfunction Effectiveness Research	NURSE ASSESSMENT FORM

Bristol Stool Chart



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		

Participant ID							NURSE ASSESSMENT FORM

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

Participant ID						AMBER Abdominal Massage for Bowel Dysfunction Effectiveness Research	NURSE ASSESSMENT FORM

6. ABDOMINAL MASSAGE continued
(Please only complete if patient is in intervention arm of the study)

(Massage demonstrated cont.) Kneading Vibration	☐ YES ☐ NO ☐ YES ☐ NO
Participant reactions Relaxed Uncomfortable	☐ YES ☐ NO ☐ YES ☐ NO
Did carer practise massage? Was there discussion on stance? Was there discussion on pressure?	☐ YES ☐ NO ☐ YES ☐ NO ☐ YES ☐ NO
Is patient doing self-massage Was this practised	☐ YES ☐ NO ☐ YES ☐ NO
Discussion re: possible response Flatus? Cramps? Tummy noises?	☐ YES ☐ NO ☐ YES ☐ NO ☐ YES ☐ NO
Was the DVD watched? Contact details for telephone support provided?	☐ YES ☐ NO ☐ 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	

DATA ENTERED ON DATABASE (SIGN & DATE)

D D – M M M – Y Y Y Y

Any other comments?	

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?

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

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? *If yes complete AE form and SAE if applicable*	☐ YES ☐ NO
Additional Information	

Telephone calls cont.

Participant ID							TELEPHONE RECORD WEEKS 1-6

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?

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

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? *If yes complete AE form and SAE if applicable*	☐ YES ☐ NO
Additional Information	

Telephone calls cont.

Participant ID							TELEPHONE RECORD WEEKS 1-6

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.		
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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?

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

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? *If yes complete AE form and SAE if applicable*	☐ YES ☐ NO
Additional Information	

Telephone calls cont.

Participant ID							TELEPHONE RECORD WEEKS 1-6

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?

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

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? *If yes complete AE form and SAE if applicable*	☐ YES ☐ NO
Additional Information	

Telephone calls cont.

Participant ID							TELEPHONE RECORD WEEKS 1-6

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.		
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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?

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

Telephone calls cont.	
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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? *If yes complete AE form and SAE if applicable*	☐ YES ☐ NO
Additional Information	

Telephone calls cont.

Participant ID							TELEPHONE RECORD WEEKS 1-6

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 ☐

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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?

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

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? *If yes complete AE form and SAE if applicable*	☐ YES ☐ NO
Additional Information	

Telephone calls cont.

Participant ID							TELEPHONE RECORD WEEKS 1-6

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

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
						CONCOMITANT MEDICATIONS LOG __/__/____ 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

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
						☐ YES ☐ NO	

Was telephone call completed?

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?

Participant ID							**24 WEEK TELEPHONE RECORD**

Telephone calls cont.	
Has there been any change in your bowel habits?	☐ YES ☐ NO
If yes, indicate how below More often Less time spent Less hard Other (specify)	 ☐ YES ☐ NO ☐ YES ☐ NO ☐ YES ☐ NO ☐ 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? *If yes complete AE form and SAE if applicable*	☐ YES ☐ NO
Have you had a change in your MS? (If YES, please give details)	☐ YES ☐ NO Details:

Participant ID							24 WEEK TELEPHONE RECORD

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

DATA ENTERED ON DATABASE (SIGN & DATE)	
	D D - M M M - Y Y Y Y

Participant ID							COMPLETION OF STUDY FORM

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

COMPLETION OF STUDY FORM

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 Abdominal Massage for Bowel Dysfunction Effectiveness Research	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? (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	

Standalone Document 2: Questionnaires and diaries completed by the participant

Questionnaires included;

- Neurogenic Bowel Dysfunction PROM Questionnaire
- Neurogenic Bowel Dysfunction Score Questionnaire (Primary outcome)
- Qualiveen Bladder Questionnaire
- Constipation Scoring System Questionnaire
- EQ-5D health Questionnaire
- Patient resource questionnaire
- Bowel diary
- Bowel and Massage diary

Participant ID							
						AMBER Abdominal Massage for Bowel Dysfunction Effectiveness Research	**QUESTIONNAIRE BOOKLET**

Abdominal massage for neurogenic bowel dysfunction in people with multiple sclerosis

This following questionnaires are included in this booklet.

- Neurogenic Bowel Dysfunction PROM Questionnaire
- Neurogenic Bowel Dysfunction Score Questionnaire
- Qualiveen Bladder Questionnaire
- Constipation Scoring System Questionnaire
- EQ-5D Health Questionnaire

Please read the instructions at the start of each questionnaire and please complete all questions.

THANK YOU!

Neurogenic Bowel Dysfuntion Questionnaire
How does your bowel problem affect you?

This questionnaire is designed to find out what symptoms you have from your bowel problem, how those symptoms affect you and how much they bother you.

When answering the questions, please think about how you have been over the **last 3 months or since you last completed this questionnaire.**

Date of Completion D D – M M M – Y Y Y Y

WEEK	PLEASE CIRCLE			
Indicate time point	0	6	24	Withdrawal

1. Do you ever have bowel accidents (uncontrolled passage of stool from the back passage)?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?
(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

2. Do you ever have an urgent need to open your bowels?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

3. Do you experience any staining of your underwear or need to wear pads because of your bowel?

(a)

0 ☐ never

1 ☐ rarely

2 ☐ some of the time

3 ☐ most of the time

4 ☐ always

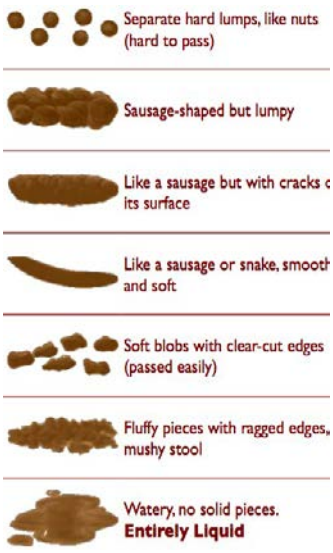
(b) How much does this bother you?

please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

Not at all a great deal

4. Using the pictures below please say how your bowel movements are most of the time: tick all that apply.



☐ Type1

☐ Type 2

☐ Type3

☐ Type 4

☐ Type 5

☐ Type 6

☐ Type 7

(b) How much does this bother you?

please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

Not at all a great deal

5. Do you ever experience bleeding from your back passage?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?

please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

6. Do you ever feel that your abdomen is bloated?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?

(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

7. Do you ever experience abdominal pain because of your bowel problem?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?

(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

8. Do you ever experience pain in or around your back passage due to your bowel problem?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

9. Do you ever find that your bowel problem interferes with your bladder?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?
(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

10. Does your bowel problem stop you from concentrating as much as you would like?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?
(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

11. Do you get autonomic dysreflexia because of your bowels?

DEFINITION: Autonomic Dysreflexia occurs due to a response to pain below the level of spinal cord injury.
HOW TO ANSWER THIS QUESTION: **This question is only applicable if a person has a spinal cord injury. If YOU DO NOT please ANSWER as follows**: a) NEVER and b) 0

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?
(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

12. Do you have a routine day or time for bowel care?

(a)

4 ☐ never
3 ☐ rarely
2 ☐ some of the time
1 ☐ most of the time
0 ☐ always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

13. Do you have less energy on the days you open your bowels?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

14. Do your bowels open when you expect them to?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?

please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

15. How long, on average, do you spend opening your bowels?

(a)

0☐Less than 15 minutes
1☐15 – 30 minutes
2☐31 – 60 minutes
3☐1 – 2 hours
4☐More than 2 hours

(b) How much does this bother you?

please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

16. Do you alter what you eat because of your bowel problem?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐alway

(b) How much does this bother you?

please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

17. Do you use medications to <u>stop</u> your bowels opening?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

18. Do you strain to open your bowels?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?
(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

19. Do you use your fingers to help your bowel to empty in any way (not including inserting a suppository or enema)?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

20. Does your <u>bowel problem</u> interfere with your ability to work outside your home?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always
0☐not working for other reasons

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

21. Do you feel your bowel care routine is reliable?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

22. Will you still go out if your bowel hasn't opened as expected?

(a)

4☐never
3☐rarely
2☐some of the time
1☐most of the time
0☐always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

23. Does your bowel problem interfere with staying away from home?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?

(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

24. Does your bowel problem interfere with your sexual activity?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always
0 ☐ not applicable

(b) How much does this bother you?

please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

25. Does your bowel problem stop you going out of your home?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?

(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

26. Does your bowel problem interfere with your personal relationships?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?
(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

27. Does your bowel problem stop you exercising?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always
0☐ don't exercise for other reasons

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

28. Is the possibility of a 'bowel accident' (uncontrolled passage of stool from the back passage) on your mind?
(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

29. Do you feel you fit your life around your bowel problem?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?

please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

30. Are you satisfied with how you manage your bowel problem?

(a)

4 ☐ never
3 ☐ rarely
2 ☐ some of the time
1 ☐ most of the time
0 ☐ always

(b) How much does this bother you?

please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

31. Does managing your bowel problem interfere with your life?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?

(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

32. Does worrying about your bowel problem interfere with your ability to work?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?
(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

33. Does worrying about your bowel problem stop you going out?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

34. Do you check where the toilet is when you go somewhere new?

(a)

0☐never
1☐rarely
2☐some of the time
3☐most of the time
4☐always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

35. Do you feel embarrassed about your bowels?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?
(please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

36. Are you embarrassed by accidental passage of wind from your bowel?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

37. Does your bowel problem make you feel low or depressed?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

38. Do you avoid eating out because of your bowel problem?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

39. Do you spend more time than you would like on your bowel problem?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

40. Do you feel you can fit managing your bowel problem into your life?

(a)

4 ☐ never
3 ☐ rarely
2 ☐ some of the time
1 ☐ most of the time
0 ☐ always

(b) How much does this bother you?
please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
Not at all a great deal

41. Does your bowel problem keep you at home more than you would like?

(a)

0 ☐ never
1 ☐ rarely
2 ☐ some of the time
3 ☐ most of the time
4 ☐ always

(b) How much does this bother you?

please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

Not at all a great deal

42. Please rate how good your ability to live with your bowel problem is now?

please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

Easy very difficult

43. Please rate how much your bowel problem restricts your life now?

please ring one number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

Not at all a great deal

.

DATA ENTERED ON DATABASE (SIGN & DATE)

D D - M M M - Y Y Y Y

NEUROGENIC BOWEL DYSFUNCTION SCORE

Date of Completion D D – M M M – Y Y Y Y

WEEK	PLEASE CIRCLE			
Indicate time point	0	6	24	Withdrawal

Consider the average for the **last week** and tick one answer per question.

1. Frequency of defaecation (passing a stool)

Daily ☐ 2-6 times every week ☐ Less than once a week ☐

2. Time used for each defaecation

0-30min ☐ 31-60min ☐ More than one hour ☐

3. Uneasiness, headache or perspiration during defaecation

No ☐ Yes ☐

4. Regular use of tablets against constipation

No ☐ Yes ☐

5. Regular use of drops against constipation

No ☐ Yes ☐

6. Digital stimulation or evacuation of the anorectum

Less than once a week ☐ Once or more than once a week ☐

7. Frequency of faecal incontinence

Less than once every month ☐ 1-4 times per month ☐

1-6 times every week ☐ Daily ☐

8. Medication against faecal incontinence

No ☐ Yes ☐

9. Flatus (wind) incontinence

No ☐ Yes ☐

10. Perianal skin problems
(e.g. redness, irritation around the anus)

No ☐ Yes ☐

DATA ENTERED ON DATABASE
SIGNATURE
DATE
D D – M M M – Y Y Y Y

QUALIVEEN BLADDER QUESTIONNAIRE

Date of Completion D D – M M M – Y Y Y Y

WEEK	PLEASE CIRCLE			
Indicate time point	0	6	24	Withdrawal

The following questions are about the bladder problems you may have and how you deal and live with them. Please fill in this questionnaire in a quiet place and preferably on your own. Take the time you need. There are no right or wrong answers. If you are not sure how to answer a question, choose the answer which best applies to you. Please note that your answers will remain strictly anonymous and confidential.

When answering the questions, think about how you pass urine at present.

Thank you for your participation.

Participant ID							QUALIVEEN BLADDER QUESTIONNAIRE

Please answer all the questions by ticking the appropriate box.

	Not at all	Slightly	Moderately	Quite a bit	Extremely
1. In general, do your bladder problems complicate your life?	☐0	☐1	☐2	☐3	☐4
2. Are you bothered by the time spent passing urine or realizing catheterization	☐0	☐1	☐2	☐3	☐4
3. Do you worry about your bladder problems worsening	☐0	☐1	☐2	☐3	☐4
4. Do you worry about smelling of urine	☐0	☐1	☐2	☐3	☐4
5. Do you feel worried because of your bladder problems	☐0	☐1	☐2	☐3	☐4
6. Do you feel embarrassed because of your bladder problems	☐0	☐1	☐2	☐3	☐4

	Never	Rarely	From time to time	Often	Always
7. Is your life regulated by your bladder problems?	☐0	☐1	☐2	☐3	☐4
8. Can you go out without planning anything in advance?	☐4	☐3	☐2	☐1	☐0

Thank you for valuable help

DATA ENTERED ON DATABASE (SIGN & DATE)	D D - M M M - Y Y Y Y

Participant ID							CONSTIPATION SCORING SYSTEM

Date of Completion D D – M M M – Y Y Y Y

WEEK	PLEASE CIRCLE			
Indicate time point	0	6	24	Withdrawal

Please tick one answer per question with average values over the **last week**

Frequency of bowel movements		**Time : minutes at toilet per attempt**	
• 1 – 2 times per 1 – 2 days	☐	• < 5 min	☐
• 2 times per week	☐	• 5 – 10 min	☐
• 1 per week	☐	• 10 – 20 min	☐
• < 1 per week	☐	• 20 – 30 min	☐
• < 1 per month	☐	• > 30 min	☐
Difficulty : painful evacuation effort		**Assistance : type of assistance**	
• never	☐	• none	☐
• rarely	☐	• laxatives	☐
• sometimes	☐	• digital assistance or enema	☐
• usually	☐		
• always	☐		
Completeness : feeling incomplete evacuation		**Failure : unsuccessful attempts for evacuation per 24 hours**	
• never	☐	• never	☐
• rarely	☐	• 1 – 3	☐
• sometimes	☐	• 3 –6	☐
• usually	☐	• 6 –9	☐
• always	☐	• > 9	☐
Pain		**History : duration of constipation (yr)**	
• never	☐	• 0	☐
• rarely	☐	• 1 – 5	☐
• sometimes	☐	• 5 – 10	☐
• usually	☐	• 10 – 20	☐
• always	☐	• > 20	☐

DATA ENTERED ON DATABASE (SIGN & DATE) D D – M M M – Y Y Y Y

Health Questionnaire

English version for the UK

Date of Completion D D – M M M – Y Y Y Y

WEEK	PLEASE CIRCLE			
Indicate time point	0	6	24	Withdrawal

Participant ID							EQ-5D-5L HEALTH QUESTIONNAIRE

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

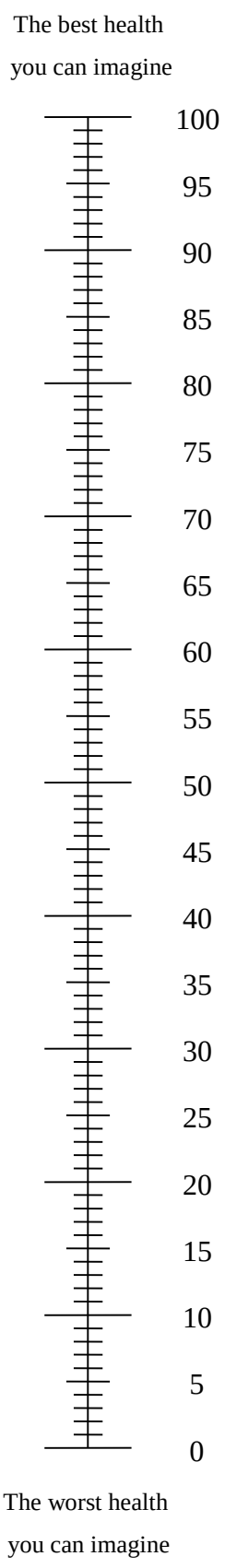
ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

Participant ID							EQ-5D-5L HEALTH QUESTIONNAIRE

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



DATA ENTERED ON DATABASE
SIGNATURE
DATE

D D - M M M - Y Y Y Y

Participant ID							PATIENT RESOURCE USE FORM

WEEK	PLEASE CIRCLE								
Indicate time point (weeks from baseline visit)	1	2	3	4	5	6	12	18	24

Date of completion D D – M M M – Y Y Y Y

Patient Resource Use Form

1. **In the last week or since you last completed this form** have you done any of the following because of your bowel problems? **If yes** please tell us the number of times (please be sure to answer 'yes' or 'no' to every question).

a) Have you been seen by your family doctor or another GP at a doctor's surgery?	☐ Yes, because of my bowel problems	☐ Please write in the number of times
	☐ Yes, because of other Health reasons	☐ Please write in the number of times
	☐ No	
b) Have you been seen by a nurse at a doctor's surgery?	☐ Yes, because of my bowel problems	☐ Please write in the number of times
	☐ Yes, because of other Health reasons	☐ Please write in the number of times
	☐ No	
c) Have you spoken to a doctor on the telephone?	☐ Yes, because of my bowel problems	☐ Please write in the number of times
	☐ Yes, because of other Health reasons	☐ Please write in the number of times
	☐ No	
d) Have you spoken to a nurse on the telephone?	☐ Yes, because of my bowel problems	☐ Please write in the number of times
	☐ Yes, because of other Health reasons	☐ Please write in the number of times
	☐ No	

Participant ID							PATIENT RESOURCE USE FORM

Patient Resource Use Form Cont.		
1. **In the last week or since you last completed this form** have you done any of the following because of your bowel problems (Continued)		
e) Have you been seen by a doctor at home?	☐ Yes, because of my bowel problems	☐ Please write in the number of times
	☐ Yes, because of other Health reasons	☐ Please write in the number of times
	☐ No	
f) Have you been seen by a nurse at home?	☐ Yes, because of my bowel problems	☐ Please write in the number of times
	☐ Yes, because of other Health reasons	☐ Please write in the number of times
	☐ No	
g) Have you visited an 'out of hours' clinic?	☐ Yes, because of my bowel problems	☐ Please write in the number of times
	☐ Yes, because of other Health reasons	☐ Please write in the number of times
	☐ No	
h) Have you been seen by a doctor at a routine hospital clinic or outpatient department?	☐ Yes, because of my bowel problems	☐ Please write in the number of times
	☐ Yes, because of other Health reasons	☐ Please write in the number of times
	☐ No	

Participant ID							PATIENT RESOURCE USE FORM

Patient Resource Use Form Cont.		
1. **In the last week or since you last completed this form** have you done any of the following because of your bowel problems (Continued)		
i) Have you been admitted to a hospital as an inpatient or day patient?	☐ Yes, because of my bowel problems	☐ Please write in the number of times
	☐ Yes, because of other Health reasons	☐ Please write in the number of times
	☐ No	
j) Have you been to a hospital casualty (A&E) department?	☐ Yes, because of my bowel problems	☐ Please write in the number of times
	☐ Yes, because of other Health reasons	☐ Please write in the number of times
	☐ No	
k) Have you seen any other allied health professionals (eg continence advisor, dietician, occupational therapist, physiotherapist)?	☐ Yes, because of my bowel problems	☐ Please write in the number of times
	☐ Yes, because of other Health reasons	☐ Please write in the number of times
	☐ No	
l) Have you attended the continence service?	☐ Yes, because of my bowel problems	☐ Please write in the number of times
	☐ Yes, because of other Health reasons	☐ Please write in the number of times
	☐ No	

Participant ID							PATIENT RESOURCE USE FORM

Medications		
2. Over the last 1 week or since you last completed this form have you been prescribed any medications, **for your bowel problem**, by a GP or hospital doctor?	☐ YES ☐ NO	
If yes, please write down the name of the medication, the dosage prescribed and how often you have to take this (continue on a separate page if needed).		
Please give the name of the medication	Dosage	How often do you take this?

Medications cont.	
3. Over the last 1 week or since you last completed this form have you bought any medications, **for your bowel problem**, from a pharmacy or other shop?	☐ YES ☐ NO
If yes, please write down the name of the medication and how much you spent (continue on a separate page if needed).	
Please give the name of the medication (brand name if possible)	How much did you pay for it overall?

Participant ID							PATIENT RESOURCE USE FORM

Equipment and clothing.		
4. Over the last 1 week or since you last completed this form have you spent any money on equipment or clothing **because of your bowel problems** (eg pads, bedding)?	☐ YES ☐ NO	
If yes, please write down what you bought and how much you spent (continue on a separate page if needed).		
Please write down the equipment/clothing	How much did you pay for it overall?	

Health or social services	
5. Over the last 1 week or since you last completed this form have you been provided with any specialist equipment by the Health Services or Social Services **because of your bowel problems**?	☐ YES ☐ NO
If yes, please write down what was provided	

DATA ENTERED ON DATABASE (SIGN & DATE)
D D – M M M – Y Y Y Y

Participant ID							7 DAY BOWEL DIARY

7 DAY BOWEL DIARY

Date of starting diary D D – M M M – Y Y Y Y

WEEK		PLEASE CIRCLE							
Indicate time point (weeks from baseline visit)	Pre-intervention	1	2	3	4	5	6	23	Withdrawal

Please complete the following diary by circling the most appropriate answer or by filling in the boxes.

DIARY							
	SUN	**MON**	**TUES**	**WED**	**THUR**	**FRI**	**SAT**
Did you pass a stool today?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
If yes, what type was it? (see chart) Type 1-7							
How many times did you try and pass stool today?							
Do you feel you have emptied your bowel?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
In total how long did you spend on the toilet? **(minutes)**							
How much did you drink today?	USUAL* MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS
Laxative use	USUAL** MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS
Did you use digital stimulation? (gentle touching of wall of anus or rectum)	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Did you have a bowel accident today?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Any comments you would like to discuss with the nurse during your next call? (such as any visits to your GP, or MS clinic or any health care professional).							
Please initial and date when completed	D D – M M M – Y Y Y Y						

* Usual is the amount you would normally drink
** Usual laxative means the amount you would have taken before entering the study

DATA ENTERED ON DATABASE (OFFICE USE ONLY)
SIGNATURE
DATE
D D – M M M – Y Y Y Y

Participant ID							7 DAY BOWEL & MASSAGE DIARY

7 DAY BOWEL & MASSAGE DIARY

Date of starting diary D D – M M M – Y Y Y Y

WEEK	PLEASE CIRCLE							
Indicate time point (weeks from base-line visit)	1	2	3	4	5	6	23	Withdrawal

Please complete the following diary by circling the most appropriate answer or by filling in the boxes.

DIARY							
	SUN	**MON**	**TUES**	**WED**	**THUR**	**FRI**	**SAT**
Did you pass a stool today?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
If yes, what type was it? (see chart) (Type 1-7)							
How many times did you try and pass stool today?							
Do you feel you have emptied your bowel?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
In total how long did you spend on the toilet? **(minutes)**							
How much did you drink today?	USUAL* MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS
Laxative use	USUAL** MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS	USUAL MORE LESS
Did you use digital stimulation? (gentle touching of wall of anus or rectum)	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Did you have a bowel accident today?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Was massage performed today?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
If yes, for how long? **(minutes)**							
Any comments you would like to discuss with the nurse during your next call? (such as any problems with the massage or any visits to your GP, or MS clinic or any health care professional).							
Please initial and date when completed	D D – M M M – Y Y Y Y						

* Usual is the amount you would normally drink
** Usual laxative means the amount you would have taken before entering the study

DATA ENTERED ON DATABASE (OFFICE USE ONLY)
SIGNATURE
DATE
D D – M M M – Y Y Y Y