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					AMBER Advisors Massage to Bowl Dy Among	SCREENING VISIT		
					Effectiveness Research	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	Υ					
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						
IT THERE ARE ANY RED TIARS DIEASE CONTACT THE PI						

Participant ID	AMBER Administration	SCREENING VISIT
		SCREENING VISIT

ELIGIBILITY	PLEASE TICK				
	YES	NO			
Is the patient eligible					
Randomisation Information required. Please tick one box regarding the patient's mo	bility.				
Walking unaided (EDSS score less than 6)					
Aided (EDSS score of 6 or 7)					
Wheelchair bound (EDSS score of 8)					
*** Researcher Please Note ***The answer to the above question is required for the randomisa of the patient. Please ensure you have this form or access to the study database at the participant baseline visit.					
	T				
	DIFAC	TICK			

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 — 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 Dyslandon (Declanors) floates	ANO-RECTAL PHYSIOLOGY		
		FORM		

Ano-Rectal Physiology Form	
Date of test	D D - M M M - 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	YES NO
(Specify if YES)	
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					AMBER Addressed Massager Early Start Devel Ophyddiol Earlyngaeth Company of the C	ANO-RECTAL PHYSIOLOGY	
					Effectiveness Research	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 data	base)					
PRINT NAME	SIGNATURE					
D D - M M M - Y Y Y						

Participant ID					AMBER Accorded Manager	NURSE ASSESSMENT FORM
						NORSE ASSESSIVIENT FORIVI

Date of Visit	D D M M M Y Y Y
Has informed consent been given?	YES NO
Patient randomised to Abdomin	nal Massage
Patient randomised to Advice	

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

)	Participant II	AMBER Adominal Massage to Beef Optionson	NUIDEE ACCECCATAIT FORM
		Commence Analysis	NURSE ASSESSMENT FORM

2. MULTIPLE SCLEROSIS						
Year of diagnosis	YYY					
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					

	Partici	pant ID		AMBER commul thasage	NUIDCE ACCECCAMENT FORM
				Chickennes hoselicit	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	
3. BOWLE STIVIF TOWIS	
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	YES NO
constipation?	
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)
	1

Participant ID	AMBER stormes through	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 of Daily 2-4 times a Once a wee Once a forti Other (plea	week k night		
 Description of Stool (see Bristol Stool Chend of the form) What percentage of time stool: Like pellets/hard lumps Sausage shaped, but lumpy Like a sausage but with cracks at its surfate. Like a sausage or snake, smooth on its surfate. Soft blobs with clear cup edge Fluffy pieces with ragged edges, a mushy Watery, no solid pieces 	ace urface	50% 25% 0%		

3. Do you have to strain to pass stool?

All the time

 $\frac{3}{4}$ of the time

½ of the time

¼ of the time

Never

Participant ID			AMBER Addomed Massage by Bowl Dyslandon					
					(Stockeross Roseard)		activeness Research	NURSE ASSESSMENT FORM
3. BOWEI	. SYMP	гомѕ	cont.					
4. Do you stool?	use digit	al stimu	ulation	to help	to pass a		All the time 34 of the time 35 of the time 36 of the time Never	2
5. Do you feel a sens							All the time % of the time % of the time % of the time Never	2
6. Do you find passing a s		e is son	nething	stoppi	ng you		All the time % of the time % of the time % of the time Never	2

Partici	n n n +	ın
raitici	pani	יוו



NURSE ASSESSMENT FORM

Bristol Stool Chart

Туре І		parate hard lumps, like nuts ard to pass)
Type 2	Sau	usage-shaped but lumpy
Туре 3		e a sausage but with cracks on surface
Type 4		e a sausage or snake, smooth d soft
Type 5		t blobs with clear-cut edges ssed easily)
Type 6		ffy pieces with ragged edges, a shy stool
Type 7		atery, no solid pieces.

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

Participant ID	AMBER Address Massage for Both Control of Effectiveness Research			
				NURSE ASSESSMENT FORM
5. ABDOMINAL EXAMINATION (Please only complete if patient is in int The participant should be lying supine and				
Does the participant have any of the following on their abdomen?				
Scars		YES	ı	NO
Open wounds		YES	ſ	NO
Skin rash		YES	ı	NO
Hernia		YES		NO
Lumps		YES		NO
Upon Palpation is there any			<u> </u>	
Tenderness		YES	1	NO
Full bowel		YES	1	NO
6. ABDOMINAL MASSAGE (Please only complete if patient is in int	ervention	arm of	the stud	ly)
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 undertak	ken		YES	NO
Repeated number of days per week			YES	NO
Is the participant positioned comfortably?			YES	NO
Has care been taken to minimise embarrassi	ment?		YES	NO
General hygiene been observed e.g. wash ha	ands?		YES	NO
			_	
Massage demonstrated:			YES	NO
Stroking			YES	NO

YES

Effleurage

NO

NO

	Partici	pant ID		AMBER to Board United
				(i)

Any other comments?

NURSE ASSESSMENT FORM

6. ABDOMINAL MASSAGE continued (Please only complete if patient is in intervention)	n arm of the study)
(Massage demonstrated cont.)	
Kneading	YES NO
Vibration	YES NO
Participant reactions	INO
	VEC. NO.
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	
DATA ENTERED ON DATABASE (SIGN & DATE)	
	D D M M M Y Y Y

Participant ID	AMB	Addominal Massage for Bowel Dystunction Effectiveness Resoarch		TELEPHONE RECORD			
		7			WEEKS 1-6		
TIMEPOINT			PLEASE CI	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]						
Data of call] [<u>, </u>	Advice only		
Date of call D D	_ M	M	Y	Y	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 Adoptined Massage To Town of Massage To Town of Massage	TELEPHONE RECORD		
	6.3	WEEKS 1-6		
Telephone calls cont.				
Has there been any change in your bown habits?	el 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 point				
Have you completed the diary this week	YES NO			
Have you completed the Patient Resour Questionnaire this week.	ce 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	AMBER Addraind Massage	TELEPHONE RECORD		
	Challenges Report	WEEKS 1-6		
Are there going to be any change of address/contact information prior to yo next study call/appointment? If yes, ple detail.				
Telephone calls cont. (massage part	icipants only)			
Did you administer the massage yoursel	f? YES NO			
Did a carer administer the massage?	YES NO			
What position was the massage administered (Lying, semi-lying, sitting)	Lying S	emi-lying Sitting		
Time of day administered (Morning, afternoon, evening)	Morning	Afternoon Evening		
Additional information.				
DATA ENTERED ON DATABASE (SIGN & DAT	E)	M M Y Y Y		

Participant ID	\top	AMBER rodonnal Massage for Board Dylandron Lifectures Research					TELEPHONE RECORD WEEKS 1-6		
TIMEPOINT				LE					
Weeks from baseline visit	1	2	3	4	5	\perp	6	Withdrawal	
Was telephone call comple	ted?		ES	N	0				
If NO please give reason: [and do not complete the rest of	the form]								
Date of call	- M	М	M -	Υ	Υ	Υ	Y	Advice only Massage	
Telephone calls – Researche									
Have you changed your diet?	mey snou	IG an.		YES	estioi	NO NO	1	res, how?	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				YES [NO		30, 112	
Have you changed your fluid ir	ntake?	[\	YES [NO	If y	es, how?	
Have you changed your defaed	 cation						If y	es, how?	
position?				YES		NO			
Are you taking more exercise?)	\dashv_{Γ}	,	YES		NO	If y	es, how?	

YES

NO

NO

If yes, how?

Have your changed any medication? If yes,

Have you changed your use of laxatives (i.e

record in Concomitant Medication Log

	Particip	oant ID					
						AMBER Rodonal Massay	TELEPHONE RECORD WEEKS 1-6
Telephone	e calls c	ont.	<u> </u>				
Has there k	oeen any	chang	e in yo	ur bow	el	YES N	0
If yes, indic	ate how	below	1				
More ofter	1					YES NO	0
Less time s	pent					YES N	0
Less hard						YES NO	0
Other (spec	cify)					YES NO	0
Have you c	omplete	d the d	diary th	is week	Κ.	YES N	0
Have you c Questionna	-		Patient	Resour	ce	YES N	0
Have there If yes comp applicable						YES N	0
Additional	Informat	cion					

Telephone calls cont.		

Participant ID	AMBER Actional Massage	TELEPHONE RECORD		
	Christiana Research	WEEKS 1-6		
Are there going to be any change of address/contact information prior to yo next study call/appointment? If yes, ple detail.				
Telephone calls cont. (massage part	icipants only)			
Did you administer the massage yoursel	f? YES NO			
Did a carer administer the massage?	YES NO			
What position was the massage administered (Lying, semi-lying, sitting)	Lying S	emi-lying Sitting		
Time of day administered (Morning, afternoon, evening)	Morning	Afternoon Evening		
Additional information.				
DATA ENTERED ON DATABASE (SIGN & DAT	E)	M M Y Y Y		

Participant ID	\top	AMBER rodonnal Massage for Board Dylandron Lifectures Research					TELEPHONE RECORD WEEKS 1-6		
TIMEPOINT				LE					
Weeks from baseline visit	1	2	3	4	5	\perp	6	Withdrawal	
Was telephone call comple	ted?		ES	N	0				
If NO please give reason: [and do not complete the rest of	the form]								
Date of call	- M	М	M -	Υ	Υ	Υ	Y	Advice only Massage	
Telephone calls – Researche									
Have you changed your diet?	mey snou	IG an.		YES	estioi	NO NO	1	res, how?	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				YES [NO		30, 112	
Have you changed your fluid ir	ntake?	[\	YES [NO	If y	es, how?	
Have you changed your defaed	 cation						If y	es, how?	
position?				YES		NO			
Are you taking more exercise?)	\dashv_{Γ}	,	YES		NO	If y	es, how?	

YES

NO

NO

If yes, how?

Have your changed any medication? If yes,

Have you changed your use of laxatives (i.e

record in Concomitant Medication Log

	Particip	oant ID					
						AMBER Rodonal Massay	TELEPHONE RECORD WEEKS 1-6
Telephone	e calls c	ont.	<u> </u>				
Has there k	oeen any	chang	e in yo	ur bow	el	YES N	0
If yes, indic	ate how	below	1				
More ofter	1					YES NO	0
Less time s	pent					YES N	0
Less hard						YES NO	0
Other (spec	cify)					YES NO	0
Have you c	omplete	d the d	diary th	is week	Κ.	YES N	0
Have you c Questionna	-		Patient	Resour	ce	YES N	0
Have there If yes comp applicable						YES N	0
Additional	Informat	cion					

Telephone calls cont.		

Participant ID	AMBER to Bowl Dyslacion	TELEPHONE RECORD		
	* Unclaimes Research	WEEKS 1-6		
Are there going to be any change of address/contact information prior to you next study call/appointment? If yes, ple detail.				
Telephone calls cont. (massage part	icipants only)			
Did you administer the massage yoursel	f? YES NO			
Did a carer administer the massage?	YES NO			
What position was the massage administered (Lying, semi-lying, sitting)	Lying S	emi-lying Sitting		
Time of day administered (Morning, afternoon, evening)	Morning	Afternoon Evening		
Additional information.				
DATA ENTERED ON DATABASE (SIGN & DAT	E)	M M Y Y Y		

Participant ID	\top		AMB	ER Abdomina	il Massage Dystunction ress Research			TELEPHONE RECORD WEEKS 1-6
TIMEPOINT					PLEAS	E CIRC	LE	
Weeks from baseline visit	1	2	3	4	5	\perp	6	Withdrawal
Was telephone call comple	ted?		ES	N	0			
If NO please give reason: [and do not complete the rest of	the form]							
Date of call	- M	М	M -	Υ	Υ	Υ	Y	Advice only Massage
Telephone calls – Researche								
Have you changed your diet?	mey snou	IG an.		YES	estioi	NO NO	1	res, how?
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				YES [NO		30, 112
Have you changed your fluid ir	ntake?	[\	YES [NO	If y	es, how?
Have you changed your defaed	 cation						If y	es, how?
position?				YES		NO		
Are you taking more exercise?)	\dashv_{Γ}	,	YES		NO	If y	es, how?

YES

NO

NO

If yes, how?

Have your changed any medication? If yes,

Have you changed your use of laxatives (i.e

record in Concomitant Medication Log

	Particip	oant ID					
						AMBER Rodonal Massay	TELEPHONE RECORD WEEKS 1-6
Telephone	e calls c	ont.	<u> </u>				
Has there k	oeen any	chang	e in yo	ur bow	el	YES N	0
If yes, indic	ate how	below	1				
More ofter	1					YES NO	0
Less time s	pent					YES N	0
Less hard						YES NO	0
Other (spec	cify)					YES NO	0
Have you c	omplete	d the d	diary th	is week	Κ.	YES N	0
Have you c Questionna	-		Patient	Resour	ce	YES N	0
Have there If yes comp applicable						YES N	0
Additional	Informat	cion					

Telephone calls cont.		

Participant ID	AMBER Actional Massage	TELEPHONE RECORD		
	Christiana Research	WEEKS 1-6		
Are there going to be any change of address/contact information prior to yo next study call/appointment? If yes, ple detail.				
Telephone calls cont. (massage part	icipants only)			
Did you administer the massage yoursel	f? YES NO			
Did a carer administer the massage?	YES NO			
What position was the massage administered (Lying, semi-lying, sitting)	Lying S	emi-lying Sitting		
Time of day administered (Morning, afternoon, evening)	Morning	Afternoon Evening		
Additional information.				
DATA ENTERED ON DATABASE (SIGN & DAT	E)	M M Y Y Y		

Participant ID	\top		AMB	ER Abdomina	il Massage Dystunction ress Research			TELEPHONE RECORD WEEKS 1-6
TIMEPOINT					PLEAS	E CIRC	LE	
Weeks from baseline visit	1	2	3	4	5	\perp	6	Withdrawal
Was telephone call comple	ted?		ES	N	0			
If NO please give reason: [and do not complete the rest of	the form]							
Date of call	- M	М	M -	Υ	Υ	Υ	Y	Advice only Massage
Telephone calls – Researche								
Have you changed your diet?	mey snou	IG an.		YES	estioi	NO NO	1	res, how?
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				YES [NO		30, 112
Have you changed your fluid ir	ntake?	[\	YES [NO	If y	es, how?
Have you changed your defaed	 cation						If y	es, how?
position?				YES		NO		
Are you taking more exercise?)	\dashv_{Γ}	,	YES		NO	If y	es, how?

YES

NO

NO

If yes, how?

Have your changed any medication? If yes,

Have you changed your use of laxatives (i.e

record in Concomitant Medication Log

	Particip	oant ID					
						AMBER Rodonal Massay	TELEPHONE RECORD WEEKS 1-6
Telephone	e calls c	ont.	<u> </u>				
Has there k	oeen any	chang	e in yo	ur bow	el	YES N	0
If yes, indic	ate how	below	1				
More ofter	1					YES NO	0
Less time s	pent					YES N	0
Less hard						YES NO	0
Other (spec	cify)					YES NO	0
Have you c	omplete	d the d	diary th	is week	Κ.	YES N	0
Have you c Questionna	-		Patient	Resour	ce	YES N	0
Have there If yes comp applicable						YES N	0
Additional	Informat	cion					

Telephone calls cont.		

Participant ID	AMBER Actional Massage	TELEPHONE RECORD		
	Christian Reads	WEEKS 1-6		
Are there going to be any change of address/contact information prior to yo next study call/appointment? If yes, ple detail.				
Telephone calls cont. (massage part	icipants only)			
Did you administer the massage yoursel	f? YES NO			
Did a carer administer the massage?	YES NO			
What position was the massage administered (Lying, semi-lying, sitting)	Lying S	emi-lying Sitting		
Time of day administered (Morning, afternoon, evening)	Morning	Afternoon Evening		
Additional information.				
DATA ENTERED ON DATABASE (SIGN & DAT	E)	M M Y Y Y		

Participant ID	\top		AMB	ER Abdomina	il Massage Dystunction ress Research			TELEPHONE RECORD WEEKS 1-6
TIMEPOINT					PLEAS	E CIRC	LE	
Weeks from baseline visit	1	2	3	4	5	\perp	6	Withdrawal
Was telephone call comple	ted?		ES	N	0			
If NO please give reason: [and do not complete the rest of	the form]							
Date of call	- M	М	M -	Υ	Υ	Υ	Y	Advice only Massage
Telephone calls – Researche								
Have you changed your diet?	mey snou	lu an.		YES	estioi	NO NO	1	res, how?
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				YES [NO		30, 112
Have you changed your fluid ir	ntake?	[\	YES [NO	If y	es, how?
Have you changed your defaed	 cation						If y	es, how?
position?				YES		NO		
Are you taking more exercise?)	\dashv_{Γ}	,	YES		NO	If y	es, how?

YES

NO

NO

If yes, how?

Have your changed any medication? If yes,

Have you changed your use of laxatives (i.e

record in Concomitant Medication Log

	Partici	pant ID						
						AMBER Addonnal Man	age ction search	TELEPHONE RECORD WEEKS 1-6
Telephor	ne calls c	ont.						
Has there habits?	been any	chang	e in yo	ur bow	el	YES	NO	
If yes, indicate how below								
More ofte	en					YES	NO	
Less time	spent					YES	NO	
Less hard						YES	NO	
Other (spe	ecify)					YES	NO	
Have you	complete	d the d	diary th	is week	Κ.	YES	NO	
Have you Questionr	-		Patient	Resour	ce	YES	NO	
Have there been any adverse events? If yes complete AE form and SAE if applicable						YES	NO	
Additiona	l Informa	tion						

Telephone calls cont.		

Participant ID	AMBER to the displaction	TELEPHONE RECORD				
	Continues reading	WEEKS 1-6				
Are there going to be any change of address/contact information prior to yo next study call/appointment? If yes, ple detail.						
Telephone calls cont. (massage participants only)						
Did you administer the massage yoursel	f? YES NO					
Did a carer administer the massage?	YES NO					
What position was the massage administered (Lying, semi-lying, sitting)	Lying S	emi-lying Sitting				
Time of day administered (Morning, afternoon, evening)	Morning	Afternoon Evening				
Additional information.						
DATA ENTERED ON DATABASE (SIGN & DAT	E)	M M 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
t					AMBER Adment Masage For Sout Option of South Option Enchances Roseith		CONCE TANT I	MEDICATIONS LC
			•				/ or	/ or
							//_ or	_/_/ or
							// or	_/_/ or
							// or	_/_/ or
							/ or	_/_/ or

¹All Laxatives used by participant should be added to this form

⁴Route of Administration: 1. Oral 2. Subcutaneous 3. Intramuscular 4. Intravenous 5. Rectal 6. Topical 7. Inhaled 8. Other

Signature	Date	D	D	M	M	Υ	Υ	Υ	Υ
-----------	------	---	---	---	---	---	---	---	---

AMBER CRF 1.1 26/05/2015 Page _____ of ____

²Units: μg, mg, g, mL, IU, tablet, capsule, puff, other (specify)

³Frequency: 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)

Description of adverse event (provide additional information on notes pages if required)	Date of onset DD/MM/YYYY	Date reported to Investigator /team	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
1 1	_/_/_	_/_/						/ or	//
	//_							/ or	_/_/_
	//							/ or	//
	//_							/ or	/
	//_	_/_/_						/ or	_/_/
	//	_/_/						/ or	_/_/_

AMBER CRF 1.1 26/05/2015

^{*} 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 Addonnal Massage To Bosel Optimized Efficiences Resign	24 WEEK TELEPHONE			
	YES NO	RECORD			
Was telephone call completed?					
If NO please give reason: [and do not complete the rest of the form]					
fame as not complete the rest of the form,					
Date of call	M - Y Y	Advice only Massage			
		Iviassage			
Telephone calls – Researcher should ask	the participant the follo	owing questions and clearly			
explain to participant that they should a					
		relation to the last 7 days.			
	nnswer each question in	relation to the last 7 days.			
Have you changed your diet?	YES NO	If yes, how?			
Have you changed your diet?	nnswer each question in	If yes, how?			
explain to participant that they should a Have you changed your diet? Have you changed your fluid intake? Have you changed your defaecation	YES NC	If yes, how? If yes, how?			
Have you changed your diet?	YES NO	If yes, how? If yes, how?			
Have you changed your diet? Have you changed your fluid intake? Have you changed your defaecation position?	YES NC	If yes, how? If yes, how? If yes, how?			
Have you changed your diet? Have you changed your fluid intake? Have you changed your defaecation	YES NO	If yes, how? If yes, how? If yes, how?			

Have you changed your use of laxatives (i.e

those not prescribed by GP)?

YES

If yes, how?

NO

Participant ID	AMBER Professional Massage Effectiveness Research	24 WEEK TELEPHONE		
		RECORD		
Telephone calls cont.				
Has there been any change in your bowe 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 bowel diary this week	YES NO			
Have you completed the Patient Resourc Questionnaire this week?	ee 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?	VEC			
(If YES, please give details)	YES NO			
	Details:			

Participant ID						AMBER Robornal Massaya	24 WEEK TELEPHONE		
						N Construction Frances	RECORD		

Telephone calls cont. (massage participa	ints 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?	
now often:	(indicate frequency)
Self or Carer massage?	Self Carer
Have you felt a benefit?	YES NO
DATA ENTERED ON DATABASE (SIGN & DATE)	

Participant ID	AMBER formered Massage	COMPLETION OF STUDY
	Stationness Rosearch	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]-	Υ	Υ	Υ	Υ
-------------------------------------	---	---	---	---	---	---	----	---	---	---	---

Change notif	ied at: (please	circle o	ne)				
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				AMB	Abdomnal Massage for Bowl Dystracion Effectiveness Research	COMPLETION OF STUDY						
Follo	du-wa					. (FORM PLEASE CIRCLE				
	Is there any follow-up required?						Yes No					
	If yes, please specify											
, c.	o, p.ca.	oc spec	,									

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

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	Participant ID AMBER Administration Checkman Reagen					
		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!

	Partici	oant ID	



NBD PROM Questionnaire

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

How does you	<u>ır bowel pro</u>	<u>oblen</u>	n af	fect y	<u>you?</u>
This questionnaire is designed to problem, how those symptoms a					
When answering the questions, 3 months or since you last co			-		been over the last
Date of Completion	D – M	M	\mathbb{N}	- Y	YYY
WEEK				PLEASE	CIRCLE
Indicate time point		0	6	24	Withdrawal
1. Do you ever have bowel ac	cidents (unco	ntrollo	d na	25200	of stool from the
back passage)?	•		u pa	ssaye	of stool from the
	(a	<i>-</i>			
	0[_	_ neve _			
	_	_rarely _			
	_			he time	•
	3_	_		e time	
	4_	_alway	/S		
(b) How much does this both (please ring one number be		all) an	d 10	(a grea	at deal)
0 1 2	3 4 5 6 7	8 9	10		
Not at all			а	great d	leal
2. Do you ever have an urg			our	bowe	ls?
	(a	_			
	0_	_lneve ¬ .			
	1	_rarely			
	²_ 3E			he time	•
	³ <u>_</u>			e time	
	4_	_alway	/S		
(b) How much does this be please ring one number be	•	at all)	anc	l 10 (a	great deal)
0 1 2	3 4 5 6	7 8	9 1	0	
Not at all			а	great	deal

Participant ID					AMBER Adornord Mussage	NPD PPOM Questionnaire
						NBD PROM Questionnaire

3. Do you experience any staining of your underwear or need to wear pads because of your bowel?							
	(a)						
	⁰ never						
	¹⊡rarely						
	²						
	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 Not at all	6 7 8 9 10 a great deal						

4. Using the pictures below plea of the time: tick all that apply.	se say how your bowel movements are most
Separate hard lumps, like nuts (hard to pass)	☐Type1
Sausage-shaped but lumpy	☐Type 2
Like a sausage but with cracks c	□ Туре3
Like a sausage or snake, smooth and soft	☐Type 4
Soft blobs with clear-cut edges (passed easily)	☐Type 5
Fluffy pieces with ragged edges,	□ Туре 6
mushy stool Watery, no solid pieces. Entirely Liquid	☐Type 7
(b) How much does this bother please ring one number between	you? en 0 (not at all) and 10 (a great deal)
0 1 2 3 Not at all	4 5 6 7 8 9 10 a great deal

Partici	ipant ID		AMBER Addrinal Massage To Bowl Dyskindon Edition To Bowl Dyskindon To Bowl Dyskindon	NBD PROM Questionnaire
				NBD PROM Questionnaire

5. Do you ever experience bleeding from	wour back passage?					
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					
C. Danier and facility of comment dance	n in blockedo					
6. Do you ever feel that your abdome	n is bloated? (a)					
	· ·					
	¹∐rarely —					
	² some of the time					
	³ most of the time					
	⁴囗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 (3 7 8 9 10					
Not at all	a great deal					
	o. 3 . 2 cm a. 2 cm					
7. Do you ever experience abdominal problem?	pain because of your bowel					
	(a)					
	⁰ _never					
	¹⊡rarely					
	² some of the time					
	³∏most of the time					
	<u> </u>					
	⁴ lalways					
(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					

Participant ID					AMBER Addrinal Massage For Bowel Dyshindon For Bowel Dyshindon For Bowel Dyshindon	NBD PROM Questionnaire
						NDD PROW Questionnaire

8. Do you ever experience pain in or around your back passage due to your bowel problem?					
your norman production	(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 (
0 1 2 3 4 5 (
Not at all	a great deal				
9. Do you ever find that your bowel p bladder?	roblem interferes with your				
	(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 yo you would like?	ou 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				
	<u> Пагмауо</u>				
(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				

	Partici	oant ID	



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) O 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) O 1 2 3 4 5 6 7 8 9 10 Not at all Not at all							
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							

Participant ID					AMBER Addressed Massage for Bowli Dyslandian internal financial	NPD PPOM Questionneiro
						NBD PROM Questionnaire

14. Do your bowels open when you expect them to?								
(a)								
⁰ <u></u> 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 <u></u> 15 – 30 minutes								
² <u></u> 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								

Participant ID					AMBER Advenue Massage the Storing Massage the	NBD PROM Questionnaire
						NBD PROW Questionnaire

47 Daniel I all and a standard							
17. Do you use medications to <u>stop</u> your bowels opening?							
(a) ⁰ □nover							
	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 ofroin to onen your howel	•2						
18. Do you strain to open your bowel	s: (a)						
	⁰∏never						
	¹□rarely						
	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						
(b) How much does this bother you?	⁴ [_]always						
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						

	Partici	pant ID		AMBER Addrinal Massage for Bowl Dykandon for Bowl Dykandon	NRD RROM Overtion mains
					NBD PROM Questionnaire

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 (r	-			
0 1 2 3 4 5 6	5 7 8 9 10			
Not at all	a great deal			
21. Do you feel your bowel care routing				
	(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 (r	not at all) and 10 (a great deal)			
0 1 2 3 4 5 6	5 7 8 9 10			
Not at all	a great deal			
22. Will you still go out if your bowel I	hasn't opened as expected? (a)			
	⁴ □never			
	³ □ rarely			
	² some of the time			
	¹☐most of the time			
	 º∐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	5 7 8 9 10			
Not at all	a great deal			

	Partici	pant ID		AMBER Addrinal Massage for Bowel Dystandon for Bowel Dystandon for Bowel Dystandon	NRD DROM Overtion mains
					NBD PROM Questionnaire

23. Does your bowel problem interfer						
	(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						
0 1 2 3 4 5	6 7 8 9 10					
Not at all	a great deal					
24. Does your bowel problem interfer	re with your sexual activity? (a)					
	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. Dogs your bowel problem stop w	ou going out of your home?					
25. Does your bowel problem stop yo	ou going out or your nome?					
	(a)					
	⁰ □never					
	¹ ⊡rarely					
	²∏some of the time					
	³∏most of the time					
	⁴ □always					
	<u>атмауз</u>					
(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					

	Partici	pant ID		AMBER Addrinal Massage for Bowl Dykandon for Bowl Dykandon	NRD RROM Overtion mains
					NBD PROM Questionnaire

26. Does your bowel problem interfer relationships?	e with your personal			
	(a)			
	⁰ □never			
	¹ ⊡rarely			
	² □some of the time			
	³☐most of the time			
	⁴ □always			
	∐aiways			
(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	3 7 8 9 10			
Not at all	a great deal			
27. Does your bowel problem stop yo	_			
	(a)			
	⁰ never			
	¹ □rarely			
	² some of the time			
	³ most of the time			
	⁴ ⊡always			
	□ don't exercise for other			
reasons				
(b) How much does this bother you? please ring one number between 0 (r	not at all) and 10 (a great deal)			
0 1 2 3 4 5 6	5 7 8 0 10			
Not at all	a great deal			
1101 at all	a great dear			
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	6 7 8 9 10			
Not at all	a great deal			

	Partici	pant ID		AMBER Adversal Massage To Brail Dykardon	NDD DDOM O
					NBD PROM Questionnaire

29. Do you feel you fit your life aroun	•				
	(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)					
	6 7 8 9 10				
Not at all	a great deal				
30. Are you satisfied with how you m	anage your bowel problem? (a)				
	⁴ ∏never				
	 ³∏rarely				
	²∏some of the time				
	¹∏most of the time				
	□ always				
	<u></u> аау				
(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	6 7 8 9 10				
Not at all	a great deal				
31. Does managing your bowel problem	em interfere with your life?				
on zooo managing your bonot probl	(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	6 7 8 9 10				
Not at all	a great deal				

	Partici	pant ID		AMBER Adversed Massage Bernell Of Andread Bernell Of Andread	
					NBD PROM Questionnaire

32. Does worrying about your bowel	problem interfere with your ability					
to work?	to work? (a)					
	o 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						
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?					
oo. Dood won ying about your bowe.	(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 (
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 <u></u> 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)						
	6 7 8 9 10					
Not at all	a great deal					

	Partici	pant ID		AMBER Adversal Massage To Brail Dykardon	NDD DDOM O
					NBD PROM Questionnaire

35. Do you feel embarrassed about y	our bowels?			
	(a)			
	⁰ _never			
	¹ ⊡rarely			
	² some of the time			
	³∏most of the time			
	⁴always			
(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 acciden	tal passage of wind from your			
bowel?	(a)			
	(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 y	ou feel low or depressed?			
orr zeee year zewer preziem make y	(a)			
	⁰ never			
	 ¹⊡rarely			
	²∏some of the time			
	³∏most of the time			
	<u> </u>			
	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			

	Partici	pant ID		AMBER (common Mussage to the property of the p	NPD PPOM Questionneiro
					NBD PROM Questionnaire

38. Do you avoid eating out because of your bowel problem?				
(b) How much does this bother you? please ring one number between 0 (number between 1)	(a) One never Independent of the time Some of the time Malways That all and 10 (a great deal)			
0 1 2 3 4 5 6 Not at all	6 7 8 9 10 a great deal			
39. Do you spend more time than you problem?	would like on your bowel			
(b) How much does this bother you? please ring one number between 0 (notes)	(a) Onever Inarely Some of the time Most of the time And always That all) and 10 (a great deal)			
0 1 2 3 4 5 6 Not at all	6 7 8 9 10 a great deal			
40. Do you feel you can fit managing life?	your bowel problem into your (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 (note: 1 to 2 to 3 to 5	6 7 8 9 10			
Not at all	a great deal			

Participant ID									



41. Does your bowel problem keep y like?	ou at home more than you would
	(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 0 1 2 3 4 5 Not at all	

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))									
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Participant ID								



NEUROGENIC BOWEL DYSFUNCTION SCORE

NEUROGENIC BOWEL DYSFUNCTION SO	CORE			
Date of Completion	M	- Y	Υ	Υ
WEEK		PLEASE (CIRCLE	
Indicate time point	0	6	24	Withdrawal
Consider the average for the last week	and tick on	e answer po	er questi	on.
1. Frequency of defaecation (passing a stool) Daily 2-6 times every week Le	ss than once a	week 🗌		
2. Time used for each defaecation				
0-30min	ore than one ho	our 🗌		
3. Uneasiness, headache or perspiration during do	efaecation			
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 anorec	tum			
Less than once a week Once or more than o	once a week			
7. Frequency of faecal incontinence				
Less than once every month 1-4 times p	er month			
1-6 times every week Daily				
8. Medication against faecal incontinence				
No Yes				
9. Flatus (wind) incontinence				
No Yes	SIC	ATA ENTERED ON GNATURE ATE	N DATABASE	

No 🗌

10. Perianal skin problems

(e.g. redness, irritation around the anus)

Participant ID	AMBER Accommod Massager to blowed Optivations	QUALIVEEN BLADDER
	A Commenta remove	QUESTIONNAIRE

QUALIVEEN BLADDER QUESTIONNAIRE

Date of Completion	D	D	_	M	M	M	_	Υ	Υ	Υ	Υ	
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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?	По	\square_1	\square_2	□₃	□ 4
2.	Are you bothered by the time spent passing urine or realizing catheterization	□ ₀	\square_1	□ ₂	□3	□4
3.	Do you worry about your bladder problems worsening	По	\square_1	□ ₂	□3	D ₄
4.	Do you worry about smelling of urine	\square_0	\square_1	\square_2	\square_3	\square_4
5.	Do you feel worried because of your bladder problems	\square_0	\square_1	□2	□3	□ 4
6.	Do you feel embarrassed because of your bladder problems	□ ₀		□ ₂	□3	D ₄
		Never	Rarely	From time to time	Often	Always
7.	Is your life regulated by your bladder problems?	\square_0	\square_1	\square_2	\square_3	□4
8.	Can you go out without planning anything in advance?	□4	□3	\square_2	\square_1	\square_0
	•					

Thank you for valuable help

DATA ENTERED ON DATABASE (SIGN & DATE)									
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AMBI		oant ID	Partici	
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CONSTIPATION SCORING SYSTEM

									$\overline{}$		
Date of Completion	D	D	-	M	\mathbb{N}	\mathbb{N}	-	Υ	Υ	Υ	Υ

WEEK		PLEAS	E CIRCLE	
Indicate time point	0	6	24	Withdrawal

Please tick one answer per question with average values over the <u>last week</u>

Francisco of houseless control		Time a main that at the link or an attached	1
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		Failure : unsuccessful attempts for	
evacuation		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	
	1	1	1

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

Participant ID

AMBER Adoned Massage
Federates Ready



Health Questionnaire

English version for the UK

Date of Completion

WEEK		PLEAS	E CIRCLE	
Indicate time point	0	6	24	Withdrawal

	Partici	pant ID		AMBER According Massage	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	

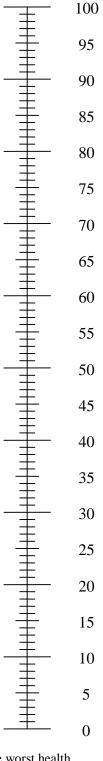
	Partici	pant ID		AMBER Administ Massage The Bear Dystrocon	EQ-5D-5L HEALTH
					QUESTIONNAIRE

The best health you can imagine

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
 0 means the <u>worst</u> 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



The worst health you can imagine

	Partici	oant 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	Υ	Υ	Υ			

Patient Resource Use Fo	rm
because of your bo	c or since you last completed this form have you done any of the following owel problems? If yes please tell us the number of times (please be sure to 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 Yes, because of other Health reasons Please write in the number of times Please write in the number of times
b) Have you been seen by a nurse at a doctor's surgery?	Yes, because of my bowel problems Yes, because of other Health reasons Please write in the number of times Please write in the number of times
c) Have you spoken to a doctor on the telephone?	Yes, because of my bowel problems Yes, because of other Health reasons Please write in the number of times Please write in the number of times
d) Have you spoken to a nurse on the telephone?	Yes, because of my bowel problems Yes, because of other Health reasons Please write in the number of times Please write in the number of times

Partici	pant ID		AMBER to bred typhration	PATIENT RESOURCE USE
				FORM

Patient Resource Use Form Cont.												
	or since you last completed this form have you done any of the following well 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	Yes, because of my bowel problems Please write in the number of times											
outpatient department?	Yes, because of other Health reasons Please write in the number of times											
	No											

Participant ID					AMBER Address Massage	PATIENT RESOURCE USE
						FORM

Patient Resource Use Form Cont.													
	c or since you last completed this form have you done any of the following well problems (Continued)	ng											
i) Have you been admitted to a hospital as an inpatient or day	Yes, because of my bowel problems Please write in the number of times												
patient?	Yes, because of other Health reasons No Please write in the number of times												
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	Yes, because of my bowel problems Please write in the number of times												
continence advisor, dietician, occupational therapist,	Yes, because of other Health reasons Please write in the number of times												
physiotherapist)?	No												
I) 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						AMBER Accommon Massager to blow Oxford com	PATIENT RESOURCE USE
						N Comments remove	FORM

Medications											
2. Over the last 1 week or since you last you been prescribed any medications, for 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 d	o you take this?								
Medications cont.											
3. Over the last 1 week or since you last you bought any medications, for your b pharmacy or other shop?	· ·		YES NO								
If yes, please write down the name of the page if needed).	ne medication and	I how much yo	ou spent (continue on a separate								
Please give the name of the medication		How much did you pay for it overall?									
(brand name if possible)											

Participant ID	AMBER Accommon Massager to blow Oxford com	PATIENT RESOURCE USE
	A Commenta remove	FORM

Equipment and clothing.											
4. Over the last 1 week or since you last completed this for you spent any money on equipment or clothing because 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).											
lease 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 for you been provided with any specialist equipment by the Services or Social Services because of your bowel proble	Health	YES NO									
If yes, please write down what was provided											
DATA ENTERED ON DATABASE (SIGN & DATE)											
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	Particip	oant ID		AMBER Accommon Massager to Bowel Oylandorn	7 DAY BOWEL DIARY
				W Commence of the Commence of	7 DAY BOWEL DIARY

7 DAY BOWEL DIARY

Date of starting diary	D	D	_	M	M	M	_	Υ	Υ	Υ	Υ
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WEEK		PLEASE CIRCLE							
Indicate time point (weeks	Pre-intervention	1	2	3	4	5	6	23	Withdrawal
from baseline visit)									

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	YES	YES	YES	YES	YES	YES				
	NO	NO	NO	NO	NO	NO	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	YES	YES	YES	YES	YES	YES	YES				
your bowel?	NO	NO	NO	NO	NO	NO	NO				
In total how long did you spend on the toilet? (minutes)											
How much did you drink today?	USUAL*	USUAL	USUAL	USUAL	USUAL	USUAL	USUAL				
	MORE	MORE	MORE	MORE	MORE	MORE	MORE				
	LESS	LESS	LESS	LESS	LESS	LESS	LESS				
Laxative use	USUAL**	USUAL	USUAL	USUAL	USUAL	USUAL	USUAL				
	MORE	MORE	MORE	MORE	MORE	MORE	MORE				
	LESS	LESS	LESS	LESS	LESS	LESS	LESS				
Did you use digital stimulation?	YES	YES	YES	YES	YES	YES	YES				
(gentle touching of wall of anus or rectum)	NO	NO	NO	NO	NO	NO	NO				
Did you have a bowel accident	YES	YES	YES	YES	YES	YES	YES				
today?	NO	NO	NO	NO	NO	NO	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	Υ	Y				

^{*} Usual is the amount you would normally drink

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

^{**} Usual laxative means the amount you would have taken before entering the study

Participant ID									



7 DAY BOWEL & MASSAGE DIARY

7 DAY BOWEL & MASSAGE DIARY

Date of starting diary

WEEK	PLEASE CIRCLE								
Indicate time point (weeks from	າ 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	YES	YES	YES	YES	YES	YES			
	NO	NO	NO	NO	NO	NO	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	YES	YES	YES	YES	YES	YES			
	NO	NO	NO	NO	NO	NO	NO			
In total how long did you spend on the toilet? (minutes)										
How much did you drink today?	USUAL*	USUAL	USUAL	USUAL	USUAL	USUAL	USUAL			
	MORE	MORE	MORE	MORE	MORE	MORE	MORE			
	LESS	LESS	LESS	LESS	LESS	LESS	LESS			
Laxative use	USUAL**	USUAL	USUAL	USUAL	USUAL	USUAL	USUAL			
	MORE	MORE	MORE	MORE	MORE	MORE	MORE			
	LESS	LESS	LESS	LESS	LESS	LESS	LESS			
Did you use digital stimulation?	YES	YES	YES	YES	YES	YES	YES			
(gentle touching of wall of anus or rectum)	NO	NO	NO	NO	NO	NO	NO			
Did you have a bowel accident today?	YES	YES	YES	YES	YES	YES	YES			
	NO	NO	NO	NO	NO	NO	NO			
Was massage performed today?	YES	YES	YES	YES	YES	YES	YES			
	NO	NO	NO	NO	NO	NO	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 -	Υ	ΥΥ			

^{*} Usual is the amount you would normally drink

DATA ENTERED ON DATABASE (OFFICE USE ONLY)											
SIGN	ATURE										
DATE											
D	D -	M	M	M -	Υ	Υ	Υ	Υ			

^{**} Usual laxative means the amount you would have taken before entering the study