

# Feasibility of abdominal massage for the alleviation of the symptoms of constipation in people with multiple sclerosis

<b>Submission date</b> 19/11/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/01/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/12/2012	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Doreen McClurg

**Contact details**  
Nursing Midwifery and Allied Health Professions Research Unit (NMAHPRU)  
Glasgow Caledonian University  
Buchanan House  
Glasgow  
United Kingdom  
G4 0BA  
+44 (0)141 331 8105  
Doreen.mcclurg@gcal.ac.uk

## Additional identifiers

**Protocol serial number**  
08/NIR02/80

## Study information

**Scientific Title**

A randomised controlled pilot study to assess the feasibility of abdominal massage for the alleviation of the symptoms of constipation in people with multiple sclerosis

**Acronym**

ABMIMS

**Study objectives**

Abdominal massage will relieve some of the symptoms of constipation in people with multiple sclerosis.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Office for Research Ethics Committees Northern Ireland (ORECNI) 25th September 2008 (ref: 08/NIR02/80)

**Study design**

Pilot study, two-group randomised controlled clinical trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Multiple sclerosis

**Interventions**

Following expressing an interest in the study, potential participants will be provided with verbal and written information concerning their involvement and informed consent will be obtained. Providing screening is satisfactory, participants will then be randomly allocated to a treatment and a control group. Baseline outcome measures will be undertaken at this point by a research assistant who will be blind to group allocation:

1. Constipation Scoring System
2. Neurogenic Bowel Dysfunction Score
3. Bowel Diary
4. 29-item Multiple Sclerosis Impact Scale (MSIS-29)
5. Qualiveen Questionnaire

The intervention group will then be visited in their own home, provided with advice on good bowel habits and they and/or their carers will be shown how to undertake abdominal massage. This will be undertaken daily for 15 minutes for 4 weeks. A DVD demonstrating the technique will be left, and they will be visited at least once a week by the clinician to provide further training and support.

The control group will be visited in their own home and provided with advice on good bowel habits. This group will be visited once a week for 4 weeks.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Constipation scoring system, undertaken at the end of the intervention period (week 4) and 4 weeks later (week 8).

**Key secondary outcome(s)**

1. Neurogenic Bowel Dysfunction Score
2. Bowel Diary
3. Qualiveen Questionnaire
4. 29-item Multiple Sclerosis Impact Scale (MSIS-29)

Outcome measures will be undertaken at the end of the intervention period (week 4) and 4 weeks later (week 8).

**Completion date**

01/11/2009

## **Eligibility**

**Key inclusion criteria**

1. Constipation as defined by the Rome II criteria
2. Age range over 18 years, male or female

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Bowel cancer
2. Stoma
3. Abdominal surgery (inside last year)

**Date of first enrolment**

01/11/2008

**Date of final enrolment**

01/11/2009

## Locations

**Countries of recruitment**

United Kingdom

Scotland

**Study participating centre**

**Nursing Midwifery and Allied Health Professions Research Unit (NMAHPRU)**

Glasgow

United Kingdom

G4 0BA

## Sponsor information

**Organisation**

Nursing Midwifery and Allied Health Professions Research Unit (UK)

**ROR**

<https://ror.org/03dvm1235>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Multiple Sclerosis Trust (UK)

**Alternative Name(s)**

The Multiple Sclerosis Trust, MS, MS Trust

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/02/2011		Yes	No