

# 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## 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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure**

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

**Secondary outcome measures**

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).

**Overall study start date**

01/11/2008

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

30

**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**

Scotland

United Kingdom

**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)

**Sponsor details**

Glasgow Caledonian University

Buchanan House

Glasgow  
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G4 OBA

**Sponsor type**

Research organisation

**Website**

<http://www/nmahpru.gcal.ac.uk>

**ROR**

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

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Multiple Sclerosis Trust (UK)

**Alternative Name(s)**

MS, MS Trust

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**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