

Abdominal massage for bowel dysfunction in people with multiple sclerosis

Submission date 17/06/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 26/06/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/07/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims?

Multiple sclerosis (MS) is a common life-long neurological condition primarily affecting younger adults. It causes a wide range of symptoms, including problems with muscle movement, balance and vision. Loss of normal bowel function, otherwise called neurogenic bowel dysfunction (NBD) occurs in 60% of these patients. This condition is caused by damage to the nerves controlling defaecation and results in constipation and faecal incontinence (FI). Constipation can cause pain, and prolonged and difficult passing of stool. It can also, if left untreated, lead to impaction (solid, immobile block of faeces in the rectum) which often needs to be treated in hospital. FI has devastating consequences for a person socially and psychologically. NBD can also result in a number of complications such as haemorrhoids, rectal prolapse, anal tear, and the worsening of urinary symptoms or limb spasticity. Treatment of the condition is a step-wise process. Patients are first advised on diet and fluid intake and treated with laxatives or constipating medication. If this proves unsuccessful, rectal interventions such as use of fingers to stimulate the bowel and suppositories are used. Finally, more expensive and invasive treatment can be used; this includes rectal irrigation (washing out the rectum with fluid), and surgery. Bowel care can play a significant part in the lives of patients with MS with some reporting spending hours trying to go to the toilet. Constipation is mainly caused by a decrease in the rate that food moves along the colon. In people with MS there is little effective or evidence based advice on management of bowel dysfunction. We did, however, conduct an initial study that suggested that it is of potential benefit as part of a package of care.

Who can participate?

Adults (18 or over) who have been diagnosed with MS and are willing give themselves a massage or have a carer able to do so for them.

What does the study involve?

Patients are allocated at random to either an intervention group (abdominal massage and optimised bowel care) or a control group (optimised bowel care). Optimised means the participants usual bowel care and small non-medicinal changes, if warranted, following discussions with the nurse e.g. fluid intake. The intervention group are seen once for one hour at their routine out-patient clinic appointment. In addition to discussions of current bowel management they and or their carer are provided with an information pack and an abdominal

massage training DVD. The nurse will undertake the massage on the participant and show them and/or the carer how to do it. The massage takes around 10 minutes and consists of 4 standard strokes: stroking, effleurage, palmar kneading and vibration. During the following 6 weeks home massage will be recommended as part of their usual bowel care programme, and weekly telephone calls will be made by the researcher to discuss the massage and bowel care. Telephone back-up during office hours will also be provided. The control group are also seen once for one hour at their routine out-patient clinic appointment. The nurse will discuss current bowel management, provide them with the information pack (minus the massage information) and will arrange to telephone them weekly during the following 6 week period to discuss bowel care.

What are the possible benefits and risks of participating?

There are no risks from the intervention per se. The benefits are an additional treatment which does not involve drugs etc, and can be part of a self-management program.

Where is the study run from?

Glasgow Caledonian University (UK)

When is study starting and how long is it expected to run for?

July 2014 to June 2017

Who is funding the study?

The Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT03166007

Protocol serial number

12/127

Study information

Scientific Title

Abdominal massage for neurogenic bowel dysfunction in people with multiple sclerosis:
Abdominal Massage for Bowel Dysfunction Effectiveness Research (AMBER)

Acronym

AMBER

Study objectives

Abdominal massage with advice on bowel management is more effective for the relief of symptoms compared to advice alone

Ethics approval required

Old ethics approval format

Ethics approval(s)

West of Scotland Rec 4, 11/06/2014, ref. 14/WS/0111

Study design

2 group parallel design RCT

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multiple sclerosis/bowel disorders

Interventions

This is a two group study where patients are allocated at random to either:

1. The intervention group - patients and/or their carers receive training in abdominal massage and optimised bowel care
2. Control group - patients receive optimised bowel care only

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Neurogenic bowel dysfunction score

Key secondary outcome(s)

1. Constipation scoring System
2. Qualiveen questionnaire
3. SF 22
4. EQ 5D
5. Bowel diary
6. Transit study tests (one centre)

All questionnaire outcome data will be collected at baseline, and at 6 and 24 weeks. A massage diary will be completed during weeks 1-6 which will record when the massage was undertaken. A bowel diary will be completed by all patients during the week before the intervention starts, Week 6 and week 24.

Completion date

30/06/2017

Eligibility

Key inclusion criteria

1. Diagnosis of MS
2. Over the age of 18
3. No contraindications to abdominal massage e.g. pelvic cancer, hiatus, inguinal or umbilical hernia, rectal prolapse, irritable bowel disease and pregnancy, skin disease
4. Willing to undertake massage or have a carer able to undertake the massage

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

MS relapse

Date of first enrolment

01/07/2014

Date of final enrolment

30/06/2017

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

NMAHP RU

Glasgow

United Kingdom

G4 0BA

Sponsor information**Organisation**

Glasgow Caledonian University (UK)

ROR

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

Funder(s)**Funder type**

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2018		Yes	No
Protocol article	protocol	29/03/2017		Yes	No
HRA research summary			28/06/2023	No	No