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Abdominal massage for bowel dysfunction in people with multiple sclerosis

Submission date
17/06/2014

Recruitment status
No longer recruiting

Registration date
26/06/2014

Overall study status
Completed

Last Edited
31/07/2019

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 called 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, led 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 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?
Dr Doreen McClurg
doreen.mcclurg@gcu.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Doreen McClurg

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03166007

Secondary identifying numbers
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

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 following contact details to request a patient information sheet: Dr Doreen McClurg, NMAHP RU, Glasgow Caledonian University, G4 0BA, or telephone 0141 331 9105 or email Doreen.mcclurg@gcu.ac.uk

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 measure
Neurogenic bowel dysfunction score

Secondary outcome measures
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.

Overall study start date
01/07/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
MS relapse

Date of first enrolment
01/07/2014

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
NMAHP RU
Glasgow
United Kingdom
G4 0BA

Sponsor information

Organisation
Glasgow Caledonian University (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?
Protocol article	protocol	29/03/2017		Yes	No
Results article	results	01/10/2018		Yes	No

HRA research summary	28/06/2023	No	No