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

Submission date
19/11/2008

Recruitment status
No longer recruiting

Registration date
05/01/2009

Overall study status
Completed

Last Edited
07/12/2012

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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

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
United Kingdom
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?
Results article	results	01/02/2011		Yes	No