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Feasibility study to compare self-help interventions of fatigue management in patients with multiple sclerosis: a randomised controlled trial

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 24/10/2016	**Condition category** Nervous System Diseases	

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
N0050171956

Study information

Scientific Title
Feasibility study to compare self-help interventions of fatigue management in patients with multiple sclerosis: a randomised controlled trial

Study objectives
Does a self-help leaflet based on cognitive behaviour therapy principles improve patients ability to cope with symptoms of fatigue compared with the current leaflet.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Multiple sclerosis (MS)

Interventions
Feasibility study organised as a pilot randomised controlled trial comparing cognitive behaviour self help leaflet with standard fatigue advice leaflet.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Increased ability to cope with fatigue scale and Hospital Anxiety and Depression Scale (HADS).

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/09/2005

Completion date
31/05/2006

Eligibility

Key inclusion criteria
All patients will be identified from the MS Nurse's current caseload and will have identified fatigue as a significant symptom in the last 12 months.
Inclusion Criteria:
1. Patients with Relapsing Remitting Multiple Sclerosis who are usually ambulant
2. Score of between 3-4 on the fatigue questionnaire
3. Over 18 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
32 participants

Key exclusion criteria
1. Patients who do not wish to be involved in the study
2. Patients receiving anti-fatigue medication (amantadine)

Date of first enrolment
16/09/2005

Date of final enrolment
31/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St lukes Hospital
Bradford
United Kingdom
BD5 0NA

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Bradford Teaching Hospitals NHS Foundation Trust

Funder Name
Bradford Royal Infirmary

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