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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

Protocol serial number
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

Study type(s)
Not Specified

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

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

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
United Kingdom

England

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

Funder(s)

Funder type
Government

Funder Name
Bradford Teaching Hospitals NHS Foundation Trust

Funder Name
Bradford Royal Infirmary

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration