

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
Registration date 29/09/2006	Overall study status Completed	☐ Protocol
Last Edited 24/10/2016	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

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