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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Miss Liz Watson

Contact details

St Lukes Hospital Little Horton Lane Bradford United Kingdom BD5 0NA +44 (0)1274 365249 liz.watson@bradfordhospitals.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

 ${\bf Clinical Trials. gov\ number}$

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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration