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Evidence-Based Self-management In Multiple Sclerosis (EBSIMS). A multi-centre, randomised controlled trial to investigate the effects of a structured educational programme on relapse management in Multiple Sclerosis.

Submission date 08/07/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/08/2004	**Overall study status** Completed	
Last Edited 19/08/2009	**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
GMQQ010401

Study information

Scientific Title

Acronym
EBSIMS

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Relapsing-remitting Multiple Sclerosis (MS)

Interventions
Intervention group:
Participants in the intervention group are provided with a brochure, critically appraising the evidence on relapses and relapse management, considering aspects of evidence-based medicine and evidence-based patient information. Participants take part in a 5-hour nurse-led training session and are subsequently given the opportunity to receive a prescription for methylpredisolone tablets (25 x 100 mg) allowing them to take 500 mg for 5 days in case of a relapse. If the medication has been used a new subscription can be obtained. Participants in the

intervention group may still decide to receive intravenous treatment at their neurologist's office or a hospital.

Control group:
Participants in the control group are given a leaflet informing them about relapse treatment, including the possibility of oral steroid therapy.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Percentage of relapses without steroid-treatment or with oral steroid-treatment within 2 years of follow-up.

Secondary outcome measures
1. Time to initiation of treatment
2. Overall costs
3. Characteristics of steroid-treatments
4. Changes in autonomy preferences
5. Protection motivation
6. Quality of life
7. Relapse severity
8. Adverse treatment effects
9. Other clinical variables

Overall study start date
01/04/2003

Completion date
30/04/2005

Eligibility

Key inclusion criteria
Patients with relapsing-remitting Multiple Sclerosis (MS), with at least 2 relapses in the last 24 months or at least one relapse in the last 12 months.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Added 19/08/09 ;

Key exclusion criteria
Patients with severe cognitive deficits or pregnancy

Date of first enrolment
01/04/2003

Date of final enrolment
30/04/2005

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Eppendorf
Hamburg
Germany
D-20246

Sponsor information

Organisation
University of Hamburg (Germany)

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Sponsor type
University/education

ROR
https://ror.org/04bs1pb34

Funder(s)

Funder type
Government

Funder Name
German Ministry of Health (Germany)

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	01/01/2009		Yes	No