

Patient education programme for early multiple sclerosis (MS)

Submission date 07/04/2009	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 14/05/2009	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 07/03/2014	Condition category Nervous System Diseases	☐ Individual participant data

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
Inims3

Study information

Scientific Title
Effectiveness of a patient education program about diagnosis, prognosis and early treatment in multiple sclerosis: a randomised controlled trial

Acronym

Study objectives

The study aims to assess the effects of an evidence-based patient education programme on multiple sclerosis (MS) diagnosis, prognosis and early treatment for patients in the first year of the disease. We hypothesise that the educational programme:

1. Increases relevant disease-related risk-knowledge and promotes informed choice
2. Promotes sense of control, decision autonomy and satisfaction
3. As a result leads to an altered, i.e., more rational approach to immunotherapies, and
4. Reduces anxiety and depression

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Hamburg Chamber of Physicians approved on the 12th March 2009 (ref: PV3164)

Study design

Multicentre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multiple sclerosis (MS)

Interventions

Experimental intervention:

Patient education programme based on the principles of evidence-based patient information comprising an educational booklet on MS diagnosis, prognosis and early therapy and a four-hour small group teaching programme.

Control intervention:

Four-hour small group stress management and coping training and standard information leaflet on diagnosis, prognosis and early therapy.

Follow-up will be 12 months for both groups.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Informed choice (IC) about initiation or continuation of immunotherapies after 6 months of follow-up using an adaptation of the Multidimensional Measure of Informed Choice (MMIC),

comprising appropriate disease-related risk-knowledge and consistency between attitude and decision.

Key secondary outcome(s)

1. Control beliefs, assessed 2 weeks before the intervention and at the end of follow-up using the German questionnaire on control beliefs in illness (KKG)
2. Decision autonomy, assessed 2 weeks before the intervention and at the end of follow-up using the using a previously used scale based on the Control Preference Scale
3. Decision conflict and satisfaction with the decision will be assessed 2 weeks before the intervention and at the end of follow-up using the Decisional Conflict Scale (DCS)
4. Anxiety and depression, assessed after randomisation, three months after the intervention, and at the end of follow-up using the Hospital Anxiety and Depression Scale (HADS)
5. Number of newly initiated and discontinued immunotherapies (participants on immunotherapy 12 months after the intervention), assessed by telephone interview at randomisation and 3, 6, 9, and 12 months after the intervention using a standardised protocol used in an earlier trial
6. Disease related resource use (costs) will be assessed by telephone interview at randomisation and 3, 6, 9, and 12 months after the intervention using a standardised protocol that has been successfully used in an earlier trials

Assessment of safety:

7. Disease progression, measured with a validated German version of the UNDS at randomisation and the end of follow-up. The instrument has been successfully used in an earlier trial.
8. Health-related quality of life, assessed 2 weeks before the intervention and at the end of follow-up using the HAQUAMS instrument

Completion date

15/04/2011

Eligibility

Key inclusion criteria

1. Possible or definite relapsing form of MS following revised McDonald criteria
2. Diagnosis within the last 12 months
3. Aged 18 - 60 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Major cognitive deficit
2. Progressive form of MS

Date of first enrolment

15/04/2009

Date of final enrolment

15/04/2011

Locations**Countries of recruitment**

Germany

Study participating centre

Institute of Neuroimmunology and Clinical MS Research (INIMS)

Hamburg

Germany

20246

Sponsor information**Organisation**

Merck Serono (Germany)

ROR

<https://ror.org/04b2dt93>

Funder(s)**Funder type**

Industry

Funder Name

Merck Serono (Germany)

Funder Name

National MS Society (USA)

Results and Publications

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	01/04/2014		Yes	No