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Patient education programme for early multiple sclerosis (MS)

Submission date	Recruitment status	[ ] Prospectively registered
07/04/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/05/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/03/2014	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
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

PEPADIP

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)

Primary study design
Interventional

Study design
Multicentre randomised controlled trial

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 succesfully 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 succesfully 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/04b2dty93

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