

Patient education programme for early multiple sclerosis (MS)

Submission date 07/04/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/05/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/03/2014	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Christoph Heesen

Contact details
Institute of Neuroimmunology and Clinical MS Research (INIMS)
Martinistrasse 52
Hamburg
Germany
20246
heesen@uke.uni-hamburg.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design

Multicentre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

15/04/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

190

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)

Sponsor details

Gutenbergstr. 5
Unterschleißheim
Germany
85716
norbert.zessack@merckserono.net

Sponsor type

Industry

Website

<http://www.merckserono.com/en/index.html>

ROR

<https://ror.org/04b2dty93>

Funder(s)**Funder type**

Industry

Funder Name

Merck Serono (Germany)

Funder Name

National MS Society (USA)

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				

[Results article](#)

01/04/2014

Yes

No