ISRCTN83438362 https://doi.org/10.1186/ISRCTN83438362

Patient Education Programme for Multiple Sclerosis (MS) Immunotherapy

Submission date	Recruitment status	[_] Prospectively registered
27/03/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/04/2016	Nervous System Diseases	

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)
Martinistr. 52
Hamburg
Germany
20246
-
heesen@uke.uni-hamburg.de

Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Effectiveness of a patient education programme on immunotherapy in multiple sclerosis - a multicentre controlled trial

Acronym
PEPIMS

Study objectives
The study aims to assess the effects of an inter-active evidence based patient education programme on disease modifying therapy (immunotherapy) in multiple sclerosis (MS). We hypothesise that the educational programme:
1. Increases relevant disease-related risk-knowledge and promotes informed choice
2. Increases decision autonomy and satisfaction
3. As a result leads to an altered, i.e., more rational approach to immunotherapies
4. Reduces anxiety and depression

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hamburg Chamber of Physicians, 03/12/2009, ref: PV3385

Primary study design
Interventional

Study design
Multicentre controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
1. Experimental intervention:
Patient education programme based on the principles of evidence-based patient information comprising an educational booklet on MS immunotherapy and a two-part 2- and 4-hour small group educational programme.

2. Control intervention:
Standard information leaflet on MS immunotherapy alongside standard rehabilitation programme.

Both interventions will be provided during patients' stay in the rehabilitation clinic (duration: usually 3 to 4 weeks).

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. Autonomy preference assessed in the first week of rehabilitation (before the intervention) and after 6 months using a previously used scale based on the Control Preference Scale (CPS)
2. Risk knowledge after 6 months
3. Decision conflict and satisfaction with the decision assessed after 6 months using the Decisional Conflict Scale (DCS)
4. Anxiety and depression assessed in the third or fourth weeks of rehabilitation (after the intervention) using the Hospital Anxiety and Depression Scale (HADS)
5. Number of newly initiated and discontinued immunotherapies (participants on immunotherapy after 6 months) assessed at baseline and by telephone interview after 3 and 6 months using a standardised protocol used in earlier trials
6. Disease related resource use (costs) assessed at baseline and by telephone interview after 3 and 6 months using a standardised protocol used in earlier trials
7. Self-efficacy assessed at baseline and after 6 months using the RIGBY scale
8. Fatigue assessed at baseline and after 6 months using the Würzburg Fatigue Inventory for Multiple Sclerosis (WEIMuS) Scale

Assessment of safety:
9. Disease progression assessed at baseline and after 6 months with a validated German version of the United Kingdom Disability Scale (UNDS) instrument
10. Health-related quality of life assessed at baseline and after 6 months using the 36-item Short Form Health Survey (SF36) instrument

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Possible or definite MS following revised McDonald criteria
2. Attending rehabilitation programme in participating rehab centres during study period
3. Aged 18 - 65 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. Inability to independently fill in questionnaires, e.g., due to ataxia

Date of first enrolment
01/04/2010

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
Germany

Study participating centre
Institute of Neuroimmunology and Clinical MS Research (INIMS)
Hamburg
Germany
20246

Sponsor information

Organisation
Association for the Advancement of Rehabilitation Research in Schleswig-Holstein (VFFR) (Germany)

Funder(s)

Funder type
Research organisation

Funder Name
Association for the Advancement of Rehabilitation Research in Schleswig-Holstein (Verein zur Förderung der Rehabilitationsforschung in Schleswig-Holstein e.V. [VFFR]) (Germany)

Funder Name

National Multiple Sclerosis Society

Alternative Name(s)
National MS Society, The National Multiple Sclerosis Society, The National MS Society, National Multiple Sclerosis Society, Inc., Association for Advancement of Research on Multiple Sclerosis, Sociedad Nacional de Esclerosis, Sociedad Nacional de Esclerosis Múltiple, NMSS

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

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	12/04/2016		Yes	No