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Informed Shared Decision making In Multiple Sclerosis immunotherapy (ISDIMS). A randomised controlled trial to investigate the effects of an evidence-based decision aid on decision-making about immunotherapy in multiple sclerosis.

Submission date
08/07/2004

Recruitment status
No longer recruiting

Registration date
09/08/2004

Overall study status
Completed

Last Edited
27/10/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

GMQQ01019401

Study information

Scientific Title
Informed Shared Decision making In Multiple Sclerosis immunotherapy (ISDIMS). A randomised controlled trial to investigate the effects of an evidence-based decision aid on decision-making about immunotherapy in multiple sclerosis.

Acronym
ISDIMS

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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

Interventions
Patients will be recruited nationwide through newspapers, self-help-group publications and the internet. Patients within a decision process about immunotherapy will be included. Those are either patients on therapy willing to re-evaluate their decision or patients about to make a therapeutic decision. A presupposition for this is an appointment with the treating neurologist in the near future.
Intervention group:
Participants in the intervention group are provided with a 'Decision Aid' including a comprehensive evidence based MS patient information about options of immunotherapy and an interactive working sheet to be dealt with before the appointment with the neurologist.

Control group:
Participants in the control group receive a set of standard information made available and recommended by the German MS-society.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Primary endpoint are the 'realized role preferences' defined as the difference between autonomy preferences (pre intervention) and performed autonomy (post appointment). A difference as small as possible is defined as the desirable outcome. Secondary endpoints include the number of continued, changed, interrupted, or newly started immunotherapies. Also, analyses of the 'shared decision process' and 'decision evaluation' are performed. We also look at a number of control parameters (eg. other information sources, time to initiation of treatment, control beliefs, etc.) and clinical variables (disability status and disease activity).

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Patients with multiple sclerosis who consider a new immunotherapy or who are willing to reconsider a decision (no selection of certain disease courses).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Total final enrolment
297

Key exclusion criteria
Patients with a major cognitive deficit and/or who do not agree to data check at health insurance companies are excluded.

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Eppendorf
Hamburg
Germany
D-20246

Sponsor information

Organisation
University of Hamburg

ROR
https://ror.org/04bs1pb34

Funder(s)

Funder type
Government

Funder Name
German Ministry of Health

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		01/12/2008	27/10/2022	Yes	No
Other publications	validation study	01/01/2011		Yes	No