

# 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.

<b>Submission date</b> 08/07/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 09/08/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/10/2022	<b>Condition category</b> 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

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## Additional identifiers

Protocol serial number

## 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

### Study design

Randomised controlled trial

### Primary study design

Interventional

### 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?
<a href="#">Results article</a>		01/12/2008	27/10/2022	Yes	No
<a href="#">Other publications</a>	validation study	01/01/2011		Yes	No

