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Nurse-led immunotherapy decision coaching in persons with relapsing-remitting multiple sclerosis (DECIMS)

Submission date	Recruitment status	[X] Prospectively registered
08/04/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/05/2014	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
31/05/2016	Nervous System Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Due to the growing number of available immunotherapy drugs for patients with Multiple Sclerosis (MS), decisions on drug treatment have become more complex. Moreover, the costs of treatments are high with many patients stopping treatment after a while. This study aims to find out whether patients with MS benefit from detailed information about immunotherapy treatment options, provided by trained MS nurses (called decision coaches). These coaches will support patients in the decision-making process. Patients will receive high-quality information and coaches will discuss this information with patients using a shared communication approach. This shared decision-making approach aims to present and discuss the available evidence on immunotherapy equally between patient and Coach. We expect that more active participation of patients in immunotherapy decision making will increase patients knowledge, improve adherence to decisions and lead to a higher decision quality.

Who can participate?
We will include 300 patients with suspected or the relapsing form of MS (relapsing-remitting MS) who are facing a decision on starting, stopping, or changing MS immunotherapy.

What does the study involve?
Interested nurses from five of 10 randomly chosen major MS centres in Germany will be trained to achieve the relevant skills in order to perform the decision coaching. In the remaining five centres, no coaches will be trained. About 30 patients per centre will take part in the study. All patients will get access to an internet-based information platform. In five centres (intervention centres), participating patients will receive the decision coaching. The decision coaching consists of up to three face-to-face coaching sessions with the decision coach, before the final consultation with the doctor takes place. Patients in the other five centres (control centres) will, apart from access to the information platform, receive regular care. Participating patients have to fill in a number of online questionnaires at different time points during the study; they will also be interviewed via telephone. After the study, results from both groups will be compared to find out whether decision coaching is helpful for patients and if it enables patients to make better and more sustainable decisions.

What are the possible benefits and risks of participating?
We expect that in the intervention centres decision coaching leads to more active participation in decision making on immunotherapy. Patients relevant knowledge will increase and lead to more informed decisions and therefore to improved adherence. We think that patients will benefit from the opportunity to reflect longer on the different options and from the personal and individually adapted contact with the decision coach. We do not foresee any serious risks concerning our intervention. However, it is possible that patients are disappointed about the scientific uncertainties of the immunotherapy options.

Where is the study run from?
The study will be conducted in 10 MS centres in Germany: Hamburg, Bochum, Heidelberg, Bad-Mergentheim, Berlin, Osnabrück, Gießen, Düsseldorf, Rostock and Münster).

When is the study starting and how long is it expected to run for?
June 2014 to November 2015

Who is funding the study?
Federal Ministry of Education and Research within the Competence Network Multiple Sclerosis (Kompetenznetz Multiple Sklerose KKNMS) (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
01GI1206

Study information

Scientific Title

Nurse-led Immunotherapy DEcision Coaching In persons with relapsing-remitting Multiple Sclerosis (DECIMS) an evaluator-blinded cluster randomised controlled trial

Acronym
DECIMS

Study objectives
We hypothesise that structural changes in immunotherapy decision making, including redistribution of tasks between specialist nurses (decision coaches) and physicians, will enhance elaborated decisions and improve health-care management in MS. First, it will empower patients to make more informed decisions tailored to their preferences and values leading to more informed choices. Second, decisional conflict will be diminished and decisional adherence maintained. Third, decisional encounters will demonstrate more sharing in decision making. Finally, self-efficacy and coping competences will be enhanced.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hamburg Chamber of Physicians, 23/01/2014, ref: PV4576

Study design
Evaluator-blinded cluster-randomised-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Experimental intervention:
One to three counselling (decision coaching) sessions with specially trained nurses, supported by an evidence-based online patient information tool prior to a decisional encounter with a physician.

Control intervention:
Counselling as usual and access to an evidence-based online information tool.

MS specialised nurses will take part in a training course to acquire relevant skills to perform immunotherapy decision coaching considering the shared decision making communication concept.

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
1. Informed choice (Multi-dimensional Measure of Informed Choice (MMIC)) including the sub-dimensions risk knowledge, attitude and uptake.
2. Attitude towards immunotherapy will be assessed using a single question directly after the final physician encounter, i.e. up to 10 weeks after inclusion in the intervention group (IG) and up to 4 weeks after inclusion in the control group (CG).
3. Uptake of immunotherapy will be assessed from the patients 6 months after the final physician encounter (IG and CG) via a standardised telephone survey
4. Risk knowledge will be assessed using a previously developed and adapted questionnaire 14 days, 3 and 6 months after the last physician encounter (IG and CG). The cut off for adequate risk knowledge will be defined a priori as the value that 30% of all patients with highest scores reach at baseline.
Informed choice is defined as adequate risk knowledge in combination with either uptake or non-uptake of immunotherapy and a corresponding (congruent) positive or negative attitude.

Key secondary outcome(s))
1. Decisional Conflict Scale (DCS): The dyadic version of the DCS will be assessed as key secondary endpoint after the last coaching session (IG) and after the final physician encounter (IG and CG).
2. Control Preference Scale (CPS): Autonomy preference will be assessed using the CPS as web-based card set at baseline, 14 days as well as 6 months after the last physician encounter (IG and CG).
3. Planned Behaviour in MS (PBMS): Behavioural beliefs and self-efficacy concerning immunotherapy will be assessed using the PBMS questionnaire at baseline, 14 days as well as 6 months after the last physician encounter (IG and CG).
4. The Coping-Self-Efficacy-Scale (CSES): The questionnaire integrates a coping instrument and a self-efficacy measure, which will be assessed at baseline, 14 days as well as 6 months after the last physician encounter (IG and CG).
5. Duration of physician encounters will be estimated by patients (evaluation questionnaire) directly after the last physician encounter (IG and CG).
6. Decision adherence (including the decision against immunotherapy) and acceptance of the intervention will be assessed from patients using a standardised questionnaire 3 as well as 6 months after the last physician encounter (IG and CG).

Assessment of safety:
1. Hospital Anxiety and Depression Scale (HADS): Anxiety and depression will be assessed at baseline, 14 days as well as 6 months after the last physician encounter (IG and CG).
2. Hamburg Quality of Life in MS Scale (HAQUAMS): Disease-specific quality of life will be assessed at baseline, 14 days as well as 6 months after the last physician encounter (IG and CG).
3. The Expanded-Disability-Status Scale (EDSS) will be assessed at baseline by a physician from the centre.
4. Relapses will be evaluated at baseline, 14 days as well as 3 and 6 months after the last physician encounter (IG and CG) using a standardised questionnaire.

Completion date
30/11/2015

Eligibility

Key inclusion criteria
1. Patients with possible or relapsing-remitting MS within a decision-making process on beginning immunotherapy or changing immunotherapy to an oral treatment
2. Internet access

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Major psychiatric disease or severe cognitive deficit
2. Progressive disease courses of MS
3. Decision on escalation immunotherapy therapy (e.g. natalizumab, fingolimode)

Date of first enrolment
09/06/2014

Date of final enrolment
30/11/2015

Locations

Countries of recruitment
Germany

Study participating centre
Institute of Neuroimmunology and Clinical MS Research (INIMS)
Hamburg
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Sponsor information

Organisation
Federal Ministry of Education and Research (Germany) (Bundesministerium für Bildung und Forschung)

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Federal Ministry of Education and Research within the Competence Network Multiple Sclerosis (Kompetenznetz Multiple Sklerose KKNMS) (Germany)

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?
Protocol article	protocol	21/03/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes