Behavioural problems in MS patients: the relation with executive functioning and psychological factors

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Demyelinating disorders
Study type	Observational invasive

Summary

ID

NL-OMON46546

Source
ToetsingOnline

Brief title
Behavioural problems in MS patients

Condition

- Demyelinating disorders

Synonym
MS

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: Via het Canisius Wilhelmina Ziekenhuis

Intervention

Keyword: Behavioural problems, Executive Function, Multiple Sclerosis, Psychological factors

Outcome measures

Primary outcome

Primary outcome measure is the amount of selfreported behavioural problems,

both reported by patients and by proxies.

Secondary outcome

Secondary research variables are:

- Executive functioning

- Fear / depression

- Fatigue

- Coping

Study description

Background summary

Multiple sclerosis (MS) is a progressive inflammatory and degenerative disease of the human central nervous system that leads to demyelisation and neuronal and axonal loss. Four disease courses have been identified: relapsing remitting MS (defined by exacerbations with partial or complete recovery), secondary progressive MS (a frequently transition from relapsing remitting, characterized by a progressive course, without exacerbations), primary progressive MS (characterized by a progressive deterioration from disease onset) and progressive relapsing MS (a progressive deterioration form disease onset with some acute periods of symptom relapse; there might or might not be recovery from these acute periods). For many years it was thought that MS mainly leads to physical disabilities. More recent studies indicate that, besides the physical consequences, cognitive deficits occur and impair 43% to 72% of the MS patients. There is an overall consensus of which kind of cognitive impairments are seen in MS, which are deficits in speed of information processing, memory, executive functioning and spatial perception. Furthermore, over the past years

emotional changes in MS patients are better recognized. Physical disabilities and cognitive impairment are considered as predictors of a reduced quality of life in MS patients and the association with depressive symptoms has been extensively studied. Half of the MS patients is diagnosed with a depressive disorder somewhere during the course of their lifetime. This could be considered as an emotional reaction or an adjustment response to the progressive illness. Also more neuropsychiatric symptoms, such as anxiety, bipolar disorder, euphoria, pseudobulbar affect and psychosis, occur more often in the MS population than in the general population. Several underlying disease-related and neurobiological factors are postulated for these neuropsychiatric symptoms, including immunological and inflammatory changes, interferon-beta treatment or structural brain abnormalities.
In addition to the emotional changes and cognitive deficits, in clinical practice we regularly observe subtle behavioural problems. In particular behavioural problems that could result from executive dysfunction, i.e. signs of rigidity, increased disinhibition and apathy. Studies addressing executive functioning in MS patients described deficits in planning and organisation skills, fluency and shifting. Studies in MS patients examining behavioural problems in the executive field, such as self-initiating behaviour, flexibility, self-inhibition, apathy and self-monitoring, are scarce.

Study objective

The aim of the present study is to examine whether MS patients report a significant higher amount of behavioural problems compared to the normal population and another patient group diagnosed with a non CNS-involved chronic disease (patients with rheumatoid arthritis). Furthermore we want to study whether proxies also report the same behavioural problems or whether they report different types and amount of problems.
We are interested what the underlying mechanisms are of the reported behavioural problems. The following mechanisms will be taken into account:
- Executive functioning. We hypothesize that a decrease in executive functioning may lead to an increase of behavioural problems. This may differ for the different types of disease courses and disease duration.
- Depression. Depression is important to take into account when studying executive and behavioural problems in MS patients. Data of several studies suggest that clinically significant depression may lead to impaired cognitive functioning, and more specifically executive dysfunction. Furthermore, depressed patients tend to overreport their executive dysfunction. It is therefore the question whether self-reported behavioural problems represent executive dysfunction or rather depression.
- Acceptance. When studying depression and the relationship with executive dysfunction and behavioural problems, it is also important to consider the role of acceptance. It has been previously found that the relationship between executive functioning and stress, depression and anxiety is mediated and moderated by coping strategies and the level of illness acceptance. Illness acceptance and the way that patients perceive and think about their disease are

also important mediators between disease and patient* well-being and account for much of the individual differences regarding physical and psychological health status. On the other hand, executive dysfunction can possibly lead to a more rigid way of thinking, resulting in maladaptive coping responses and changes in illness cognition and illness acceptance. We would like to investigate whether there is an association between the amount of self-reported depressive symptoms, illness acceptance, executive dysfunction and self-reported behavioural problems.
- Fatigue. we are interested in the relationship between fatigue and behavioural changes. Fatigue is apart from physical and cognitive symptoms one of the most common symptoms of MS, with negative impacts extending from general functioning to quality of life. Furthermore, people with MS may be at the lowest end of the physical activity participation spectrum when compared to people without MS, and people with other chronic diseases. One could argue that the physical inactivity e.g. apathy, is an expression of fatigue, rather than executive disfunction. On the other hand, loss of planning ability and loss of initiative (e.g. executive disfunction) may in itself lead to apathy. To regain more insight in this underlying mechanism, fatigue will be considered as a secondary parameter in this study.
- Disease characteristics: The neurological impairment, the disability, and the dependence of the patients are measured by an Expanded Disability Status Scale (EDSS). The EDSS score will be used to quantify disability in multiple sclerosis and to investigate whether there is a correlation between a higher level of neurological disability, depression and the amount of behavioral changes. Furthermore, disease type and disease duration will be taken into account.

Study design

The study is a cross-sectional design.

Study burden and risks

All adverse events reported spontaneously by the subject or observed by the investiga¬tor or her staff will be recorded. Examples of adverse events are some psychological distress during completion of the neuropsychological tasks, due to time constraints for example. Any psychological discomfort will be minimalized by creating breaks when the participant requires one. Furthermore, the subject is free to stop with the neuropsychological tests at any time.
Prior to completing the neuropsychological tests, the subject will be informed by a flyer and the administrator of the neuropsychological test regarding what a neuropsychological test entails, so subjects can prepare themselves. Another adverse event is a high score on the HADS, indicating a possible depression or anxiety disorder. Above a total cut-off score of 15 points on the HADS, subjects will be informed and invited for a follow up session at the medical psychology department to investigate the need for further psychological

treatment. If a subject wishes so, options for psychological treatment will be explained. If a test subject does not want to be approached after a high score on the HADS, this subject cannot participate in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: 1) diagnoses of MS (relapsing remitting, primary progressive or secondary progressive) according to the criteria of Poser (Poser et al., 1983; Poser & Brinar, 2001), 2) age of 18 years or more and 3) be willing to undergo a neuropsychological examination. ;Subjects in the control group must meet all of the following criteria: 1) diagnosis of rheumatoid arthritis, according to either 2010 ACR RA and/or 1987 RA criteria and/or clinical diagnosis of the treating rheumatologist (fulfilled at any time point between start of the

disease and inclusion), 2) a disease duration of at least one year after diagnosis, 3) age of 18 years or more and 4) be willing to complete five self-report questionnaires.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: 1) former brain disorders other than MS, 2) former or present severe psychiatric disorders (e.g. psychosis), 3) problems understanding the Dutch language, 4) history of alcohol/drugs abuse, 5) exacerbation during last 4 weeks, and 6) patients who have undergone cognitive examination in the 12 months prior to the study.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-12-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	20-03-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL64039.091.17