Predictors of employment status and work absenteeism in relapsing-remitting Multiple Sclerosis

Published: 12-02-2014
Last updated: 24-04-2024

The main aim of this study is to examine predictors of (changes in) employment status and work absenteeism in relapsing-remitting MS patients and subjects without a chronic disease over a period of three years

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system infections and inflammations
Study type	Observational non invasive

Summary

ID

NL-OMON47448

Source
ToetsingOnline

Brief title
MS Employment study

Condition

- Central nervous system infections and inflammations
- Lifestyle issues

Synonym
MS, Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Nationaal MS Fonds
Source(s) of monetary or material Support: ZonMw Topzorg subsidie,Nationaal MS

Fonds en Teva Nederland BV,TEVA Pharma

Intervention

Keyword: Cognition, Employment, Multiple Sclerosis, Psychological factors

Outcome measures

Primary outcome

The outcome variables include changes in employment status (i.e. stable versus deteriorated) and work absenteeism (i.e. days missed from work during a specified period) from baseline to endpoint

Secondary outcome

The secondary study parameters include the predictor variables, i.e. cognitive performance and cognitive complaints, physical ability, psychological functioning (i.e. anxiety, depression, psychosocial stress, quality of life, fatigue, empathy, personality traits and coping strategies), gene set data, polygenetic risk score, and type of immunomodulatory treatment.

Study description

Background summary

Multiple Sclerosis (MS) is the most common cause of disability in young and middle-aged adults. At this stage in life most people are in the midst of their working career. However, the majority of MS patients are unable to retain employment within 10 years from disease onset. Leading up to unemployment, many may experience a reduction in hours or work responsibilities and increased time missed from work. Cross-sectional studies have identified several factors associated with decreased employment status and work absenteeism in MS. These include cognitive impairments, physical dysfunction, psychological problems and type of treatment. Prospective studies are rare, or take into account a limited number of factors. By examining possible predictors of (changes in) employment status and work absenteeism in patients with relapsing-remitting MS and subjects without a chronic disease during a period of three years, we aim to

provide useful information about preventative factors for physicians, psychologists and vocational rehabilitation therapists.

Study objective

The main aim of this study is to examine predictors of (changes in) employment status and work absenteeism in relapsing-remitting MS patients and subjects without a chronic disease over a period of three years

Study design

An observational, prospective cohort study

Study burden and risks

At four time points (i.e. baseline, after 1, 2 and 3 years) participants will be asked to complete questionnaires (1-2 hours), and undergo neurological (half an hour) and neuropsychological examinations (2 hours). After 6 months participants will be asked to complete questionnaires without undergoing a neurological or neuropsychological examination. The subjects without a chronic disease will undergo a neuropsychological examination (2 hours) at baseline only. At four time points (i.e. baseline, after 1, 2 and 3 years) the subjects without a chronic disease will be asked to complete questionnaires (1-2 hours). Several MS-specific questionnaires, questionnaires for caregivers and the neurological examination will not be part of their examination. The questionnaires can be completed at home, and contain questions about the patient's cognitive functioning, work situation and psychological functioning. The neurological and neuropsychological examinations will be performed on the same day (including as many breaks as necessary) and should preferably take place at the outpatient clinic where the patient is treated. If this is not possible, testing can take place at the patient*s home. A subset of MS patients will be approached for the interviews (appendix 5 protocol), and/or will be asked to provide a blood sample (10 ml) for the genome wide association study (appendix 7 protocol).

For the subjects without a chronic disease testing will take place at their homes, at the National MS Foundation, or Leiden University.
The examinations will be performed by a research nurse or psychologist and a neurologist in training. There are no risks involved. The participants may not benefit individually, but the study should reveal typical patterns leading to unemployment in MS and aims to identify preventative factors.

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

-Patients with a diagnosis of relapsing-remitting Multiple Sclerosis according to the McDonald criteria 2010 and healthy controls not diagnosed with any neurological, psychiatric or other chronic disorder
-18 years or older
-currently employed or within 3 years since their last employment

Exclusion criteria

-co morbid psychiatric or neurological disorders
-substance abuse
-MS relapse within 1 month prior to the study visit

-unable to speak and/or read Dutch
-neurological impairment that might interfere with cognitive testing (e.g. upper limb weakness, dysarthria, vision worse than 20/70)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2014
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO Date:	12-02-2014
Application type:	First submission
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	24-04-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	25-08-2014
Application type:	Amendment

Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	03-11-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	02-02-2015
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	22-04-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-10-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-05-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-07-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-04-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL43098.008.12

Study results

Results posted: 28-05-2020

First publication
01-01-1900