The MS-CEBA study: determining Cognitive, Energetic, Behavioural and Affective (CEBA) profiles in Multiple Sclerosis

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

Summary

ID

NL-OMON53263

Source
ToetsingOnline

Brief title
MS-CEBA

Condition

- Central nervous system infections and inflammations

Synonym
Multiple Sclersosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Stichting MS Research

Intervention

Keyword: Multiple Sclerosis, neuropsychological consequences, quality of life, societal participation

Outcome measures

Primary outcome

The main study parameter is CEBA profile, which is latent and thus needs to be derived from the neuropsychological tests and questionnaires regarding the CEBA domains. To decide whether a CEBA domain is impaired, raw scores on the neuropsychological tests and questionnaires regarding each CEBA domain will be converted into normed scores. These normed scores will be compared to a cut-off score, based on which will be decided whether the domain at hand is either impaired or not impaired. See 8. METHOD of the research protocol for the neuropsychological tests and questionnaires used in each of the CEBA domains.

Secondary outcome

Secondary parameters are demographic information (derived from medical records), level of societal participation (derived from the score on the Impact on Participation and Autonomy (IPA) questionnaire), and subjective burden (obtained by conducting a short anamnesis).

Study description

Background summary

Multiple Sclerosis (MS) is an invalidating neurological disease known to cause physical symptoms, which usually are the main focus of treatment. However, non-physical, more neuropsychological, symptoms also frequently occur,

concerning the Cognitive, Energetic, Behavioural and Affective (CEBA) domains. Symptoms in the CEBA domains are known to negatively affect societal participation, and thereby quality of life. Unfortunately, despite their negative consequences, CEBA symptoms are not always timely recognized in pwMS. Moreover, despite the fact that there are various effective neuropsychological treatments available for neurological patients with these symptoms, most pwMS do not yet receive these treatments.

Although findings in group studies confirm that each of the CEBA domains can be affected in pwMS and correlations between symptoms regarding different CEBA domains can be present, there are large differences between individual pwMS with regard to which CEBA symptoms co-occur and which CEBA symptoms prevail. Therefore, in order to optimize care for pwMS (e.g. timely referring patients to suiting neuropsychological treatment) there is need for a large scale study investigating over the whole range of CEBA symptoms how frequent these occur, whether and how symptoms co-occur, and thus if CEBA profiles can be identified. If CEBA profiles are identified, it is considered likely that multiple CEBA symptoms will be prominent within a single CEBA profile. Here, subjective burden of pwMS can play an important role in determining which symptoms the main focus should be on in possible neuropsychological treatment.

Currently, a clear and standardized procedure with a feasible neuropsychological screening tool quickly identifying and combining CEBA profile and subjective burden, providing a suitable indication for possible neuropsychological treatment, is lacking.

Study objective

The aim of the present study is identifying CEBA profiles in pwMS and subsequently developing a feasible screening tool allowing quick identification of CEBA profile and subjective burden of pwMS in clinical practice, providing a suitable indication for possible neuropsychological treatment. If needed, combining of or adjustments to existing neuropsychological treatments will be suggested in order meet the needs of pwMS with CEBA symptoms. All of this with the ultimate aim to improve societal participation, and accordingly quality of life, among pwMS.

Study design

This study is an observational, prospective, multicentre cohort study

Study burden and risks

The current project concerns an observational study for which no health risks are known. The NPA is given by experienced neuropsychologists, who will

carefully monitor patients* energetic status and well-being. These neuropsychologists have extensive clinical experience with neuropsychological assessment of pwMS, based on which we know that the majority of these patients is able to undergo around two hours of testing. The test battery used in the study is particularly short; around 45-60 minutes. Questionnaires will be send to patients before the NPA takes place, so these can be completed at home. Also, if necessary patients can be tested at home. On request, patients can be provided with a short report about their results which provides them with more insight in their possible CEBA consequences of MS as well as their strong points. This can serve to seek available support if patients are open to this. In addition, we expect longer-term benefits for pwMS, because with the knowledge gained from this research we hope to optimize neuropsychological care for pwMS in general and thereby improve their societal participation and overall quality of life.

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

Criteria for inclusion: confirmed diagnosis of MS (subtypes: remitting MS [RRMS], primary progressive MS [PPMS] and secondary progressive MS [SPMS]), age 18 to 70, being able to participate in a short neuropsychological assessment (NPA) as judged by the MS clinician (neurologist, rehabilitation physician) and/or investigator (neuropsychologist), with adequate control of the Dutch language. In order to be eligible to participate in this study, the group of HC*s must be matched to the patient group on age and education level. This will be done by the investigator (experienced neuropsychologist).

Exclusion criteria

Patients as well as HC*s whose physical and/or cognitive condition is impaired in such a way that they are not able to complete the NPA cannot participate in this study. In addition, patients and HC*s cannot participate when they suffer from other self-reported neurological and/or major psychiatric conditions.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-07-2023
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	05-07-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL83954.042.23