The effects and costs of a multidisciplinary symptomatic treatment strategy on quality of life of people severely affected by MS

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

Summary

ID

NL-OMON44570

Source
ToetsingOnline

Brief title
MS-Care NU

Condition

- Demyelinating disorders

Synonym
Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Stichting Vrienden van Nieuw Unicum;Innovatiefonds Zorgverzekeraars

Intervention

Keyword: Quality of life, severely affected Multiple Sclerosis, Symptomatic treatment

Outcome measures

Primary outcome

The change in quality of life, caregivers burden and functional domains from baseline to endpoint will be evaluated. The primary outcome parameters are the Euroqol (EQ-5d-5l) and the Adult Social Care Outcome Toolkit (ASCOT) for respectively health-related- and social related quality of life.

Secondary outcome

1. Disability (meetinstrumenten: Functional independent measure en Multiple Sclerosis Impact Profile)

2. Caregiver strenght (Caregiver Strain Index)

3. Costs (Medical Consumption Questionnaire)

Study description

Background summary

In the current climate of economic rationalization and budget restrictions in the Dutch health care system, there is an increasing pressure to show the effects and costs of interventions as part of routine clinical practise. In the Netherlands, the residential and facility center Nieuw Unicum (NU) delivers continuous, systematic, long-term multidisciplinary symptomatic treatment for patients in their later stages of Multiple Sclerosis (MS) and their caregivers. However, the needs, physical and social well-being of this population have not

been studied in detail. Therefore, it remains unknown whether the health care services of NU are adequately tailored to the needs of these patients. Furthermore, the effects in terms of quality of life and functioning and costs of the health care services provided by NU are unclear. This proposed study is conducted in a *real world* clinical setting to investigate these remaining questions.

Study objective

The aim of the proposed study is to obtain insight into the needs, functioning and quality of life and changes in these outcomes of people with severe MS who are treated in NU and to identify the experiences, facilitators and barriers using the health care services of NU. In addition, the costs of the treatments in NU will be determined.

Study design

The proposed study is a 1.5-year longitudinal observational study with a mixed-methods design.

Study burden and risks

The treatments are part of regular care given in NU. The participants have to fill in a set of questionnaires five times in the study period of 18 months. Filling in the set of questionnaires takes approximately 90 minutes. The patients will be provided a digital or a paper version depending their preference.
Most of the items are multiple choice what makes answering more easy for people with upper extremity disabilities. A pilot showed an increase in fatigue and a reduced concentration level after completion of the questionnaire. Furthermore, subjects mentioned the confrontation with their disease as inconvenient. Filling in the set of questionnaires was found doable in view of duration, usability and consequences as confrontation with their situation and fatigue. There are no individually benefits for the participants. To generate more knowledge about the care for advanced MS patients will be their contribution.

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

a referral to Nieuw Unicum and a diagnosis Multiple Sclerosis

Exclusion criteria

Individuals who are mentally incompetent to give informed consent will not be included in the study.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-01-2018
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL62369.029.17