Walking fatigability and the relation to walking economy and walking quality and the impact on social role participation and daily life activity in persons with Multiple Sclerosis.

Published: 19-12-2018
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49047

Source
ToetsingOnline

Brief title
Walking fatigability in persons with Multiple Sclerosis

Condition

- Autoimmune disorders

Synonym
Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Energy Expenditure, Fatigability, Gait, Multiple Sclerosis

Outcome measures

Primary outcome

- Walking fatigability

- Walking economy

Secondary outcome

I

- Walking fatigability & walking economy

- Walking characteristics

II

- Walking fatigability & walking economy

- Daily life activity

III

- Walking fatigability & walking economy

- Social role participation and quality of life

Study description

Background summary

Walking capacity is reported as one of the most important bodily functions for maintaining a high quality of life in persons with Multiple Sclerosis (pwMS). It has been shown that limitations in walking capacity in pwMS are related to fatigue, which subsequently leads to a decreased daily physical activity. This may impact physical fitness and ultimately lead to a decreased social role participation. However, it is not well known whether this limitation in walking capacity, measured during walking (walking fatigability) is related to less energy efficient walking and thus a poor walking economy. It is proposed that assessing the relation between walking fatigability, walking economy and walking characteristics (e.g. spatiotemporal parameters, kinematic and kinetic profiles, muscle coordination patterns) can lead to a better understanding of the determinants of fatigue and walking fatigability in pwMS. In addition, exploring its impact on daily activities and social participation will aid rehabilitation of pwMS .

Study objective

The main objective is to investigate the association between walking fatigability during the 6 minute walking test (6MWT) and walking economy in pwMS who are able to walk independently. Secondary objectives are to investigate the role of I. walking characteristics II. daily life activity and III. social role participation and quality of life on walking fatigability and economy in pwMS

Study design

Observational cross-sectional study

Study burden and risks

The participants can feel fatigued after performing the 6 minute walking test

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

- Diagnosed MS
- EDSS score 1- 5.5
- Able to walk for 6 minutes without walking aid and orthoses
- Age between 18-65 years

Exclusion criteria

- Recent (3months) relapse
- Recent (12 months) arthroplasty or fracture
- Comorbidities affecting functioning (such as diabetes mellitus, malignancies or COPD)
- Contra-indication for physical activity or exertion tests
- Botulinum treatment in lower extremity <6 months before measurement

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2019
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-03-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26405
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67805.068.18
OMON	NL-OMON26405

Study results

Date completed:	02-01-2021
Actual enrolment:	32