Patient-specific measurement of functional movement disorders

Published: 21-03-2016
Last updated: 20-04-2024

We aim to study the contributing factors to movement disorder symptoms in subjects with a FMD using a web based diary. At the same time, objective symptom assessment will be performed using an actigraphy wristband. Associations between potential...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON46241

Source
ToetsingOnline

Brief title
Patient-specific measurement of functional movement disorders

Condition

- Movement disorders (incl parkinsonism)
- Somatic symptom and related disorders

Synonym
Functional movement disorders

Research involving
Human

Sponsors and support

Primary sponsor: Neurologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ambulant monitoring, Contributing factors, Functional movement disorders

Outcome measures

Primary outcome

Contributing factors to objective (and/or) subjective symptom fluctuation in

individual patients.

Secondary outcome

The following possible contributing factors will be studied:

- Positive And Negative Affect Schedule (PANAS)

- Physical activity

- Fatigue

- Attention (in terms of social or mental activities)

- Personal factor

Furthermore, to measure the effect of the study, patient will complete

questionnaires on self-belief (General Self-Efficacy Scale), quality of life

(EQ-5D), and clinical global impression (CGI)

Study description

Background summary

Functional movement disorders (FMD) are hard to diagnose and treat. The underlying etiology of FMDs remains poorly understood with several postulated mechanisms and an acknowledgement of the contribution of biological, psychogenic, and cultural factors. The old term *psychogenic* movement disorders suggests a psychological background of FMD, but case-control studies have demonstrated only an assocation, and not causation, between psychogenic

factors and FMDs in a subset of patients. Besides, many somatic symptoms are strongly associated with psychiatric disorders, so these psychogenic factors are probably also relevant in neurological movement disorders disorders.
An alternative means of investigation is to study patients on an individual basis, attempting to identify which factors contribute the most to the patient*s symptoms. This is possible by applying a multivariate time-series analysis. In this study, we will use a web based diary system to focus on contributing factors that are known to modulate functional symptoms. At the same time we will use actigraphy to objectively assess the patients symptoms.

Study objective

We aim to study the contributing factors to movement disorder symptoms in subjects with a FMD using a web based diary. At the same time, objective symptom assessment will be performed using an actigraphy wristband. Associations between potential contributing factors and symptom fluctuations in FMD patients will be compared with those in a group with other neurological movement disorders.

Study design

A replicated single-subject time-series design will be used. Patients with a (functional or neurological) movement disorder will be monitored for 30 days, five times a day, by using a web based diary. In addition, patients will wear an actigraphy wristband during daytime.

Study burden and risks

There are no risks involved in participating in the study. The burden associated with participation consists of:
(1) An inclusion interview with video measurement; a screening for depression, anxiety, and somatisation; and completing questionnaires on self-efficacy, quality of life, and clinical global impression (total of 45 minutes).
(2) Wearing an actigraphy wristband during daytime, and completion of an internet based diary at fixed times (5 x 5 minutes a day) during the study period (30 days).
(3) At the end of the study period, subjects will receive an e-mail to give general feedback to the study and will be asked for the second time to complete the questionnaires on self-efficacy, quality of life, and clinical global impression (30 minutes)
(4) One month the end of 30 days measuring, subjects will receive a third time the questionnaires on self-efficacy, quality of life, and clinical global impression to determine whether they benefited from participating in this study (10 minutes).

Contacts

Public
Selecteer

Hanzeplein 1
Groningen 9700 RB
NL
Scientific
Selecteer

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age > 18
- Functional movement disorder, according to Fahn criteria, as judged by a neurologist
Or a neurological movement disorder, as judged by a neurologist.
- Symptom duration > 1 year
- capable of keeping an electronic diary five times a day and have acces to internet at 9.00; 12.00; 15.00; 18.00; 21.00

Exclusion criteria

- current medical treatment with botulinum

- psychological treatment in the previous 6 months

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:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	21-03-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-04-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-04-2017
Application type:	Amendment
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	NL55993.042.15

Study results

Date completed:	14-11-2020
Actual enrolment:	43