A retrospective and prospective longitudinal observational study to assess changes in working capacity related to disease specific factors in Huntington*s disease

Published: 14-03-2019
Last updated: 12-04-2024

By following participants for two years we want to map out what changes are taking place in employed gene carriers of Huntington's disease. The research does not solely focus on whether a participant is employed or not, but wants to highlight...

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

Summary

ID

NL-OMON48893

Source
ToetsingOnline

Brief title
Working capacity and burn out in Huntington's Disease (HD-work)

Condition

- Movement disorders (incl parkinsonism)

Synonym
Huntington's Disease, movement disorder

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: LUMC;HD research groep

Intervention

Keyword: Burn-out, Employment, Huntington

Outcome measures

Primary outcome

- To investigate changes in employment (e.g. a job change, work cessation/early retirement, changes in working hours, and changes in duties/responsibilities) in HD, with a focus on improving the understanding of reasons behind work cessation.

- To relate possible work related changes to psychiatric, behavioural, cognitive and motor (dys)function.

Outcome measures questionnaires.

- Work assessment: detailed demographics on employment and work cessation. This questionnaire is filled in by the participant as well as the proxy.

- UBOS: overall total score and score per subscale; exhaustion, emotional distance and competence score. The test can be used to assess whether someone has a burn-out or not. This questionnaire is filled in by the participant as well as the proxy.

- FrSBe: overall total score and total score per subscale; apathy, disinhibition, and executive dysfunction. This questionnaire is filled in by the participant as well as the proxy.

- UCL: total scores per coping subscale; active and passive coping (7 * 28), palliation (8 * 32), avoidance (8 * 32), seeking support (6 * 24) , emotional expression (3 * 12) and seeking reassurance (5 * 20). This questionnaire is filled in by the participant as well as the proxy.

- HADS-SIS: score per subscale; anxiety (0 * 21), depression (0 * 21), inward- and outward irritability (0 * 12). This questionnaire is filled in by the participant as well as the proxy.

Outcome measures motor assessments

- UHDRS-TMS: total motor score (0 * 124)

- UHDRS-TFC: total functional capacity (0 * 13)

Outcome measures psychiatric and behavioural evaluation.

- PBA-s: total score per symptom is calculated by multiplying severity by frequency.

Outcome measures neuropsychological assessment.

- SDMT: total number of correct responses after 90 seconds.

- Stroop: number of correct response after 45 seconds per trial.

- TMT trial A and B: total seconds to complete the task.

Secondary outcome

- Determining whether burn out related symptoms are more prevalent in patients with HD than in the general population and ascertain in how many cases burn-out related symptoms can be marked as the onset of HD.

- Report if work type and cultural background of participants influences employment and how this relates to cognitive, psychiatric and motor (dys)function.

- Identifying whether limited self-insight influences work cessation by means

of proxy measurement.

- To contribute to better supply of information for patients, family,

employers, health and safety officers and offices regarding employment and

Huntingtons disease progression.

- Identifying whether coping influences working capacity.

For outcome measures see primary study parameters.

Study description

Background summary

Huntington*s disease (HD) is a rare autosomal dominant inherited neurodegenerative disorder, clinically characterized by motor, cognitive and behavioral symptoms. Due to the relative early age at onset patient* quality of life is impacted, especially by loss of functionality. Patients at our outpatient clinic often encounter work related changes or become incapable of working. Previous retrospective research has shown that work cessation is associated with cognitive dysfunction and apathy. However, patients and employers do not seem to assign the work related problems to Huntington*s Disease. This leads to faulty decision making such as not renewing a patients contract or the patient enters the WW (Dutch unemployment law), instead of ending up in the Sickness Benefit Act.

Study objective

By following participants for two years we want to map out what changes are taking place in employed gene carriers of Huntington's disease. The research does not solely focus on whether a participant is employed or not, but wants to highlight which changes lead up to unemployment. Therefore we will collect a lot of demographical information on working status and work problems participants encounter, consisting of but not limited to the prevalence of burn-out in HD compared to the general population. We want to relate this information to cognitive, psychiatric and motor symptoms of HD. This study aims to provide more insight into the work-related problems that patients encounter at an early stage of Huntington's disease and will thereby contribute to finding leads for further research and (better) support at the psychosocial

level.

Study design

The current study is a retrospective and prospective longitudinal observational study in Huntington*s Disease gene carriers.

Study burden and risks

Since this study is an observational study in which no interventions take place, there are no risks associated with the study. The burden on the participants is limited.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All eligible participants must meet the following inclusion criteria:
- Have a confirmed CAG-expansion of *36 in the HTT gene.
- Be employed, or have been employed 2 years prior to assessment, in any capacity (e.g. full time (paid job for 36 hours or more), part-time (paid job for less than 36 hours) or volunteer (unpaid job)).
- Be at least 18 years of age.
- Be at most 64 years of age, due to the longitudinal set up of the research and the age of retirement in the Netherlands.

Exclusion criteria

All eligible participants must meet none of the following exclusion criteria:
- Major general or neurological comorbidity that is unrelated to HD.
- Any other condition that in the opinion of the investigator warrants exclusion of the study.
- Inability to understand the information about the study.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-04-2019
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO

Date:	14-03-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL67070.058.18