Exercise Rehabilitation Trial in Huntington*s disease

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The specific aims for this study are to identify whether a structured exercise programme:a. is feasible for people with HD, in terms of adherence, process and safetyb. improves physical fitness in people with HDc. improves physical function and...

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

Summary

ID

NL-OMON40355

Source
ToetsingOnline

Brief title
ExeRT-HD

Condition

- Movement disorders (incl parkinsonism)

Synonym
Huntington's disease

Research involving
Human

Sponsors and support

Primary sponsor: Cardiff University, Cardiff, UK
Source(s) of monetary or material Support: Jacques & Gloria Gossweiler Foundation

Intervention

Keyword: Exercise, Huntington's disease, Rehabilitation, Trial

Outcome measures

Primary outcome

The primary aim of this study is to assess feasibility of the exercise intervention in terms of adherence, safety and process. This will be achieved through the documentation of adherence and any adverse events, as well as any health-related changes such as falls, hospital admissions, or healthcare service use that occur during the intervention period. Duration of participation and dropout from the intervention will also be recorded. In order to assess benefits, a range of outcomes that are representative of participation, activities and body functions, as defined by the World Health Organisation Classification of Functioning, Disability and Health, will be obtained. These will include measures of physical fitness, cognitive ability, and motor function. Standard clinical measures of disease severity and function as well as health-related quality of life will also be obtained.

Secondary outcome

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Study description

Background summary

The efficacy of a long term exercise rehabilitation program on quality of life and functioning in patients with Huntington's disease is unclear. In other chronic conditions exercise rehabilitation proved to be efficacious on parameters of well-being and functioning.

Study objective

The specific aims for this study are to identify whether a structured exercise programme:
a. is feasible for people with HD, in terms of adherence, process and safety
b. improves physical fitness in people with HD
c. improves physical function and functioning in other domains, such as cognition and quality of
life, in people with HD

Study design

The proposed trial is a single blind, exploratory phase II randomised, controlled multi-site trial of an exercise-based intervention. A total of 42 participants will be recruited across five EHDN Registry/ENROLL sites: Cardiff, Birmingham, Oxford, Leiden, and Muenster. Cardiff and Oxford sites will each recruit 9 participants; Birmingham, Leiden and Muenster sites will each recruit 8 participants.

Intervention

The intervention is an exercise-based intervention with an aerobic component, three times per week
for 12 weeks.

Study burden and risks

1) Patients have to travel to Topaz Huntington Centrum Overduin in Katwijk 3 times a week for the duration of 12 weeks.
2) The risk of health deterioration is estimated low as the rehabilitation program will performed at an aerobic level. Furthermore patients will be supervised by trained physiotherapists on 20 out of 36 occasions.

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

1) diagnosis of manifest HD, confirmed by genetic testing
2) above the age of 18
3) stable medication regime for four weeks prior to initiation of trial, and anticipated to be able to
maintain a stable regime for the course of trial
4) enrolled in EHDN Registry study

Exclusion criteria

1) any physical or psychiatric condition that would prohibit the participant from completing the

intervention or the full battery of assessments
2) inability to independently use the exercise bike
3) unable to understand or communicate in spoken English (UK sites only)
4) currently involved in any intervention trial or within four weeks of completing an intervention trial
5) current, regular participation in a structured exercise programme five times per week or more

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2014
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO

Date:	22-05-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL47421.058.13