

# Exercise rehabilitation trial in Huntington's disease

<b>Submission date</b> 24/01/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/01/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/07/2016	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Huntington's disease (HD) is an inherited neurological disease, which over time results in progressive problems with movement, thinking and behaviour, and ultimately difficulties in undertaking the usual activities of daily living. It is known that keeping physically active is important for any person who has a chronic health condition. Additionally, there is a growing interest in the potential that aerobic exercise may have for brain health, particularly for people with degenerative diseases such as HD. Engaging in regular exercise, however, can be difficult for people with HD given the complex and varied problems that they are faced with on a daily basis. This study aims to evaluate the feasibility and benefit of a supported, structured exercise intervention in people with early to mid-stage HD.

### Who can participate?

Men and women aged 18 and over diagnosed with HD.

### What does the study involve?

People with HD who enrol in the study will be asked to attend two research assessments (focussing on physical fitness, movement, thinking and walking abilities) over a three-month period at their local HD clinics. After the first assessment, they will be randomly allocated to either the exercise intervention group or the control group. In the intervention group, exercise trainers will work with each participant on an individualised exercise programme, either in their home or at a community gym. The intervention will take place three times per week for 12 weeks, and trainers will supervise the participant in just over half of the sessions. The remainder of the sessions will be conducted by the participant independently, or with the support of a carer or family member.

### What are the possible benefits and risks of participating?

There may, or may not be, direct benefits to anyone taking part in this study. The study aims to find out whether or not the exercise intervention is safe, feasible and beneficial to people with HD. By taking part, participants will be helping us to answer this question, which may be of benefit to people with HD in the future. The assessments and intervention are unlikely to cause

any undue stress. Care and comfort of participants will be ensured at all times. The proposed exercise training is of moderate intensity and has been developed in line with established protocols, and therefore poses minimal risk.

Where is the study run from?

Leiden (Netherlands), Munster (Germany), Cardiff (Wales), Birmingham (England), Oxford (England)

When is the study starting and how long is it expected to run for?

February 2014 to August 2014

Who is funding the study?

Jacques and Gloria Gossweiler Foundation (Switzerland)

Who is the main contact?

Ms Katy DeBono

debonok1@cardiff.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Ms Katy DeBono

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

15832

## Study information

**Scientific Title**

A randomised exercise rehabilitation trial in Huntington's disease

**Acronym**

ExeRT-HD

**Study objectives**

This randomised study aims to evaluate the feasibility (in terms of adherence, process and safety) and benefit of a supported, structured aerobic exercise intervention in people with early to mid-stage HD.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

South East Wales Research Ethics Committee, 06/11/2014, ref.:13/WA/0315

**Study design**

Randomised interventional; Design type: Process of Care

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Huntingtons Disease; Disease: Huntington's disease

**Interventions**

People with HD who enrol in the study will be asked to attend two research assessments (focussing on physical fitness, movement, thinking and walking abilities) over a three-month period at their local HD clinics or university research facilities. After the first assessment, they will be randomly allocated to either the an aerobic exercise programme group or the control group. If they are assigned to the intervention, professional trainers will work with each participant on an individualised exercise programme, either in their home or at a community gym. The intervention will take place three times per week for 12 weeks, and trainers will supervise the participant in just over half of the sessions. The remainder of the sessions will be conducted by the participant independently, or with support of a carer or family member.

Participants who are assigned to the control group will be instructed to continue as normal for the 13 weeks between assessments, and will be instructed to not begin any new exercise or

physical activity routines. Following completion of the second assessment, the participants in the control group will be offered gym membership for 12 weeks, so long as the results from the intervention group do not indicate any potential harm. This will include two visits by a trainer to instruct the participant in an appropriate exercise programme.

**Intervention Type**

Behavioural

**Primary outcome measure**

Feasibility in terms of adherence, safety and process. Measures will be taken at baseline and 13 weeks. A follow-up telephone call will be made at 26 weeks to conduct the IPAQ and EQ-5D.

**Secondary outcome measures**

Assess benefit including physical fitness, cognitive ability and motor function. Measures will be taken at baseline and 13 weeks. A follow-up telephone call will be made at 26 weeks to conduct the IPAQ and EQ-5D.

**Overall study start date**

01/02/2014

**Completion date**

31/08/2014

**Eligibility****Key inclusion criteria**

1. Diagnosis of manifest HD, confirmed by genetic testing
2. Male and female 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 European Huntington Disease Network (EHDN) Registry/ENROLL-HD study

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned sample size: 42. UK sample size: 26. International sample size: 16

**Key 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 cycle ergometer
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

**Date of first enrolment**

01/02/2014

**Date of final enrolment**

31/08/2014

## Locations

**Countries of recruitment**

Germany

Netherlands

United Kingdom

Wales

**Study participating centre**

**Cardiff University**

Cardiff

United Kingdom

CF14 4XN

## Sponsor information

**Organisation**

Cardiff University (UK)

**Sponsor details**

Research, Innovation and Enterprise Services

7th Floor McKenzie House

30-36 Newport Road

Cardiff

Wales

United Kingdom

CF24 0DE

**Sponsor type**

University/education

**Website**

<http://www.cardiff.ac.uk/>

**ROR**

<https://ror.org/03kk7td41>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Jacques and Gloria Gossweiler Foundation (Switzerland)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No