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Exercise rehabilitation trial in Huntington's disease

Submission date
24/01/2014

Recruitment status
No longer recruiting

Registration date
24/01/2014

Overall study status
Completed

Last Edited
19/07/2016

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 Gossweiller Foundation (Switzerland)

Who is the main contact?
Ms Katy DeBono
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Contact information

Type(s)
Scientific

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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
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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 Gossweiller 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?
Results article	results	01/10/2016		Yes	No
HRA research summary			28/06/2023	No	No