ISRCTN94284668 https://doi.org/10.1186/ISRCTN94284668

Task-related TRAINing in Huntingtons Disease

Submission date
24/05/2012

Recruitment status
No longer recruiting

Registration date
24/05/2012

Overall study status
Completed

Last Edited
27/02/2015

Condition category
Mental and Behavioural Disorders

[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) leads to loss of mobility, with individuals eventually requiring assistance with all activities of daily living. Our research has provided evidence that people with early stage HD can benefit from a physiotherapy-led home-based exercise programme, aimed at improving muscle strength, balance and overall fitness. While this research provides an important first step into the potential benefits of physiotherapy-related interventions for people with HD, further research in this area is needed. The purpose of this study is to evaluate the feasibility, acceptability and potential benefit of home-based physiotherapy targeted for people with early to mid-stage HD who currently receive no or minimal physiotherapy.

Who can participate?
We will recruit 30 people who have been diagnosed with HD and have difficulties with walking and/or balance.

What does the study involve?
Participants will be randomly allocated into either an intervention group, in which they receive a home-based physiotherapy programme, or a control group who will be asked to continue as normal. Participants will be assessed at the start of the study and after 8 and 16 weeks. The effectiveness of the programme will be assessed, including its effects on general physical functioning, walking ability and balance. In addition, each participant will set individual goals related to their functional abilities, in collaboration with a physiotherapist. If the programme is found to be beneficial and safe, the control group will be offered the intervention at the end of the study.

What are the possible benefits and risks of participating?
There may be no direct benefits to anyone taking part in this study. The study is being undertaken to find out whether or not the physiotherapy intervention is beneficial to people with HD. Participants will be helping to answer this question, which may be of benefit to people with HD in the future. The assessments are unlikely to cause any undue stress. Participant care and comfort will be ensured at all times. The proposed physiotherapy training is of low to moderate intensity and therefore poses minimal risk. It will not involve any heavy load bearing activities. If a participant has any specific problems or difficulties, they will be provided with a

contact telephone number to speak to the research team. If necessary they will be seen at their HD clinic for review. Before and during the study they will also be given the opportunity to discuss any concerns with the researchers in private.

Where is the study run from?
The study is being organised by the School of Healthcare Studies, Cardiff University and has six study sites: Cardiff, Oxford, Manchester, Sheffield, Birmingham and London.

When is the study starting and how long is it expected to run for?
The study started in September 2012 and will finish in December 2013.

Who is funding the study?
Huntington's Disease Association (UK).

Who is the main contact?
Katy Debono
Debonok1@cardiff.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Katy DeBono

Contact details
Cardiff University
Department of Physiotherapy
Heath Park
Cardiff
United Kingdom
CF14 4XN
-
debonok1@cardiff.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12400

Study information

Scientific Title

Task-related TRAINing in Huntingtons Disease: a home-based intervention trial

Acronym
TRAIN

Study objectives
The proposed trial will investigate the potential benefits of a physiotherapy programme for people with mid-stage

Huntington's Disease (HD) who currently receive no or minimal physiotherapy input.

We will recruit 30 individuals who have been diagnosed with HD. Participants will be randomly allocated into either a group in which they receive a home-based physiotherapy programme (called the intervention group), or a group who will be asked to continue as usual (control group). The trial will start after participants are recruited and consented. Participants will be assessed on enrolment into the trial. They will be randomly allocated their group immediately following the first (baseline) assessment. Those in the group which receive home-based physiotherapy programme will begin this within 2 weeks of the baseline assessment. They will be reassessed at 8 weeks following the start of the physiotherapy programme, and again at 16 weeks from the start of physiotherapy programme. These timescales mean that each participant will be involved in the trial for a minimum of 16 weeks and a maximum of 18 weeks (if there is a delay for anybody in the intervention group between enrolment and starting the physiotherapy programme).

The effectiveness of the programme will be assessed using various measures, including general physical functioning, walking ability and balance. In addition, each participant will set individual goals related to their functional abilities, with the physiotherapist delivering the home-based programme.

To maximise recruitment and ensure consistency of care, the control group will be offered the intervention at the end of the trial, provided that results so far give no reason to question safety or potential for benefit. If shown to be an acceptable and beneficial intervention, the results from the proposed trial could help to provide a structured framework to guide physiotherapy service delivery according to clinical need for people with HD.

More details can be found at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=12400

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales Research Ethics Committee, 16/05/2012, ref: 12WA0151

Study design
Randomised interventional trial

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
Dementias and neurodegenerative diseases

Interventions
Home-based exercise programme: Physiotherapy exercise programme targeted at people with early / mid stage HD. The intervention group is an 8-week (2x/week) programme providing task-related training and functional activity exercise to improve sit to stand, balance and walking.

Intervention Type
Behavioural

Primary outcome measure
Physical Performance Test measured at 0 weeks (baseline), 8 weeks and 16 weeks

Secondary outcome measures
1. 30 second chair stand test measured at 0 weeks (baseline), 8 weeks and 16 weeks
2. 30-second chair stand test by the treating therapists measured at once a week
3. Depression will be quantified by the Hospital Anxiety and Depression Scale (HADS) at 0 weeks (baseline), 8 weeks and 16 weeks
4. Quality of life as measured by the Huntington's Disease Quality of Life Measure (HD-QOL) measured at 0 weeks (baseline), 8 weeks and 16 weeks
5. The Berg Balance Scale measured at 0 weeks (baseline), 8 weeks and 16 weeks
6. Timed Up and Go walking speed as measured by 10 m walk measured at 0 weeks (baseline), 8 weeks and 16 weeks

Overall study start date
03/07/2012

Completion date
03/12/2013

Eligibility

Key inclusion criteria
1. Diagnosis of manifest HD, confirmed by genetic testing
2. Self-reported or physician-reported difficulties with walking and/or balance
3. Between ages of 18 and 70 years
4. Capacity to give informed consent
5. Total functional capacity (TFC) of at least 4
6. Stable medication regime for 4 weeks prior to initiation of trial, and be able to maintain a

stable regime for the course of trial
7. Enrolled on EHDN Registry/ENROLL study
8. Target Gender: Male & Female
9. Upper Age Limit 70 years
10. Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
1. History of prior neurological condition, such as stroke
2. Unable to understand or communicate in spoken English
3. Moderate to severe arthritis in the hips, knees or ankles, or orthopaedic condition that limits walking ability
4. Cardiac precautions that would prevent subject from completing the intervention or the full battery of outcomes
5. Currently in receipt of active physiotherapy input
6. Are currently involved in any interventional trial or within 2 months of completing an interventional trial
7. Are not enrolled (or interested in enrolling) on the EHDN Registry/ ENROLL study
8. Demonstrate uncontrolled psychiatric symptoms / have active psychosis

Date of first enrolment
03/07/2012

Date of final enrolment
03/12/2013

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre

Cardiff University
Cardiff
United Kingdom
CF14 4XN

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
Research and Commercial Division
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
Huntingtons Disease Association (UK)

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	01/11/2014		Yes	No