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Inspiratory muscle training in people with Huntington's disease

Submission date
13/01/2013

Recruitment status
No longer recruiting

Registration date
26/02/2013

Overall study status
Completed

Last Edited
24/06/2016

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
People with neurodegenerative (relating to or characterized by degeneration of nervous tissue) conditions often have reduced breathing ability which impairs their ability to cough. Early findings from an ongoing study in people with Huntingtons disease (HD) show decreased strength in the muscles used to breathe in. This suggests that breathing muscle weakness may underlie the tendency to chest infections as HD progresses. Weak breathing muscles may also influence the ability to carry out physical activity. This study aims to investigate the feasibility of inspiratory (breathing in) muscle training in people with early and mid-stage HD and whether the training programme strengthens the breathing muscles. This small study is needed in order to design future investigations into the effectiveness of inspiratory training and guide physiotherapists in the best management of respiratory problems in people with HD.

Who can participate?
People aged over 18, with early or mid-stage Huntingtons disease, who are able to follow instructions and can commit to six weeks training.

What does the study involve?
The exercise programme involves breathing in through a hand held device that provides resistance to the breath. Twenty people with early and mid-stage HD will be divided into two groups. Each group will carry out the same training, with one group breathing against a higher resistance than the other. Participants will be asked to use the device twice daily for six weeks. We will assess participants before and after the training programme and look to see if there are any changes in breathing strength, cough strength and a functional task. We will also ask 10 people to take part in an interview that will allow them to discuss how they felt about the training programme, the device and whether they felt any benefit from a regular training programme focussed on breathing.

What are the possible benefits and risks of participating?
There may be no direct benefits to anyone taking part in the study. The study is being undertaken to find out whether or not the intervention is beneficial to people with HD. By taking part in the study, participants will be helping us answer this question irrespective of the group they are in. There is low risk associated with inspiratory muscle training. Participants may

feel some discomfort during training, but this will not cause any harm. This will be explained to the participants during the initial visit.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to last?
The study started in October 2011 and will run for 2 years

Who is funding the study?
European Huntingtons Disease Network

Who is the main contact?
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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
Version 2

Study information

Scientific Title
Feasibility and benefit of Inspiratory Muscle Training in people with Huntingtons Disease: a pilot randomised controlled feasibility study

Acronym
FIMTHD

Study objectives
Inspiratory muscle training increases inspiratory muscle strength in people with Huntingtons Disease (HD)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee, 21/07/2011, ref: 11/WA/0183

Study design
Pilot randomised controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Huntington's disease

Interventions
All subjects will carry out training of 30 breaths through the training device, two times per day, seven days per week. The resistance given to subjects in the training group will be 50% of their maximal inspiratory strength. This can be set automatically by the training device.

Resistance given to subjects in the control group will be set at 8cmH2O, which is known to have no training effect (Geddes 2008).

The participant will not know to which group they are assigned.

Intervention Type
Device

Primary outcome measure

Inspiratory muscle strength, measured using sniff nasal inspiratory pressure at baseline and end of training.

Secondary outcome measures
1. Inspiratory muscle strength, measured using maximal inspiratory pressure at baseline and end of training
2. Cough strength, measured by peak cough flow at baseline and end of training
3. Functional activity, measured by 30 second sit to stand at baseline and end of training

Overall study start date
03/10/2011

Completion date
03/10/2013

Eligibility

Key inclusion criteria
1. Age > 18, either sex
2. Genetically confirmed HD
3. Capacity to give informed consent
4. Inspiratory muscle strength < 80% predicted for age and height
5. Maintenance of a stable medical regime for 4 weeks prior to initiation of study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. History of additional prior neurological condition, such as stroke
2. Uncontrolled psychiatric symptoms
3. History of spontaneous pneumothorax / unstable asthma / chronic respiratory condition

Date of first enrolment
03/10/2011

Date of final enrolment
03/10/2013

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
Cardiff
United Kingdom
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Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
Research and commercial division
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Sponsor type
University/education

Website
http://www.cardiff.ac.uk/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Research organisation

Funder Name
European Huntington's Disease Network ref: seed fund 268

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	23/06/2016		Yes	No