

# Inspiratory muscle training in people with Huntington's disease

<b>Submission date</b> 13/01/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/02/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/06/2016	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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?  
Una Jones  
jonesuf@cardiff.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mrs Una Jones

**Contact details**  
School of Healthcare Studies  
Cardiff University  
Heath Park  
Cardiff  
United Kingdom  
CF14 4XN  
-  
jonesuf@cardiff.ac.uk

## Additional identifiers

**Protocol serial number**  
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

### **Primary study design**

Interventional

### **Study design**

Pilot randomised controlled feasibility study

### **Study type(s)**

Quality of life

### **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 8cmH<sub>2</sub>O, 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(s)**

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

### **Key secondary outcome(s)**

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

### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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

CF14 4XN

**Sponsor information**

## Organisation

Cardiff University (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

### 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	23/06/2016		Yes	No