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# Respiratory function in people with Huntington's disease

**Submission date**
13/06/2008

**Recruitment status**
No longer recruiting

**Registration date**
30/01/2009

**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**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
SPON579-08; PRF/08/3

## Study information

**Scientific Title**
Respiratory function in people with Huntington's disease: a cross-sectional study

## Study objectives
There is no difference in respiratory function in people with Huntington's disease compared to healthy controlled subjects at different stages of the disease.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Research Ethics Committee for Wales, 31/10/2008, ref: 08/MRE09/65
2. Amendments to the protocol approved 20/05/2009

## Primary study design
Observational

## Study design
Observational cross-sectional study

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Huntington's disease

## Interventions
As of 24/06/2009 this record was updated to include information on the updated protocol. Both participants with HD and matched healthy control subjects will also perform, as part of their respiratory function tests, a peak cough flow (PCF) test. Peak cough flow indicates whether an individual can cough sufficiently to clear secretions. In addition, participants with HD will also undergo a measurement of physical activity. This will enable the categorisation of subjects into active and sedentary lifestyles and will be used to gain a deeper understanding of exercise tolerance, functional capacity and posture measurements. Physical activity will be measured using the International Physical Activity Questionnaire (IPAQ).

Study design
This cross sectional study aims to assess respiratory function and factors related to respiratory function in people with HD and compare this to healthy control subjects. There will be no intervention in the study.

Methodology: People with HD
Potential subjects attending their routine clinic will be approached by Professor Anne Rosser, the clinician responsible for their care, and will be invited to participate in the programme alongside the 'Registry' study. Many patients attending the HD clinic are already enrolled in the Registry study (04//WSE05/89). One of the optional components within the Registry project includes permission to be contacted between visits. Patients who have consented to this component will be contacted by letter and informed of the study. The researcher will assume responsibility for any further telephone follow up of the postal information sheet. Potential subjects will be given an information sheet and will only be contacted to discuss their involvement in the study once they have had sufficient time, approximately 1 week, to consider the information provided. When informed consent has been gained, the researcher will meet with the subject and discuss the study and arrange a convenient time for the assessment to take place. The assessment will take place either at the HD clinic or at the Research Centre for Clinical

Kinaesiology (Cardiff University) or at the person's home dependent upon the wishes of the subject.

Assessment protocol for people with HD
Relevant medical history, medication history and clinical data, will be accessed through the 'Registry' study, as most people in the HD clinic are involved in this study. This will reduce the time necessary to collect data from the subjects. Information relating to motor, cognitive and behavioural status will also be available for further analysis.

Session 1 - all subjects
1. The assessment will be explained to the subject. The subject will be asked about current and past respiratory problems to gain a picture of their general respiratory health.
2. Basic information such as height, weight and BMI will be collected.
3. Respiratory rate and respiratory function will be assessed. Respiratory function will be assessed by taking measurements of lung volumes, rate of expiratory flow, inspiratory and expiratory muscle strength and respiratory muscle endurance.
4. Swallow capacity will be assessed. Subjects will be timed during swallowing a predetermined volume of water and the number of swallows recorded. They will also be asked questions about signs and symptoms related to swallowing.
5. Posture will be assessed. A short video, approximately 1 minute, will be taken of the subjects posture in either a chair or the subject's wheelchair.
6. Functional capacity will be assessed. The subject, with help from the researcher if necessary, will complete a questionnaire on their ability to carry out activities of daily living including feeding, bathing, dressing.
7. Exercise capacity will be assessed in those subjects who are able to walk. Subjects will be asked to walk between two cones, a set distance apart, for 6 minutes. Resting within the test is allowed. The distance covered in 6 minutes and the number of rests will be recorded.

Up to 15 participants will also be selected from the sample to investigate perceptions of respiratory problems. A questionnaire will be used to gain a deeper understanding of how people feel about their breathing. If the person with HD is unable to answer the questions a carer will be asked to complete the questionnaire. The number of people being asked to complete the questionnaire is dependent upon the information gained and when no new information is gained from subjects, data collection will be complete. Completion of the questionnaire will take place during the assessment session.

Assessment protocol for matched healthy control subjects
Potential healthy control subjects will be recruited from carers, friends or relatives of people with HD introduced to us by the patient and in the same manner as the subjects with HD. All potential subjects will receive an information sheet and will be given at least one week to consider the information, before being contacted to discuss their involvement. The assessment will take place either at the HD clinic or at the Research Centre for Clinical Kinaesiology (Cardiff University) or at the person's home dependent upon the wishes of the subject.

Assessment session
1. The assessment session will be explained to the subject. The subject will be asked about current and past respiratory problems to gain a picture of their general respiratory health.
2. Respiratory rate and respiratory function will be assessed. Respiratory function will be assessed by taking measurements of lung volumes, rate of expiratory flow, inspiratory and expiratory muscle strength and respiratory muscle endurance.

The methodology has been chosen to enable the objectives of the study to be achieved with least burden to the subject. Healthy control subjects will only have measurements taken of those outcome measures that will be compared with people with HD. The additional measurements being undertaken by people with HD are necessary in order to potentially explain any changes that may occur in the respiratory system as the disease progresses. Methods for assessment of respiratory function, swallow, functional capacity, exercise capacity are all accepted and reliable measurement tools.

Measurement of posture by means of computer analysis of images will be validated before the commencement of the study. The questionnaire will also be tested for validity and reliability before the commencement of the study.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
Respiratory function including:
1. Forced vital capacity (FVC)
2. Forced expiratory volume in 1 second (FEV1)
3. Forced expiratory ratio (FEV1/FVC)
4. Flow volume loops
5. Sniff nasal inspiratory pressure (SNIP)
6. Maximal inspiratory pressure (PIMax)
7. Maximal expiratory pressure (PEMax)
8. Respiratory muscle endurance (TLim)

### Key secondary outcome(s)
1. Swallow capacity (mls/sec)
2. Perception of respiratory problems

Relational outcome measures:
1. Posture: thoracic angle, cervical angle, head tilt
2. Exercise capacity: 6 minute walk test (distance walked in 6 minutes)
3. Functional capacity: Barthel index (questionnaire measuring ability to carry out activities of daily living)

### Completion date
31/12/2014

## Eligibility

### Key inclusion criteria
People with Huntington's disease:
1. Both males and females, aged 18 years or older
2. Confirmed diagnosis of HD
3. Able to understand instructions in English

Healthy subjects:
1. Age, sex and body mass index (BMI) matched individuals
2. Able to understand instructions in English

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Key exclusion criteria
Inability to understand English

### Date of first enrolment
01/01/2009

### Date of final enrolment
31/12/2014

## Locations

### Countries of recruitment
United Kingdom

Wales

### Study participating centre
**Cardiff University**
Cardiff
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## Sponsor information

### Organisation

Cardiff University (UK)

**ROR**
https://ror.org/03kk7td41

# Funder(s)

**Funder type**
Charity

**Funder Name**
Physiotherapy Research Foundation (UK) (ref: PRF/08/3)

**Funder Name**
Research Capacity Building Collaboration, Wales (RCBC Wales) (UK) - in the form of a part-time PhD fellowship

# 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? |
|---|---|---|---|---|---|
| Results article | results | 23/06/2016 | | Yes | No |