ISRCTN72770961 https://doi.org/10.1186/ISRCTN72770961

Respiratory function in people with Huntington's disease

Submission date	Recruitment status	[ ] Prospectively registered
13/06/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/01/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/06/2016	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Una Jones

Contact details
Department of Physiotherapy
Cardiff University
Heath Park
Cardiff
United Kingdom
CF14 4XN
+44 (0)29 2068 7690
jonesuf@cardiff.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Other

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
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 measure
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)

Secondary outcome measures
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)

Overall study start date
01/01/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

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
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.cf.ac.uk/racdv/resgov/index.html

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

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