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A study to establish reference values for the incremental shuttle walk test in a healthy population

Submission date 17/12/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/02/2011	**Overall study status** Completed	
Last Edited 02/09/2014	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10860

Study information

Scientific Title
A single-centre observational study to establish reference values for the incremental shuttle walk test in a healthy population

Acronym
ISWT

Study objectives
To establish normal values for the Incremental Shuttle Walk Test (ISWT) in a group of healthy adults who are aged between 40 and 90 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northamptonshire and Rutland Research Ethics Committee 2, 13/01/2010, ref: 09/H0402/108

Study design
Single-centre observational study

Primary study design
Observational

Secondary study design
Single-centre

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Chronic obstructive pulmonary disease (COPD)

Interventions
Subjects attend an initial visit at Glenfield Hospital where once they have consented to participate in the study all the necessary subjective information, including height, weight and blood pressure, will be obtained. Subjects also complete a lung function test and a muscle strength test during this first visit. Once subjects' medical notes have been received and reviewed, subjects attend a second visit at Glenfield Hospital. During the second visit they

complete the exercise performance test and fill in three questionnaires. In the time between the two study visits subjects wear an activity monitor on two consecutive weekdays.

Incremental Shuttle Walk Test (ISWT):
Before commencing the test a standardised set of verbal instructions will be played to the subject via a CD player. The test requires participants to walk up and down a 10 metre course which is marked out by two cones placed 9 metres apart. The walking speed is externally paced and is dictated by a pre-recorded audio signal (a 'bleep') which is played on a CD player. The test is maximal and progressive. The test will stop when the subject completes the test, their legs feel too tired, they are too breathless to continue or they fail to keep up with the speed of the test. A failure to keep up with the speed of the test is characterised by a subject being more than 0.5 metre away from the next cone after one verbal instruction to speed up has been given. Subjects will be asked to speed up if they fail to be within 0.5 metre of the next cone before the 'bleep'. HR and Sa02 will be monitored via a pulse oximeter throughout the ISWT and recorded pre and post the ISWT. The Borg breathlessness score will also recorded pre and post and rating of physical exertion (RPE) will be recorded post the ISWT. The test is repeated after a 30-minute rest.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Incremental Shuttle Walk Test (ISWT) measured at baseline and repeated after a 30-minute rest.

Secondary outcome measures
Measured on a one-off occassion:
1. Isometric quadriceps strength measured using a Kern CH 50 K 100 Strain Gauge
2. Physical activity measured using the Duke Physical Activity Questionnaire and The Physical Activity Questionnaire
3. Anxiety and depression measured using The Hospital Anxiety and Depression Scale (HADS)

Overall study start date
01/02/2010

Completion date
01/11/2011

Eligibility

Key inclusion criteria
1. Patients over the age of 40 years, either sex
2. Medical Research Council (MRC) grade of 1 or 2
3. Normal spirometry diagnosed by forced expiratory volume in one second (FEV1) greater than 80% or FEV1/forced vital capacity (FVC) ratio of greater than 70% of their predicted age group average (NICE, 2004; BTS, 2005)
4. Willingness to participate (informed consent)

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Subjects less than 40 years old or more than 90 years old
2. Subjects with any co-morbidities that affect their mobility
3. Subjects with known cardiovascular disease or any unstable cardiac conditions
4. Body mass index (BMI) less than 18.5 or greater than 40 kg/m2 (Food Standards Agency [FSA])
5. Subjects with a resting systolic blood pressure (SBP) greater than 180 mmHg or resting diastolic blood pressure (DBP) greater than 100 mmHg
6. Subjects with pulmonary dysfunction diagnosed by FEV1 less than 80% or FEV1/FVC less than 70% of their predicted age group average (NICE, 2004; BTS, 2005)
7. Subjects without the capacity to give informed consent; if they are confused or if they are impaired by pain

Date of first enrolment
01/02/2010

Date of final enrolment
01/11/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
CLAHRC Research Office, Ward 25
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Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospitals of Leicester NHS Trust (UK) - Pulmonary Rehabilitation Department

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	01/09/2013	Yes	No