

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
Registration date 18/02/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/09/2014	Condition category Respiratory	☐ 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
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

Primary study design

Observational

Study design

Single-centre observational study

Study type(s)

Diagnostic

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 SaO₂ 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(s)

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

Key secondary outcome(s)

Measured on a one-off occasion:

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

CLAHRC Research Office, Ward 25

Leicester

United Kingdom

LE3 9QP

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (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

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