ISRCTN78843393 https://doi.org/10.1186/ISRCTN78843393

Physical Activity and Respiratory Health (PhARaoH) study

Submission date
11/12/2013

Recruitment status
No longer recruiting

Registration date
09/01/2014

Overall study status
Completed

Last Edited
04/10/2018

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a lung disease causing difficulty or discomfort in normal breathing. COPD is the fourth leading cause of death worldwide and should not simply be considered as a smokers cough, but a highly under-diagnosed disease influenced by a range of factors. This study aims to find out the role of physical activity and psychological and social factors in the development and progression of COPD.

Who can participate?
Adults aged 40 75 years of age residing in Leicestershire and Rutland (UK) are eligible to participate.

What does the study involve?
Participants will be asked to attend one 2-hour testing visit at Glenfield Hospital. Testing will involve spirometry (to assess lung function); measures of height, weight, waist circumference and percentage body fat; a blood sample from the arm (to test for cholesterol and glucose levels); blood pressure measurement; 10-metre shuttle walk test (fitness) and strength tests (leg and grip). On completion of the visit, participants will be asked to wear two activity monitors (one worn on the waist and one worn on the wrist) for eight days. A small number of them, up to 50 COPD patients, will be invited to participate in a one-on-one interview in which they will discuss their feelings and beliefs surrounding their diagnosis and indications towards physical activity programmes.

What are the possible benefits and risks of participating?
Participants will receive a comprehensive health check as well as written information and explanation of their physical activity levels. Any clinically important results will be passed on to their GP. Ultimately, taking part in the research will help to facilitate better care for COPD patients and those at risk of developing COPD. As with all physical activity, there is a very small risk of accident or injury during the exercise tests (walking and strength tests). All the exercise will be supervised by trained research staff and will take place on NHS premises with resuscitation equipment available and trained staff on hand to use it. Taking blood samples from the arm may cause slight pain or bruising afterwards.

Where is the study run from?
The study is run from the Respiratory Biomedical Research Unit, Glenfield Hospital, Leicestershire, UK.

When is the study starting and how long is it expected to run for?
Recruitment started in January 2014 and the study will end in May 2014.

Who is funding the study?
The study is funded by the Department of Health, UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Physical and psycho-social profiling of patients with mild-to-moderate chronic obstructive pulmonary disease data to inform an intervention

Acronym
PhARaoH

Study objectives
To investigate demographic characteristics, symptoms, fitness, childhood disadvantaged factors, function, objectively assessed physical activity/sedentary behaviour, health-related quality of life (HRQL) and psychosocial characteristics (e.g. anxiety, depression, self-efficacy, perceptions of disease, etc) in COPD patients and non-COPD controls grouped by spirometric classification and self-reported disability (MRC breathlessness score).

A secondary objective is to conduct one-on-one interviews to obtain real life experiences/stories about developing COPD and the impact of timing and personal context on these responses. To examine environmental factors influencing willingness or motivation to exercise and receptivity towards physical activity programmes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Nottingham 2, 01/11/2012, ref: 13/EM/0389

Study design
Observational cross-sectional single-centre study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
COPD patients will be identified from GP records. Control (smoking and non-smoking) participants and some COPD patients will respond to newspaper/radio/website advertisements.

Participants will be required to attend the testing site on one occasion for approximately two hours. Blood pressure, height, weight and waist circumference will be measured and percentage body fat will be assessed using a bioelectrical impedance scale. Upon anthropometry completion, a single (4-hour fasted) blood draw will be taken to assess cardio-metabolic markers (total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, glucose, C-reactive protein, HbA1c). A spirometery assessment will require each participant to take a maximal inspiration before performing a forced exhalation. Participants will be asked to complete an incremental shuttle walking test (ISWT), which is a standardized field walking test that provokes a symptom-limited maximal performance providing an objective measurement of disability. Participants will be asked to walk up and down a 10 m course with the speed of the walk dictated by an audio signal played on a CD. Participants will continue walking until they feel unable to maintain the necessary speed without becoming unduly breathless. Participants will complete the tests twice, with a 30-minute rest period in between and the highest value (distance walked) of the two walks will be recorded. Quadriceps (leg) strength will be tested by asking participants to perform a maximal knee extension of the dominant leg against resistance. A grip strength test will require participants to squeeze a dynamometer with as much force as possible. Questionnaires will be used to collect information on childhood experiences (e.g., number of siblings, access to a car and access to hot water in the house during childhood) that may be associated with respiratory disease in later life; domain-specific (occupation, transportation, home-based and leisure-time) physical activity levels over the last 7 days; time spent sitting during a weekday and weekend day whilst travelling, at work, watching television, using a computer and for leisure; domestic, work and recreational physical activity over the past 12 months; participants perceived health status; shortness of breath severity; physical, social,

emotional and functional well-being; self-efficacy to pulmonary rehabilitation; impact of COPD on a persons life, and how this changes over time. Lastly, participants will be asked to wear a wrist-worn and a waist-worn activity monitor (i.e., accelerometer) for 8 days and then return the monitor by mail. A sub-sample of up to 50 COPD patients will be followed up and invited to participate in optional one-to-one interviews. COPD patients will be asked to share their thoughts on coping with and managing their disease and whether (and how) they feel disease may limit their activity levels. The interview would be digitally recorded and professionally transcribed; with transcripts returned to participants for verification.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Time spent sedentary and in light, moderate and vigorous physical activity objectively assessed using an Actigraph GT3x-BT accelerometer and a wrist-worn GeneActiv.

All primary and secondary outcome measures will be taken at one time point for each participant. A sub-study of COPD patients will be invited, within 3 weeks on the baseline measure, to take part in a qualitative interview at their home.

Key secondary outcome(s))
1. Exercise capacity - meters on the best Incremental Shuttle Walk Test (ISWT)
2. Biographical themes obtained from qualitative interviews

Completion date
05/12/2016

Eligibility

Key inclusion criteria
Male and female, 40-75 years and residing in Leicestershire, UK

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Clinically relevant medical or psychiatric condition(s) which could interfere with completing the testing protocol 2. Pregnancy

3. Impaired hearing sufficient to prevent the participant carrying out the shuttle walk tests, which require walking at a speed controlled by an external audible bleep signal. Use of walking aids will be allowed as long as the same aids are used in the walking tests as in free living

Date of first enrolment
10/03/2014

Date of final enrolment
29/08/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Loughborough University
Epinal Way
Loughborough
United Kingdom
LE11 3TU

Study participating centre
Respiratory Biomedical Research Unit
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from http://www.lboro.ac.uk/research/mi-lab/research/pharaoh/pharaohconditionsofuse/ (data request form submitted to MI-Lab@lboro.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2017		Yes	No
Results article	results	01/06/2018		Yes	No
Results article	results	01/08/2018		Yes	No
Dataset	dataset	05/12/2016		No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes