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Can a physical activity programme or pulmonary rehabilitation reduce the risk of heart and circulation disease in people with COPD?

Submission date
01/04/2019

Recruitment status
Stopped

Registration date
05/04/2019

Overall study status
Stopped

Last Edited
21/01/2022

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a lung disease that involves difficulties breathing and increased phlegm (mucus) production. Cardiovascular (heart and circulation) disease is common in patients with COPD. Being more active can help to reduce the risk of getting heart disease. In addition, being more active can help to reduce risk factors for heart disease, for example, high blood pressure, a high cholesterol level or diabetes. There is lots of evidence supporting a role for physical activity in improving a variety of health outcomes in healthy individuals. For people with COPD, pulmonary rehabilitation (a combination of health education and training in breathing techniques and physical exercise) has been shown to help reduce the symptoms of breathlessness and improve the ability to exercise. However, there is little evidence on whether pulmonary rehabilitation influences risk markers for heart disease. Equally it is not clear whether increasing levels of physical activity reduces the risk of heart disease in COPD patients. This study aims to compare the benefits of a structured exercise programme delivered as part of pulmonary rehabilitation with a more general physical activity programme on cardiovascular health and well-being in people with COPD.

Who can participate?
People aged 40-85 years who have COPD

What does the study involve?
Participants will be randomly allocated assigned to one of three groups: physical activity group, pulmonary rehabilitation group or usual care group. The researchers will measure a number of different things before and after the 6-week treatment period to see if there are any changes. The measurements will include aerobic fitness (walking test), strength tests, physical activity levels, quality of life, levels of body fat and risk markers for heart disease such as fasting cholesterol, glucose and markers of inflammation.
A total of 20 participants (10 from the physical activity group and 10 from the pulmonary rehabilitation group) will also be invited to take part in a sub-group study involving three additional visits, resulting in a total of five visits. One visit will involve a magnetic resonance imaging (MRI) scan to assess the amount of fat stored around the internal organs. Two visits

(before and after the intervention) will involve a meal test where the amount of fat in blood will be measured after participants have eaten a meal with a known fat content.

What are the possible benefits and risks of participating?
There are no guaranteed benefits of taking part in this study. However, the participants might benefit from a detailed assessment of their risk of cardiovascular disease. This includes measures such as cholesterol, glucose and the amount of body fat. The participants' physical activity levels, strength and aerobic fitness level will also be assessed. Participation may help in developing strategies to manage COPD by giving a broader view of the participant's well-being. It will also help researchers to understand the importance of physical activity and pulmonary rehabilitation on COPD symptoms and cardiovascular risk factors.
The risks for taking part in the research project are very similar to the risks associated with the pulmonary rehabilitation programme. All exercise tests will be supervised by trained research staff trained in basic first aid and cardiac (heart) life support. Participants may experience some muscle soreness after completing the muscle strength tests in visits 1 and 2, although this should subside soon after the test. Blood sampling during visits 1 and 2 and visits B and C (sub-group participants only) carries a small risk of causing minor discomfort and bruising of the surrounding area; however, the researchers will try and minimise this.
Participants in the sub-group study will be asked to undergo an MRI scan during visit A to measure the body fat stored around the organs. Participants will be asked to complete a safety questionnaire before the scan which will be checked by a trained radiographer to ensure it is safe for them to undergo the scan. There are no known side effects of having an MRI scan but you may not be able to undergo the scan if you have any medical metallic implants (e.g. metal surgical implants, pacemakers, metal fragments in the eye etc). Any metallic objects, including piercings, must be removed before the scan. The noise of the scanner can cause anxiety in a small number of participants so they will be provided with headphones to minimise the noise. The MRI scan may cause some individuals to feel claustrophobic. The MRI staff and a researcher will be available throughout the scan and the scan will be terminated at the onset of any sign of undue stress. Every effort will be taken to ensure participants are comfortable and they can withdraw from this aspect of the study at any time. There may be a rare occasion where the radiographer may spot an incidental finding which may or may not have health implications and participants may be advised to seek further medical advice.

When is the study starting and how long is it expected to run for?
January 2018 to October 2020

Where is the study run from?
University Hospital Leicester NHS Trust (UK)

Who is funding the study?
1. Loughborough University (UK)
2. University Hospital Leicester NHS Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT03869112

Protocol serial number
109501

Study information

Scientific Title
The effectiveness of a physical activity intervention versus pulmonary rehabilitation on cardiovascular risk markers for individuals with chronic obstructive pulmonary disease: a feasibility study

Acronym
PARC

Study objectives
This study is to examine the feasibility of conducting a trial to compare the impact of pulmonary rehabilitation and physical activity interventions in a number of important clinical outcomes

including cardiovascular risk. Feasibility will be assessed by various factors including ease of recruitment, uptake into a combined rehabilitation programme and the feasibility of assessing a suite of outcome measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/11/2018, East Midlands - Leicester South Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8109; NRESCommittee.Eastmidlands-LeicesterSouth@nhs.net), ref: 18/EM/0270.

Study design
Three-arm single-centre randomised feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiovascular disease in people with chronic obstructive pulmonary disease (COPD)

Interventions
At visit 1, the investigators will use https://www.sealedenvelope.com for randomisation following consent. The ratio for randomisation will be 2:2:1 (pulmonary rehabilitation: physical activity: usual care respectively). The researchers will measure waist circumference, body fat percentage, weight and arterial stiffness and will take blood. The participants will complete questionnaires on risk factors for CVD, breathlessness, health status, COPD knowledge, impact of COPD on their life, anxiety and depression, and self-efficacy. They will also undergo two tests of their exercise capacity. During the week before the intervention starts, participants will wear an ActiGraph physical activity monitor.

In a subgroup study, 20 participants will have additional visits and measures. These include magnetic resonance imaging (MRI) to assess fat tissue around the abdomen and a postprandial lipaemic test before and after the intervention to allow for comparison.

Participants assigned to the physical activity group will be given a FitBit Charge 2 (a heart rate and fitness wristband that tracks activity and exercise). This is a watch that also measures physical activity levels and allows the investigators to provide feedback to the participant through the watch. The device cannot be worn when doing water-based activities (such as bathing, showering, swimming etc.). The FitBit Charge 2 will be tracking participants in order to verify their step count. Researchers will not have access to the GPS tracking data. If the participant reaches their initial steps target, the researchers will increase the target by 500 steps. The target calculation will be obtained by calculating the mean of the four most active days plus 500 steps and if it is achieved, the target has been met and a new target will be set at an additional 500 steps. However, if the mean of the four most active days does not exceed the target then the researchers will calculate the median of the four most active day plus 500 steps. If the participant met the target, they will get a new target and if not, the target will remain the same. Participants will be monitored remotely as the Fit Bit device has the feature of automatic

syncing to their smartphone. The investigator can receive data from the FitBit device including physical activity level, intensity and time in addition to other features that include heart rate and sleep quality. The investigator can send messages to the participants through Charge 2 when needed and they will receive it on the charge 2 screen.

Participants assigned to the pulmonary rehabilitation group will be scheduled to start a 6-week programme that consists of two 2-h sessions each week at the University Hospitals of Leicester NHS Trust (Glenfield Hospital , Leicester Hospital or The National Centre for Sport and Exercise Medicine pulmonary rehabilitation services), which will follow the British Thoracic Society guideline on pulmonary rehabilitation in adults. The sessions will involve a combination of exercise training and education supervised by staff from the rehabilitation team.

Participants randomised to the usual care group will have full access to their usual treatment for 6 weeks but will not be involved in any physical activity or pulmonary rehabilitation during this time.

After the 6-week intervention period, all participants will be asked to complete an exit assessment which will repeat the measurements, blood sampling, questionnaires and exercise assessments completed during visit 1, plus the additional measurements if they are in the sub-group. They will be given an accelerometer again to wear for 7 consecutive days, starting the day immediately after this visit. The researchers will collect the device at a convenient time and place to collect the device from participants after they have worn it for 7 days. All participants who were allocated to the physical activity group or the usual care group will be offered a pulmonary rehabilitation programme at the end of the study.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility will be determined using, but not restricted to, the following criteria:
1. How many patients are eligible for inclusion (i.e. meet the inclusion criteria)
2. Recruitment/response rate (i.e. number and proportion of those eligible who consent to take part)
3. Refusal rate
4. Willingness of patients to be recruited and randomised to either intervention or usual care and the willingness of healthcare professionals to refer to this study and future trials
5. Service provider and multi-disciplinary team willingness and ability to deliver the new intervention
6. Suitability of the inclusion criteria
7. Acceptability, utility and practicality of evaluation measures regarding burden of measurement and compliance
8. The practicality of delivering the intervention in the proposed setting
9. The time needed to collect and analyse the data
10. Test methods for the collection of baseline and follow-up data as well as data completeness and accuracy (including changes in clinical health outcome measures)
11. The acceptability (how individual recipients react to the intervention) of the rehabilitation programme and the research trial will be assessed through interview
12. Feasibility of conducting outcome measures to compare the effectiveness of physical activity intervention and the conventional pulmonary rehabilitation programme outcomes
13. Feasibility of investigating arterial stiffness response to pulmonary rehabilitation programme and physical activity interventions

14. Feasibility of investigating postprandial lipaemia response before and after interventions as a sub-group study
15. Feasibility of investigating the relationship between visceral adipose lipid amount and study outcomes as a sub-group study

Key secondary outcome(s))

1. Waist circumference measured at the narrowest part of the torso above the umbilicus and below the xiphoid process using a measuring tape before and after the intervention
2. Body fat in percentage will be measured in %BF using bioelectrical impedance analysis before and after the intervention
3. Fasted triglyceride concentration in blood before and after the intervention
4. Fasted total cholesterol concentration in blood before and after the intervention
5. Fasted high-density lipoprotein (HDL) cholesterol concentration in blood before and after the intervention
6. Fasted low-density lipoprotein cholesterol concentration in blood before and after the intervention
7. Fasted C-reactive protein (CRP) concentration in blood before and after the intervention
8. Fasted insulin concentration in blood before and after the intervention
9. Fasted glucose concentration in blood before and after the intervention
10. Arterial stiffness assessed using aortic pulse wave velocity will be used to assess arterial stiffness, an independent predictor of cardiovascular disease risk. A noninvasive device (Vicorder) will be used to assess arterial stiffness which measures pulse wave velocity between the carotid and the femoral arteries.
11. Risk of developing CVD over the next 10 years assessed using the QRISK2 questionnaire before and after the intervention
12. Weight in kg will be measured using an electronic measuring station before and after the intervention
13. Body mass index in kg/m2 will be calculated from height in cm and weight in kg before and after the intervention
14. Effect of breathlessness on mobility assessed using the Medical Research Council dyspnoea scale before and after the intervention
15. Breathlessness assessed using the Borg Dyspnoea Scale before and after the intervention
16. Step counts per day measured using an actigraph physical activity monitor. Participants will wear the device for one week at week 1 (before the intervention) and week 8 (after the intervention).
17. Health status assessed using the Chronic Respiratory Disease Questionnaire Self-Reported (CRQ-SR) before and after the intervention
18. COPD knowledge assessed using the Bristol COPD Knowledge Questionnaire (BCKQ) before and after the intervention
19. Impact of COPD on a person's life assessed using the COPD Assessment Test (CAT) Questionnaire before and after the intervention
20. Anxiety and depression assessed using the Hospital Anxiety and Depression Scale (HADS) before and after the intervention
21. Self-efficacy assessed using the Pulmonary Rehabilitation Adapted Index of Self-Efficacy (PRAISE) before and after the intervention. PRAISE is a tool that predicts the reduction in sedentary time following pulmonary rehabilitation in individuals with COPD.
22. Exercise capacity assessed using the Incremental Shuttle Walking Test (ISWT) before and after the intervention
23. Exercise capacity assessed using the endurance shuttle walk test (ESWT) before and after the intervention
24. Postprandial triglyceride concentrations in blood measured after an overnight fast and 4 h

after consuming a high-fat meal to measure the postprandial TAG response. The test will be conducted before and after the intervention in a sub-group of participants.
25. Postprandial total cholesterol concentration in blood measured after an overnight fast and 4 h after consuming a high-fat meal to measure the postprandial total cholesterol response. The test will be conducted before and after the intervention in a sub-group of participants.
26. Postprandial high-density lipoprotein cholesterol concentration in blood measured after an overnight fast and 4 h after consuming a high-fat meal to measure the postprandial high-density lipoprotein cholesterol response. The test will be conducted before and after the intervention in a sub-group of participants.
27. Postprandial low-density lipoprotein cholesterol concentration in blood measured after an overnight fast and 4 h after consuming a high-fat meal to measure the postprandial low density lipoprotein cholesterol response. The test will be conducted before and after the intervention in a sub-group of participants.
28. Postprandial total C-reactive protein (CRP) concentration in blood measured after an overnight fast and 4 h after consuming a high-fat meal to measure the postprandial C-reactive protein response. The test will be conducted before and after the intervention in a sub-group of participants.
29. Postprandial total insulin concentration in blood measured after an overnight fast and 4 h after consuming a high-fat meal to measure the postprandial insulin response. The test will be conducted before and after the intervention in a sub-group of participants.
30. Postprandial total glucose concentration in blood measured after an overnight fast and 4 h after consuming a high-fat meal to measure the postprandial glucose response. The test will be conducted before and after the intervention in a sub-group of participants.
31. Visceral adipose tissue quantified before the intervention using magnetic resonance imaging (MRI).

Completion date
01/10/2020

Reason abandoned (if study stopped)
The study was closed due to public health guidance causing restrictions to study activities

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the study
2. Aged 40 years to 85 years.
3. Diagnosed with COPD
4. Able (in the Investigators opinion) and willing to comply with all study requirements.
5. Participant is willing to attend visits at baseline and 8 weeks (sub-group: baseline, 8 weeks)
6. Able to read and understand English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Attended a pulmonary rehabilitation programme or participating in a physical activity intervention study in current time or in the last 6 months
2. Any other significant diseases or disorders that are a contraindication to be enrolled in a pulmonary rehabilitation programme

Date of first enrolment
18/02/2019

Date of final enrolment
01/07/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Glenfield Hospital
Groby Rd
Leicester
United Kingdom
LE3 9QP

Study participating centre
National Centre for Sport and Exercise Medicine
Loughborough University
Loughborough
United Kingdom
LE11 3TU

Sponsor information

Organisation
University Hospital Leicester

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
University/education

Funder Name
Loughborough University

Alternative Name(s)
Lboro

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
University Hospitals of Leicester NHS Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No