ISRCTN15892972 https://doi.org/10.1186/ISRCTN15892972

Can an activity monitor be used to set exercise level in patients with chronic obstructive pulmonary disease during an outpatient based course of pulmonary rehabilitation?

Submission date
24/02/2017

Recruitment status
No longer recruiting

Registration date
12/05/2017

Overall study status
Completed

Last Edited
20/01/2021

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name given to a collection of diseases which affect the lungs. It is characterised by breathlessness, cough and excess mucus production and is often caused by smoking. People suffering from COPD often have lower levels of physical activity and exercise capacity than those without the condition, increasing their risk of hospitalisation or death. Pulmonary rehabilitation (PR) is a is a universally recognised program of exercise, education and support that is used in patients with COPD to help them improve their physical condition. PR is therefore recommended in national and international guidelines for the management of patients with COPD for all those experiencing physical restrictions to daily life. Activity monitors that record steps could be used to help patients monitor exercise training sessions and better understand their background physical activity levels; until now this has only been carried out using research style equipment, which gives no feedback to the patient. The aim of this study is to find out whether it is feasible to use a commercial activity monitor, which offers real time feedback to patients, to prescribe an exercise training programme (i.e. step count per minute of exercise), and whether this can be identified from the data retrieved from the device.

Who can participate?
Adult COPD patients who have been referred by their clinician for outpatient PR delivered from a hospital site.

What does the study involve?
After agreeing to take part, participants are instructed about how to wear and use the activity monitor device. They then complete a walking test usually used in the hospital's pulmonary rehabilitation programme with the device in place. Using the information from the device, participants are told about their walking exercise intensity based on steps per minute and how to check this speed during exercise bouts using the activity monitor device. Participants then attend twelve pulmonary rehabilitation classes, usually over the course of six weeks. After the

twelfth class participants attend a discharge assessment where the activity monitor will be returned to the researcher.

What are the possible benefits and risks of participating?
Participants may benefit from becoming more active. There are no notable risks involved with participating.

Where is the study run from?
Glenfield Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2016 to August 2017

Who is funding the study?
University Hospitals of Leicester NHS Trust (UK)

Who is the main contact?
Ms Sarah Ward
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
71186

Study information

Scientific Title
Can a commercial activity monitor be used to effectively prescribe exercise and increase physical activity levels in chronic respiratory patients undertaking outpatient pulmonary rehabilitation? - A feasibility study

Study objectives
Study aims:
1. To to determine if patients undergoing pulmonary rehabilitation will wear an activity monitor daily to monitor their exercise
2. To determine whether it is possible to prescribe exercise using steps/min rather than traditional expressions of walking intensity
3. To determine if it is possible to identify these bouts of exercise from the data collected from the device

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Newcastle & North Tyneside 1, 12/07/2016, ref: 16/NE/0236

Study design
Single-centre non-randomised feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Participants will be identified from clinical service during routine assessment for pulmonary rehabilitation. If interested will be given an information sheet and an appointment for consenting made for a date coinciding with the participants first rehabilitation class.

Following consent being obtained the participant will undergo a walking test (same test carried out during routine assessment) with the device in place to gain specific exercise prescription parameters of steps per minute. Participants will then attend the routine pulmonary rehabilitation classes during which the researcher will analyse the data stored on the activity

monitor device since the last session and spend a short time, during the usual session, giving feedback to the participant and setting new activity goals with them for the coming week. At the end of the pulmonary rehabilitation programme the participants will undertake a routine discharge assessment where the activity monitor will be collected. In total participants will be expected to attend one additional visit of approximately 30-45 minutes and complete one additional questionnaire at discharge, compared with routine clinical care.

The duration of the intervention will last as long as the course of pulmonary rehabilitation; approximately 8 weeks and there will be no follow up.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
1. Agreement between participant reported exercise bouts and data uploaded from activity monitor device at each rehabilitation class visit
2. Agreement of walking intensity (steps per minute) from uploaded data identifying exercise bouts and prescribed walking intensity

Secondary outcome measures
Physical activity levels of participants across the course of pulmonary rehabilitation measured by average daily step count uploaded from the activity monitor device from week one to week six of the programme

Overall study start date
20/06/2016

Completion date
01/08/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. Diagnosis of COPD (FEV1/FEV <0.7 measured by spirometry)
3. Stable condition, medically optimised and free of exacerbations for 30 days
4. Able (in the investigators opinion) and willing to comply with all study requirements; able to appropriately place the activity monitor device to their person
5. Willing and able to give informed consent
6. Willing to undergo a course of pulmonary rehabilitation at Glenfield Hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
19

Key exclusion criteria
1. Comorbidities that would limit participation in a pulmonary rehabilitation programme such as significant musculoskeletal, neurological or psychological conditions
2. Comorbidities that contraindicate field exercise tests such as severe ventricular dysfunction, severe aortic stenosis, hypertrophic obstructive cardiomyopathy, severe pulmonary hypertension, myocardial infarction within previous 6 weeks, hypertension with resting systolic pressure >210mmHg and/or diastolic pressure >110mmHg, abdominal aortic aneurysm >5.5cm in diameter
3. Unwilling to enrol onto the supervised outpatient pulmonary rehabilitation programme
4. No diagnosis of chronic obstructive pulmonary disease
5. Unable/unwilling to use activity monitor device throughout pulmonary rehabilitation
6. Any other significant disease or disorder which, in the opinion of the investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study
7. Unable to understand written or spoken English

Date of first enrolment
11/10/2016

Date of final enrolment
01/05/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Glenfield Hospital
UHL NHS Trust
Groby Road
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust

Sponsor details
Research & Innovation Office
Leicester General Hospital
Gwendolen Road
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United Kingdom
LE5 $PW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospitals of Leicester NHS Trust

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
Participant level data will be held securely; hardcopy on secure cabinets and offices, electronic data password protected on NHS computer. Data will not be made available as it is a small feasibility study dataset carried out for an academic qualification. If a larger study is warranted as a result of this study's results this may be made available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/01/2021	20/01/2021	Yes	No
HRA research summary			28/06/2023	No	No