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Is it possible to predict a worsening of lung disease symptoms using wearable technology measuring heart rate, breathing rate, skin temperature and physical activity?

Submission date
07/11/2018

Recruitment status
No longer recruiting

Registration date
27/03/2019

Overall study status
Completed

Last Edited
08/04/2024

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 a group of lung conditions that cause breathing difficulties. The course of COPD is characterised by a worsening of symptoms or exacerbations requiring a change of medication, more intensive treatment, and possibly an admission to hospital. What would be of greater value to the health service would be the identification of indicators of such worsening in order to help patients manage their condition better. Therefore, this study aimed to find out whether it is possible to predict a worsening of COPD symptoms using device worn on the body.

Who can participate?
Patients aged 40 years or above with COPD

What does the study involve?
Participants are recruited from either hospital wards or from a routine assessment for pulmonary rehabilitation. Patients will then be given information about the study. Individuals recruited from the wards complete some questionnaires and measures of physical function before they leave hospital. Individuals recruited from pulmonary rehabilitation assessments complete the same measures during a study visit. All participants are asked to complete a symptom diary at the end of each day and to wear a vest-like monitor which measures their heart rate, breathing rate, skin temperature and physical activity for 6-7 weeks. After this period, participants attend a final visit to repeat the previous measures.

What are the possible benefits and risks of participating?
There are no direct benefits to participants taking part in this study due to its observational nature; however, participants will be sent a summary of their data on request. There are no known risks to participants taking part in this study and the research team are happy to reimburse travel costs.

Where is the study run from?
Glenfield Hospital, University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
December 2016 to February 2020

Who is funding the study?
Pfizer Limited (USA)

Who is the main contact?
Dr Mark Orme
mark.orme@uhl-tr.nhs.uk

Contact information

Type(s)
Public

Contact name
Dr Mark Orme

ORCID ID
http://orcid.org/0000-0003-4678-6574

Contact details
NIHR Leicester Biomedical Research Centre - Respiratory
Glenfield Hospital, Groby Road
Leicester
United Kingdom
LE3 9QP

Type(s)
Scientific

Contact name
Dr Mark Orme

ORCID ID
http://orcid.org/0000-0003-4678-6574

Contact details
NIHR Leicester Biomedical Research Centre - Respiratory
Glenfield Hospital, Groby Road
Leicester
United Kingdom
LE3 9QP
01162502762
mark.orme@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
SYMPHONY (SYMptoms and PHysiology to Observe and uNderstand activitY): Using continuous, passive, non-invasive wearable technology to understand the interactions between physiology, behaviour, the environment and exacerbations of chronic obstructive pulmonary disease (COPD)

Acronym
SYMPHONY (SYMptoms and PHysiology to Observe and uNderstand activitY)

Study objectives
1. On days with elevated symptom severity, breathing rate, heart rate and skin temperature will be higher and physical activity will be lower than days with stable or milder symptom severity
2. It will be possible to predict symptom-based and event-based exacerbations of COPD using the physiological and behavioural information obtained from wearable technology
3. It will be feasible to collect behavioural and physiological data using wearable technology
4. The wearable technology will be acceptable to patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - City & East Research Ethics Committee, 26/10/2017, ref: 15/LO/2055

Study design
Observational prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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

Interventions
This prospective study has two groups; patients admitted for an acute exacerbation of COPD (acute group) and patients with stable disease (Stable group). The acute group will be recruited from hospital wards following admission for an acute exacerbation of COPD. The stable group will be recruited from hospital-based and community-based pulmonary rehabilitation assessment appointments as part of the usual care pathway.
For the acute group, patients admitted for an acute exacerbation of COPD will be screened by COPD Specialist Nurses for eligibility. Eligible patients will then be provided verbal and written information about the study. A member of the research team will speak to the patient to determine whether they wish to participate in the study. Written informed consent will be obtained. Participants will be asked to complete some questionnaires (outlined below), and their balance, walking speed and ability to rise from a chair will be assessed. Following discharge, participants will be asked to wear a light-weight device made from thin, breathable fabric for 6 weeks (±3 days for patient preference). Participants will be asked to wear this during waking hours only (except any water-based activities). Participants will be asked to charge the device overnight or during water-based activities for at least 30-60 minutes each day. Participants will be provided with cleaning equipment and instructions. A member of the research team will contact participants every fortnight by telephone to check how they are getting on.
For the stable group, a member of the pulmonary rehabilitation team will provide written and verbal information about the study during their pulmonary rehabilitation assessment visit as part of usual care. A member of the research team will contact eligible participants by telephone to find out if they would like to take part in the study and answer any questions they may have. This phone call may occur less than 12 hours after the completion of their pulmonary rehabilitation assessment if they are due to start pulmonary rehabilitation within two weeks of that date. People wishing to take part will be asked to attend the Respiratory Biomedical Research Unit at Glenfield Hospital. The visit will last no longer than 1 hour. Following informed consent, participants will be asked to complete some questionnaires (outlined below), and their balance, walking speed and ability to rise from a chair will be assessed. Participants will be asked to wear the chest-worn device for 1 week in order to obtain pre-rehabilitation (baseline) information about their physical activity and physiology. If the time between study visit and starting rehabilitation is less than 1 week, the participant will be asked to wear the device for that duration (e.g. 4 days). Once participants begin their pulmonary rehabilitation programme, they will be asked to wear the device for 6 weeks (the length of the pulmonary rehabilitation programme) with the same instructions as the acute group. Participants who do not go on to complete pulmonary rehabilitation will still be allowed to remain in the trial if they wish.
All patients will be asked to monitor their exacerbations using the EXAcerbations of Chronic pulmonary disease Tool (EXACT) patient-reported outcome (PRO) daily diary. The diary assesses breathlessness, cough and sputum, chest symptoms, difficulty bringing up sputum, feeling tired or weak, sleep disturbance, and feeling scared or worried about their COPD. Participants will be given an electronic device or paper version to complete the diary.
Environmental data will be obtained from the Met Office and will include physical, chemical and biological data on the lat-long co-ordinate of each participants home address during their study involvement.
Qualitative interviews will be conducted for a sub-sample of both acute and stable participants during their follow-up appointment. Participants will be asked about their COPD management,

coping, and experiences of exacerbations. They will also be asked about their experiences of the study, the study technology and symptom diary, providing valuable feedback on how they could be improved.
Participants are free to withdraw at any time without providing a reason and with no change to their usual care.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
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Primary outcome measure
Associations between the following will be assessed daily throughout the study:
1. Physical activity, assessed using daily summary data from the wearable technology
2. Physiology, assessed using daily summary data from the wearable technology
3. Environmental data, obtained from the Met Office
4. Symptoms, assessed using the EXACT-PRO daily diary

Secondary outcome measures
1. Feasibility of the wearable technology, assessed by qualitative interviews and field notes during fortnightly phone calls and at the follow-up appointment
2. Acceptability of the wearable technology, assessed by qualitative interviews, field notes and adherence to wearing and charging the device
3. Dyspnea, assessed using the Medical Research Council (MRC) dyspnea scale at the baseline and follow-up
4. Knowledge of COPD, assessed using the Bristol Knowledge Questionnaire at the baseline and follow-up
5. Depression and anxiety, assessed using the Hospital Anxiety and Depression Scale (HADS) at the baseline and follow-up
6. Impact of COPD, assessed using the COPD Assessment Test (CAT) at the baseline and follow-up
7. Health-related quality of life, assessed using the Chronic Respiratory Disease Questionnaire (CRQ) at the baseline and follow-up
8. Cognitive impairment, assessed using the Montreal Cognitive Assessment (MoCA) at the baseline and follow-up
9. Breathlessness, assessed using the Multidimensional Dyspnoea Profile at the baseline and follow-up
10. Balance, ability to rise from a chair and 4 metre walking speed, assessed using the Short Physical Performance Battery (SPPB) at the baseline and follow-up
11. Waist circumference, assessed by staff at the baseline and follow-up

Overall study start date
01/12/2016

Completion date
01/02/2020

Eligibility

Key inclusion criteria
Acute group:
1. Willing and able to give informed consent for participation in the study
2. Aged ≥40 years
3. Medical Research Council (MRC) grade 2-5 when stable
4. Able (in the opinion of the COPD Specialist Nurses) and willing to comply with all study requirements

Stable group:
1. Willing and able to give informed consent for participation in the study
2. Aged ≥40 years
3. Confirmed diagnosis of COPD
4. Medical Research Council (MRC) grade 2-5 when stable
5. Attendance to pulmonary rehabilitation assessment visit
6. Able (in the opinion of the Pulmonary Rehabilitation assessor) and willing to comply with all study requirements

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants
100 (50 in the acute group and 50 in the stable group)

Total final enrolment
100

Key exclusion criteria
All participants:
1. Female participants who are pregnant or lactating
2. 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
3. Unable or unwilling to comply with study requirements
4. Inability to take part in light intensity physical activity due to significant mobility issues (e.g. neurological/musculoskeletal disorder)

Acute group only:
1. Diagnosis of any other chronic respiratory condition as the primary cause of their hospital admission

Date of first enrolment
15/01/2018

Date of final enrolment
01/12/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester NHS Trust
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University of Leicester

Sponsor details
Research Governance Office
Research & Enterprise Division
University of Leicester
Leicester General Hospital
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW

Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Industry

Funder Name
Pfizer UK

Alternative Name(s)
Pfizer Ltd, Pfizer Limited

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer review journal and disseminated at conferences in 2020. The results of the study will be shared with the participants and relevant staff.

Intention to publish date
31/03/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	Proof of concept	26/04/2022	27/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		16/02/2022	08/04/2024	Yes	No