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RALPMH: Remote assessment of lung disease and impact on physical and mental health

Submission date
09/03/2021

Recruitment status
No longer recruiting

Registration date
10/03/2021

Overall study status
Completed

Last Edited
16/05/2024

Condition category
Respiratory

[X] Prospectively registered
[X] 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 for a group of lung conditions that cause breathing difficulties. The term ILD encompasses a wide range of conditions affecting the lung tissue (as opposed to asthma and COPD which affect the airways)
The study aims to investigate the potential benefit and feasibility of remote monitoring of patients' symptoms and physiology via wearables and phone sensors in patients with a range of high-burden pulmonary disorders.
Remote monitoring will use our open-source RADAR-base (https://radar-base.org) mHealth platform to collect and analyse multiple datasets associated with respiratory disorders. This will include continuous data collected from wearable devices (e.g. heart rate, spO2), including pulse oximeters, spirometer, mobile phones (audio, location), digital tests and smartphone symptoms questionnaires in 3 different disorder areas (COPD, ILD and Post Hospitalisation Covid).
During these unprecedented times, an urgent measure must be taken to ensure vulnerable patients with diseases, like COPD and ILD, continue to receive the quality of care they need. Currently, COVID-19 is a challenge for anyone, but especially for such vulnerable patients with pre-existing conditions and diseases when their routine care cannot be done properly. Remote monitoring of physiology and symptoms of patients via wearable devices is more timely and essential than ever. It could be used to support these patients and detect any potential disease exacerbation or progression.

Who can participate?
Patients with Chronic Obstructive Pulmonary Disorder (COPD), Interstitial Lung Disease (ILD) and Post Hospitalised COVID-19 patients.

What does the study involve?
We use various devices to remotely collect data on your physiology like Heart Rate and Oxygen Saturation. You would also provide daily samples of Spirometry and Pulse Oximetry. A number of questionnaires are also delivered so we can collect information such as symptom reporting from you.
Wearing a Garmin Vivoactive 4 wristband, Using the https://radar-base.org platform Questionnaire App (aRMT), a smart Spirometer (NextFlow AirNext), and a Finger Pulse Oximeter.

What are the possible benefits and risks of participating?
This is a research study and does not have any clinical intervention or any benefit to your treatment. You may keep the pulse oximeter at the end of the study. All devices used conform to CE marked safety standards and should present no risk to you.

Where is the study run from?
The study is run out of the Royal Free Hospital and University College London. This is in collaboration with King's College London and The South London and Maudsley NHS Trust (UK).

When is the study starting and how long is it expected to run for?
October 2020 to March 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Amos Folarin, amos.folarin@kcl.ac.uk

Study website
https://phidatalab.org/portfolio/ralpmh/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
274070

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 274070

Study information

Scientific Title
Remote Assessment of Lung Disease and Impact on Physical and Mental Health

Acronym
RALPMH

Study objectives
Feasibility study for the use of wearable sensors (Garmin Vivoactive 4), spirometry (NuvoAir Airnext) and finger pulse oximetry for the purpose of remote and near real-time participant exacerbation and disease trajectory observation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/05/2021, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8284; blackcountry.rec@hra.nhs.uk), ref: 21/WM/0087

Study design
Observational longitudinal

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Home

Study type(s)
Diagnostic

Participant information sheet
https://docs.google.com/document/d/11pv6sEUDF4B5r-mUFEoSgJFbB02zzizlLs3_RZkttFY/edit?usp=sharing

Health condition(s) or problem(s) studied
Lung diseases (COPD, ILD, COVID19)

Interventions
This study will investigate the potential benefit and feasibility of multiparametric remote monitoring of patient symptoms and physiology using commercially available wearables sensors for heart rate, activity, SpO2; spirometry, phone sensors, questionnaires and digital tests in patients with a range of pulmonary disorders.

Participants with lung diseases are enrolled and will wear wearable devices, use spirometers, finger pulse oximeters and app delivered questionnaires to monitor their disease remotely and in real-time over the course of 6 months.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Garmin Vivoactive 4, NuvoAir Airnext, and finger pulse oximetry

Primary outcome measure
1. Participant acceptability (TAMF, Interview) and drop-out rates at end of the study. The study will test the feasibility of tasks for participants. On completion of data collection periods a measurement of total available data as a function of a theoretical maximum and data quality measured by a range of criteria including missingness and contiguity
2. Detection of clinically important events such as exacerbations (inc. sub-clinical exacerbation) and disease progression, ERS, Sensor data, near real-time, 6 months. Detect exacerbation /symptom e.g. changes in wearable data (e.g. HR, SpO2, Activity) before, during and after the reported period of exacerbation (symptoms, FVC, death). A real-time algorithm will be included to predict exacerbations with patients notified with the Exacerbation Rating Scale (ERS) to confirm the prediction at or close to the time of the event
3. Quantification of symptoms (physical and mental health), various symptom questionnaires and scales, 6 months
4. Impact of disease on mood and wellbeing/QoL, GAD/PHQ8, weekly for 6 months
5. The trajectory-tracking of main outcome variables, symptom fluctuations, sub-clinical exacerbations and ordering
6. Report longitudinal mental health symptoms measures as reported by GAD7 and PHQ8 associated with the three diseases
7. Fatigue is the major reported symptom for those experiencing "long COVID". A range of

modalities for evaluating fatigue are included 1) Garmin Body Battery value and 2) Fatigue Severity Scale (FSS), continuous/weekly respectively, duration of study
8. The assessment of novel phone based tests (Audio, Breathing Tests see: non-questionnaire Active App tests) for remote monitoring of respiratory health. The ubiquity of smartphones presents an opportunity to use the phone itself as a health measuring tool for both application in COVID-19 as part of this study but also wider application to other respiratory diseases. These phone based tests will be compared with other devices such as Pulse, Heart Rate and Spirometry data to establish potential value

Secondary outcome measures
Measured at the end of the study using patient records and data recorded through wearable devices:
1. Proportion of participants that complete the study
2. Number of participants that experience one exacerbation within the stopping criteria for each group
3. Number of exacerbations that were detected by i) spirometry ii) PROMs iii) wearable data, within the stopping criteria for each group

Overall study start date
18/10/2020

Completion date
31/03/2023

Eligibility

Key inclusion criteria
COPD cohort
1. Clinical Conditions: 20 patients with a diagnosis of COPD
2. Gender: M/F
3. Age range: 18+ years
4. Prior mobile phone use: required
5: Willingness to use monitoring devices and complete study questionnaires
6. History of exacerbation: 2 or more exacerbations in last 1 yr

ILD cohort
1. Clinical Conditions: 20 patients with a diagnosis of interstitial lung disease
2. Gender: M/F
3. Age range: 18-90
4. Prior mobile phone use: required
5: Willingness to use monitoring devices and complete study questionnaires

COVID-19 cohort
1. Clinical Conditions: a clinical diagnosis of COVID-19 (within 4-13 weeks of enrolment) who either and report symptoms interfering with day to day activity present for more than 28 days following the onset of COVID-19
2. Gender: M/F
3. Age range: 18+
4. Prior mobile phone use: required
5: Willingness to use monitoring devices and complete study questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
Non-English language Speaker

Date of first enrolment
24/05/2021

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free Hospital
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Study participating centre
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Sponsor type
Hospital/treatment centre

Website
http://www.slam.nhs.uk/

ROR
https://ror.org/015803449

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
South London and Maudsley NHS Foundation Trust

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype

Local government

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Amos Folarin (amosfolarin@gmail.com). Data collected using the RADAR-base platform (https://radar-base.org) flat files (.csv or .avro) from mobile phone sensor data (RADAR-base passive app), Garmin Vivosmart 4, NuvoAir AirNext Spirometer, Questionnaires collected with RADAR-base active app, Demographics data collected with REDCap. Strongly de-identified data are available on request on a collaborative basis (see comments on data anonymisation). Data may be stored for up to 15 years. On the basis of collaborative work. Signed “data access request” (“DAR”) will also be needed. The researchers are open to considering most analyses provided they meet ethics requirements and anonymisation is preserved. The mechanism of data sharing is to be decided but it will probably be accessed on /via KCL infrastructure. Only the pseudonymised dataset is available for researchers. The pseudonymised dataset will be generated using mobile applications, wearable devices and sensors. These data will be collected using the novel mHealth platform RADAR Base (https://radar-base.org/) deployed on KCL servers. Data will be stored on a secure storage server administered by King's College London University (https://rosalind.kcl.ac.uk/) and KCL sFTP located in the KCL Institute of Psychiatry, Psychology & Neuroscience (IOPPN). The data will be analysed by the researchers with the help of clinicians involved in the study at UCL and KCL. Consent was obtained. Most data in the study are pseudonymised. Some data are considered potentially sensitive and are not shareable on this basis in a raw form (e.g. active speech test data). The researchers are bound by the ethics provided in the study

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/06/2021	29/07/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article		24/11/2023	14/05/2024	Yes	No
Results article		08/04/2024	16/05/2024	Yes	No