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COPD Pal Phase 2: A self-management app for Chronic Obstructive Pulmonary Disease. A pilot study

Submission date
16/12/2020

Recruitment status
No longer recruiting

Registration date
17/12/2020

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Respiratory

[_] 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. COPD is responsible for 3 million deaths worldwide every year. In the UK, the condition costs the NHS over £500 million. Even though people with COPD need to use many healthcare services, they spend a very small amount of time (about 1%) of their time with a healthcare professional. The rest of the time, people with COPD need to self-manage their condition, which includes exercising, taking medication, and being aware of their symptoms. To encourage better self-management, Bond Digital Health have created a mobile phone app called COPD Pal that helps people with COPD keep track of their condition.

We have designed this study to help us to look at how people use COPD Pal and to look at how safe it is, so that we can design larger studies in the future.

Who can participate?
Adults over 18 years with COPD

What does the study involve?
Participants will be asked to use COPD Pal over 6 weeks. Participants will be asked to complete a questionnaire about self-management at the beginning and end of the study, we will record information about any COPD exacerbations they have had prior to and during the study and there will be a feedback form to fill in, asking questions about their experience of using COPD Pal.

What are the possible benefits and risks of participating?
Taking part in the study may help you with managing your COPD and associated symptoms. It will also help develop the app, which may help future patients.
There is no additional risk associated with participating in this study apart from the time needed to access the app. There is a small chance that you feel tired whilst using the app or completing the questionnaires. In which case, please take as many breaks as you need and take part at your own pace.

Where is the study run from?
Prince Philip Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2019 to July 2020

Who is funding the study?
Llywodraeth Cymru (Welsh government) (UK)

Who is the main contact?
Sarah Rees, sarah.rees7@wales.nhs.uk

Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
235302

Study information

Scientific Title
COPD Pal Phase 2: Assessing the uptake, engagement, and safety of a self-management app for Chronic Obstructive Pulmonary Disease. A pilot expediency study in a real-world setting

Acronym
COPD Pal Phase 2

Study objectives
This project aims to answer the research question: ‘For people with COPD, is a self-management mobile phone app safe and feasible and do people engage?’
Secondary objectives include:
1. Determine feasibility of large-scale trial based on recruitment to and completion of the study.

2. Determine user engagement and frequency of use of app
3. Safety of using the app in terms of impact on clinical outcomes
4. Usability and acceptability of using the app

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/01/2020, Wales REC 4, (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 230457; Wales.REC4@wales.nhs.uk) ref: 19/WA/0347

Primary study design
Interventional

Study design
Single-centre interventional non-randomized trial

Study type(s)
Other

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

Interventions
Participants will be given a mobile smart phone with the COPD Pal app and instructed in its use. At baseline participants will be asked to complete the UCOPD questionnaire and data on COPD exacerbations (including hospital/GP attendances) and steroid/antibiotic use over the previous three months will be collected. Participants will be asked to use COPD Pal for 6 weeks before returning for a follow up visit where they will complete the UCOPD questionnaire, provide data on COPD exacerbations (including hospital/GP attendances) and use of steroids/antibiotics, and complete a feedback questionnaire.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
COPD Pal app

Primary outcome(s)
1. Acceptable recruitment is defined as >50% of eligible people consenting to participate and follow-up data available for the self-management questionnaire (UCOPD) for >60% of enrolled participants at the end of the study period
2. Engagement will be measured in terms of active use of the App. Participant use will be automatically collected by COPD Pal and acceptable engagement defined as over 70% using app daily
3. Safety will be measured as the mean number of exacerbations or hospitalisations and deemed acceptable if not 20% more in the 3 months whilst using the app than the 3 months immediately

pre-app. (GP contact and steroid/antibiotic use may increase as a result of better patient awareness of symptoms and as such will not be used as an indicator of safety)

Key secondary outcome(s)
1. HRQoL measured using the COPD Assessment Test at baseline and weekly within the app for 6 weeks
2. Impact of the app on self-management confidence measured using the UCOPD questionnaire at baseline and 6 weeks

Completion date
27/07/2020

Eligibility

Key inclusion criteria
1. Willing and able to sign informed consent
2. Clinical diagnosis of COPD as defined by GOLD, i.e. greater than 40 years old, ≥10 pack years smoking history, post-bronchodilator FEV1/FVC ratio of 0.7, with FEV1 less than 80% predicted
3. Life expectancy greater than 6 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
25

Key exclusion criteria
1. Cognitive, visual, or motor impairment that would affect ability to see or use a smart phone
2. Current hospital inpatient or nursing home resident

Date of first enrolment
20/01/2020

Date of final enrolment
16/02/2020

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Prince Philip Hospital
Bryngwyn Mawr
Dafen
Llanelli
United Kingdom
SA14 8QF

Sponsor information

Organisation
Hywel Dda University Health Board

ROR
https://ror.org/012gye839

Funder(s)

Funder type
Government

Funder Name
Llywodraeth Cymru

Alternative Name(s)
Welsh Government, The Welsh Government

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be 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?
Results article		24/02/2021	11/11/2021	Yes	No
HRA research summary			20/09/2023	No	No
Participant information sheet	version V2.0	19/12/2019	17/12/2020	No	Yes
Protocol file	version V2.0	19/12/2019	17/12/2020	No	No