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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
16/12/2020		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/12/2020	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
20/09/2023	Respiratory			

## 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

#### Contact name

Mrs Sarah Rees

#### Contact details

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

235302

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

#### Study design

Single-centre interventional non-randomized trial

#### Primary study design

Interventional

#### 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

Αll

#### 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V2.0	19/12/2019	17/12/2020	No	No