# Digital interventions for chronic obstructive pulmonary disease (COPD)

| Submission date           | Recruitment status No longer recruiting | [X] Prospectively registered   |  |  |
|---------------------------|---|--------------------------------|--|--|
| 26/08/2015                |   | Protocol                       |  |  |
| Registration date         | Overall study status                    | Statistical analysis plan      |  |  |
| 27/08/2015<br>Last Edited | Completed  Condition category           | Results                        |  |  |
|                           |   | [] Individual participant data |  |  |
| 19/03/2018                | Respiratory                             | [] Record updated in last year |  |  |

#### Plain English summary of protocol

Background and study aims

Chronic obstructive pulmonary disease (COPD) is the name used to refer to a number of progressive devastating and debilitating lung diseases, which includes chronic bronchitis, emphysema and chronic obstructive airways disease. People that have COPD typically feel breathless after physical activity, have a persistent cough with phlegm and suffer frequently from chest infections. There is no cure for the condition, but making lifestyle changes (such as stopping smoking) and taking medications (inhalers and/or tablets) can alleviate symptoms. Staying physically active is vital for successful self-management of COPD, although people with COPD often find that they are not as physically active as they were. This research will answer key questions regarding how best to develop and deliver an accessible digital health intervention aimed at motivating people with COPD to increase their level of physical activity, building on our previous experience of developing web-based materials for people with varied levels of literacy, health literacy and computer skills.

#### Who can participate?

People with COPD from participating GP practices in the Southampton area.

#### What does the study involve?

This study compares different types of online materials for people with COPD to see which is more helpful. To find this out, participants are randomly allocated into one of two groups. Those in group 1 are given access to an interactive web-based programme. Those in group 2 are given access to standard online written materials. All participants are then assessed in terms of their attitude towards physical activity and whether they will do more, how easy they found using the website, how much they liked using the website and also how much they know about their condition.

What are the possible benefits and risks of participating?

We don't expect the study to involve any risk to participants. They may not like the website, but they will be able to log off or close the browser if that is the case. Potential benefits are that participants may learn new information about COPD and be motivated to improve their selfmanagement.

Where is the study run from? University of Southampton (UK)

When is the study starting and how long is it expected to run for? July 2015 to February 2016

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

Who is the main contact? Dr Ingrid Muller

# **Contact information**

#### Type(s)

Scientific

#### Contact name

Dr Ingrid Muller

#### **ORCID ID**

http://orcid.org/0000-0001-9341-6133

#### Contact details

University of Southampton University Road Southampton United Kingdom SO17 1BJ

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers 18909

# Study information

#### Scientific Title

Digital interventions to promote physical activity for people with chronic obstructive pulmonary disease (COPD)

#### **Study objectives**

Can interactive digital materials enhance people with COPDs engagement and motivation to increase physical activity compared to standard written materials?

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Newcastle and North Tyneside REC, 24/04/2015, ref: 15/NE/0153

#### Study design

Feasibility randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Internet/virtual

#### Study type(s)

Treatment

#### 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

#### **Interventions**

An interactive digital intervention to promote physical activity will be compared to standard online written materials.

#### Intervention Type

Other

#### Primary outcome measure

Attitudes and intentions to physical activity; Timepoint(s): immediately post-intervention

#### Secondary outcome measures

- 1. User engagement
- 2. Enablement
- 3. Website satisfaction
- 4. COPD knowledge

#### Overall study start date

15/07/2015

#### Completion date

01/02/2016

# **Eligibility**

#### Key inclusion criteria

Patients with COPD aged 18 years or more, who are able to consent.

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

Planned Sample Size: 100; UK Sample Size: 100

#### Key exclusion criteria

- 1. Inability to read / speak English
- 2. Potential difficulties, for instance; severe mental health problems, palliative care, recent bereavement, known opposition to involvement in research or inability to complete research measures

#### Date of first enrolment

01/10/2015

#### Date of final enrolment

01/02/2016

# Locations

#### Countries of recruitment

England

**United Kingdom** 

# Study participating centre University of Southampton

University Road Southampton United Kingdom SO17 1BJ

# Sponsor information

#### Organisation

University of Southampton

#### Sponsor details

Aldermoor Health Centre Aldermoor Close Southampton England United Kingdom SO16 5ST

#### Sponsor type

University/education

#### **ROR**

https://ror.org/01ryk1543

# Funder(s)

#### Funder type

Government

#### **Funder Name**

National Institute for Health Research

#### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

**United Kingdom** 

# **Results and Publications**

Publication and dissemination plan

Study results will be published in peer-reviewed journals and disseminated at academic conferences.

## Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

| Output type          | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------|---------|--------------|------------|----------------|-----------------|
| HRA research summary |         |              | 28/06/2023 | No             | No              |