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 Completed Condition category	Statistical analysis plan		
27/08/2015		Results		
Last Edited		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 self-management.

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

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Contact details

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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