Video to increase rehabilitation uptake following hospitalised exacerbations of COPD

Submission date 14/01/2015	Recruitment status No longer recruiting	[X] Prospectively registered	
		Protocol	
Registration date 15/01/2015	Overall study status Completed	 Statistical analysis plan [X] Results 	
Last Edited 11/05/2020	Condition category Respiratory	[] Individual participant data	

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. Pulmonary rehabilitation (PR), a programme of physical exercise and education, can also help people manage their condition and lead to improvements in health. Recent evidence suggests that providing PR shortly after a hospital admission for an acute exacerbation (worsening of symptoms) helps with breathing, quality of life and walking ability. It also reduces the risk of being admitted to hospital in the future. However, a recent study suggests that high numbers of patients hospitalised with an acute exacerbation of COPD (AECOPD) and offered PR turn down this treatment as many do not understand what PR involves and think they are too ill to exercise. We want to find out whether showing a patient-designed video to patients hospitalised with an AECOPD can significantly increase the number of patients taking up early pulmonary rehabilitation following their discharge from hospital.

Who can participate?

Adults over the age of 40, diagnosed with COPD living in the borough of Hillingdon, admitted to hospital with AECOPD and fit enough to take part in PR.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (control group) are given standard verbal information about early pulmonary rehabilitation and a leaflet about pulmonary rehabilitation. Those in group 2 (intervention group) are also provided with the standard verbal information about early pulmonary rehabilitation and leaflet. However, they are also asked to watch a 5 minute patient-designed video promoting early pulmonary rehabilitation.

What are the possible benefits and risks of participating?

There are no direct benefits to the patients taking part in this research. However, the information that we gain from this study will help improve the treatment of patients

hospitalised with an exacerbation of COPD. There are no significant risks associated with participating in this research study.

Where is the study run from? Harefield Hospital (UK)

When is the study starting and how long is it expected to run for? January 2015 to July 2018

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

Who is the main contact? Ms Sarah Jones

Contact information

Type(s) Scientific

Contact name Ms Sarah Jones

Contact details

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Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 18104

Study information

Scientific Title

Video to Increase RehabiliTation Uptake following hospitalised Exacerbations of COPD: a randomised controlled trial

Acronym VIRTUE

Study objectives

The aim of the research study is to determine whether delivering a patient designed video to hospitalised patients with an acute excaerbation of COPD (AECOPD) can increase the uptake of early pulmonary rehabilitation following hospital discharge.

Ethics approval required Old ethics approval format

Ethics approval(s) London – City and East, 18/11/2014, ref: 14/LO/1740

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet Not available in web format, please use contact details to request a patient information sheet

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

Interventions

1. Control Group: Standard verbal information about early pulmonary rehabilitation will be provided to the patient, supplemented by an A5 leaflet about pulmonary rehabilitation 2. Intervention Group: Participants will be provided with standard verbal information about early pulmonary rehabilitation, supplemented by an A5 patient information leaflet about pulmonary rehabilitation. They will also be asked to watch a 5 minute patient-designed video promoting early pulmonary rehabilitation

Intervention Type Behavioural

Primary outcome measure Uptake is defined as attending an initial assessment for pulmonary rehabilitation.

Secondary outcome measures N/A

Overall study start date 26/01/2015

Completion date 17/05/2019

Eligibility

Key inclusion criteria

1. Adults over the age of 40, with a known diagnosis of COPD living in the borough of Hillingdon. 2. Adults admitted to Hillingdon Hospital with a primary diagnosis of an acute exacerbation of COPD or a primary diagnosis of pneumonia and a secondary diagnosis of acute exacerbation of COPD.

3. Eligible for post-hospitalisation early pulmonary rehabilitation (able to walk 5 m; no evidence of acute coronary syndrome or unstable ischaemic heart disease or any condition that would make exercise unsafe).

Participant type(s) Patient

Age group Adult

Sex Both

Target number of participants Planned Sample Size: 200; UK Sample Size: 200

Total final enrolment 196

Key exclusion criteria

- 1. Unable to walk 5 m without assistance
- 2. Unstable cardiac condition that would make exercise unsafe
- 3. Unable to consent due to cognitive dysfunction or poor English
- 4. Receiving palliative care with expectation of death within 3 months

Date of first enrolment 26/01/2015

Date of final enrolment 17/05/2018

Locations

Countries of recruitment England

United Kingdom

Study participating centre Royal Brompton & Harefield NHS trust Harefield Hospital Hill End Road Harefield Uxbridge United Kingdom UB9 6JH

Sponsor information

Organisation Royal Brompton & Harefield NHS trust

Sponsor details

Clinical Trials and Evaluation Unit Sydney Street London England United Kingdom SW3 6NP

Sponsor type Hospital/treatment centre

ROR https://ror.org/02218z997

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

Planned publication in a high-impact peer reviewed journal within 1 year of completion of the study, by July 2019.

Intention to publish date

01/07/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made 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 results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/06/2020	11/05/2020	Yes	No
HRA research summary			28/06/2023	Νο	No