

# InterSPACE: feasibility of an integrated telehealth and self-management programme for individuals hospitalised with an exacerbation of COPD

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<b>Registration date</b> 12/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/06/2021	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Chronic obstructive pulmonary disease (COPD) is a term used to describe a collection of lung diseases including chronic bronchitis, emphysema and chronic obstructive airways disease. It is estimated that up to one in four people may develop COPD in their lifetime. Sufferers often face disabling breathlessness which leads to a vicious cycle of reduced activity, social isolation and depression. Around the time of an exacerbation (worsening of the condition) resulting in a hospital admission, the individual is at a greater risk of worsening health and, once discharged, is at risk of being readmitted back into hospital. Pulmonary rehabilitation is recommended by recent National Institute for Clinical Excellence guidelines at this stage, and should ideally be offered within 4 weeks of discharge from hospital. However, despite its proven benefits, pulmonary rehabilitation programmes can be unappealing to a large number of patients. There is, therefore, a need to develop alternative ways to support patients being discharged from hospital with COPD in order to manage their breathlessness, their stress levels and help them regain their physical and social abilities. The internet may provide the opportunity to increase the provision of accessible information to help patients better understand and self-manage their condition. A website has been developed in collaboration with both experts in pulmonary rehabilitation and patients. The plan is to offer a self-management programme to patients with COPD for a period of 3 months after discharge from hospital using tablet computers to help, guide, support and encourage them to better understand and manage their condition and thereby reduce unnecessary readmission to hospital.

### Who can participate?

Patients admitted to hospital with a diagnosis of exacerbation (worsening) COPD

### What does the study involve?

Participants are given access to the self-management programme. Participants are supported through the programme for 3 months, but have access for a year. The tablet computers are preloaded with the web-based version of the SPACE for COPD programme and are offered face-

to-face video conferencing with clinicians/nurses. Normal care is not disrupted including referral and attendance to pulmonary rehabilitation. The study assesses whether this intervention increases patient uptake of pulmonary rehabilitation services offered.

What are the possible benefits and risks of participating?

The participant will have increased access to resources online and the support and guidance through this web-based self-management programme for 3 months. In addition the research participant will be able to book an online appointment to speak to a specialist respiratory nurse about any worry or concerns they have about their lung condition and symptoms. This may in turn prevent an unnecessary admission to hospital. This project will address directly the concerns expressed in the British Lung Foundation survey 'ready for home'. There would be no adverse effects in terms of pain, discomfort or inconvenience. All patients will receive usual care. The only potential adverse effect would be the patients having to remember to login onto the website to access the self-management programme with potentially issues around remembering password, and navigation. Such issues will be minimised by the use of specialist respiratory nurses to advise and support eligible patients, checking their progress. Patients are encouraged to phone or video conference the respiratory discharge nurses for advice or help, this is routine proactive currently. The trialists are keen to explore the aim of video conferencing facilities to be able to advise the individual on inhaler technique, breathing control or physical activity strategies more effectively than over the telephone. A specifically trained nurse who has helped design and implement a similar web-based programme for cardiac patients will be available to support the respiratory nurses and is part of the project team.

Where is the study run from?

University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?

September 2014 to March 2018

Who is funding the study?

Academic Health Science Networks (UK)

Who is the main contact?

Dr Linzy Houchen-Wolloff

Linzy.Houchen@uhl-tr.nhs.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Linzy Houchen-Wolloff

### Contact details

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## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Protocol version 6

## **Study information**

### **Scientific Title**

InterSPACE: feasibility of an integrated telehealth and self-management programme for individuals hospitalised with an exacerbation of COPD

### **Acronym**

interSPACE

### **Study objectives**

To assess the feasibility and acceptability of an integrated telehealth self-management programme for individuals hospitalised with an exacerbation of their COPD.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

NRES Committee East Midlands-Derby, 22/09/2014, ref: 14/EM/1105

### **Study design**

Single-centre non-randomised feasibility study

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised study

### **Study setting(s)**

Internet/virtual

### **Study type(s)**

Treatment

**Participant information sheet**

<http://www.leicestershospitals.nhs.uk/aboutus/departments-services/pulmonary-rehabilitation/research-and-development/>

## **Health condition(s) or problem(s) studied**

Respiratory COPD exacerbations

## **Interventions**

Participants are given access to the self-management programme. Participants are supported through the programme for 3 months, but have access for a year. The tablet computers are preloaded with the web-based version of the SPACE for COPD programme and are offered face-to-face video conferencing with clinicians/nurses. Normal care is not disrupted including referral and attendance to pulmonary rehabilitation. The study assesses whether this intervention increases patient uptake of pulmonary rehabilitation services offered.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

The reason for this project is to understand the feasibility and acceptability of the novel tablet based self management support at the time of a hospital discharge. The primary consideration for the study will be uptake and acceptability. Uptake will be reported and web usage will be closely monitored through a sophisticated web monitoring component embedded in the existing site.

## **Secondary outcome measures**

Current secondary outcome measures as of 21/03/2016:

1. Readmission rates, measured using hospital record checks
2. Health-related quality of life, measured using CAT and CRQ questionnaire
3. Anxiety and depression, measured using HADS questionnaire
4. Physical activity, measured using PACER questionnaire
5. Impact on clinical team (staff time/cost)
6. Patient and clinician thoughts about the study and intervention, assessed using qualitative interviews

Collected at 3 and 6 months.

Previous secondary outcome measures:

1. Health-related quality of life
2. Anxiety and depression
3. Hospital readmissions

These will be collected at baseline and after 6 and 12 months.

## **Overall study start date**

22/09/2014

## **Completion date**

05/03/2018

## **Eligibility**

### **Key inclusion criteria**

Patients admitted with a primary diagnosis of exacerbation COPD. This may include patients with existing disease or patients who are newly diagnosed on admission to hospital. All patients who are admitted into the Glenfield Hospital with an exacerbation of or newly diagnosed COPD will be screened for eligibility i.e. willing to take part in this pilot study. Individuals do not necessarily have WiFi access and so a 3G connection is provided as part of the package. Eligible patients will however need to have a current email account and be computer literate. Willing participants will be given full instructions on how to access the SPACE self-management programme website via their chosen device.

**Participant type(s)**

Patient

**Age group**

All

**Sex**

Both

**Target number of participants**

100

**Total final enrolment**

100

**Key exclusion criteria**

1. Unwilling to participate
2. Individuals with significant co-morbidities to limit physical activity
3. Unable to read or write English
4. Not computer literate

**Date of first enrolment**

08/05/2015

**Date of final enrolment**

05/09/2017

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Centre for Exercise and Rehabilitation Science (CERS)**

NIHR Leicester Biomedical Research Centre - Respiratory  
Glenfield Hospital

Leicester  
United Kingdom  
LE3 9QP

## Sponsor information

### Organisation

University Hospitals of Leicester NHS Trust (UK)

### Sponsor details

Trust HQ  
Level 3 Balmoral Building  
Leicester Royal Infirmary  
Infirmary Square  
Leicester  
England  
United Kingdom  
LE1 5WW

### Sponsor type

University/education

### ROR

<https://ror.org/02fha3693>

## Funder(s)

### Funder type

Government

### Funder Name

Academic Health Science Network East Midlands (UK)

## Results and Publications

### Publication and dissemination plan

The protocol has not published as this is a feasibility study but it can be made available on request from Dr Linzy Houchen-Wolloff (Linzy.Houchen@uhl-tr.nhs.uk).

As the primary aim of this study is to inform a definitive trial, the results of this study will be disseminated widely with appropriate stakeholders (commissioning groups, service managers and service users). This will take the form of steering groups meeting (held monthly), PPI feedback (local group held every 3 months) and abstract submission to national conferences.

### **Intention to publish date**

30/11/2018

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available because participants have not consented to make their data available to anyone other than the study team, the sponsor, NHS Trust or from regulatory authorities.

### **IPD sharing plan summary**

Not expected to be made available

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Abstract results</a>	conference abstract	01/12/2018		No	No
<a href="#">Abstract results</a>	conference abstract	01/12/2018		No	No
<a href="#">Results article</a>		11/06/2021	14/06/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No