ISRCTN13081008 https://doi.org/10.1186/ISRCTN13081008

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

Submission date
17/11/2014

Recruitment status
No longer recruiting

Registration date
12/01/2015

Overall study status
Completed

Last Edited
14/06/2021

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Centre for Exercise and Rehabilitation Science (CERS)
NIHR Leicester Biomedical Research Centre - Respiratory
Glenfield Hospital
Leicester
United Kingdom
LE3 9QP

+44 (0)116 250 2759
Linzy.Houchen@uhl-tr.nhs.uk

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 feasiblity 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 exercabations

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?
Abstract results	conference abstract	01/12/2018		No	No
Abstract results	conference abstract	01/12/2018		No	No
Results article		11/06/2021	14/06/2021	Yes	No
HRA research summary			28/06/2023	No	No