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Optimising the feasibility and acceptability of a multi-component, digital health intervention to improve outcomes for people with chronic obstructive pulmonary disease

Submission date
05/06/2019

Recruitment status
No longer recruiting

Registration date
05/07/2019

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Digital healthcare can address a number of health care needs arising from long-term conditions, including the requirement to support people in their own homes and to provide a greater focus on self-management. Substantial amounts of data are routinely captured during NHS usual care, including vital sign data (such as blood pressure and pulse rate) whilst patients are in hospital. Linking data routinely collected in hospital with data collected by monitoring devices at home has the potential to provide a better overview of health status, but the feasibility of doing this is currently unknown. Large numbers of admissions associated with an exacerbation of chronic obstructive pulmonary disease (COPD) are recorded each year with 1 in 4 patients re-admitted within 3 months of discharge. Linking data from these sources may help inform subsequent studies in developing more accurate predictive algorithms to identify deterioration and prevent readmission.

Who can participate?
Patients aged 40 years or older diagnosed with COPD who are a current or ex-smoker.

What does the study involve?
EDGE2 will recruit 200 patients diagnosed with chronic obstructive pulmonary disease (COPD). Patients will be approached if they visit hospital because of their COPD. A COPD exacerbation is a severe worsening of symptoms beyond usual day-to-day variation and can be a frightening experience. Participants will be given a tablet computer and two monitors to track oxygen saturation levels, heart rate and step count. Patients will access these devices whilst in hospital and for 6 months after discharge. EDGE2 will investigate the feasibility of accessing hospital data and see if it can be linked to self-monitored data. Linking this data together is important to develop predictive algorithms to identify and support responses to early changes in their health. EDGE2 will also monitor patients for 5 years after hospital discharge to identify hospital visits and deaths using data from NHS Digital.

What are the possible benefits and risks of participating?
Participants will be able to self-monitor their vital signs (including oxygen saturation), COPD symptoms, mood and physical activity on a regular basis over several months. They will also be able to access educational resources to support their COPD self-management, such as videos to demonstrate correct inhaler technique. In doing so participants may feel more anxious about their COPD by monitoring their condition more closely or may consider this a replacement to usual care. Incoming data will, however, be monitored by a member of the clinical research team twice-weekly and participants will also be able to contact the team themselves.

Where is the study run from?
Oxford University Hospitals NHS Foundation Trust, UK.

When is the study starting and how long is it expected to run for?
May 2019 to January 2021

Who is funding the study?
1. National Institute for Health Research Oxford Biomedical Research Centre
2. Engineering and Physical Sciences Research Council

Who is the main contact?
1. Prof. Andrew Farmer,
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Study website
https://www.phc.ox.ac.uk/research/diabetes/studies/EDGE2

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
249148

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PID:13866 (internal sponsor reference)

Study information

Scientific Title
sElf-management anD support proGrammE (EDGE2) for COPD

Acronym
EDGE2

Study objectives
The aim of EDGE2 is to assess the feasibility of extracting and linking hospital data with self-monitoring data collected in a community setting by a digital health system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/12/2018, London - Surrey Research Ethics Committee (Surrey University, London, GU2 7XH, United Kingdom; +44 (0)207 104 8088; surrey.rec@hra.nhs.uk), ref: 18/LO/1939

Study design
Prospective cohort study

Primary study design
Interventional

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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 (COPD)

Interventions
EDGE2 is a cohort study and all participants will access the intervention. The intervention will comprise an internet-linked tablet computer and two monitoring devices to support their self-management of their condition. The monitoring devices will capture oxygen saturation levels, pulse rate and step count. Patients will be encouraged to wear the physical activity monitor and to use the pulse oximeter daily for 6 months after discharge. Using the tablet computer, participants will be able to answer questions about their COPD symptoms (daily) and mood (monthly) and will be able to access educational videos about COPD.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
EDGE2 Home Monitoring System

Primary outcome measure
1. Proportion of participants in whom data can be obtained and matched from the in-hospital system and the EDGE2 platform – extract and link in-hospital data with other study data for each patient, success pre-defined as 80-90% – initiation of linkage will take place upon provision of consent with in-hospital data retrieved from point of index attendance/admission to discharge.
2. Proportion where there is sufficient data to provide clinically relevant data for use across the care pathway – obtain and link in-hospital data with other study data for each patient, success pre-defined as 80-90% – initiation of linkage will take place upon provision of consent with in-hospital data retrieved from point of index attendance/admission to discharge.

Secondary outcome measures
1. Quality of life - using St George's Respiratory Questionnaire for COPD (SGRQ-C) - at baseline and 6 months after hospital discharge
2. Generic health status - using the EuroQol-5 Dimension (EQ-5D-5L) scale - at baseline and 6

months after hospital discharge
3. Number of hospital admissions - at baseline and 6 months after hospital discharge
4. Number of ICU admissions - at baseline and 6 months after hospital discharge
5. Number of contacts with health professionals - at baseline and 6 months after hospital discharge
6. Use of medications - at baseline and 6 months after hospital discharge
7. Physical function – using the sit-to-stand test - at baseline, 4 weeks, 12 weeks and 24 weeks after hospital discharge
8. Death - using NHS Digital's Data Access Request Service
9. Attendance and admissions to hospital – using NHS Digital's Data Access Request Service

Overall study start date
01/04/2019

Completion date
27/01/2025

Eligibility

Key inclusion criteria
1. Be willing and able to give informed consent
2. Be aged 40 years or older
3. Have a clinical diagnosis of chronic obstructive pulmonary disease recorded in their medical history
4. Be a current or ex-smoker
5. Be an acute hospital attendance/admission for an exacerbation of chronic obstructive pulmonary disease or pulmonary infection
6. Be able to complete questionnaires (electronic or paper) and use the tablet computer
7. Confirm their post-discharge destination is not a medical facility or prison
8. Lives in Oxfordshire or surrounding counties
9. Be able to adequately understand verbal and written English

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants
200 (minimum of 100)

Total final enrolment
41

Key exclusion criteria
1. Another significant lung disease e.g. lung cancer
2. Chronic heart failure defined by the New York Heart Association classification system as severe (Grade IV)
3. Have a life expectancy of less than six months or be on a palliative pathway

Date of first enrolment
13/05/2019

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
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Sponsor information

Organisation
Clinical Trials and Research Governance – University of Oxford

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Sponsor type
University/education

Website
http://www.admin.ox.ac.uk/researchsupport

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Oxford Biomedical Research Centre

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings of this study will be disseminated through publication in a peer-reviewed journal. Findings may also be presented at international and national conferences. Participants will be informed of the trial results through an information sheet prepared for a lay audience made available on the department’s website.

Intention to publish date
01/01/2026

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be 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	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 3	06/10/2021	16/11/2023	No	No