

Self management and support programme (EDGE) for COPD

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| Submission date 17/10/2012 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 17/10/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 05/05/2017 | Condition category Respiratory | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A pilot study and randomised trial of a multicomponent mobile-health based intervention compared with usual care to improve outcomes in chronic obstructive pulmonary disease

Study objectives

Chronic obstructive pulmonary disease (COPD) is a chronic respiratory condition that affects 210 million people globally and an estimated 3 million people in the UK alone. COPD is a progressive disease without cure and it is estimated that COPD will become the third leading cause of death worldwide by 2020. The potential of mHealth technology in providing updates on patient status without the need for home visiting may offer opportunities for providing greater support than currently available for COPD patients. The mHealth system incorporates support for all aspects of care currently provided through personalised treatment plans, educational material in the form of videos and access to medical and medication records, to increase the impact of measures to improve care already in place. The system also includes a monitoring module allowing oxygen saturation measurement and a symptom diary with trend analysis to allow both patients and clinicians to identify deterioration. The sELf management and support proGrammE (EDGE) for COPD is a clinical trial to evaluate the efficacy of an mHealth application used with a community respiratory nurse service to support patients with moderate to severe COPD in improving quality of life in comparison with usual care. There will be a pilot phase to refine the intervention and measures in preparation for the main trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Central - Berkshire research ethics committee, ref: 12/SC/0437

Added 21/11/2013: ethical approval granted for amended criteria by South Central - Berkshire research ethics committee on 09/05/2013

Study design

Randomised interventional process of care study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease.

Interventions

An mHealth system to monitor health and provide additional educational support compared to usual care

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

St George's Respiratory Questionnaire for COPD patients (SGRQ-C) measured at baseline, six months and twelve months

Secondary outcome measures

No secondary outcome measures

Overall study start date

05/11/2012

Completion date

30/01/2015

Eligibility

Key inclusion criteria

Current inclusion criteria as of 21/11/2013:

1. Aged > 40 years
2. A forced expiratory volume in 1 second (FEV1) post-bronchodilatory <80% AND predicted ratio of FEV1 to forced vital capacity (FVC) <0.70 OR clinical decision of suitability for patients who are unable to provide a spirometry reading (on clinical grounds) at full assessment. The patient must have prior clinical evidence of COPD, i.e. obstructive spirometry within the last ten years; radiological evidence of emphysema.
3. Smoking history > 10 pack years
4. MRC Dyspnoea scale >or = to 2
5. Registered with a general practice and with an exacerbation of COPD requiring hospital admission or home treatment in the previous year, or referred for pulmonary rehabilitation
6. Absence of other significant lung disease
7. Absence of chronic heart failure defined by the New York Heart Association classification system as severe (Grade IV)
8. Able to give informed consent
9. Able to complete questionnaires and use the mHealth system
10. Life expectancy of >3 months
11. No recent participation in a COPD self-management clinical trial programme

12. Patients unable to transmit data from the tablet due to insufficient internet access will not be eligible to enter the study

Previous inclusion criteria:

1. Aged > 40 years
2. Forced expiratory volume in 1s (FEV1) post-bronchodilatory <70%
3. Predicted ratio of FEV1 to forced vital capacity (FVC) <0.70
4. Smoking history > 10 pack years
5. MRC Dyspnoea scale >or = to 2
6. Registered with a general practice and with an exacerbation of COPD requiring hospital admission or home treatment in the previous year, or referred for pulmonary rehabilitation
7. Absence of other significant lung disease
8. Absence of chronic heart failure
9. Able to give informed consent
10. Able to complete questionnaires and use the mHealth system
11. Life expectancy of >3 months
12. No recent participation in a COPD self-management clinical trial programme

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

UK Sample Size: 295

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

05/11/2012

Date of final enrolment

30/01/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Oxford

Oxford

United Kingdom
OX3 7LF

Sponsor information

Organisation

Oxford University (UK)

Sponsor details

Joint Research Office
Block 60
Churchill Hospital
Old Road
Headington
Oxford
England
United Kingdom
OX3 7LE

Sponsor type

University/education

Website

<http://www.ox.ac.uk/>

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Research organisation

Funder Name

Wellcome Trust (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 08/01/2014 | | Yes | No |
| Results article | results | 07/03/2017 | | Yes | No |
| Results article | results | 03/05/2017 | | Yes | No |