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Self management and support programme (EDGE) for COPD

Submission date	Recruitment status	[X] Prospectively registered
17/10/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/10/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/05/2017	Respiratory	

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

13281

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
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Headington
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England
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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