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Feasibility of an at-home intervention to reduce prolonged sitting in patients hospitalised for an acute exacerbation of chronic obstructive pulmonary disease

Submission date
28/10/2015

Recruitment status
No longer recruiting

Registration date
30/10/2015

Overall study status
Completed

Last Edited
13/04/2018

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is important for everyone to try to limit prolonged periods of sedentary behaviour (i.e. sitting and lying down) in daily life. Following an exacerbation (severe worsening of symptoms) of chronic obstructive pulmonary disease (COPD), sitting time can often increase which may not help individuals to maintain or improve their physical capabilities and quality of life. As a result, patients feel less able to attend pulmonary rehabilitation, a program of exercise, education and support to help people manage their COPD symptoms and function as normally as possible. It is therefore important to find effective ways for some people to sit less and move more after being discharged from hospital. We aim to look at whether it is feasible to deliver an intervention (i.e. program) developed to reduce sedentary behaviour at home for COPD patients admitted to hospital.

Who can take part?
Adults aged 40-85 with a clinical diagnosis of COPD who have been admitted to Glenfield Hospital, Leicester, UK for an acute exacerbation.

What does the study involve?
Patients are randomly allocated to one of three groups. Those in group 1 are placed in the usual care group. Those in group 2 are placed in the education group. Those in group 3 are placed in the feedback group. The education group receive information in the hospital about ways to reduce their sitting at home following discharge. The feedback group receive the same information as the education group plus feedback on their sitting behaviour from a wearable device via a mobile application. The usual care group receive standard care. Patients return to the hospital for a follow-up appointment after 4 weeks. We also collect data on their physical function, symptoms and body composition (that is percentage of fat, muscle etc.) . We will use information from this study help plan a larger study.

What are the possible benefits and risks from participating?
Patients may benefit from improved physical health in terms of reduced sedentary behaviour, increased activity and possibly improved physical functioning and well-being. No risks are foreseen but patients who reduce their sitting and increase their activity may experience associated breathlessness and other symptoms.

Where is the study run from?
Glenfield Hospital, University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January to June 2016

Who is funding the study?
Loughborough University (UK)

Who is the main contact?
Mark Orme

Contact information

Type(s)
Scientific

Contact name
Mr Mark Orme

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Feasibility of a home-based self-monitoring sedentary behaviour intervention for chronic obstructive pulmonary disease patients hospitalised following an acute exacerbation

Acronym
COPD-SEAT (Sitting and ExacerbAtions Trial)

Study objectives
This is a feasibility trial of a home-based self-monitoring sedentary behaviour intervention for chronic obstructive pulmonary disease patients. The aim is to use the information from this study to inform a larger randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Leicester Central Research Ethics Committee, 27/10/2015, ref:15/EM/0433

Study design
Feasibility small-scale randomised controlled trial, single-centre

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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 (COPD)

Interventions
Patients will be randomised (1:1:1) to one of three groups:
1. Usual Care (control): will not receive information or advice about sedentary behaviour. They will receive the educational material at the end of the follow-up appointment
2. Education: will receive written and verbal information about the importance of reducing their sedentary behaviour as well as top tips to achieve this
3. Feedback: will receive wearable self-monitoring technology which provides real-time feedback on their behaviour and prompts them to break up their sitting time

Added on 31/05/2016:
The intervention period will be 14 days following hospital discharge.

Previous
The intervention period will be 28 days following hospital discharge.

Intervention Type
Behavioural

Primary outcome measure
Assessing the feasibility of the processes, tools and management fundamental to the success of a future definitive intervention. Measurements include:
1. The number of eligible patients
2. Response rate of eligible patients
3. The number of eligible patients who refuse the intervention
4. Willingness of patients to be randomised
5. The practicality of delivering the intervention in the proposed setting
6. Follow-up rates, completion of measures, compliance with technology, level of missing data
7. The time needed to collect and analyse the data
8. The occurrence of adverse events related to the intervention

Added on 31/05/2016:
All outcomes are assessed at a follow-up appointment 2 weeks after commencement of the intervention.

Previous
Patient outcomes are assessed at a follow-up appointment 4 weeks after commencement of the intervention.

Secondary outcome measures
1. Sedentary behaviour as determined by inclinometry
2. Physical activity as determined by accelerometry
3. Physical function measured using the Short Physical Performance Battery, grip strength and 20m gait analysis using foot-worn inertial sensors
4. Breathlessness measured by the modified Medical Research Council dyspnea scale
5. Health status measured by the COPD Assessment Test and EuroQol (EQ-5D-5L)
6. Fatigue measured by the Functional Assessment of Chronic Illness Therapy (FACIT-F)
7. Anxiety and depression measured by the Hospital Anxiety and Depression Scale
8. Fear of falling measured by the Falls Efficacy Scale-International
Added 31/05/2016:
9. Body composition determined by body mass index index and waist circumference

Previous:
9. Body composition determined by body mass index index, waist circumference and body fat percentage

Added on 31/05/2016:
All outcomes are assessed at a follow-up appointment 2 weeks after commencement of the intervention.

Previous
All outcomes are assessed at a follow-up appointment 4 weeks after commencement of the intervention.

Overall study start date
04/01/2016

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Aged between 40 and 85 years
2. Have a confirmed diagnosis of COPD
3. Have experienced fewer than 4 exacerbations requiring hospital admission in the last 12 months
4. Have a confirmed acute exacerbation as the reason for hospitalisation
5. Are willing and able to comply with the trial protocol
6. Are physically able to participate in light intensity physical activity (i.e. walking with an aid)
7. Are able to provide informed consent (read and understand English)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Added 31/05/2016: as many as possible as this is a feasibility study. Previous: 45 to 60 (15 to 20 in each arm)

Key exclusion criteria
1. If the Respiratory Discharge Service (REDS) nurses or clinicians deem them unsuitable for the project for any reason (e.g. terminally ill)
2. Patients with an injury or additional health condition that precludes their ability to take part in light intensity physical activity
3. Patients with an overlying medical disorder that interferes with provision of consent, completion of measurements, intervention, interview, or follow-up

Date of first enrolment
04/01/2016

Date of final enrolment
29/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Glenfield Hospital
Groby Rd
Leicester
United Kingdom
LE3 9QP

Study participating centre
Loughborough University
Epinal Way
Loughborough
United Kingdom
LE11 3TU

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
Level 3
Balmoral Building
Leicester Royal Infirmary
Infirmary Square
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United Kingdom
LE1 5WW
+44 (0)116 258 8351
RDAdmin@uhl-tr.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.leicestershospitals.nhs.uk

ROR
https://ror.org/02fha3693

Funder(s)

Funder type

University/education

Funder Name
Loughborough University

Alternative Name(s)
Lboro

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results of the study will be published in scientific journals and also disseminated in the form of academic abstracts, posters and oral presentations. Publications dates are projected to occur late 2016.

Intention to publish date
01/11/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/10/2016		Yes	No
Results article	results	11/04/2018		Yes	No
HRA research summary			28/06/2023	No	No