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A randomised controlled trial of an intervention to promote the effects of Health Enhancing Physical Activity (HEPA) on physical and psychosocial outcomes in patients with mild Chronic Obstructive Pulmonary Disease (COPD) who are being treated with tiotropium

Submission date 24/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/02/2008	**Overall study status** Completed	
Last Edited 13/05/2015	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims?
Chronic obstructive pulmonary disease (COPD) is the name for a collection of lung diseases. People with COPD have difficulties breathing due to the narrowing of their airways. Pulmonary rehabilitation (PR) is a programme of exercise and education that is recommended to help patients with COPD. The aim of this study was to determine the additional effect of a PR programme on patients with mild COPD who are taking tiotropium (a drug that widens the airways in the lungs).

Who can participate?
Adult patients with mild COPD.

What does the study involve?
Patient records from local GP practices were searched to identify early-stage COPD patients. All patients were prescribed tiotropium for a minimum of 4 weeks before attending an assessment where their height and weight were measured and they underwent a lung function test and a walking test. Study questionnaires were also completed. Participants were then randomly allocated to one of two groups. One group took part in 8 weeks of once weekly, 90-minute supervised exercise and education sessions and were also encouraged to take part in a home-based exercise program. An exercise diary and pedometer was used to record home-based exercise participation. The other group were requested to continue normal care as instructed by their GP. All participants then took part in a follow-up assessment.

What are the possible benefits and risks of participating?
The benefits of taking part included regular physical activity under the guidance of a trained

exercise practitioner. The education sessions were also deemed valuable as they were used to increase participants' awareness of how to manage the symptoms of COPD. There are no known risks associated with participating in this study.

Where was the study run from?
University of Exeter (UK).

When is the study starting and how long is it expected to run for?
The study started in 2007. GP practice and participant recruitment was completed in 2009, with study findings published in 2010.

Who is funding the study?
The International Primary Care Respiratory Group (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
200601

Study information

Scientific Title
A randomised controlled trial of an intervention to promote the effects of Health Enhancing Physical Activity (HEPA) on physical and psychosocial outcomes in patients with mild Chronic Obstructive Pulmonary Disease (COPD) who are being treated with tiotropium

Acronym
HEALTH

Study objectives
Chronic Obstructive Pulmonary Disease encompasses chronic bronchitis, emphysema, chronic obstructive airways disease, chronic airflow limitation, and some cases of chronic asthma. The disease is chronic, slowly progressive, irreversible and debilitating, and has a devastating effect on individuals, causing significant mortality and morbidity and carrying a huge cost to both the health service and society. The symptoms of Chronic Obstructive Pulmonary Disease include increasing breathlessness and fatigue which gradually removes the individual's ability to partake in everyday activities such as walking, shopping and even minor physical exertion. As patients tire quickly, progression of the disease requires significant modification to lifestyle and activity and has consequences on psychological well being, employment and finances with impacts on social functioning, family and mood.

Hypothesis:
What is the additional effect of a Health Enhancing Physical Activity programme (HEPA) on physiological and psychosocial outcomes in participants with mild Chronic Obstructive Pulmonary Disease (COPD) who are receiving tiotropium in accordance with National Institute for Clinical Excellence (NICE) guidelines?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Devon and Torbay Research Ethics Committee, 05/06/2007, ref: 07/Q2102/42

Study design
Single-centre single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease

Interventions
A single-centre, single-blind randomised controlled trial of participants with mild COPD randomised equally to health enhancing physical activity intervention or normal care.

Health Enhancing Physical Activity Programme (HEPA):
Once weekly exercise and education session for 8 weeks, delivered by a qualified Exercise Practitioner, with instruction on exercising at home, exercise diaries and pedometer.

Control:
Continuation of normal care from General Practitioner (GP).

All participants will be followed up for a period of one year.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tiotropium

Primary outcome measure
1. Maximal exercise capacity measured using an Incremental Shuttle Walking Test (ISWT), measured at screening assessment (baseline - 5 weeks), baseline, weeks 9, 25 and 52
2. Total score on Chronic Respiratory Disease Questionnaire, measured at baseline, weeks 9, 13, 25, 52

Timepoints:
Visit 1: Study Week (-5): Screening assessment
Visit 2: Study Week 0: Baseline/randomisation
Visit 3: Study Week 9: End of 8 week intervention period
Study Week 13: 3 months post-baseline questionnaire survey
Visit 4: Study Week 25: 6 month post-baseline follow-up assessment
Visit 5: Study Week 52: 12 months post-baseline follow-up assessment

Secondary outcome measures
1. Spirometry including inspiratory capacity, measured at screening assessment (baseline - 5 weeks), baseline, weeks 9, 25, 52
2. MRC dyspnoea score, measured at screening assessment (baseline - 5 weeks), baseline, weeks 9, 25, 52
3. Questionnaires:
3.1. Lung Information Needs Questionnaire, measured at baseline, weeks 9, 25, 52
3.2. Chronic Respiratory Disease Questionnaire: domain scores, measured at baseline, weeks 9, 13, 25, 52
3.3. Hospital Anxiety and Depression Scale scores, measured at baseline, weeks 9, 13, 25, 52

Exploratory:
1. Self-efficacy to regulate exercise questionnaire, measured at baseline, weeks 9, 13, 25, 52
2. Seven Day Physical Activity Recall Questionnaire, measured at baseline, weeks 9, 13 , 25, 52

3. Physical Self Perception Questionnaire, measured at baseline, weeks 9, 13, 25, 52
4. Smoking Status Questionnaire, measured at baseline, weeks 9, 13, 25, 52
5. Perceived Autonomy Support measure (Health Care Climate Questionnaire), measured at week 9

Timepoints:
Visit 1: Study Week (-5): Screening assessment
Visit 2: Study Week 0: Baseline/randomisation
Visit 3: Study Week 9: End of 8 week intervention period
Study Week 13: 3 months post-baseline questionnaire survey
Visit 4: Study Week 25: 6 month post-baseline follow-up assessment
Visit 5: Study Week 52: 12 months post-baseline follow-up assessment

Overall study start date
01/11/2007

Completion date
30/04/2009

Eligibility

Key inclusion criteria
1. Adult patients (male and female) with clinical diagnosis of mild COPD
2. Smoking history greater than 10 pack years
3. Suitable for treatment with tiotropium according to NICE guidelines
4. Willing and able to undertake a health enhancing physical activity programme

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Body Mass Index (BMI) greater than 30 or less than 18 kg/m^2
2. History of asthma
3. Recent respiratory tract infection
4. Oxygen desaturation at rest less than 90%
5. Presence of serious co-morbid condition (orthopaedic, cardiovascular, muscular or neurological condition) that would interfere with regular exercise training
6. Prior participation in a pulmonary rehabilitation programme

Date of first enrolment
01/11/2007

Date of final enrolment
30/04/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Exeter
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Funder(s)

Funder type

Charity

Funder Name
International Primary Care Respiratory Group (UK) (ref: 200601)

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?
Results article	feasibility results	01/06/2010		Yes	No