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Exercise Training and Weight Loss in Overweight Patients With Obstructive Sleep Apnoeal Hypopnoea Syndrome Receiving Treatment With Continuous Positive Airway Pressure (CPA)

Submission date
30/09/2005

Registration date
30/09/2005

Last Edited
16/04/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

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

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
N0265150473

Study information

Scientific Title
Exercise Training and Weight Loss in Overweight Patients With Obstructive Sleep Apnoeal Hypopnoea Syndrome Receiving Treatment With Continuous Positive Airway Pressure (CPA)

Study objectives
Obstructive Sleep Apnoea/Hypopnoea Syndrome (OSAHS) is a condition characterised by obstruction of the airways during sleep which leads to disordered breathing and fragmented sleep patterns Symptoms include excessive daytime sleepiness and poor concentration. Many patients with OSAHS are overweight, which is known to increase the severity of the condition Treatment for OSAHS includes the use of CPA therapy, which is a form of non-invasive ventilation which reduces the airway obstruction that occurs during sleep. However, CPAP is an expensive form of treatment and while it alleviates the symptoms associated with OSAHS, it does not target the cause of the problem.

The principal aim of the study is, therefore, to investigate the effect of a 24-week programme of exercise training and dietary intervention in obese patients with OSAHS who are established on CPA therapy. It is hypothesized that weight loss may be associated with a reduction in the severity of the condition and may, alleviate the necessity for CPA therapy.

Secondary questions include firstly, to investigate the longevity of the observed effects? Secondly we wish to investigate the effect of the investigate on serum leptin. Leptin is a protein in the blood that is involved in fat metabolism, control of energy expenditure and regulation of food intake. Patients with OSAHS have abnormally high leptin levels which may contribute to the high incidence of obesity. CPA has been demonstrated to alter leptin levels in patients with OSAHS and exercise training may also impact on the levels of leptin in the blood.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Nervous System Diseases: Obstructive Sleep Apnoea/Hypopnoea Syndrome

Interventions
Each patient will be entered into a four-week period during which measurements will made on two occasions in order to allow for habituation to the tests and to cheek that the patients are stable in terms of body weight and severity of sleep related breathing disorder. Measurements of lung function, exercise capacity, health status, overnight oximetry, body composition, sleep diary, serum leptin and energy expenditure will be obtained. Patients will then be randomised to receive either:
1. Exercise training and dietary modification, or
2. Usual care (CPAP therapy)
For a period of 6 months. The randomisation will be performed on a 2:1 basis using a stratified design in order to ensure that the groups are balanced in terms of age, sex and body weight. Randomisation will be based on a computer generated random number sequence. Following the 24 week programme all patients will be followed up at 36, 48 and 60 weeks after the start of the study in order to evaluate the longevity of the observed effects.

Usual care will consist of CPAP therapy, the pressure required being obtained from an auto titration study. Patients will receive advice and instruction regarding the use of the treatment the importance of compliance, and maintenance of consumables. Patients in both groups will be receiving CPAP therapy and will receive similar information and advice regarding the treatment. Patients in the usual care group will be given the 'usual' advice regarding sleep hygiene and weight loss but will not receive any additional guidance or help during the programme.

The exercise training programme will consist of a 24 week programme of aerobic exercise training (walking, jogging, cycling) with patients being required to attend 3 times weekly for the first 3 months and once weekly thereafter. Training intensity will be targeted at 80% of the maximum heart rate achieved on the baseline exercise test and each training session will last for approximately one hour. This will include 45 minutes of high intensity exercise and a standardised warm up and cool down sequence. The training intensity will be increase as tolerated during the 12 week period in order to ensure that the intensity remains at the required level.

Dietary advice and lifestyle modification will be in the form of a 12 week programme which will include weekly group sessions for the duration of the study. Dietary advice will include basic nutritional information, guidelines for healthy weight loss, suggested diet sheets, recipes and the role of eating behaviour and physical activity in the maintenance of an optimal body weight. Patients will also receive an information pack containing all relevant nutritional advice and information and will also be required to maintain a food diary throughout the programme. Other aspects of the programme will address smoking cessation (where appropriate), lifestyle modification (exercise, sleep hygiene, alcohol consumption) and education regarding the condition of OSAHS, its development causative factors, treatment and consequences.

Intervention Type
Mixed

Primary outcome measure
1. Lung function, measured via Maximal Flow Volume Curves according to the ARTP/BTS guidelines
2. Exercise capacity, assessed using a maximal incremental cycle ergometer test in order to obtain peak oxygen uptake
3. Endurance exercise capacity, assessed on the cycle ergometer at 80% of the peak exercise achieved on the incremental test

During these tests breath by breath measurements of ventilation, oxygen uptake and carbon dioxide output will be obtained and heart rate will be monitored via a 12-lead ECU.

Secondary outcome measures
1. Overnight oximetry, performed on two consecutive nights at each time point indicated on the attached schedule. The first night will be performed without the CPAP machine with the second night being performed with the treatment as usual
2. Severity of OSAHS, evaluated using the number or desaturations greater than 4% together with the number of arousals during the night
3. Sleep hygiene, monitored using a sleep diary in which a record will be kept regarding number of hours sleep, awakening, daytime naps and daytime somnolence
4. Health status, assessed using the 36-item short form health survey (SF36), the Epworth Sleepiness Scale and the Hospital Anxiety and Depression (HAD) questionnaire
5. Body composition, measured using bioelectrical impedance analysis (Bodystat 1500) in order to provide an estimate of fat and fat free mass
6. Leptin, homocysteine, insulin, OH and NEFA (Non Esterified Fatty Acids) levels, evaluated using a blood sample and analysed using standard biochemical assays

Overall study start date
24/09/2004

Completion date
01/12/2007

Eligibility

Key inclusion criteria
Research participants will be recruited from those attending a specialist OSAHS clinic based at the Lung Investigation Unit, Queen Elizabeth Hospital. Suitable patients will be identified by the Consultant Clinical Scientist treating the patients at the clinic. The Consultant Clinical Scientist will approach the patients during scheduled clinic visits in order to explain the purpose and nature of the research and to ask for their potential involvement. At this time patients will be given a patient information sheet to read and will be allowed to take this home in order to think about participation and any questions they may have regarding the study requirements and protocol.

Following this, interested patients will be asked to return to the department of respiratory medicine for further explanation of the study and to sign a consent form regarding participation. At this time patients will be required to undergo a medical examination in order to ensure that they meet the inclusion/exclusion criteria for participation.

Principal inclusion criteria:
1. Patients must be established on CPAP therapy as the aim of the study is to compare usual care

with exercise training/dietary intervention
2. Diagnosis of OSAI-IS (SIGN guidelines, 2003): Overweight (BMI>25kg/m2). Patients must be overweight in order to benefit from the exercise training and weight loss programmes. OSAHS that is not attributable to being overweight will not be expected to improve at the end of the programme
3. Evidence of daytime somnolence (Epworth> 10.0). Daytime somnolence is a potentially disabling symptom of OSAHS and would be expected to improve with a reduction in severity of OSAHS
4. Documentation of symptoms such as snoring, cognitive impairment and sleep fragmentation

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Unstable heart disease or angina which may pose risks for the performance of exercise
2. Untreated hypothyroidism. This may decrease the effectiveness of a weight loss regime and therefore decrease the validity of the study
3. Severe lung disease. Patients with severe lung disease may be unable to tolerate a high intensity exercise programme and may require ventilation with CPAP despite being of a normal weight.
4. Pregnancy. High intensity exercise and strict dietary modification are not recommended for those who may be pregnant as this may result in damage to the developing foetus.
5. Facial abnormalities. Individuals in which facial abnormalities may contribute to the severity of OSA1~IS would not be expected to benefit from weight loss strategies and may require CPA even when of a normal weight.
6. Eating disorders. Individuals with eating disorders would be unlikely to benefit from the dietary and exercise training programme and should be given help and advice for this problem rather than being recruited to the study
7. Arthritis. Patients with severe arthritis will not be able to perform the exercise training sessions

Date of first enrolment
24/09/2004

Date of final enrolment
01/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK), NHS R&D Support Funding

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