

# Positive airway pressure in older people: a randomised controlled trial

<b>Submission date</b> 11/06/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/03/2016	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Obstructive sleep apnoea hypopnoea syndrome (OSAHS) is the name given to difficulty in breathing during sleep due to blockage of the airway behind the tongue. It causes profound daytime sleepiness, high blood pressure, an increased risk of heart attack/stroke and possibly memory problems. OSAHS is the third most common respiratory disorder, after asthma and chronic obstructive pulmonary disease, affecting 2 - 4% of middle aged people. In older people prevalence is almost 10 times greater, with up to 20% of older people having OSAHS. OSAHS can be treated with continuous positive airway pressure (CPAP). A CPAP device delivers compressed air through a mask covering the nose and mouth, which prevents the throat from closing. A recent report concluded that CPAP is an extremely cost effective treatment for OSAHS in middle-aged people. Unfortunately the beneficial effects of CPAP cannot be presumed to be the same in older people because the causes and consequences of the disease change with age. Very little information is available for doctors and healthcare professionals regarding the best way to treat OSAHS in older people. This study will measure the effect of treating OSAHS on sleepiness and other health-related factors, such as risk factors for heart disease and memory function, in patients over 65 years old.

### Who can participate?

Patients aged over 65 with OSAHS

### What does the study involve?

Participants are randomly allocated to be treated with either CPAP or a best supportive care package (consisting of advice, a general medical review and heart disease risk assessment). Both groups are monitored for 12 months, particularly their use of healthcare facilities, to show whether CPAP effectively treats older people with OSAHS and whether it is cost effective.

### What are the possible benefits and risks of participating?

The UK population is ageing, thereby increasing the burden of disease. One of the best ways to reduce these costs is to maintain the independence of older people. Treating OSAHS appropriately in older people will benefit both individual patients and reduce the economic burden of disease in the UK.

Where is the study run from?  
Churchill Hospital (UK)

When is the study starting and how long is it expected to run for?  
February 2009 to May 2012

Who is funding the study?  
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?  
Magda Laskawiec

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mrs Magda Laskawiec

**Contact details**  
Oxford Centre for Respiratory Medicine  
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## Additional identifiers

**Protocol serial number**  
HTA 08/56/02

## Study information

**Scientific Title**  
A randomised controlled trial of continuous positive airway pressure treatment in older people with obstructive sleep apnoea/hypopnoea syndrome

**Acronym**  
PREDICT

**Study objectives**  
This study will measure the effect of treating obstructive sleep apnoea hypopnoea syndrome (OSAHS) with continuous positive airway pressure (CPAP) on sleepiness and other health related factors, such as risk factors for heart disease and memory function, in patients over 65 years old.

More details can be found at <http://www.nets.nihr.ac.uk/projects/hta/085602>  
Protocol can be found at [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0015/53007/PRO-08-56-02.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0015/53007/PRO-08-56-02.pdf)

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Brompton, Harefield and NHLI Research Ethics Committee, 22/05/2009, ref: 09/H0708/33

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Sleep apnoea

### **Interventions**

Treatment (Continuous positive airway pressure) limb

Obstructive sleep apnoea will be diagnosed from a diagnostic overnight polysomnographic sleep study. After trial entry, subjects assigned to CPAP therapy will be started on self-adjusting nasal CPAP therapy (AutoSet®, ResMed Plc). This therapy automatically adjusts airway pressure to be sufficient to prevent snoring and sleep apnoea without being excessive. The initiation of this therapy will be in keeping with the recruiting centres normal clinical practice (and minimisation by centre at trial entry will ensure that subjects with slightly varying CPAP initiation protocols are evenly distributed between the trial groups). At months 3 and 12 of trial follow-up the stored memory of the CPAP machines will be interrogated to define treatment efficiency over multiple nights. This will define how well sleep apnoea has been controlled over time in the intervention group. Overnight arterial pulse oximetry recording will be performed to quantify sleep apnoea control on one night in both trial groups. The active treatment limb will also receive the best supportive care package.

Control limb (Best supportive care only)

Best supportive care will consist of:

1. Advice on minimising daytime sleepiness through sleep hygiene and advice about using the nap/caffeine assaults management strategy
2. Advice on weight loss strategies
3. A general medical review to confirm optimal healthcare for any co-morbid conditions
4. Cardiovascular risk assessment with intervention (co-ordinated through the General Practitioner) to minimise vascular risk. Consistent with national guidelines.

Total duration of interventions and follow-up: 12 months

### **Intervention Type**

Other

## Phase

Not Specified

## Primary outcome(s)

The following will be measured throughout the whole of the 12-month trial period:

1. Subjective sleepiness: average weekly Epworth Sleepiness Scale (ESS)
2. Health economic analysis: measured from health care utilisation and cost utility analysis using the EQ-5D

## Key secondary outcome(s)

Current secondary outcome measures as of 07/04/2010:

The following will be measured throughout the whole of the 12-month trial period:

1. Objective sleepiness: Oxford Sleep Resistance Test (OSLER) maintenance of wakefulness test (x 2 morning tests)
2. Self reported health status (quality of life and mood): 36-item Short Form questionnaire (SF-36), and Sleep Apnoea Quality of Life Index (SAQLI; a disease specific sleep apnoea questionnaire which includes CPAP side effects), Hospital Anxiety and Depression Scale (HADS)
3. Functional index of activities of daily living: Townsend Disability Scale (TDS)
4. Frequency of nocturia: Self reported using the patient [monthly] diary
5. Mobility: Timed to up and go test
6. Accidents: Including self-reported road accidents and domestic accidents
7. Cognitive function: Mini-mental state, Trail making B time, the Digit Symbol Substitution test, simple and four-choice reaction time
8. Cardiovascular Risk Index: Change in combined stroke and myocardial infarction risk measured by the Framingham vascular risk index, which includes office blood pressure, cholesterol, smoking status, hyperglycaemia
9. Adverse cardiovascular events: Myocardial infarction, stroke, transient ischemic attack, new angina, new atrial fibrillation, new peripheral vascular disease

Previous secondary outcome measures at time of registration:

The following will be measured throughout the whole of the 12-month trial period:

1. Objective sleepiness: measured using the maintenance of wakefulness test of the Oxford sleep resistance test (OSLER)
2. Self-reported health status (quality of life): the 36-item Short Form health survey (SF-36), CASP-19, the Short Sleep Apnea Quality of Life Index (SAQLI) questionnaire (which includes CPAP side effects)
3. Accidents, including road accidents
4. Change in combined stroke and myocardial infarction risk: measured by the Framingham Index
5. Individual components of the Framingham vascular risk index; blood pressure, cholesterol, smoking, glycaemia
6. Myocardial infarction/ stroke/ vascular event rate, left ventricular hypertrophy (ECG)
7. Cognitive function
8. Systemic inflammatory status
9. Functional index of activities of daily living (Townsend disability scale)

## Completion date

31/05/2012

## Eligibility

## **Key inclusion criteria**

Current inclusion criteria as of 07/04/2010:

1. Aged greater than 65 years, either sex
2. A clinical diagnosis of OSAHS: more than/equal to 4% oxygen desaturation index greater than 7.5 events/hour and an Epworth sleepiness scale more than/equal to 9
3. Ability to give written informed consent

Previous inclusion criteria at time of registration:

1. Both males and females, aged greater than 65 years
2. Apnoea hypopnoea index greater than or equal to 15 events/hour of sleep on multi-channel sleep study, and at least two symptoms of excessive daytime sleepiness or Epworth sleepiness scale greater than or equal to 11
3. Written informed consent

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Senior

## **Sex**

All

## **Key exclusion criteria**

1. Previous exposure to nasal CPAP therapy
2. Arterial oxygen saturation less than 93%
3. Forced expiratory volume in one second (FEV1) less than 65% predicted
4. Substantial problems with sleepiness driving (in those who are still driving); currently using Heavy Goods Vehicle (HGV) or Public Service Vehicle (PSV) driving licence (where applicable)
5. Shift work
6. Inability to give informed consent or comply with the protocol
7. Irreversible visual impairment

## **Date of first enrolment**

01/02/2009

## **Date of final enrolment**

31/05/2012

## **Locations**

### **Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Churchill Hospital**  
Oxford  
United Kingdom  
OX3 7LJ

## Sponsor information

**Organisation**  
University of Oxford (UK)

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

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Health Technology Assessment Programme

**Alternative Name(s)**  
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

**Study outputs**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results	01/10/2014		Yes	No
<a href="#">Results article</a>	results	01/06/2015		Yes	No