A Lifestyle Modification Programme for People with Obstructive Sleep Apnoea (OSA) at High Risk of Cardiovascular Disease (CVD) and Dysglycaemia.

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Abstract

A Lifestyle Modification Programme for People with Obstructive Sleep Apnoea (OSA) at High Risk of Cardiovascular Disease (CVD) and Dysglycaemia.

Maria-Anna Thomasouli

The aim of the work reported in this thesis was centred on the development of a fit for purpose structured education lifestyle modification programme for the self-management of Obstructive Sleep Apnoea (OSA). The programme aimed to promote compliance to Continuous Positive Airway Pressure (CPAP) therapy and increase physical activity levels.

A mixed method study, the Predicting the Use of Continuous Positive Airway Pressure Therapy in Obstructive Sleep Apnoea in a UK population: The PUCOSA-UK study was carried out to explore the interplay of potential psycho-social predictors of CPAP adherence using a strong framework of psychology models in newly diagnosed and established OSA patients. The study showed that adherence to CPAP therapy was heavily dependent on the early formation of strong beliefs and preconceptions of the condition and CPAP therapy prior to trialling the therapy. The qualitative element of the study identified a number of common barriers associated with CPAP compliance including inability to recognise symptoms and link to with being diagnosed with OSA, initial negative reactions to the idea of using CPAP therapy, discomfort and inconvenience caused when wearing a CPAP mask and operating a CPAP device, lack of spousal or peer support and self-image issues.

A systematic review and meta-analysis was conducted to evaluate the impact of diet, exercise and lifestyle modification interventions with or without CPAP therapy on obesity indices, OSA parameters and quality of life in adults with OSA. Intensive lifestyle intervention programmes were found to be more effective in reducing indices of obesity and in improving OSA parameters than less intensive lifestyle interventions or routine care.

A structured education curriculum was written and piloted in small groups. The results of the pilot work combined with the results of the aforementioned studies informed the content of the curriculum. Overall, the patients benefited from attending the education programme and learnt useful self-management skills.

Concluding, the findings from the work reported here warrant formal testing of the educational programme in a definitive randomised controlled trial.
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The author, Maria-Anna Thomasouli declares that the work reported in this thesis is a presentation of original research work. Wherever contributions of others are involved, acknowledgement of collaboration is reported in each thesis chapter and other sources are acknowledged by explicit references and appendices.
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<td>AASM</td>
<td>American academy of sleep medicine</td>
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<tr>
<td>AHI</td>
<td>Apnoea hypopnoea index</td>
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<tr>
<td>BMI</td>
<td>Body mass index</td>
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<tr>
<td>CBT</td>
<td>Cognitive behavioural therapy</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
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<tr>
<td>CPAP</td>
<td>Continuous positive airway pressure</td>
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<tr>
<td>CVD</td>
<td>Cardiovascular disease</td>
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<tr>
<td>DASS-21</td>
<td>Depression Anxiety and Stress-21 scale</td>
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<tr>
<td>DBP</td>
<td>Diastolic blood pressure</td>
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<tr>
<td>DESMOND</td>
<td>Diabetes Education and Self-Management for Ongoing and Newly Diagnosed</td>
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<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
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<tr>
<td>EDS</td>
<td>Excessive daytime sleepiness</td>
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<tr>
<td>EEG</td>
<td>Electroencephalogram</td>
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<tr>
<td>EMG</td>
<td>Electromyogram</td>
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<tr>
<td>EOG</td>
<td>Electro-oculogram</td>
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<td>ESS</td>
<td>Epworth sleepiness scale</td>
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<td>FSS</td>
<td>Fatigue severity scale</td>
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<tr>
<td>GP</td>
<td>General practitioner</td>
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<tr>
<td>HbA1c</td>
<td>Haemoglobin A1c</td>
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<tr>
<td>HC</td>
<td>Hip circumference</td>
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<tr>
<td>HDL</td>
<td>High density lipoprotein</td>
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<tr>
<td>ICER</td>
<td>Incremental cost-effectiveness ratios</td>
</tr>
<tr>
<td>ICH-GCP</td>
<td>International Conference on Harmonisation-Good Clinical Practice</td>
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<tr>
<td>ILI</td>
<td>Intensive lifestyle intervention</td>
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<td>IPQ-R</td>
<td>Illness perceptions questionnaire-revised</td>
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<td>MetS</td>
<td>Metabolic syndrome</td>
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<td>MRC</td>
<td>Medical research council</td>
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<td>NHP</td>
<td>Nottingham health questionnaire</td>
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<td>NHS</td>
<td>National Health Service</td>
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<tr>
<td>NC</td>
<td>Neck circumference</td>
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<tr>
<td>NICE</td>
<td>National institute of clinical excellence</td>
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<tr>
<td>NIHR</td>
<td>National institute of health research</td>
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<tr>
<td>ODI₄</td>
<td>Oxygen desaturation index</td>
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<tr>
<td>OR</td>
<td>Odds ratio</td>
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<td>OSA</td>
<td>Obstructive Sleep Apnoea</td>
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<tr>
<td>POMS</td>
<td>Profile of mood state score</td>
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<tr>
<td>QALY</td>
<td>Quality adjusted life years</td>
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<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
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<tr>
<td>PSG</td>
<td>Polysomnography</td>
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**PREPARE**  |  Pre-diabetes Risk Education and Physical Activity Recommendation and Encouragement study
**SEMSA-OE** |  Self-Efficacy Measure for Sleep Apnoea-Outcome Expectancies
**SEMSA-SE** |  Self-Efficacy Measure for Sleep Apnoea-Self-Efficacy
**SF-36**    |  Short form health survey
**SRDB**     |  Sleep related breathing disorders
**SBP**      |  Systolic blood pressure
**SOS**      |  Social support scale
**SD**       |  Standard deviation
**SE**       |  Standard error
**T2DM**     |  Type 2 diabetes mellitus
**TG**       |  Triglycerides
**VLCD**     |  Very low calorie diet
**WC**       |  Waist circumference
Chapter 1

Introduction: Stating the facts
1.0 Chapter overview

In this chapter I provide a detailed account of Obstructive Sleep Apnoea (OSA), the most common form of sleep-related breathing disorder. Chapter one is organised into four sections. Within the first section, the focus will be on the prevalence, epidemiology, risk factors, medical definitions and clinical diagnosis of the condition. In section two, I will discuss the impact and complications of undiagnosed and/or untreated OSA upon society and provide an update of the current evidence in the literature of the associations between OSA, cardiovascular disease (CVD) and metabolic outcomes. In section three, I discuss the current treatment guidelines for OSA and in section four I provide a summary of the aims and hypotheses of this PhD.

1.1 Obstructive Sleep Apnoea (OSA)

Obstructive Sleep Apnoea (OSA) is a chronic respiratory condition characterised by loud snoring and intermittent collapse of the upper airway resulting in complete (apnoea) or partial (hypopnoea) cessation of airflow.\(^1\) OSA is approximately 2 to 3 times more common in men that in women.\(^2\) Current prevalence estimates for OSA range from 2-10% in the general population.\(^3\) Apnoeas and hypopnoeas last for ≥10 seconds and may occur up to 100 times per hour of sleep. This breathing anomaly results in arterial oxygen desaturation (hypoxaemia) and when repeated frequently leads to a gradual increase of arterial carbon dioxide levels (hypercapnoea).\(^3-4\) Imbalance of blood gases stimulates increased sympathetic activity and the individual wakes up briefly from sleep to reinitiate breathing.\(^4-6\) The process of inadequate oxygenation and arousals from sleep becomes repetitive and as a result sleep becomes fragmented. Individuals with OSA are usually unaware of their breathing complications
during sleep. Despite the advances in sleep diagnostic technology and numerous attempts to increase public awareness of the condition, a recent study by Pang and colleagues, showed that 93% of women and 83% of men with moderately severe OSA remain undiagnosed.  

OSA is a major health issue with great direct and indirect costs. The consequences on overall health status associated with undiagnosed and untreated OSA have a major impact upon society. Subjects with OSA experience excessive daytime sleepiness which then impacts upon health and functional status. Daytime sleepiness has been associated with poor work performance and low concentration, alterations in mood, depression, poor memory, increased risk of motor vehicle accidents and poorer quality of life. There is increasing evidence that OSA is an independent risk factor for long term vascular and cardiovascular outcomes including that of increased risk of stroke, diabetes, hypertension and all cause mortality. The association of OSA with cardiovascular and metabolic complications is very complex and it has been hypothesised to involve multiple interactions between sleep disordered breathing, metabolic and lifestyle factors.

Continuous positive airway pressure (CPAP) therapy is the ‘gold standard’ treatment for OSA. Despite its effectiveness in ameliorating OSA related symptoms, in improving insulin sensitivity, reducing hypertension and improving quality of life, it is not a curative therapy and its efficacy relies on long term compliance which remains a major challenge. Central obesity plays a leading role in the progression and severity of a wide range of chronic conditions including OSA. Prevalence estimates of OSA are expected to rise as the epidemic of obesity increases worldwide. Effective treatment of OSA combined with management of obesity is the way forward in improving clinical status and reducing cardiovascular and metabolic risk.
1.1.1 OSA indices and definitions

Clinically, OSA is defined as the combination of symptoms including excessive daytime sleepiness (that cannot be explained by other factors), choking or gasping during sleep, unrefreshing sleep, frequent awakening from sleep, impaired concentration and a minimum requirement of five or more obstructive breathing events per hour measured by overnight testing. According to the American Academy of Sleep Medicine an apnoea is defined as a reduction in airflow of ≥70% from baseline lasting for ≥10 seconds. OSA severity is defined by the Apnoea-Hypopnoea Index (AHI) which is the frequency of ≥10 seconds of apnoeic and hypopnoeic events per hour of sleep. The AHI cut points of 5-15 events/hour, 15-30 events/hour and >30 events/hour are indicative of mild, moderate and severe OSA. Alternatively, an AHI of 0 to 4 events per hour is considered to be normal. There are three types of apnoeas including: obstructive, central and mixed. During an obstructive apnoea, respiratory effort is maintained but ventilation decreases or disappears because of partial or total obstruction in the upper airway. A hypopnoea is defined as a reduction in airflow of ≥30-50% from baseline lasting for ≥10 seconds that is associated by either an arousal from sleep or a decrease in oxyhaemoglobin saturation >3-4%.

1.1.2 Diagnosis

Once referred to the sleep laboratory, individuals with suspected OSA undergo a screening assessment which is a quick and cost effective method in identifying those at high risk. The assessment may involve the completion of two validated sleep questionnaires. The Berlin questionnaire (BQ) provides information on the risk level of a person developing OSA (questions related to OSA risk factors including snoring,
obesity, blood pressure and excessive daytime sleepiness) while the Epworth Sleepiness Scale (ESS) questionnaire assesses the level of daytime sleepiness a person experiences (questions measure the propensity of falling asleep while performing everyday activities, i.e watching television).

The ‘gold-standard’ method for OSA diagnosis is full channel polysomnography (PSG). However, ambulatory monitoring is also a validated method of objective evaluation of OSA and is more cost-effective. A PSG study enables the recording of multiple physiological parameters that distinguish between sleep stages and produces a picture of sleep architecture. This test generally requires an overnight stay at a sleep laboratory under the supervision of qualified sleep professionals. Electrodes are positioned on the scalp and at the surface of the face and body for recording brain activity (via electro-encephalography, EEG), heart activity (via electro-cardiography), eye movement (via electro-oculography, EOG), muscle tone (via electro-myography, EMG), nasal airflow (via thermistor), thoracic and abdominal wall movements (via impedance belts), snoring (via microphone and nasal cannula), haemoglobin saturation (via oximetry), sleep position (via body sensors) and video monitoring during sleep. This process however is expensive, labour intensive and time consuming. Furthermore, the results from a single PSG may not capture the true physiologic sleep parameters if the individual cannot sleep or feels anxious due to unfamiliar surroundings. Occasionally a second PSG will be required to prevent what is therefore known as the ‘first-night’ effect. An ambulatory sleep respiratory study at the patient’s home is another option for assessing patients suspected to have OSA. For this patient group, it has been shown that standard PSG shows no significant advantage over the ambulatory approach in terms of diagnosis. This type of sleep study is limited as the diagnostic
devices do not allow simultaneous recording of EEG, EOG and EMG parameters. However, advanced models (Embletta Gold®) can be programmed to allow the recording of the minimum required signals (oximetry, nasal airflow, and respiratory effort) and one of the following parameters: EEG, EOG or EMG. Suspected OSA patients are shown how to complete positioning and connection of the equipment themselves when preparing for bed. Individuals are able to sleep with the recording device in their own bedroom thus reducing the likelihood of the ‘first night’ effect. Diagnosis of OSA using portable devices should be made in conjunction with a comprehensive evaluation by a sleep physician. Other screening tools have been introduced, offering a less expensive alternative method to diagnose OSA including overnight oximetry.

1.1.3 Prevalence and epidemiology

Several studies have been conducted worldwide to provide estimates of OSA prevalence over the past two decades. Young and colleagues, utilising data from the longitudinal Wisconsin Sleep cohort study, estimated the prevalence of OSA (defined as an AHI ≥5) in middle-aged men and women aged between 30-60 years old to be 4% in men and 2% in women. Until recently, OSA was believed to be more widespread in the developed world. Emerging data derived from population based studies from North America, Europe and Asia confirm approximately the same prevalence in the developing countries. In a recent study by Punjabi, estimates of disease prevalence are in the range of 3% to 7% in men and 2% to 5% in women in the general population as shown in table 1-1. Population based studies suggest that OSA is more prevalent in certain ethnic groups. In the Cleveland Family study, a cohort of 537 OSA patients and their families, Redline found that in participants less than 25 years of age, the
prevalence of OSA was higher in African-Americans than in Caucasians possibly due to craniofacial features. The prevalence of OSA therefore is heavily dependent on the study population and multiple co-morbidities which may significantly increase OSA incidence.

Table 1-1: Recent studies on the prevalence of OSA in different ethnic groups

<table>
<thead>
<tr>
<th>Country</th>
<th>Author (Year)</th>
<th>N</th>
<th>Ethnicity</th>
<th>Diagnostic Test</th>
<th>Prevalence</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>Young (1993)</td>
<td>602</td>
<td>White</td>
<td>Polysomnography</td>
<td>4.0%</td>
<td>2.0%</td>
</tr>
<tr>
<td></td>
<td>Bixler (2001)</td>
<td>1.741</td>
<td>White</td>
<td>Polysomnography</td>
<td>3.9%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Australia</td>
<td>Bearpark (1995)</td>
<td>485</td>
<td>White</td>
<td>MESA IV (Portable Sleep Kit)</td>
<td>3.1%</td>
<td>-</td>
</tr>
<tr>
<td>India</td>
<td>Udwalia (2004)</td>
<td>250</td>
<td>Indian</td>
<td>Polysomnography</td>
<td>7.5%</td>
<td>4.5%</td>
</tr>
<tr>
<td></td>
<td>Sharma (2006)</td>
<td>150</td>
<td>Indian</td>
<td>Polysomnography</td>
<td>4.9%</td>
<td>2.1%</td>
</tr>
<tr>
<td></td>
<td>Reddy (2009)</td>
<td>365</td>
<td>Indian</td>
<td>Polysomnography</td>
<td>4%</td>
<td>1.5%</td>
</tr>
<tr>
<td>China</td>
<td>Ip (2001)</td>
<td>258</td>
<td>Chinese</td>
<td>Polysomnography</td>
<td>4.1%</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Ip (2004)</td>
<td>258</td>
<td>Chinese</td>
<td>Polysomnography</td>
<td>-</td>
<td>2.1%</td>
</tr>
<tr>
<td>Korea</td>
<td>Kim (2004)</td>
<td>457</td>
<td>Korean</td>
<td>Polysomnography</td>
<td>4.5%</td>
<td>2.3%</td>
</tr>
</tbody>
</table>

Adapted from Punjabi with the addition of Sharma

1.1.4 Risk factors

Risk factors for OSA include male gender, advanced age, ethnicity (as described above), obesity, alcohol consumption and smoking. The mechanisms contributing to upper airway collapsibility are currently not very well understood. However, it has been suggested that the pathways linking these risk factors for OSA can in part be explained by anatomical abnormalities, increased pharyngeal dilator muscle dysfunction, increased ventilatory control instability and reduced lung volume. Upper body and
central obesity is a risk factor for OSA however, it is also believed that OSA can in turn predispose an individual to become obese. Daytime sleepiness and fatigue due to sleep fragmentation may reduce energy levels and lead to reduced physical activity. Supported by data, individuals with OSA may tend to lead a more sedentary lifestyle. Obesity in OSA affects the upper airway where it is believed that fat accumulation near the neck and soft tissues may change its geometry and increases its propensity to collapse. Central obesity and OSA are associated with hypertension, Type 2 Diabetes Mellitus (T2DM) and hyperlipidaemia (increased levels of cholesterol and triglycerides). Epidemiological studies have demonstrated higher prevalence of OSA in men when compared to women with a ratio 2 to 3:1. It has been suggested that males are more likely to develop the condition due to the differences in anatomical and functional properties of the upper airway and body fat deposition between men and women. Magnetic resonance imaging studies have shown that men tend to have a shorter and thicker neck as well as increased fat accumulation around the pharyngeal airway compared to women. OSA is also more common in middle-age and the elderly. Data from the Sleep Heart Health Study showed that 25% of men and 11% of women between the age of 40 to 98 years old had an AHI ≥ 15. Ancoli-Israeli and colleagues showed that 70% of men and 56% of women between the age of 65 to 99 years old had an AHI ≥ 10. Upper body and central obesity is an important risk factor for the development and progression of OSA, as demonstrated by data from longitudinal studies. Approximately, 70% of subjects with OSA are obese and prevalence of OSA in obese men and women is estimated to be 40%. It has been proposed that fat accumulation on the upper airway, near the neck region can significantly alter the size of the airway and its propensity to collapse. As obesity is an important modifiable risk factor, weight reduction can result in OSA severity.
improvement and in some cases it has been found to be curative.\textsuperscript{2} Peppard reported a weight gain of 10\% was associated with a 32\% increase in the AHI whilst a 10\% weight loss resulted in an AHI reduction of 26\%.\textsuperscript{51} Smoking and alcohol consumption are also risk factors for OSA. In the Wisconsin Sleep Cohort Study, smokers had a greater risk of moderate or worse degree of OSA (odds ratio 4.44) compared with non-smokers.\textsuperscript{2, 52} Smoking is believed to cause airway inflammation and damage which could change the structural and functional properties of the upper airway, thus increasing the risk of collapsibility during sleep. Alcohol acts as a muscle relaxant. Experimental studies showed that alcohol reduces the genioglossus muscle activity leading to increase in the collapsibility of the upper airway.\textsuperscript{53}

1.2 Impact of OSA on health

A large number of OSA patients complain of excessive daytime sleepiness and fatigue due to poor sleep quality. OSA affects cognitive function, concentration, work performance, mood and memory.\textsuperscript{4, 10-11} People with daytime sleepiness have an increased tendency to fall asleep even when performing daily activities such as driving and are unable to control and prevent these episodes from occurring. As a result, individuals with OSA are more prone to have occupational and motor accidents and reduced quality of life.\textsuperscript{14, 54-56} Sassani and colleagues in a recent meta-analysis showed a 2.5 increased likelihood of road traffic accident in individuals with OSA compared to those without OSA.\textsuperscript{54} Horne and colleagues showed that 20\% of all motorway accidents are due to daytime sleepiness and falling asleep at the wheel.\textsuperscript{55} In 2006, Ellen and colleagues reviewed more than 20 studies of sleep apnoea patients and car accidents and found that an excess accident rate in OSA could be three to four times that of those without OSA.\textsuperscript{56} Mulgrew and colleagues reported that individuals with
OSA are at risk of having more severe accidents compared to controls. However, continuous positive airway therapy (CPAP) treatment can effectively reduce the incidence of OSA related road traffic accidents. OSA can also contribute to absenteeism and loss of work productivity thus resulting in additional financial costs. Worldwide economic evaluation studies have shed light into identifying the huge economic burden in our society caused by untreated OSA. OSA is also implicated with the progression of cardiometabolic conditions (section 1.2). The total costs attributed to traffic accidents, loss of life, cardiovascular complications and absenteeism are high. OSA has been identified as a contributory factor in several conditions including coronary artery disease, diabetes mellitus, hypertension, cardiac arrhythmias, and stroke. There is also increased incidence of OSA among obese women with polycystic ovary syndrome. Early diagnosis and effective treatment of OSA is therefore of paramount importance.

1.2.1 OSA, cardiovascular and metabolic complications

OSA affects cardiovascular and metabolic function in a variety of ways. Increased sympathetic activation, systemic inflammation, increased oxidative stress; endothelial dysfunction and metabolic dysregulation are believed to be some of the underlying mechanisms which contribute to increased cardiometabolic risk in OSA. Evidence demonstrates the increased incidence of impaired glucose tolerance, diabetes, insulin resistance, metabolic syndrome, hypertension and stroke among undiagnosed and/or untreated OSA individuals. Evidence also implicates OSA with an increased risk of fatal and non-fatal cardiovascular events. Several expert and government panels have published reports to increase awareness amongst clinicians of the cardiometabolic risks
associated with OSA. These reports highlight the importance of multidisciplinary approaches for the early detection and management of OSA.\textsuperscript{65-67}

The increased association of Type 2 Diabetes Mellitus (T2DM), the Metabolic Syndrome (MetS) and hypertension in people with OSA are thought to result from a complex interaction between increased sympathetic activity, hypoxia, systemic inflammation and suppression of slow wave sleep.\textsuperscript{1, 68} OSA and T2DM have been described as the ‘interacting epidemics’. Both conditions often share common risk factors and ‘co-exist’.\textsuperscript{68} In the SLEEP AHEAD study, Foster and colleagues identified the prevalence of OSA amongst obese subjects with diabetes to be 86%.\textsuperscript{79} Studies showed there is an association between T2DM and OSA that is independent of adiposity.\textsuperscript{68} The metabolic syndrome is a commonly used term that describes a cluster of risk factors including dyslipidemia, glucose intolerance, hypertension, central obesity and insulin resistance.\textsuperscript{70-71} MetS has shown to be a proinflammatory and prothrombotic condition and is associated with an increased risk of cardiovascular disease, T2DM and OSA.\textsuperscript{1} MetS is highly prevalent affecting approximately 20-30% of adults.\textsuperscript{1,17} OSA has been recognised as an independent risk factor for hypertension.\textsuperscript{15} Fifty percent of OSA individuals have been found to be hypertensive and the prevalence of OSA in subjects with hypertension is estimated to be 30%.\textsuperscript{72} The Wisconsin Sleep Study, showed that in patients with mild OSA severity (AHI 5-15), the odds of developing hypertension over 5 years was 2.89.\textsuperscript{65} Studies have shown the prevalence of stroke amongst OSA subjects to be between 60%.\textsuperscript{73} In addition, data derived from the Sleep Health Heart study, showed a high prevalence of coronary artery disease (in the range of 40-50%) among OSA subjects.\textsuperscript{73}
1.3 Treatment options

According to the clinical guideline from the Adult OSA Task Force of the American Academy of Sleep Medicine (AASM), successful treatment and management of OSA requires a multidisciplinary approach as well as patient education on several topics including the pathophysiology, risk factors, natural history, long term cardiovascular and metabolic complications of the condition and the risks of ‘drowsy’ driving. All OSA patients should be encouraged to follow a good sleep hygiene routine together with implementing conservative measures as a way of altering lifestyle factors. Sleep hygiene is a menu of simple recommendations to improve poor sleep habits. Such recommendations include avoiding alcohol and caffeinated drink consumption 4 to 6 hours before sleep, fixing a bed time routine and avoiding strenuous exercise two hours before sleep to name a few. Conservative measures include weight loss especially for obese or overweight individuals, moderation of alcohol consumption, smoking cessation, avoidance of sedatives, sleeping in lateral positions and sleeping enough hours. Sleep physicians utilise a variety of methods in encouraging education of patients on these topics. This may include use of information leaflets, brochures and the recommendation of websites, books and CDs. Treatment decisions should be made whilst taking into account the psychosocial factors and personal circumstances of the newly diagnosed patient. Although the ‘gold standard’ treatment is CPAP therapy there are additional alternative therapies including behavioural therapy, the use of oral appliances and upper airway surgery, depending on the severity of the individual’s disease, anatomy, risk factors and treatment preference. Patients should be encouraged to play an active role in deciding their treatment options.
1.3.1 Oral appliances

The AASM recommends the use of oral appliances for the treatment of mild to moderate OSA as an alternative option when behavioural therapy and CPAP cannot be tolerated by the patient. Oral appliances including mandibular repositioning and tongue retaining appliances require good dentition. Some tailor-made appliances work by preventing the collapse of the tongue and soft tissues of the throat thus preventing obstruction of the airway. They do so by holding the tongue forward thus maintaining the size of the airway behind the tongue base. Palatal tone may also be increased through the glosso-pharyngeal muscles. A dental sleep specialist can help the patient decide on the selection and fitting of the appliance which is tailor-made to meet the requirements and needs of the individual. Oral appliances are comfortable, small and portable. Usually, an individual may require a few weeks to become accustomed to sleeping with these devices. The AASM guide encourages clinicians to follow-up patients using oral appliances regularly so to evaluate the device deterioration and assess the patient for signs and symptoms of worsening OSA. A recent Cochrane review by Lim and colleagues showed that oral appliances can alleviate OSA related symptoms in more than 50% of patients including those with a moderate form of OSA. However, effectiveness of this therapy in subjects with severe OSA still remains uncertain. Common side effects include tooth displacement, jaw discomfort and pain, gum irritation, dry mouth and bruxism.

1.3.2 Surgery

Several surgical techniques have been widely employed in the treatment of OSA in cases of anatomical abnormalities including tracheostomy, uvulo-palatopharyngoplasty (UPPP), laser-assisted uvulo-palatoplasty (LAUP), tongue reduction surgical
procedures and maxillo-mandibular advancement surgery. In addition the AASM also recommends bariatric surgery as a surgical therapeutic option for obese OSA individuals, although this is not standard practice in the UK. However, surgical treatment of OSA remains controversial and expensive. Robust evidence of the long term effectiveness of such procedures is currently lacking.

1.3.3 Behavioral and lifestyle management strategies

Behavioral therapy refers to dietary weight loss programmes, increased physical activity and the implementation of conservative measurements. According to the AASM guide behavioural therapy should be regarded as an adjunct treatment option to CPAP therapy due to the low cure rate by dietary and lifestyle interventions alone.

Robust evidence of the effectiveness of such programmes from randomised controlled trials (RCT) was lacking until recently. A number of RCTs which employed caloric restriction with or without CPAP therapy have been published. There is conflicting evidence among studies regarding the effectiveness of such interventions in reducing weight and OSA parameters. More recently, a number of randomised trials have been conducted investigating the impact of intensive lifestyle modification intervention programmes in obese subjects with OSA have demonstrated that weight loss can be sustained for 12 and 24 months post intervention without additional support and further costs. A previous Cochrane review assessing the impact of lifestyle modification interventions in subjects with OSA failed to identify associations between lifestyle management interventions and improved OSA parameters due to the lack of randomised controlled trials.
1.3.4 Continuous Positive Airway Pressure (CPAP) therapy

CPAP therapy was first introduced by Dr. Colin Sullivan in 1980’s.\textsuperscript{1} CPAP is a mechanical device consisting of an airflow generator which delivers positive airway pressure at the back of the throat via a flexible tube connected to a facial mask. The CPAP apparatus has a built-in algorithm which controls the air flow to generate a set pressure. The positive pressure is measured in centimetres of water (cmH\textsubscript{2}O) and the therapeutic pressure level can range from 4 to 20 cmH\textsubscript{2}O. The pressure level can be either automatic or fixed to a precise setting according to the individual’s requirements following a period of titration. Automatic CPAP machines can detect when the airway is going to collapse and a few seconds prior to the narrowing of the airway the device increases the level of the delivered positive pressure to prevent the occurrence of an apnoeic or hypopnoeic event, prior to the event. In this way a CPAP device instantly stabilises the upper airway allowing normal breathing during sleep to take place. Sleep quality is restored and as a result OSA-related symptoms (i.e daytime sleepiness, fatigue and poor concentration) gradually disappear. It is increasingly common practice in the UK for sleep laboratories to provide patients with automatic CPAP equipment. Modern CPAP devices offer other useful features including the objective monitoring of compliance and other sleep related respiratory parameters. Software algorithms can give clinicians access to patient compliance data via an online interface.

Initiation of CPAP therapy requires a short stay of approximately 45 to 60 minutes at a sleep laboratory where a sleep technician provides a brief overview of the process. An important aspect of the treatment is the mask selection as many patients may suffer from claustrophobia, dry mouth, anxiety and may have difficulty tolerating a facial mask. However, several different masks are now available to increase patient comfort.
and compliance including nasal, full-face and hybrid models along with humidifiers. It is vital for the patient and the technician to decide together on which mask a patient feels most comfortable with. This informed decision is tailor-made to suit the facial features and breathing preference of an individual. A large amount of contact time with the technician is required to optimise tolerance to the therapy. The patient is asked to wear the mask for a few minutes so to become familiar with having something attached on the face. At this point most patients feel slightly uncomfortable however, the presence of the technician provides reassurance. The technician makes the appropriate adjustments on the mask straps to avoid loose fitting and air leakage from the mask thus ensuring patient comfort. It can be very difficult and distressing for someone who is awake to attempt to breathe at ease while using a CPAP apparatus. It is crucial at this point for the sleep technician to reassure the patient that this is normal and somewhat expected, emphasising that determination and keeping calm are of great importance. After a few minutes and when the patient feels more in control of their breathing (and having some time to adjust to these changes) the patient is asked to lie down on the bed and to relax. In this way the patient is able to experience how it feels wearing a mask and resting with a CPAP device in a controlled environment. Following this short trial the patient is encouraged to discuss any concerns or problems with the technician.

Typical side effects include dryness of the mouth and nasal congestion which can be alleviated with the addition of a heated humidification system. A less common side effect of CPAP therapy is abdominal bloating. Most laboratories also offer patients telephone support and ad-hoc advice in the form of drop-in clinics in addition to their follow-up plan. This is to ensure optimal compliance with the therapy. CPAP therapy initiation is relatively time consuming and expensive when taking into account the costs involved with the CPAP machines, masks, humidifiers, technician time and follow-up
support. Although the effectiveness of CPAP therapy in improving vigilance and reducing sleepiness, in improving hypertension, insulin resistance and cardiac dysfunction and in reducing arrhythmias as well as improvement in the quality of life is well documented in the literature,\textsuperscript{18-21} successful treatment requires patient commitment in adhering to CPAP therapy and despite the educational support and follow-up arrangements compliance remains challenging. Because healthcare resources are limited, evaluating costs and benefits of healthcare interventions is important in helping to decide which therapies offer best value for money. The cost-effectiveness of medical therapies is usually assessed by the incremental cost-effectiveness ratio, which is the ratio of the incremental costs associated with therapy divided by the incremental quality adjusted life years gained (QALYs).\textsuperscript{88} The National Institute for Clinical Excellence (NICE) produced a technology appraisal report in 2010 and four published economic evaluations were identified by the Assessment Group, all of which compared CPAP with a 'do nothing' alternative.\textsuperscript{89} Table 1-2 indicates the resulting incremental cost-effectiveness ratios (ICERs). These figures indicate CPAP therapy for the treatment of OSA to be highly cost-effective.

<table>
<thead>
<tr>
<th>Table 1-2: NICE economic evaluation report results \textsuperscript{89}</th>
</tr>
</thead>
<tbody>
<tr>
<td>US $3354 (approximately £1688, currency conversions were calculated in August 2007) per quality-adjusted life year (QALY) gained from a third-party payer perspective</td>
</tr>
<tr>
<td>US $314 (£158) per QALY gained from a societal perspective</td>
</tr>
<tr>
<td>€7861 (£5348) per QALY gained over a 5-year time horizon and €4938 (£3359) per QALY gained for a lifetime time horizon</td>
</tr>
<tr>
<td>£8300 per QALY gained at 1 year and £5200 per QALY gained at 2 years</td>
</tr>
<tr>
<td>Canadian $9809 (£4654) per QALY gained for the high-cost estimate and Canadian $3523 (£1672) per QALY gained for the low-cost estimate</td>
</tr>
</tbody>
</table>
1.3.4.1 Adherence with CPAP

Several studies in the literature (using an arbitrary cut off point of CPAP compliance for 4 hours per night to define adherence) report 28-83% of non-adherence rates. Studies have shown a dose response relationship with CPAP so that the longer the duration of night compliance the greater the improvement in objective and subjective sleepiness, memory and daily functioning. Campos-Rodriguez and colleagues conducted a study investigating the effect of CPAP night duration on 5 year survival rates and found that use greater than 1 hour per night significantly lowered mortality by 91.3% [95% CI 0.88 to 0.94, p = 0.01]. Therefore, taking into account the association between CPAP compliance and improved outcomes it is of paramount importance to optimise compliance to CPAP therapy. Patient compliance is thought to be increased by advances in technology and ergonomics of devices and masks which increase patient comfort. However, a recent systematic review evaluating the effectiveness of 24 such trials in enhancing CPAP use concluded that there is no evidence to support this concept. As CPAP is managed by the individual at home researchers have shifted the focus to psycho-educational interventions in the hope that these strategies would have a positive effect on CPAP adherence. In this field numerous approaches have been employed to enhance compliance from cognitive behavioural therapy (CBT), intensive patient education programmes with written literature, video education, and increased clinician support via telephone calls as well as frequent hospital visits. Aloia and colleagues conducted a study to examine the efficacy of a CBT intervention in a group of 6 OSA adults ranging in age from 63 to 67 years. The intervention group received two 45 minute sessions designed to educate participants on the consequences of OSA and the efficacy of CPAP while the control group received only CPAP. The intervention resulted in increased hours of CPAP use in the CBT group at 12 weeks.
compared to the control group (CBT group 7.8 hours/night, control group 4.6 hours/night). Richards and colleagues examined whether an education intervention based on components of social cognitive theory and executed using CBT could improve acceptance and adherence to CPAP in 100 OSA participants ranging in age from 32 to 81 years. The results showed the intervention group increased compliance by 2.9 hours per night in 28 days compared with the control group. The results achieved could also be influenced by the increased input and contact with the clinicians. This is also supported by another prospective study conducted by Hoy and colleagues for OSA patients and their partners in the UK. The intervention arm received an intensive education programme and nursing support while the control group received standard support. Compliance was improved in the intervention group by 1.6 hours per night at 6 months compared with the control group. These studies provide early evidence that psychological interventions indeed have a positive effect on maintenance of increased compliance to CPAP therapy.

A major obstacle is the identification of predictive variables which could inform new strategies to increase compliance. A small number of descriptive studies have been conducted to inform the theoretical and empirical basis for developing a psycho-educational intervention to improve patient compliance to CPAP. These studies suggest that a patient’s perception with regards to the symptoms after initiating CPAP therapy and their view in terms of health value has been shown to be greater after CPAP use. In addition, patient perceptions of their illness, benefits of treatment and decision to use the therapy as well as self efficacy for using CPAP have been predictive of CPAP use. It has been reported that 20% of the variance in CPAP adherence may be explained by the way patients troubleshoot CPAP problems and those employing a
problem-solving approach were more compliant.\textsuperscript{102,103} The impact of social support (spouse, family members and/or friends) has been investigated on CPAP compliance and it was found to have a positive influence.\textsuperscript{104, 105} The more supported individuals with OSA felt the better they adhered to CPAP therapy. The sleep quality of a partner prior to treatment and quality of life proved to be a key determinant of treatment adherence.\textsuperscript{106} When the idea of seeking medical advice was initiated by a partner and not by the patient, this adversely affected the patient’s adherence to the therapy.\textsuperscript{107} In addition, depression rates were found to be very high in OSA patients\textsuperscript{108,109} thus supporting the multidisciplinary approach to OSA treatment which is a risk factor for poor self-care. In conclusion, taking into account these studies, psychological factors account for 20-40\% of variance in CPAP compliance. Published studies however have explored contributing factors in isolation from each other and most importantly, lack the theoretical work to explain how these factors influence CPAP compliance. The UK Medical Research Council (MRC) guidelines for developing complex intervention strongly recommend the completion of sound theoretical and modeling research prior to undertaking any research trials.\textsuperscript{110}

1.4 Research aims and hypotheses

OSA is a potentially disabling condition implicated in an increased risk of cardiovascular disease, hypertension, diabetes and mortality. Effective treatment of OSA combined with management of obesity is the way forward in improving clinical status and reducing cardiometabolic risk. Although CPAP therapy is very effective in improving OSA-related short and long term complications, compliance remains a major issue. To identify what psycho-social factors hinder CPAP compliance the ‘Predicting
the Use of CPAP therapy in Obstructive Sleep Apnoea in a UK population (the PUCOSA-UK) study was carried out. This study was a prospective, questionnaire based study of carefully characterised sleep clinic patients with appropriate measurements of potential predictors of CPAP adherence. The PUCOSA-UK study is described in Chapter 2 and the qualitative analysis in Chapter 3.

Weight loss and lifestyle changes are actively encouraged in obese individuals with OSA. However, there is currently no robust evidence from randomised trials to evaluate the effectiveness of such programmes. To consolidate the evidence in this area due to the recent publication of relevant studies, a systematic review and meta-analysis was conducted to evaluate the impact of weight loss through diet, exercise and lifestyle modification interventions on OSA parameters, indices of obesity and quality of life (QoL) in adults with OSA (Chapter 4).

Finally, the results from the systematic review and the PUCOSA-UK study were collated for the development of a structured education curriculum titled: A randomised controlled trial of a structured education programme to promote physical activity and CPAP compliance in people with Obstructive Sleep Apnoea (Arise & Shine pilot study, Chapter 5). The curriculum was based on an existing programme111,112 and was tailored to the needs of individuals with OSA. The main aim of the education curriculum was to alter patient’s behaviour and facilitate lifestyle changes in order to improve anthropometric, biomedical and psychological outcomes as well improving CPAP compliance. Pilot work was carried out to refine the curriculum so that it can be tested in an RCT.
Hypotheses:

1) PUCOSA-UK study: Psycho-social factors play an important role in determining CPAP adherence. These predictors of CPAP adherence include: mood, fatigue, illness representations, self efficacy and social support.

2) The impact of diet and lifestyle management strategies for obstructive sleep apnoea in adults: A systematic review and meta-analysis: diet and lifestyle management strategies can significantly reduce indices of obesity, OSA parameters and quality of life in adults with OSA.

3) Arise & Shine pilot study: a structured education programme promoting CPAP compliance and physical activity for this at risk patient population will empower individuals to alter their behaviour via setting personalised goals, make choices suitable to their lifestyle and self-manage their condition better.
Chapter 2

Predicting the Use of Continuous Positive Airway Pressure in Obstructive Sleep Apnoea in a UK population. The PUCOSA-UK Study
2.0 Chapter overview

The PUCOSA study is an international collaboration between the University of Leicester, the University Hospitals of Leicester NHS Trust and two Australian research institutions, the University of Western Australia and the Combined Universities Centre for Rural Health. The PUCOSA study, for the first time in the UK and Australia, has explored a variety of psycho-social predictors of usage of CPAP treatment together based on a theoretical framework that includes psychology health belief models and theories suitable for this patient population. The study design and supporting documents were originally developed by the Australian research team who have an expertise in health psychology. These documents were extensively reviewed and adapted for use within our UK Sleep Disorders Service. The author of the thesis, MAT, performed the following activities in relation to this study:

- Obtained research and development approval
- Reviewed the protocol and designed the study documents
- Managed the study logistics
- Performed administrative duties for the study
- Recruited and consented all the participants
- Arranged and attended every study visit with every participant
- Collected and managed patient data
- Took blood samples
- Communicated study results to the patients and their GPs
- Analysed and interpreted data
The above activities were performed under the supervision of MJD, KK, EMB and APH. Ethical and R&D approval, was obtained in collaboration with EMB, JH and SE. Data analysis was supervised by EMB and DHM. The PUCOSA-UK study is powered to run as an independent study. The power calculation was conducted by LJG. In this chapter I provide the study design and the results from the empirical study.

2.1 Background

The major challenges facing most developed nations are those related to the rising incidence of common, complex chronic diseases and the increasing complexity of their diagnosis, prevention and treatment. Obstructive Sleep Apnoea (OSA) as discussed in Chapter 1, is a common breathing disorder and a complex condition with substantial, long-term morbidity. Continuous positive airway pressure (CPAP) therapy is recommended as the first line therapy in the majority of patients with moderate to severe OSA (AHI≥15). CPAP therapy has been shown to be effective in ameliorating OSA related symptoms, in improving insulin sensitivity, reducing hypertension and improving quality of life. The efficacy of CPAP therapy relies on long term compliance. Despite the evidence supporting the effectiveness of CPAP therapy, patient adherence to CPAP can be poor. Several studies in the literature using an arbitrary cut point of CPAP compliance of 4 hours per night to define adherence, report between 28-83% non-adherence rates. It has been estimated that more than 50% of those initiating CPAP therapy will not use their CPAP devices after one year. In addition, of those OSA patients using their CPAP equipment are not able to tolerate their CPAP device for the duration of the entire night one year later.
As discussed in Chapter 1, a major obstacle is the identification of predictive factors which could inform new strategies to increase compliance. Published studies have explored contributing factors in isolation from each other not allowing direct associations between these factors and most importantly, lack the theoretical work to explain how these factors influence CPAP compliance. In order to explore the interplay of potential psycho-social predictors of CPAP adherence together for the first time and thus to bridge the gap in the literature, the identification and utility of specific theoretical models was of great importance. Two theoretical models were identified as appropriate in this field including Leventhal’s Common Sense Model of Illness Behaviour\textsuperscript{117, 118} and Bandura’s Social Cognitive Theory.\textsuperscript{119,120} Leventhal’s model suggests that individuals conceptualise a health threat based on five dimensions including the identity, cause, timeline, consequence and control/treatment of the threat and these dimensions can influence potential coping strategies. Bandura’s model focuses on the self-confidence of an individual to practice a set of behaviors and follow action plans. Combining the above two health belief models, we propose a new model in predicting adherence to CPAP therapy. This model is centred around the belief that an individual with OSA will be ready to accept and adhere to CPAP therapy based on their perceived consequences of their condition in their life and overall health status and the perceived seriousness of their illness. The patient’s belief in the prescribed treatment (CPAP therapy) is based on their personal assessment of the perceived benefits to their health and well-being if they adhere to the treatment versus the perceived barriers of adherence to the therapy. The patient’s self-confidence, their ability to use the therapy despite facing barriers and encouragement from their social environment were also included in our model. We expected this new model to have a great utility in identifying predictors of CPAP use in those patients newly diagnosed with OSA. This in turn would inform the development
of our psycho-education intervention to enhance CPAP compliance in line with the UK Medical Research Council guidelines for developing complex interventions.\textsuperscript{121}

2.1.2 Aims, hypotheses and research questions

The aim of this study was to explore the utility of the Common Sense Model of Illness Behaviour and the Social Cognitive Theory in predicting CPAP adherence among established and newly diagnosed OSA participants treated with CPAP therapy.

We hypothesised that psycho-social factors including mood, fatigue, daytime sleepiness, illness representations, self efficacy and social support play an important role in determining CPAP adherence. These factors were assessed via a standard battery of validated questionnaires outlined below:

- Mood was assessed via the Depression, Anxiety and Stress Scales (DASS-21)\textsuperscript{122}
- Daytime sleepiness was assessed via the Epworth Sleepiness Scale (ESS)\textsuperscript{29, 123}
- Fatigue was assessed via the Fatigue Severity Scale (FSS)\textsuperscript{124}
- Illness representations: was measured by the Illness Perceptions Questionnaire-Revised (IPQ-R).\textsuperscript{125} The IPQ-R Cause, IPQ-R Symptoms and Coherence, IPQ-R Consequences and IPQ-R Timeline scales were utilised. Memory problems were assessed with the Multifactorial Memory Questionnaire (MMQ)\textsuperscript{126, 127} and the MMQ-Contentment (MMQ-C) and MMQ-Ability (MMQ-A) subscales were employed.
- Self-efficacy in CPAP outcome expectancies and treatment beliefs were assessed via the Self-Efficacy Measure for Sleep Apnoea SEMSA-SE and SEMSA-OE scales.\textsuperscript{128}
- Social support: was assessed by the Significant Others Scale (SOS). The Social Support Spouse (SOS-S) and Social Support Other (SOS-O) was utilised.

The above validated questionnaires were incorporated and formed the PUCOSA-UK questionnaire booklets (T1, T2, T3 and T4). A more detailed description of the booklets and the questionnaire scales is provided in section 2.2.5.2

The following hypotheses were made:

- CPAP use (as assessed by mean hours/night) and/or CPAP compliance (as assessed by ≥ 4 hours/night) will confer improvements in:
  - Subjective daytime sleepiness (as assessed by the ESS), fatigue (as assessed by the FSS), subjective memory ability and contentment (as assessed by the MMQ-A and MMQ-C), depression, anxiety and stress levels (as assessed by the DASS-21).

- CPAP use and/or CPAP compliance will be positively associated with:
  - Increased self–confidence (as assessed by the SEMSA-SE) and strong beliefs around CPAP efficacy (as assessed by the SEMSA-OE) in ameliorating OSA related symptoms
  - Increased social support (as assessed by the SOS) and strong illness perceptions (as assessed by the IPQ-R)
  - Reduced anthropometric and obesity indices (as assessed by weight, BMI, waist-hip-neck circumference, body fat %)
Improved glycaemic and liver function indices (as assessed by HbA1c, Albumin, Bilirubin, Alkaline Phosphatase and Alanine Transaminase)

The following research questions were formed:

1. Is CPAP therapy (as assessed by mean hours/night) associated with improvements in the baseline daytime sleepiness (ESS), fatigue (FSS), memory complaints (MMQ), mood (DASS-21), social support (SOS), self-efficacy (SEMSA), Illness perceptions (IPQ-R) anthropometric and biomedical data in the established OSA group?

2. Which baseline exploratory psycho-social factors best predict CPAP compliance (as assessed by ≥4 hours/night) at 3 and 6 months post CPAP therapy in the newly diagnosed group?

3. If the newly diagnosed group is CPAP compliant at 3 and 6 months post CPAP therapy, are there any improvements observed in the daytime sleepiness (ESS), fatigue (FSS), memory complaints (MMQ), mood (DASS-21), social support (SOS), self-efficacy (SEMSA) and Illness perceptions (IPQ-R), anthropometric and biomedical data at the same time points?

2.2 Study design and methods

2.2.1 Sample size and power calculation

The sample size for this study was based on the sample size in previously published studies in this field. One small study (n=54) by Stepnowsky et al\textsuperscript{130} used social cognitive variables to account for 11.5\% of variance in CPAP use (in long term CPAP
users). We were aware of no study that explored the Common Sense Model of Illness in people with OSA. However, a meta-analysis by Vandeputte et al\textsuperscript{131}, examining the relationship between the Common Sense Model and illness outcomes, across a range of chronic conditions, indicated that these variables would account for 9% of variance in problem focused coping (adherence was not included in the analysis). As problem focused coping is a generic measure, we anticipated that the variance explained by the Common Sense Model variables (identity, cause, timeline, consequence and control/treatment) would be slightly higher than this, and equivalent to that of Social Cognitive Theory. However, there was some overlap in constructs between the two models. Therefore, we anticipated an increase of 20% of variance explained by the combination of the constructs from the theoretical models, above that explained by demographic and medical characteristics. Using GPower 3.0, with a power of .95, and an alpha of .05, a sample size of 104 would be required. However, with regression including demographic differences (age, gender) and OSA severity (AHI scores) as well as psychological predictors, to maintain an adequate case to variable ratio needs 10 cases to 1 predictor variable.\textsuperscript{132} Thus, 160 participants (13 predictors, 3 covariates) were required to complete the study, allowing for an attrition rate of 20% over follow-up.

\textbf{2.2.2 Inclusion and exclusion criteria}

\textbf{Inclusion criteria}

\textbf{Suspected/Newly diagnosed group:}
Individuals newly referred to the Leicester Sleep Disorders Service for suspected OSA and subsequently diagnosed with moderate to severe OSA (AHI>15) willing to be treated with CPAP therapy.

Established OSA group:

- Patients under the care of Leicester Sleep Disorders Service
- Confirmed diagnosis of moderate to severe OSA (AHI>15),
- Currently treated with CPAP therapy

Exclusion criteria

- Inability to speak English and provide informed consent
- Inability to complete the questionnaire booklet in unaided
- Current enrolment in another study
- Patients with predominantly central sleep apnoea and those who have another primary sleep disorder (i.e periodic leg movements of sleep) and those with dementia or stroke.

2.2.3 Recruitment

Participants were recruited from the Leicester Sleep Disorders Service at the Leicester General Hospital, UK. Two participant groups were formed in this study, one for those patients who attended the sleep clinic for their first assessment for presence of OSA (suspected/newly diagnosed group) and those previously diagnosed with OSA,
receiving CPAP therapy and were returning to the clinic as part of routine care (established group). All patients referred to the sleep clinic for suspected OSA or patients with established OSA receiving CPAP therapy were sent an invitation pack and a letter outlining the study and why they were being approached (Appendix 3). Additionally, patients with established OSA attending an appointment at the Sleep clinic were verbally invited. No data were obtained prior to informed consent.

2.2.4 Patient visits and study flow

The patient visits are outlined below in figure 2-1. All visits were part of routine care with only the completion of the questionnaire booklets T1, T2, T3 and T4 forming the research intervention. A detailed description of the questionnaire booklets is provided in section 2.2.5.2.
2.2.5 Study measures

2.2.5.1 CPAP therapy compliance and use

Patient compliance (as assessed by ≥4 hours per night) and use (as assessed by hours/night) to CPAP therapy was objectively measured by an inbuilt meter in the
CPAP apparatus. Recordings were made during the participants scheduled appointments at 3 and 6 months post CPAP treatment for the newly diagnosed group and once in the established group (Table 2-2).

### 2.2.5.2 Questionnaire and routine data collection

The PUCOSA-UK questionnaire booklets comprised of validated questionnaires that measured different psycho-social factors at each time point in the intervention. The T1 questionnaire booklet was administered to those participants with suspected OSA and it strategically assessed early formed perceptions and beliefs of the participants suspected sleep problem, illness perceptions, and current levels of social support, mood, memory complaints, fatigue and daytime sleepiness. Post formal OSA diagnosis and post CPAP initiation at the sleep laboratory, the T2 questionnaire booklet was administered to newly diagnosed participants. This booklet focused on capturing the participant’s understanding on the symptoms caused due to their OSA diagnosis and assessed their self-confidence in CPAP therapy as an effective therapeutic treatment together with their commitment to sleeping with the therapy despite facing challenges. Post 3 months CPAP therapy the participants were administered the T3 questionnaire booklet that assessed all the aforementioned physco-social factors aiming to identify changes from the baseline in the participant’s perceptions and beliefs. Post 6 months CPAP therapy the final T4 questionnaire booklet was administered to assess the participant’s beliefs and illness perceptions, social support, mood, memory complaints, fatigue and sleepiness at this stage.

The established group completed the T4 questionnaire booklet only and the suspected/newly diagnosed group completed the complete battery of questionnaires
including the T1 (pre-diagnosis), T2 (post-diagnosis), T3 (post 3 months CPAP therapy) and T4 (post 6 months CPAP Therapy) booklets. These booklets were specifically designed to capture the following psycho-social predictors:

**Mood**

Mood was assessed using the Depression, Anxiety and Stress Scales (DASS-21). The DASS-21 is a set of 3 self-report validated scales (each consisting of 7 items) used for measuring the severity of negative emotional states of depression, anxiety and stress over a period of a week.\(^{122}\) The score ranges of each subscale are shown below (Table 2-1) with higher scores indicating higher levels of depression, anxiety and stress.

<table>
<thead>
<tr>
<th></th>
<th>Depression</th>
<th>Anxiety</th>
<th>Stress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>0-4</td>
<td>0-3</td>
<td>0-7</td>
</tr>
<tr>
<td>Mild</td>
<td>5-6</td>
<td>4-5</td>
<td>8-9</td>
</tr>
<tr>
<td>Moderate</td>
<td>7-10</td>
<td>6-7</td>
<td>10-12</td>
</tr>
<tr>
<td>Severe</td>
<td>11-13</td>
<td>8-9</td>
<td>13-16</td>
</tr>
<tr>
<td>Extremely Severe</td>
<td>14(^+)</td>
<td>10(^+)</td>
<td>17(^+)</td>
</tr>
</tbody>
</table>

**Fatigue**

The impact of fatigue on an individual’s general functioning was assessed with the Fatigue severity Scale (FSS). FSS is a validated self-administered 9 item questionnaire rated in a Likert scale with 1 denoting as strongly disagree and 7 as strongly agree. It has been shown to be sensitive in OSA patients. A mean score of 0-2 indicates normal fatigue and a mean score of >3 indicates a high level of fatigue.\(^{124}\)
Daytime Sleepiness

Subjective daytime sleepiness was assessed with the Epworth Sleepiness Scale (ESS) questionnaire. The ESS is a validated self administered 8 item questionnaire measuring the likelihood of falling asleep in eight routine daytime situations rated on a 0-3 scale with 0=would never doze to 3=high chance of dozing. Scores range from 0 to 24 with higher scores indicating a greater likelihood of falling asleep.\textsuperscript{123}

Memory Complaints

The Multifactorial Memory Questionnaire (MMQ) is a validated tool used to assess memory problems using two subscales the MMQ-Ability and the MMQ-Contentment.\textsuperscript{127} The MMQ-Ability subscale contains 20 memory failures, such as forgetting appointments, telephone numbers and names during the past 2 weeks. Individuals indicated the level of frequency with which each failure occurred on a 5 point scale with 0 denoting all the time and 4 never. Scores range from 0 to 80 with higher scores indicating better subjective memory ability. The MMQ-Contentment subscale was used to assess a variety of feelings such as confidence, embarrassment and worry that individuals may have experiences about their memory ability. Individuals rated their level of agreement on a 5 point scale with 0 denoting strongly disagree and 4 as strongly agree. Scores range from 0 to 72 with higher scores indicating higher contentment of memory ability. Both scales are reliable (alpha = .95 and .93 respectively) and have been shown to have good validity.\textsuperscript{127}

Illness Representations

The Illness Perception Questionnaire–Revised (IPQ-R) was used to assess illness perceptions. It has five scales including:
1. identity (the symptoms the patient associated with OSA),
2. cause (personal beliefs regarding the aetiology of OSA)
3. timeline (perceived duration and chronicity of OSA)
4. consequences (expected effects and outcomes of OSA) and
5. cure/control (how can a patient control OSA).

The IPQ-R was developed as a generic tool, which can be modified for specific conditions, to assess all 5 dimensions of illness representations. In this study, of the above 5 scales we utilised only the first 4 (identity, cause, timeline and consequences) as the cure/control element was assessed via the SEMSA tool described below. The identity scale comprised of 15 core symptoms and the participants were asked if they experienced these symptoms since the start of their sleep problem and if they believed that these symptoms were directly related with their sleep problem. The symptom coherence scale includes 5 items and participants were asked to state their personal views using a 1 to 5 scale (1= strongly agree, 2= agree, 3= uncertain, 4= disagree, 5= strongly disagree). The cause scale consists of 17 potential causes and the participants were asked to state using a 1 to 5 scale (same as above) if they considered any of the 17 factors to have caused their OSA. The timeline scale consists of two questions regarding the duration of their condition. High scores in the identity, cause and consequences scales indicate more somatic complaints due to OSA and more interference in life and functioning because of the condition, strongly held beliefs about the number of symptoms attributed to the illness and negative consequences of OSA to the patients overall health. High scores on the illness coherence represent an overall understanding of OSA, high scores on consequences represent positive beliefs about the controllability and personal understanding of the condition.
Self-Efficacy

Self-Efficacy Measure in Sleep Apnoea (SEMSA) is a validated tool specifically designed for the OSA patient population. Outcome expectancies are assessed by a 9 item scale rated on a 4 point scale seeking responses to (not at all true, barely true, somewhat true and very true) to statements of general outcomes (i.e if CPAP is used I will be more active, I will be more alert, I will feel better). Self-efficacy was evaluated by asking the participants to rate on the same 4 point scale the level of their confidence in using CPAP despite certain challenges including stuffy nose, embarrassment, travel, disturbing bed-partners sleep, claustrophobia and wearing a tight mask.

Social Support

Social support was assessed by the Significant Others Scale (SOS) which is a validated questionnaire. The SOS assesses 4 different social support functions including that of the spouse, other family members (son, daughter), close friend and colleagues (2 emotional and 2 practical functions). For each of the four social support functions, the individual being rated is scored in terms of the actual level of support received and the ideal level of support desired. Ratings are made using a 7-point scale from 1 (never) to 7 (always). Scores are derived for actual and ideal levels of support. The SOS scale is designed to examine the quality of the individual’s most important relationships and measures perceived support in preference to received support.
Routine data collection

As part of routine practice the Leicester Sleep Service collect a number of anthropometric data using standard operating procedures. For this study, blood pressure was measured in the sitting position (Omron, Healthcare, Henfield, UK), three measurements were obtained and the average of the last two measurements was used. Body weight was measured with Tanita TBE 611, Tanita, West Drayton, UK to the nearest Kg, waist circumference was measured from midpoint between the lower costal margin and iliac crest height to the nearest cm and neck circumference was measured to the nearest cm with a tape measure. The measuring tape was positioned at a point just below the larynx and at the same height at the back of the neck. When the reading was taken the patients were asked to look straight ahead. All anthropometric data were collected at T1, T3 and T4 for participants with newly diagnosed OSA and at T4 only for those with established OSA.

Additionally non-fasting bloods were taken to measure HbA1c, cholesterol (Total, High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL) and triglycerides (TG)) and liver function tests. These were collected at T1 and T4 for newly diagnosed participants and at T4 for those with established OSA (Table 2-2).
**Table 2-2: PUCOSA-UK Data collection**

<table>
<thead>
<tr>
<th>Study measures</th>
<th>Established OSA patient group</th>
<th>Suspected OSA patient group:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time Point</td>
<td>T1</td>
</tr>
<tr>
<td><strong>Primary outcome: CPAP use (hours/night) and compliance (≥4 hours/night)</strong></td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

**Questionnaires: Psychological Outcomes**

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Established OSA patient group</th>
<th>Suspected OSA patient group:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epworth Sleepiness Scale (ESS)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Fatigue Severity Scale (FSS)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Multifactorial Memory Questionnaire (MMQ)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>MMQ-A;ility</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>MMQ-Contentment</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Depression, Anxiety and Stress Scales (DASS-21)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>DASS-21 Depression</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>DASS-21 Anxiety</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>DASS-21 Stress</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

**Questionnaires: Predictors of CPAP use**

<table>
<thead>
<tr>
<th>Social support: Significant Others Scale (SOS)</th>
<th>Established OSA patient group</th>
<th>Suspected OSA patient group:</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOS-Spouse (perceived &amp; ideal)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>SOS-Other (perceived &amp; ideal)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Self-Efficacy Measure for Sleep Apnoea (SEMSA)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>SEMSA Treatment Beliefs (SEMSA-OE)</td>
<td>x</td>
<td>X</td>
</tr>
<tr>
<td>SEMSA Self-Efficacy (SEMSA-SE)</td>
<td>x</td>
<td>X</td>
</tr>
<tr>
<td>Illness Perception Questionnaire Revised (IPQ-R)</td>
<td>x</td>
<td>X</td>
</tr>
<tr>
<td>IPQ-R identity (Symptoms &amp; coherence)</td>
<td>x</td>
<td>X</td>
</tr>
<tr>
<td>IPQ-R Cause</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>IPQ-R Time</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>IPQ-R Consequences</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

**Anthropometrics**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Established OSA patient group</th>
<th>Suspected OSA patient group:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure (mmHg)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Body Fat (%)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Waist Circumference (cm)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Hip Circumference (cm)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Neck Circumference (cm)</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

**Biomedical**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Established OSA patient group</th>
<th>Suspected OSA patient group:</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (mmol/mol)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Cholesterol (Total, HDL-LDL, Triglycerides)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Liver Function Test</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

*Clarification of time point in the established group: T4 post prolonged CPAP use (range 1 to 18 years).
*Clarification of time points in the newly diagnosed group: T1*: pre-diagnosis, T2*: post-diagnosis, T3*: post 3 months CPAP therapy and T4*: post 6 months CPAP therapy.
2.2.6 Diagnosis and treatment

An overnight home sleep respiratory study (Embletta Gold®, Embla Broomfield, USA) was conducted to confirm diagnosis and OSA severity.\textsuperscript{37} The Embletta Gold® is an ambulatory polygraphic device compliant with the American Academy of Sleep Medicine recommendations for portable monitoring.\textsuperscript{31} All sleep reports were analysed using the Somnologica software and these were assessed by specialist sleep consultants. Patients were diagnosed with moderate OSA if their AHI=15-30 and severe OSA if their AHI ≥ 30 events/hour of sleep. CPAP therapy was prescribed and initiated by a qualified team of Sleep physicians and technologists. CPAP use and compliance was measured objectively via collecting data direct from the participants CPAP machine to capture: a) number of nights CPAP was used, b) number of nights CPAP used for ≥4 hours and c) mean nightly duration of CPAP use.

2.2.7 Ethical issues and data confidentiality

Ethical approval was granted by the Leicestershire, Northamptonshire and Rutland Research Ethics Committee and R&D approval was granted by the University Hospitals of Leicester NHS Trust R&D Committee (10/H0406/84, Appendix 3). Informed consent of all participants was taken prior to any data collection by appropriately trained members of the research team in accordance with International Conference of Harmonisation Good Clinical Practice (ICH-GCP) guideline. Each participant was assigned a unique identification number upon recruitment. The research team complied with the data protection policy of the University Hospitals of Leicester NHS Trust.
2.2.8 Statistical analysis

Statistical analyses were conducted using the IBM-SPSS Statistics programme (Version 20, Chicago, Illinois). Continuous data are reported as mean ± SD and non-continuous as percentage, number and range. Initially, SPSS syntax was utilised to calculate the total scores of each questionnaire variable. Analysis was conducted in stages depending on the patient group. In the established group, linear regression was carried out to identify if CPAP use (hours/night) was associated with improvements in the baseline questionnaire and biomedical data and the results were reported as Beta coefficients and 95% Confidence Intervals (CI). Adjusted and unadjusted models are shown for both the questionnaire data (adjusting for age, sex, BMI, anti-depressant tablets, sleeping tablets and diuretics) and for the biomedical data (adjusting for age, sex, oral-antihyperglycaemics, lipid-lowering tablets and steroids). In the newly diagnosed group, logistic regression was carried out to identify which baseline variables predicted CPAP compliance (defined as ≥4 hours/night) at 3 and 6 months. Unadjusted models were produced as were models that adjusted for the same variables as previously and the results are reported as odds ratio (OR) and 95% CI. Following this analysis, the change from baseline to 3 months was calculated for each variable and linear regression was carried out to identify if CPAP compliance at 3 months was associated with an improvement from baseline in the questionnaire, anthropometric and biomedical measures. Two adjusted models were produced (model 1: adjusted for each outcome’s baseline value, model 2: adjusted for each outcome’s baseline value + age, BMI, sex, [anti-depressants, sleeping tablets, diuretics only for the questionnaire data] or [oral-antihyperglycaemics, lipid-lowering tablets and steroids for the biomedical and anthropometric data]) and the data are shown as Beta coefficients plus 95% CI. Analogous analyses were conducted for the 6 month follow-up. Finally, paired-t tests
were carried out (T3-T1 and T4-T1) to identify potential changes from baseline in all questionnaire, anthropometric and biomedical variables regardless of CPAP compliance.

2.3 Results

2.3.1 Recruitment response rate and study population

Three hundred and six patients were invited to participate in this study. Three hundred were invited by a postal invitation and six were approached at the sleep clinic. Two hundred and fifteen patients responded to the invitation (70.3%). 16.3% (n=50) of those who responded did not want to participate and 1.6% (n=5) were unable to attend their appointment so they were excluded from the study. 52.3% of those who responded (n=160) were eligible to participate in the study and were recruited successfully (Figure 2-2). The study cohort was recruited between November 2011 to February 2012 and consisted of 160 predominately male (73.8%), middle aged (53.7±11.7 years old) and obese (BMI of 31.9±6.8 kg/m²) participants. Overall, 50% (n=80) of the recruited participants had established OSA and the remaining 50% (n=80) had suspected OSA at the point of recruitment. The baseline demographic characteristics of the 160 recruited participants are shown in Table 2-3.
Table 2-3: Baseline characteristics of the 160 recruited participants

<table>
<thead>
<tr>
<th>Variables</th>
<th>53.7±11.7 (range 21-77years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>73.8 %, (n=118)</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>96.2±20.3</td>
</tr>
<tr>
<td>BMI(Kg/m²)</td>
<td>31.9±6.8</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>90 %, (n=144)</td>
</tr>
<tr>
<td>Any other White background</td>
<td>3.8 %, (n=6)</td>
</tr>
<tr>
<td>White and Asian</td>
<td>0.6 %, (n=1)</td>
</tr>
<tr>
<td>Any other mixed race</td>
<td>0.6 %, (n=1)</td>
</tr>
<tr>
<td>Indian</td>
<td>2.5 %, (n=4)</td>
</tr>
<tr>
<td>Any other Asian background</td>
<td>2.5%, (n=4)</td>
</tr>
<tr>
<td>Employment Status</td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>50 %, (n=80)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>9.4%, (n=15)</td>
</tr>
<tr>
<td>Self-employed</td>
<td>9.4%, (n=15)</td>
</tr>
<tr>
<td>Retired</td>
<td>30.6%, (n=49)</td>
</tr>
<tr>
<td>Student</td>
<td>0.6%, (n=1)</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
</tr>
<tr>
<td>Married/Civil Partner</td>
<td>90%, (n=144)</td>
</tr>
<tr>
<td>Single</td>
<td>5.6%, (n=9)</td>
</tr>
<tr>
<td>Divorced/Separated</td>
<td>3.8%, (n=6)</td>
</tr>
<tr>
<td>Widow/Widower</td>
<td>0.6%, (n=1)</td>
</tr>
<tr>
<td>Alcohol Consumption</td>
<td></td>
</tr>
<tr>
<td>Drinker</td>
<td>65.6%, (n=105)</td>
</tr>
<tr>
<td>Non-drinker</td>
<td>34.4%, (n=55)</td>
</tr>
<tr>
<td>Smoking Status</td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>50.6%, (n=81)</td>
</tr>
<tr>
<td>Non-smoker</td>
<td>30.6%, (n=49)</td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>18.8%, (n=30)</td>
</tr>
</tbody>
</table>

Data are expressed as (mean± SD) or as percentage %, n.

Following a home sleep respiratory study 12.4 % of the suspected OSA participants (n=38) were excluded as they were not diagnosed with OSA as shown in Figure 2-2. The final study population consisted of 122 participants, 80 with established OSA and 42 newly diagnosed patients with an AHI>15 requiring CPAP therapy.
**Figure 2-2**: PUCOSA-UK participant recruitment

**2.3.2 Demographics of the final study population by patient group**

Of the 122 participants who formed the final study population, 80 had established OSA and 42 were newly diagnosed. The mean age of the established group was 58.3 ± 8.31 and 73.8% of the participants were males (n=74) of White British origin. The newly diagnosed group were younger than the established group (50.3±11.3 years old) and again were predominantly White British males (81%). The demographic characteristics of the final study population are shown in Table 2-4.
Table 2-4: Demographics of the final study population by patient group

<table>
<thead>
<tr>
<th>Variables</th>
<th>Established Group (n=80)</th>
<th>Newly Diagnosed Group (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>58.3± 8.31 (range 34-77 years)</td>
<td>50.3± 11.3 (range 26-74 years)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male 73.8 %, (n=59)</td>
<td>81%, (n= 34)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>White British 92.5%, (n=74)</td>
<td>85.7%, (n=36)</td>
</tr>
<tr>
<td></td>
<td>Any other White background 3.8%, (n=3)</td>
<td>0.0%, (n=0)</td>
</tr>
<tr>
<td></td>
<td>White and Asian 0.0%, (n=0)</td>
<td>2.4%, (n=1)</td>
</tr>
<tr>
<td></td>
<td>Any other mixed race 0.0%, (n=0)</td>
<td>2.4%, (n=1)</td>
</tr>
<tr>
<td></td>
<td>Indian 3.8%, (n=3)</td>
<td>2.4%, (n=1)</td>
</tr>
<tr>
<td></td>
<td>Any other Asian background 0.0%, (n=0)</td>
<td>7.1%, (n=3)</td>
</tr>
<tr>
<td>Employment Status</td>
<td>Employed 37.5%, (n=30)</td>
<td>71.4%, (n=30)</td>
</tr>
<tr>
<td></td>
<td>Unemployed 11.3%, (n=9)</td>
<td>7.1%, (n=3)</td>
</tr>
<tr>
<td></td>
<td>Self-employed 8.8%, (n=7)</td>
<td>9.5%, (n=4)</td>
</tr>
<tr>
<td></td>
<td>Retired 42.5%, (n=34)</td>
<td>9.5%, (n=4)</td>
</tr>
<tr>
<td></td>
<td>Student 0.0%, (n=0)</td>
<td>2.4%, (n=1)</td>
</tr>
<tr>
<td>Marital Status</td>
<td>Married/Civil Partner 87.5%, (n=70)</td>
<td>92.9%, (n=39)</td>
</tr>
<tr>
<td></td>
<td>Single 5.0%, (n=4)</td>
<td>4.8%, (n=2)</td>
</tr>
<tr>
<td></td>
<td>Divorced 6.3%, (n=5)</td>
<td>2.4%, (n=1)</td>
</tr>
<tr>
<td></td>
<td>Widow/Widower 1.3%, (n=1)</td>
<td>0.0%, (n=0)</td>
</tr>
<tr>
<td>Alcohol Consumption</td>
<td>Drinker 70%, (n=56)</td>
<td>52.4%, (n=22)</td>
</tr>
<tr>
<td></td>
<td>Non-drinker 30%, (n=24)</td>
<td>47.6%, (n=20)</td>
</tr>
<tr>
<td>Smoking Status</td>
<td>Current smoker 58.7%, (n=47)</td>
<td>59.5%, (n=25)</td>
</tr>
<tr>
<td></td>
<td>Non-smoker 23.8%, (n=19)</td>
<td>21.4%, (n=9)</td>
</tr>
<tr>
<td></td>
<td>Ex-smoker 17.5%, (n=14)</td>
<td>19%, (n=8)</td>
</tr>
</tbody>
</table>

Data are expressed as (mean± SD) or as percentage %, n.

2.3.2.1 Anthropometric, biomedical and medication data by patient group

When examining the baseline anthropometric data the newly diagnosed group were found to be slightly more overweight than the established group (101.8 ± 16.3 versus 100.2±15.5 kg) and had a higher mean systolic (138±9.7 versus 131±11.5 mmHg) and mean diastolic (91 ±5.1 versus 86±9.2 mmHg) blood pressure than the participants in the established group. The baseline anthropometric data of both groups are shown in Table 2-4a.
Table 2-4a: Baseline anthropometric data by patient group

<table>
<thead>
<tr>
<th>Variables</th>
<th>Established Group (n=80)</th>
<th>Newly Diagnosed Group (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>100.2±15.5</td>
<td>101.8±16.3</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.72±0.1</td>
<td>1.75±0.1</td>
</tr>
<tr>
<td>BMI (kg/m$^2$)</td>
<td>33.8±5.4</td>
<td>33.2±8.5</td>
</tr>
<tr>
<td>BMI (kg/m$^2$) by range:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight (%)</td>
<td>0.0%, (n=0)</td>
<td>0.0%, (n=0)</td>
</tr>
<tr>
<td>Healthy Weight (%)</td>
<td>2.5%, (n=2)</td>
<td>9.5%, (n=4)</td>
</tr>
<tr>
<td>Overweight (%)</td>
<td>25%, (n=20)</td>
<td>23.8%, (n=10)</td>
</tr>
<tr>
<td>Obesity I (%)</td>
<td>31.3%, (n=25)</td>
<td>42.9%, (n=18)</td>
</tr>
<tr>
<td>Obesity II (%)</td>
<td>32.5%, (n=26)</td>
<td>14.3%, (n=6)</td>
</tr>
<tr>
<td>Obesity III (%)</td>
<td>8.8%, (n=7)</td>
<td>9.5%, (n=4)</td>
</tr>
<tr>
<td>Body Fat (%)</td>
<td>32.8±6.0</td>
<td>31.2±5.6</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>99.9±6.1</td>
<td>103.5±14.2</td>
</tr>
<tr>
<td>Hip circumference (cm)</td>
<td>101.4±6.1</td>
<td>104.1±13.5</td>
</tr>
<tr>
<td>Neck circumference (cm)</td>
<td>43.6±2.7</td>
<td>44.5±3.5</td>
</tr>
<tr>
<td>Blood Pressure Systolic (mmHg)</td>
<td>131±11.5</td>
<td>138±9.7</td>
</tr>
<tr>
<td>Blood Pressure Diastolic (mmHg)</td>
<td>86±9.2</td>
<td>91±5.1</td>
</tr>
</tbody>
</table>

Data are expressed as (mean± SD) or as percentage %, n. Obesity is graded according to the Body Mass Index (BMI). BMI categories: Underweight ≤18.4 kg/m$^2$, Healthy weight: 18.5 to 24.9 kg/m$^2$, Overweight 25 to 29.9 kg/m$^2$, Obesity I:30 to 34.9 kg/m$^2$, Obesity II:35-39.9 kg/m$^2$, Obesity III ≥40+ kg/m$^2$.

In the established group 43.7% (n=35) had an established diagnosis of diabetes. The mean HbA1c was 40.3±9.6 mmol/mol (range 28 to 77.0 mmol/mol). In the newly diagnosed group 23.8% (n=10) had an established diagnosis of diabetes of which 4 were on regular medication. The mean HbA1c was 41.2±5.8, mmol/mol (range 25 to 72 mmol/mol). The baseline biomedical data for both groups are shown in Table 2-4b.
<table>
<thead>
<tr>
<th>Variables</th>
<th>n</th>
<th>Established Group (n=80)</th>
<th>n</th>
<th>Newly Diagnosed Group (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (mmol/mol), %</td>
<td>76</td>
<td>40.3±9.6,</td>
<td>35</td>
<td>41.2±5.8,</td>
</tr>
<tr>
<td>Cholesterol (mmol/L)</td>
<td>76</td>
<td>4.77±1.67</td>
<td>34</td>
<td>4.6±1.62</td>
</tr>
<tr>
<td>Low Density Lipoprotein - LDL (mmol/L)</td>
<td>76</td>
<td>2.4±0.5</td>
<td>34</td>
<td>2.9±0.7</td>
</tr>
<tr>
<td>High Density Lipoprotein - HDL (mmol/L)</td>
<td>76</td>
<td>1.3±0.3</td>
<td>34</td>
<td>1.4±0.5</td>
</tr>
<tr>
<td>Triglycerides (mmol/L)</td>
<td>76</td>
<td>1.48±0.87</td>
<td>34</td>
<td>1.46±0.84</td>
</tr>
<tr>
<td>Alanine Transaminase (iu/L)</td>
<td>74</td>
<td>32.4±12.7</td>
<td>34</td>
<td>31.1±12.0</td>
</tr>
<tr>
<td>Bilirubin (umol/L)</td>
<td>74</td>
<td>10.3±4.2</td>
<td>34</td>
<td>10.8±3.2</td>
</tr>
<tr>
<td>Albumin (g/L)</td>
<td>74</td>
<td>43.9±2.6</td>
<td>34</td>
<td>43.4±4.2</td>
</tr>
<tr>
<td>Alkaline Phosphatase (iu/L)</td>
<td>74</td>
<td>90.9±24.0</td>
<td>34</td>
<td>86.3±17.5</td>
</tr>
</tbody>
</table>

Data are expressed as (mean± SD) or as n.

In the established group 73.8% of the participants were taking regular medication. 40% were on anti-depressant tablets and 12.5% were taking regularly sleeping tablets. In the newly diagnosed group 76.2% of the participants were on regular medication. 23.8 % were on anti-depressant medication and 40% were taking sleeping tablets either over the counter or as a regular prescription. The medication intake data for both groups is shown in Table 2-5.
Table 2-5: Regular medication intake by patient group

<table>
<thead>
<tr>
<th>Variables</th>
<th>Established Group (n=80)</th>
<th>Newly Diagnosed Group (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants on Medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>73.8%, (n=59)</td>
<td>76.2%, (n=32)</td>
</tr>
<tr>
<td>No</td>
<td>26.3%, (n=21)</td>
<td>23.8%, (n=10)</td>
</tr>
<tr>
<td>ACE-Inhibitor</td>
<td>52.5%, (n=42)</td>
<td>69%, (n=29)</td>
</tr>
<tr>
<td>Alpha-Blocker</td>
<td>40%, (n=32)</td>
<td>71.4%, (n=30)</td>
</tr>
<tr>
<td>Beta-Blocker</td>
<td>35%, (n=28)</td>
<td>45.2%, (n=19)</td>
</tr>
<tr>
<td>Calcium Channel Blockers</td>
<td>37.5%, (n=30)</td>
<td>35.7%, (n=15)</td>
</tr>
<tr>
<td>Oral-Antihyperglycaemic agents</td>
<td>43.7%, (n=35)</td>
<td>9.5%, (n=4)</td>
</tr>
<tr>
<td>Diuretics/Thiazides</td>
<td>78.8%, (n=63)</td>
<td>42.9%, (n=18)</td>
</tr>
<tr>
<td>Aspirin</td>
<td>62.5%, (n=50)</td>
<td>45.2%, (n=19)</td>
</tr>
<tr>
<td>Lipid Lowering – Statin</td>
<td>52.5%, (n=42)</td>
<td>54.8%, (n=23)</td>
</tr>
<tr>
<td>Lipid Lowering- Fibrate</td>
<td>28.7%, (n=23)</td>
<td>11.9%, (n=5)</td>
</tr>
<tr>
<td>Steroids</td>
<td>6.3%, (n=5)</td>
<td>4.8%, (n=2)</td>
</tr>
<tr>
<td>Depression / Anxiety Tablets</td>
<td>40%, (n=32)</td>
<td>23.8%, (n=10)</td>
</tr>
<tr>
<td>Sleeping Tablets</td>
<td>12.5%, (n=10)</td>
<td>59.5%, (n=25)</td>
</tr>
</tbody>
</table>

Data expressed as %, n.

2.3.2.2 CPAP use and compliance data by patient group

The mean baseline CPAP duration per night in the established group was 5.88 hours/night (range 3.0 to 8 hours). Overall this patient group was compliant to CPAP therapy as only 1.3% (n=1) used CPAP for less than 4 hours. 70% (n=56) used their CPAP between 4.1 to 6.5 hours per night and 28.8% (n=23) used their CPAP for more than 6.6 hours per night. In the newly diagnosed group the 3 month mean CPAP duration was 3.93 hours per night (range 2.2 to 5.5 hours). Overall, 59.5% (n=25) were classed as non compliant to CPAP therapy and 40.5% (n=17) were using CPAP for ≥4 hours per night. At 6 months the mean CPAP use increased to 4.64 hours per night (range 3 to 6.5 hours). 45.2% were non compliant to CPAP therapy and 54.8% (n=23) were using CPAP for ≥4 hours per night.
2.3.3 Questionnaire Data

2.3.3.1 Epworth Sleepiness Scale (ESS) and Fatigue Severity Scale (FSS)

In the newly diagnosed group, the level of daytime sleepiness reported prior to CPAP therapy (T1) was twice as high of that observed post 3 months of CPAP therapy (T3). Post 6 months of CPAP therapy the reduction of daytime sleepiness observed increased further and 83.3% (n=30) of the participants reported experiencing normal levels of sleepiness (Table 2-6). Reductions in the fatigue severity scale were also observed between different time points. Before CPAP therapy 76.3% (n=32) of the participants experienced fatigue however following 3 and 6 months of CPAP therapy only 47.6% (n=20) and 42.8% (n=18) of the participants felt fatigued respectively. In the established group, the majority of the participants, 68.8% (n=55) experienced normal levels of daytime sleepiness however, 52.5% (n=42) felt fatigued. The mean scores in the ESS and FSS scales together with the severity break down for both patient groups are shown in Table 2-6.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Newly Diagnosed Group (n=42)</th>
<th>Established Group (n=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1†</td>
<td>T3†</td>
</tr>
<tr>
<td>ESS</td>
<td>14.22 ± 4.09</td>
<td>7.84 ± 2.25</td>
</tr>
<tr>
<td>Normal</td>
<td>(0-8)</td>
<td>10%, (n=4)</td>
</tr>
<tr>
<td>Mild</td>
<td>(9-11)</td>
<td>17%, (n=7)</td>
</tr>
<tr>
<td>Moderate</td>
<td>(12-15)</td>
<td>35.7%, (n=15)</td>
</tr>
<tr>
<td>Severe</td>
<td>(16-20)</td>
<td>33.3%, (n=14)</td>
</tr>
<tr>
<td>Extremely severe</td>
<td>(21-24)</td>
<td>5%, (n=2)</td>
</tr>
<tr>
<td>FSS</td>
<td>4.84 ± 1.34</td>
<td>3.51 ± 1.34</td>
</tr>
<tr>
<td>Normal</td>
<td>(0-2)</td>
<td>23.7% (n=10)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>(3+)</td>
<td>76.3% (n=32)</td>
</tr>
</tbody>
</table>

Data expressed as (mean ±SD) and as %, n. †Clarification of time points in the newly diagnosed group: T1: pre-diagnosis, T3: post 3 months CPAP therapy and T4*: post 6 months CPAP therapy. *Clarification of time point in the established group: T4 post prolonged CPAP use (range 1 to 18 years).
2.3.3.2 Multifactorial Memory Questionnaire (MMQ)

In the newly diagnosed group, the majority of the participants scored on the low category on the subjective memory ability (MMQ-A) at all time points as shown in Table 2-7. However, the MMQ-Contentment subscale showed that the majority of the participants were content with their memory ability. In the established group, 97.5% (n=78) of the participants reported better subjective memory and 95% (n=76) felt content with their memory ability (Table 2-7). The mean scores in the MMQ-A and MMQ-C scales together with the severity break down for both groups are shown in Table 2-7.

### Table 2-7: Multifactorial Memory Questionnaire (MMQ)-Ability and MMQ Contentment results by patient group

<table>
<thead>
<tr>
<th>Variables</th>
<th>Newly Diagnosed Group (n=42)</th>
<th>Established Group (n=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1</td>
<td>T3</td>
</tr>
<tr>
<td>MMQ-A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low (0-42)</td>
<td>66.7%</td>
<td>71.4%</td>
</tr>
<tr>
<td></td>
<td>(n=28)</td>
<td>(n=30)</td>
</tr>
<tr>
<td>Normal (43-80)</td>
<td>33.3%</td>
<td>28.6%</td>
</tr>
<tr>
<td></td>
<td>(n=14)</td>
<td>(n=12)</td>
</tr>
<tr>
<td>MMQ-C</td>
<td>53.09±6.58</td>
<td>54.23±7.37</td>
</tr>
<tr>
<td>Low (0-37.9)</td>
<td>52.4%</td>
<td>45.2%</td>
</tr>
<tr>
<td></td>
<td>(n=22)</td>
<td>(n=19)</td>
</tr>
<tr>
<td>Normal (38-72)</td>
<td>47.6%</td>
<td>54.8%</td>
</tr>
<tr>
<td></td>
<td>(n=20)</td>
<td>(n=23)</td>
</tr>
</tbody>
</table>

Data expressed as (mean ±SD) and as %, n. *Clarification of time points in the newly diagnosed group: T1*: pre-diagnosis, T3*: post 3 months CPAP therapy and T4*: post 6 months CPAP therapy.*Clarification of time point in the established group: T4 post prolonged CPAP use (range 1 to 18 years)

2.3.3.3 The Depression Anxiety and Stress Scales (DASS-21)

The newly diagnosed group reported lower depression and stress rates at 6 months post CPAP therapy from baseline (Table 2-8). In the anxiety scale however the group reported higher anxiety post 6 months of CPAP therapy from baseline (Table 2-8). The
The majority of the participants in the established group reported low and normal levels of depression, anxiety and stress (Table 2-8). The mean scores in the DASS-21 scales together with the severity break down are shown in Table 2-8.

<table>
<thead>
<tr>
<th></th>
<th>Newly Diagnosed Group (n=42)</th>
<th>Established Group (n=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Variables</strong></td>
<td>T1*</td>
<td>T3*</td>
</tr>
<tr>
<td><strong>Depression</strong></td>
<td>14.04±11.14</td>
<td>10.28±12.76</td>
</tr>
<tr>
<td>Normal</td>
<td>37.5%, (n=15)</td>
<td>47.6%, (n=20)</td>
</tr>
<tr>
<td>Mild (0-4)</td>
<td>19%, (n=8)</td>
<td>21.4%, (n=9)</td>
</tr>
<tr>
<td>Moderate (7-10)</td>
<td>21.4%, (n=9)</td>
<td>26.2%, (n=11)</td>
</tr>
<tr>
<td>Severe (11-13)</td>
<td>11.9%, (n=5)</td>
<td>4.8%, (n=2)</td>
</tr>
<tr>
<td>Extremely Severe (14+)</td>
<td>11.9%, (n=5)</td>
<td>0.0%, (n=0)</td>
</tr>
<tr>
<td><strong>Anxiety</strong></td>
<td>7.95±5.91</td>
<td>5.76±5.44</td>
</tr>
<tr>
<td>Normal</td>
<td>52.4%, (n=22)</td>
<td>52.4%, (n=22)</td>
</tr>
<tr>
<td>Mild (4-5)</td>
<td>11.9%, (n=5)</td>
<td>28.6%, (n=12)</td>
</tr>
<tr>
<td>Moderate (6-7)</td>
<td>19%, (n=8)</td>
<td>14.3%, (n=6)</td>
</tr>
<tr>
<td>Severe (8-9)</td>
<td>11.9%, (n=5)</td>
<td>4.8%, (n=2)</td>
</tr>
<tr>
<td>Extremely Severe (10+)</td>
<td>4.8%, (n=2)</td>
<td>0.0%, (n=0)</td>
</tr>
<tr>
<td><strong>Stress</strong></td>
<td>13.32±8.95</td>
<td>10.14±8.59</td>
</tr>
<tr>
<td>Normal</td>
<td>57.1%, (n=24)</td>
<td>62%, (n=26)</td>
</tr>
<tr>
<td>Mild (8-9)</td>
<td>7.1%, (n=3)</td>
<td>24%, (n=10)</td>
</tr>
<tr>
<td>Moderate (10-12)</td>
<td>26.2%, (n=11)</td>
<td>9.5%, (n=4)</td>
</tr>
<tr>
<td>Severe (13-16)</td>
<td>9.5%, (n=4)</td>
<td>4.8%, (n=2)</td>
</tr>
<tr>
<td>Extremely Severe (17+)</td>
<td>0.0%, (n=0)</td>
<td>0.0%, (n=0)</td>
</tr>
</tbody>
</table>

Data expressed as (mean ±SD) and as %, n. *Clarification of time points in the newly diagnosed group: T1*: pre-diagnosis, T3*: post 3 months CPAP therapy and T4*: post 6 months CPAP therapy. *Clarification of time point in the established group: T4 post prolonged CPAP use (range 1 to 18 years)
2.3.3.4 Self-Efficacy Measure in Sleep Apnoea (SEMSA): Outcome Expectancies

In the SEMSA outcome expectancies scale, the newly diagnosed group increased confidence in CPAP therapy as an efficacious therapy in improving their OSA related symptoms (snoring, sleepiness etc) and quality of sleep of their partner post 3 and 6 months of CPAP therapy compared to their perceived expectancies of the therapy prior initiating CPAP therapy (Table 2-9). The newly diagnosed group, also showed strong beliefs and perceptions of CPAP therapy as an effective therapy in treating their OSA and conferring improvements in their sleep quality and that of their partner (Table 2-9).

<table>
<thead>
<tr>
<th>Table 2-9: Self-Efficacy Measure in Sleep Apnoea (SEMSA)- Outcome Expectancies (OE) subscale results by patient group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Newly Diagnosed Group (n=42)</strong></td>
</tr>
<tr>
<td><strong>If I use CPAP as instructed:</strong></td>
</tr>
<tr>
<td>% perceived CPAP would produce positive outcomes responding somewhat true or very true</td>
</tr>
<tr>
<td>I will be more active</td>
</tr>
<tr>
<td>My desire and sexual performance will improve</td>
</tr>
<tr>
<td>My job performance will improve</td>
</tr>
<tr>
<td>My relationships will improve</td>
</tr>
<tr>
<td>I will feel better</td>
</tr>
<tr>
<td>It will decrease the chance of driving accident</td>
</tr>
<tr>
<td>I will be more alert</td>
</tr>
<tr>
<td>Then I will not snore</td>
</tr>
<tr>
<td>My partner will sleep better</td>
</tr>
</tbody>
</table>

Data expressed as (mean ±SD) and as %. *Clarification of time points in the newly diagnosed group: T2*: post-diagnosis, T3*: post 3 months CPAP therapy and T4*: post 6 months CPAP therapy. *Clarification of time point in the established group: T4 post prolonged CPAP use (range 1 to 18 years)
2.3.3.5 Self-Efficacy Measure in Sleep Apnoea (SEMSA): Treatment Beliefs

In the SEMSA Self-efficacy treatment beliefs scale, the majority of participants in the newly diagnosed group were more likely to continue using CPAP therapy at T2, T3 and T4 time points despite facing several barriers (Table 2-10). The established group felt strong about persevering using the therapy despite experiencing common barriers as shown in Table 2-10.

**Table 2-10:** Self-Efficacy Measure in Sleep Apnoea (SEMSA) - Self Efficacy (SE) subscale results by patient group

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Newly Diagnosed Group (n=42)</th>
<th>Established Group (n=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I will use CPAP:</td>
<td>T2’</td>
<td>T3’</td>
</tr>
<tr>
<td>Even if it makes my nose stuffy</td>
<td>59.5%, (n=25)</td>
<td>64.3%, (n=27)</td>
</tr>
<tr>
<td>Even if I have to wear a tight mask</td>
<td>54.8%, (n=23)</td>
<td>59.5%, (n=25)</td>
</tr>
<tr>
<td>Even if it is a bother</td>
<td>47.6%, (n=20)</td>
<td>57.1%, (n=24)</td>
</tr>
<tr>
<td>Even if it makes me feel embarrassed</td>
<td>28.6%, (n=12)</td>
<td>24%, (n=10)</td>
</tr>
<tr>
<td>Even if it makes me claustrophobic</td>
<td>9.6%, (n=14)</td>
<td>47.6%, (n=20)</td>
</tr>
<tr>
<td>Even if it means taking longer to get ready for bed</td>
<td>40%, (n=17)</td>
<td>43%, (n=18)</td>
</tr>
<tr>
<td>Even if I have to pay for some of the cost</td>
<td>4.8%, (n=12)</td>
<td>21.4%, (n=9)</td>
</tr>
<tr>
<td>Even when I travel</td>
<td>40.5%, (n=17)</td>
<td>45%, (n=19)</td>
</tr>
<tr>
<td>Even if it disturbs my partner</td>
<td>14.3%, (n=6)</td>
<td>36%, (n=15)</td>
</tr>
</tbody>
</table>

Data expressed as (mean ±SD) and as %. *Clarification of time points in the newly diagnosed group: T2’: post-diagnosis, T3’: post 3 months CPAP therapy and T’ : post 6 months CPAP therapy. *Clarification of time point in the established group: T4 post prolonged CPAP use (range 1 to 18 years)
2.3.3.6 Social support: Significant Other Scale (SOS) scale

Overall, the participants in both groups were well supported. The newly diagnosed participants perceived that they received less support than that of their ideal requirement especially during the T1 time point. However, their perceptions altered post 3 and 6 months of CPAP therapy. The established group participants also perceived that they required more support from their spouse and close friend. The total perceived and ideal scores for both groups are shown in Table 2-11.
Table 2-11: Significant Others Scale (SOS) results by patient group

<table>
<thead>
<tr>
<th>Variables</th>
<th>Newly Diagnosed Group</th>
<th>Established Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1'</td>
<td>T3'</td>
</tr>
<tr>
<td></td>
<td>(mean ± SD)</td>
<td>(n, range)</td>
</tr>
<tr>
<td>SOS-spouse perceived</td>
<td>4.41±1.23</td>
<td>(n=42), (3.8-7)</td>
</tr>
<tr>
<td>SOS-spouse ideal</td>
<td>5.02±0.73</td>
<td>(n=42), (4.9-7)</td>
</tr>
<tr>
<td>SOS-daughter/son perceived</td>
<td>3.41±1.09</td>
<td>(n=38), (1-7)</td>
</tr>
<tr>
<td>SOS-daughter/son ideal</td>
<td>3.51±0.67</td>
<td>(n=38), (1-7)</td>
</tr>
<tr>
<td>SOS-mother/father perceived</td>
<td>4.40±1.15</td>
<td>(n=32), (2.3-7)</td>
</tr>
<tr>
<td>SOS-mother/father ideal</td>
<td>4.45±0.65</td>
<td>(n=32), (2.5-7)</td>
</tr>
<tr>
<td>SOS-close friend perceived</td>
<td>5.32±1.36</td>
<td>n=42, (3.2-7)</td>
</tr>
<tr>
<td>SOS-close friend ideal</td>
<td>5.76±1.49</td>
<td>n=42, (3.25-7)</td>
</tr>
</tbody>
</table>

Data expressed as (mean ±SD) and as %, n. *Clarification of time points in the newly diagnosed group: T1*: pre-diagnosis, T3*: post 3 months CPAP therapy and T4*: post 6 months CPAP therapy. *Clarification of time point in the established group: T4 post prolonged CPAP use (range 1 to 18 years)
2.3.3.7 Illness Perceptions Questionnaire–Revised (IPQ-R)

Identity

In the IPQ-R identity scale (Symptoms and coherence) participants were asked prior their formal diagnosis if they experienced any symptoms since their sleep problems started and the majority reported experiencing a variety of symptoms of which many were attributed direct to their sleep problem (Table 2-12). Their level of understanding of the condition and related symptoms increased post 3 and 6 months of CPAP therapy (Table 2-12) Post 3 and 6 months therapy the participants reported less symptoms and were able to demonstrate a high level of symptom understanding and relate these with their OSA. The participants in the established group showed a greater understanding of their symptoms and their condition than the patients in the newly diagnosed group. The detailed results are shown in Table 2-12.
<table>
<thead>
<tr>
<th>Table 2-12: Illness Perceptions Questionnaire-Revised Identity (Symptoms and Coherence subscales) results by patient group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Newly Diagnosed Group</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>I have experienced this symptom since my sleep problem started</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>T1</strong></td>
</tr>
<tr>
<td><strong>Pain</strong></td>
</tr>
<tr>
<td><strong>Sore Throat</strong></td>
</tr>
<tr>
<td><strong>Nausea</strong></td>
</tr>
<tr>
<td><strong>Breathlessness</strong></td>
</tr>
<tr>
<td><strong>Weight Loss</strong></td>
</tr>
<tr>
<td><strong>Fatigue</strong></td>
</tr>
<tr>
<td><strong>Irritable</strong></td>
</tr>
<tr>
<td><strong>Stiff Joints</strong></td>
</tr>
<tr>
<td><strong>Sore Eyes</strong></td>
</tr>
<tr>
<td><strong>Wheeziness</strong></td>
</tr>
<tr>
<td><strong>Headaches</strong></td>
</tr>
<tr>
<td><strong>Upset Stomach</strong></td>
</tr>
<tr>
<td><strong>Weight Gain</strong></td>
</tr>
<tr>
<td>Symptom</td>
</tr>
<tr>
<td>--------------------------------</td>
</tr>
<tr>
<td>Dizziness</td>
</tr>
<tr>
<td>Loss of Strength</td>
</tr>
<tr>
<td>The symptoms of my condition are puzzling to me</td>
</tr>
<tr>
<td>My sleep problems are a mystery to me</td>
</tr>
<tr>
<td>I don’t understand my sleep problems</td>
</tr>
<tr>
<td>My sleep problems don’t make any sense to me</td>
</tr>
<tr>
<td>I have a clear picture or understanding of my condition</td>
</tr>
</tbody>
</table>

Data expressed as (mean ±SD) and as %, n. *Clarification of time points in the newly diagnosed group: T1*: pre-diagnosis, T2*: post-diagnosis, T3*: post 3 months CPAP therapy and T4*: post 6 months CPAP therapy. *Clarification of time point in the established group: T4 post prolonged CPAP use (range 1 to 18 years)
Cause

In the IPQ-R Cause scale, the newly diagnosed participants perceived that stress, negative thinking, ageing and alcohol consumption were the most important causes (Table 2-13). The established group participants perceived that heredity, own behaviour, environmental pollution and smoking were causal factors of their condition (Table 2-13).

<table>
<thead>
<tr>
<th>Causes</th>
<th>Newly Diagnosed Group (n=42)</th>
<th>Established Group (n=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1*</td>
<td>T3*</td>
</tr>
<tr>
<td></td>
<td>Strongly Agree &amp; Agree % (n)</td>
<td></td>
</tr>
<tr>
<td>Stress or worry</td>
<td>64.3% (n=27)</td>
<td>76.2% (n=32)</td>
</tr>
<tr>
<td>Hereditary</td>
<td>11.9% (n=5)</td>
<td>16.6% (n=7)</td>
</tr>
<tr>
<td>A germ or virus</td>
<td>2.4% (n=1)</td>
<td>5% (n=2)</td>
</tr>
<tr>
<td>Diet or eating habits</td>
<td>9.5% (n=4)</td>
<td>90.5% (n=38)</td>
</tr>
<tr>
<td>Chance of bad luck</td>
<td>54.8% (n=23)</td>
<td>14.3% (n=6)</td>
</tr>
<tr>
<td>Poor medical care in my past</td>
<td>42.9% (n=18)</td>
<td>16.6% (n=7)</td>
</tr>
<tr>
<td>Pollution in the environment</td>
<td>28.6% (n=12)</td>
<td>42.9% (n=18)</td>
</tr>
<tr>
<td>My own behaviour</td>
<td>16.6% (n=7)</td>
<td>12% (n=5)</td>
</tr>
<tr>
<td>My mental attitude e.g. thinking about life negatively</td>
<td>90.5% (n=38)</td>
<td>76.2% (n=32)</td>
</tr>
<tr>
<td>Family problems or worries caused my sleep problems</td>
<td>14.3% (n=6)</td>
<td>45.2% (n=19)</td>
</tr>
<tr>
<td>Overwork</td>
<td>83.3% (n=35)</td>
<td>54.8% (n=23)</td>
</tr>
<tr>
<td>My emotional state e.g. feeling down, lonely, anxious, empty</td>
<td>59.5% (n=20)</td>
<td>54.8% (n=23)</td>
</tr>
<tr>
<td>Ageing</td>
<td>88.1% (n=37)</td>
<td>93% (n=39)</td>
</tr>
<tr>
<td>Alcohol</td>
<td>45.2% (n=19)</td>
<td>67% (n=28)</td>
</tr>
<tr>
<td>Smoking</td>
<td>19% (n=1)</td>
<td>42.9% (n=6)</td>
</tr>
</tbody>
</table>
Consequences

In the IPQ-R Consequences scale, the majority of the participants in the newly diagnosed group perceived that OSA has major consequences on their life and impact on the way other people view them and causing difficulties to those who live close to them. This result became more apparent following 3 and 6 months of CPAP treatment (Table 2-14). The established group shared similar perceptions with the newly diagnosed participants (Table 2-14).

Table 2-14: Illness Perceptions Questionnaire-Revised Consequences results by patient group

<table>
<thead>
<tr>
<th>Consequences</th>
<th>Newly Diagnosed Group (n=42)</th>
<th>Established Group (n=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1*</td>
<td>T3*</td>
</tr>
<tr>
<td>My sleep problem is a serious condition</td>
<td>47.6% (n=20)</td>
<td>76.2% (n=32)</td>
</tr>
<tr>
<td>My sleep problems have major consequences on my life</td>
<td>59.5% (n=25)</td>
<td>71.4% (n=30)</td>
</tr>
<tr>
<td>My sleep problems do not have much effect on my life</td>
<td>40.5% (n=17)</td>
<td>38.1% (n=16)</td>
</tr>
<tr>
<td>My sleep problems strongly affect the way other see me</td>
<td>85.7% (n=36)</td>
<td>90.5% (n=38)</td>
</tr>
<tr>
<td>My sleep problems have serious financial consequences</td>
<td>33.3% (n=14)</td>
<td>24% (n=10)</td>
</tr>
<tr>
<td>My sleep problems cause difficulties for those who are close to me</td>
<td>92.9% (n=39)</td>
<td>71.4% (n=30)</td>
</tr>
</tbody>
</table>

Data expressed as (mean ±SD) and as %, n. *Clarification of time points in the newly diagnosed group: T1*: pre-diagnosis, T3*: post 3 months CPAP therapy and T4*: post 6 months CPAP therapy. *Clarification of time point in the established group: T4 post prolonged CPAP use (range 1 to 18 years)
Timeline

The newly diagnosed group, held strong beliefs regarding the chronicity of their condition post 3 and 6 months of CPAP therapy compared to their beliefs prior CPAP treatment initiation. The established group also held very strong beliefs regarding living with OSA (Table 2-15)

| Table 2-15: Illness Perceptions Questionnaire-Revised IPQR-Timeline results by patient group |
|-------------------------------------------|------------------------------------------|--------------------------------|
| Newly Diagnosed Group (n=42) | Established Group (n=80) |
| T1* | T3* | T4* | T4* |
| Strongly Agree & Agree | % | (n) | % | (n) | % | (n) | % | (n) |
| My illness is likely to be permanent rather than temporary | 59.5% (n=25) | 83.3% (n=35) | 88.1% (n=37) | 97.6% (n=78) |
| I expect to have this illness for the rest of my life | 40.5% (n=17) | 76.2% (n=32) | 90.5% (n=38) | 86% (n=69) |

Data expressed as (mean ±SD) and as %, n. *Clarification of time points in the newly diagnosed group: T1*: pre-diagnosis, T3*: post 3 months CPAP therapy and T4*: post 6 months CPAP therapy. *Clarification of time point in the established group: T4 post prolonged CPAP use (range 1 to 18 years)
2.3.4 Established Group-Linear Regression Results

Is CPAP therapy (as assessed by mean hours/night) associated with improvements in the baseline daytime sleepiness (ESS), fatigue (FSS), memory complaints (MMQ), mood (DASS-21), social support (SOS), self-efficacy (SEMSA), Illness perceptions (IPQ-R) anthropometric and biomedical data in the established OSA group?

The linear regression analysis showed a strong negative association between mean CPAP use and the ESS, FSS, MMQ-C, and SOS scales. For every hour CPAP was used a reduction of 1.01 (95% CI: -1.92, -0.11) was observed in the subjective sleepiness scale, a reduction of 1.47 (95% CI: -4.05, 1.11) was observed in the fatigue scale, a reduction of 1.02 (95% CI: -2.94, 0.90) in the memory contentment scale and a non-significant reduction of 0.04 (95% CI: -0.22, 0.14) in the SOS-Spouse perceived subscale and the remaining social support scales (Table 16a). However, these did not reach statistical significance. Negative associations were also observed in the IPQ-R (cause, timeline and consequences subscales) and DASS-21 (depression and stress) scales but these were not statistically significant. Strong positive association were observed in the SEMSA scales so that for every hour CPAP was used self-confidence and positive treatment expectancies of CPAP therapy increased but these were not statistically significant (Table 2-16a).
Table 2-16a: Linear Regression results—Questionnaire outcomes related with CPAP use.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Unadjusted Model Beta (95% CI)</th>
<th>p</th>
<th>Adjusted Model Beta (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESS</td>
<td>-1.01 (-1.92, -0.11)</td>
<td>0.029</td>
<td>-0.82 (-1.85, 0.22)</td>
<td>0.119</td>
</tr>
<tr>
<td>FSS</td>
<td>-1.47 (-4.05, 1.11)</td>
<td>0.260</td>
<td>-0.24 (-3.09, 2.61)</td>
<td>0.867</td>
</tr>
<tr>
<td>MMQ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMQ-A</td>
<td>-0.11 (-1.36, 1.15)</td>
<td>0.866</td>
<td>-0.36 (-1.74, 1.02)</td>
<td>0.604</td>
</tr>
<tr>
<td>MMQ-C</td>
<td>-1.02 (-2.94, 0.90)</td>
<td>0.292</td>
<td>-1.78 (-3.89, 0.33)</td>
<td>0.096</td>
</tr>
<tr>
<td>SEMSA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEMSA-OE</td>
<td>0.40 (-0.69, 1.49)</td>
<td>0.469</td>
<td>0.55 (-0.69, 1.79)</td>
<td>0.378</td>
</tr>
<tr>
<td>SEMSA-SE</td>
<td>0.78 (-0.40, 1.95)</td>
<td>0.192</td>
<td>0.69 (0.64, 2.02)</td>
<td>0.302</td>
</tr>
<tr>
<td>SOS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SOS-Spouse perceived</td>
<td>-0.04 (-0.22, 0.14)</td>
<td>0.694</td>
<td>0.04 (-0.16, 0.24)</td>
<td>0.707</td>
</tr>
<tr>
<td>SOS-Spouse ideal</td>
<td>0.08 (-0.04, 0.20)</td>
<td>0.192</td>
<td>0.11 (-0.02, 0.25)</td>
<td>0.106</td>
</tr>
<tr>
<td>SOS-Other 2 perceived</td>
<td>-0.32 (-0.58, -0.06)</td>
<td>0.015</td>
<td>-0.31 (-0.60, 0.02)</td>
<td>0.038</td>
</tr>
<tr>
<td>SOS-Other 2 ideal</td>
<td>-0.12 (-0.32, 0.08)</td>
<td>0.244</td>
<td>-0.08 (-0.29, 0.12)</td>
<td>0.421</td>
</tr>
<tr>
<td>SOS-Other 3 perceived</td>
<td>-0.30 (-0.55, -0.04)</td>
<td>0.024</td>
<td>-0.27 (-0.55, 0.01)</td>
<td>0.058</td>
</tr>
<tr>
<td>SOS-Other 3 ideal</td>
<td>-0.20 (-0.45, 0.04)</td>
<td>0.106</td>
<td>-0.21 (-0.47, 0.05)</td>
<td>0.106</td>
</tr>
<tr>
<td>SOS-Other 4 perceived</td>
<td>-0.40 (-0.78, -0.02)</td>
<td>0.041</td>
<td>-0.49 (-0.90, -0.08)</td>
<td>0.021</td>
</tr>
<tr>
<td>SOS-Other 4 ideal</td>
<td>-0.30 (-0.66, 0.06)</td>
<td>0.096</td>
<td>-0.41 (-0.77, -0.04)</td>
<td>0.031</td>
</tr>
<tr>
<td>DASS-21</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DASS-21 Depression</td>
<td>-0.12 (-1.94, 1.71)</td>
<td>0.898</td>
<td>0.02 (-2.08, 2.12)</td>
<td>0.985</td>
</tr>
<tr>
<td>DASS-21 Anxiety</td>
<td>0.37 (-1.28, 2.02)</td>
<td>0.657</td>
<td>0.09 (-1.80, 1.97)</td>
<td>0.929</td>
</tr>
<tr>
<td>DASS-21 Stress</td>
<td>-0.27 (-2.05, 1.52)</td>
<td>0.767</td>
<td>-0.04 (-2.08, 2.00)</td>
<td>0.968</td>
</tr>
<tr>
<td>IPQ-R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IPQ-R number of symptoms due to sleep problems</td>
<td>0.27 (-0.67, 1.21)</td>
<td>0.565</td>
<td>0.39 (-0.62, 1.40)</td>
<td>0.445</td>
</tr>
<tr>
<td>IPQ-R Cause</td>
<td>-0.06 (-0.41, 0.30)</td>
<td>0.753</td>
<td>-0.02 (-0.41, 0.38)</td>
<td>0.929</td>
</tr>
<tr>
<td>IPQ-R Time</td>
<td>-0.02 (0.12, 0.07)</td>
<td>0.663</td>
<td>-0.04 (-0.14, 0.07)</td>
<td>0.484</td>
</tr>
<tr>
<td>IPQ-R Consequences</td>
<td>-0.25 (-0.98, 0.47)</td>
<td>0.489</td>
<td>-0.46 (-1.28, 0.37)</td>
<td>0.270</td>
</tr>
</tbody>
</table>

Epworth Sleepiness Scale (ESS), Fatigue Severity Scale (FSS), Multifactorial Memory Questionnaire (MMQ), Self-Efficacy Measure for Sleep Apnoea (SEMSA), Significant Others Scale (SOS), Depression, Anxiety and Stress Scales (DASS-21), Illness Perception Questionnaire Revised (IPQ-R)

Results reported as Beta and 95% Confidence Interval

*Adjusted for age, sex, BMI and anti-depressants, sleeping tablets and diuretics.

The linear regression analysis showed a trend towards negative associations between mean CPAP use and blood pressure (systolic and diastolic), High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL) and Albumin but these reductions did not reach statistical significance in both adjusted and unadjusted models. Strong positive associations were observed between CPAP use and weight gain (Table 2-16b).
However as this is an observational study causality cannot be inferred (i.e. CPAP use result in greater weight gain or vise versa) and therefore the results should be interpreted with caution.

**Table 2-16b:** Linear Regression results-Anthropometric and Biomedical outcomes related with CPAP use.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Unadjusted Model</th>
<th>p</th>
<th>Adjusted Model</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Beta (95% CI)</td>
<td></td>
<td>Beta (95% CI)</td>
<td></td>
</tr>
<tr>
<td><strong>Anthropometrics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>-0.01 (-2.31, 2.29)</td>
<td>0.996</td>
<td>-0.71 (-3.27, 1.85)</td>
<td>0.580</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>-0.11 (-1.96, 1.74)</td>
<td>0.908</td>
<td>-0.52 (-2.61, 1.57)</td>
<td>0.621</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>5.47 (2.62, 8.32)</td>
<td>&lt;0.001</td>
<td>4.68 (1.87, 7.48)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>1.39 (0.36, 2.42)</td>
<td>0.009</td>
<td>1.56 (0.62, 2.50)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Body Fat (%)</td>
<td>0.51 (-0.69, 1.71)</td>
<td>0.398</td>
<td>-0.42 (-1.44, 0.60)</td>
<td>0.414</td>
</tr>
<tr>
<td>Waist Circumference (cm)</td>
<td>0.93 (-0.28, 2.13)</td>
<td>0.129</td>
<td>-0.78 (-1.69, 0.13)</td>
<td>0.092</td>
</tr>
<tr>
<td>Hip Circumference (cm)</td>
<td>0.99 (-0.20, 2.19)</td>
<td>0.101</td>
<td>-0.38 (-1.32, 0.57)</td>
<td>0.431</td>
</tr>
<tr>
<td>Neck Circumference (cm)</td>
<td>0.82 (0.31,1.33)</td>
<td>0.002</td>
<td>0.31 (-0.16, 0.79)</td>
<td>0.187</td>
</tr>
<tr>
<td><strong>Biomedical</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c (mmol/mol)</td>
<td>0.52 (-1.50, 2.53)</td>
<td>0.613</td>
<td>0.57 (-1.74, 2.88)</td>
<td>0.623</td>
</tr>
<tr>
<td>Total Cholesterol (mmol/L)</td>
<td>0.03 (-0.14, 0.20)</td>
<td>0.723</td>
<td>0.04 (-0.15, 0.24)</td>
<td>0.659</td>
</tr>
<tr>
<td>Triglycerides (mmol/L)</td>
<td>0.15 (0.00, 0.31)</td>
<td>0.050</td>
<td>0.15 (-0.02, 0.32)</td>
<td>0.086</td>
</tr>
<tr>
<td>HDL (mmol/L)</td>
<td>-0.04 (1.00, 0.01)</td>
<td>0.131</td>
<td>-0.05 (-0.11, 0.02)</td>
<td>0.144</td>
</tr>
<tr>
<td>LDL (mmol/L)</td>
<td>-0.01 (-0.16, 0.14)</td>
<td>0.906</td>
<td>0.03 (-0.14, 0.20)</td>
<td>0.709</td>
</tr>
<tr>
<td><strong>Liver Function</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albumin (g/L)</td>
<td>-0.22(-0.77, 0.34)</td>
<td>0.438</td>
<td>-0.13(-0.71, 0.46)</td>
<td>0.669</td>
</tr>
<tr>
<td>Bilirubin(umol/L)</td>
<td>0.35(-0.53, 1.23)</td>
<td>0.433</td>
<td>0.51(-0.44, 1.47)</td>
<td>0.287</td>
</tr>
<tr>
<td>Alkaline Phosphatase (iu/L)</td>
<td>3.59(-1.45, 8.62)</td>
<td>0.160</td>
<td>2.98 (-2.57, 8.52)</td>
<td>0.288</td>
</tr>
<tr>
<td>Alanine Transaminase (iu/L)</td>
<td>0.74(-1.95, 3.43)</td>
<td>0.585</td>
<td>0.03 (-2.79, 2.84)</td>
<td>0.984</td>
</tr>
</tbody>
</table>

Results reported as Beta and 95% Confidence Interval
*Adjusted for age, sex, BMI and Oral anti-hyperglycaemics, Lipid lowering tablets, steroids
*Adjusted for age, sex, Oral anti-hyperglycaemics, Lipid lowering tablets, steroids
2.3.5 Newly Diagnosed Group-Main analysis

Which baseline variables predict CPAP compliance (as assessed by ≥4 hours/night) at 3 and 6 months post CPAP therapy in the newly diagnosed group?

Logistic Regression was employed to identify which study outcomes were predictors of CPAP compliance. Results from the adjusted and unadjusted models for this analysis are reported below in Table 2-17a and 2-17b. At 3 months baseline variables including high subjective sleepiness (ESS score), memory problems (MMQ-C) and neck circumference were found to be independent predictors of CPAP compliance. Therefore, participants with higher subjective sleepiness, memory problems and high neck circumference at baseline were more likely to comply with CPAP therapy at 3 months (ESS: OR 1.19, (95% CI 0.099, 1.43), FSS: OR 1.02, (95% CI 0.96, 1.07), MMQ-C: OR 1.09 (0.98, 1.20)) in comparison with those who experienced low or no subjective sleepiness, no memory problems and had regular size neckline at baseline. At 6 months high scores in memory problems (MMQ-C), Social support (SOS), increased neck circumference and HbA1c levels were associated with CPAP compliance (Table 2-17a). Participants with higher memory problems, social support, increased neck circumference, and HbA1c levels at baseline were more likely to comply with CPAP therapy at 6 months (MMQ-C: OR 1.10, (95% CI 0.99, 1.22), SOS: OR 4.18, (95% CI 0.92, 19.05), neck: OR 1.28, (95% CI 1.02, 1.60) and HbA1c: OR 1.23, (95% CI 1.03, 1.47)). No other baseline variables were found to be significant predictors of CPAP compliance at 6 months.
<table>
<thead>
<tr>
<th>Baseline explanatory variables</th>
<th>3 Months</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unadjusted Model OR (95%CI)</td>
<td>P</td>
</tr>
<tr>
<td>ESS</td>
<td>1.19 (0.99, 1.43)</td>
<td>0.065</td>
</tr>
<tr>
<td>FSS</td>
<td>1.01 (0.96, 1.07)</td>
<td>0.627</td>
</tr>
<tr>
<td>MMQ-A</td>
<td>1.00 (0.95, 1.05)</td>
<td>0.982</td>
</tr>
<tr>
<td>MMQ-C</td>
<td>1.09 (0.98, 1.20)</td>
<td>0.119</td>
</tr>
<tr>
<td>SEMSA-SE</td>
<td>1.04 (0.91, 1.18)</td>
<td>0.603</td>
</tr>
<tr>
<td>SOS-Spouse perceived</td>
<td>1.05 (0.54, 2.02)</td>
<td>0.893</td>
</tr>
<tr>
<td>SOS-Spouse ideal</td>
<td>1.70 (0.41, 7.02)</td>
<td>0.469</td>
</tr>
<tr>
<td>SOS-Other 2 perceived</td>
<td>0.87 (0.49, 1.57)</td>
<td>0.654</td>
</tr>
<tr>
<td>SOS-Other 2 ideal</td>
<td>0.83 (0.35, 1.99)</td>
<td>0.675</td>
</tr>
<tr>
<td>SOS-Other 3 perceived</td>
<td>0.96 (0.58, 1.59)</td>
<td>0.867</td>
</tr>
<tr>
<td>SOS-Other 3 ideal</td>
<td>1.15 (0.58, 2.26)</td>
<td>0.688</td>
</tr>
<tr>
<td>SOS-Other 4 perceived</td>
<td>1.18 (0.61, 2.25)</td>
<td>0.627</td>
</tr>
<tr>
<td>SOS-Other 4 ideal</td>
<td>1.18 (0.46, 3.00)</td>
<td>0.728</td>
</tr>
<tr>
<td>DASS-21</td>
<td>1.04 (0.98, 1.10)</td>
<td>0.230</td>
</tr>
<tr>
<td>DASS-21 Depression</td>
<td>0.96 (0.86, 1.07)</td>
<td>0.450</td>
</tr>
<tr>
<td>DASS-21 Anxiety</td>
<td>1.05 (0.98, 1.13)</td>
<td>0.202</td>
</tr>
<tr>
<td>IPQ-R Symptoms due to sleep</td>
<td>1.17 (0.92, 1.49)</td>
<td>0.211</td>
</tr>
<tr>
<td>IPQ-R Cause</td>
<td>1.24 (0.94, 1.63)</td>
<td>0.132</td>
</tr>
<tr>
<td>IPQ-R Timeline</td>
<td>1.12 (0.89, 1.41)</td>
<td>0.325</td>
</tr>
<tr>
<td>IPQ-R Consequences</td>
<td>1.10 (0.85, 1.52)</td>
<td>0.313</td>
</tr>
</tbody>
</table>

Epworth Sleepiness Scale (ESS), Fatigue Severity Scale (FSS), Multifactorial Memory Questionnaire (MMQ), Self-Efficacy Measure for Sleep Apnoea (SEMSA), Significant Others Scale (SOS), Depression, Anxiety and Stress Scales (DASS-21), Illness Perception Questionnaire Revised (IPQ-R)Results reported as odds ratio (OR) and 95% Confidence Interval

Adjusted for age, sex, BMI, anti-depressants, sleeping tablets, diuretics
<table>
<thead>
<tr>
<th>Baseline explanatory variables</th>
<th>3 Months</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unadjusted Model</td>
<td>Adjusted Model</td>
</tr>
<tr>
<td></td>
<td>OR (95%CI)</td>
<td>P</td>
</tr>
<tr>
<td></td>
<td>OR (95%CI)</td>
<td>P</td>
</tr>
<tr>
<td><strong>Anthropometrics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>0.93 (0.85, 1.01)</td>
<td>0.076</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>0.88 (0.76, 1.01)</td>
<td>0.072</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>1.01(0.99, 1.03)</td>
<td>0.471</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>1.04 (0.96, 1.12)</td>
<td>0.331</td>
</tr>
<tr>
<td>Body Fat (%)</td>
<td>1.05 (0.94, 1.17)</td>
<td>0.431</td>
</tr>
<tr>
<td>Waist Circumference (cm)</td>
<td>1.02 (0.98, 1.07)</td>
<td>0.348</td>
</tr>
<tr>
<td>Hip Circumference (cm)</td>
<td>1.03 (0.98, 1.09)</td>
<td>0.279</td>
</tr>
<tr>
<td>Neck Circumference (cm)</td>
<td>1.20(0.98, 1.48)</td>
<td>0.077</td>
</tr>
<tr>
<td><strong>Biomedical</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c (mmol/mol)</td>
<td>1.08 (0.96, 1.22)</td>
<td>0.218</td>
</tr>
<tr>
<td>Total Cholesterol (mmol/L)</td>
<td>0.94 (0.52, 1.70)</td>
<td>0.843</td>
</tr>
<tr>
<td>Triglycerides (mmol/L)</td>
<td>0.61 (0.25, 1.48)</td>
<td>0.276</td>
</tr>
<tr>
<td>HDL (mmol/L)</td>
<td>1.76 (0.53, 5.85)</td>
<td>0.555</td>
</tr>
<tr>
<td>LDL (mmol/L)</td>
<td>11.17(0.21, 5.08)</td>
<td>0.234</td>
</tr>
<tr>
<td>Albumin (g/L)</td>
<td>0.89(0.70, 1.13)</td>
<td>0.331</td>
</tr>
<tr>
<td>Bilirubin (umol/L)</td>
<td>1.01(0.83, 1.23)</td>
<td>0.921</td>
</tr>
<tr>
<td>Alkaline Phosphatase (iu/L)</td>
<td>0.99(0.96, 1.02)</td>
<td>0.444</td>
</tr>
<tr>
<td>Alanine Transaminase (iu/L)</td>
<td>0.94(0.88, 1.00)</td>
<td>0.056</td>
</tr>
</tbody>
</table>

* Adjusted for age, sex, Oral anti-hyperglycaemics, Lipid lowering tablets, steroids
** Adjusted for age, sex, BMI, Oral anti-hyperglycaemics, Lipid lowering tablets, steroids

Adjusted for age, sex, Oral anti-hyperglycaemics, Lipid lowering tablets, steroids

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If the newly diagnosed group is CPAP compliant at 3 and 6 months post CPAP therapy, are there any improvements observed in the daytime sleepiness (ESS), fatigue (FSS), memory complaints (MMQ), mood (DASS-21), social support (SOS), self-efficacy (SEMSA) and Illness perceptions (IPQ-R), anthropometric and biomedical data at the same time points?

Linear regression was employed to identify if in those who are CPAP compliant there are observed improvements from baseline and the results from the two adjusted models for this analysis are reported below in Table 2-18a and 2-18b. At 3 months negative non-significant associations were observed in the subjective daytime sleepiness (ESS), emotional well-being (DASS-21 Anxiety) and Social support (SOS) scales in those compliant with CPAP therapy. Therefore, for those participants compliant with CPAP therapy at 3 months the ESS score was on average 0.12 points lower (95% CI -1.00, 0.77), the DASS-21 Depression score was on average 6.76 points lower (95% CI -14.23, 0.70) and required less support in comparison with those who were non-compliant at baseline. In the anthropometric data reductions were observed in the blood pressure (systolic and diastolic) waist and neck circumference. Expected positive associations and improvements were observed in the self-efficacy, treatment beliefs (SEMSA) and Memory scales (Table 2-18a).

At 6 months negative associations were observed in the subjective daytime sleepiness (ESS), memory contentment (MMQ-C), emotional well-being (DASS-21) and Social support (SOS) scales. Expected positive associations and improvements were observed in the self-efficacy (SEMSA) and Social support (SOS) and IPQ-R scales (Table 2-
18a). In the anthropometric and biomedical data reductions were observed in the blood pressure (systolic and diastolic), body fat, HbA1c, cholesterol and Albumin (2-18b).
Table 2-18a: Linear Regression Questionnaire data results

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>3 Months</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adjusted Model 1</td>
<td>Adjusted Model 2</td>
</tr>
<tr>
<td></td>
<td>Beta (95% CI)</td>
<td>P</td>
</tr>
<tr>
<td>ESS</td>
<td>-0.12(-1.00, 0.77)</td>
<td>0.793</td>
</tr>
<tr>
<td>FSS</td>
<td>0.22(-1.63, 2.07)</td>
<td>0.814</td>
</tr>
<tr>
<td>MMQ</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMQ-A</td>
<td>3.96 (-1.63, 9.55)</td>
<td>0.160</td>
</tr>
<tr>
<td>MMQ-C</td>
<td>0.58 (-1.00, 2.16)</td>
<td>0.462</td>
</tr>
<tr>
<td>SEMSA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEMSA-OE</td>
<td>0.27 (-3.04, 2.51)</td>
<td>0.847</td>
</tr>
<tr>
<td>SEMSA-SE</td>
<td>1.15 (-1.82, 4.12)</td>
<td>0.438</td>
</tr>
<tr>
<td>SOS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SOS-Spouse perceived</td>
<td>-0.07 (-0.36, 0.23)</td>
<td>0.640</td>
</tr>
<tr>
<td>SOS-Spouse ideal</td>
<td>0.03 (-0.03, 0.08)</td>
<td>0.335</td>
</tr>
<tr>
<td>SOS-Other 2 perceived</td>
<td>-0.10 (-0.31, 0.10)</td>
<td>0.325</td>
</tr>
<tr>
<td>SOS-Other 2 ideal</td>
<td>0.13 (-0.05, 0.31)</td>
<td>0.158</td>
</tr>
<tr>
<td>SOS-Other 3 perceived</td>
<td>-0.28 (-0.66, 0.11)</td>
<td>0.155</td>
</tr>
<tr>
<td>SOS-Other 3 ideal</td>
<td>-0.13 (-0.46, 0.21)</td>
<td>0.441</td>
</tr>
<tr>
<td>SOS-Other 4 perceived</td>
<td>0.13 (-0.22, 0.47)</td>
<td>0.454</td>
</tr>
<tr>
<td>SOS-Other 4 ideal</td>
<td>0.09 (-0.18, 0.35)</td>
<td>0.518</td>
</tr>
<tr>
<td>DASS-21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DASS-21 Depression</td>
<td>-6.76 (-14.23, 0.70)</td>
<td>0.074</td>
</tr>
<tr>
<td>DASS-21 Anxiety</td>
<td>-0.55 (-2.14, 1.04)</td>
<td>0.490</td>
</tr>
<tr>
<td>DASS-21 Stress</td>
<td>-0.96 (-3.53, 1.62)</td>
<td>0.456</td>
</tr>
<tr>
<td>IPQ-R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IPQ-R Symptoms due to sleep</td>
<td>0.53 (-0.73, 1.79)</td>
<td>0.399</td>
</tr>
<tr>
<td>IPQ-R Cause</td>
<td>-0.92 (-2.18, 0.34)</td>
<td>0.148</td>
</tr>
<tr>
<td>IPQ-R Timeline</td>
<td>0.01 (-0.25, 0.27)</td>
<td>0.929</td>
</tr>
<tr>
<td>IPQ-R Consequences</td>
<td>1.02 (-0.33, 2.37)</td>
<td>0.134</td>
</tr>
</tbody>
</table>

Epworth Sleepiness Scale (ESS), Fatigue Severity Scale (FSS), Multifactorial Memory Questionnaire (MMQ), Self-Efficacy Measure for Sleep Apnoea (SEMSA), Significant Others Scale (SOS), Depression, Anxiety and Stress Scales (DASS-21), Illness Perception Questionnaire Revised (IPQ-R).
Table 2-18b: Linear Regression Anthropometric and Biomedical data results

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>3 Months</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adjusted Model 1</td>
<td>Adjusted Model 2</td>
</tr>
<tr>
<td></td>
<td>Beta (95% CI)</td>
<td>Beta (95% CI)</td>
</tr>
<tr>
<td></td>
<td>P</td>
<td>P</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>-2.67 (-0.48, 5.81)</td>
<td>0.094</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>-0.28 (-3.10, 3.65)</td>
<td>0.869</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>0.38 (-0.66, 1.41)</td>
<td>0.468</td>
</tr>
<tr>
<td>BMI (Kg/m^2)</td>
<td>0.11 (-0.24, 0.48)</td>
<td>0.526</td>
</tr>
<tr>
<td>Body Fat (%)</td>
<td>-0.11 (-1.05, 0.83)</td>
<td>0.816</td>
</tr>
<tr>
<td>Waist Circumference (cm)</td>
<td>-1.66 (-0.593, 0.91)</td>
<td>0.143</td>
</tr>
<tr>
<td>Hip Circumference (cm)</td>
<td>6.45 (0.39, 12.52)</td>
<td>0.038</td>
</tr>
<tr>
<td>Neck Circumference (cm)</td>
<td>-0.13 (-0.43, 0.70)</td>
<td>0.638</td>
</tr>
<tr>
<td>HbA1c (mmol/mol)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Cholesterol (mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triglycerides (mmol/L)</td>
<td>0.21 (-0.20, 0.61)</td>
<td>0.316</td>
</tr>
<tr>
<td>HDL (mmol/L)</td>
<td>0.04 (-0.06, 0.14)</td>
<td>0.459</td>
</tr>
<tr>
<td>LDL (mmol/L)</td>
<td>0.09 (-0.39, 0.57)</td>
<td>0.701</td>
</tr>
<tr>
<td>Liver Function Test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albumin (g/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilirubin (umol/L)</td>
<td>0.16 (-1.40, 1.72)</td>
<td>0.832</td>
</tr>
<tr>
<td>Alkaline Phosphatase (iu/L)</td>
<td>9.35 (0.26, 18.45)</td>
<td>0.044</td>
</tr>
<tr>
<td>Alanine Transaminase (iu/L)</td>
<td>7.19 (0.99, 13.39)</td>
<td>0.024</td>
</tr>
</tbody>
</table>

Results reported as Beta coefficient and 95% Confidence Interval, Adjusted Model 1: Adjusted for each outcome’s baseline value; Adjusted Model 2: Adjusted for each outcome’s baseline value, age, sex, BMI, anti-depressants, sleeping tablets and diuretics; Adjusted Model 2: Adjusted for each outcome’s baseline value, age, sex, BMI, oral anti-hyperglycaemics, lipid lowering tablets and steroids; Adjusted Model 2: Adjusted for each outcome’s baseline value, age, sex, oral anti-hyperglycaemics, lipid lowering tablets and steroids.
2.3.6 Changes observed between time points

Paired sample t-tests were conducted so to identify changes from baseline, 3 and 6 months (where available) post CPAP therapy in the biomedical, anthropometric and questionnaire data and the results are shown below (Tables 2-19, 2-20 and 2-21).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Time point</th>
<th>Mean ± SD, Mean change from baseline</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (mmol/mol)</td>
<td>T1 (Baseline)</td>
<td>41.2±5.8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>38.9±4.6 -2.3</td>
<td>&lt;0.000</td>
</tr>
<tr>
<td>Cholesterol (mmol/L)</td>
<td>T1 (Baseline)</td>
<td>4.6±1.62</td>
<td></td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>4.3±1.45 -0.3</td>
<td>0.112</td>
</tr>
<tr>
<td>HDL (mmol/L)</td>
<td>T1 (Baseline)</td>
<td>1.34±0.47</td>
<td></td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>1.33±0.45 -0.01</td>
<td>0.431</td>
</tr>
<tr>
<td>LDL (mmol/L)</td>
<td>T1 (Baseline)</td>
<td>3.49±0.49</td>
<td></td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>3.45±0.52 -0.03</td>
<td>0.582</td>
</tr>
<tr>
<td>Triglycerides (mmol/L)</td>
<td>T1 (Baseline)</td>
<td>1.51±0.8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>1.49±0.72 -0.02</td>
<td>0.305</td>
</tr>
<tr>
<td>Alanine Transaminase (iu/L)</td>
<td>T1 (Baseline)</td>
<td>31.2±5.8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>32.0±6.4 0.8</td>
<td>0.776</td>
</tr>
<tr>
<td>Bilirubin (umol/L)</td>
<td>T1 (Baseline)</td>
<td>10.59±3.23</td>
<td></td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>9.67±2.45 -0.92</td>
<td>0.090</td>
</tr>
<tr>
<td>Albumin (g/L)</td>
<td>T1 (Baseline)</td>
<td>45.08±2.76</td>
<td></td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>44.15±3.22 -0.92</td>
<td>0.055</td>
</tr>
<tr>
<td>Alkaline Phosphatase (iu/L)</td>
<td>T1 (Baseline)</td>
<td>79.74±9.81</td>
<td></td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>75.28±9.76 -4.46</td>
<td>0.186</td>
</tr>
</tbody>
</table>

At 6 months significant reductions were observed in the HbA1c levels (Table 2-19). Reductions were also observed in the cholesterol, HDL, LDL, triglyceride and liver function data but these reductions were not statistically significant. At 3 months post CPAP therapy significant reductions were observed in the systolic and diastolic blood
pressure, body fat %, neck and waist circumference (Table 2-20). Reductions were also observed in weight and BMI but these were not significant. At 6 months post CPAP treatment significant reductions were observed in the systolic blood pressure, weight, body fat, BMI, neck and waist circumference (Table 2-20).

**Table 2-20: Changes between time points in the anthropometric data**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Time point</th>
<th>Mean ±SD</th>
<th>Mean change from baseline</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure Systolic (mmHg)</td>
<td>T1 (Baseline)</td>
<td>138 ±9.74</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T3 (3 months)</td>
<td>133 ±6.92</td>
<td>-5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>135±7.35</td>
<td>-3</td>
<td>0.023</td>
</tr>
<tr>
<td>Blood Pressure Diastolic (mmHg)</td>
<td>T1 (Baseline)</td>
<td>91±5.14</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T3 (3 months)</td>
<td>89±5.45</td>
<td>-2</td>
<td>0.013</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>90±4.27</td>
<td>-1</td>
<td>0.031</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>T1 (Baseline)</td>
<td>101.8±16.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T3 (3 months)</td>
<td>101.4±16.1</td>
<td>-0.4</td>
<td>0.311</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>100.7±15.4</td>
<td>-0.1</td>
<td>0.021</td>
</tr>
<tr>
<td>Body Fat (%)</td>
<td>T1 (Baseline)</td>
<td>31.2±5.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T3 (3 months)</td>
<td>30.7±5.2</td>
<td>-0.5</td>
<td>0.341</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>30.1±4.9</td>
<td>-1.1</td>
<td>0.062</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>T1 (Baseline)</td>
<td>33.2±8.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T3 (3 months)</td>
<td>33.1±8.3</td>
<td>-0.1</td>
<td>0.105</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>32.9±8.2</td>
<td>-0.3</td>
<td>0.301</td>
</tr>
<tr>
<td>Hip circumference (cm)</td>
<td>T1 (Baseline)</td>
<td>104.1±13.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T3 (3 months)</td>
<td>105.1±14.2</td>
<td>1</td>
<td>0.904</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>105.4±14.3</td>
<td>1.3</td>
<td>0.943</td>
</tr>
<tr>
<td>Neck circumference (cm)</td>
<td>T1 (Baseline)</td>
<td>44.5±3.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T3 (3 months)</td>
<td>44.2±3.3</td>
<td>-0.3</td>
<td>0.062</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>43.8±2.9</td>
<td>-0.7</td>
<td>0.003</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>T1 (Baseline)</td>
<td>103.5±14.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T3 (3 months)</td>
<td>102.1±13.4</td>
<td>-1.4</td>
<td>0.020</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>101.6±12.2</td>
<td>-1.9</td>
<td>0.001</td>
</tr>
</tbody>
</table>
At 3 months significant reductions were also observed in the subjective sleepiness and DASS-21 depression and stress scales (Table 2-21). A reduction of 1.33 in the fatigue score and a reduction of 2.19 points in the DASS-21 Anxiety scale were observed but these reductions were not significant. At 6 months greater and significant reductions in subjective sleepiness, fatigue and DASS-21 Depression and Stress levels from baseline were observed. In addition, a significant increase of 3.90 points in the DASS-21 Anxiety scale was also observed (Table 2-21).

**Table 2-21:** Changes between time points in the questionnaire data

<table>
<thead>
<tr>
<th>Variable</th>
<th>Time point</th>
<th>Mean±SD</th>
<th>Mean change from baseline</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1 (Baseline)</td>
<td>14.23±4.09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESS</td>
<td>T3 (3 months)</td>
<td>7.84±2.25</td>
<td>-6.39</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>3.46±1.40</td>
<td>-10.77</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>FSS</td>
<td>T1 (Baseline)</td>
<td>4.84±1.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T3 (3 months)</td>
<td>3.51±1.01</td>
<td>-1.33</td>
<td>0.657</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>2.64±0.27</td>
<td>-2.20</td>
<td>0.095</td>
</tr>
<tr>
<td>DASS-21 Depression</td>
<td>T1 (Baseline)</td>
<td>14.04±11.14</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T3 (3 months)</td>
<td>10.28±12.76</td>
<td>-3.76</td>
<td>0.062</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>12.61±8.38</td>
<td>-1.43</td>
<td>0.635</td>
</tr>
<tr>
<td>DASS-21 Anxiety</td>
<td>T1 (Baseline)</td>
<td>7.95±5.91</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T3 (3 months)</td>
<td>5.76±5.44</td>
<td>-2.19</td>
<td>0.237</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>11.85±8.00</td>
<td>3.90</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DASS-21 Stress</td>
<td>T1 (Baseline)</td>
<td>13.32±8.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T3 (3 months)</td>
<td>10.14±8.59</td>
<td>-3.18</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>T4 (6 months)</td>
<td>9.42±8.43</td>
<td>-3.90</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

At 3 and 6 months post CPAP treatment participants formed strong positive beliefs about the efficacy of CPAP in reducing their perceived OSA related symptoms and increased their self-confidence with CPAP. There was also a shift in the participants perceptions of their illness and the majority (76%, n=32) were able to recognise OSA as a long lasting and serious condition. As participants increased their CPAP
compliance they required less support from their social circle however, the level of support they received from their spouse did not decrease.

2.4 Discussion

The PUCOSA-UK study was designed to bridge the gap in the literature by exploring the interplay of potential psycho-social predictors of CPAP use and adherence (as defined by using CPAP ≥4 hours/night) in a newly diagnosed and established OSA patient population. Secondary objectives for the newly diagnosed group included the investigation of the impact of CPAP adherence and potential improvements in anthropometric, biomedical and psycho-social data whilst in the established group we aimed to investigate the relationship between CPAP use in the anthropometric, biomedical and psycho-social data.

2.4.1 Predictors of CPAP adherence

Newly diagnosed group

Participants with strong perceptions of OSA as a serious health threat prior to diagnosis and treatment (being able to associate OSA as a serious chronic condition, affecting and causing symptoms to individuals, as determined by the IPQ-R questionnaire) were found to be 63-77% more compliant to CPAP at 3 months and 42-45% at 6 months when compared to those who failed to make these association (Table 2-17a). Patients with high self-confidence who formed strong positive beliefs on CPAP treatment (as determined by the SEMSA questionnaire) as an efficacious therapy in conferring potential benefits prior to being diagnosed and using the therapy itself were 4-8% more likely to comply with the treatment than those with less self-confidence and those who formed less positive perceptions on the therapy (Table 2-17a). Those participants with
higher levels of support (as determined by the SOS questionnaire) by their spouse at baseline were 5% more likely to comply with CPAP therapy at 3 months while at 6 months their compliance increased to 20% from those who were less supported. Similar and higher variance in CPAP compliance was observed in the remaining 3 levels of social support (Table 2-17a). In addition, low emotional well-being (as determined by the DASS-21 questionnaire) including higher depression scores and higher levels of stress prior diagnosis and CPAP prescription were associated with increased likelihood of CPAP compliance by 5-9% at 3 months and by 8% at 6 months when compared to those participants who did not experience low emotional well being at baseline. Participants who experienced high anxiety levels prior OSA diagnosis were less likely to adhere to CPAP therapy (Table 2-17a). Participants who experienced higher excessive daytime sleepiness at baseline were 19-21% more likely to adhere to CPAP at 3 months and 9-5% more likely to be compliant at 6 months. Participants who experienced higher memory problems at baseline where 9-12% more likely to adhere to CPAP therapy and 10-12% more likely to be CPAP compliant at 6 months (Table 2-17a). Participants with increased neck circumference at baseline were 20-37% more likely to be CPAP compliant and 28-48% more likely to accept and adhere with CPAP at 6 months than those with regular neck size.

2.4.1.2 Associations with the existing literature

To the best of our knowledge this is the first study to report what best predicts CPAP compliance prior OSA diagnosis and treatment with CPAP therapy based on a strong theoretical schema (Common Sense Model of Illness Behaviour and Social Cognitive Theory) by utilising a standard battery of validated questionnaires to assess a variety of
psycho-social predictors of CPAP adherence together. Although no similar studies have been identified, three relevant papers have been published that support our findings. Olsen et al\textsuperscript{133} investigated the utility of a health belief model in 77 newly diagnosed OSA patients who were CPAP naive to determine the contribution of psychological factors in predicting CPAP adherence at 4 months. They reported that this health belief model based on four categories of subjective beliefs including (1) perceived susceptibility to illness, (2) perceived severity, (3) benefits and (4) barriers predicted 21.8\% of the variance in CPAP adherence. Wild et al\textsuperscript{134} conducted a similar study to establish if pre-treatment cognitive variables contribute to the explanation of variance in CPAP treatment and his model reported 24\% of the variance in CPAP use which identified 75\% of adherers and 53\% non-adherers. The study of Ye et al\textsuperscript{135} investigated the impact of multiple pre-treatment (demographic and clinical factors, patients perceived self-efficacy, treatments delivery (mask leak and side effects)) and immediate early treatment factors (respiratory events and flow limitation) during the first week of CPAP therapy in a cohort of 91 newly diagnosed patients and CPAP naive patients. They reported that 25.4\% of the variance in CPAP use during the first week was accounted for being of black ethnic minority, having higher AHI and the treatment side effect of being less intimate with partners. Our study however adds to these three reports as it was designed to assess multiple psycho-social predictors of CPAP adherence in an established and newly diagnosed cohort prior to a formal OSA diagnosis and CPAP prescription that enabled the identification of what best predicts CPAP adherence at 3 and 6 months post CPAP therapy. The results from our findings facilitated the exploration of associations between these factors and therefore contribute to enhance our understanding of patient acceptance especially when considering the
early formed conceptions of potential patients with OSA regarding acceptance and use of CPAP treatment.

2.4.2 Biomedical, anthropometric and psycho-social data

Clinically and statistically significant improvements were observed in the anthropometric (blood pressure, weight, body fat, hip-neck and waist circumference) and biomedical (HbA1c, cholesterol and bilirubin levels) at 3 and 6 most post CPAP therapy (Tables 2-19). Our findings are also in line with previous studies in the field.136

In the questionnaire data significant improvements were observed in the subjective sleepiness (ESS) and fatigue (FSS) levels (Table 2-21) 3 and 6 months post CPAP therapy. These findings are also supported in previously published studies as CPAP therapy has been shown to facilitate healthy breathing during sleep resulting in improved sleep quality and reduction of subjective daytime sleepiness and fatigue.

Although significant reductions in the DASS-21 Depression and Stress scales were observed post 3 and 6 months CPAP therapy contrary to our beliefs as CPAP compliance increased the anxiety levels of the participants which almost doubled post 6 months CPAP therapy.

2.4.2.1 Established group

In the established group on CPAP therapy, no positive associations were observed between mean CPAP use and experiencing lower daytime sleepiness, fatigue, memory problems and well being. Increased CPAP use has been shown to reduce daytime sleepiness, fatigue and improve cognitive functioning (including concentration and memory) and well-being. For every hour CPAP was used self-efficacy measures
improved. This finding supports our hypothesis of a positive association between increased CPAP use and self confidence in using CPAP and forming positive beliefs.

2.4.3 CPAP therapy compliance

The established group was classed as compliant to CPAP therapy as the mean CPAP use reported was 5.9 hours/night (range 3 to 8 hours). Only one of the total 80 participants (1.3%) was not able to tolerate CPAP therapy for more than 4 hours/night. The newly diagnosed group was classed as borderline non-compliant at 3 months post CPAP therapy as the mean CPAP use was reported to be 3.9 hours/night (range 2.2 to 5.5 hours). The majority of the participants (59.5%, n=25) were not able to tolerate CPAP therapy for more than 4 hours/night. At 6 months, the mean compliance had increased to 4.6 hours/night (range 3 to 6.5 hours) and only 19 of the total 42 participants (45.2%) were non compliant to CPAP therapy. Our findings demonstrate a low level of initial CPAP use leading to an increase in compliance in the long term. However, a 45.2% non compliance rate is still a poor result thus highlighting that this is the most important barrier in the management of OSA and signifies the requirement to develop effective strategies to improve compliance.

2.4.4 Strengths and limitations

One notable limitation of this study is the small sample size, particularly in the newly diagnosed group. Although the initial number of consecutive participants recruited in this group was 80, only 42 were subsequently diagnosed with OSA therefore the study may have insufficient power which may contribute the lack of many significant findings between psycho-social determinants of CPAP use. Moreover, this study has a number of strengths including the systematic collection of a wide range of
measurements utilising a battery of validated questionnaires. In addition, the anthropometric and biomedical data were collected by the same member of the research team utilising the same equipment for each participant following standard operating procedures developed by the Leicester Diabetes Centre. CPAP compliance was objectively measured by the inbuilt meters of the CPAP devices. The biomedical data analysis was performed at a certified laboratory within an NHS setting, while a team of Sleep specialists and technicians were involved in the diagnosis, initiation and follow-up care of the participants.

2.4.5 Conclusions and future research directions

In conclusion, the results of the PUCOSA-UK study suggest that psycho-social factors based on a health belief model (Bandura’s and Leventhal's models) can predict 23% of CPAP adherence in a group of newly diagnosed patients with OSA prior to formal diagnosis and trial of CPAP therapy. The finding that the likelihood of adherence to CPAP therapy is heavily dependent on the early formation of strong beliefs and preconceptions of the medical condition and CPAP therapy prior trialling the therapy is very important as this information can be utilised when developing educational lifestyle interventions early so that they can be offered soon after diagnosis. Enabling participants to assess their personal risk perceptions, outcome expectancies, barriers and illness beliefs will motivate them to enact in changing their behaviour so to achieve better self-management of their condition and health status. The results from the PUCOSA-UK empirical study combined with the results from the qualitative element of this study described in chapter 3 underpin the development of our structured education programme described in chapter 5. Future research is required in this field as CPAP therapy is the cornerstone therapy in treating OSA.
Chapter 3

The PUCOSA-UK Qualitative Study: Perceptions of OSA and CPAP treatment experiences among established and newly diagnosed patients.
3.0 Chapter overview

In this chapter, the qualitative component of the PUCOSA-UK study is presented and discussed.

The author of the thesis, MAT, performed the following activities in relation to this study:

- Developed the interview topic guide
- Recruited and consented participants
- Arranged and conducted the telephone interviews with every participant
- Managed the study logistics
- Performed administrative duties for the study
- Collected and managed patient data
- Developed the initial thematic code
- Analysed and interpreted data

The above activities were carried out under the supervision of MJD, KK, EMB and APH. The interview topic guide was developed in collaboration with MS. The interviews were transcribed by LJ. The initial coding frame was carried out in collaboration with MS and I analysed all the interview transcripts.

In order to explain the choice of qualitative methods for this section of the overall programme of work, differences between qualitative and quantitative methods are first outlined in section 3.1.
3.1 Qualitative versus Quantitative research

In health-related research, quantitative research methods aim to investigate a hypothesis-testing approach whilst qualitative research methods aim to explore the subjective factors that may influence human behaviour (peoples’ beliefs, views, emotions, preferences and choices) on a particular therapy or service. Quantitative and qualitative research methods differ not only in their analytical objectives and the type of data collection instruments they employ but also in the types of questions they pose, the form of data they produce and their degree of flexibility in the study design (Table 3-1). Qualitative methods are more flexible and allow greater spontaneity and adaptation of the interaction between the researcher and the participants compared to quantitative methods. This flexibility allows the researcher to use open-ended questions thus giving the participants the opportunity to respond using their own words. In addition, qualitative research generates explanatory theories which can be utilised as a foundation to develop interventions whose effectiveness is studied via quantitative methods. Therefore, despite the distinct differences between qualitative and qualitative research methodologies, when both methods are combined they provide a new ‘drive’ to the research process and a new dimension to the research findings. With this in mind, a complementary qualitative element was added to the empirical PUCOSA-UK study in order to explore peoples’ beliefs, views, opinions and preferences regarding CPAP therapy and how these perceptions may affect compliance with the therapy.
### Table 3-1: Differences between Qualitative and Quantitative research methods

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Qualitative Research</th>
<th>Quantitative Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>To understand and interpret social interactions</td>
<td>To test hypotheses and make predictions</td>
</tr>
<tr>
<td>Research Objectives</td>
<td>Explore, discover &amp; construct</td>
<td>Describe, explain &amp; predict</td>
</tr>
<tr>
<td>Research Design</td>
<td>Flexible</td>
<td>Specific</td>
</tr>
<tr>
<td>Scientific Method</td>
<td>Exploratory: the researcher generates a new hypothesis and theory from the data collected</td>
<td>Confirmatory: the researcher tests the hypothesis and theory with the data.</td>
</tr>
<tr>
<td>Sampling</td>
<td>Samples are purposively selected, generally in order to capture the views of a range of relevant people</td>
<td>Samples are selected to represent the target population</td>
</tr>
<tr>
<td>Group Studied</td>
<td>Small-based on achieving ‘saturation’ when no new ideas are emerging. Not randomly selected</td>
<td>Large (generally, but not always) - based on power calculation &amp; randomly selected</td>
</tr>
<tr>
<td>Type of Data Collected</td>
<td>Descriptive, textual (words, images)</td>
<td>Numerical (numbers and statistics)</td>
</tr>
<tr>
<td>Form of Data Collected</td>
<td>Ethnographic observations, interviews, focus groups, field notes, reflections, free text questionnaire data</td>
<td>Biomedical data, fixed response questionnaire data</td>
</tr>
<tr>
<td>Type of Data Analysis</td>
<td>Exploratory (based on identifying patterns, features &amp; themes)</td>
<td>Statistical</td>
</tr>
<tr>
<td>Reliability and Validity</td>
<td>Determined through multiple sources or information</td>
<td>Determined through statistical and logical methods</td>
</tr>
<tr>
<td>Reporting</td>
<td>Narrative report with contextual description &amp; direct quotations from research participants</td>
<td>Statistical report with correlations, comparisons of means &amp; statistical significance of findings</td>
</tr>
</tbody>
</table>

Table adapted from: Silverman D (2000)\(^{137}\) and \(^{138}\)

### 3.2 Study design and aims

The proposed exploratory study utilised qualitative methodology techniques including semi-structured telephone interviews of purposively sampled sleep clinic patients. The main goal of purposively sampling was to capture the views of a range of people relevant for answering the specific research questions, rather than to aim for a
representative sample. Newly diagnosed and established participants with OSA from the PUCOSA-UK study were eligible to take part in this qualitative component of the study.

The aim of this study was to gain a better understanding of peoples’ perceptions and beliefs of OSA and CPAP therapy. Therefore we aimed to explore in more depth:

1 Experiences leading to seeking sleep-related help.
2 Perceptions and understanding relating to perceived OSA related problems (including causes and treatments) prior to consultation.
3 Expectations of initial and subsequent consultation.
4 Actual experiences of initial and subsequent consultation for OSA including impact on perceptions and understanding of causes and treatments.
5 Initial reactions to prescription of CPAP.
6 Perceptions about reactions of partner or other relevant people regarding prescription of CPAP.
7 Experiences relating to actual use of CPAP including impact on OSA-related symptoms and problems and barriers to use as prescribed.
8 Self-strategies used to address barriers and whether these were successful.
9 General suggestions for ways of improving adherence to using CPAP as prescribed in people with OSA including suggestions for additional help from health care providers.
10 Perceptions about influence of partners or other relevant people on CPAP adherence (in general and from their own experience), including positive support and negative reactions to actual use of CPAP.

3.2.1 Methods

As this was an exploratory study, qualitative methods including semi–structured interviews were used as the form of data gathering from participating patients. An interview topic guide was developed for each patient group (newly diagnosed and established OSA patients) to ensure standardised and systematic data collection. The
interview topic guide development was a collaborative approach between members of the research team led by an experienced senior qualitative researcher (MS). The interview topic guide was revised on multiple occasions prior to the actual interviewing process and a ‘mock’ interview was organised to assess the content validity of the guide in extracting the required information and to practice interviewing skills.

### 3.2.2 Participants

Participants in the PUCOSA-UK study were invited to participate in the qualitative element of the study consented to being approached. Two methods of inviting patients to participate were used. The first method involved sending an invitation pack to participants via the post with a letter outlining the qualitative study and why they were being approached. The invitation pack also included the patient information sheet (Appendix 3) which clarified what would be involved and gave details outlining the telephone interview process. Participants were contacted by an investigator via the telephone at least 48 hours after receiving the invitation packs to confirm their willingness to participate. For the second method of invitation, consented participants were approached during their routine follow-up visit at the Leicester Sleep Disorders Service and were provided with the related information leaflet in agreement with the study protocol.

### 3.2.3 Telephone interviews

Semi-structured telephone interviews were scheduled with participants at two stages for the newly diagnosed patients (before and after OSA diagnosis). A single interview was conducted for the established OSA participants. All interviews were conducted
promoting open sharing of information. The interview duration ranged between 15-45 minutes. Interview topic guides, consisting of specific questions and prompts to encourage focus on the particular topic of interest were used for each interview (Appendix 3). The newly diagnosed participants’ first interview focused on previous knowledge of OSA; perceived symptoms; impact of the diagnosis; length of time before seeking help; pre-treatment perceptions of CPAP; the reasons which led the participant to seek medical care and the role of a partner (where applicable) in encouraging them to visit their GP. The second interview focused on their reactions and emotions on being diagnosed with OSA; their understanding of OSA and CPAP after diagnosis; perceived benefits of treatment with CPAP; supportive mechanisms or barriers to using CPAP; and how beliefs and perceptions about the diagnosis and the treatment experiences might have influenced CPAP adherence levels. The established OSA participant interview combined the aforementioned topics but focused on troubleshooting CPAP related problems; self-management strategies; and ideas about how to increase compliance. Understanding of the content of their responses was deepened using additional questions.

3.2.4 Data analysis

Data analysis was carried out using a multi-step process. First, the interview audio-recordings were anonymised and sent in an electronic format (mp3 files) to be transcribed verbatim by an external professional transcriber not affiliated with the study. The transcribed data were thematically analysed using the Framework analytic approach consisting of five steps including:
1 Familiarisation.
2 Identifying a thematic framework.
3 Indexing.
4 Charting.
5 Mapping and interpretation.

These highly interconnected steps allow systematic analysis by following a well-defined step-by-step procedure and are described in more detail below.

3.2.4.1 Familiarisation

This stage involves immersion in the gathered data, by reading and listening to the recordings, transcripts and observational notes. In this study all transcripts were read by two investigators (MS and MAT) independently to gain a sense of the whole dataset.

3.2.4.2 Identifying a thematic framework

This stage involves the identification of key concepts and themes according to which the data can be examined and referenced. Devising and refining a thematic framework involves making judgements about the relevance and importance of the issues addressed. Two investigators identified and discussed statements, concepts and emerging themes. Emergent subthemes were also identified as thematic content analysis progressed. An example of a theme in this study is ‘impact of lack of sleep’ and examples of subthemes of this theme are ‘depression’, ‘relationships’, ‘work life’. A thematic framework was agreed between the two investigators and validation of the themes was established through constant comparison of the transcripts independently by the two investigators. Any disagreement was resolved by discussion.
3.2.4.3 Indexing

Indexing refers to the systematic coding of the data in its textual form and provides a mechanism for labelling data in a manageable manner for further exploration.\textsuperscript{137} The transcripts were coded by one investigator (MAT) utilising the NVivo7 software and coding was selectively cross-checked by the expert qualitative researcher (MS) to confirm the validity of the application of the codes to the transcripts.

3.2.4.4 Charting

Charting involves abstraction and synthesis and refers to the rearranging of data according to the appropriate part of the thematic framework to which they relate.\textsuperscript{137} For each key theme identified a chart was developed which included entries for all the interviewees consisting of brief summaries of views and experiences. Where possible, passages for possible quotations were also referenced by transcript page and number. An example of charting can be viewed in Appendix 5. The development of appropriate charts was particularly useful as it allowed a quick ‘view’ and conceptualisation of the data as a whole.

3.2.4.5 Mapping and interpretation

The key objectives of this step include:

1. Defining concepts (understanding internal structures).
2. Mapping the range, nature and dynamics of phenomena.
3. Creating typologies (categorizing different types of behaviours or beliefs).
Finding associations (between experiences and attitudes).

Seeking explanations (explicit or implicit).

Developing new ideas, strategies or theories.  

An example of typology that was explored was based on participants’ initial reactions to prescription of CPAP therapy; participants were categorised according to whether or not they had positive perceptions at this stage. An additional typology was explored based on whether or not participants described positive early experiences of actually using CPAP. Deviant cases were also considered as part of the exploration of the data. Deviant cases describe elements of the data that do not support and appear to contradict patterns of explanations that are emerging from the data. The Framework analysis steps described above proved to be useful in data management prior to mapping and interpretation. The study aimed for good methodological rigour with multiple checks implemented to ensure validity and reliability.

3.2.5 Ethical considerations

Ethical approval was granted by the local research ethics committee (described in Chapter 2). All participants consented to take part after being informed that any information collected during the interview would be treated as confidential and anonymity would be guaranteed. Additional consent was obtained via the phone and participants were asked to confirm their name and the date of the scheduled interview. The consent process was audio-recorded in a separate file from the actual interview. Each participant was assigned a unique study number and no patient identifiable data
was included during the interview. Participants were also informed that they could withdraw from the study without any explanation or consequences for their future care.

3.3 Findings

3.3.1 Sample recruited

Saturation point (Table 3-2) was considered to have been reached after 9 full interviews had been conducted, as no new themes appeared to be emerging from the interviews. The participants were predominantly white British, middle-aged (age ranges 32-39, 40-59 and 60-67 years) and male (n=6). Of the nine participants five were newly diagnosed and four had established OSA. The demographic characteristics of the participants are described in Table 3-2.

Table 3- 2: Demographic characteristics of the nine interviewed participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>(n=9)</th>
</tr>
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<tbody>
<tr>
<td>Age (by range):</td>
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<tr>
<td>32-39</td>
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<tr>
<td>40-59</td>
<td>4</td>
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<tr>
<td>60-67</td>
<td>3</td>
</tr>
<tr>
<td>Gender:</td>
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</tr>
<tr>
<td>Men</td>
<td>6</td>
</tr>
<tr>
<td>Women</td>
<td>3</td>
</tr>
<tr>
<td>Study Arm:</td>
<td></td>
</tr>
<tr>
<td>Established</td>
<td>4</td>
</tr>
<tr>
<td>Newly diagnosed</td>
<td>5</td>
</tr>
<tr>
<td>Race/Ethnicity:</td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>8</td>
</tr>
<tr>
<td>Asian British</td>
<td>1</td>
</tr>
<tr>
<td>Marital Status:</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>8</td>
</tr>
<tr>
<td>Single</td>
<td>1</td>
</tr>
<tr>
<td>Partner –Sharing bed</td>
<td>8</td>
</tr>
<tr>
<td>Education:</td>
<td></td>
</tr>
</tbody>
</table>
Further education 2
Higher education 7
Employment Status:
Employed 6
Retired 3

3.3.2 Experiences prior to seeking help

Prior to seeking help, most of the participants were unaware they had a sleep-related medical condition or that they had stopped breathing during sleep.

‘Erm ... well actually I didn’t ... we didn’t realise what was happening ... completely unaware there was a problem or that there is such a thing as sleep apnoea ... I hadn’t heard of it.’ (PUC-179, male, newly diagnosed)

‘I was unaware because erm ... it never used to wake me up.’ (PUC-054, male, established)

Most of the participants were able to describe a few daytime OSA related symptoms such as tiredness and excessive daytime sleepiness occurring for an extensive period of time (2 to 10 years) prior to diagnosis.

‘Erm ... I was extremely tired all the time, even right from when I got up in the morning ... erm ... I was diagnosed erm ... six years ago ... though looking back I think probably I’d had it for some years before that.’ (PUC-044, male, established OSA patient)

A few of the participants also described how they had suffered from snoring for a long period of time and how loud snoring caused sleep disturbances to their bed partner.
‘I’ve been a snorer for a long time erm ... basically my partner telling me the ... the noise I made in my sleep was unacceptable she ... she would erm ... wake up because of my snoring.’ (PUC-044, male, established OSA patient)

Participants felt that both their own and their partners’ disturbed sleep increased the risk of mood swings, leading to irritation, arguments and depression that affected relationships in a negative way.

‘It was causing her restlessness because she found it difficult to sleep because she thought she’d gotta be awake to listen for me to stop breathing so it ... it didn’t just affect me it affected her as well and because she wasn’t getting the quality of sleep at night, not to the same degree as myself, but again she was getting irritable, she wasn’t getting the quality of sleep that she needed, and again we ... we were erm ... picking at each other for silly little things erm ... and ... and we didn’t realise what it was.’ (PUC-113, male, newly diagnosed OSA patient)

Their extreme tiredness sometimes led to difficulties in expressing emotions, decreased libido (erectile dysfunction in male participants), depression and, as a consequence, a non-existent sex life.

‘I think it did ... it has affected my relationship yes... certainly sexually cos I’m always tired and with that tiredness also comes probably erm ... depression which brings on if you like ... like mood swings if you like.’ (PUC-179, male, newly diagnosed OSA patient)

‘Well I think yes, I think it’s erm ... I was virtually impotent.’ (PUC-044, male, established OSA patient)
‘Yes it was, working life, personal life, erm ... and if you don’t mind me saying, sex life. Absolutely everything was affected on a day to day basis because of it yes.’ (PUC-113, male, newly diagnosed OSA patient)

Most of the participants described severe tiredness and daytime sleepiness. They felt that the frequent awakenings and disturbed sleep made them very tired and sleepy during the day. The tiredness was a total feeling of fatigue or lack of energy, with both mental and physical effects and they could not prevent themselves from falling asleep in different situations including during driving.

‘Some of the things about me feeling very, very tired, er ... you know dropping off to sleep very easily, er ... and also that was probably during the day er ... er ... you know there was a couple of times where I sort of er ... towards the end of the day where I was driving and I sort of er ... er ... sort of nodding off at the wheel.’ (PUC-054, male, established OSA patient)

In addition, participants felt embarrassed about falling asleep in front of other people without realising that they were doing so and expressed the need to consume energy drinks to remain alert and keep awake.

‘I work with some young girls they used to laugh and I was so embarrassed cos I didn’t realise anybody knew because ... I knew I was going to sleep but I didn’t think I was going to sleep with my eyes shut, you know I can’t explain it ... It might only be for momentarily, it ... it was if I’d like sit down, and ... I work with little children, and perhaps if I nursed a child to sleep, you know cuddled them to sleep or something I’d find I’d just ... with them ... I’d have to get up and do something, move about, and I’ve lived for a lot of time on Coca-Cola and erm ... Red Bull ... and they laughed at a staff
Participants described how they suffered from depression and even experienced suicidal thoughts. They perceived their life situation as hopeless as it affected their work performance and family life, though this was also attributed to stress.

‘I think it had a great impact on my life. in fact it got to the point where I think I was suffering from depression, er ... it made me very depressed, I felt suicidal, but this was also down to erm ... business failings and a few other problems in the life ... in my life and I just put it down to stress.’ (PUC-179, male, newly diagnosed OSA patient)

Participants believed that their OSA related symptoms were due to other factors including working long hours, having a young baby, stress and old age. Others associated their symptoms with cardiovascular conditions including diabetes and stroke. Participants were puzzled about the causes of their symptoms.

‘I’d say that I feel tired a lot of the time but I’ve got a young baby so I will be ... I ... don’t erm ... know what is causing this.’ (PUC-174, male, newly diagnosed OSA patient)

‘We assumed that I’d had a minor stroke.’ (PUC-179, male, newly diagnosed OSA patient)
In many cases the role of the spouse or friend and/or colleague was crucial in encouraging them to seek help.

‘Well I was at work erm ... at <institution> erm ... and another gentleman there, who was sitting across the desk, ... I was yawning, looking quite tired erm ... head on my hands, elbows on the desk and he asked me if I was okay, I explained what the wife had told me and he said to me, <name>, you’ve got sleep apnoea, I suffer with it, go to your doctor straight away.’ (PUC-113, male, newly diagnosed OSA patient)

In one particular case the spouse’s approach in informing her partner of loud snoring and stopping breathing proved to be vital in encouraging him to seek help:

‘I probably had the condition for quite a few years, erm ... Well my for ... my former wife erm ... she’d lived in an environment where her father used to er ... snore and obviously she’d grown up in the house and she could sleep through it, erm ... when we got married, I mean we’d been married for twenty three years, she never complained at all about er ... me snoring or anything so obviously I didn’t know I ... I snored. Well er ... my ... my ... my new wife er ... erm ... she er ... was disturbed through the night’s sleep so erm ... you know she ... she would erm ... wake up because of my snoring and also er ... I used to take deep breaths s ... and stop breathing and then sort of start again and it erm ... it ... it ... it ... it worried her very much that I was going to ... (laughs) stop breathing.’ (PUC-054, male, established OSA patient)
3.3.3 Factors delaying diagnosis

Participants were unanimously in agreement about the lack of knowledge and awareness about OSA on their part, overall in the wider population and in healthcare professionals. Many believed that this had led to delays in seeking help and receiving appropriate care.

‘Erm ... I’d been to the doctor’s many times saying I felt exhausted all the time and my doctor didn’t pick up on it... with all my symptoms he should have said let’s have these tests done years ago ... I was not happy with my doctor, not knowing about this.’ (PUC-179, male, newly diagnosed OSA patient)

Two of the interviewees were healthcare professionals (General Practitioners) and they themselves had failed to recognise the condition despite of the spouse indicating problems with stopping breathing.

‘My first wife did sort of say I wasn’t sort breathing properly so er ... yeah... But it was never diagnosed ... no ... nobody ever put a label on it.’ (PUC-044, male, established OSA patient)

‘I had previously thought that maybe there was a problem but probably only mild and not very significant.’ (PUC-144, male, newly diagnosed OSA patient)

Patients emphasised the lack of available information about OSA in surgeries and how under advertised this condition is. In one case an interviewee argued that this can be detrimental as people maybe suffering with OSA but are unaware due to the lack of available information.
‘I don’t think enough people are aware of it. Until <name> told me at work I’d never even heard of the condition. Erm … I … you … you don’t see it in … on leaflets in erm … doctors’ surgeries like you see other things, erm … I … I’d spoken to the doctors about things before but they never even talked about sleep apnoea or anything like that about it. Erm … I do think there ought to be more information out there more visible, erm … you see plenty of things on TV about all other sorts of aspects of illnesses and everything else and I do think there’s an awful lot of people, not just in this country probably throughout the world, who suffer with sleep apnoea, don’t know they’re suffering with it and have no idea what to do about it and I think there ought to be more information available everywhere, doctors’ surgeries, dental surgeries, dispensaries, Boots’s clinics, everywhere that you go. I think it’s very under-advertised.’ (PUC-113, male, newly diagnosed OSA patient)

3.3.4 Reactions to receiving diagnosis

The majority of the interviewees accepted the results of their diagnosis, felt positively about being ‘labelled’ and expressed a feeling of relief that their symptoms could be attributed to a real cause. Participants felt more in control knowing what was causing their symptoms as they could do something about it.

‘Well I felt relieved erm … that I think we’d come to the what was causing all my problems, because there was a reason for it, it’s the unknown that frightens people, or frightens me anyway, erm … at least if you know what it is and there’s a treatment available you can start to get it corrected erm … so it was the not knowing.’ (PUC-113, male, newly diagnosed OSA patient)
A few participants, however, needed more time to accept their diagnosis as they felt shocked, frightened and surprised to find out about stopping breathing in their sleep particularly when they had not experienced any symptoms. In one case an interviewee expressed feeling anger that his diagnosis was delayed due to lack of awareness of his GP at the time.

‘I was extremely surprised erm ... and angry ... I f ... I er ... I don’t know whether anger is the right word but I wasn’t very happy with my doctor not knowing about this. I was shocked you know ... like I said I had no symptoms, I had no trouble sleeping, I wasn’t aware that I stopped breathing and I wasn’t aware if I woke up during the night, so it ... it ... it took me a while to assimilate the information.’ (PUC-179, male, newly diagnosed OSA patient)

Others felt very anxious finding out about OSA and stopping breathing.

‘Er ... I thought it was a ... a ... sleep apnoea was a killer, killer disease ... I was quite frightened actually because it was three hundred and, if I can remember correctly, three hundred and ninety something times in one night ... that I stopped er ... stopped sleeping and up for ... up to a minute and a half erm ... so that ... that was quite frightening because I didn’t realise I could hold my breath for a minute and a half, erm ... so obviously something had got to be done about it but er ... at that particular time quite frightening.’ (PUC-092, female, newly diagnosed OSA patient)

The interviewees’ knowledge of OSA after receiving a diagnosis significantly improved as they felt that the information they were given was clear and they were able to describe in some detail what OSA means and how their symptoms made sense.
'Yes indeed, yes er ... he did explain and I felt quite ... it was very clear... my throat closes or something and then I don't breathe properly so I'm not having a ... a restful sleep, I'm having a disturbed sleep, and I do get up and down a lot at night.’ (PUC-172, male, newly diagnosed OSA patient)

3.3.5 Feelings about CPAP prescription

Participants’ perceptions and reactions to being prescribed CPAP varied as some were very positive and others felt less enthusiastic. Those who had positive perceptions were more likely to accept and comply with CPAP than those who were not happy with being prescribed this therapy.

‘Erm ... what did I think to it. I thought er ... well it just made sense to me. I felt that if it could turn my life around then it would be of great help and I was so relieved and happy to be given the erm ... opportunity to ... opportunity to have this treatment... we were getting to the bottom of it and if it meant that I’ve gotta wear this mask for the rest of my life so be it ... if it’s gonna help me sleep then in the long run I’ll have a better life than what I have got.’ (PUC-179, male, newly diagnosed OSA patient)

‘I was very upset ... upset because I had to wear a mask, I didn’t like it but er ... it was something like a foreign ... foreign part in your body or something like er ... I brought it home and it took me I think about three four months before I could get used to it... it was reassuring to know that there’s a treatment but still a little bit apprehensive about what was going to go on.’ (PUC-092, female, newly diagnosed OSA patient)
Various barriers were identified including the idea of sleeping with a mask on, claustrophobia, bulky equipment and discomfort. A participant also raised the concept of self-image.

'I was expecting it to be very alien, erm ... very uncomfortable and, quite probably, claustrophobic. I thought it’d be like a big thing ... like a great big machine or something, and it was scary ... it is scary... I thought it might be noisy I really thought it’d be like Darth Vada.' (PUC-172, female, newly diagnosed OSA patient)

'It’s not very pleasant you know if you’re wanting the ... to cohabit er ... with your husband, erm ... it’s not very nice to have this piece of machinery ... er ... it takes away any spontaneity, if I can be very frank it takes away any er ... erm ... sexual activity during the evening ... ... er ... you know during the night if you roll over and er ... you’ve got this machine on it’s not very conducive to erm ... to ... cohabit with your husband (laughs).’ (PUC-012, female, established OSA patient)

3.3.6 Experiences of using CPAP

Participants who felt initially very positive about CPAP prescription continued to feel positive after trialling CPAP. Many described how life changing the therapy had been and would recommend it to others. In addition, they felt that their own quality of sleep and that of their spouse had also improved. Perceived benefits included the gradual alleviation of OSA related symptoms and feelings that their life was back on track.

'No, no negative er ... no negative, it was all positive obvious er ... obviously that it was going to help, er ... there ... there was no downside, it would be better for me, better for my partner, better for everyone.' (PUC-054, male, established OSA patient)
'It improved my life amazingly, unbelievably ... it made a big difference in my life my ... everything has improved in my whole body.’ (PUC-179, male, newly diagnosed OSA patient)

A few of the participants who were initially apprehensive of CPAP, felt surprisingly comfortable sleeping with it after trialling the therapy.

‘I was pleasantly surprised, when I spent the twenty to thirty minutes at the sleep clinic with it on, erm ... it ... it wasn’t as bad as what you know you ... you think it’s going to be, again it was that unknown part of it.’ (PUC-113, male, newly diagnosed OSA patient)

However a minority still struggled to make sense of the therapy and found it difficult to tolerate CPAP as certain barriers were central in preventing them from relaxing while using the apparatus.

‘I really couldn’t tolerate it ... think just the ... the alien-ness of actually having something on your face to breathe when you’re trying to go to sleep, you know, if you’re fidget sleeper where I lay on my side, I roll on my back, that it’s there erm ... it marks your face for the morning... it marks your face, you know because you have to have it on fairly tightly because the erm ... otherwise it would just roll around on your head er ... when you’re moving around er ... during your ... your pre-sleep or sleep, erm ... it’s very quiet so that’s one of the things I was concerned with er ... so that doesn’t disturb me, it’s just actually the physical fact that you’ve got something on your head.’ (PUC-012, female, established OSA patient)
‘Sometimes I take it off in my sort of ... not in my sleep but in my half sleep. Erm ... because er ... after four or five hours it does get uncom ... a little uncomfortable ... so I take it off and then of course I get noisy.’ (PUC-044, male, established OSA patient)

Participants made several attempts to overcome barriers by persevering with the therapy even though common problems including discomfort and air-leaking were occurring. Some would seek help at the drop-in clinic for further advice. When interviewees were asked what advice they would give to those who struggle to use their devices for more than four hours per night many suggested that perseverance would be the way forward.

‘They would have to persevere er ... several days or ... or weeks er ... with ... with it, erm ... when they’re first starting obviously the ... the nasal passages could be a little bit sore but erm ... er ... I would ask them to persevere with it because it is er ... er ... a hundred percent perfect, it’s just a matter of getting used to it.’ (PUC-054, male, established OSA patient)

Others recommended the usefulness of having patient groups for support and that knowing somebody with OSA would have been helpful.

‘I think peer pressure ... peer support would be fairly useful in the beginning.’ (PUC-012, female, established OSA patient).

Participants when asked about situations where they would deliberately avoid using CPAP therapy many did so in case of a severe cold or breathing problems.

‘The reason I wouldn’t use it is if I had a very bad cold and I couldn’t breathe and er ... you know sort of erm ... that that would be the reason why I couldn’t use it because I’d got a very bad nasal cold and I was sort of er ... congested in ... in the nose so I would
have to breathe through my mouth rather than the nose.’ (PUC-054, male, established OSA patient)

‘I only missed it for a couple of ... two or three times because I had a cold, I had er ... chest infection and which I couldn’t breathe, that’s the only time I missed it but otherwise I’m wearing it all the time’. (PUC-092, female, established OSA patient)

Overall participants understood the benefits of using CPAP therapy and described how the therapy has helped to alleviate OSA related symptoms.

‘If I use ... if I use the machine I’m perfect, you know more alert and alive and er ... that that sort ... you know things like that... then driving back from <port> to <city>, getting back at sort of two o'clock in the ... the early hours of the morning and er ... with ... with perfect you know awareness, not falling asleep or anything, so that’s how beneficial it was to me.’ (PUC-054, male, newly diagnosed OSA patient)

‘Now I feel I've got more and more energy now.’ (PUC-092, female, established OSA patient)

‘Even the kids have noticed ... that I’m ... I’m not so snappy and irritable and I get up in the morning now and I feel as though I’m ready to take the day on ... so it’s not a challenge anymore to want to get out and go to work, it’s er ... quite nice to wake up in a morning refreshed, batteries charged and ready to go.’ (PUC-113, male, newly diagnosed OSA patient)
Another typology that was explored was related to whether or not participants described support or lack of support from a spouse or partner in encouraging them to seek help. Well supported participants were generally more compliant to CPAP therapy than those who were not as well supported by their spouses.

‘My wife’s been very supportive ... very, very supportive... not just for my health but I think selfishly for hers as well (amused tone) so that she gets a good night’s sleep as well.’ (PUC-113, male, newly diagnosed OSA patient)

‘Oh he’s (husband) very supportive and he said whatever is right for your health is right and er ... you know, so no problems whatsoever.’ (PUC-172, female, newly diagnosed OSA patient)

An example of a deviant case that was identified when exploring the typology relating to support from spouses and partners was a participant who was well supported by his spouse to seek help however her reaction to noisy CPAP was acting as a barrier to using the therapy.

‘My wife does grumble about the ... the sort of hissing noise that comes out of it sometimes depending on the exact position of the mask on the face which can vary several times in the course of a night. She’s put up with me for six years... she is not a good sleeper, I’m a very good sleeper, erm ... nothing disturbs me, I mean the house would burn down but I’d still be sitting there, lying there and snoring.’(PUC-044, male, established OSA patient)
3.4 Discussion

This study was designed to explore people’s beliefs, views and perceptions of newly diagnosed and established OSA participants, in order to identify potential barriers to CPAP therapy. The results showed that a number of barriers can influence peoples’ attitudes towards CPAP therapy. The barriers cited by the participants can be grouped in four categories as shown below:

Pre-diagnosis related barriers

1) Barriers related to the lack of awareness of OSA in the participants and their social networks (partner/family/colleagues/friends) leading to delay in seeking help

2) Barriers related to the lack of knowledge from healthcare professionals and dissatisfaction with information available regarding the condition leading to delay in diagnosis (inability to recognise the symptoms, lack of publicity).

Pre and post CPAP prescription related barriers

3) Barriers related to the initial reactions to the idea of CPAP therapy

4) Barriers related to initial experiences of sleeping with a CPAP machine & mask (bulky equipment, discomfort, claustrophobia, inconvenience) and sharing a bedroom with a spouse.

3.4.1 Pre-diagnosis related barriers

Participants in this study emphasised their unawareness of OSA as a medical condition with many stating that they had not heard of OSA before being diagnosed. Prior to diagnosis, the majority of the participants were also unaware of their night time
symptoms including sleep disordered breathing. In most cases, the spouse played the leadin
g role in informing the participants of their loud snoring and how it progressively be
came worse, as well as observed episodes of stopping breathing during sleep. Many
of the participants described how loud snoring proved to be a social handicap leadin
to irritation by causing disturbed sleep (in the spouse and the participant) and marital
tensions. However, the spouses’ observations acted as a positive reinforcement for the
participants to seek sleep related help. In addition, knowing somebody (a friend and/or
colleague) who had been previously diagnosed with OSA or was aware of the condition
also encouraged participants to seek help. Another finding is that participants failed to
link daytime OSA-related symptoms including excessive daytime sleepiness, lack of
energy, fatigue and headaches to sleep related problems but attributed these symptoms
to other causes including (old age, stress, long working hours, diabetes etc).
Participants felt ashamed of their inability to control falling asleep and explained the
embarrassing social implications (sleeping in front of colleagues, during meetings) and
described their fear of falling asleep during driving. Participants were able to associate
excessive daytime sleepiness with depression and as a consequence erectile dysfunction
and decreased libido. Although, prior to diagnosis, participants were unable to link their
symptoms with sleep related problems, their level of understanding of OSA improved
after diagnosis.

Another finding is lack of knowledge among healthcare professionals and their failure
to recognise OSA related symptoms. Indeed, two of the interviewees were themselves
GPs and they failed to make a clear association between their symptoms and OSA. The
majority of the participants felt dissatisfied with the lack of adequate information and
available resources and they highlighted the need for a systematic approach to
increasing awareness of OSA.
3.4.2 Pre and post CPAP prescription related barriers

Participants’ initial reaction to the idea of CPAP and their initial experiences of using the therapy proved to be a key factor in predicting CPAP use. In particular, those participants who made positive associations of CPAP therapy (comfortable, not inconvenient to use) and perceived the therapy to be effective in improving their quality of life by alleviating their OSA symptoms were more likely to comply with the therapy. On the contrary, those who found the therapy problematic during early stages of the treatment and identified many barriers to using CPAP, were not able to identify many benefits of using the therapy or continue using CPAP when experiencing common problems. A few participants required more time to assimilate the information of having OSA and using a CPAP machine. On the other hand, those participants well supported by their spouse and social network were more likely to use CPAP therapy than those who were less supported.

3.4.3 Comparison with existing literature

Prior to carrying out this qualitative study, no similar studies had been identified, suggesting an important gap in the literature. Recently, however, three relevant papers have been published. Our findings are consistent with the findings of these studies, conducted by Sawyer A et al\textsuperscript{139} Broström AM et al\textsuperscript{140} and Shoukry G et al.\textsuperscript{141} Sawyer A et al\textsuperscript{139} conducted a mixed methods study that included telephone interviews to explore 15 OSA patients’ beliefs and perceptions of the diagnosis and CPAP treatment that differentiate between adherent and non adherent patients before and after the first week of treatment. The authors reported that the experience and perception of symptoms contributed to the participants’ motivation to seek diagnosis and treatment and to
adhere to CPAP therapy. The authors showed that social support (spouse, family, friend, colleague) was also an important facilitator of CPAP use among adherent patients and those who were well supported were more likely to comply with CPAP and persevere with using the therapy despite experiencing common problems. The authors reported that common barriers to CPAP therapy included wearing a mask, self-image issues and inconvenience. Broström AM et al conducted telephone interviews in 20 untreated patients with OSA to explore how they perceived their sleep situation and how the condition affected their life. The authors reported that some of their participants’ were able to describe a few OSA related symptoms, and that snoring and excessive daytime sleepiness were identified as a social handicap causing embarrassment and marital problems. In addition, the authors also reported that their participants described a great need for adequate information and effective treatment. Shoukry G et al conducted semi-structured interviews in 20 participants to explore the unique experiences of people with OSA who seek treatment through community pharmacies. The authors reported lack of adequate information from healthcare professionals to satisfy the participants’ needs. Personal health beliefs, coping strategies and social support were reported to be the most influential factors predicting CPAP compliance. The qualitative study we report adds to these three reports as it was designed to capture perceptions and views of newly diagnosed and established OSA individuals during different stages (before diagnosis/after diagnosis and post CPAP treatment) to explore potential changes in accepting and using CPAP therapy. This is the first study in the UK that explored perceptions on OSA and CPAP therapy in newly diagnosed and established OSA participants in the secondary health care settings. The data from our findings therefore contribute to the understanding of barriers and their
impact on CPAP compliance and identify a need to educate patients and healthcare practitioners alike.

3.4.4 Strengths and limitations

This study has several strengths including good methodological rigour. To increase reliability two researchers were involved in this study from the development of the interview topic guide to the data analysis. All the interviews were conducted by the same researcher, transcribed by a professional transcriber and checked by the interviewer to minimise the risk of inaccuracy. The use of Framework analysis facilitated systematic analysis; furthermore, utilising the NVivo 7 analysis package allowed instant and rigorous comparisons between the raw data and the final categories developed in the thematic framework. A systematic and thorough approach was adopted for the interpretation of results, including comparisons between people in different categories within a typology.

One limitation of this study is the small size of the sample, although it was considered that after recruitment of 9 participants saturation had been broadly reached in terms of the emergence of new ideas. Moreover, this did limit the scope for additional purposive sampling based on obtaining additional data from people who might be similar to any deviant cases identified, and from people in different demographic groups. Those recruited included predominantly male, white European, middle-aged participants. Replicating this study in a more heterogeneous cohort would be useful for exploring potential differences between ethnic populations age ranges and genders, in terms of understanding of OSA and how beliefs about the condition and its treatment may influence CPAP use.
3.4.5 Application of findings

This study identified a number of common barriers to compliance with CPAP therapy (Table 3-3). These findings were used to inform the development of a patient centred education curriculum aiming to increase CPAP compliance by overcoming barriers identified by this study (Table 3-3).

Table 3-3: Identified barriers

| → Inability to recognise symptoms and link them with being diagnosed with OSA. (Although this finding may be more relevant as a barrier to seeking help it also applies to the poor understanding of the symptoms and using CPAP therapy) |
| → Initial reactions to the idea of CPAP and initial experiences of using CPAP therapy |
| → Discomfort and inconvenience caused when wearing a mask and operating a CPAP machine (marking of the face, noisy and bulky equipment, claustrophobia, removing the CPAP mask during the night without being aware, demanding cleaning routine). |
| → Inability to experience improvement and alleviation of OSA related symptoms after CPAP therapy. |
| → Self-image issues and spontaneity in sexual activity |
| → Lack of support from bed-partner |
| → Not having peer support (support from fellow- CPAP users) and feeling low. |

These findings were used to develop an educational programme following the MRC guidance on developing complex interventions (Chapter 5). To help participants to recognise perceived symptoms and link these with being diagnosed with OSA, an education component of the curriculum was developed dedicated to the exploration of symptoms and how these may affect people with OSA. To address initial reactions and negative thoughts about CPAP therapy (discomfort and barriers related to wearing a mask and operating a CPAP machine) a session was developed utilising non-didactic approaches to facilitate discussion among participants and find out how they can
overcome their fears/troubles and learn how to trouble shoot common problems. To help participants to explore how CPAP therapy may benefit their OSA related symptoms or delay the development of long term complications, a session was developed to allow exploration of this topic. To help participants overcome barriers related to self-image and sexual relationships another session was developed to facilitate discussion among the participants to explore their feelings and thoughts on this subject. To address the importance of the bed-partners’ support, we have asked participants to bring their partner (if applicable) to the education session, and we have developed a section to discuss their influential role in providing support. In addition, another section of the curriculum explores participants’ feelings and thoughts about living with OSA and sleeping with a CPAP machine. Participants are also signposted to local services that offer peer support and advice. Finally, participants with the aid of appropriate resources are encouraged to create action plans and increase their hours of CPAP use.

3.5 Conclusions

This is the first study in the UK that explored peoples’ beliefs, views, opinions and preferences around CPAP therapy from seeking help to treatment and highlighted barriers influencing compliance with CPAP in a group of newly diagnosed and established OSA patients. The findings have informed the development of an education curriculum described in Chapter 5. This educational intervention aims to alter patients’ behaviour and facilitate lifestyle changes in order to improve CPAP compliance by overcoming the identified barriers. Additionally, our findings may be useful for informing the development of health policy guidelines aimed at increasing awareness of
OSA. They suggest, for example, that information and publicity materials should be
aimed not only at the potential OSA patients but should also target their spouses as they
are the ‘front line’ in identifying OSA breathing and reporting their observations to the
person displaying these symptoms.
Chapter 4

The impact of diet and lifestyle management strategies for obstructive sleep apnoea in adults: A systematic review and meta-analysis of randomised controlled trials
4.0 Chapter overview

Chapter 4 presents a systematic review and meta-analysis which was conducted to evaluate the impact of diet, exercise and lifestyle modification programmes on indices of obesity, OSA parameters and quality of life in adults with OSA.

The author of this thesis, MAT, performed the following activities in relation to this study:

- Developed the protocol and search strategy
- Ran the searches, retrieved the abstracts and full text articles
- Responsible for the inclusion/exclusion of studies
- Developed the data extraction form
- Carried out data extraction and quality assessed each study
- Prepared the data into an xsl format suitable for meta-analysis
- Interpreted the data

The above activities were performed under the supervision of MJD, KK, EMB, APH and SS. EMB is the second reviewer of this study and was heavily involved in every step of this review. Statistical analysis and meta-analysis was conducted by LJG and DHM.

The findings of this chapter were published in the Sleep and Breathing Journal.

4.1 Introduction

The prevalence of Obstructive Sleep Apnoea (OSA) is currently estimated to be about 2 to 7% in middle-aged adults in the general population.\(^2\) Central obesity plays the leading role in the development and severity of chronic conditions including OSA.
Approximately, 70% of OSA subjects are obese and the incidence of OSA in obese men and women is estimated to be 40%. Left untreated, mild OSA has a natural rapid progression to a moderate and/or severe state. Risk factors for OSA include male gender, middle age, ethnicity, with obesity being the most important modifiable risk factor. In 2000, Peppard et al reported that a weight gain of 10% (n=39) was associated with a 32% increase in the disease severity index (Apnoea-Hypopnoea Index - AHI) while a 10% weight loss (n=17) resulted in an AHI reduction of 26%. OSA is recognized as an independent risk factor for cardiovascular disease (CVD), hypertension and Type 2 Diabetes Mellitus (T2DM). OSA and T2DM often coexist as both conditions share common risk factors including central obesity. The prevalence of undiagnosed OSA among obese diabetic patients is reported to be 86.6% whilst prevalence of diabetes among patients with OSA is 40%. As the epidemic of obesity increases worldwide, the prevalence of OSA is expected to increase further resulting in increased direct healthcare costs, associated additional societal costs relating to co-morbid conditions, absenteeism and accidents.

Continuous positive airway pressure (CPAP) therapy is the ‘gold standard’ treatment for OSA. Although the effectiveness of CPAP in ameliorating OSA related symptoms, improving insulin sensitivity, reducing hypertension and improving quality of life is evident in the literature, it is not a curative therapy and its efficacy relies on long term compliance which remains a major challenge. Lifestyle modification interventions promoting physical activity and weight loss are actively encouraged in obese OSA subjects and are recommended by expert panels. However, the evidence to date of the effectiveness of lifestyle modification interventions with and without CPAP therapy from randomised controlled trials are conflicting. A number of randomised trials have been conducted investigating the impact of
intensive lifestyle modification intervention programmes in obese OSA subjects\textsuperscript{69,84, 155} which demonstrated weight loss can be sustained for 12 and 24 months post intervention without additional support and further costs.\textsuperscript{158} In contrast, a review assessing the impact of lifestyle modification interventions failed to identify associations between lifestyle management interventions and improved OSA parameters due to a lack of randomised controlled trials.\textsuperscript{117} A systematic review and meta-analysis of both randomised and observational studies in obese OSA participants found a significant reduction in both BMI and AHI following weight loss with a dietary intervention.\textsuperscript{159} A literature review comparing surgical and non-surgical interventions also showed reductions in BMI and AHI for the diet and lifestyle interventions.\textsuperscript{160} To consolidate the evidence in this area we conducted a systematic review and meta-analysis of randomised controlled trials aiming to evaluate the impact of weight loss through diet and lifestyle modification interventions with and without CPAP therapy on obesity indices (including BMI, weight, waist circumference), OSA parameters (AHI, ODI\textsubscript{4},) and quality of life (QoL) in adults with OSA.

4.2 Methods

4.2.1 Literature search

This systematic review and meta-analysis was conducted in accordance to the ‘Preferred Reporting Items for Systematic reviews and Meta-Analyses’ PRISMA guidelines.\textsuperscript{161} The development of the systematic review protocol and search strategy was a collaborative approach between members of our research team and the university librarian (Appendix 4). The search syntax coined three main MeSH terms including obstructive sleep apnoea (OSA), lifestyle (diet and/or physical exertion) and
randomised controlled trials. Detailed individual search strategies for each of the following bibliographic databases were developed: OVIDSP Medline (1996 to October 2012), OVIDSP Embase (1996 to October 2012) the Cumulative Index to Nursing and Allied Health Literature-CINAHL (from inception to October 2012) and the Cochrane library including CENTRAL, CDSR and DARE databases (from inception to October 2012). Expert opinions were sought and reference lists from eligible studies and review articles were cross-examined to identify relevant studies.

**4.2.2 Study selection and inclusion criteria**

Randomised controlled trials with an intervention based on dietary weight loss, exercise and/or lifestyle programme of at least 2 month follow-up in adult subjects (≥18 years of age) with OSA and a disease severity index of an AHI≥5 were eligible for inclusion. A language restriction was applied and only studies in the English language which met the inclusion criteria were considered in this review. Studies prescribing CPAP therapy to their participants in addition to diet and lifestyle intervention were also included. Pilot studies were excluded from this review.

One reviewer performed the electronic searches (MAT) and two reviewers (MAT and EMB) independently screened titles and abstracts as well as citations retrieved by the electronic searches to assess eligibility. Following retrieval and scrutiny of full text articles, both reviewers independently assessed studies for inclusion based on the criteria for participants, intervention, comparator, outcomes and study design. We resolved disagreement by assigning a panel of three independent reviewers (KK, MJD and APH).
4.2.3 Data extraction and synthesis

Data was extracted independently by two reviewers (MAT and EMB) from those identified as eligible utilising a pre-tested data extraction form specifically designed to capture details of study design, participant characteristics, diet/lifestyle interventions and outcome measures. Upon completion of the data extraction one reviewer (MAT) checked for data reliability and any disagreement was resolved by discussion with the second reviewer (EMB).

4.2.4 Validity assessment

Study quality was assessed independently by two reviewers (MAT and EMB) utilizing the Jadad scale. The main quality criteria of interest were whether an adequate method of randomisation, blinding and flow of participants had been reported or not throughout the study. We assigned a maximum score of two points for each of the three main criteria if found to be adequate and allowed a score from zero to six (six indicating the highest quality).

4.2.5 Statistical Methods

Meta-analyses were carried out of studies comparing similar interventions (i) diet weight loss programme or advice to reduce weight versus a diet plus CPAP therapy and (ii) intensive lifestyle intervention programme (specific weight loss and/or exercise plan) versus routine care (based on dietary and/or exercise advice only) comparisons. The primary outcome was weight loss (kg) and secondary outcomes included AHI, ODI₄, BMI, waist circumference, ESS and QoL. Continuous outcomes were reported in
a variety of ways either as the mean change and standard deviation per arm from baseline to follow-up or the final absolute mean and standard deviation per arm, the differences between these were assumed to be equal. Data were pooled using a random effect model to account for statistical heterogeneity between studies. The Weight Mean Difference (WMD) statistic and 95% confidence intervals were calculated. Heterogeneity was assessed with the chi-squared ($\chi^2$) test and variation between studies attributable to heterogeneity was calculated using the $I^2$ statistic. We predefined heterogeneity ($I^2=0\%$ for no heterogeneity, $I^2=25\%$ for low, $I^2=50\%$ for medium and $I^2 \geq 75\%$ for high).\textsuperscript{163} Significance was set at $p<0.05$ and 95% confidence intervals are indicated throughout. The data were analysed with Stata (StataCorp. 2007. \textit{Stata Statistical Software: Release 10}. College Station, TX: StataCorp LP.)

4.3 Results

4.3.1 Search results

Figure 4-1 summarises the results of the search. 765 articles were identified of which only eighteen articles investigated the impact of diet, exercise and lifestyle management strategies on OSA subjects. Three studies were excluded due to a non-randomised design.\textsuperscript{164-166} One study included participants with Sleep Related Breathing Disorders (SRBD) who underwent surgical treatments\textsuperscript{167} one involved oral appliances\textsuperscript{168} and another was a pilot study.\textsuperscript{79} Consequently these were excluded.\textsuperscript{79, 164-168} Twelve eligible studies satisfying all the inclusion criteria for the systematic review were identified\textsuperscript{76-78, 80-157} with one study\textsuperscript{157} publishing ESS and QoL results in a second publication.\textsuperscript{169}
Figure 4-1: Flow diagram of study selection

The baseline characteristics of these studies are shown in Table 4-1.
<table>
<thead>
<tr>
<th>Study details</th>
<th>Final Sample Size</th>
<th>Age</th>
<th>Intervention</th>
<th>OSA Diagnostic Test</th>
<th>OSA Severity Index [AHI/ODI]</th>
<th>Body Mass Index [BMI: Kg/m²]</th>
<th>ESS</th>
<th>QoL</th>
<th>NHP Sleep</th>
<th>Treatment Duration (months)</th>
<th>Jadad Quality Score</th>
<th>Included in meta-analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ballester E</td>
<td>105 men and women</td>
<td>53 ± 10</td>
<td>Conservative treatment + CPAP (Sleep hygiene &amp; weight loss programme, home diet prescribed by a dietician)</td>
<td>Partially attended Night Time Respiratory Recording [NTRR].</td>
<td>Severe Whole group 56 ± 20 AHI (mean ±SEM)</td>
<td>Whole group 32 ± 6 (mean ±SEM)</td>
<td>Whole group 12 ± 5 (mean ±SEM)</td>
<td>NHP Sleep Whole group 26.6 ± 3.5 (mean ±SEM)</td>
<td>3</td>
<td>4</td>
<td>√</td>
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<tr>
<td>Monasterio C</td>
<td>125 men and women</td>
<td>54 ± 9</td>
<td>Conservative measures + CPAP (Weight loss programme following a home diet, avoidance of sedatives and alcohol consumption, avoidance of supine position during sleep and adequate hours of sleep)</td>
<td>Versus: Conservative treatment only</td>
<td>Moderate Whole group 20 ± 6 AHI (mean ± SD)</td>
<td>Whole group 12.6 ± 4.6 (mean ± SD)</td>
<td>NHP: Whole group 20.5 ± 18 (mean ± SD)</td>
<td>6</td>
<td>3</td>
<td>√</td>
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<tr>
<td>Kajaste S</td>
<td>31 men</td>
<td>49.1 ± 7.9</td>
<td>Weight reduction strategy + CPAP (Individualised CBT approach and dietary counseling)</td>
<td>Versus: CBT, and dietary counseling.</td>
<td>Moderate Whole group 20 ± 6 AHI (mean ± SD)</td>
<td>Whole group 43.8 ± 5.4 (mean ± SD)</td>
<td>Not assessed via NHP</td>
<td>24</td>
<td>3</td>
<td>√</td>
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<tr>
<td>Foster GD</td>
<td>264 men and women</td>
<td>61.2 ± 6.5</td>
<td>Intensive lifestyle intervention (Group weight loss programme based on low calorie diet and physical activity prescription of 175 min/wk of moderate, developed specifically for obese T2DM patients)</td>
<td>Versus: 3 group diabetes support education sessions focused on diet, physical</td>
<td>Unattended PSG Moderate Whole group 23.2 ± 16.5 AHI (mean ± SD)</td>
<td>Whole group 36.7 ± 5.7 (mean ± SD)</td>
<td>Not assessed</td>
<td>12</td>
<td>5</td>
<td>√</td>
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<tr>
<td>Study</td>
<td>Country</td>
<td>Sex</td>
<td>Mean Age (±SD)</td>
<td>Intervention Description</td>
<td>Comparison Group</td>
<td>AHI Mean (±SD)</td>
<td>Study Design</td>
<td>Notes</td>
<td></td>
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<tr>
<td>Tuomilehto HP</td>
<td>Finland</td>
<td>Men/Women</td>
<td>50.9 ± 8.6 (mean ± SD)</td>
<td><strong>Lifestyle intervention</strong> (Individual tailored counseling weight reduction programme—with emphasis placed on diet, exercise and modification of lifestyle focusing on eating behaviour) <strong>Versus:</strong> 1 dietary and exercise counseling session</td>
<td>Embletta.</td>
<td>Mild: Whole group 9.65 ± 12 AHI (mean ± SD)</td>
<td>Interventio</td>
<td>10.9 ± 9.8 (mean ± SD)</td>
<td>Not assessed via NHP</td>
<td>12 4 □√</td>
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<tr>
<td>Kemppainen T</td>
<td>Finland</td>
<td>Men/Women</td>
<td>51 ± 8.3 (mean ± SD)</td>
<td><strong>Lifestyle intervention</strong> (Individual tailored counseling and weight reduction programme with emphasis on diet, exercise and lifestyle modification focusing on eating behaviour.) <strong>Versus:</strong> 1 dietary and exercise counseling session</td>
<td>Embletta.</td>
<td>Mild: Whole group 10.1 ± 6.3 AHI (mean ± SD)</td>
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<td></td>
<td>Not assessed via NHP</td>
<td>3 2 □√</td>
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<tr>
<td>Papandreou C</td>
<td>Greece</td>
<td>Men/Women</td>
<td>48.1 ± 12.4 (mean ± SD)</td>
<td><strong>Intensive lifestyle intervention</strong> (Individualised weight reduction programme based on a low calorie Mediterranean diet and physical activity prescription of at least 30 min/day, developed specifically for obese OSA patients who were under CPAP treatment.) <strong>Versus:</strong> Individualised weight reduction programme based on a low calorie prudent diet and physical activity prescription of at least 30 min/day, developed</td>
<td>PSG</td>
<td>Severe: Whole group 46.2 ± 32.7 AHI (mean ± SD)</td>
<td></td>
<td></td>
<td>Not assessed via NHP</td>
<td>6 4 □√</td>
<td></td>
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</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Gender</td>
<td>Sample Size</td>
<td>Mean ± SD (±SE)</td>
<td>Treatment Details</td>
<td>Control Group</td>
<td>AHI (Mean ± SD)</td>
<td>NHP Assessment</td>
<td></td>
<td></td>
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<tr>
<td>Kline C</td>
<td>USA</td>
<td>Men and women</td>
<td>43</td>
<td>46.9 ± 1.2 (±SE)</td>
<td>Intensive lifestyle intervention (Group exercise training based on 150 min/week of moderate intensity aerobic activity followed by resistance training twice/week)</td>
<td>Versus:Stretching exercises</td>
<td>Moderate 28.3 ± 5.6</td>
<td>Not assessed via NHP</td>
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<tr>
<td>Ackel-D’Elia C</td>
<td>Brazil</td>
<td>Men</td>
<td>32</td>
<td>48.9 ± 8.45 (±SD)</td>
<td>Intensive lifestyle intervention (2 month supervised aerobic exercise three times/week + CPAP therapy)</td>
<td>Versus:CPAP therapy only</td>
<td>Moderate &gt;15 AHI</td>
<td>Not assessed via NHP</td>
<td></td>
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</tr>
<tr>
<td>Sengul Y</td>
<td>Turkey</td>
<td>Men</td>
<td>20</td>
<td>51.2 ± 7 (±SD)</td>
<td>Exercise training programme (Breathing and aerobic exercises)</td>
<td>Versus:No treatment</td>
<td>Moderate 16.5 ± 5.94</td>
<td>Not assessed via NHP</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Stradling J</td>
<td>UK</td>
<td>Men and women</td>
<td>≥18</td>
<td>≥18, (Adults, the authors do not provide this information)</td>
<td>Intervention Arm 1: Dietary advice and hypnotherapy type 1 (with emphasis on ego strengthening centred on stress reduction)</td>
<td>Intervention Arm 2: Dietary advice and hypnotherapy type 2( with emphasis on ego strengthening centred on altering attitudes to food using the Spiegel and Spiegel approach)</td>
<td>Not stated</td>
<td>Not assessed via NHP</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

* Data obtained from Kline 2012

**Data from: Kline C, 2011; Ackel-D’Elia C, 2012; Sengul Y, 2009; Stradling J, 1997**
| Johansson K | 63 men | 49 ± 7.3 (mean ±SD) |
| 2009 | Sweden |

**Versus:** Dietary advice on two occasions only.

**Weight loss programme** (Very low energy diet using a standard 2.3 MJ/day liquid energy intake protocol—Cambridge diet)

**Versus:** Usual diet.

Two consecutive unattended sleep studies using a six channel ambulatory polygraphy equipment.

**Severe**

| Whole group | 37 ± 15 AHI (mean ±SD) |
| Whole group | 34.6 ± 2.9 (mean ±SD) |
| Whole group | 8 ± 5 (mean ±SD) |
| Not assessed | 2.25 |

ODI: Oxygen Desaturation Index, (The number of oxygen desaturation events per hour of sleep exceeding 4% from the baseline)

ESS: Epworth Sleepiness Scale questionnaire

NHP: Nottingham Health Profile, NHP Sleep: Nottingham Health Profile –domain: Sleep
4.3.2 Intervention programmes

Three studies compared a diet programme with diet plus CPAP therapy.\textsuperscript{76-78} Another six studies compared intensive lifestyle modification interventions which prescribed a specific dietary and/or exercise programme with routine care which included dietary and/or exercise advice only.\textsuperscript{69,82,84,155-157} One study compared a very low calorie diet with usual diet,\textsuperscript{83} one study compared an exercise training programme based on breathing and aerobic exercises\textsuperscript{81} the final study compared a dietary advice programme with three different hypnotherapy options as a mean of weight loss.\textsuperscript{80} All twelve studies employed multidisciplinary teams of highly trained staff to deliver the intervention programmes. All included regular follow-up appointments and assessments with the study participants. The length of diet, exercise and lifestyle interventions ranged from 2 to 18 months.

4.3.3 Study quality and publication bias

None of the studies met all the criteria of the quality assessment tool with all papers missing a full score for blinding. In addition, we identified one study in which the authors reported intention to treat analysis\textsuperscript{77} however, this was compromised as the lost to follow-up participants were not included in the analysis and subsequently it only gained a single score on the flow of participants criterion. Publication bias was not assessed in this meta-analysis due to the small number of studies.
4.3.4 Diet programmes with diet plus CPAP therapy systematic review results

Table 4-1(i) shows the study characteristics for the three European studies comparing diet programmes with diet plus CPAP (n=261).\(^{76-78}\) The sample sizes ranged from 31 to 125, the mean participant age from 49 to 54 years and the mean BMI across the studies ranged from 29 to 43.8 kg/m\(^2\). Weight (kg) was available in two studies only. The AHI was employed as the OSA severity index in two studies\(^{76,77}\) that was measured objectively by the in-built CPAP smart card reader with the 4% Oxygen desaturation index (ODI\(_4\)) reported in one study.\(^{78}\) The cut-off points for AHI severity were set as mild=5-14 events/hour, moderate=15-29 events/hour and severe \(\geq\)30 events/hour. Daytime sleepiness using the Epworth Sleepiness Scale (ESS) was measured in two studies and quality of life was measured in two studies using the Nottingham Health Profile (NHP) questionnaire.

Ballester and colleagues\(^ {76}\) randomised 105 consecutive subjects with severe OSA (AHI=56±20 events/hour) to receive an intervention combining conservative measures including a weight loss diet plan plus CPAP (n=68) whilst the remaining subjects (n=37) were allocated to the control group and were treated with conservative measures only. At baseline, age, gender, BMI, AHI and OSA related symptoms did not significantly differ between groups. The mean prescription of CPAP was 9.1±2 cmH\(_2\)O and adequate compliance of 4.5 hours/night was achieved by 73% of subjects. The mean average nightly use was reported to be 5.2±2 hours. A greater relief of sleepiness and other OSA related symptoms was reported at 3 months post-intervention in those subjects receiving the conservative measures plus CPAP (78% of participants) when compared to those receiving conservative measures only (37% of participants). The odds ratio of experiencing a treatment effect when receiving a diet plus CPAP
compared with diet only was 6.52 (95% Confidence Interval (CI) 2.51 to 17.6) based on the ESS, Sleep Apnoea Hypopnoea (SAHS) related symptoms questionnaire and the energy domain from the NHP questionnaire. However, the weight loss achieved by the intervention group was only 1.1 kg compared to 3.1 kg (p<0.05) of weight loss achieved by the control group. The authors attributed this finding with the low motivation levels of OSA subjects to reduce their body weight as they benefited from CPAP therapy. A greater well-being and comfort of patients was observed in the conservative measures plus CPAP group supporting CPAP as the treatment of choice for moderate to severe OSA. This study supports the effectiveness of CPAP in treating symptomatic subjects with severe OSA. The authors highlight the non-curative modality of CPAP therapy while emphasizing the need to redirect focus on conservative measures including sleep hygiene and weight loss.

Monasterio and colleagues\textsuperscript{77} conducted a study of similar design to Ballester.\textsuperscript{76} 142 consecutive subjects with an AHI of 10-30 (events/hour) were randomised to receive an intervention based on conservative treatment including a weight loss diet plan plus CPAP (n=77) whilst the remaining 65 subjects formed the control group and were treated with conservative treatment only.\textsuperscript{77} At baseline, age, gender, BMI, AHI and OSA related symptoms did not significantly differ between groups. The mean prescription of CPAP was 7±1.7 cmH\textsubscript{2}O. The mean average nightly use was reported to be 4.8±2.2 hours at 6 months. The authors similarly reported greater improvements in OSA related clinical symptoms post 3 and 6 months intervention in the group receiving CPAP therapy compared to subjects receiving conservative treatment only. The overall weight loss reported at 6 months was 2.7± 4.3 kg in the control group and no significant change in weight (+0.1±3.4 kg) was observed in subjects receiving conservative
treatment plus CPAP (p<0.001). Similar, Monasterio and colleagues\textsuperscript{77} explained this effect on the lack of motivation of OSA individuals to reduce their body weight since they benefited from CPAP therapy. The reduction in AHI from baseline reported at 6 months was significantly greater in the intervention group (AHI 14±2 events/hour) compared with the control group (AHI 4±4 events/hour). However, the authors reported a significant improvement in SAHS directly related symptoms suggesting a potential role of CPAP in treating mild OSA patients on the basis of a beneficial effect on symptoms.

Kajaste S and colleagues\textsuperscript{78} randomised 30 obese male symptomatic OSA subjects (mean BMI 43.8±5.4 kg/m\textsuperscript{2}) to receive a two-year very low calorie diet (VLCD) and a cognitive behavioural therapy (CBT) weight reduction programme (n=14) or an intervention which combined a VLCD, CBT with the addition of CPAP therapy (n=17) for the first 6 months. The mean pressure level was 13 (range 7.5-18.5) cmH\textsubscript{2}O however the authors reported that objective compliance could not be documented. At baseline, age, BMI, weight and ODI\textsubscript{4} did not significantly differ between groups. The mean weight loss reported was 19.1±10.2 kg (14% of the original weight) for the whole group at 6 months, 18.3 ± 13.2 kg at 12 months and 12.6 ± 4.7kg at 24 months. The addition of CPAP therapy for the first 6 months of the programme did not result in greater weight loss at any time point. The mean difference in ODI\textsubscript{4} between the two groups were not significant from baseline to 6 months however the authors reported a correlation in the increase and decrease of the ODI\textsubscript{4} in relation to the weight change (13±2 kg). The addition of CPAP was not associated with the improvement in ODI\textsubscript{4}. The authors report that these results support previous work conducted by Lojander et al.
This study supports the implementation of active weight loss programmes and control of weight when treating obese OSA patients.

4.3.5 Diet programmes with diet plus CPAP therapy meta-analyses results

Meta analyses were conducted for the three identified studies\textsuperscript{76-78} and the pooled results are shown in Table 4-2(i). A significant reduction in weight of -2.64 kg was observed in subjects receiving the diet plus CPAP intervention compared to the control which received diet only. No heterogeneity was observed for this group ($I^2 =0\%$, $p =0.657$). A non clinically significant reduction was observed for BMI (-0.18 kg/m\textsuperscript{2} between groups). There was a significant reduction in ESS score of -3.19 points in the intervention group compared with the control however, a high level for heterogeneity was observed for this outcome ($I^2 = 82.7\%$, $p=0.016$). No significant improvement in quality of life was seen in those receiving the intervention.

| Table 4-2: Meta-analysis results (i) diet + CPAP (ii) intensive lifestyle interventions |
|-------------------------------------|-----------------|-------------------|-----------------|-----------------|
| Comparison                          | No of studies   | Cases/non cases   | Pooled WMD (95% CI) | Heterogeneity (I\textsuperscript{2} %) value | p       |
| (i)                                 |                 |                  |                  |                  |         |
| Weight (kg)                         | 3\textsuperscript{76,77,78} | 151/110           | -2.64 (-3.98 to -1.30) | 0%          | 0.657   |
| BMI (kg/m\textsuperscript{2})       | 2\textsuperscript{77,78} | 83/73             | -0.18 (-3.62 to -3.27) | 57.4%      | 0.126   |
| ESS                                 | 2\textsuperscript{77,78} | 134/96            | -3.20 (-6.62 to 0.23) | 82.7%      | 0.016   |
| QoL                                 | 2\textsuperscript{76,77} | 134/96            | -0.93 (-5.93 to 4.06) | 0%         | 0.481   |
| (ii)                                |                 |                  |                  |                  |         |
| Weight (kg)                         | 4\textsuperscript{69,84,156,157} | 198/202           | -5.65 (-10.91 to -0.40) | 95.7%      | 0.0001  |
| Waist circumference (cm)            | 4\textsuperscript{69,84,156,157} | 198/202           | -5.80 (-8.64 to -2.96) | 77.7%      | 0.001   |
| BMI (kg/m\textsuperscript{2})       | 3\textsuperscript{69,82,156} | 171/186           | -2.33 (-3.41 to -1.24) | 78.8%      | 0.003   |
| AHI (events/hour)                   | 6\textsuperscript{69,82,84,155-157} | 262/292           | -4.55 (-7.12 to -1.98) | 54.4%      | 0.041   |
| ESS                                 | 2\textsuperscript{84,157} | 62/52             | -0.31 (-2.03 to -1.40) | 33.5%      | 0.220   |
4.3.6 Intensive lifestyle intervention programmes with usual care systematic review results

Table 4-1(ii) shows the study characteristics of the six studies that compared intensive lifestyle intervention programmes with usual care (n=483). Two were conducted in Finland,\textsuperscript{82,84} two in USA\textsuperscript{69,157} one in Brazil\textsuperscript{155} and one in Greece.\textsuperscript{156} The mean sample size ranged from 21 to 264, mean participant age ranged from 46.9 to 61 years and BMI from 28.2 to 36.7 kg/m\textsuperscript{2}). Weight (kg) was available in four studies only.\textsuperscript{69,84,156,156} The AHI was used to measure OSA severity in all six studies that was measured objectively by the in-built CPAP smart card reader with two studies also reporting the 4\% Oxygen desaturation index (ODI\textsubscript{4}).\textsuperscript{69,169} Daytime sleepiness measured using the ESS was reported in two studies only.\textsuperscript{84,169}

Foster and colleagues\textsuperscript{69} recruited 264 obese (mean BMI 36.7 ±5.7 kg/m\textsuperscript{2}) subjects with type 2 diabetes mellitus (T2DM) and moderate OSA (mean AHI 23.2 ± 16.5 events/hour). The intervention group (n=125) received a 12 month intensive lifestyle modification programme (ILI) based on a LCD and moderate physical activity (175 min/week). The control group (n=139) attended three diabetes support education (DSE) sessions focused on diet, physical activity and social support over one year. The authors do not provide information regarding the prescription or mean compliance of CPAP therapy. Subjects using CPAP were asked to refrain from using their devices 72 hours prior to formal assessments. A greater weight loss of -10.8 kg was observed in the ILI group post one year intervention when compared to the weight loss of 0.6 kg achieved by the control group (p<0.001). Moreover, while a reduction in the AHI was reported in the ILI group, among the DSE group the AHI increased from 23.5±15.0 events/hour to 28.3±20.7 events/hour (p<0.01). The ILI treatment was associated with an adjusted
mean decrease in the AHI of 9.7 events/hour (95% CI, -13.6 to -5.7 p<0.001). Furthermore, weight loss resulted in clinically significant changes in OSA categories over 1 year. The authors report the remission of OSA at 1 year was 3 times more common in the ILI group (13.6%, n=14) than in the control group (3.5%, n=4), (10.8 kg v 0.6 kg , p<0.001). In the DSE group the percentage of participants who had severe OSA at 1 year was more than twice as great (18.4%, n=21) than in the ILI group (37.9%, n=39). More than twice as many ILI participants showed improvement in their OSA category over 1 year. The authors reported that greater levels of AHI at baseline were associated with greater decreases in AHI over 1 year and these results support previous work by Tuomilehto.\textsuperscript{34} This study showed that weight reduction via an intensive lifestyle intervention significantly improved OSA among obese T2DM subjects. This treatment effect was greater in male subjects, with severe OSA and in those who lost the most weight.

Tuomilehto and colleagues\textsuperscript{84} randomised 71 consecutive subjects with mild OSA and a BMI of 28 to 40 kg/m\textsuperscript{2}. The intervention group (n=35) received a VLCD programme with supervised lifestyle modification and the control group (n=36) received routine lifestyle counseling on three occasions over one year. At baseline and despite randomisation BMI, weight and weight circumference were significantly higher in the intervention group. No subject was prescribed CPAP therapy. The mean change in weight post 1 year intervention was -10.7 kg in the intervention group and -2.4kg in the control group (p<0.001). The authors reported that in the intervention group a 40% reduction in AHI was achieved from baseline and 2 of every 3 subjects achieved an AHI ≤5 events/hour. 61% of subjects in the intervention group (n=22) and 32% in the control group (n=12) achieved an AHI<5 events/hour (p=0.019). This change was
found to be maintained one year post intervention. The adjusted odds ratio for having mild OSA at 1 year was 0.24 (95% CI, 0.08-0.72, p=0.011) in the intervention group as compared with the control group. Changes in AHI during the 12 month follow-up were associated with changes in weight and waist circumference. A weight reduction of 5kg from initial body weight was associated with a reduction in AHI of 2 events/hour (95% CI, 1.1 to 3.0). In addition a reduction of 5cm in waist circumference was associated with a reduction in AHI of 2.5 events/hour (95% CI, 1.5-3.5). The authors recently published the results of the post-intervention two year follow-up of this cohort. In the intervention group one year after the intervention ended a weight reduction of 7 kg was observed and a 40% reduction in AHI was achieved from baseline. 3 of 5 subjects were considered to have achieved an AHI<5 events/hour. The authors reported that the lifestyle intervention reduced the risk of OSA by 65% and a 50% decrease was found in the progression of the disease compared with the control group during the 2 year follow-up period. This study demonstrated that a lifestyle modification intervention based on a VLCD and physical activity can improve clinical symptoms in overweight OSA subjects and the weight reduction can be sustained at 2 years. The evidence supports the belief of the authors that such an intervention should be a first line of treatment for mild OSA.

Kemppainen and colleagues\textsuperscript{82} randomised 52 subjects and follow them up for three months with a BMI of 24-40 kg/m\textsuperscript{2} and mild OSA AHI$\geq$5 events/hr to receive a supervised, individual lifestyle intervention with a weight reduction counselling programme via consuming a very low calorie diet or to receive a single dietary and exercise session. The authors reported a greater reduction in BMI in the intervention group of 5.4 kg/m\textsuperscript{2} compared to 0.49 kg/m\textsuperscript{2} in the control group.
Ackel-D’Elia and colleagues\textsuperscript{155} randomised 32 male subjects with a moderate to severe OSA diagnosis requiring CPAP treatment to receive a two month supervised aerobic exercise training or CPAP therapy only. The authors reported no significant differences in both groups on weight measurements. The study showed that both treatments were effective in improving subjective sleepiness. The authors reported that the intervention group showed lower values of tension and fatigue on the profile of mood state score (POMS) and higher values of physical functioning, general health perceptions and vitality on the Short Form Health Survey (SF-36) quality of life questionnaire suggesting exercise training as an adjunct intervention strategy in the management of patients with OSA.

Papandreou and colleagues\textsuperscript{156} randomised 21 sedentary and obese (mean BMI 36.6 ± 3.7 kg/m\textsuperscript{2}) subjects with a moderate to severe OSA diagnosis to receive CPAP therapy and a six month lifestyle intervention based on a low calorie Mediterranean diet and physical activity or CPAP therapy and consuming a low calorie prudent diet.\textsuperscript{38} The authors reported a greater reduction in weight -10.8 kg, BMI -3.9 kg/m\textsuperscript{2}, waist circumference -9.9 cm and body fat percentage -4.7 % in the intervention group following the Mediterranean diet and CPAP therapy compared with the control group (p<0.05).

Kline et al\textsuperscript{157,169} randomised 43 sedentary and obese subjects to receive a 12 week 150 min/week of moderate intensity aerobic activity followed by resistance training twice/week or low intensity stretching exercises designed to increase whole body flexibility. The authors reported a significant reductions in AHI -7.6 events/hour and ODI\textsubscript{4} -3 events/hour in the intervention group compared with the control group (p<0.01.
and \( p=0.03 \) respectively). The authors reported that the reductions observed in AHI and ODI\(_4\) were achieved without a significant decrease in body weight. The intervention group also conferred significant improvements in depressive symptoms fatigue and vigor and QoL assessed by the SF-36 compared with the control group (\( p<0.05 \)).

4.3.7 Intensive lifestyle intervention (ILI) programmes with usual care meta-analyses results

Meta analyses were also carried out for the six identified studies\(^{69, 83-84, 155-157} \) and the pooled results are shown in Table 4-2. For the four studies reporting on weight loss, participants receiving the ILI had an overall weight loss of -5.65kg (CI -10.91 to -0.40) with a high level of heterogeneity \( (I^2=95.7\%, \ p=0.0001) \) (Figure. 4-2). Significant reduction in waist circumference of -5.8 cm (CI -8.64 to -2.96) was also seen with high heterogeneity also observed for this outcome \( (I^2 = 77.7\%, \ p=0.001) \) and in BMI of -2.33 kg/m\(^2\) with a high level of heterogeneity \( (I^2 = 78.8\%, \ p=0.003) \) observed. A significant reduction in the AHI was identified of -4.55 events/hour in those subjects receiving an ILI compared to the control groups but with medium heterogeneity observed \( (I^2 = 54.4\%, \ p=0.041) \). A reduction in ESS score of -0.31 was observed with a medium level of heterogeneity \( (I^2 = 33.5\%, \ p=0.220) \).
**Figure 4-2:** Forest plot for change in weight (kg) by length of follow up (2, 6 and 12 months) following an intensive lifestyle programme versus usual care using the random-effects model.

The size of the box indicates the study’s relative weight based on standard error. The diamond reflects the 95% confidence interval of the summary estimate.

### 4.3.8 Other types of programmes systematic review results

Breathing and aerobic exercise programme

Sengul and colleagues\(^8\) randomised 20 consecutive patients with mild to moderate OSA (AHI 5-30 events/hour) to assess the effect of breathing and physical exercise on pulmonary functions, AHI and quality of life in patients with OSA. Ten individuals
were randomised to receive a 12 week intervention consisting of 1.5 hour 3 days per week programme based on breathing and aerobic exercises while the control group (n=10) did not receive any exercise. The breathing exercises included lip breathing and relaxation techniques lasting for 15 to 30 minutes. After the breathing exercises the participants did warm up exercises consisted of slow jogging, calisthenics (simple exercises encouraging co-ordination) and stretching. The aerobic exercises consisted of low to moderate activity treadmill and bicycle exercises lasting for 45 to 60 minutes. The quality of life was assessed by two questionnaires including the Functional Outcomes of Sleep Questionnaire (FOSQ-tr, a decreased 26 item Turkish version without the sexual functioning sub-scale) and the Short Form-36 (SF-36) questionnaire which was administered during a face-to-face interview by a physiotherapist. Subjective sleepiness was assessed via the Epworth Sleepiness Scale (ESS) questionnaire. In the control group, no significant differences were identified before and after 12 weeks. In the exercise group, improvements were found in the AHI, FOSQ-tr and ESS. However, after the follow-up period the authors reported that the improvement in the intervention group did not lead to statistically significant difference between the two groups.

Dietary advice and hypnotherapy programme

Stradling and colleagues\textsuperscript{80} randomised 46 obese (BMI<30 kg/m\textsuperscript{2}) OSA subjects on CPAP therapy (AHI>5), in three parallel groups including dietary advice only (n=15), dietary advice and hypnotherapy type 1 (focused on stress reduction) (n=16) and dietary advice with hypnotherapy type 2 (with specific suggestions about food, Spiegel and Spiegel approach) (n=15) to establish whether hypnotherapy, as an adjunct weight
loss method, can produce greater short and long term weight loss than conventional dietary advice only. All three groups were given dietary advice from a fully qualified and experienced dietician on two occasions (baseline and 1 month post intervention). Those participants receiving hypnotherapy did so in two occasions (baseline and 1 month post intervention) from a medical hypnotherapist (a member of the British Society of Medical and Dental Hypnosis) and a local general practitioner. Assessments of weight were scheduled at 1, 3, 6, 9, 12, 15 and 18 months, as a percentage of original body weight. The authors reported that all three groups lost 2-3% of their body weight three months post intervention. At 18 months the authors observed a significant (p<0.02) but small mean weight loss (3.8kg) only in the hypnotherapy type 1 group and concluded that a more intensive hypnotherapy course could have been more successful.

Very low energy diet and usual diet

Johansson and colleagues\(^{83}\) randomised 63 obese (BMI 30 to 40 kg/m\(^2\)) subjects with moderately severe OSA (AHI≥15) treated with CPAP to receive either a 9 week intervention programme based on a low energy liquid diet (2.3 MJ/day) for seven weeks to promote weight loss, followed by two weeks gradual introduction to normal food (reaching 6.3 MJ/day at week 9) or to adhere to their usual diet.\(^{110}\) 30 participants were randomised to receive the intervention and 33 participants formed the control group. Two participants in the control group were dissatisfied with the treatment allocation and were discontinued. However, the authors included data from all randomised participants in an intention to treat analysis. The pooled mean AHI for both groups was 37 events/hour at baseline. At 9 weeks a greater weight loss was reported in the intervention group of 18.7 kg compared with 1.1kg in the control group (p<0.001). In addition, a greater reduction in AHI was also reported in the intervention group when
compared to the control. The authors concluded that long term treatment studies will be required in the future to validate weight loss as a primary treatment strategy for OSA.

4.4 Discussion

The current systematic review and meta-analysis showed that ILI programmes which employed caloric restriction and/or physical activity were effective in reducing indices of obesity and improve severity of OSA. Lower intensity lifestyle modification programmes which combined dietary advice and CPAP therapy are also effective but to a lesser degree for these outcome measures. The results indicate an additional benefit of CPAP therapy to the dietary advice. Although a significant weight reduction was observed in this group (-2.64kg) the overall weight loss was not clinically significant (Table 4-2). However, the impact of CPAP therapy on this patient group is evident in the reported improvements observed in general well-being and alleviation of OSA related symptoms leading to improvements in the quality of life. This is the first systematic review of non-surgical and non-pharmacological randomised controlled trials to our knowledge reporting the effectiveness of lifestyle modification interventions on indices of obesity and parameters of OSA in adult OSA subjects. A systematic review and meta-analysis of observational and randomised studies investigated the effects of dietary weight loss only on OSA.\textsuperscript{157} It showed that these programmes were effective in reducing severity of OSA and BMI among obese OSA subjects. The review included in total six observational studies and only three randomised controlled trials representing 577 subjects. A comparison of non-surgical and surgical interventions also showed within group reductions in BMI and AHI after diet and lifestyle interventions (-4.51 kg/m\textsuperscript{2} and -18.45 events/hour respectively).\textsuperscript{158} Both studies pose several limitations including the utility of randomised and non-
randomised trials and the exploration of only a limited number of outcome measures. This systematic review however, holds the exclusive design of utilising randomised controlled trials only with multiple outcome measures. We also observed a reduction in BMI and AHI in the intervention groups receiving diet and/or intensive lifestyle interventions but to a lesser degree. However, this may be due to the inclusion of both observational and randomised studies by\textsuperscript{159, 160} because observational studies tend to report higher reductions.\textsuperscript{171} Therefore the results need to be viewed with caution as the true effect may be over estimated. In our review we included randomised controlled trials employing diet, physical activity and lifestyle management strategies only. The present study showed that weight reduction programmes based on caloric restriction and/or physical activity can induce significant weight loss. Concerns over the sustainability of weight loss produced by diet related and lifestyle modification interventions have been widely expressed by several health related taskforces which recommend their utility as an adjunct to CPAP therapy. In the present study we also observed an additive effect of CPAP therapy on weight loss highlighting that a lifestyle modification intervention combined with CPAP therapy may confer additional benefits for this at risk population. CPAP therapy is the gold standard therapy in the treatment of moderate and severe OSA and previous studies have demonstrated its effectiveness in reducing cardiovascular risk in ameliorating OSA symptoms and improving quality of life among OSA subjects.\textsuperscript{18} Lifestyle modification programmes however may hold the key for better long term outcomes as their primary goal is change in behaviours towards nutritional intake and physical activity offering counselling support and therefore enabling participants to understand the implications of obesity on OSA but also empowering them to change their lifestyle choices to further reduce the physiological and psychological impacts of this chronic condition. This approach
emphasised how small changes in everyday living can potentially confer great changes in their health status. Weight reduction strategies in the form of diet or lifestyle modification programmes are effective in reducing weight and OSA indices among obese OSA subjects and their utility should be explored further.

4.4.1 Strengths and limitations

Limitations include significant heterogeneity between the included studies for some outcomes and so overall conclusions must be regarded with caution. However, for the primary outcome measure no to high heterogeneity levels were observed. Another limitation is the difference in the length of follow up between the studies ranging from 2 to 24 months. This difference in follow up time had a great impact on the overall weight loss observed in the ILI group. In particular when comparing the weight loss between the two studies with similar follow up\textsuperscript{69,84} the mean weight reduction achieved was -9.53 kg but when combining the results of other studies with shorter follow up\textsuperscript{156,157} this reduced the overall effect resulting in lower weight reduction of -5.65 kg. Parameters of OSA severity were not routinely assessed in these studies, resulting in inability to perform a meta-analysis on AHI in the CPAP group. Given the limited number of studies we were unable to assess publication bias. The pooled data is poorly representative of females and therefore the results may not be truly generalisable. An important strength in our study is the inclusion of randomised controlled trials only. A quality element was applied using the Jadad scale of which 5 of 9 studies scored ≥4 which was set to denote good quality.

A systematic and broad search was carried out on multiple databases of both medical subject headings and keywords so to capture all studies available in the literature that covered obstructive sleep apnoea (OSA), lifestyle (diet and physical exertion) and
randomised controlled trials. The methodological strengths of this study also include the independent data extraction carried out by two authors.

4.4.2 Future research

Intensive lifestyle programmes should be further explored in patients with OSA with several additional co-morbidities such as T2DM and CVD where intensive lifestyle interventions have proven effect. Furthermore, exploration of the utility of such programmes in newly diagnosed OSA subjects in primary healthcare is recommended as early intervention may prevent the progression rate and potentially cure OSA. The results highlight the effectiveness of lifestyle modification interventions in reducing weight and as a result improve OSA parameters among obese subjects. Further exploration into most effective type of intensive lifestyle management programmes is warranted. It is important to unravel which groups based on disease severity (AHI) such programmes are most effective in terms of overall weight loss, reduction in AHI and sustainability of these patient outcomes and indeed whether these programmes are cost-effective.

4.5 Conclusions

In conclusion, the results from our meta-analysis support the implementation of intensive lifestyle modification programmes as effective interventions for aggressive weight reduction and prevention of progression of OSA for those subjects with mild severity of the condition and in improving if not curing parameters of OSA in obese patients at high risk of cardiometabolic co-morbidities. This could potentially prove to be invaluable within the primary care setting. There is a call for research to assess the utility of such programmes in healthcare settings as well as to investigate further the role of CPAP therapy in improving metabolic parameters.
Chapter 5

Development of a structured education programme for people with Obstructive Sleep Apnoea (OSA) at high risk of Cardiovascular disease (CVD) and Dysglycaemia: The Arise & Shine Structured Education Programme
5.0 Chapter overview

The PUCOSA-UK study (Chapters 2 and 3) shed light on the interplay of psycho-social factors in predicting CPAP use and explored the beliefs and perceptions of OSA and CPAP therapy in a group of newly diagnosed and established patients with OSA. Results from the systematic review (Chapter 4), indicate that intensive lifestyle management interventions are more effective in reducing indices of obesity and reducing the severity of OSA. The findings from the above studies were collated and informed the development of the Arise & Shine programme, which is a group based, structured education programme tailored for patients with OSA. The curriculum is additionally based on proven psychological theories that underpin the award winning Diabetes Education and Self Management for Ongoing and Newly Diagnosed (DESMOND) programme. In this chapter, I provide an overview of the development of the Arise & Shine education curriculum, including the underpinning theories, its content and the results from the pilot work which informed it. I also discuss the future research and areas of limited evidence.

The author of this thesis, MAT, performed the following activities in relation to this study:

- Developed the written structured education curriculum and patient resources
- Delivered the education sessions in two pilots
- Managed the pilot logistics
- Developed the topic guide for the patient evaluation
- Modified the curriculum following the evaluation
The above activities were performed under the supervision of MJD, KK, EMB, APH and members of the DESMOND collaborative. The selection of the psychological theories that underpin the education programme was carried out in collaboration with YD. MB and SJ designed the patient resources of the programme. Together with LMS, we delivered the pilot sessions. The interview topic guide used to gauge participants feedback was developed in collaboration with MH. Interviews were carried out by MH and PM. I analysed and collated the evaluation data. I and LMS modified the curriculum following the evaluation.

The development of the Arise & Shine curriculum comes under the existing umbrella of the DESMOND-family of lifestyle education interventions that follow the Medical Research Council (MRC) framework for the development of complex interventions. Here, I discuss this iterative process and provide an outline of the process of developing lifestyle education programmes for the self-management of diabetes and pre-diabetes.

5.1 Structured group-based education and the MRC framework

Structured group-based education refers to a group-based patient-centred education programme that has a clear underlying philosophy, a written curriculum, is delivered by trained educators, it is quality assessed and includes a process of audit of the programme outcomes (including biomedical, psychosocial, and patient experience). The aim of a lifestyle structured education programme is not only to alter a person’s behaviour in everyday living but to equip individuals with the required life-long skills and knowledge that can empower them to play an active role in the self-management of their condition. However, the design, development, delivery, evaluation and long term implementation of education lifestyle interventions is a very complex process and poses
many challenges. Therefore the Medical Research Council (MRC) has developed a systematic approach ensuring that educational interventions following these guidelines have a robust design. The current MRC framework includes four equally important interlinked phases including that of development, feasibility and piloting, evaluation and implementation phases. The guidelines states that one must not necessary pursue a linear or cyclical sequence of these four phases but researchers can go from one phase to an earlier phase as the development of complex interventions requires an iterative process (Figure 5-1). A brief description of the four phases is outlined below.

5.1.1 Development

The development phase includes the identification of the existing evidence on the chosen topic of research preferably by conducting a systematic review. It also includes the identification and development of a theoretical understanding that is related to what is required to change utilizing existing theory or by conducting new primary research. Finally, the modelling design process of the intervention and the identification of the long term outcomes are essential. This can be identified via conducting a pre-trial evaluation study.

5.1.2 Feasibility and piloting

The feasibility and piloting phase requires not only the testing of the acceptability, delivery and compliance of the intervention but also the estimation of recruitment and retention rates of the intervention. In addition, determination of the effect and the sample size is also a requirement (Figure 5-1). A mixed method design combining
qualitative and quantitative methods maybe essential to gain a clear insight of potential participation barriers and to estimate response rates.\textsuperscript{121}

5.1.3 Evaluation

The evaluation phase includes assessing the effectiveness of the intervention by conducting a randomised controlled trial where applicable as this is a robust method of preventing selection bias.\textsuperscript{121} If the randomised design in not appropriate other experimental designs may be considered. The evaluation process also includes the understanding of the change process and process evaluations than ensure fidelity and quality of the intervention outcomes. Finally, assessing the cost-effectiveness of the intervention by conducting an economic evaluation is also considered (Figure 5-1).\textsuperscript{121}

5.1.4 Implementation

The implementation phase includes the dissemination of the research results so that the findings can be effectively implemented into routine practice or policy.\textsuperscript{121} It also involves the surveillance, monitoring and long term follow-up to establish if the potential benefits of the intervention can be maintained post the intervention (Figure 5-1).\textsuperscript{121}
**Figure 5-1:** The MRC framework for developing complex interventions

Adapted from Craig P. 2008

5.2 The Leicester Diabetes Centre: expertise in developing complex interventions

The Leicester Diabetes Centre research group has expertise in the development of complex interventions that are in line with the MRC framework. Two structured education lifestyle intervention programmes developed by our group are discussed in sections 5.2.1-5.2.2.
5.2.1 Diabetes Education and Self Management for Ongoing and Newly Diagnosed: The DESMOND Programme

The DESMOND programme was tested in one of the largest randomised controlled trials of a structured education intervention globally. It has proven effectiveness and it is an evidence-based self-management group-education programme designed for patients with newly T2DM. The programme has a philosophy which is centred on patient empowerment and it is underpinned by a number of psychological theories including Leventhal’s Common Sense Model of Illness, Chiaken’s dual processing theory and Bandura’s Social Learning Theory. The DESMOND curriculum was developed by a multi-disciplinary team of experts in health psychology, physicians, nurses, dieticians and allied healthcare personnel that form the DESMOND collaborative. The content of the curriculum was centred on lifestyle factors including food choices, physical activity and cardiovascular risk factors. The main aim of the programme was to enable participants to review their personal risk factors to select which they wanted to improve by forming action plans and setting goals. The delivery of the programme was conducted by trained educators that promoted patient centred non-didactic approaches. In this way learning was elucidated and not taught. In addition, the programme included a clear quality assurance process (for internal and external assessment). DESMOND was delivered either as a 6 hour one day session or as 3 hour sessions on two days in a community setting integrated as part of routine care. The DESMOND intervention successfully improved lifestyle, depression, illness beliefs, weight and cardiovascular risk in over a period of 12 months. Furthermore, it provided evidence that group structured education focused on behaviour change can lead to additional effective lifestyle changes including smoking cessation. Recently the 3 year results have been published and although no changes in the biomedical,
lifestyle and medication data were observed significant benefits in the intervention group in the illness beliefs were sustained 3 years post intervention. Following the success of the DESMOND programme a number of structured education programmes have been developed by our group that utilise the DESMOND-based philosophies and underpinning theories and are discussed in the following sections.

5.2.2 Pre-diabetes Risk Education and Physical Activity Recommendation Education: The PREPARE Programme

The PREPARE structured education programme was the first study in the UK designed to increase physical activity objectively measured with the use of a pedometer in patients with pre-diabetes. The PREPARE programme was underpinned by the same psychological theories with the DESMOND programme and it was delivered as a one day 3-hour group education intervention designed to promote walking. This pilot study found that the intervention group showed greater reductions in the 2 hour-glucose at 3 and 12 months. Following the success of the DESMOND and PREPARE study a larger randomised controlled trial titled Let’s Prevent was developed for those with pre-diabetes and this study is still currently active.

5.3 Development and aims of the Arise & Shine programme

The DESMOND and Let’s Prevent existing curricula were adapted to fit purpose for the OSA population. These curriculums however were designed for people with diabetes and pre-diabetes. Therefore, extensive work was carried out to ensure that the underpinning theories and the content of the curriculum were suitable to alter patient’s
behavior and facilitate lifestyle changes in order to promote CPAP compliance and increase physical activity and not be centred on diabetes. The development and content of the Arise & Shine structured education programme was informed from the results of the systematic review and meta-analysis described in Chapter 4 and from the findings of the PUCOSA-UK qualitative study described in Chapter 3.

The aim of the Arise & Shine education programme was to promote CPAP adherence and physical activity in individuals diagnosed with OSA and treated with CPAP therapy. This was achieved by targeting early formed perceptions, beliefs and knowledge of OSA (pre-and post formal diagnosis) in addition to perceived barriers and benefits of CPAP therapy. The concepts of illness perceptions, depression and low mood, self-efficacy and societal support were strategically addressed with the development of appropriate education sessions forming an important component of the curriculum. The key aim of the programme was to alter patient’s perceptions and improve their self-efficacy with CPAP use. Furthermore, the programme was designed to enable participants to explore their personal barriers related with CPAP use and physical activity. Additionally, by assessing their risk factors together with their personal long term OSA-related complications this would enable participants to set personal goals so to improve their CPAP compliance and physical activity levels thus develop a clear self-management strategy in living with OSA and sleeping with CPAP therapy.

5.3.1 Behavioral changing theories of the Arise & Shine programme

Reviewing the evidence from the semi-structured interviews of the PUCOSA-UK study (Chapter 3) an expert health psychologist (YD) proposed three social cognitive models
including the Theory of Planned Behavior\textsuperscript{184} the Common Sense Model of Self-Regulation of Health and Illness Theory\textsuperscript{117} and the Relapse Prevention Behavioural Model\textsuperscript{186} suitable to facilitate change in health behaviour in order to promote CPAP compliance and increase physical activity. In addition, depression was a common finding among the OSA interviewees and therefore the Six Cycles Maintenance Model was also recommended.\textsuperscript{187} These models are described in sections 5.3.2 -5.3.5.

5.3.2 The Theory of Planned Behavior

The theory of planned behavior was developed by Ajzen\textsuperscript{184} and it is based on:

1) Behavioral beliefs (beliefs on the likely consequences of the behavior),

2) Normative beliefs (beliefs about the normative expectations of others), and

3) Control beliefs (beliefs about the presence of factors that may facilitate or not performance of the behavior).

According to Ajzen, behavioral beliefs produce a favorable or unfavorable attitude toward the behaviour while normative beliefs result in perceived social pressure or subjective norm; and control beliefs lead to perceived behavioural control. Figure 5-2 provides a schematic representation of the theoretical model. This model would allow an individual with OSA to ‘value’ CPAP use depending on the perceived benefit gained by this behaviour. As an example if a person believed that by using CPAP this attitude would made the individual feel less tired and fatigued then the person would be more likely to continue using CPAP therapy (behavioral beliefs). In addition, if a socially important person advised the patient with OSA to continue using CPAP because the
patient evidently looked less fatigued or tired the person with OSA would be more likely to continue using the therapy (normative beliefs). Finally, if an individual showed high confidence in using CPAP therapy then the person would be more likely to continue using the treatment (control beliefs).

**Figure 5-2: The Theory of Planned Behavior**

![Diagram of the Theory of Planned Behavior]

Adapted from Ajzen I\(^ {184} \)

### 5.3.3 The common sense model of self-regulation of health and illness

Leventhal’s model (explored in Chapter 2) suggests that individuals conceptualise a health threat based on five dimensions including the identity, cause, timeline, consequence and control/treatment of the threat and these dimensions can influence potential coping strategies.\(^ {117} \) This model was believed to be very useful as it would enable patients to review their beliefs and relate these beliefs with how well they could control their condition.
5.3.4 The relapse prevention model

The relapse prevention model was proposed by Marlatt and Gordon aiming to identify and prevent high risk situations in alcoholism treatment.\textsuperscript{186} In this model high risk situations, coping skills, outcome expectancies and lifestyle factors are perceived as setbacks or lapses that may lead to returning to a state of a previous problematic behaviour—the so called relapse.\textsuperscript{186} This model was considered important in the development of the Arise and Shine study as lapses and relapses may be a relevant issue to OSA patients when dealing with certain barriers including wearing a CPAP mask and using CPAP therapy.

5.3.5 The six cycles maintenance model

The ‘vicious’ flower is a visual representation of a feedback loop commonly used in cognitive behavioural therapy for depression.\textsuperscript{187} The flower consists of 6 petals each of which represent unhelpful behaviours including automatic negative thinking, ruminations and self-attacking, mood/emotion, withdrawal and avoidance, unhelpful behaviours and motivation/physical symptoms.\textsuperscript{187} These six petals of the depression ‘vicious’ flower are interlinked. This visual was adapted for the OSA patient population and four petals formed the basis of the ‘OSA vicious flower’ consisting of:

1. Being self critical and having negative thoughts
2. Low in energy and lacking motivation
3. Unhelpful behaviours including avoidance
4. Having strong emotions.
This visual was believed be very useful as it would enable the patients with OSA to review how these emotional ‘petals’ are interlinked and their influential impact on CPAP use (Figure 5-3).

**Figure 5-3:** The OSA vicious flower

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5.4 The broad curriculum

Careful consideration of the aforementioned findings, extensive adaptation of existing curricula and utility of appropriate behavioural and visual models led to the development of the core Arise & Shine curriculum. The content of the curriculum is outlined in Table 5-1 and a summary of each session is provided below.
### Table 5-1: Outline of the Arise & Shine structured education curriculum

<table>
<thead>
<tr>
<th>DAY 1</th>
<th>Duration</th>
<th>DAY 2</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>10 mins</td>
<td>Welcome back</td>
<td>10 mins</td>
</tr>
<tr>
<td>Participant Story</td>
<td>30 mins</td>
<td>Reviewing my CPAP and Physical Activity diaries</td>
<td>20 mins</td>
</tr>
<tr>
<td>Professional Story 1 (Understanding Obstructive Sleep Apnoea)</td>
<td>45 mins</td>
<td>Professional Story 2 (Risks and Complications)</td>
<td>45 mins</td>
</tr>
<tr>
<td>Break</td>
<td>10 mins</td>
<td>Taking Control 2 (Physical Activity)</td>
<td>30 mins</td>
</tr>
<tr>
<td>Understanding and Using Continuous Positive Airway Pressure Therapy</td>
<td>40 mins</td>
<td>Break</td>
<td>10 mins</td>
</tr>
<tr>
<td>Taking Control 1 (Weight Management)</td>
<td>35 mins</td>
<td>How am I feeling? (OSA Flower)</td>
<td>25 mins</td>
</tr>
<tr>
<td>How am I Doing?</td>
<td>10 mins</td>
<td>Self Management Plan</td>
<td>30 mins</td>
</tr>
<tr>
<td>Total</td>
<td>180 mins</td>
<td>Total</td>
<td>180 mins</td>
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</tbody>
</table>

### DAY 1

**A. Introduction:**

This introductory section welcomes participants to the programme and provides housekeeping information. Participants become aware that they will come away from the course understanding what OSA is, knowing the cardiovascular and metabolic risks associated with OSA, knowing what they can do to self-manage their OSA and reduce their future health risks and have answers to the questions about their OSA with which they may have arrived with. Finally participants learn that the programme incorporates fun activities including games, visual aids and booklets to enhance understanding on selected topics.
B. Participant Story

This brief session allows participants to explore their health beliefs around pre and post diagnosis of OSA. The educator elicits information from each participant by asking questions (regarding their symptoms, causes, therapeutic options, other people’s beliefs on OSA and any burning questions they may have) and records their response on pre-labelled flip charts so that these can be revisited at a later stage. In this way the group understands and appreciates that everyone has their own story about their OSA and that not everybody shares the same beliefs, knowledge and experiences about OSA.

C. Professional Story: Understanding Obstructive Sleep Apnoea

This session aims to explore the process of healthy breathing and uncover what goes wrong in the body during OSA breathing and why, the causes and the self management options for OSA.

D. Understanding and Using CPAP Therapy

The first section of this session was developed to help participants explore the health benefits of CPAP therapy, the current recommendations for CPAP use and useful practical aspects of the therapy aiming to increase the participant’s self-efficacy. The second section titled ‘Your thoughts and feelings about OSA and CPAP therapy’ was incorporated in this session with the aim to explore the participant’s thoughts and feelings about living with OSA and sleeping with CPAP therapy. The key message is for participants to understand that it is ok to have negative thoughts and feelings and it
is important to acknowledge these feelings as sometimes emotional reactions can have a major impact on the self-management of a condition.

**E. Taking Control 1 (Weight Management)**

In this session, participants have the opportunity to explore their past experiences with weight management and consider the health benefits of physical activity. With the use of appropriate resources participants are shown how they can increase their physical activity levels. Participants are also sign posted to related NHS services for support if they wish to work on managing their weight and pedometers are handed to those that wish to take one home. In addition, participants are asked to complete if they wish the physical activity diary and record their daily step count.

**F. How am I doing?**

In this session participants have time to review their experiences and feelings so far and consider about the lifestyle changes they wish to make based on the information they received so far.

**DAY 2**

**G. Welcome back**

This brief session, welcomes back participants to day 2 sessions of the Arise and Shine programme and summarises the main topics to be covered in the rest of the course.
H. Reviewing my CPAP and Physical Activity diaries

This session provides an opportunity for participants to share their experiences and personal barriers to using CPAP therapy and physical activity since the last session. In addition the benefits of keeping a CPAP diary and an activity log are discussed.

I. Professional Story 2: Risks and Complications

In this session participants learn that OSA is associated with an increased risk of cardiovascular and metabolic conditions. Participants have the opportunity to jot down their personal biomedical and CPAP data results in the patient handbook and view their overall health status. Importantly, participants learn how OSA is linked with high blood pressure, cholesterol, diabetes, stroke and heart conditions and what they can do to reduce the chance of long term damage to their health.

J. Taking Control 2- Physical Activity

This session informs participants how physical activity contributes to weight loss and maintenance in a comprehensive manner. Importantly, participants learn how physical activity contributes to reducing the chances of heart and circulation problems as well as stroke. Participants learn the current recommendations for activity levels, discuss barriers to physical activity, and develop strategies to become more active in their daily lives.
**K. How am I Feeling?**

In this session participants learn how depression and low mood can impact on individuals with chronic conditions including OSA. The OSA flower is introduced and participants explore how each of the four petals representing a specific behaviour influences each other and creates a vicious cycle. Participants learn how to break this cycle and reverse these unhelpful behaviours.

**L. Self-Management Plan**

In this session participants reflect on what they want to change and are encouraged to write an action plan and set goals. Participants are asked to consider high risk situations and come up with solutions that will help prevent their barriers.

**M. Questions and Future Care**

This is the concluding session of the programme and it aims to provide answers to the participant’s questions. In addition, further information about additional support is provided.

**5.5 Piloting the Arise & Shine programme**

Six middle-aged patients (age range 45-68 years old) predominantly male (4 males and 2 females), volunteered to take part in piloting the curriculum and evaluated the content of the proposed programme. The structured education programme was delivered as a two three hour, morning sessions held two weeks apart at the education centre seminar
room at the Leicester General Hospital. Two educators, (a trainee sleep technician and a nurse), who had previously been trained as DESMOND educators (one experienced DESMOND accredited educator (LMS) and one core–DESMOND trained educator (MAT)) led these sessions. All participants were interviewed by two independent researchers (MH and PM) not involved in the actual delivery of the programme at the end of each day so to evaluate the content of the curriculum and feedback on the delivery style, available resources and content of the programme. Additionally, observations from the educators that led the programme were also utilised in the evaluation of the programme.

5.5.1 Pilot 1 and 2

Although four scheduled patients agreed to take part in pilot 1 of the Arise & Shine curriculum due to unexpected bad weather conditions two participants were unable to attend. Four participants volunteered to take part in the second pilot and all attended the programme. The overall participant’s comments and feedback are reported below.

5.5.2 Overall feedback

Overall, attendees enjoyed the DESMOND-based non-didactic style of education and found the programme very useful, interesting, knowledgeable and helpful. They commented very positively on the resources and activity games used in the Arise & Shine sessions and found them helpful and useful. In addition, participants felt that they learned something new even though they have been using CPAP therapy for a long time (range 2-13 years) and they were able to understand how high blood pressure,
cholesterol, cardiovascular disease, diabetes and OSA are interlinked. During the first pilot of the programme the physical activity session was delivered during day one but a participant found very hard to understand how physical activity was incorporated in the curriculum and what we were aiming to achieve with this session. After careful consideration and in response to the confusion caused to the participant regarding the physical activity session this was moved to day 2 sessions to avoid causing confusion during pilot 2. After a brief discussion with the participant it became clearer how physical activity and weight management can also help to self-manage OSA effectively. Although participants were very positive they felt that the ‘your thoughts and feelings about OSA and CPAP therapy’ and the ‘OSA Flower’ sections were an ‘eye-opener’ and felt the drawing of the OSA Flower ‘stuck in their memory’ as it touched upon negative and positive aspects of the condition and they could easily go back to it if needed. Importantly, by attending this programme they felt that they were not isolated and that other people experience similar barriers related with being diagnosed with OSA and sleeping with CPAP therapy.

5.5.3 Feedback by education session

DAY 1:

Patient Story

Participants were able to understand and appreciate that everybody in the group had different thoughts and perceptions of OSA and CPAP therapy. They were able to understand that not everyone experienced the same symptoms, consequences, problems and barriers. In addition, they found this session interesting as they understood that at the end of the programme they would be able to have an answer to their ‘burning’
question either covered within the content of the programme or as part of the questions section.

Professional Story

Overall, participants enjoyed the simplicity of this section and found useful the use of the man model and related resources in building up the OSA breathing story. Only one participant suggested the use of a mannequin instead of a man model and another found the ‘factories’ as something ‘not healthy’ but all were happy that there was not any medical terminology in the programme. Participants thought that the role play, demonstrating control of breathing pace was very important and made them focus of their breathing and think about the way we breathe during the day and how the body copes in comparison to what happens in OSA breathing. Overall, participants were able to interlink the causes and consequences of OSA and gain a clearer understanding on how OSA breathing can lead to long term complications, low emotional-well being as well as reduced sex drive and erectile dysfunction. On the other hand, participants identified most of the therapeutic options available to treat OSA and as the programme focuses on CPAP therapy they were able to recognise the benefits of CPAP therapy in improving health, emotional-well being and ameliorate OSA related symptoms.

Understanding CPAP therapy

Participants found this session ‘extremely’ useful, especially on how to manage their CPAP-masks and they thought the practical part helped them to learn something useful. After playing the truth or myth card game they were able to identify what they needed to change so to have maximum benefit from CPAP therapy. Positioning a CPAP mask, dealing with air-leakage, cleaning the CPAP apparatus were among the contents
covered in this practical. Although participants were experienced users the level of their knowledge in trouble shooting common problems associated with wearing a CPAP-mask and using CPAP therapy increased after this session. Many participants in this programme have reported that the appointment time slots at the sleep clinic may need to be increased as this information should be included as part of their usual care. When using the glass-head models, participants mentioned that ‘image’ is very important and therefore having the masks on the glass models in the beginning may frighten and intimidate newly-diagnosed participants. Participants recommended that the masks should be placed during the practical. Overall, participants were aware of the current recommendation on CPAP use and felt that jotting down their CPAP usage helped them see where they are on the scale. Participants were reminded to complete a CPAP-diary prior attending day 2. The thoughts and feelings session was perceived to be very useful as it allowed participants to revisit how they felt when they first started CPAP therapy and that it was ok they felt this way. Participants’ also commented on how useful this section will be for those newly diagnosed patients who may experience strong negative emotions.

Taking Control 1 (Weight Management)
All participants felt they learnt something new in this session. It made them more aware of how weight management combined with physical activity can help them enjoy a healthier lifestyle. Participants also acknowledged that importance and confidence play a key role in enabling a person to be successful to achieve their personal goals. Participants mentioned that it was good to include the confidence/importance matrix as part of the session as some people need more encouragement and might not be as confident about their condition as others. These participants would require help with
their motivation and set small goals and this section would be able to help with this. At the end of this session participants were asked if they wished to take a pedometer with them so to monitor their activity levels and were shown how to use them.

**Day 2**

Welcome back and reviewing diaries

Participants found the diaries and pedometers very useful and made them realise how well they complied with CPAP therapy or that they were more active than they originally thought. This made them feel ‘good’ and acknowledged how important diaries can be in terms of identifying what has gone well or not so that they can make changes to improve their activity or CPAP use. Some participants were not able to complete their diaries or wear their pedometers because of lack of time, being forgetful or due to challenging work environment (operating heavy machinery etc) but they also acknowledged the importance of monitoring CPAP use and activity levels. One participant stated:

‘*These resources help you to look in the long term how you are getting on and your progress and keeping your condition in control –you’re controlling it it’s not controlling you*.’ (Participant 3, male)

Other mentioned:

‘*The diary would be useful for people who do not use CPAP therapy and who are tired from lack of sleep, as this will soon show them how much energy and strength they can get from therapy*.’ (Participant 2, female)
Professional Story 2

Participants felt that they learnt a lot from this session and found the content very useful as they were able to make links between the OSA causes and long term consequences. An attendee of the programme mentioned:

*Before I didn’t know a lot about this, now it’s all related*. (Participant 1, female)

Writing down their personal results on the health profile helped them identify where their current status on the scale which allowed them to focus on what they need to change. Also participants were asked what they thought about the benefits of physical activity and they were able to interlink the benefits of physical activity and CPAP use in achieving a healthier lifestyle and successful self-management of their condition.

Taking control 2: Physical Activity

Participants found this session very informative and useful. This session in particular made them aware of how active they need to be. They found the activity continuum card game very useful in realising that every opportunity during the day can be used to increase physical activity (from common housework to a loved sport e.g. swimming) as well as to understand the difference between activities with regards to the intensity of the exercise. Participants mentioned the importance of keeping a diary and using a pedometer when possible to monitor their progress. Participants realised that despite the recommendations everybody is different and therefore setting unrealistic goals will lead to failure so they recommended that it will be easier to build up gradually activity levels.
How am I feeling (OSA Flower)

Participants found the OSA flower very useful and felt the drawing ‘stuck in their memory’ as it touched upon negative and positive aspects of the condition and they could easily go back to it if needed. A participant mentioned:

‘I related OSA with being only fatigued and tired but then I realised that they are all (negative emotions/not willing to use CPAP therapy, feeling low) interlinked’.

(Participant 2, female)

Another participant mentioned:

‘It struck me when I read (in the being self-critical and having negative thoughts petal: Would you speak to a person they way you speak to yourself, it’s so true this voice is like a self-attack and made me realise I would never speak to a person in this way [using an example: you are stupid and pointing his finger] but I do it to myself’.

(Participant 6, male)

Overall participants gained a lot from this session and made them reflect on their feelings/thoughts and actions when the grey cloud and wind was upon their personal OSA flower. Patients also thought that this resource will be very useful for them when things don’t go very well in their life and it will help them to break this negative cycle.
Self Management Plan

Patients found the action planning very useful tool as it helped them to come up with strategies to achieve their personal goals. As most participants were good CPAP users they focused on losing weight or reduce their blood pressure. They found the use of action plans a good idea as people can reflect on what may not go so well so to revise their goals.

Next steps and Questions

Participants had the opportunity to reflect on what they have learnt so far and revisit the questions flip chart. Their questions were centred around practical aspects of CPAP-masks to more specific questions regarding how many people have managed to achieve weight loss that ‘cured’ their OSA. Participants were reminded that OSA is a complex chronic condition and although weight may play the key role in the development, progression and severity of OSA other factors (gender, respiratory physiology, craniofacial features and other conditions) can also determine and increase the likelihood of developing OSA. Patients reflected that CPAP is a ‘friend’ and it is important to have good usage to reduce tiredness. This will help the individual to focus on increasing physical activity and weight management which in turn will improve health status and emotional well–being.
5.5.4 Main findings

The following seven statements summarise the participant’s views:

1. Participants recognised that they may have been suffering with OSA for many years prior a formal diagnosis at a sleep laboratory without realising that there was a problem although they experienced OSA related symptoms (excessive daytime sleepiness, tiredness, fatigue, loud snoring, poor concentration & memory and nocturia to mention a few.)

2. The majority of the participants dealt with stigma on a personal and professional level (underperforming, falling asleep at meetings-lectures-at the wheel without being able to control their urge to sleep, experienced nervous breakdown, depression and divorce). In addition participants reported that healthy (OSA-free) individuals have strong negative perceptions on those with an OSA diagnosis and that they were being labelled as ‘lazy’ and ‘fat’.

3. Participants reported lack of information on the condition and emphasised that more public awareness should be raised as OSA is an under-advertised condition. Some also suggested that peer support groups would help.

4. The majority of the participants were motivated by a spouse; friend and/or colleague to seek sleep related help.

5. Most participants felt that being told of stopping breathing in their sleep was frightening and some felt shocked.
6. CPAP therapy made sense to some of them straight away and they had no problems sleeping with the mask all night especially after they felt that their symptoms ‘disappeared’ the next morning. Others felt that the therapy was ugly and experienced problems with the CPAP mask (claustrophobia, marking, air-leakage, and discomfort) but gradually increased their CPAP use. Participants mentioned that despite facing challenges with CPAP, persevering was key to continue using the therapy. Most described that they felt ‘a sense of relief’ about the fact that a condition was causing all their symptoms and it was not their fault.

7. The majority of the participants reported that they were aware of neither OSA nor CPAP therapy prior their diagnosis but their level of knowledge improved after diagnosis and treatment. Participants after diagnosis (and post the Arise and Shine Sessions) were able to describe what went wrong in OSA breathing and were able to identify personal potential risk factors as well as short and long term consequences. This allowed them to prioritise what they wanted to focus on changing. The majority of the participants were aware of the benefits of physical activity and weight management in managing OSA and improving well-being. In addition, they thought making action plans using goal setting to be invaluable.

5.5.5 Actions based on the participants feedback

Reviewing the content of the Arise and Shine curriculum it is evident that a lot of effort was put to ensure that the programme provided the required level of information, tools and delivery techniques to address the barriers and psycho-social predictors identified in previous studies. In particular to help participants to recognise perceived symptoms
and link these with being diagnosed with OSA, an education component in the curriculum was developed dedicated to the exploration of symptoms and how these may affect people with OSA. To address discomfort and barriers related to wearing a mask and operating a CPAP machine to increase self-efficacy, a session was developed utilising non-didactic approaches to facilitate discussion among participants and find out how they can overcome their fears/troubles and learn how to trouble shoot common problems. To help participants to explore how CPAP therapy may benefit their OSA related symptoms or delay the development of long term complications, a session was developed to allow exploration of this topic. To help participants overcome barriers related to self-image and sexual relationships another session was developed to facilitate discussion among the participants to explore their feelings and thoughts on this subject. In addition, another section of the curriculum explores participants’ feelings and thoughts about living with OSA and sleeping with a CPAP machine. Participants are also signposted to local services that offer peer support and advice. Finally, participants with the aid of appropriate resources are encouraged to create action plans and increase their hours of CPAP use. However, when examining the influence of the social support (spouse and/or friend) we have asked participants to bring their partner (if applicable) to the education session.

As a result of the comments made by the attendees of this programme, small changes were made in the curriculum reflecting their views and improving the content of the programme. These changes were centred around the presentation of patient resources including the glass head models which were used to demonstrate how to correctly position a CPAP mask and utility of CPAP masks. Also, the way educators offered pedometers using a more relaxed approach and wording such as ‘there are pedometers for those who wish to take one home’, instead of handing over pedometers to everyone
as individuals may feel obliged to take one home. The revised curriculum is shown in appendix 6.

5.6 Discussion

The aim of the development of the Arise and Shine programme was to address effectively the gap in the literature on the need for developing an effective lifestyle behavioural modification programme in this high-risk patient population promoting CPAP compliance and physical activity. Although the results from the systematic review discussed in Chapter 4 showed that intensive lifestyle interventions were more effective in improving obesity indices and in improving OSA severity, these interventions were based on following a specific nutritional plan and exercise regime. The decision to invest in the development of a patient-centred lifestyle modification programme that promoted change in behaviour towards CPAP use, weight management and increase in physical activity was of paramount importance. This is because the key message of the DESMOND-based lifestyle programmes relies on empowering individuals to make custom-made changes in their lifestyle and thus make them the driving force in terms of the self-management of their condition.

The development of the programme was a multistep iterative process as discussed in section 5.1 using the MRC framework. First, a systematic review was conducted to identify the impact of diet and lifestyle interventions in adults with OSA (Chapter 4). Following this a qualitative study was carried out (Chapter 3) aimed to explore patients perceptions, beliefs and barriers of individuals with OSA. In addition existing evidence based curricula (DESMOND and Let’s Prevent) were used as templates and were adapted to fit purpose for the OSA patient population. The Arise and Shine curriculum
was developed by collating the evidence from the above mentioned studies. Furthermore, evaluation of the content of the curriculum and patient resources was carried out by piloting the program in two small groups of six patients with established and newly diagnosed OSA.

Finally, the results from the empirical PUCOSA-UK study that aimed to explore the psycho-social predictors of CPAP use were incorporated in the final curriculum. Extensive work was carried out with the help of members of the DESMOND collaborative to ensure that all aspects of the programme were targeting those modifiable behavioral factors to promote change in health behavior but overall, I was responsible for leading the development of this programme.

5.6.1 Recommendations and future research directions

After careful consideration of the personal circumstances of individuals with no or limited social support and liaison with the members of the team and the health psychologist it was suggested to develop a section in the curriculum to address this more efficiently. In this session those who require support will be sign posted to patient peer-support groups including the Leicester Sleep Apnoea Patient Association Group and for those with mobility problems, advice will be offered by the clinic’s telephone hot-line or utilising trusted Sleep Apnoea websites. It was also suggested to encourage attendees in the programme to acts as ‘supporting friends’ and engage in counseling meetings if they wished. In addition it is important to pilot the programme in larger groups ideally of 6 to 7 people.

To the best of our knowledge this is the first structured education curriculum developed for people with OSA in the UK. Following the work reported in this chapter the next
phase will include piloting this curriculum as a lifestyle modification intervention by conducting a randomised controlled trial. Selecting increased step count as a primary outcome, a total sample size of 160 participants (80 in each group) would be needed with an estimated dropout rate of 10% during the 12 month follow-up period. Participants will be randomized into two groups including routine care (control group) or routine care plus the structured education programme (intervention group). In the control group participants will receive an information leaflet distributed as part of routine care at the Leicester Sleep Disorders Service informing subjects about OSA and the importance of weight loss, physical activity and CPAP compliance. The intervention group will receive a group education programme specifically tailored for OSA patients. The RCT will assess the effectiveness of the intervention programme in improving CPAP compliance, in increasing physical activity, in reducing cardiovascular risk and in improving the quality of life in adults with OSA. The purpose of this study will be to determine if a structured education programme tailored for moderate to severe subjects with OSA promoting CPAP compliance and physical activity may result in behaviour change leading to benefits outlined above in comparison to usual patient care. Biomedical, anthropometric and objectively measured CPAP compliance data will be assessed at baseline post 6 and 12 months of the intervention. If the intervention is found to be effective a multi centre RCT will be carried out to test if the results can be replicated across multiple primary care settings.
Chapter 6

Overall Discussion
6.0 Chapter overview

The previous chapters of this thesis have reported the role of psycho-social factors in predicting CPAP use and compliance in patients with established and newly diagnosed OSA. I have explored the perceptions of OSA and CPAP treatment experiences among this patient group, reviewed the association between diet, exercise and lifestyle management strategies in improving obesity indices, OSA parameters and quality of life in adults with OSA. I have then detailed the development of a group based structured education lifestyle modification programme aimed to increase physical activity and CPAP compliance in this patient population. Here, I will discuss and summarise the main findings, strengths and limitations of the three research projects forming this PhD. I will then discuss the future research in this field.

6.1 Research aims

The overall aim of this PhD was centred on conducting the preliminary work towards the development of a fit for purpose structured group education lifestyle modification programme for patients with OSA at high risk of developing cardiovascular disease (CVD) and dysglycaemia. The programme aimed to increase physical activity and promote CPAP compliance for this at risk patient group. In order to contribute effectively to the existing body of evidence-based research in developing complex interventions, including self-management lifestyle modification interventions, a multi-step approach was devised using the MRC framework and three interlinked studies were carried out to bridge the gap in the literature and to address previous limitations. These three studies are summarised in section 6.2.
6.2 Research studies and findings

The first study described in Chapter 2, titled ‘Predicting the Use of Continuous Positive Airway Pressure in Obstructive Sleep Apnoea in a UK population: The PUCOSA-UK study. This was a prospective, questionnaire based study aimed to explore the interplay of potential psycho-social predictors of CPAP adherence together for the first time utilising a strong framework of psychological models (Bandura’s and Leventhal’s models) in newly diagnosed and established OSA patients. The study utilised a comprehensive assessment of psycho-social determinants of CPAP use in different stages including pre OSA diagnosis, post CPAP trial, post 3 and 6 months of CPAP therapy. This design allowed to strategically evaluate the change of patient perceptions and beliefs in different stages of the condition that provided a clear insight of how early formed strong beliefs and conceptions (on disease severity, perceived symptoms, long term implications and chronicity of the condition together with the perceived benefits of CPAP use and the level of social support) influence the patients decision to adhere and comply to the therapy. The finding that the likelihood of adherence to CPAP therapy was heavily dependent on the early formation of strong beliefs and preconceptions of the condition and CPAP therapy prior to trialling the therapy was very important. This finding was utilised effectively when developing the education curriculum that aimed to alter these early formed beliefs to promote CPAP compliance and increased physical activity.

The qualitative element of the PUCOSA-UK study described in Chapter 3, titled ‘Perceptions of OSA and CPAP treatment experiences among established and newly diagnosed OSA patients’ explored people’s beliefs, views, opinions and preferences
regarding CPAP therapy and how these perceptions may affect compliance with the therapy. Semi-structured telephone interviews were conducted that aimed to capture perceptions and views during different stages (pre and post diagnosis and post CPAP treatment) to explore potential changes in accepting and using CPAP therapy. The study identified a number of common barriers to compliance including inability to recognise symptoms and link them with being diagnosed with OSA, initial negative reactions to the idea of using CPAP therapy, discomfort and inconvenience caused when wearing a CPAP mask and operating a CPAP device, lack of spousal or peer support and self-image issues. These barriers were taken into consideration and were addressed in developing the structured education programme. We aimed to empower patients and equip them with life-long skills so to enhance their self-confidence when dealing with problems around CPAP therapy and become aware of where they can receive support if they needed to. Interestingly, the results from this study indicated not only lack of public awareness of OSA but also suggest that information resources and publicity material should target both the patient and the spouse. This is because spouses are the first-line in recognising OSA breathing and thus contributing effectively in informing the person to seek help thus aiding early diagnosis and treatment.

A systematic review and meta-analysis of randomised controlled trials was conducted to assess the impact of diet and lifestyle management strategies for obstructive sleep apnoea in adults and this study was described in Chapter 4. The review evaluated the impact of diet, exercise and lifestyle modification interventions with or without CPAP therapy on obesity indices, OSA parameters and quality of life in adults with OSA. The results consolidated the evidence in this area and indicated that intensive lifestyle interventions which employed caloric restriction and/or physical activity were more
effective in reducing indices of obesity and improve severity of OSA. Furthermore, an additional benefit of CPAP therapy was observed to the dietary advice in the general well-being and alleviation of OSA related symptoms leading to improvements in the quality of life. The review emphasised the need to develop and invest in lifestyle modification interventions as these may hold the key for better long-term outcomes by advocating behaviour modification and promoting effective self-management of OSA.

The development of a fit for purpose structured education programme is an iterative and complex process as discussed in Chapter 5. The final part of this PhD was a small pilot of the Arise & Shine curriculum which was specifically designed to address the needs of people with OSA and promote CPAP compliance and increased physical activity (Chapter 5). The programme was piloted in two small patient groups consisting of established and newly diagnosed individuals with OSA. The results demonstrated that participants overall found the content of the programme very beneficial. After attending the course, participants perceived that their level of understanding of the condition, long term complications and practical aspects of CPAP therapy improved. Additionally, attendees felt that the programme helped them to start making changes in their lifestyle in terms of increasing and monitoring their daily physical activity levels, thus taking a more active role in the effective management of their condition.

6.3 Strengths and limitations

The three research projects carried out for the purpose of this PhD pose several limitations. In the PUCOSA-UK study a larger number of recruited participants in the newly diagnosed patient group would have been desirable as 11% were lost due to
failure to inclusion criteria. However, the results reported in this thesis are based on 89% of the completed data. Those recruited included predominantly male, white European and middle-aged participants, indicative characteristics of this disorder. However this does mean the results may not be generalisable to a wider population. Replicating this study in a more heterogeneous cohort would be useful for further exploring potential differences between ethnic populations age ranges and genders, particularly the understanding of OSA and how beliefs about the condition and its treatment may influence CPAP use.

A limitation in the systematic review and meta-analysis study was the heterogeneity identified between the included studies for some outcomes. Although no heterogeneity was observed in the primary outcome, difference in the length of follow-up time between the studies. Furthermore, poor representation of female patients and the inability to assess publication bias due to the limited number of studies identified are also limitations. However, a systematic and broad search was carried out in multiple databases to capture randomised controlled trials, with two independent researchers conducting the data extraction.

The development of the education curriculum was based on the utility and adaptation of pre-existing curricula (DESMOND & Let’s Prevent) aimed for patient populations with diabetes and pre-diabetes. These programmes were extensively piloted and tested as discussed in Chapter 5. In addition, extensive work was carried out to ensure the Arise and Shine programme met the needs for those with OSA.
The work reported in this thesis has several strengths including a robust mixed method approach with both qualitative and quantitative research methods combined with a systematic synthesis of existing evidence. Another strength is the utility of the MRC framework towards the development of the education programme together with the identification and utility of appropriate psychology theories complimenting behaviour modification.

The PUCOSA-UK study is the first study in the UK to date that has focused on what psycho-social factors predict CPAP adherence using a comprehensive assessment of these factors based on a strong framework of psychology models and theories. In addition, we report the first systematic review and meta-analyses of randomised controlled trials only to date that evaluated the impact of diet, exercise and lifestyle management strategies in improving OSA parameters, obesity indices and quality of life in adults with OSA. Finally, we provide a detailed account of the the first systematic work carried out to develop an education curriculum for the self-management of OSA patients in the UK.

6.4 Future research directions

Structured education programmes have been advocated as a vital component in the effective management of chronic conditions. In patients with diabetes, the availability and participation in such programmes has become established in practice however the use of education programmes in adults with OSA is a new clinical scope. To our knowledge, the Arise and Shine structured education programme is the first group based non-didactic patient centred programme for people with OSA. Future randomised controlled trials should be carried out to assess the effectiveness of this intervention and
evaluate the sustainability of any effect on CPAP compliance, in physical activity, reduction, cardiovascular and metabolic risk and in quality of life. Future work should also focus in educating GPs and spouses that are the first point of contact to those who seek sleep related help or are unaware of their sleep disordered breathing.

### 6.5 Conclusions

The research findings reported in this thesis have contributed to bridging the gap in the available literature on what psycho-social factors predict CPAP adherence, what type of interventions are most effective in reducing indices of obesity, parameters of OSA and in improving quality of life in adults with OSA. It added to the limited evidence on the development of a structured education programme in patients with OSA, potentially promoting behaviour modification and effective self-management of OSA. The preliminary work centred on the development and piloting of a structured education programme suitable for patients with OSA, promoting behavior modification, increase in physical activity and CPAP compliance has highlighted the potential benefits of a group-based education in enhancing knowledge and equipping patients with the required skills to self-manage their condition better. The utility and further exploration of such programmes in the UK primary health care settings will prove to be invaluable if found to be pragmatic and cost-effective.
Appendices

Appendix 1-Publications and Abstracts From Thesis


Poster Presentation, British Sleep Society Annual Scientific Meeting, Cambridge 2010

- Predicting the Usage of CPAP in Obstructive Sleep Apnoea - The PUCOSA-UK Study

Maria-Anna Thomasouli, Emer. M. Brady, Laura J. Gray Melanie J. Davies, Andrew P. Hall, Timothy Skinner, Romola Bucks, Kamlesh Khunti

Poster Presentation, British Sleep Society Annual Scientific Meeting, Cambridge 2012

- The impact of diet and lifestyle management strategies for obstructive sleep apnoea in adults: a systematic review and meta-analysis of randomised controlled trials

Maria-Anna Thomasouli, Emer. M. Brady, Melanie J. Davies, Andrew P. Hall, Kamlesh Khunti, Laura J. Gray.

Poster Presentation, British Sleep Society Annual Scientific Meeting, Edinburgh 2013

- Predicting the Use of Continuous Positive Airway Pressure Therapy in Obstructive Sleep Apnoea: The PUCOSA-UK Study Results

Maria-Anna Thomasouli, Emer. M. Brady, Andrew P. Hall, Kamlesh Khunti, Danielle H. Morris, Melanie J. Davies
# Appendix 2: Thesis Contributors

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<tr>
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<td>Andrew P. Hall</td>
<td>PhD Supervisor, Sleep Consultant, Leicester Sleep Disordered Service</td>
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<td>DHM</td>
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<tr>
<td>EMB</td>
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<td>PhD Supervisor, Senior Research Associate</td>
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<td>KK</td>
<td>Kamlesh Khunti</td>
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<td>LMS</td>
<td>Lorraine M. Stacey</td>
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<td>MAT</td>
<td>Maria-Anna Thomasouli</td>
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Appendix 3: The PUCOSA-UK Study

➢ Ethics approval letter
➢ Patient recruitment documents
  • Recruitment poster
  • Invitation letter
  • Reply slip
  • Information sheets
  • Consent forms
  • GP letter
  • Thank you letter

➢ Interview topic guides
16 March 2011

Dr Andrew P Hall
Consultant in Anaesthesia, Intensive Care & Sleep Medicine
University Hospitals of Leicester
Sleep Disorders Service
Harvington Sleep Laboratory
Leicester General Hospital
LE5 4PW

Dear Dr Hall,

Study Title: Predicting Usage of CPAP in Obstructive Sleep Apnoea (PUCOSA) in a UK population at high risk of Type 2 Diabetes and Cardiovascular disease.

REC reference number: 10/H0406/84
Protocol number: 1

Thank you for your letter of 10 March 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.niresearch.nhs.uk.
Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in iRAS. Further advice should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

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Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.
After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website → After Review.

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H0406/84 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely,

Dr Carl Edwards
Chair

Email: jasica_chair@nottspct.nhs.uk

Enclosures:

Copy to:

"After ethical review – guidance for researchers"
Student – Ms Maria-Anna
R&D office for NHS care organisation at road site – UHL.
Volunteers Needed for the PUCOSA UK Study!

We are exploring what things make CPAP more difficult for people

Have you been previously diagnosed with Obstructive Sleep Apnoea and are currently using breathing support called CPAP when you sleep?

OR

Have you been recently referred to the Leicester Sleep Disorders Service for an overnight Home Sleep Respiratory Study?

If YES you might be eligible to participate in this study being carried out by the Leicester Sleep Disorders Service.

Taking part in this research would involve completing a questionnaire when you attend your routine visits. A small number of volunteers will be further contacted to take part in focus groups and telephone interviews.

If interested please contact us for further information and an invitation pack.

Contact: Maria-Anna Thomasouli
Tel: 0116 258 8106
E-mail: maria-anna.thomasouli@uhl-tr.nhs.uk

Principal Investigator:
Dr. Andrew P. Hall
Consultant in Anaesthesia
Intensive Care & Sleep Medicine
MA, MSc, FRCR, FRCA

University Hospitals of Leicester
Leicester General Hospital
Leicester Sleep Disorders Service
Hannington Sleep Laboratory
L15 4PW
Tel: 0116 258 8106
sleepservices@uhl-tr.nhs.uk

University of Leicester
University Hospitals of Leicester
NHS Trust
Dear

You have been referred to the Leicester Sleep Disorders Service and we would like to invite you to participate in a research project designed to investigate what factors may influence people’s decision on how and when to use their CPAP machines.

This study will be conducted at the Leicester Sleep Disorders Service and is collaboration between Dr. Andrew Hall and colleagues including Professor Melanie Davies, Professor Kamlesh Khunti, Dr. Emer Brady and Maria-Anna Thomasouli.

We aim to recruit 180 participants who are either newly diagnosed or established OSA patients with at least a moderately severe condition and are on CPAP therapy. Please find enclosed the Patient Information Sheet with the study details and information regarding your participation. We are also enclosing a pre-paid reply slip and envelope for you to complete if you are interested in participating.

If you would like further information please do not hesitate to contact one of the investigators:

PhD Researcher, Maria-Anna Thomasouli:
T: 0116 258 8106 E: maria-anna.thomasouli@uhl-tr.nhs.uk

Diabetes Project Manager, Dr. Emer Brady:
T: 0116 258 7442 E: emerbrady@uhl-tr.nhs.uk

We would like to thank you in advance for your consideration.

Yours Sincerely,

Dr. Andrew Hall
Consultant Anaesthetist
1. I would not like to participate in the PUCOSA-UK study
2. I would like to participate in the PUCOSA – UK study

Your Contact Details

Name

Address

Telephone Number

Best time to Contact

Date of birth

(Patient Reply Slip Version: 1 Oct 2010)
Predicting Usage of CPAP in Obstructive Sleep Apnoea (PUCOSA)-UK

Principal Investigators:
Dr Andrew Hall (University Hospitals of Leicester, Sleep Disorders Service)
Professor Melanie Davies (Department of Cardiovascular Sciences, University of Leicester)
Professor Kamlesh Khunti (Department of Health Sciences, University of Leicester)
Dr Emer Brady (University Hospitals of Leicester, Diabetes Research)
Ms Maria-Anna Thomasouli (University Hospitals of Leicester, Sleep Disorders Service)
Dr Romola Bucks (School of Psychology, University of Western Australia)
Dr Timothy Skinner (Combined Universities Centre for Rural Health)

We would like to invite you to take part in a research study. Before you decide whether or not to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish; we have given you the contact details of the researchers at the end if you want to ask them any questions.

What is the purpose of the study?

Continuous positive airways pressure (CPAP) therapy is an effective treatment for people with obstructive sleep apnoea (OSA). However, we know that many people do not use their CPAP machines as often as needed to gain the maximum benefit from the treatment. In this study we are hoping to gain a better understanding of what helps people decide when and how to use their CPAP machines.

Why have I been invited?

We are inviting everyone over 18, who speaks English as a first language, and who has been referred to the Leicester Sleep Disorders Service and currently receives CPAP therapy, to help with the study, and not currently participating in any other study with an intervention.
Do I have to take part?

No you do not have to take part. If you do not wish to take part in the study, all you will need to do is complete the enclosed reply slip and post back in the pre-paid envelope provided. Your usual medical care will NOT be affected if you decide NOT to participate. Additionally, if you do decide to participate you may withdraw your consent and stop participating at anytime. Again this will NOT affect your usual medical care.

What will happen to me if I take part?

When attending your CPAP review as part of routine care we will ask you to complete a questionnaire booklet, which asks about your experiences of CPAP, on how you are feeling, and what effect the treatment has had on your symptoms.

Each participating person will additionally be invited to attend a focus group and/or a home telephone interview. These are to further determine what your opinions are of the care you currently receive and how it may be improved.

Will my taking part in the study be kept confidential?

Yes. The only people who will know if you have taken part in the study will be yourself, and the researchers who collect the data and your GP. All data to be analysed will not contain any patient identifiable data and therefore any reports will be completely anonymised.

What are the possible benefits of taking part?

Individuals who take part in the study will complete a more comprehensive assessment of their psychological well-being and cognitive skills than is part of routine care. If these assessments identify any problems that are not received following treatment with CPAP, we will feed back these results to you and, if you wish, provide some information on where you can go to get further help if this needed.

We also hope the results of the study will help us find out how we can best support people with sleep apnoea to gain the most benefit from CPAP. So, we hope that the results will help us improve the way doctors and nurses help people understand their sleep apnoea and its treatment, and how best to encourage people to get the most benefit from the treatment.
What if there is a problem?

If you have a concern or any questions about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (see below).

What happens at the end of the study?

The results will be analysed and it is hoped that results of the study will be written up for publication in one or more journals and as a series of student projects (undergraduate and graduate). Furthermore we will send you a summary of our findings.

Maria-Anna Thomasouli
Leicester Sleep Disorders Services
Leicester General Hospital
LE4 5PW
(0116) 2588106
(0116) 2584223

Emer Brady
Diabetes research
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LE4 5PW
(0116) 2584223
Patient Information

Predicting Usage of CPAP in Obstructive Sleep Apnoea (PUCOSA)-UK

Principal Investigators:
Dr Andrew Hall (University Hospitals of Leicester, Sleep Disorders Service)
Professor Melanie Davies (Department of Cardiovascular Sciences, University of Leicester)
Professor Kimchok Khunti (Department of Health Sciences, University of Leicester)
Dr Emer Brady (University Hospitals of Leicester, Diabetes Research)
Ms Maria-Anna Thomacouli (University Hospitals of Leicester, Sleep Disorders Service)
Dr Romola Ducks (School of Psychology, University of Western Australia)
Dr Timothy Skinner (Combined Universities Centre for Rural Health)

We would like to invite you to take part in a research study. Before you decide whether or not to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish; we have given you the contact details of the researchers at the end if you want to ask them any questions.

What is the purpose of the study?

Continuous positive airways pressure (CPAP) therapy is an effective treatment for people with obstructive sleep apnoea (OSA). However, we know that many people do not use their CPAP machines as often as needed to gain the maximum benefit from the treatment. In this study we are hoping to gain a better understanding of:
- what helps people decide when and how to use their CPAP machines
- how you feel about having OSA
- your opinions on the care you currently receive
- your personal experiences with OSA

Why have I been invited?

We are inviting a number of people, who are taking part in the PUCOSA UK study.
Do I have to take part?

No you do not have to take part. If you do not wish to take part this will not affect your participation in the main study or the current care you are receiving for OSA.

What will happen to me if I take part?

We are asking people to be interviewed on the telephone or take part in a focus group at a time which is convenient to them.

- Interview - If you take part in the interview and we will make the telephone call, so there will be no call charges. Before the interview, the researcher will need to confirm that you are willing to take part. The consent process and interview will usually last about 30 to 45 minutes and both will be audio recorded. If you volunteer for the interviews, we will need you to give the researcher carrying out the interviews a telephone number on which you can be contacted. However, this telephone number will be deleted from the researcher’s records once the interview has been completed.

- Focus groups - If you are invited to take part in a focus group, this will take place in a location convenient to you. Your travel expenses will be reimbursed up to £15. Before the focus group the facilitator will confirm with you the arrangements (time and venue). The facilitator will obtain your consent before starting the group discussion. There will be 6-8 other patients that have OSA. The group discussion will be directed by the facilitator and will last about an hour. There are no right or wrong answers but it is an opportunity to hear your views. The focus group will be audio recorded.

Will my taking part in the study be kept confidential?

Any information that we collect during the interview/focus group will be treated as confidential and your name will not be put on the audio recording. The consent process will need to include your name, but this will be recorded and stored separately. When we have looked at the information from all the interviews/focus groups, we won’t use any names in the findings that we report. At the end of the research study, we will destroy the audio recordings.

Who is responsible for the study?

This research is being carried out by University Hospitals of Leicester and the University of Leicester. The Principal Investigator, who will take responsibility for the study, is Dr Andrew Hall.

Who has reviewed this study?

To protect your safety, rights, well-being and dignity, all research involving patients is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed by the appropriate ethics committee in accordance with local regulations.
What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (see below).

What will happen if I don’t want to carry on with the study?

It is hoped that results of the study will be written up for publication in one or more journals and as a series of student projects (undergraduate and graduate).

What if I have some questions I want to ask?

If you have any further questions about the study please contact

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Dr Romola Bucks (School of Psychology, University of Western Australia)
Dr Timothy Skinner (Combined Universities Centre for Rural Health)

Please read and initial each box to confirm that you have read and understood each statement:

1. I have read the participant information sheet (Version 2b, 10th March 2011) of the above project and have been given a copy to keep. I have had the opportunity to ask questions about the project and I am satisfied with the information I have been given.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care and legal rights being affected.

3. I understand that relevant sections of my medical notes may be looked at by responsible individuals from the study team or from regulatory authorities where it is relevant to my taking part in the research. I give permission for these individuals to access my records.

4. I agree to take part in the above study.

5. I give permission for my GP to be informed of my participation in the above study.

6. I give permission to be contacted at a later stage for the purpose of attending either focus groups or an interview. I understand that the named researchers will contact me by telephone for this purpose.

Name of patient

Date

Signature

Name of person taking consent

Date

Signature
Predicting Usage of CPAP in Obstructive Sleep Apnoea (PUCOSA)-UK

Principal Investigators:
Dr Andrew Hall (University Hospitals of Leicester, Sleep Disorders Service)
Professor Melanie Davies (Department of Cardiovascular Sciences, University of Leicester)
Professor Kamlesh Khunti (Department of Health Sciences, University of Leicester)
Dr Emer Brady (University Hospitals of Leicester, Diabetes Research)
Ms Maria Thomassouli (University Hospitals of Leicester, Sleep Disorders Service)
Dr Romola Buckley (School of Psychology, University of Western Australia)
Dr Timothy Skinner (Combined Universities Centre for Rural Health)

Please read and initial each box to confirm that you have read and understood each statement:

1. I have read the participant information sheet (Version 1.0, April 2010) of the above project and have been given a copy to keep. I have had the opportunity to ask questions about the project and I am satisfied with the information I have been given.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care and legal rights being affected.

3. I understand that relevant sections of my medical notes may be looked at by responsible individuals from the study team or from regulatory authorities where it is relevant to my taking part in the research. I give permission for these individuals to access my records.

4. I agree to take part in the above study.

5. I give permission to be contacted at a later stage for the purpose of attending focus groups. I understand that the named researchers will contact me by telephone for this purpose.

6. I give permission to be contacted at a later stage for the purpose of attending a focus group or an interview. I understand that the named researchers will contact me by telephone for this purpose.

Name of patient Date Signature

Name of person taking consent Date Signature
Predicting Usage of CPAP in Obstructive Sleep Apnoea (PUCOSA)-UK

Dear Dr. GP

This patient is participating in the above study on Obstructive Sleep Apnoea. He/She consented to join the study on __________. This study involves a more comprehensive assessment of the patients’ psychological well-being and cognitive skills than is part of a routine care, in the form of multiple questionnaires, but does NOT involve any changes in standard treatment. A copy of the patient information sheet and consent form are enclosed.

Yours Sincerely,

Dr. Andrew Hall
Consultant Anaesthetist

Trust Headquarters, Gwendolen House, Gwendolen Road, Leicester, LE5 4QF
Tel: 0116 258 4000 Fax: 0116 258 4000 Website: www.uh-tr.nhs.uk
Chairman Mr. Martin Hindle Chief Executive Malcolm Lowe-Lauri
Dear Mr /Mrs

On behalf of the Sleep Disorders Service and the PUCOSA-UK Research Team, I would like to thank for your participation in our research study. Your efforts made all the difference in the success of enabling us to provide the best support to patients with Obstructive Sleep Apnoea gaining the most benefit from their Continuous Positive Airway Pressure (CPAP) treatment.

A report summarizing the results of the study will be produced next year and we will be sending a copy to each participant.

Thank you again for your help and wish you every success in the future with your CPAP therapy.

Yours Sincerely,

Dr. Andrew Hall  
Consultant Anaesthetist
**A. Introduction to the Interview**

[Aim = to explain about the interview and to reassure the person being interviewed. Note: this section does not necessarily need to be recorded]

Hello Mr/Mrs/Ms ________,
My name is ___________, thank you for volunteering to participate.

This part of the PUCOSA-Study is for us to find out more about:
- What are your thoughts on sleep problems
- The impact of sleep problems on everyday life

Our research team will use your feedback in improving the way doctors and nurses help people understand their OSA and its treatment, and how best to encourage people to get the most benefit from their therapy. With this in mind, I would like you to respond with your own feelings and thoughts to the questions, there are no right or wrong answers. We are interested in hearing about your experiences even if this is something negative. If any of the questions are not clear to you just let me know. At any point if you do not wish to answer a question or you want to stop the interview please let me know.

The interview will be around 30-45 minutes in length. I will be taping the interview so that I have an accurate record of what you say. Everything discussed today will remain private and confidential and you will not be identified in any report coming from this research.

Note: *Tape to be switched on* at this point

**B. Consent Taking**

*As deemed by the R&D NHS-Trust Consent Policy*

- Confirm patient details [Name, Surname, DOB *(switch tape off)*] !!!Keep the patient identification data on separate files so to ensure anonymity!! *(switch tape on)* and continue.
- Explain PIS
- Read consent form & record patient’s response.

**C. Background Information / Invitation to Talk**

[Aim = to provide background information so that the research team will be able to describe the sample of patients who contribute to the study, also to start the interview with non-challenging questions]
➢ I would like to start by asking you to tell me your age and your ethnic background?
   [Some people have described themselves as white British or South Asian, how would you
describe yourself?]

➢ Do you mind telling me what your marital status is? [Prompt Are you single/married/divorced or widowed?]
   ☑ In case of SINGLE: I hope you don’t mind telling me if you share your bedroom
   with a partner? If sleeping in separate bedrooms clarify if this is because of the
   sleep disorder. May I ask if this is related to your sleep problem?
   ☑ In case of MARRIED I hope you don’t mind telling me if you share your bedroom
   with your wife/husband? If sleeping in separate bedrooms clarify if this is because
   of the sleep disorder. May I ask if this is related to your sleep problem?
   ☑ In case of DIVORCED: I hope you don’t mind telling me if you share your
   bedroom with a partner? If sleeping in separate bedrooms clarify if this is because
   of the sleep disorder. If WIDOWED: ask I hope you don’t mind me asking if you
   have a new partner and share a bedroom with him/her? If sleeping in separate
   bedrooms clarify if this is because of the sleep disorder.

**Discussion Guide**

Note: The order of the lines of questioning can be varied to fit the flow of the interview.

1. **Sleep problems & perceptions (part 1)**
   [Aim = to find out the reasons which lead people to seek sleep-related help; explore their
   perceptions and understanding of sleep problems before attending the Sleep clinic.]

   ➢ Do you mind telling me what made you visit your GP and seek sleep related help?
   Potential answers: (my wife/husband/partner/children etc mentioned I snore very loud and/or
   I stop breathing in my sleep, I feel very tired) Explore further each reported symptoms/reason
   [Prompt: Some people have told us that they felt very tired/lazy during the day and
   regardless of how many hours they slept they still felt not very refreshed. Would you say you
   have felt the same way, or not? OR consider giving an example with another symptom i.e
   snoring Exhaust: Is there anything else you can think of?
   ➢ For how long have you felt this way?
   ➢ Do you think the way you feel might influence or not your everyday life/work/family etc?
   ➢ Does this worry you or not?
   ➢ Do you mind telling me if your wife/husband/partner is worried or not?
   ➢ If you don’t mind me asking what do you think might be causing your symptoms?
   Potential answers (old age, not sleeping well, I am not sure, OSA)
   Continue ONLY if the answer is OSA Do you mind telling me if you know what is the
   treatment for OSA?
   Continue ONLY if the answer is CPAP or breathing device. If you are diagnosed with OSA
   how would you feel about sleeping with a CPAP machine/breathing device? Explore further
   and prompt more questions
   • How do you think your wife/husband/partner might react if you need to sleep with a
   CPAP machine/breathing device?
Thank you very much for taking part. We really appreciate you giving up your time to share your personal experiences and thoughts with us.

**Arrange second part of interview after formal diagnosis with Sleep consultant**

2. **OSA & CPAP perceptions** (part 2)

   [After attending the Sleep clinic]

   - Do you mind telling me what is the name of your sleep disorder? **[Prompt: Do you remember what was the name/term your doctor used to describe your sleep disorder/problem? Continue: Have you heard that name/term before?]**
   - Was it helpful or not to put a name on the condition that was causing you to have sleep problems?
   - How did you feel when the doctor explained to you, your sleep test results and diagnosed you with OSA?
   - Is there anything your doctor told you about OSA that might have explained the way you felt/behaved before your diagnosis? **[Prompt: Could you tell me more about that?]**
   - Do you mind telling me what is the name of the treatment for sleep apnoea? **[Prompt: Do you remember what was the name/term your doctor used to describe the therapy for sleep apnoea?]**
   - How did you feel/react when the doctor prescribed you to start on CPAP therapy? **[Prompt: What made you think that? Were there any other reasons?]** **[Exhaust: Is there anything else you can think of?]**

   **Continue with one of the following:**

   - **If single (not married) and living with a partner:** Can you tell me how did your partner felt about CPAP therapy and what were his/hers initial reactions and thoughts on you using a CPAP machine? **[Prompt: What do you think made him/her think/react like that? Were there any other reasons?]**
   - **If single and living with a partner and other people (i.e children/friends):** Can you tell me how did your partner and children/friends felt about CPAP therapy and what were their initial reactions and thoughts on you using a CPAP machine? **[Prompt: What do you think made them think/react like that? Were there any other reasons?]**
   - **If Married and living with other people (children etc):** Can you tell me how did your wife/husband and children felt about CPAP therapy and what were their initial reactions and thoughts on you using a CPAP machine? **[Prompt: What do you think made them think/react like that? Were there any other reasons?]**
   - **If Divorced/Widowed and living with a partner:** Can you tell me how did your partner felt about CPAP therapy and what were his/hers initial reactions and thoughts on you using a CPAP machine? **[Prompt: What do you think made him/her think/react like that? Were there any other reasons?]**
   - **If Divorced/Widowed and living with a partner and other people (children etc):** Can you tell me how did your partner and children felt about CPAP therapy and what were their initial reactions and thoughts on you using a CPAP machine? **[Prompt: What do you think made them think/react like that? Were there any other reasons?]**
➢ Does anybody else that you know of have sleep apnoea and have they felt better or not after using CPAP?

➢ Do you mind telling me if you think CPAP is going to help you or not with your symptoms (customise according to the related symptoms reported by the participant, tiredness, snoring etc)?

Thank you very much for taking part. We really appreciate you giving up your time to share your personal experiences and thoughts with us.
A. Introduction to the interview

[Ann = to explain about the interview and to reassure the person being interviewed. Note: this section does not necessarily need to be recorded]

Hello Mr/Mrs/Ms __________,
My name is __________, thank you for volunteering to participate.

This part of the PUCOSA Study is for us to find out more about:
✦ What helps people decide when and how to use their CPAP machines,
✦ How you feel about having Obstructive Sleep Apnoea (OSA),
✦ Your personal experiences with OSA,
✦ Your opinions on the care you currently receive.

Our research team will use your feedback in improing the way doctors and nurses help people understand their OSA and its treatment, and how best to encourage people to get the most benefit from their therapy. With this in mind, I would like you to respond with your own feelings and thoughts to the questions, there are no right or wrong answers. We are interested in hearing about your experiences even if this is something negative. If any of the questions are not clear to you just let me know. At any point if you do not wish to answer a question or you want to stop the interview please let me know.

The interview will be around 30-45 minutes in length. I will be taping the interview so that I have an accurate record of what you say. Everything discussed today will remain private and confidential and you will not be identified in any report coming from this research.
Note: *Tape to be switched on* at this point

**B. Consent Taking**

*As deemed by the R&D NHS Trust Consent Policy*

- Confirm patient details [Name, Surname, DOB (*switch tape off*)] [*Keep the patient identification data on separate files so to ensure anonymity!* *Switch tape on* and continue.]
- Explain PIS
- Read consent form & record patient’s response.

**C. Background Information / Invitation to Talk**

[Aim = to provide background information so that the research team will be able to describe the sample of patients who contribute to the study, also to start the interview with non-challenging questions]

- I would like to start by asking you to tell me your age and when you were diagnosed with a sleep disorder?
- Do you mind telling me how you would describe your ethnic background? [*Some people have described themselves as white British or South Asian, how would you describe yourself?]*
- Do you mind telling me what your marital status is? [*Prompt Are you single/married/divorced or widowed?]*
  
  ☑ In case of SINGLE: I hope you don’t mind telling me if you share your bedroom with a partner? [*If sleeping in separate bedrooms clarify if this is because of the sleep disorder*] May I ask if this is related to your sleep problem?
  
  ☑ In case of MARRIED I hope you don’t mind telling me if you share your bedroom with your wife/husband? [*If sleeping in separate bedrooms clarify if this is because of the sleep disorder*] May I ask if this is related to your sleep problem?
  
  ☑ in case of DIVORCED: I hope you don’t mind telling me if you share your bedroom with a partner? [*If sleeping in separate bedrooms clarify if this is because of the sleep disorder*] if WIDOWED: ask I hope you don’t mind me asking if you have a new partner and share a bedroom with him/her? [*If sleeping in separate bedrooms clarify if this is because of the sleep disorder*]

- How long have you been using a CPAP machine?

- We know that CPAP may affect other people living in a house and based on this do you mind telling me how many people live in your house? *-Keep a note of this information as it will determine following questions*  
  
  Potential answers: *‘I live on my own’  
  ‘I live with my wife/husband/partner  
  ‘I live with my wife/husband/partner and (x number of) children  
  ‘I live with my children’  
  ‘I live with my friends and/or other family members (parents/ grandchildren etc etc)*
Discussion Guide

Note: The order of the lines of questioning can be varied to fit the flow of the interview.

1. OSA+ CPAP Perceptions (part 1)
   [Aim = to find out the reasons which lead people to seek sleep-related help; explore their perceptions and understanding of OSA+CPAP before attending the Sleep clinic.]

   ➢ Do you mind telling me what is the name of your sleep disorder? [Prompt: Do you remember what was the name/term your doctor used to describe your sleep disorder/problem? Continue: Have you heard that name/term before? [Prompt: Was it helpful or not to put a name on the condition that was causing you to have sleep problems?]

   ➢ Thinking back to the time before you saw the doctor at the hospital, can you tell me a bit about what you thought might be causing your Obstructive sleep apnoea (OSA)? [Rephrase: Before you saw the doctor at the hospital did you have any ideas about what might have been causing your OSA?] [Prompt: Why did you think you were having problems to do with sleeping? [Prompt: Some people have told us that they felt very tired/lethargic during the day and regardless of how many hours they slept they still felt they could sleep a couple of hours more. Would you say you felt the same way, or not? OR consider giving an example with another symptom i.e snoring Exhaust: Is there anything else you can think of?]

   ➢ Still thinking before you were diagnosed with OSA-can you tell me if you knew anything about potential treatment options? [If YES: Where did you obtain/ get this information from?] [Continue where appropriate [What were your reactions and thoughts on CPAP therapy then?] [Prompt: Perhaps you would like to tell me how did you feel you were going to cope with CPAP at this stage? What made you think that?]

   ➢ What were your expectations of your consultation with the doctor before attending the Sleep clinic? [Rephrase: What did you think you were going to find out from the doctor before attending the Sleep clinic?]

OSA+ CPAP Perceptions (part 2)
   [Aim = to find out people’s perceptions and understanding of OSA+CPAP after attending the Sleep clinic.]

   ➢ How did you feel when the doctor explained to you, your sleep test results and diagnosed you with OSA? [Continue: Is there anything your doctor told you about OSA that might have explained the way you felt/behaved before your diagnosis?] [Prompt: Could you tell me more about that?]

   ➢ How did you feel/react when the doctor prescribed you to start on CPAP therapy? [Rephrase: Still thinking after you were diagnosed with OSA but before trying a CPAP machine at the sleep clinic with the technician-can you recall your initial reactions and thoughts on CPAP? [Rephrase: Perhaps you would like to tell me a little bit more about how did you feel about sleeping with a CPAP machine before you tried the actual therapy at the sleep clinic with the technician?] [Prompt: What made you think that? Were there any other reasons?] [Exhaust: Is there anything else you can think of?]
Continue with one of the following:

- **If single (not married) and living with a partner**: Can you tell me how did your partner felt about CPAP therapy and what were his/her initial reactions and thoughts on you using a CPAP machine? [Prompt: What do you think made him/her think/react like that? Were there any other reasons?]
- **If single and living with a partner and other people (i.e children/friends)**: Can you tell me how did your partner and children/friends felt about CPAP therapy and what were their initial reactions and thoughts on you using a CPAP machine? [Prompt: What do you think made them think/react like that? Were there any other reasons?]
- **If Married and living with other people (children etc)**: Can you tell me how did your wife/husband and children felt about CPAP therapy and what were their initial reactions and thoughts on you using a CPAP machine? [Prompt: What do you think made them think/react like that? Were there any other reasons?]
- **If Divorced/Widowed and living with a partner**: Can you tell me how did your partner felt about CPAP therapy and what were his/her initial reactions and thoughts on you using a CPAP machine? [Prompt: What do you think made him/her think/react like that? Were there any other reasons?]
- **If Divorced/Widowed and living with a partner and other people (children etc)**: Can you tell me how did your partner and children felt about CPAP therapy and what were their initial reactions and thoughts on you using a CPAP machine? [Prompt: What do you think made them think/react like that? Were there any other reasons?]

Continue:

- **How did you find the actual CPAP trial at the Sleep clinic with the technician?** [Prompt: Perhaps you would like to tell me a little bit more about the information you received by the technician at the Sleep clinic - do you think it was helpful or not? Did you find the information you received from the technician helpful or not for you to understand how CPAP works? [Prompt Could you tell me more about that?]

- **What were your thoughts on sleeping with a CPAP machine after your CPAP trial at the Sleep clinic?** [Prompt: Did you find easier to tolerate it than expected, or not?]

- **Can you tell me about your: wife's, husband's, partner's, children's, friends (use these were appropriate) reactions and thoughts after your CPAP trial at the Sleep clinic?**

2. **CPAP Perceptions & Barriers**

[Aim = to explore what helps people decide when and how to use their CPAP machines, the impact of CPAP barriers on people with OSA, the impact of bed partner's (family/friends) negative perceptions on CPAP use]

- **Since you last saw the technician have you actually used your CPAP machine?** [If NO Do you mind telling me what has stopped you from using it? If YES Continue below.]

- **How frequently do you use your CPAP machine?** [Rephrase: Some people have told us that they don’t use their CPAP very often - would you say you use yours regularly or not?]
3. Improving CPAP Compliance

- If you knew somebody who had to use a CPAP machine how would you describe what was it like?

- What advice would you give them if they were struggling to use it or to use it for more than 4hrs per night? Prompt: Is there anything else you can think of?

- If your partner had to use a CPAP machine how would that make you feel and what practical help would you give him/her?

4. Additional Information & Closing of the interview
[Aim = to find out if the interviewee has anything else to add that has not been covered so far and to make them feel that their contributions have been valuable]

4.1 Improving Current Sleep service

- Thinking overall about the Sleep disorders service what are your thought on the care you currently receive?

- Is there anything you can recommend/suggest so to improve the overall service?
That has all been very helpful. Before we finish the interview, I would like to ask you if there is anything else that you would like to say that we haven’t discussed.

Thank you very much for taking part. We really appreciate you giving up your time to share your personal experiences and thoughts with us.
Appendix 4 - Systematic Review Supplementing Material

Search strategy:

1. exp Sleep Apnea, Obstructive/ or exp Sleep Apnea Syndromes/ or exp Sleep Disordered Breathing/ or exp Obesity Hypoventilation Syndrome/
2. Obstructive Sleep Apnea Hypopnea.mp.
3. (apn$ or hypopn$).tw,ti,ab,sh.
4. (osa$ or osh$).tw,ti,ab,sh.
5. 1 or 2 or 3 or 4
6. lifestyle.mp. or exp Life Style/ or exp life style$/
7. exp Diet, Fat-Restricted/ or exp Diet, Carbohydrate-Restricted/ or exp Diet, Mediterranean/ or exp Diet, Atherogenic/ or exp Diet, Reducing/ or exp Ketogenic Diet/ or exp Diet Surveys/ or exp Diet Therapy/ or exp Diet/ or diet.mp. or exp Diet, Protein-Restricted/ or exp Diet, Sodium-Restricted/ or exp Diet, Vegetarian/
8. physical exertion.mp. or exp Physical Exertion/
9. exercise.mp. or exp Exercise/
10. 6 or 7 or 8 or 9
11. 5 and 10
12. exp Research Design/ or exp Randomized Controlled Trials as topic/ or randomised controlled trials as topic.mp. or exp Evidence-Based Medicine/
13. exp random allocation/
14. exp single-blind method/
15. exp double-blind method/
16. clinical trials.mp. or exp Clinical Trial as topic/
17. ((singI$ or doubl$ or treb$ or trip$) adj3 (mask$ or blind$)).tw,ti,ab,sh
18. exp research design/
19. exp intervention studies/
20. exp prospective studies/
21. exp comparative studies/
22. exp follow-up studies/
23. exp review literature as topic/
24. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
25. 11 and 24
26. limit 25 to (english language and humans and "all adult (19 plus years")

213
### Appendix 5-Example of Charting

**1A) Views on: Experiences prior to seeking help**  
**Patient Group:** Suspected/ Newly diagnosed OSA patients

<table>
<thead>
<tr>
<th>P.ID</th>
<th>Knowledge of OSA</th>
<th>Actual symptoms reported</th>
<th>Attributing symptoms to other reasons</th>
<th>Length of time before seeking help</th>
<th>Reasons for seeking help</th>
<th>The role of the other person</th>
<th>Impact of lack of sleep</th>
</tr>
</thead>
</table>
| **PUC-179**  
British male  
56 yrs old  
married | Never heard of it/never realised there was a problem QQQ Q p1+3  
Yes | All the time (EDS) QQ pg1  
'Always tired' p2  
Not a heavy snorer | Stroke/Minor fits/business failings/Depression stress/BP/other problems QQQQ Q p2 | Many years | Spouse knew somebody with OSA & due to a violent fit QQ p1  
Spouse was very supportive | Spouse was very suicidal QQQQ p2  
Yes, felt suicidal QQ p2  
Mood swings QQ Qp2 | Depression  
Relationships  
Work life |
| **PUC-172**  
British Female  
60 yrs old  
married | n/a, probably not aware | Yes, 'I am forever lasting tired' | n/a | Yes, only 2-3 hrs sleep per night | Worries | Depression and spouse mentioned to the GP sleep problems | Spouse was supportive | Very depressed, Emotionally mixed up QQ p4  
Very tearful | Yes, Irritable with family  
Yes, embarrassed/staffs laughing QQQQ p2 |
| **PUC-174**  
British male  
35 yrs old  
married | Not aware of it | Yes, (EDS) after 6pm  
Yes heavily | Having a young baby QQ | A while, almost over a year | Spouse complained of heavy snoring | Spouse was supportive | n/a | Yes | 'I was keeping her awake and couldn't believe that I wasn't aware' QQ p1 |
| **PUC-144**  
British male  
55 yrs old  
married | No...  
(he is a GP!!) | Yes, continually falling asleep QQQQ Q p1 | n/a | n/a | Anaemia, thyroid problem, being unfit, low mood, DiabetesQQQ | Spouse mentioned stopping breathing during sleep | n/a | Yes | 'Not able to get things done, not able to cope'QQ |
| **PUC-113**  
British male  
53 yrs old  
married | Not aware, 'I didn't realise how bad it had got until I was diagnosed'  
Yes | Yes, absolute tiredness QQQQ Q p1 | Restless sleep | Working long hours | About 2 years | Spouse & work colleague | Spouse was very supportive QQ p7 | n/a | Yes | Spouse was getting irritable, bad sleep quality  
Sex life QQ |

| 214 |
Appendix 6 The Arise and Shine Educational Curriculum Supplementing Material

➢ Preparing for the Arise & Shine Programme

➢ The Curriculum
  • Session A:
  • Session B
  • Session C
  • Session D
  • Session E
  • Session F
  • Session G
  • Session H
  • Session I
  • Session J
  • Session K
  • Session L
  • Session M

➢ Participant resources
WHAT IS ARISE & SHINE ALL ABOUT?

This booklet aims to answer some basic questions about Obstructive Sleep Apnoea, often shortened to OSA and its self management to give you a better idea of what coming to the Arise & Shine sessions is all about.

What can I expect at Arise and Shine?

The sessions aim to help you to understand more about your OSA, how to self manage and live with OSA and how a change in lifestyle can possibly help.

At Arise & Shine you can:

- Talk about your concerns around OSA and sleeping with Continuous Positive Airway Pressure (CPAP) therapy
- Get answers to your questions
- Discuss the options for dealing with the signs and symptoms of OSA
- Be supported in making your own choices about how you deal with your OSA and necessary lifestyle changes.
- Find out about what support you can expect from your local health service

Arise & Shine is run in groups because:

- People report that it is helpful to talk to people in a similar situation
- People can learn from each other
- People can often help each other and share ideas
- People enjoy the sessions - even if they come along thinking they won’t!

The sessions aim to be relaxing, friendly and fun. Because the numbers in the group are small, it's more like being among friends. The sessions are run by trained health professionals.

This training means they are able to:

- Answer your questions
- Support and encourage you to think about how you would like to manage your OSA in the future.
WHAT CAN I DO TO PREPARE FOR MY ARISE & SHINE SESSIONS?

You may feel that you have enough to think about right now, and would just like to come along on the day, and take it from there. Sometimes it can help to think about what you might like from the Arise & Shine sessions, you may want to think about the following:

- What do you want to know?
- What are the questions that you or your family have at the moment about OSA?
- Are you unsure as to how it will affect your life?

Jot down some questions in the space below - it’s easy to forget them on the day.

What do I want to know...

SLEEPING WITH CPAP THERAPY

CPAP therapy plays a large part in helping you manage your OSA. It might help you to think a little about how long and how frequently you sleep with your CPAP before you start Arise & Shine session.

To understand more about your use of CPAP therapy tick (✓) the statements that apply to you.

<table>
<thead>
<tr>
<th>Statements</th>
<th>True</th>
</tr>
</thead>
<tbody>
<tr>
<td>I sleep with my CPAP machine for less than 4 - 4.5 hours per night every night</td>
<td></td>
</tr>
<tr>
<td>I sleep with my CPAP machine for more than 4 - 4.5 hours per night every night</td>
<td></td>
</tr>
<tr>
<td>I sleep with my CPAP machine all night every night.</td>
<td></td>
</tr>
<tr>
<td>I am more likely to take my mask off in the middle of my sleep when I feel hot.</td>
<td></td>
</tr>
<tr>
<td>I am more likely to take my mask off in the middle of my sleep when I wake up to go to the bathroom and forget to put it on.</td>
<td></td>
</tr>
<tr>
<td>I am more likely to not use my mask when my CPAP mask is leaking.</td>
<td></td>
</tr>
<tr>
<td>I feel refreshed most days when I wake up in the morning</td>
<td></td>
</tr>
<tr>
<td>I don’t feel refreshed when I wake up in the morning.</td>
<td></td>
</tr>
</tbody>
</table>

How did you do?

Maybe your answers to the questions have highlighted the areas where you are doing well. They may have also helped you to think about where you are not doing so well and you can discuss these at Arise & Shine.
**HOW LIKELY AM I TO FALL ASLEEP DURING THE DAY?**

Having OSA and not sleeping with your CPAP therapy for enough hours per night can affect how tired you feel during the day. This may lead to falling asleep and dozing off while doing everyday activities.

The questions on the opposite page will help you check on how likely you are to fall asleep or not during daily tasks. Do complete the questions if you can. They will be useful when you attend Artse & Shine.

Please write your score next to each of the eight situations described on the next page and mark the total score.

Don’t take too long over your responses; your first reaction to each statement will be more accurate than a long thought-out response.

---

**ESS EPWORTH SLEEPINESS SCALE**

<table>
<thead>
<tr>
<th>Situation</th>
<th>Responses</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting and Reading</td>
<td>0 = would never doze&lt;br&gt;1 = slight chance of dozing&lt;br&gt;2 = moderate chance of dozing&lt;br&gt;3 = high chance of dozing</td>
<td></td>
</tr>
<tr>
<td>Watching Television</td>
<td>0 = would never doze&lt;br&gt;1 = slight chance of dozing&lt;br&gt;2 = moderate chance of dozing&lt;br&gt;3 = high chance of dozing</td>
<td></td>
</tr>
<tr>
<td>Sitting inactive in a public place (for example, theatre or while at a meeting)</td>
<td>0 = would never doze&lt;br&gt;1 = slight chance of dozing&lt;br&gt;2 = moderate chance of dozing&lt;br&gt;3 = high chance of dozing</td>
<td></td>
</tr>
<tr>
<td>As a passenger in a car for an hour without a break</td>
<td>0 = would never doze&lt;br&gt;1 = slight chance of dozing&lt;br&gt;2 = moderate chance of dozing&lt;br&gt;3 = high chance of dozing</td>
<td></td>
</tr>
<tr>
<td>Lying down to rest in the afternoon when circumstances permit</td>
<td>0 = would never doze&lt;br&gt;1 = slight chance of dozing&lt;br&gt;2 = moderate chance of dozing&lt;br&gt;3 = high chance of dozing</td>
<td></td>
</tr>
<tr>
<td>Sitting and talking to someone</td>
<td>0 = would never doze&lt;br&gt;1 = slight chance of dozing&lt;br&gt;2 = moderate chance of dozing&lt;br&gt;3 = high chance of dozing</td>
<td></td>
</tr>
<tr>
<td>Sitting quietly after lunch when you’ve had no alcohol</td>
<td>0 = would never doze&lt;br&gt;1 = slight chance of dozing&lt;br&gt;2 = moderate chance of dozing&lt;br&gt;3 = high chance of dozing</td>
<td></td>
</tr>
<tr>
<td>In a car while stopped for a few minutes in traffic</td>
<td>0 = would never doze&lt;br&gt;1 = slight chance of dozing&lt;br&gt;2 = moderate chance of dozing&lt;br&gt;3 = high chance of dozing</td>
<td></td>
</tr>
</tbody>
</table>

**Total Score**
WHAT DO THE ESS NUMBERS MEAN?

In the scale below, the higher your total score, the more likely to fall asleep you will be feeling.

0-9
This indicates a normal score and you are unlikely to fall asleep during the day.

10-15
This indicates a moderately high score and that you are more likely to fall asleep during the day. This score is also indicative of mild to moderate OSA. If you are prescribed CPAP therapy to self manage your OSA it is possible to still score as much and this may be because you experience problems sleeping with CPAP therapy and not sleeping with the therapy enough hours every night. It is worth discussing this with your doctor or nurse.

16+ and above
This indicates a very high score and that you fall asleep very often during the day. This score is also indicative of severe OSA and other sleep related conditions including narcolepsy. If you are scoring in this area it is important that you seek help and make an appointment to discuss this with your doctor or nurse.

BEING ACTIVE

You may be aware that physical activity plays a large part in helping you manage your OSA. It might help you to think a little about how physically active you are before you start Arise & Shine. Physical activity is not about going to the gym - it is really about increasing how much you move around.

How active am I?

To understand more about your activity tick (✓) the statements that apply to you:

<table>
<thead>
<tr>
<th>Statement</th>
<th>True</th>
</tr>
</thead>
<tbody>
<tr>
<td>I do some activity in my home most days (housework, gardening, washing the car etc.).</td>
<td></td>
</tr>
<tr>
<td>I try to do 30 minutes of activity most days.</td>
<td></td>
</tr>
<tr>
<td>I try to avoid driving if it is possible to walk.</td>
<td></td>
</tr>
<tr>
<td>I always use the stairs instead of the lift.</td>
<td></td>
</tr>
<tr>
<td>I am active as part of my daily routine/job.</td>
<td></td>
</tr>
</tbody>
</table>

How did you do?

Maybe your answers to the questions have highlighted the areas where you are doing well. They may have also helped you to think about where you could fit more activity into your life. These are things you can discuss at Arise & Shine.
**EXPERIENCES WITH WEIGHT MANAGEMENT**

You may have previously considered weight management and weight loss in the past.

Weight management may be difficult for us all and we want you to think about what things got in the way when you tried to maintain or lose weight. How important is weight management for you? We don’t often think about this, but spending a little time reflecting on how you can improve your confidence it may help you to get the most from your *Arisa & Shino* sessions.

Firstly, think about how confidence and importance may determine your likelihood to give weight management a go.

1. If weight management is of high importance to you and you have high confidence in yourself to achieve your goal how likely are you to give weight management a go?

2. If weight management is of high importance to you but you don’t have high confidence in yourself to achieve your goal how likely are you to give weight management a go?

3. If weight management is not of high importance to you and you don’t have high confidence in yourself to achieve your goal how likely are you to give weight management a go?

4. What can you do to place weight management in a higher place on your importance list?

**HOW AM I FEELING?**

Having OSA can affect your mood, and your mood can affect how you self-manage your OSA. The questions below will help you check on how positive or depressed you are feeling. Do complete the questions if you can. They will be useful when you attend *Arisa & Shino*.

Please circle the number for each statement that best describes how often you felt or behaved this way during the past week. Don’t take too long over your responses, your first reaction to each statement will probably be more accurate than a long thought-out response. Your score is the total of all the numbers you have circled.

<table>
<thead>
<tr>
<th>During the past week...</th>
<th>Rarely or none of the time (less than 1 day)</th>
<th>Some or a little of the time (1 to 2 days)</th>
<th>Occasionally or a moderate time (3 to 4 days)</th>
<th>Most or all of the time (5 to 7 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I was bothered by things that don’t usually bother me</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>I did not feel like eating: appetite = poor</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>I felt that I could not shake off the blues even with help from friends or family</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>I felt that I was just as good as other people</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>I had trouble keeping my mind on what I was doing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Please continue over the page
## What do the numbers mean?

In the scale below, the lower your total score, the more positive you will be feeling.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-16</td>
<td>0-2</td>
</tr>
<tr>
<td>17-24</td>
<td>3-12</td>
</tr>
<tr>
<td>25+</td>
<td>13-40+</td>
</tr>
</tbody>
</table>

### 0-16

This indicates you are likely to be positive, and unlikely to be depressed. However, if there are worries you wish to share, and/or help you feel you need, do make an appointment to see your doctor or nurse.

### 17-24

This indicates that you are possibly depressed — that is, it is possible that you may be going through a period of depression. If you have felt like this for several months or more, this is a good indicator that you may be going through an episode of depression. However, you may be feeling like this because you have just been diagnosed with CSA, or because of some other factors in your life at present. If you have only been feeling this way for a short time, it may be worth looking at this again in a couple of months.

### 25+ and above

This indicates probable depression — that is, if you are scoring in this area it is likely that you are going through an episode of depression, especially if you have felt like this for a few weeks. Even if this is caused by events going on in your life at present, or has been made worse by being told you have CSA, it is worth discussing this with someone, such as your doctor or nurse.

And finally - you now probably have the information you need. If you have any urgent questions which need answering before you come to Arise & Shine, please contact your doctor or nurse.
Session A: Introduction & Housekeeping
Duration: 10 minutes

Key messages
Overall aim of the course is to enable participants to understand more about obstructive sleep apnoea (OSA) and their long term cardiovascular and metabolic risk and what actions they can take to reduce this risk.

Participant learning opportunities
Participants will have the opportunity to explore/learn:

- The overall aim of the course
- The structure of the day
- Knowing the risks and what you can do about them
- When and how refreshments will be served
- Health/safety information

Educator activity
Session specific activity:

- Prepares room and resources for the programme
- Welcomes participants and their accompanying person
- Begins the session on time and introduces themselves/any observers and their roles
- Provides necessary housekeeping and health and safety information
- Explains the aim of the day and the rationale for the course
- Outlines the style of the sessions
- Answers questions relevant to this session
- Introduces the ARISE & SHINE patient handbook and the Self Management Plan

Participant activity
- Listens to the introductions and housekeeping arrangements
- Asks questions
- Reviews the ARISE & SHINE patient handbook and the Self Management Plan
Content framework

- Housekeeping details, e.g. fire drill, refreshment breaks, location of toilets, register of attendance etc.
- Introduction to the day and rationale for the course
- Outline of the day and the main topics to be covered
- Information that although sessions will contain some bad news, people will gain knowledge and skills in how to self-manage problems with their OSA

Resources required

- List of participants and their relevant sleep and biomedical data
- Register of attendance/signing in sheet and pens
- Flip chart and pens
- Blue/white tac
- ARISE & SHINE Patient Handbook and Self Management Plan
- Name badges (optional)

Philosophy Alert

We cannot be responsible for what people take away from our sessions, we can only be responsible for providing an environment in which they can learn.

Session Plan

AI Prepare room

Fix 5 pieces of flip chart paper on the walls of the teaching area and label from left to right

- Flipchart 1 Names (top half) / How Long (bottom half)
- Flipchart 2-Affects on the body -Day (top half) /Night (bottom half)
- Flipchart 3-Causes
- Flipchart 4-Long-term Effects (top half) Self management therapies (bottom half)
- Flipchart 5-Other Peoples Beliefs about OSA
- Flipchart 6-Burning Issues/ Important Questions
Welcome participants as they arrive. Ask each person to sign in, both patients and their accompanying person, so that you have a register of attendees not only for your records, but also in the case of fire, or other emergency.

If there are observers at the session, ensure they sign the register and find out how they would like to be introduced.

Once the group is complete, begin the session

Ensure each person with OSA is given the ARISE & SHINE patient handbook and Self Management Plan
Start the group by introducing yourselves and anyone else in the room (apart from participants at this stage), e.g. observers.

You will also need to make sure the group has basic ‘housekeeping’ information, so ensure you tell everyone where the toilets are, where the fire escape and assembly points are located, whether there will be a fire alarm test, arrangements for refreshments, etc.

Explain to participants that the education is two 3 hour sessions one to three weeks apart and that they will get the most benefit from attending both parts of the course in order to come away with the full picture about OSA.

The course contains both good and difficult news to hear, the second part contains more information about what you can do to reduce the risk of complications. Then in your own words explain the purpose of the sessions, i.e. that they come away from the course:

- Understanding what is OSA
- Knowing the cardiovascular and metabolic risks associated with OSA
- Knowing what they can do to self-manage their OSA and reduce their future health risks
- Having answers to most of the questions about their OSA with which they may have arrived

Introduce the ARISE & SHINE handbook and Self Management Plan as their personal resources which have been written to summarise the information covered on the course. Participants will be using the handbook in certain sessions, to carry out some activities such as using their own sleep study results and other medical results to make action plans.

Why do you think we included making a self-management action plan? Briefly outline the challenge to all human beings in changing our habits or actions and that research has shown that setting goals and developing action plans helps people achieve these kinds of goals.

Has anyone experienced using self-management action plans before? This is just to introduce the sheet and get participants thinking. Avoid getting involved with discussions about how hard/easy it is to change things!

You might want to explain that although some material has been prepared during the sessions, you hope that people will be encouraged to ask questions or make observations, as this is the best way for them to learn the things they really want to know.

Point out to people the space on the back of the My Health Profile worksheet for those who may want to make notes - perhaps during sessions, or in refreshment breaks, or at home.

This course may be different to other education sessions you have experienced. It’s different because it is based on us discussing about OSA and CPAP therapy and that we will:
Ask lots of questions…
Get you to explore the answers yourselves etc…..
Not necessarily answer all your questions directly. Instead our role today is to enable you to work out the answer for yourself OR to know how to find out the answer yourself
Ensure we do not miss any of your questions we are going to record them on a Burning Issues/Important Questions flip chart

Session B: The Participant Story
Duration: 30 minutes

Key messages
Everyone has their own story about their OSA
Some people have different beliefs, knowledge and experiences of OSA
People may have different questions to be answered

Participant learning opportunities
Participants will have the opportunity to explore/learn:

The different experiences and perception of OSA as held by the group.
Their own experiences and health beliefs in relation to their diagnosis of OSA
A burning issue/important question about living with OSA which they would like answered/discussed

Educator activity
Session specific activity:

Uses open questions and generic behaviours to enable participants to share their personal understanding of their OSA
Records each participant’s response to the questions concerning their story
Ensures that everyone in the group is heard, and given time to tell their story
Demonstrates empathy by using reflections
Uses a participant’s own words and clarifies their understanding of each participant’s contribution and story as it is written up
Compiles a list of the participants’ burning issues/important questions to be answered
Reviews the whole group story to illustrate similarities and differences

Participant activity

Explores their personal story
Identifies a burning issue/important question
Listens to the personal stories of other group participants in a structured way, supported by the facilitator
Philosophy Alert

Non-judgement - note that this can be negative or positive judgement. Most of us find it easy to avoid the negative judgement but avoiding the positive can be harder. Praising someone for the right answer/behaviour can be compelling but avoiding this prevents you assuming incorrectly that this person feels the same, and also prevents one person in the group being rewarded for getting things right, rather than perhaps being rewarded for exploring.

Theory Thought: Using participants’ own words

This session uses Leventhal’s model to enable participants to review their, beliefs about their OSA and themselves, so ensure that you use and write down participants’ own words. If something is ‘incorrect’ or does not ‘fit’, then at this stage it is important to collect it (as it is a belief from this person about their OSA story). You will have an opportunity to review this at the end of the session when you review the whole picture with the group - by this time, they or another participant may have questioned it! If you do not understand the meaning of the words they are using then seek clarification from the participant.
Session Plan: Example Script

Introduce the session by explaining that you are going to ask each person to tell their story about their obstructive sleep apnoea. Explain that you will do this by asking a series of questions and capturing what is said on the relevant flip charts to enable the ‘group story’ to be illustrated.

In this session you will be collecting and recording people’s stories as told in their own words, not responding to incorrect information or answering questions. These stories will be explored throughout the rest of the sessions.

Use the flip chart headings as your guide!

**Flip chart 1: Names / How long?**

**Names**

<table>
<thead>
<tr>
<th>How</th>
<th>Long?</th>
</tr>
</thead>
</table>

**What is your name?**

*Having found a person to begin, in your own words, ask them their first name or establish what they would like to be called. Write this down on flip chart 1.*

With each individual, continue to use the flip chart headings to guide their telling of their own story. We have included some prompts in the description below, but you may feel free to use your own if they come more naturally to you.

**How long do you think you have had obstructive sleep apnoea?**

**Flip chart 2: Affects on the body – daytime and night time**

Elicit how obstructive sleep apnoea was identified in each participant
Make a note of this on the flip chart. You may want to refer back to this in other sessions. All the mentioned signs and symptoms can be grouped into daytime and night time. Later on in the professional story this grouping will prove to be useful.

People with OSA may **OR** may not have any symptoms, but if a symptom is elicited, reflect back to participant, for example; let’s reflect on symptom (x). Do you think it’s related to OSA?

If they believe the symptom is related to their risk, list the symptom on flip chart. Do not make any further comments or explore the symptom at this point.

Summarise the key points on flip chart 2. Also ask if they had any symptoms which, before being diagnosed, they did not think were anything to do with obstructive sleep apnoea and write these too on the flip chart.

Once they have finished, move on to the next flip chart.
In the same way as you did with flip chart 2, use open questions to encourage participants to share their opinions and their knowledge. Once they have finished, move on to the next flip chart theme.

**Flip chart 4: Long-term Effects/ Self-management therapies**

What therapy have you used to self manage your OSA or do you now about?

What do you think are the long term effects of obstructive sleep apnoea?

Again, note answers on the flip chart in the relevant places

People are likely to report CPAP therapy and weight loss (or even surgery however this will not be explored in this curriculum)

**Flip chart 5: Other Peoples Beliefs on OSA**
What do other people for example friends, family or work colleagues think about people who have OSA?

Flip chart 6: Burning Issues / Important question?

Once an individual cannot think of anything else to add, thank them, and in your own words ask:

What would you like to know when you leave this course?

Note their answer on flip chart 6, and tell them that the work the group will be doing will attempt to answer this question before the end of the course.

Once this has been completed for the first individual, move on to the next person in the group and repeat the same questions. If this is someone’s accompanying person, ask their name, put this on flip chart 1 in the relevant place.

Do not repeat the whole process with an accompanying person but do check there is nothing they would like to add to the flip chart and, in your own words, ask:

If there is one question you would like to leave this course with an answer to, what would it be?
As you repeat this exercise for each member of the group:

• When a person gives a response that is repeating or agreeing with something already on the flip chart, just add a check mark (√) to the response on the flip chart
• Write in full each person’s answer to the ‘one question you would like to leave. This session with an answer to’. You will come back to these at the end of the course, and everyone needs to be able to identify their response/ own question

At the end of the session thank everyone for his or her contribution and use what time you have left to review and explore the ‘group story’.

Explain you will use the information they have generated in the forthcoming sessions to try and enable them to make sense of their obstructive sleep apnoea. It's also fine to praise the group at this point. They will have worked hard in this session - and so will you! So encourage everyone to feel good about all the information you have generated together.

Session C: The Professional Story 1
C1.Understanding Obstructive Sleep Apnoea (OSA)
Duration: 45 minute session

Key messages
Obstructive Sleep Apnoea (OSA) is a common breathing disorder. The group will gain a better understanding of:
- What goes wrong in the body during OSA and why
- The causes and treatments of Self-management options of OSA

Participant learning opportunities
Participants will have the opportunity to explore/learn:

➤ The process of healthy breathing and the oxygen journey from the environment to the body and vital organs
➤ What goes wrong in the body during OSA
➤ What is an apnoea and a hypopnoea
➤ How sleep disordered breathing may explain the signs and symptoms experienced before diagnosis
➤ What factors contribute to causing OSA
➤ Different options to self-manage OSA
Session Plan: Example Script

This section describes one way to get through all the information. This is an example of the content and the process.

The main thing is to cover the relevant information by assisting the group to work out as much as they can by themselves with occasional prompting by you, and provide new knowledge only as necessary to keep the story moving.

Begin by using an outline body shape and the magnetic resources below:
John man model (poster picture):

Healthy Breathing

OSA Breathing
C1. Understanding Obstructive Sleep Apnoea (OSA)

In your own words explain that the group is going to try and make sense of the information they have just shared to try and understand what obstructive sleep apnoea is and how they can actively self-manage their condition. Explain to the group that they are going to start by thinking:

- How we breathe normally
- Work out the changes occurring in breathing whilst asleep.
- Discuss what happens during sleep disordered breathing by working through a picture they are going to help you to build up.
- Aim to describe the above using a magnetic board.
- Explain to the group that you will complete the board bit by bit as you go through the whole of the session.

What is Obstructive Sleep Apnoea (OSA)?

Collect answers and acknowledge responses. Acknowledge and thank the group for all their contributions but at this stage do not correct anyone as you will now start to build a picture of the process of OSA.

In OSA something goes wrong in the body, more specifically on the upper airway, breathing becomes abnormal and irregular. As a result, the oxygen levels in the body become lower than is good for your health.
Explain to the group that to understand OSA breathing, it may be useful to start by thinking what changes happen to the breathing in someone who does not have OSA.

We all have some thoughts on what OSA is – some of us may know more than others. With the help of our man model (Introduce John), we will now try and build up a picture of what happens to the breathing when sleeping to someone who does not have OSA. Once we have a clear picture of this – we will then consider what happens in the body of someone with OSA.

1. The Oxygen journey and Healthy breathing

In this sections we will explore healthy breathing and the oxygen journey.

What is breathing?

Collect answers and acknowledge responses.

Breathing is a process which enables the body to get air into the body and waste products out of the body

What is air?

Air is a mixture of gases including oxygen and water. We breathe in oxygen rich air from the environment and breathe out carbon dioxide and water.

Let’s now consider that the blue trucks carry oxygen and the black trucks carry carbon dioxide through the air passages. With these images we are now going to build the story.

Why is breathing important?

Without breathing humans cannot survive. The process of breathing is important as the body needs oxygen to survive and function (i.e for eating, sleeping, walking, thinking etc).

How do we get air into the body?
We breathe air in through our nose and mouth.

Place a blue truck towards the nose and mouth of John.

Where does air go to next?

Air goes to the throat.

Place another blue truck in the throat region.

Where does air from the throat go to next?

Air goes to the lungs.

Place another blue truck near the lungs.

Where is oxygen stored in the lungs?

Oxygen is stored in very small sacs known as alveoli.

Place the alveoli picture near the lungs and add the open truck image with the air bubbles.

How is oxygen transported from the alveoli to the body?

With the help of blood, oxygen is transported via a network of arteries and veins all over the body and to vital organs such as the brain and the heart.

Place the image indicating blood vessels.

How is carbon dioxide/waste released from the lungs?

When we breathe out.

Place the black trucks to show the journey out.
Control and Pace of Breathing

Next we will consider pace and control of breathing in a person with no breathing problems (healthy breathing). First we will consider breathing whilst awake:

Which organ controls breathing?

The brain is the control centre.

Let’s consider breathing in someone who is awake in 3 different scenarios. In this activity I would like you to observe:

- the pace of breathing (fast/slow)
- and the type of breathing (nose/mouth)

Role play all three scenarios before taking feedback from the group

Breathing Activity

**Scenario 1: eating, drinking & having a conversation**

**Educator:** Simulate this example by eating a biscuit while drinking water in between bites and pretend you are having a conversation at the same time with a friend over the phone.

Elicit answers

**Scenario 2: vigorous exercise & talking**

**Educator:** Simulate this example by pretending you are jogging and are out of breath and singing / or while dancing and talking. Try to demonstrate nose and mouth breathing as well as the pace of breathing increasing.

Elicit answers

**Scenario 3: Breathing control (find out how long you can last without taking a breath)**

**Invite everyone to** hold their breath and squeeze their nose for a few seconds.

Elicit answers

What have you learnt from this activity?

Listen to responses
During the day the brain controls breathing and a person is aware of breathing. The pace of breathing depends on what activity a person is performing. In these 2 scenarios the type and pace of breathing was very different and the person is aware of that.

The brain controlled the breathing process to maintain sufficient oxygen in the body.

During the day the brain controls breathing.

Can a person influence or have control over their breathing whilst awake?

While awake a person also has control and choice of how and with what we want to breathe (fast/slow breathing, hold breath, nasal/mouth or a combination of both).

1.2 Breathing during Sleep

Before we consider what happens to the breathing of a healthy individual during sleep, it is important to discuss why sleeping is important to maintain a good health.

Why does the body need to sleep?

The truth is we don’t really know why we need to sleep. Lack of sleep makes us feel tired/exhausted and causes problems in our behaviour (psychological/emotional well being) and overall health. When we sleep the body is utilizing this time to heal itself, revive and relax and it uses less energy than when we are awake. We know however that certain hormones (substances) which regulate growth and repair are released only during sleep and this is what makes sleep vital for our brain and body development.

What happens to the pace of breathing during sleep?

The trucks go slower as the breathing pace becomes slower with deeper breaths compared to when a person is awake and active.

Why does this happen?
The body is in ‘resting mode’ and it does not require a lot of oxygen (breaths) to maintain ‘healthy’ breathing levels since activity is kept to a minimum and energy is conserved.

What happens to the awareness and control of breathing during sleep?

When fast asleep a person is not aware of breathing and can not control how they breathe. Some people open their mouth and start to mouth breathe. In the Breathing Activity we learnt that a person can have control of the pace of breathing whilst performing different activities and is aware of the breathing changes. When asleep we are not aware of changes in breathing.

1.3 What goes wrong in OSA?

We are now going to spend some time looking at what happens to the body and the oxygen levels during obstructive sleep apnoea with the aid of John and the trucks.

What goes wrong in OSA?

Elicit answers

The upper airway narrows and closes. The trucks struggle to go through or stop for a while as the road narrows or closes completely for a while. (The educator may also mention that the body experiences either suffocation or a form of breathing that is not enough to support healthy function of the body)

Place the traffic sign image indicating narrowing or closure of the airway and the trucks to demonstrate how this looks

What word is used to describe breathing stopping?

Apnoea describes the event during which breathing stops for ≥10 seconds due to the complete closure of the upper airway. (The educator may mention that the body in other words experiences suffocation)

Show the appropriate image and indicate what happens at the back of the throat, road complete closed, trucks clashing, etc

What word is used to describe reduced breathing?
A hypopnoea describes the event during which airflow is reduced for ≥ 10 seconds due to the partial closure of the upper-airway. (The educator may mention that breathing in this case is not sufficient to support healthy function of the body)

Show the appropriate image and indicate what happens at the back of the throat, trucks struggling to go through, road narrowing etc

Let’s now use the blue and black trucks and think what happens to the oxygen and carbon dioxide levels during an apnoea and a hypopnoea

What happens to the number of blue and black trucks?

The blue trucks lessen and the black trucks multiply. In other words the oxygen levels drop while the carbon dioxide levels increase

Remove the blue trucks and add more black trucks

What happens next?

The brain is activated and sends a signal like an alarm to wake the person just enough so to start breathing again only for a moment as the process becomes cyclical.

Place the alarm image near the brain to demonstrate this

1.4 How does OSA affect me?

We explored how the body keeps your oxygen levels within a healthy range when we worked out what happens in someone who does not have OSA. We are now going to look at OSA diagnosis and work out how OSA affects you.

How is a diagnosis made of OSA?

Ask participants to refer to the flipchart body signs/ daytime & night time symptoms developed in session A.

Prepare a new flipchart and divide the paper into three sections: Sleep test, Symptoms & Questionnaire (Epworth Sleepiness Scale- comment patients are aware of this as they complete it when attending the sleep service)
All of you were diagnosed based on the results of an overnight sleep study. A positive test for OSA is established if two out of the three of the following criteria occur:

**American Academy of Sleep Medicine Criteria: Andrew’s comments too much detail**

1) Stopping breathing as detected by the sleep study (AHI>5)

2) Two or more of the following symptoms: awakening unrefreshed from sleep, daytime fatigue, choking/gasping for breath during sleep, recurrent arousals from sleep and impaired concentration

3) Excessive daytime sleepiness that cannot be explained by other causes as detected by the Epworth Sleepiness Scale (ESS)

**Let’s now work on how OSA affects you**

Draw attention to the flip chart with ‘Body signs/ daytime & night time symptoms identified in the earlier session. Work through the list of signs and symptoms recorded on the flip chart.

An example of participant’s contributions may include:

- Poor sleep quality
- Tiredness and Fatigue
- Poor concentration
- Poor memory
- Loss of libido (reduced sex drive)
- Depression and low mood
- Irritability.

**How can OSA breathing affect sleep quality?**

The multiple apnoeas and hypopnoeas result in poor sleep quality as sleep becomes broken because your in-built alarm goes off to wake you up just enough to start breathing. The brain wakes up a little, but generally not enough for it to be remembered. In some more severe airway blockages people can remember waking up with a big snort or choking feeling.

**What effect could poor sleep quality have on a person during the day?**

People are likely to say they felt tired/exhausted/lethargic/irritable. Headaches even migraines, with the tendency to fall asleep against their will when sitting down (to watch tv, have a cup of tea etc) may be experienced.

Refer back to the truck traffic and poor oxygenation
What causes the person to have poor concentration and work performance?

**Elicit answers**

OSA is causing insufficient oxygenation of the vital organs including the brain. If the brain does not have enough oxygen it can not function well and as a result concentration, memory, and alertness become low.

Refer back to the truck traffic and poor oxygenation

How can OSA make you feel in yourself?

**Elicit answers**

lack of sleep can cause mood swings, irritability and affect psychological well being. People can become more prone to depressive episodes and feel low/unable to cope with everyday life.

How can OSA affect sex life and decrease sex drive?

**Elicit answers**

Chronic tiredness and sleep disturbances can also cause impotence and as a result lead to marital/low self esteem and relationship problems.

We have now worked through the most common symptoms. If we look at your experiences on the Patient Story flip chart, we can see if we can work out any other symptoms.

Refer to Patient Story ‘Signs and Symptoms’ flip chart - if any points recorded are not signs or symptoms of OSA, facilitate a discussion about it and ask permission to cross it off the list if it is not a symptom.

Explain that we often find that people report a wide range of symptoms that they think are part of their OSA, but that aren’t necessarily related.

**Long term effects of OSA**
How can OSA breathing affect your health in other ways?

How can OSA affect your weight?

OSA can result in gaining excess weight/fat stored in the upper body (neck) and around the middle.

Place the image demonstrating fat (Fat scarf image to go around the neck and upper airway to emphasize this)

When fat is stored around the neck it makes the road to narrow so that cars can’t travel freely and are stuck. (airways more prone to collapse).

Excessive fatty tissue makes the levels of fat in the blood (cholesterol), glucose and blood pressure all rise too high for good health. We will discuss this in a different session (prof story 2).

How might an increase in blood fat levels, blood pressure and blood glucose levels affect your health?

OSA can increase your risk of developing heart conditions – heart attack, stroke, hypertension and Type 2 Diabetes Mellitus (T2DM).

1.5 What causes OSA

So, now we have considered what OSA is and how it affects you, what causes OSA in the first place?

The group has already given you their ideas in the Patient Story so refer back to the ‘Causes’ flip chart.

Potential answers include:
- Having central and upper body obesity
- Genetics and family history (Craniofacial and upper airway abnormalities)
- Male gender
- Getting older
- Alcohol & Smoking
- Nasal congestion (leading to mouth breathing)
- Other co morbidities e.g. acromegaly
If the Causes list is not completed seek the group’s permission to add the missing causes.

How could these symptoms be reversed?

By enabling healthy breathing and preventing the closure of the upper airway in the body. This not only helps you feel better, but also helps prevent long-term health problems (complications) which we are going to discuss in the next few sessions.

1.6 OSA Therapy Options

What kind of therapy options are you aware of?

The Patient Story flip charts self-management therapies will already have recommended some of the things participants know or have heard about as treatments. Refer to this as a prompt.

Participants’ examples may include:

- CPAP therapy.
- Positional therapy
- Oral appliances
- Losing weight
- Being more active.
- Surgery

Positional therapy:
Some people snore or have sleep apnoea only when sleeping on their back. Such people can reduce or stop airway blockage simply by learning to sleep on their side. Most bed-partners know this therapy from experience. They often try to make their snoring partner move to their side during the night to stop their snoring. A cheap solution to promote side-sleeping is the tennis ball technique. This involves dropping a tennis ball in a sock and then pinning the sock to the back of the pajama top. Positional therapy alone is not recommended as an effective way for treating OSA in severe cases.

Oral appliances
Oral appliances look like the mouth guards worn by swimmers. The oral appliances for treating sleep apnoea and snoring are specially designed for that purpose. The appliance is worn in the mouth during sleep. Most appliances work by positioning the lower jaw slightly forward of its usual rest position. This small change is, in many people, enough to keep the airway open during sleep. Oral appliances are not recommended as an effective way for treating OSA in severe cases.
1.7 Summary and Close

Having built up this picture about OSA breathing what are your thoughts now about what you may want to change?

Review learning by listening to responses.
If time allows invite participants to share their thoughts with the group. By asking:

Who would like to share their thoughts?
Educators may arrange a break at this point as participants will have worked hard in this session.

Session D: Understanding and Using Continuous Positive Airway (CPAP) Therapy
Duration: 40 minute session

Key messages

CPAP therapy is an effective treatment option to facilitate healthy breathing and confer many health benefits.
Sleeping with a CPAP machine can generate negative thoughts and strong emotions.

Participant Learning Opportunities

Participants will:

- Understand how CPAP therapy improves OSA symptoms and reduces their long term cardiovascular risks
- Know the current recommendations of CPAP use and what it means to them
- Understand the benefits of keeping a CPAP diary
- Explore their thoughts and emotions on being diagnosed with OSA and sleeping with a CPAP mask and machine.

Content covered

- The positive effects of CPAP therapy on OSA related symptoms
- The benefits of CPAP therapy on health and how people feel
- The current recommendations of CPAP use
- Benefits of keeping a CPAP diary
- Thoughts and feelings on OSA and CPAP therapy
**Session Plan**

In this next session there is time to explore what CPAP is, the benefits of CPAP treatment some practical aspects of using the CPAP equipment.

### 1. Understanding Continuous Positive Airway Pressure (CPAP) therapy?

**What is Continuous Positive Airway Pressure (CPAP) therapy?**

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**Educator activity**

- Use open questions to generate a list of the benefits of CPAP use, current recommendations and options
- Utilises CPAP use resources to assist participant understanding
- Provide information, where necessary to address gaps in participants knowledge.
- Encourage the use of CPAP diary for self monitoring.
- Encourages participants to explore their feelings on being diagnosed with OSA and sleeping with a CPAP mask and machine.

**Participant activity**

- Explores what they understand to be the potential benefits of CPAP use
- Consider the CPAP recommendations
- Consider the benefits of keeping a CPAP diary for self monitoring
- Consider their feelings and emotions on being diagnosed with OSA and sleeping with a CPAP machine

**Resources required**

- Flip charts and pens
- Blue /white tac
- CPAP diary
- A1 ‘My health profile’
- A5 ‘My health profile’
- A1 ‘OSA Bubbles’ (comments: this is the emotional well being resource)
- A5 ‘OSA Bubbles’
CPAP stands for **Continuous Positive Airway Pressure** therapy and it is a treatment for OSA. The therapy consists of a CPAP machine which works by generating an air stream that keeps the upper airway open during sleep. The air stream is pushed through tubing via a mask to the back of the throat.

**How can CPAP help OSA?**

*Collect answers and acknowledge responses and try and elicit the following*

CPAP therapy helps to prevent the airways collapsing so that the road is open and the trucks can drive freely. The machine detects that the airways are about to narrow down and collapse so a split second before this is about to happen; the CPAP machine increases the amount of pressurised air delivered at the back of the throat.

Use the John model to demonstrate. Place the image that represents the CPAP machine

### 2. Benefits of CPAP Use

**What are the benefits of using CPAP therapy?**

*It might be useful to reflect back to the flip chart of causes, and reflect how CPAP therapy can reduce risk factors*

Add the magnetic piece labelled ‘**health benefits**’. You will add more images to represent health benefits of CPAP therapy throughout this session.

That’s right, CPAP therapy can help to:

- support healthy breathing
- reduce sleepiness, excessive daytime sleepiness, fatigue and morning headaches
- diminish the feeling of tiredness
- improve memory and concentration
- improves quality of sleep
- improve motivation for physical activity

Place the image that represents the above on the magnetic chart labelled ‘**health benefits**’.
What other general health benefits may result from CPAP therapy?

Elicit the following answers and place images that represent the health benefit on the magnetic chart labelled ‘health benefits’

- Helps keep heart healthy,
- Helps blood pressure
- Helps cholesterol
- Helps relieve stress and anxiety and improves mood
- Improves diabetes markers
- Reduces the risk of heart and circulation problems, as well as strokes

We can see from this session that there are specific benefits linked to breathing and sleep quality and other benefits related to heart conditions, circulation problems, strokes and wellbeing.

2.1 Recommendations for CPAP use

What are the current recommendations for the number of hours and how often you use your CPAP machine?

Listen to responses and note these down on a flip chart

The current recommendation for using a CPAP machine is:

- For at least 4 or more hours per night
- Every night (except in the cases of a person developing a productive cough, or other health related reason) to feel the benefits of the therapy.

How is the severity of OSA determined?

The severity of OSA is determined by the Apnoea Hypopnoea Index (AHI). The AHI index shows the number of apnoeas and hypopnoeas occurring per hour of sleep. The severity of OSA falls into three categories including mild, moderate and severe. An AHI score of 5-14 indicates mild OSA. An AHI score of 15-29 indicates moderate OSA and an AHI score equal to or greater than 30 indicates severe OSA.
Is the recommendation any different for people who have mild/moderate or severe OSA?

Regardless of the severity of the condition, CPAP usage recommendations remain the same.

Four hours is suggested as a minimum what is the recommended total time for CPAP use per night?

Acknowledge responses

Four hours per night of continuous CPAP use is the minimum. However, it is recommended to use CPAP therapy as many hours as the person sleeps.

3. Where am I with CPAP?

Invite participants to take out their My Health Profile

As you will see on your Health Profile there is an opportunity to record where you are now in terms of your AHI score and use of CPAP therapy.

What do the colours on the profile represent to you?

Educators display the A1 My Health Profile and generate a discussion about the meaning of the colours on the profile and the recommended range.

If someone is in the green section they stop breathing between 0-5 times per hour of sleep when using their CPAP machine and this is within the normal range.

If someone is in the yellow section they stop breathing between 6-14 times per hour of sleep when using their CPAP machine and this is higher than the normal range.

If someone is in the red section, they stop breathing 15 or more times per hour of sleep when using their CPAP machine and this is very high.

*The AHI information is available to every participant and stored in their CPAP machine

**If already on CPAP, we expect to see values between 0-5, however if the mask fitting settings are not as they should be we observe air leakage and as a result higher AHI. This is resolved when the patient attends a drop in clinic or their routine follow-up.

Ask participants to record their personal score and continue:
Let’s have a look now on the Health Profile in the section named CPAP hours of use.

What do you think about where you are on the scale?

In DAY 2 sessions there is an opportunity to discuss common barriers to CPAP use and what can you do to overcome these barriers. Also there will be an opportunity to set yourself some goals for increasing your hours of CPAP use if you wish to.

Let’s now discuss about the Epworth Sleepiness Scale score which is shortened to ESS score. As you know having OSA and not sleeping with your CPAP therapy enough hours per night can affect how tired you feel during the day. This may lead to falling asleep and dozing off while doing everyday activities.

What do you know about the ESS score?

The ESS score is a questionnaire that aims to measure how likely is for a person to fall asleep and doze off during the day in eight different situations using a scale from 0 (never) to 3 (high chance). The higher the score the more likely a person is to doze off.

Some of you may have already completed the ESS score found in your Prepare for Arise & Shine handdbook. If you haven’t completed this can you please work out your score and mark it in your Health Profile in the section named ESS score.

What do you think about where you are on the scale?

Elicit responses and continue:

Let’s now discuss about feeling tired and doing certain activities including driving and operating heavy machinery. Some people with OSA have mentioned that while driving and/or waiting on the traffic lights momentarily fell asleep without being able to control their feeling (maybe urge) to fall asleep.

Have you ever experienced a similar situation now or in the past? if yes continue
How did this make you feel?

If no one in the group experienced something like this change the question to:

If you found yourself in a situation like this how would this make you feel?

Do you think you would be able to do something to stop falling asleep at the wheel?

Some people may suggest that having an open window or loud music in the car could prevent somebody from falling asleep but this is not true.

### 3.1 Getting to grips with CPAP

You all currently use CPAP therapy. Some of you may have more experience sleeping with a CPAP device than others and possibly many of you may have encountered problems with both the CPAP machine and the mask.

In this session we will explore a few practical aspects of operating a CPAP device and wearing a mask. This will be a practical ‘hands-on’ session.

**CPAP Myths Game**

Hand out to the participants cards with the following statements

1. All mask models are suitable and comfortable for everybody
2. There is only one correct way to position a CPAP mask on the face
3. The tighter fitting of the mask ensures prevention of air leakage
4. CPAP machines become noisy because of a faulty built in system
5. Cleaning of the CPAP apparatus should be done according to individual’s needs

Discuss how they feel about the statements and ask if they think these are myths or truths.
Place a few CPAP devices and the glass head models on a table. Place at the front of each glass head model a mask (nasal and full face model).

Invite participants to move closer to either the nasal or full face mask depending on their circumstances.

Who will show the group how to position the nasal mask and turn on the CPAP device please?

Encourage the group to describe the process and generate a discussion if someone suggests another option

Potential answer:

- Place the mask so to cover the nose.
- Ensure the top part of the mask is sitting on the bridge of the nose and the bottom part is resting above the top lip.
- Place the head straps around the head and lock the straps to the mask.
- Ensure the mask straps are not too tight or too loose to prevent air leakage and marking.
- Move gently the mask so that it feels comfortable on the face.
- To turn the CPAP machine on push the main button.

Do other people in this group wear it in a different way?

Elicit answers

Who will show the group how to position the full face mask?

- Place the mask so to cover the nose and the mouth.
- Ensure the top part of the mask is sitting on the bridge of the nose and the bottom part is resting just below the lower lip.
- Place the head straps around the head and lock the straps to the mask. Ensure the mask straps are not too tight or too loose to prevent air leakage and marking.
- Move gently the mask so that it feels comfortable on the face.

Do other people in this group wear it in a different way?

Generate a discussion if someone suggests another option
What do you do to correct a ‘leaking’ nasal mask?

Potential answers:

- Check the mask fitting settings. If necessary stop the CPAP machine, take off the mask and wear it again.
- The top part of the mask should be on the bridge of the nose while the bottom part should be resting above the upper lip.
- The straps should not be very loose or tight.
- Ensure the hose is connected well to the CPAP machine.

Does anybody else in this group have a different way to correct an air leakage?

Elicit answers

How do you deal with a ‘leaking’ full face mask?

Potential answers:

- Check the mask fitting settings. If necessary stop the CPAP machine, take off the mask and wear it again.
- The top part of the mask should be on the bridge of the nose while the bottom part should be resting at the bottom of the lower lip.
- The straps should not be very loose or tight.
- Ensure the hose is connected well to the CPAP machine.

Does anybody else in the group have a different way to correct an air leakage?

Elicit answers

How do you deal with a ‘noisy’ equipment?

Potential answers:

- Ensure the mask fitting settings are correct and the noise is not caused because of air leak.
- Check the air filter on your CPAP machine to make certain it is unblocked and clean.
- Do not remove the data reading card found at the back of the CPAP machine.
- Contact the sleep laboratory if noise persists.
Does anybody else in the whole group have a different way to correct a ‘noisy’ equipment?

Generate a discussion if someone suggests another option

How frequently do you need to clean your mask, hose, filter and humidifier (where applicable)?

Potential answers:

- Mask: everyday
- Mask straps: at least twice a month
- CPAP filter: once a week
- Humidifier chamber: every day (and change the water everyday)
- Hose: everyday

Why do you think it is important to have a good cleaning routine?

It is important to have a good CPAP ‘MOT’ routine as failing to clean regularly the CPAP mask and other parts can cause infections and skin irritation (breathing through dusty filters/uncleaned masks etc).

Who will show the group how to access the personal data stored in each CPAP device and records how many hours a person has slept with their CPAP on, the percentage of air leakage and the number of apnoeas and hypopnoeas per night please?

If volunteers in the group are not aware the educator will show how to access this information.

Summary: In this section the group has gained a better understanding of the practical aspects of using CPAP therapy and wearing a mask on by exploring the following myths:

**CPAP therapy myths:**
- All mask models are suitable and comfortable for everybody
- There is only one correct way to position a CPAP mask on the face
The tighter fitting of the mask ensures prevention of air leakage.
CPAP machines become noisy because of a faulty built in system.
Cleaning of the CPAP apparatus should be done according to individual’s needs.

Let’s now have a look at your CPAP diary found in your handbook.

What can having a CPAP diary help you to know?

Elicit answers.

A CPAP diary is a way of monitoring how many hours you have used your CPAP machine per night. If you then compare your hours of CPAP use diary in relation to how refreshed you feel when you wake up this can help you see how things are improving.

It can also help you to set yourself small targets to get to where you want to be. Also a CPAP diary can help you identify what problems you experienced during the night that may have prevented you from using the therapy the recommended hours.

Ask participants to find the ‘Two week CPAP diary recourse’ found in their handbook and explain how it should be completed.

Is everybody happy with how to go about completing their diary?

Remind participants to complete their personal CPAP diary before they attend Day 2.

3.2 Your thoughts and feelings about OSA & CPAP therapy

In the previous section we explored some practical tips on using a CPAP machine and wearing a mask. We will now set aside a little time for you to think about and explore your own thoughts and feelings about OSA and CPAP therapy.

Place a piece of flip chart on the table you are sitting around and in front of the participants draw a number of thought bubbles.

As you are talking, in the thought bubbles write some words e.g. down, angry, irritable, alone etc. Leave several of the thought bubbles blank.
‘Having OSA and sleeping with a CPAP machine and a mask can bring up negative thoughts and feelings which makes people to be self-critical. Some negative thoughts and feelings are very common such as feeling low, angry or thinking that life is not fair (the things you have written). What sort of thoughts and feelings have you experienced?’

Elicit participant’s thoughts and feelings about living with OSA and sleeping with CPAP now and how they may have felt about it in the past, particularly around the time of their diagnosis.

Handout pens to participants and invite them to write their responses down in their balancing life and OSA sheet.

Facilitate a discussion around what they have written and ask permission to include these on your large piece of flip chart that is on the table.

Ask participants if they have any further to add as a result of the discussion.
Elicit participant’s reactions. The most common reactions are listed below.

This is just a guide and not a list to elicit you must only go with what the participants themselves disclose.

- Fear about stopping breathing
- Feeling low depressed and down
- Being angry, irritable and short tempered
- Thinking ‘it is not fair’.
- Having more worries and anxieties about their health
- Feeling more vulnerable to other health problems and/or more vulnerable in general
- Worrying about the future and what it might bring
- Not feeling able to cope or manage in general particularly things that might have felt easy previously
- Struggling to get their head around having OSA
- Feeling sad, angry about having OSA and using CPAP
- Worry about intimacy (wearing a mask etc)
- Not wanting to think about their OSA or telling themselves they don’t have it
- Struggling with feelings that they caused the OSA or are somehow to blame for it
- Keeping feelings bottled up and not talking it

Thank you for sharing these thoughts and feelings. (It can sometimes be difficult to share how we think and feel). How have people found doing that?

Elicit reactions and acknowledge feelings expressed about it being uncomfortable for some helpful for others.

It might seem strange or odd that we have included this in this session. How come it is so important?

The way you think and feel with yourself about your OSA and CPAP can have a major impact on the way you use your CPAP therapy and manage your OSA.

How can your reactions to OSA and CPAP therapy may affect your CPAP use and how you look after it?

Listen to and acknowledge all responses.

If you are feeling down what might happen?

Listen to and acknowledge all response.

What do you tend to do when you feel down?
Elicit that they may drink more, eat more, be less active not use their CPAP

If you are worrying a lot what might you do to cope?

Elicit: If you feel overwhelmed with worry you sometimes try to put it things to the back of your minds and try not to think about things. Worrying and feeling worn out by worry can stop you from having the time or energy to do the things that might help your OSA.

If you are angry and irritable what effect might that have?
Elicit: You may feel guilty for being bad tempered with others, it could stop you asking people for help or you may isolate yourselves or keep your feelings bottled up in order not to lose your temper.

So an important part of self-managing OSA and sleeping with a CPAP machine is acknowledging the feelings and reactions to having the condition itself. Sometimes your emotional reactions or the ways you might try to manage your feelings can have a major impact upon how you look after yourselves.

Session E: Taking Control 1 (Weight Management)
Duration: 40 minutes

Key messages
The benefits of weight management and how to overcome potential barriers to weight management

Participant learning opportunities
Participants will have the opportunity to explore/learn:

→ The concept of weight management
→ How confidence and importance can influence weight management

Educator activity
→ Deliver this session in response to the groups needs
→ Discuss the concept of weight management
→ Explore the challenges around weight management
→ Consider solutions to overcome these challenges
→ Use open questions, empathic reflections and visual tools to create a warm and safe
→ Use the creative suggestions and solutions produced by the group

Participant activity
→ To explore the concept of weight management
→ To identify their personal challenges with food choices to achieve a healthy weight/neck/waist
→ To consider personal solutions to these challenges by using the Confidence/Importance matrix resource
Session Plan: Example script

So far we have explored how you can self manage OSA with CPAP therapy and increasing physical activity.

We can not cover all the issues on weight management but we have thought that the best way to use the available time would be to explore your experiences of weight management.

In this next session we will explore your experiences with weight management and how you feel with yourselves leaving with OSA and sleeping with a CPAP machine and mask.

1. Weight management

Some of you may have talked many times about weight management and weight loss.

What does weight management mean to you?

Acknowledge responses

Weight management does not necessarily mean weight loss but weight maintenance. Weight maintenance refers to either maintaining the same weight or losing weight without putting it back on.
Let’s use Johns, woolen scarf piece (representing fat) and the trucks to consider what happens at the back of the throat (we have covered this in Prof Story 1)

How do you feel when weight is raised as an issue?

Record responses on a chart

What factors make weight management difficult for everyone of us?

Record responses to a chart

Potential answers:

- Availability of food
- Sedentary lifestyle/jobs
- Body’s desire to store calories
- Medical conditions - OSA

What factors have got in the way when you managed your weight in the past?

Potential answers:

- Goal not being realistic (trying to cut out too many things at once)
- Lack of motivation
- Low mood
- Lack of energy

How might you improve your confidence in these areas?

Listen to responses

Can I please bring your attention to the Confidence/Importance in weight management matrix please and ask you to get hold of your personal resource found in your packs.
**CONFIDENCE/IMPORTANCE MATRIX**

<table>
<thead>
<tr>
<th>IMPORTANCE</th>
<th>CONFIDENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>HIGH</td>
</tr>
<tr>
<td></td>
<td>LOW</td>
</tr>
<tr>
<td>LOW</td>
<td>HIGH</td>
</tr>
<tr>
<td></td>
<td>LOW</td>
</tr>
</tbody>
</table>

How important is weight management in your life and how confident do you feel about your weight management in a scale from 1-10?

Ask participant to refer to the relevant resource and plot their result.

Listen to responses

Explain how the matrix works and the potential scenarios:

1. **High importance/high confidence** (most likely to give it a go)

   If weight management is of high importance to you and you have high confidence in yourself to achieve your goal how likely are you to give weight management a go?

   Most likely to give it a go

2. **High importance/low confidence** (less likely to give it a go)

   If weight management is of high importance to you but you don’t have high confidence in yourself to achieve your goal how likely are you to give weight management a go?
Less likely to give it a go

What can you do to improve your confidence?

Set SMART and realistic goals, work on bite size chunks rather than trying to make too many changes at one, reward yourself for every achievement you make however big or small it may be.

(3) low importance/ low confidence (not likely to give it a go)

If weight management is not of high importance to you and you don’t have high confidence in yourself to achieve your goal how likely are you to give weight management a go?

Not likely to give it a go

What can you do to place weight management in a higher place on your importance list??

Reflect on how beneficial weight management will be on your health and what it will mean for you, your family and friends. Think about how weight management may improve your confidence and self esteem (feeling of achievement).

This is how the matrix will look like after completing this session:
Do you know where you can get help and support if you wish work on your weight management?

Sign post to local services and schemes available.

What else other than food choices can help with weight management?

Increasing physical activity can contribute to weight loss and weight management.

What are your thoughts about Physical Activity?

Listen to responses

Let us consider the benefits of being more physically active,

1. Health benefits of physical activity
What are the health benefits of being more physically active?

Have visible the Health Benefits of CPAP therapy and as participants offer suggestions move the images that relate to both the benefits of CPAP Therapy and Physical Activity to the central area of the board. Place the magnetic headings on the board.

<table>
<thead>
<tr>
<th>Health benefits of CPAP</th>
<th>Double Whammy</th>
<th>Health Benefits of PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilitates healthy breathing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Helps keep heart healthy</td>
<td>√</td>
<td>Helps keep heart healthy</td>
</tr>
<tr>
<td>Improves sleep quality</td>
<td>√</td>
<td>Improves sleep quality</td>
</tr>
<tr>
<td>Reduces:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o sleepiness,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o excessive daytime sleepiness,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o fatigue and morning headaches</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diminishes the feeling of tiredness and increases energy levels</td>
<td>√</td>
<td>Diminishes the feeling of tiredness and increases energy levels</td>
</tr>
<tr>
<td>Improves memory, vigilance and concentration</td>
<td></td>
<td>Improves mood</td>
</tr>
<tr>
<td>Helps mood</td>
<td>√</td>
<td>Helps blood pressure</td>
</tr>
<tr>
<td>Helps blood pressure</td>
<td>√</td>
<td>Helps blood pressure</td>
</tr>
<tr>
<td>Helps cholesterol</td>
<td>√</td>
<td>Helps cholesterol</td>
</tr>
<tr>
<td>Reduces the risk of cardiovascular and metabolic disease (heart attacks, strokes &amp; diabetes)</td>
<td>√</td>
<td>Reduces the risk of cardiovascular and metabolic disease (heart attacks, strokes &amp; diabetes)</td>
</tr>
</tbody>
</table>

How could you measure your activity levels?

Listen to and acknowledge responses

You could use a pedometer, or an activity diary

In the ARISE and SHINE education course there is an opportunity to take home a pedometer if you wish. There is also a diary for you to record your daily step count.

Show participants where they can find their physical activity diary.

Demonstrate the correct positioning on the waist band of trousers or skirts in line with the armpit.
Have pedometers available for participants if they wish to take one.

If you would find it helpful to have a pedometer, then please record your daily step count and bring your diary to the next session. You will not need to share your step count with anyone unless you wish to.

**Session F: How am I Doing and Next Steps?**
**Duration: 10 minutes**

**Key messages**

Review of experience and feelings so far

Some of the questions can be answered and some will be answered in the next session after related topic is discussed.

**Participant Learning Opportunities**

Participants will:

- Identify initial lifestyle changes that might benefit their health based on messages covered so far

**Educator activity**

- Uses open questions to elicit main messages that have been covered in Part One
- Uses open questions to enable participants to reflect on what changes they may wish to consider changing

**Participant activity**

- Actively thinks about what they have learnt so far
- Reflects on their completion of *Preparing for Arise & Shine* leaflet
- Begins to think about which changes would be useful to consider further

**Content Framework**

- Review of how participants are feeling at the end of Part 1
- Review of important questions
- Ongoing education and content of next sessions
- Closing and thanks
Session Plan

For a few moments we are going to take some time to review what we’ve covered today and for you to think about your next steps.

**What are the main points that have been covered today?**

Listen to and acknowledge responses

Invite participants to take out their *Preparing for Arise & Shine*’ booklet and *Participant Handbook*.

**How are you doing on these things?**

You may have started making changes already, but there may be things that you think you could do to benefit your health. If you have completed your *Preparing for Arise & Shine*’ booklet, this may help you to think about any changes you want to make. You have also recorded your CPAP hours in your Participant Handbook.

In your Handbook you will find a CPAP and Activity Diary for you to use to monitor and record your CPAP use and step count if you wish to, from now until your next ARISE and SHINE session.

Please turn to your Activity and CPAP Diary in your Handbook.

Allow time for participants to review the diary.

**Thinking about the sessions today what are your thoughts about things you may like to work on?**

Listen to and acknowledge participant responses.

**Have you any questions or concerns about using the Diary?**

Generate an answer from the group to any questions or provide the answer if the information is not provided by the group.

In the next session we have time to consider:

- your experiences of monitoring your activity levels and CPAP use
• How using CPAP therapy affects your life, emotions and mood
• The barriers to using CPAP and being more physically active.
• The impact and consequences of OSA on your long term health
• The good news about what you can do to minimize the risks to your health from OSA
• Developing your own Self-management action plan for OSA

Lastly before you leave today we will return to the Questions flip chart and see if the session today has answered any of your questions. Any outstanding questions can be carried over to the next ARISE and SHINE session.

Session G: Welcome Back
Duration: 10 mins

Key messages
What Part 2 is all about

Participant learning opportunities
Participants will have the opportunity to explore/learn:

→ Their personal thoughts/experiences so far
→ The topics to be covered in the rest of the programme

Educator activity
Session specific activity:

→ Facilitates participants expressing their current concerns and questions resulting from the first part of the course
→ Uses open questions to enable participants to reflect on their thoughts and feelings
→ Acknowledges feelings and offers support outside the session for those who are distressed
→ Summarises the main topics to be covered in the rest of the course
→ Facilitate participants to share changes they have made
Welcome participants back as they arrive. Invite each person to sign in, both participants and their accompanying person, so that you have a register of attendees not only for your records but also in case of fire or other emergency.

If there are any observers at the session, ensure that they are introduced to the group.

Have on display the flip charts generated during the sessions in Part 1 of the module.

In your own words welcome the group back and repeat the basic “housekeeping” information:

- Toilets
- Location of fire exits and assembly points
- Arrangements for refreshments
In today’s session together you will have the opportunity to:

- Share if you wish, how you have got on with your CPAP and activity (PA) diaries.
- Consider how OSA affects your long term health risk – cardiovascular health
- The good news about how you can manage your OSA and reduce future risks to your health
- Consider your feelings, mood and emotions related to OSA and weight management
- Your own self-management action plan for OSA

As a result of what you have learnt and experienced so far in our time together, what changes have you made or started to think about?

Explain that specific feedback about the pedometer and CPAP therapy will be explored in the next session

Listen to and acknowledge responses.

How are you feeling as a result of what you have learnt or experienced on this course?

Listen to and acknowledge responses

Have you any further questions that you wish to add to the list of “Questions”
Session H: Reviewing my CPAP and Physical Activity Diaries

Duration: 20 mins

Key messages
People have different experiences and barriers using CPAP therapy and being physically active

Participant learning opportunities
Participants will have the opportunity to explore/learn:
- The experiences and perceptions of the group in relation to increasing the hours of CPAP therapy and physical activity levels
- That barriers exist when sleeping with CPAP therapy and when being physically active

Educator activity
Uses open questions to
- Facilitate a discussion to share experiences of attempts to increase hours of CPAP use and physical activity
- Explore the barriers and solutions to sleeping with a CPAP and increasing physical activity

Participant activity
- Shares experiences of increasing the hours of CPAP therapy and physical activity levels.
- Explores solutions to the barriers

Content framework
- Increasing the hours of CPAP use and physical activity levels can be difficult

Resources required
- Flip chart and pens
- CPAP Diary
- Physical Activity Diary
Session Plan: Example script

This session provides an opportunity for participants to share their experiences with each other. Some may have had less positive experiences and the group may explore some potential solutions.

In the previous session we gave you a CPAP and an activity diary to complete. In this section we will review how you are doing with using your CPAP machine and your activity levels.

Record responses on a flip chart and explore the experiences that participants share. Positive and negative experiences will be shared and recorded.

1. Reviewing my CPAP & PA diaries

How have you got on with your CPAP machine since we last met?

Listen and explore responses. Record any barriers

What do you think about your CPAP hours of use and activity levels?

Elicit how participants feel about their results

What can having a CPAP and an activity diary help you to know?

Elicit answers.
A CPAP diary is a way of:

- Monitoring how many hours you have used your CPAP machine per night.
- Comparing your hours of CPAP use diary in relation to how refreshed you feel when you wake up this.
- Can see how things are improving.
- Can set small targets to get to where you want to be.
- Helps to identify problems experienced during the night that may prevent use of the therapy for the recommended hours.

1.2 Barriers to CPAP therapy and facilitator

Let us go back to the barriers and discuss possible solutions.

Facilitate a discussion within the group to identify different options for solutions.

*We will cover the activity barriers in the Physical Activity Session K*

Session 1: Professional Story 2 (Risks and Complications)

Duration: 45 minutes

**Key messages**

OSA is associated with long term risks to health and potential OSA complications.

It is possible to reduce some of the risks associated with OSA.

People may already be doing things to reduce their risk and may wish to consider other factors to reduce their risks.

**Participant learning opportunities**

Participants will have the opportunity to explore/learn:

- The possible long term complications of OSA
- What can be done to reduce the risk of complications
- Personal risk factors for the development of complications
- Reviewing and recording their personal anthropometric and biomedical data and how that applies to personal risk of complications
- The benefit of identifying personal risk factors
- What they are already doing to reduce their risks and to begin to think about what they may wish to change to reduce their risks
Session Plan: **Example script**

In this section we have set some time to explore and build upon what you already know about the possible long-term risks to your health that is associated with OSA.
In your first session there was a session on how OSA breathing can affect you. Today you will have the opportunity to discover more about your own risk factors and think about and plan how you might reduce your personal risks.

OSA may be thought of as a condition that affects breathing and sleep

**What are the long term consequences of OSA?**

*(Consequences not related to breathing or sleep which are discussed in Professional Story 1)*

Refer to Flip Chart : Long term effects

- Heart conditions
- Stroke
- High blood pressure (hypertension)
- High cholesterol levels (hyperlipidemia)
- Type 2 Diabetes
- Weight gain

All of these factors can lead to damage to the heart and circulation and premature death.

**How do you feel when you hear this?**

The good news is that there is a lot you can do to reduce the chance of damage to your long term health.

In this section we will work out together how OSA is linked with the above long term complications and what you can do to reduce the chance of long term damage to your health

**What is blood pressure?**

Elicit answers

Blood pressure is the pressure on the walls of your arteries. As people get older arteries become stiff and they can fur up, resulting in a higher blood pressure.

**Why is blood pressure so important?**

As blood pressure increases, so does the risk of heart attacks, strokes and premature death.
What is considered to a healthy blood pressure level?

A blood pressure of 130/80 or less is considered to be healthy.

Is the blood pressure higher or lower when we sleep?

Elicit answers.

The blood pressure is lower during sleep compared to when we are active.

What about people with OSA?

Elicit answers.

The blood pressure is higher. The body experiences a stress /‘fight or flight’ response. The brain realises that oxygen levels are on very low supply and carbon dioxide levels have risen, the blood pressure increases and the heart rate become faster until the person breathes again. This is repeated throughout the night and the body ‘fights’ these attacks in the same way.

Invite participants to plot their own blood pressure measurement on the Health Profile

Now let’s talk about cholesterol.

How can having a cholesterol level cause heart attack or strokes?

Cholesterol can be deposited in the arteries which cause them to narrow.

What can happen as a result of this?

It causes narrowing or blockage, which can slow or stop the blood and oxygen getting to where it is going or some fatty deposit can break off and cause blockage of another part of the body.
If participants ask about types of cholesterol then facilitate a discussion to elicit:

- There is good and bad cholesterol
- LDL cholesterol tends to clog up the blood vessels
- HDL cholesterol is good and helps to smooth out the furring inside the arteries.

What is a healthy level for cholesterol?

In the general population the level of cholesterol is 5 or less, in those with diabetes the level is 4 or less.

Invite participants to plot their cholesterol on their Health Profile

How do you think OSA may contribute to the development of heart disease and stroke?

Elicit answers

During OSA breathing the heart and brain are not oxygenated well and the risk of heart disease and stroke are increased.

Also draw a blood vessel on a flip chart and illustrate the impact of a build up of cholesterol and the effect of high blood pressure on the vessels and how this can lead to stroke and heart attack.

How do you think OSA may contribute to developing Type 2 Diabetes?

Elicit answers

Lack of adequate sleep due to stopping breathing can disrupt the body’s normal regulation of blood sugars and hunger levels. This may also lead to over eating and weight gain which increases the likelihood of someone with OSA developing diabetes.
Invite participants to plot their HbA1c on their Health Profile

**What is the benefit of finding out if your blood pressure, cholesterol and HbA1c are above the healthy range?**

Elicit answers and acknowledge responses

- I can then do something about it
- I can get treatment
- I can reduce the risk of further damage

**Sign post participants to their health care provider for more support or information**

- How do you think OSA may cause weight gain?

Research has shown that disrupted sleep due to OSA breathing can affect appetite and lead to overeating or craving more fatty foods. Also, OSA people have reduced activity levels due to feeling tired and lethargic because their quality of sleep is very poor.

Hand out BMI charts, explain what BMI is and give patients own score.

Invite participants to plot their BMI on their Health Profile

- How can OSA make you feel in yourself?

Elicit answers

lack of sleep can cause mood swings, irritability and affect psychological well being. People can become more prone to depressive episodes and feel low/unable to cope with everyday life.

Invite participants to plot their Depression score on their Health Profile

- What can you do to reduce your likelihood of OSA complications?

Some examples of what participants might say:

What decreases my risk?
- Using CPAP
- Quitting smoking
- Increase physical activity
- Losing weight

What have you already done to reduce your risk of complications?

Elicit Answers

You have had the opportunity to identify the things you are doing to reduce your risk of complications and highlighted some of the things you may choose to work on.

In the Self Management Plan session you will have the opportunity to plan some goals and make an Action plan - What am I Going to do Now? as a result of any risks that you have identified in this session.

Session J: Taking Control 2 Physical Activity
Duration: 30 minutes

Key messages

The benefits of physical activity.

Participant learning opportunities

Participants will have the opportunity to explore/learn:

- The concept of physical activity.

Educator activity

- Deliver this session in response to the groups needs
- Discuss the concept of physical activity
- Explore the challenges around physical activity
- Consider solutions to overcome these challenges
## Participant activity
- To explore the concept of physical activity
- To identify their personal challenges with physical activity to achieve a healthy weight/neck/waist
- Share these experiences with others in the group (only if they feel comfortable to do so)
- Ensure that everyone gets an opportunity to share experiences

## Content framework
- The concept of physical activity and how to gain confidence in doing so
- The challenges of trying to maintain a healthier weight/neck/waist
- People will have different solutions to dealing with the challenges

## Resources required
- Activity Continuum game

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**Session Plan:** Example script

So far we have explored how you can self manage your OSA and the risks to your health associated with OSA by using CPAP therapy and managing weight.

In this next section we will spend some time exploring physical activity.

**Why is physical activity part of this education course?**

Listen to and acknowledge responses.

Physical activity can contribute to weight loss and maintenance and also importantly contribute to reducing the chances of heart and circulation problems as well as stroke. Refer back to Health Benefits flip chart

In the last session we provided pedometers and activity diaries.

**How have you got on with them?**
What did the pedometer and diary help you to know?

Elicit answers.

Using a pedometer can help you work out how active you are. It can also keep you motivated to increase your activity levels.

1.1 Recommendations for physical activity

What are the recommendations for physical activity?

Listen to responses

The recommendation for reducing cardiovascular risk/heart health is 30 minutes of moderate activity 5 days a week

How much activity would you need to do to reduce the risk of developing diabetes?

Studies suggest that to reduce the risk of diabetes 30 minutes of moderate activity everyday

How much activity would you need to do to lose weight?

Studies suggest that to lose weight you would need to do 60 minutes of moderate activity everyday.

What are your thoughts about these recommendations?

Listen to participants views.

Participants feel that the recommendations for weight loss is unrealistic clarify that these recommendations are for activity alone. Making changes to diet would have additional benefits in terms of weight loss.
What is ‘moderate’ activity?

Collect answers and acknowledge responses and try and elicit the following. If no answers are forthcoming move on and give the correct answer.

Moderate exercise is exercise that makes you breathe harder, your heart beats a little faster and makes you sweaty (warm), but not so much that you can’t talk and not so easy that you could sing.

If there is room demonstrate examples of low intensity, moderate intensity and vigorous walking activity by walking around the room.

Does the recommended activity need to be done all in one chunk?

Acknowledge responses

The minutes can be broken down into smaller chunks and accumulated throughout the day.

What is the smallest amount of time you need to do activity for, for it to help you?

Acknowledge responses

The smallest amount of time is 10 minutes. Let's think about how this might be possible.....

Activity Continuum

This activity is aimed at trying to get you to work out which types of physical activity might count towards your activity goals.

Ask the group to sort out this pack of cards showing different everyday activities and rate them from low intensity activity progressing up to moderate intensity activity.
Facilitate a discussion as to how the activities could move up or down the continuum. i.e. how the low intensity activities could be made to become a moderate intensity activity.

<table>
<thead>
<tr>
<th><strong>Moderate intensity</strong> – could count towards your activity goals</th>
<th><strong>Low intensity</strong> – could not be used towards your activity goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking (brisk)</td>
<td>Dusting</td>
</tr>
<tr>
<td>Vacuuming (brisk)</td>
<td>Cooking</td>
</tr>
<tr>
<td>Mowing the lawn</td>
<td>Watching sport</td>
</tr>
<tr>
<td>Scrubbing the floor</td>
<td>Walking slowly</td>
</tr>
<tr>
<td>Climbing the stairs</td>
<td>Light vacuuming</td>
</tr>
<tr>
<td>Playing a Sport</td>
<td>Hosing the flowers</td>
</tr>
<tr>
<td>Cleaning the windows</td>
<td></td>
</tr>
<tr>
<td>Swimming</td>
<td></td>
</tr>
<tr>
<td>Going to the gym</td>
<td></td>
</tr>
<tr>
<td>Cycling</td>
<td></td>
</tr>
</tbody>
</table>

*If there is an activity that someone likes to do that is not represented by the cards, they can chose something similar or use the joker card*

Encourage the group to think about how these activities could be added together to achieve the recommendation that has been chosen for the individual e.g. 30 or 60 mins. One way would to be to ask participants to select activity cards from the continuum game and put them together to make up the recommended minutes. i.e. walking for 10 minutes, vacuuming for 10 minutes, and mowing the lawn for 10 minutes = 30 minutes of moderate intensity physical activity

**Summary of main messages:**

- It is recommended that people should aim to do a minimum of 30 minutes of activity a day on top of their current activity levels if very sedentary.

- Small amounts of activity can be added up through the day to make up the recommended amount.

- To get the health benefits, the activity should make you breathe a little harder but you should still be able to talk!
2. **Measuring activity**

Some people find it useful to think about the minute’s activity recommendation in terms of the number of steps they walk.

**What have you heard about the number of steps recommended for walking daily?**

Listen to and acknowledge responses

- 10,000 steps per day.

**If you think about the 30 minute recommendation, take a guess as to how many steps you would walk if you walked for 30 minutes?**

- It would be approximately 3000 steps

**How could you measure the number of steps you walk?**

Listen to and acknowledge responses

- You could use a pedometer

**How can using a pedometer help you to be more active?**

- A pedometer is a way of measuring how many steps you are doing. It can help you see what you are doing and help you decide how much you want to do. It can also help you to set yourself small goals/targets to get to where you want to be. We are giving you a pedometer to keep so that if you want to, you can look at the activity you do, set yourself goals/targets and see how you do.

Hand out pedometers to everyone in the group and invite participants to put them on. Allow time for participants to put on their pedometers. Check that participants understand how to wear their pedometer correctly.
The correct positioning is on the waist band of trousers or skirts in line with the armpit. Where there is no attachment point available, the pedometer may be placed on the waistband of undergarments. In this case the device should be positioned facing inwards so it is facing the body.

**What do you think about your activity levels?**

_Elicit how participants thoughts about their current activity levels._

_Invite participants to take out their My Health profile and generate a discussion about:_

- _What the colours mean_
- _The recommended range_

In your own words, explain that if someone is in the green section they are doing more than 10,500 steps already, and so they are highly active, meeting the recommendations for activity.

If someone is in the yellow section they are doing 7500-10499 steps so they are at moderate risk of diabetes and may like to think about increasing their activity on some days of the week to 10,500 steps.

If someone is in the red section, explain that they are doing less activity than is recommended. Try and elicit from participants what would be a reasonable target towards if in the red section

_'What would be a reasonable number of steps to work towards if in red section?'_

**Measuring Activity Game**

Some people find it helpful to think of the 30 minutes of activity in terms of steps so let’s look now at how we can relate different activities to number of steps.

Use the physical activity magnetic sheet and magnetic pedometer step number cards. 

(1,500, 1,750, 2, 500, 3,000, 3,500, 4500, 5,000, 5250, 7,500)

To help participants, place some cards on the magnetic sheet. Under the fifteen minute slot, place the 1,500 card by the picture of walking, the 2,500 card by the picture of swimming and the 1,750 card by the picture of cycling.

So we can see that walking for 15 minutes is equivalent to walking 1500 steps, so……
How many steps would you do, if you walked for 30 minutes?

That's right; you would walk about 3000 steps.

Place the 3000 step card in the appropriate place on the magnetic board

Let's try and work out how we can relate other activities to steps. We can see that if you do 15 minutes of swimming this is like walking 2,500 steps

So, how many steps would be the same as swimming for half an hour?

Half an hour of swimming would be like walking 5000 steps.

Place the 5000 step card in the appropriate place on the magnetic board

So what does that tell you about swimming compared to walking?

So looking back at the sort of activities you do, how do you think they would relate to steps?

Elicit answers. Acknowledge that it can be difficult to equate all activities with steps but that comparing the activity to a similar one that we have talked about will give estimation.

Barriers to physical activity and facilitators

What makes it hard to fit in moderate activity into your day?

Acknowledge responses. If no suggestions are forthcoming, give an example of a personal barrier to activity e.g. time

Ok thank you for sharing those barriers. Can anyone think of solutions to these problems?
Facilitate some discussion around managing barriers. This will be discussed in more detail in the self management plan.

Session K: How am I feeling (OSA Flower)
Duration: 20 minutes

Key messages

Having OSA can impact upon an individual’s thoughts and feelings about the condition, themselves, their life and the future.

Life events also place individuals under greater pressure.

These issues can impact on the way the person copes with OSA and their OSA self management.

The OSA Flower is a tool that aims to summarise these events in order to help individuals to decide which cycle or ‘petal’ would be best for them to focus upon.

Participant learning opportunities

Participants will have the opportunity to explore/learn:

- The influence to thoughts and feelings about their OSA and their OSA self-management.
- In a safe environment each of the maintenance cycles described in the OSA flower.
- Which cycle or ‘petal’ is most relevant to them.
- Strategies for breaking the maintenance cycle for each petal.
- To consider ways to cope with or adjust to issues that are not readily resolved to these in a way that lessens the impact on their OSA self-management.

Educator activity

- Deliver this session in response to the groups needs.
- Use open questions, empathic reflections and visual tools to create a warm and safe environment to discuss the OSA flower.
- Ensure that individuals feel listened to and understood.
- Facilitate group discussions so individuals are given the opportunity to share thoughts, feelings and experiences as appropriate, without any one person dominating.
- Introduce and employ the idea of breaking maintenance cycles by introducing their own individually determined strategies.
- Use the creative suggestions and solutions produced by the group.

Participant activity

- Reflect upon the OSA flower and consider which, if any of its maintenance cycles (petals) may be relevant to them.
- Share these experiences with others in the group (only if they feel comfortable to do so).
- Ensure that everyone gets an opportunity to share experiences.
Content framework

- Introduce the OSA flower as a way of summarising the challenges or issues that can maintain negative thoughts and behaviours around OSA
- Ask participants to consider which flower petal seems most relevant to them or is getting most in the way of them managing their OSA
- As a group discuss strategies that might be helpful for each petal
- Encourage people to note it down on their Balancing Life and OSA worksheet

Resources required

- Balancing life and OSA sheet
- OSA Flower resource

1. Emotional well-being Session

The OSA Flower

- Being self-critical and having negative thoughts
- Low in energy and lacking motivation
- Unhelpful behaviours including avoidance
- Having strong emotions

Example Script:

We have previously discussed how living with OSA and using CPAP therapy can make you feel. In this next session we will explore emotional well-being in OSA.
You may remember that at one of our first sessions we talked about how having OSA and sleeping with a CPAP machine made you feel? We wrote them down on a piece of flipchart.....What sort of things did we discuss?

Ask the participants what they remember from the first session. You could suggest that they look back at their worksheets. If they can’t recall, prompt them to think about the thoughts emotions and feelings they wrote on the flip chart around their reactions to having OSA.

As you discuss this put on the petal: Having strong emotions. Ask them to think about how strong emotions can keep us from feeling better.

Write down responses on the white board.

There were many emotions and reactions that people experience. I think in the end we decided that it was fairly normal to feel this way when getting your head around having OSA. However we did discuss the impact these emotions could have upon how we took care of ourselves and how we felt in general.

Put on the: Being self critical and having negative thoughts

Prompt questions include:

• What happens when you feel angry or sad or low?
• How do these feelings affect how you think?
• If you are anxious or worried what kind of thoughts do you have?
• How does having these negative thoughts and feelings make you feel?

Write down responses on the white board.

What happens if you have low energy levels and lack motivation to look after yourselves?

Put on the petal: Low in energy and lacking motivation

Prompt questions include
So if you are lacking energy and not feeling able to do what you would like, what impact does that have on your feelings and (pointing to the petal and centre of the flower) your thoughts and beliefs (pointing to the petal)?

Write down responses on the white board.

What kind of things have you done? Or what do people do in general when feeling low, anxious angry or sad? What sort of unhelpful things do people do?

Put on the petal: **Unhelpful behaviours including avoidance**

Invite participants to think about what strategies they have used in the past to manage that have not been helpful. Elicit some of the unhelpful behaviours such as overeating, drinking, not using their CPAP machines or being physically active.

How does that interact with the other petals? How does it impact on how they think and feel about themselves?

What thoughts, feelings or reactions come to mind when you look at this flower?

**Prompt questions include**

- It can for some make them feel low or fed up to look at this or angry. Others may think it is a pretty accurate description of how they feel.
- What are your immediate responses?

_Elicit: The participants’ immediate thoughts and feelings that come to mind when they look at the flower. They may find it depressing, very relevant or not at all like them. Try to elicit that each petal and the soil has an impact on all the others and that is the theory in depression that some cycles or petals need to be changed or managed for the individual to be free of the negative thoughts and feelings._

_Elicit: It can be depressing to look at these things but the good news is that by exploring these issues they can try to put different strategies in place._
Which petal is most relevant to you? Which thing do you think would benefit you most to deal with?

*Invite participants to write their thoughts down in their worksheets and then ask them to consider strategies to help.*

*Here are some examples:*

- Making time for self
- Consider alternatives to unhelpful behaviours
- Increase CPAP use
- Increase physical activity
- Discuss or talk to someone they find helpful and supportive
- Look for self help materials such as the internet, books etc
- Write thoughts and feelings down
- Take a steady approach to doing more things, particularly previously enjoyed activities
- Use problem solving

As patients work out how to overcome and break the cycle of:

- *Having strong emotions*
- *Being self critical and having negative thoughts*
- *Low in energy and lacking motivation*
- *Unhelpful behaviours including avoidance*

Use the colourful pieces and ask participants to observe the change in the flower. So that from a grey flower it becomes a ‘happier’ flower.

*So how do you feel when you see the flower now?*
Session L: OSA Self-Management Plan

Duration: 30 minutes

**Key messages**
The risk of complications in OSA can be reduced by small behaviour changes

Behaviour change is easier for some than others and can change at different times in life

Successful behaviour change is increased with a clear plan

**Participant learning opportunities**

Participants will have the opportunity to explore/learn:

- A personal factor to reduce their risk of OSA related complications
- At least one behavioural goal they can aim for to improve their complications risk profile and working on through a goal setting process
- Their own personal barriers to change in relation to achieving their goal, and problem solve how to overcome these
- A realistic plan of action for this behaviour change

**Educator activity**

Session specific activity:

- Uses open questions to enable participants to identify one risk factor for OSA complications or problem which they wish to change.
- Uses open questions to enable participants to select a self management behaviour to work on
- Uses open questions to enable participants to develop a Specific, Measureable Action that is a Realistic and Time limited goal
- Uses open questions to enable participants develop a clear action plan to enable them to achieve their goal
- Provides enough space and time to enable participants to quietly reflect on their plan and identify barriers to success
- Ensures participants go away with a written and completed goal setting sheet

**Content framework**

- Recapping of personal risk factors using My Health Profile
- Recapping of realistic goal setting for preparing an action plan
- Recapping of how to use goal setting sheet (What Am I Going To Do Now?)
Session Plan: Example script

Throughout this programme you have been given time to consider what you have changed, may want to change and may need to change. Now is the time to consider your next steps in relation to these thoughts.

Give participants time to reflect on what they want to change and why. Acknowledge that some people may have already started making changes and that they may want to use this session to consider how they can keep these changes going!

1. Behavior change

What are people’s experiences of changing their behavior (i.e increasing the hours of CPAP use, increase physical activity levels?)

Elicit:

• It can be hard
• Often too much change at once
• Easy to find reasons not to do something you don’t really want to do
What might be the benefits of making a plan for change?

* Elicit:
  - Being clear about what could be done and when
  - Being able to think about what would get in the way
  - Talking it through with someone may help it be realistic

What are the benefits of monitoring your action plans from time to time?

* Elicit:
  - To monitor my progress
  - To see if I have achieved my goals
  - To see if I need to change any of my actions to achieve my goals

2. Goal Setting and developing an action plan

In this session we will look at goal setting and writing an action plan. It has been found that when making behaviour change, success is more likely if an action plan is written down.

Before we start, please look at your health profile and consider which risk factor you want to change. Circle this on your What Am I Going To Do Now? worksheet.

* Allow time for participants to choose what they wish to work on.

Who would like to share what they want to work on, so that we can have an example to illustrate how to develop a plan?
Example: The goal is: Increase hours of CPAP use

Why do you want to do this? (establishing personal motivation)

So to be more energetic and improve my sleep quality

What are the possible actions you could take to increase your CPAP use?

- Try to wear the mask longer for 15-20 mins more per night to begin with for week one and the following week aim to wear the mask for one hour per night every night
- Try to wear the mask longer for 30-40 mins more per night to begin with for week one and the following week aim to wear the mask for an hour and a half per night every night
- Think positive about wearing the mask
- Seek help when having problems

Which of these actions are you more likely to be able to do?

- Try to wear the mask longer for 15-20 mins more per night for week one and the following week aim to wear the mask for one hour per night every night

How often will you do this?

Every night until I reach my personal goal

Ok let’s discuss for a moment and work out together a few ‘high risk time situations’ when a person with OSA is more likely not to use their CPAP.

High risk time situations:
In which situations a person with OSA is more likely not to use their CPAP therapy?

Elicit:

1. Taking the mask off in the middle of the night because it gets hot wearing the mask for a couple of hours
2. Waking up to go to the bathroom and forgetting to wear the mask on
3. Forgetful
4. Feeling Claustrophobic /anxious and finding the mask uncomfortable

Record any other responses

What will you need to do to overcome these barriers?

Potential answers:

In case of experiencing scenario 1: Sleeping with an open window may help to prevent taking the mask off. Alternatively using a fan will be as effective as sleeping with a window open.

In case of experiencing scenario 2: CPAP offers a quick release system that allows the hose (long tube) to be disconnected from the mask without taking the mask off. Leaving the mask on while going to the bathroom will eliminate the chances to not use it.

In case of experiencing scenario 3 and having a spouse: You can ask your spouse to remind you to wear your CPAP and generally keep an eye on you.

If a participant doesn’t have a spouse they can ask a friend to call before bedtime or send a text message to remind them. Another option would be for the person to set an alarm event on their mobile so to remind them.

In case of experiencing scenario 4: Wearing the mask before going to bed or in the afternoon while watching TV or reading a book will help the person to relax and get used to the idea of having a mask on their face.

If participants mention other high risk situations ask the group what they think they can do to overcome the potential problem.

Let’s continue now with completing the plan

What is likely to stop you doing this?
o Taking the mask off in the middle of the night because it gets hot wearing the mask for a couple of hours
o Forgetful
o Feeling claustrophobic

How confident are you that you can carry out this plan on a scale of 1 to 10?

6.

How could your plan change to make that a 7 or more and so increase your confidence that this plan will succeed?

• Sleep with an open window
• Tell my children/husband what I’m doing so to keep an eye on me
• Wear the mask while watching TV or reading to relax

Now you have almost completed your plan there is just one more step, adding in a date when you will review your plan

When and will you review your plan to increase your CPAP use?

In 2 weeks

How will you use this action plan between now and in 2 weeks time?

Elicit the need to:
• Set a renew date
• Set new goals once achieved, encouraging them to complete more ‘What am I going to do now’ sheets
• Getting back on track
• Relapse is a normal part of the process
• Share with family, friends and health care providers
• Use as part of annual review and care planning

How will you reward yourself for success?
A trip to the theatre!

Now make time for the participants to complete their own action plans. Both Educators will need to work with participants to facilitate this process.

If there is time, use this to facilitate a discussion about being realistic in setting behavioural goals. One way to do this is:

If I am not used to sleep with my CPAP for more than 4 hours per night what would happen if I suddenly forced myself to use it 6 hours per night?

Listen to and acknowledge responses. Each individual will have different realistic goals.

What changes might I make to my action plan to make it realistic?

Note responses on the flip chart.
It is better to build up to 20-30 minutes extra gradually- then if the person can tolerate for more than 4 hours per night then try to gradually increase up to 6 hours per night and then maintain the hours of compliance

Another example would be:

If I am not used to being active what would happen if I suddenly started to do 45 minutes of activity or 4500 steps?

Collect answers and acknowledge responses and try and elicit the following. If no answers are forthcoming move on and give the correct answer.

It is better to build up to the 45 minutes or extra steps slowly-if using a pedometer suggest could set goal /aim to increase by 500 steps and then if achieve can increase again.

Making such a big change straight away is likely to lead to sore muscles, which in turn will make it unlikely the activity will be sustained because it will hurt. Trying to make such a big change all at once is also mentally hard and is likely to lead to de-motivation and failure.

Can anyone share an experience of making an action plan that was unrealistic and how you might, or did, change that plan?

If no one offers experiences then move on.

By increasing the CPAP use what benefits this may bring?

Refer back to the Double Whammy resource

<table>
<thead>
<tr>
<th>Health benefits of CPAP</th>
<th>Double Whammy</th>
<th>Health Benefits of PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilitates healthy breathing</td>
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</table>
Encourage the participants to complete their personal action plan and allow sufficient time to cover questions etc.

Session M: Next Steps and Questions

Duration: 10 mins

Key messages

What could be your next steps for self managing your OSA

Participant Learning Opportunities

Participants will:

- Know the answers (or know how to get the answers) to the questions they had at the start of the programme
- Know how to access ongoing care and support as part of the ARISE&SHINE study
Ensure all participants know what will happen after the course and that they know whom the contact person for follow up and ongoing support.

Move the flip chart on which you have marked the group's questions from the first session into the middle of the teaching area, and get two or three marker pens. In your own words explain:

We are now coming to the end of the workshop and we would just like to clear up a few things. Firstly, we would like to check whether we have answered the questions you had at the start of the day. Here is your list of questions. Take a moment to identify your question. If you feel it has been answered, please come up and take one of these marker pens and put a line through it. If it has not been answered, please leave it. Once everyone has finished this, we will then go through and answer the questions that are left on the list.

Once everyone who wants to has marked off their question, go through each one of the remaining questions, and attempt to answer them. If you are unable to answer them, tell the individual that you will take their details and get back to them with an answer.
Thank them all for coming and participating

Remind them that if anyone wants to talk about any problem privately on a one-to-one basis that the Educators will be remaining behind for them to do this.

Ensure that an Educator says goodbye to each group member and gives him or her or her best wishes.
ABOUT MY 'BEING ACTIVE!' DIARY

The aim of this diary is to support you in keeping a record of the amount of physical activity you do each day. As well as making a note of your step count, you can record what kinds of activities you do or take part in.

There is enough space in this diary to keep you going for 2 weeks! People who continue to record their progress are more likely to be successful.

Pedometer Instructions

Pedometers measure your physical activity levels by counting how many steps you take. It is important to follow the instructions carefully, as wearing the pedometer incorrectly may make it count the number of steps inaccurately.

- Please read the instructions for your pedometer
- Press the reset button each day, the screen display will return to zero
- Attach the pedometer to the top of your trousers, skirt or belt above your right hip, as demonstrated in the picture. Where no attachment point is available on your clothing, the pedometer may be placed on the waistband of your under garments; in this case the pedometer should be attached facing inwards so that it is facing your body
- Wear the pedometer during all waking hours
- Record the number of steps you take each day in this diary
- Reset the pedometer at the start of each day.
- You may wish to share this diary with your health care provider (e.g. GP, practice nurse or dietitian)
### WEEK 1

<table>
<thead>
<tr>
<th>Date Started:</th>
<th>Date Finished:</th>
<th>What activity did I do today?</th>
<th>For how long for?</th>
<th>Total number of steps taken today</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sun</td>
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<td>Sat</td>
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</table>

Total for the week:

**Activity Experiences**

- What has gone well with my activity this week?

- What's not gone so well / stopped me?

### WEEK 2

<table>
<thead>
<tr>
<th>Date Started:</th>
<th>Date Finished:</th>
<th>What activity did I do today?</th>
<th>For how long for?</th>
<th>Total number of steps taken today</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sun</td>
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</table>

Total for the week:

**Activity Experiences**

- What has gone well with my activity this week?

- What's not gone so well / stopped me?
# Pedometer Step Equivalents for Exercises and Activities

There are some activities and exercises for which it is not possible to use your pedometer to calculate your step count, or you may choose not to use your pedometer and estimate your steps using this chart. Here is a table to enable you to estimate step equivalents for some other activities to add to your daily step count.

**Walking Pedometer Step Equivalents**
- Walking 3 mph for 5 mins = 500 steps
- Walking 3 mph for 20 mins = 2,000 steps (1 mile)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Steps per 15 minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking 3 mph</td>
<td>1,500</td>
</tr>
<tr>
<td>Aerobic dance</td>
<td>3,000</td>
</tr>
<tr>
<td>Badminton</td>
<td>2,000</td>
</tr>
<tr>
<td>Ballroom dancing - fast</td>
<td>2,500</td>
</tr>
<tr>
<td>Ballroom dancing - slow</td>
<td>1,350</td>
</tr>
<tr>
<td>Bicycling</td>
<td>1,800</td>
</tr>
<tr>
<td>Bowling</td>
<td>1,350</td>
</tr>
<tr>
<td>Football</td>
<td>3,000</td>
</tr>
<tr>
<td>Gardening</td>
<td>1,800</td>
</tr>
<tr>
<td>Golf (walking)</td>
<td>2,000</td>
</tr>
<tr>
<td>House cleaning</td>
<td>1,100</td>
</tr>
<tr>
<td>Lawn mowing - power mower</td>
<td>2,000</td>
</tr>
<tr>
<td>Rowing machine</td>
<td>3,000</td>
</tr>
<tr>
<td>Shopping</td>
<td>1,000</td>
</tr>
<tr>
<td>Square dancing</td>
<td>2,000</td>
</tr>
<tr>
<td>Squash</td>
<td>5,500</td>
</tr>
<tr>
<td>Stationary bicycling - moderate effort</td>
<td>2,000</td>
</tr>
<tr>
<td>Swimming</td>
<td>2,500</td>
</tr>
<tr>
<td>Tai chi</td>
<td>1,800</td>
</tr>
<tr>
<td>Tennis</td>
<td>3,180</td>
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<tr>
<td>Water aerobics</td>
<td>1,800</td>
</tr>
<tr>
<td>Yoga</td>
<td>1,000</td>
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</tbody>
</table>
# Two Week CPAP Diary

**WEEK 1**

<table>
<thead>
<tr>
<th>Date Started:</th>
<th>Date Finished:</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is your AHI score?</td>
<td>How refreshed you feel when you woke up this morning? (Circle your choice)</td>
</tr>
<tr>
<td>Sun</td>
<td>Refreshed</td>
</tr>
<tr>
<td>Mon</td>
<td>Refreshed</td>
</tr>
<tr>
<td>Tue</td>
<td>Refreshed</td>
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<td>Wed</td>
<td>Refreshed</td>
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<td>Thu</td>
<td>Refreshed</td>
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<td>Fri</td>
<td>Refreshed</td>
</tr>
<tr>
<td>Sat</td>
<td>Refreshed</td>
</tr>
</tbody>
</table>

Total number of CPAP use hours per week

**CPAP Experiences**

What has gone well with my CPAP therapy this week?

What’s not gone so well / stopped me?
### WEEK 2

<table>
<thead>
<tr>
<th>Date Started:</th>
<th>Date Finished:</th>
</tr>
</thead>
</table>

#### What is your AHI score?  
- Refreshed  
- Not Refreshed  
- Tired  
- Very Tired

#### How refreshed did you feel when you woke up this morning? (Circle your choice)
- Refreshed  
- Not Refreshed  
- Tired  
- Very Tired

#### How many hours did you sleep with your CPAP mask on?
- Refreshed  
- Not Refreshed  
- Tired  
- Very Tired

#### (ESS) EPWORTH SLEEPINESS SCALE

<table>
<thead>
<tr>
<th>Situation</th>
<th>Responses</th>
<th>Score</th>
</tr>
</thead>
</table>
| Sitting and Reading                                                      | 0 = would never doze  
1 = slight chance of dozing  
2 = moderate chance of dozing  
3 = high chance of dozing                                                  |           |
| Watching Television                                                      | 0 = would never doze  
1 = slight chance of dozing  
2 = moderate chance of dozing  
3 = high chance of dozing                                                  |           |
| Sitting inactive in a public place (for example, theatre or while at a meeting) | 0 = would never doze  
1 = slight chance of dozing  
2 = moderate chance of dozing  
3 = high chance of dozing                                                  |           |
| As a passenger in a car for an hour without a break                     | 0 = would never doze  
1 = slight chance of dozing  
2 = moderate chance of dozing  
3 = high chance of dozing                                                  |           |
| Lying down to rest in the afternoon when circumstances permit           | 0 = would never doze  
1 = slight chance of dozing  
2 = moderate chance of dozing  
3 = high chance of dozing                                                  |           |
| Sitting and talking to someone                                           | 0 = would never doze  
1 = slight chance of dozing  
2 = moderate chance of dozing  
3 = high chance of dozing                                                  |           |
| Sitting quietly after lunch when you've had no alcohol                  | 0 = would never doze  
1 = slight chance of dozing  
2 = moderate chance of dozing  
3 = high chance of dozing                                                  |           |
| In a car while stopped for a few minutes in traffic                     | 0 = would never doze  
1 = slight chance of dozing  
2 = moderate chance of dozing  
3 = high chance of dozing                                                  |           |

#### CPAP Experiences

- What has gone well with my CPAP therapy this week?
- What’s not gone so well / stopped me?

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[Logo: Leicester Diabetes Centre]
EMOTIONAL WELL-BEING AND OBLITERATIVE SLEEP APNEA (OSA): WORKSHEET 2

THE OSA FLOWER

In the previous sessions you have had a chance to think and explore:

Your thoughts, emotions and feelings about OSA and sleeping with Continuous Positive Airway Pressure (CPAP) therapy and how these can impact on your feelings and your OSA self-management.

This section is about trying to pull all these things together to help you to decide what is most important for you to focus on. We have used a tool called the OSA flower which has been adapted from work carried out in depression. The idea is that sometimes we can be keeping difficult thoughts and feelings going without realising it. The flower is a way of allowing yourself to think about what might be most relevant to you.

Is it that OSA makes you feel low? Sleeping with CPAP therapy could leave you feeling concerned or worried? For some people getting OSA and sleeping with CPAP therapy has had a positive impact on their life it doesn’t always have to be negative. The Educator in the session will encourage you to write your thoughts and feelings in each petal of the flower. Each petal has a different theme.
Low in Energy and Lacking Motivation

Feeling low can have a big impact on you physically making you feel drained, tired and losing motivation to sleep with CPAP therapy. It can be difficult to manage these feelings and sometimes they lead to people calling themselves ‘lazy’. How might you break this vicious cycle of doing less?

Having Strong Emotions

When someone feels low and depressed, or is worried and anxious or angry these feelings can have an effect on their thoughts, how they feel physically and this in turn can impact on their feelings. You will have discussed some examples of this in your Arise & Shine sessions. For instance, if you feel low and down, this can make you feel tired and lacking energy, you can then be critical of yourself for not doing enough or not being good company which can lead to you feeling more depressed.

Unhelpful Behaviours including Avoidance

Another way that you might try to cope is to eat or drink more, be less active or not sleeping with CPAP therapy. You will have discussed this in your Arise & Shine sessions and the effects this will have on your OSA and on how you feel about yourself.

So what might you do to cope with difficult thoughts, emotions and feelings?

One strategy is to avoid things. If self critical thoughts are telling you that you are not doing things well you might stop giving things a try or put them off. You might try to stuff negative thoughts and feelings away to try and keep them under control and avoid family and friends. In the short term these may seem to be good solutions. What happens in the longer term? You may end up being more critical of yourself and you could be stopping yourself from getting support and help.
So what can I do?

So an important part of self-managing OSA and sleeping with CPAP therapy is acknowledging the feelings and emotions to having the condition itself. Sometimes your emotional reactions or the ways you might try to manage your feelings can have a major impact upon how you look after yourself.

As we have said before it would be nice if there was an easy way of managing thought feelings and emotions. However, beginning to see that these are common experiences and not something personally wrong with you can help. It can also be of benefit to think about which of these petals is most relevant to you right now and consider how you might begin to make changes.

There is space below for you to write down which things you might like to try to change:

What I would most like to focus on?

What things can I try to manage this?
WEIGHT MANAGEMENT: CONFIDENCE/IMPORTANCE MATRIX
INTRODUCTION

Firstly, think about how confidence and importance may determine your likelihood to give weight management a go.

1. If weight management is of high importance to you and you have high confidence in yourself to achieve your goal how likely are you to give weight management a go?

2. If weight management is of high importance to you but you don’t have high confidence in yourself to achieve your goal how likely are you to give weight management a go?

3. If weight management is not of high importance to you and you don’t have high confidence in yourself to achieve your goal how likely are you to give weight management a go?

4. What can you do to place weight management in a higher place on your importance list?
### Confidence/Importance Matrix

#### High/High

- Most likely to give it a go
- Bite-size chunks
- SMART goals
- Rewards

#### Low/Low

- Personally relevant information
- Benefits for me, my family and friends
- Improving my confidence/self esteem
- Feeling I have achieved something

#### High/Low

- Not likely to give it a go

#### Low/High

- Not likely to give it a go

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**Leicester Diabetes Centre**

Consortium for Chronic Inflammatory Diabetic Kidney Disease & Innovation
YOUR THOUGHTS AND FEELINGS ABOUT OBSTRUCTIVE SLEEP APNEA (OSA) & CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) THERAPY: WORKSHEET 2

In this section we aim to give you a chance to share your thoughts and feelings (if you feel comfortable to do so) and discuss ways to self-manage your OSA and other stresses that come up in your life in a way that is right for you. You will not be made to talk about things you do not wish to discuss or share with other members of the group.

You might be asking yourself: Why is it important to consider my thoughts and feelings when I have a condition like OSA? We now know that OSA can have a big impact upon how you feel about yourself and your life and this can affect how you manage the condition. We are also aware that thoughts and feelings about other aspects of your life can get in the way of how you look after your health and your OSA. So an important part of self-managing OSA and sleeping with a CPAP machine is acknowledging the feelings and reactions to having the condition itself.

SO HOW DOES HAVING OSA MAKE YOU FEEL?

It is not uncommon for people to have quite a strong emotional reaction when diagnosed with OSA and required to sleep with CPAP therapy. Some people describe a feeling of loss; others get very angry, but everyone has their own individual response. These feelings can change over time, but that does not mean that they go away.

How does having OSA and sleeping with CPAP therapy make you feel?
Of course not everyone reacts in the same way. Below are some of the common feelings people may have with a long term condition.

- Why me?
- Frustration
- Feeling alone
- Sadness
- Feeling different
- Guilty
- Anger

Any other common feelings you would like to include?

HOW CAN YOUR REACTIONS TO YOUR OSA AFFECT HOW YOU LOOK AFTER YOUR HEALTH?

If you are feeling down....

Feeling down and sad can have an impact on energy levels and motivation. You may not have the ‘get up and go’ to engage in all the things you need to do to manage your OSA. Feeling low also affects thoughts and beliefs. For example, you might be harder on yourself in general and when you do not get things ‘right’. Sometimes people believe they are not worth looking after and this means that they will be less likely to do the things they need to do to manage their health.

On occasions feeling low can result in eating, drinking too much and not sleeping with CPAP therapy which again can have an effect on your OSA. Avoiding friends, family or people who offer support can also be part of feeling low and down.

If you are worrying a lot....

One way of coping with anxiety and worrying thoughts is to try to put them to the back of your mind and tell yourself that you don’t have OSA and you don’t need to sleep with CPAP therapy. Worrying and feeling worn out by worry can stop people from having the time or energy to do the things that might help their OSA. Sometimes people cope with worry by eating or drinking more.
If you are angry and irritable......

It is very common for people managing OSA to feel angry about having the condition. Sometimes this anger can make you irritable and short tempered with others and you can end up feeling guilty for being bad tempered.

Sharing your thoughts and feelings with others......

It might be difficult to share your thoughts and feelings with family, friends or other people in the Arise & Shine group. You may not want to worry people or fear you will look foolish. You might be concerned that people will not understand or take you seriously. Sometimes when trying to help, friends and family try to “suck it up” and although at times it can help to be kept busy it can sometimes leave you feeling as if no one takes your feelings seriously. However, it is important to think about these reactions as they can affect your quality of life, relationships and possibly how you manage your OSA.

So what can I do?

It would be nice if there was an easy solution to managing these thoughts and feelings. Quite often they are a completely normal response to having a long term condition that gets in the way of how you live your life and places your health at risk. It can feel like a burden with feelings of sadness and loss mixed with anger. However, we can rarely bypass the feelings that come with life changes and sometimes just realising that others feel like you can help you to feel less isolated and alone.

In most cases these feelings do change over time but if they are interfering with your life it may be worth discussing your concerns with them, your practice nurse or GP.
MY ARISE & SHINE HANDBOOK

ARISE&SHINE

ARISE&SHINE

A flexible and sustainable tool for individual education programs to promote weight loss and physical activity to patients with obstructive sleep apnea.
THIS HANDBOOK IS FOR PEOPLE WHO ATTEND THE ARISE & SHINE EDUCATION PROGRAMME.

WHY ARISE & SHINE?

Obstructive Sleep Apnoea (OSA) is a chronic breathing condition that affects 2-4% of women and men in the general population. In OSA something goes wrong in the body, more specifically on the upper airway, breathing becomes abnormal and irregular. As a result the oxygen levels in the body become lower than is good for your health.

People with OSA experience a variety of daytime symptoms including excessive daytime sleepiness, fatigue, headaches, irritability, mood swings, low energy levels, low concentration and memory problems. Sometimes people with OSA may also be aware of their night time symptoms such as loud snoring, going to the bathroom frequently during the night and stopping breathing during sleep but usually the partner or spouse recognises these symptoms first.

Studies have shown that Continuous Positive Airway Pressure (CPAP) therapy supports healthy breathing and reversing OSA related symptoms. Many studies have also shown that CPAP therapy can improve sleep quality, increase energy levels and reduce the likelihood of developing cardiovascular and other conditions including Type 2 Diabetes, Heart disease and Strokes. However some people find it difficult to sleep with a CPAP mask and machine for more than 4 to 4.5 hours per night.

Approximately 70% of people with OSA are overweight or obese which further increases the risk of heart and circulation problems as well as the risk of developing Type 2 Diabetes Mellitus (T2DM).

Making lifestyle changes like increasing physical activity and weight management can reduce the risk of developing T2DM, heart disease and stroke in the future.

UNDERSTANDING HEALTHY AND OSA BREATHING

In your Arise & Shine sessions, you will have explored the process of breathing, OSA breathing and how it affects individuals. This section highlights the main points to remember about breathing and OSA breathing.

Breathing is a process which enables the body to get air into the body and waste products out of the body. Without breathing humans cannot survive. The process of breathing is important as the body needs oxygen to survive and function (i.e. for eating, sleeping, walking, thinking etc).

1. We breathe in through our nose and mouth
2. The air goes to the throat and from the throat to the lungs
3. The lungs expand and cause the diaphragm muscle to contract and move down
4. With the help of blood, oxygen is transported via a network of arteries and veins all over the body and to vital organs such as the brain and the heart.
In OSA breathing something goes wrong in the body, more specifically on the upper airway.

1. The upper airway narrows and closes
2. The trucks struggle to go through or stop for a while as the road narrows or closes completely for a while
3. Breathing becomes abnormal and irregular

4. When OSA breathing happens the brain is activated and sends a signal like an alarm to wake the person just enough so to start breathing again only for a moment as the process becomes cyclical. As a result, individuals experience:
   - Poor sleep quality
   - Tiredness and fatigue
   - Poor concentration
   - Poor memory
   - Loss of libido (reduced sex drive)
   - Depression and low mood
   - Irritability
OSA DIAGNOSIS

To make a diagnosis of OSA, a person needs to have at least two out of the following three categories present.

1. Stopping breathing as detected by the sleep study Apnoea Hypopnoea Index (AHI)
2. Two or more of the following symptoms: awakening unrefreshed from sleep, daytime fatigue, choking/gasping for breath during sleep, recurrent arousals from sleep and impaired concentration
3. Excessive daytime sleepiness that cannot be explained by other causes as detected by the Epworth Sleepiness Scale (ESS)

There are other signs and symptoms which are associated with OSA but are not part of the diagnosis such as being overweight. The treatment for the signs and symptoms of OSA will be discussed during your Arise & Shine course.

THERAPY OPTIONS FOR OSA

Positional therapy

Some people snore or have sleep apnoea only when sleeping on their back. Such people can reduce or stop airway blockage simply by learning to sleep on their side. Most bed-partners know this therapy from experience. They often try to make their snoring partner move to their side during the night to stop their snoring. A cheap solution to promote side-sleeping is the tennis ball technique. This involves dropping a tennis ball in a sock and then pinning the sock to the back of the pajama top. Positional therapy alone is not recommended as an effective way for treating OSA in severe cases.

CPAP therapy

CPAP therapy helps to prevent the airways collapsing so that the road is open and the trucks can drive freely. The machine detects that the airways are about to narrow down and collapse so a split second before this is about to happen; the CPAP machine increases the amount of pressurised air delivered at the back of the throat as shown below.
Oral appliances

Oral appliances look like the mouth guards worn by swimmers. The oral appliances for treating sleep apnoea and snoring are specially designed for that purpose. The appliance is worn in the mouth during sleep. Most appliances work by positioning the lower jaw slightly forward of its usual rest position. This small change is, in many people, enough to keep the airway open during sleep. Oral appliances are not recommended as an effective way for treating OSA in severe cases.

Surgery

There are different types of surgery (from removing excess tissue from the soft palate to tongue base reduction and jaw reconstruction) available to treat sleep apnoea patients when they can not tolerate CPAP therapy. It is not a common choice of treatment for OSA as surgery is associated with many complications.
SO WHAT CAN I DO TO REDUCE MY RISK OF OTHER HEALTH COMPLICATIONS?

- Increasing CPAP hours of use per night
- Increase Activity

Reducing the risk of Type 2 diabetes?
- Increase physical activity
- Diet:
  - Lose weight and waist
  - Reduce saturated fat intake

Reducing Cholesterol
- Increase physical activity
- Diet:
  - Reduce fat and saturated fat
  - Increase fruit and vegetable intake (5 per day)
  - Tablets if necessary

Reducing Blood Pressure
- Increase physical activity
- Diet:
  - Reduce salt
  - Reduce weight
  - Tablets if necessary

Getting support with depression
- Talking to your GP
- Counselling
- Tablets if necessary
- Increase physical activity

Giving up smoking
- Attend “stopping smoking” sessions (information available from your GP)
- Nicotine patches/gums

MY HEALTH PROFILE

- BP Systolic
- Less than
- BP Diastolic
- Less than
- Total Cholesterol
- More than
- HbA1c
- 5.5%
- BMI
- 18.5 to 24
- Steps
- More than
- Smoking
- Non-smoker
- Depression
- 0 to 2
- CPAP hours
- 3
WHAT AM I GOING TO DO NOW? MAKING MY ACTION PLAN

How will making an action plan help me?

Having time to think about and identify the things you may wish to work on in the sessions will give you a starting point for your action plan. An action plan takes you through a number of steps to work out exactly:

What will I do?

- When will I do this?
- How often will I do this?
- What are the obstacles for me in making changes?
- How will I make sure things don’t stop me getting to my goal?
- How confident am I to make the changes?

When people make a plan that sets out clearly exactly what to do to achieve a change then success is increased. The **What Will I Do Now?** sheet gives you the opportunity to record the details of your plan.

Is there anything else I can do to make sure my plan works?

If you have ever tried to make changes before such as, stopping smoking or being more active, you may have recognised that often when trying to change, we either don’t plan or we have an unrealistic view of what we can tackle.

**Top Tips for Success!**

- Make myself a plan - seeing it written down makes it real!
- Be very clear in this plan about what I will/can do
- Be realistic and think about small changes I can make
- Celebrate successes however small I feel they are. Small success build into big successes!
### What Am I Going to Do Now?

<table>
<thead>
<tr>
<th>Which of these do I want to work on?</th>
<th>Which of these actions am I more likely to do?</th>
<th>What will I do about that?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure</td>
<td></td>
<td>How confident do I feel that I can do this? (Choose a number between 1 and 10 (where 1 is not at all confident and 10 is very confident))</td>
</tr>
<tr>
<td>Cholesterol</td>
<td></td>
<td>The number I choose is:</td>
</tr>
<tr>
<td>HbA1c</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td></td>
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<tr>
<td>Steps</td>
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<td></td>
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<tr>
<td>Depression</td>
<td></td>
<td></td>
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<tr>
<td>CPAP Hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>What will I do to increase my confidence? (For when my confidence score is below 7)</td>
</tr>
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<td></td>
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</tr>
<tr>
<td></td>
<td>What's going to stop me?</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>When will I revisit this plan?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Date:</td>
</tr>
</tbody>
</table>
WHERE AM I WITH CHANGE?

People go through different stages when trying to change their behaviour. Thinking about these stages and where you are with change can help. Having diabetes often means making changes to how we live our lives - at times this can be hard for everyone.

- **Avoiding** - The person is not thinking about change. They may be avoiding thinking about it, or may not understand that change is necessary or helpful.

- **Thinking about it** - Starting to think about change and weighing up the advantages and disadvantages of changing.

- **Preparation and planning** - Deciding to make a change. At this point making an action plan and getting going with the changes can increase the possibility of success.

- **Keeping it going** - Carrying out the plan in daily life. Discovering some actions are easier and some harder than others. Enjoying the success and health benefits of change.

- **Relapsing** - Keeping it going can be hard, and sometimes people go back to what they were doing before. Relapse is a normal part of this cycle. People can go through the cycle a number of times and often learn something on the earlier cycle which can help the next time round.

All stages of the cycle and the whole sequence can vary from individual to individual. Making an action plan can increase your chances of success by helping you to think through the changes you wish to make and guiding you to think about what will get in the way.

There may be some obstacles you want to think about, and ideas you have about how to overcome them. Some obstacles are more easily tackled than others. In diabetes, depression is common and may not be recognised as an obstacle.
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