

Research Article





# A comparison of continuous positive airway pressure initiation techniques in the treatment of obstructive sleep apnoea/hypopnoea syndrome in adults

#### **Abstract**

**Introduction:** This project assesses the differences between CPAP usage, a year after initiation, when patients were introduced to therapy via inpatient respiratory studies, outpatient auto-titration studies or a combination of the two.

**Methods:** The retrospective review of 98 CPAP patients' usage data was collected and statistically analysed using ANOVA tests, Chi-squared and Kruskal Wallace testing.

Results: The findings showed a small clinically significant difference but no statistically significant differences in usage across the three groups (p>0.05). Combining initiation techniques improved yearly CPAP usage by up to 365 hours. The difference between RESP and APAP average usage was 90 hours a year. No statistically significant difference in usage between the three groups was seen. The APAP pathway is the most cost-effective and significantly reduces the time taken to get on to CPAP treatment. Demographic variables are not found to predict nightly usage. All patients increased in weight over the year.

**Conclusion:** The results demonstrate higher levels of usage when combining initiation techniques, indicating initiation with high levels of interaction with healthcare professionals is beneficial. Significant weight gain across all groups poses the moral question of whether CPAP should be issued prior to initial weight loss attempts.

**Keywords:** continuous positive airway pressure, obstructive sleep apnoea/hypopnoea syndrome, adherence to treatment, treatment initiation

Volume 3 Issue 6 - 2018

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Received: November 08, 2018 | Published: December 26, 2018

# Introduction

Healthy sleep is critical to daily functioning enable consolidation of memory and synthesise important products such as hormones and proteins to repair the body. It is recommended, each night, that around 7-9 hours of sleep is needed to enable a fully functioning day to follow.¹ Sleep can be affected by a multitude of disorders, a common chronic disorder is Obstructive Sleep Apnoea/Hypopnoea Syndrome (OSAHS), which affects between 4% of males and 2% of females.²³ OSAHS can be categorised by severity using an Apnoea/Hypopnoea Index (AHI) which is the number of apnoeas or hypopnoeas that occur during each hour of sleep (Table 1).

Symptoms of OSAHS vary within the patient population and can include: snoring, Excessive Daytime Sleepiness (EDS), night gasping, morning headaches, nocturia and chronic fatigue.<sup>4</sup> The impact of OSAHS can be assessed using the Epworth Sleepiness Score (ESS) can be used. An ESS score above 10 can be used to classify patients as having EDS.<sup>5</sup>

Risk factors for developing OSAHS include obesity, age, gender, ethnicity, nasal obstruction, genetics, excessive alcohol intake, long-term smoking habits, hypothyroidism and hypertension. <sup>6-10</sup> OSAHS has been shown to reduce the quality of life (QOL) in the affected population. <sup>11</sup> Long term OSAHS is associated with many comorbidities that relate to a chronic lack of poor-quality sleep

such as hypertension, respiratory failure and diabetes mellitus.<sup>7,12,13</sup> Mental health manifestations pertaining to OSAHS include sufferers becoming more easily agitated, depressive and memory impairment.<sup>14</sup> Uncontrolled OSAHS has widespread effects on the public, with consequences including fatal traffic accidents and reducing QOL in cohabitants.<sup>15,16</sup>

Table I Severity of OSAHS<sup>4</sup>

Severity	AHI/Hour	
Normal	0-4	
Mild	4-14	
Moderate	15-30	
Severe	>30	

Currently, OSAHS can be diagnosed by two different sleep studies, full polysomnography (PSG) or limited sleep studies, and screened for using overnight pulse oximetry. Limited sleep studies assess respiratory effort, airflow and pulse oximetry to assess severity and type of apnoeic events. Full polysomnography (PSG) adds Electroencephalogram, Electrooculogram and Electromyogram, allowing stages of sleep to be scored. This tool is useful in diagnosing more complex sleep disorders such as narcolepsy, insomnia and REM behavioural disorders, but can be used for OSAHS.



Continuous Positive Airway Pressure (CPAP) therapy is considered the gold standard treatment for moderate to severe OSAHS.4 CPAP applies a positive pressure on the airways, acting as a pneumatic splint which prevents the airways from collapsing. Systematic reviews of CPAP as a treatment have shown a reduction in ESS of between 1.8 and 3.8, greater than that given by placebos or dental devices. <sup>19</sup> Automated Positive Airway Pressure (APAP) therapy can also automatically titrate a therapeutic pressure. APAP uses the same mechanism as CPAP, but changes the pressure automatically, by responding to obstructive events in the airways.<sup>20</sup> Lifestyle modification can aid in the treatment of OSAHS and is recommended as a treatment for mild OSAHS prior to CPAP issue, unless patients are symptomatic.<sup>17</sup> Choices such as weight loss, smoking cessation and the reduction of alcohol and caffeine intake before sleeping can improve OSAHS Literature suggests that untreated OSAHS significantly impacts on people's lives and has varying levels of compliance, therefore it is important to treat effectively. The aim of this study is to determine if there is a significant difference in CPAP device usage, one year after diagnosis, across the three initiation techniques. Secondary aims include identification of demographic characteristics such as gender, ethnicity or severity of condition that can predict CPAP usage as well as assessing the cost-effectiveness of each initiation techniques.

## Literature review

It is commonplace for CPAP therapy to be initiated in either an inpatient or outpatient setting. In an inpatient environment, a patient will undertake a sleep study, where they will have APAP initiated at some point to titrate a pressure. In the outpatient setting, APAP devices are used to automatically titrate a pressure whilst the patient sleeps. Some studies have demonstrated that home APAP use, to initiate CPAP therapy for OSAHS, is just as useful as inpatient overnight studies pertaining acceptance of therapy, time to treatment and benefit received from therapy, when measured using AHI as the primary outcome. 21-24 However, Mulgrew et al. 25 saw that initiating CPAP as an outpatient can improve device usage by 0.6 hours each night in comparison to PSG initiation.<sup>25</sup> Rather than using just one technique for initiating patients on to CPAP, it may be beneficial to combine the two methods of acclimatisation. Hoy et al.26 demonstrated that using a home initiation, followed by an inpatient stay and continual intensive support from nurses, can improve device usage by 1.4 hours per night, when usage was measured after six months. <sup>26</sup> This must be in person though, to be effective.<sup>27</sup> Wozniak et al.<sup>28</sup> further demonstrated that supportive interventions can improve device usage by up to 50 minutes each night, improved patient education can increase usage by 35 minutes per night and behavioural therapy improves device usage by up to 1.44 hours per night.<sup>28</sup> Cooksey & Balachandran suggested that patients who are initiated to therapy at home, gradually produce the correct psychological and behavioural changes within their attitudes to treatment that improve their device usage more readily than those initiated as inpatients.<sup>29</sup> However, no data was found on the effect of combining initiation techniques.

Adherence to CPAP therapy is low and approximately 50% of patients prescribed CPAP are using their devices 1 year after their diagnosis. <sup>30</sup> Of those who are using their devices one year later, most are not using them to prescribed levels. <sup>31</sup> Wolkove et al. found 30% never started using their devices at home and only 54% were still using their devices 64 months after their initial diagnosis when initiated using a PSG. <sup>32</sup> Wang et al. found that 52% of patients initiated

on CPAP during PSGs were still using their devices 30 months after their initial diagnosis.<sup>33</sup> The guidelines for treating OSAHS in the UK are set by the Scottish Intercollegiate Guidelines Network (SIGN). Currently they offer no guidance regarding the number of hours per night devices should be used for, but state that patients using their devices for less than two hours per night should have their treatment reviewed.<sup>4</sup> However, a commonly used threshold is defined as usage ≥4 hours a night for 70% of nights. <sup>[34]</sup> It is estimated that only 46% of patients achieve this level of successful usage.<sup>35</sup>

Although patient characteristics have shown little association with CPAP usage, people from African-American backgrounds have been seen to be more likely, than people from a white background, to be non-adherent to treatment in the US and in New Zealand. This is thought to be due to the socio-economic disparities across ethnicities and the difficulties accessing the required health services. <sup>36–38</sup>

Thus far, no significant differences between the device usage of patients initiated on CPAP during inpatient studies or home APAP trials have been found and both methods of initiation offer similar therapeutic pressures and rates of acceptance. <sup>24,29,39,40</sup> Berry et al.<sup>22</sup> studied 106 patients who were initiated on CPAP via APAPs or PSGs, 79 accepted CPAP therapy.<sup>22</sup> They found an increased mean nightly usage of 0.05 hours in the PSG group and an ESS reduction of 0.47 in comparison to the APAP group, however, they found no statistical differences between the two methods. Cross et al. noticed an increased mean usage of devices in the inpatient branch of 0.01 hours each night after three months of usage. 40 Their patient acceptance of CPAP was 97.5%. Contrastingly, Rosen et al. tested 373 patients across seven sleep centres in the USA and found, after three months of CPAP therapy, patients in the group initiated at home used their devices for 1 hour more each night in comparison to the group introduced to CPAP as an inpatient.<sup>24</sup> CPAP acceptance remained at 91-92% and a 25% reduction in cost was observed for the home branch.

## **Methods**

This single-site retrospectively study reviewed routine CPAP compliance data collected between August 2014 and February 2016, to assess if any treatment initiation technique yields greater device usage after a year of therapy. All patients were required to be over the age of 18 years, on CPAP therapy for OSAHS and attend their first annual CPAP review within the allotted timeframe to be included in this study. Both males and females were included, but any patient who suffered from a secondary sleep disorder was excluded. In some cases patients were initiated on CPAP therapy as an inpatient and an outpatient. When this occurred, the data for both methods were combined to assess if initiation via multiple methods provided greater clinical outcomes.

# **Patient protocol**

Each patient was given two nights of home oximetry before attending a consultation with a doctor prior to being given a home APAP trial or respiratory sleep study. They then followed one of three pathways to start CPAP treatment. The decision to issue an APAP trial or respiratory study was based on whether or not the oximetry results showed evidence of OSAHS and the examination highlighted excessive daytime sleepiness. If this was the case, the patient was referred for an APAP trial to initiate CPAP therapy. If the patient was borderline or the oximetry results were not acceptable, they were

referred for an inpatient respiratory study, where CPAP was initiated half-way through the night. The APAP trial involved the patient being issued an APAP device which they took home for two weeks and were instructed to use every night. After two weeks, the patient exchanged their device for the same model CPAP device set at the 95th percentile pressure observed over the two weeks. The patients completing the aforementioned pathway will now be referred to as the "APAP" group. The respiratory study pathway required the patient to stay in the sleep centre overnight and use an APAP device for half or the whole night depending on whether their study was a "split night" or "titration". They are then issued with a CPAP device set at the 95th percentile pressure observed during that night. This group will now

be referred to as the "RESP" group. In some instances, the patients had both a respiratory study and APAP trial and will be referred to as the "Combined" group. The combined group, in most cases did not cope with one diagnostic pathway to titrate a pressure or use the device effectively (greater than 5 hours per night). See figure 2 for a summary of these pathways. All patients used a ResMed S9 APAP device with a starting pressure of 4cmH2O and a maximum of 20cmH2O. Once a pressure had been obtained they were given a ResMed S9 CPAP device to keep and were reviewed annually, where component parts are renewed and their usage was checked. At each point in the pathway, patients were lost due to exclusion of OSAHS or the declination of treatment (Figure 1).

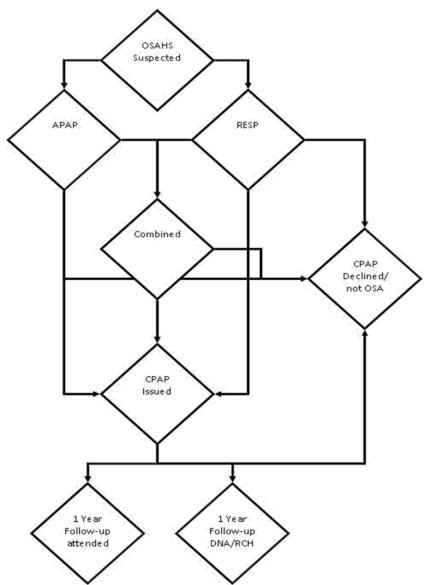


Figure I Patient Pathway Diagram This diagram shows the three patient pathways (RESP, APAP and Combined). DNA, Did Not Attend; RCH, Rescheduled appointment.

# **Data collection**

Routinely available clinical data was used to compile enough information to statistically evaluate which initiation technique gave greater nightly usage one year after diagnosis. To collect and

present the data collected effectively, the variables were categorised as demographic or outcome variables and split into two tables. The data collected was statistically analysed using International Business Machines' (IBM) Statistical Package for the Social Sciences (SPSS).

# **Outcome variables**

The primary outcome variables were designed to give a comprehensive picture of the comparative device usage between RESP, APAP and combined pathways. The primary outcome variables included:

Nightly Usage - Average CPAP usage by the patient each night in hours

Total Hours Used-The number of hours the device was used in total

Percentage Usage—The total number of nights used as a percentage of the time to follow-up (Table 2).

Table 2 List of outcome variables

Initial variables obtained:	
Referral date	Group/individual issue (APAP only)
Sex(Male/Female)	Diagnostic/therapeutic study length (RESP only)
Age (Years)	Pressure (cmH2O)
Height (Metres)	Post AHI/ODI after titration/ study
Weight (Kilograms)	Post ESS after study/initial CPAP
BMI (Kg/M2)	Leak (Litres/Second)
Ethnicity	Nightly usage (hours)
Epworth Sleepiness Score (/24)	Trial usage (hours)
ODI/AHI (/hr)	Percentage compliance
Route (Inpatient/outpatient)	Total hours used
Start/end study dates (APAP only)	Mask size
Study duration (APAP only in days)	Time to treatment
Severity of disease	
Data Obtained from follow-up appoir	ntments include:
I year follow-up date	Change in ESS
Pressure (cmH2O)	Nightly usage (hours)
Change in pressure	Total hours used
Epworth Sleepiness Score	Days used
Percentage Usage	

# Statistical analysis

Traditional two-sided hypothesis testing was used to find differences between the nightly device usages of the three groups. The null hypothesis stated there would be no difference between any of the groups' usages at the one-year follow-up. Firstly, the data was assessed for normality using a Shapiro-Wilk test. Once normality had been proved, non-parametric analysis of the hourly usage data was performed using a one-way ANOVA test. Where a P-value of less than 0.05 (5%) was seen, post-hoc testing was performed. To test the mean percentage usage rank of the three groups, a Kruskal-Wallis H test was performed. Two Distribution-based methods of assessing clinical significance were used. Firstly, a modified version of the Minimal Clinically Important Difference (MCID) as suggested by Wright et al. was used to set a clinically important threshold.<sup>41</sup> This enabled the comparison of a single acclimatisation technique (RESP or APAP alone) in comparison to a combination of techniques. If the Combined group's usage exceeded that of the APAP or RESP group, the results would be deemed clinically significant. The second method used involved the calculation of the effect size (ES) of the RESP and APAP groups. This required a modified version of the formula to find the ES. If the ES was 0.2-0.5, 0.5-0.8 or >0.8 then the observed effect would be of small, medium or large clinical significance respectively. The secondary aims were achieved by plotting scatter graphs of any continuous variable against the nightly usage of each of the three groups. If a correlation was observed graphically, a regression analysis of the variable was performed. For categorical variables, bar graphs were produced and Chi-Squared tests assessed any correlations. Where means were assessed, ANOVA and post-hoc testing was once again used.

### **Results**

Initially, 352 patients were suspected to have OSAHS, 186 had a respiratory study and 166 had an APAP trial initially. 42 patients then required a combination of the two to obtain a CPAP pressure. The number of patients who obtained a useable pressure from each group was 110 RESP, 112 APAP and 23 Combined. 57 RESP patients were excluded for not having OSAHS. Of the 245 patients who obtained a pressure, 42 (17%) declined treatment before CPAP was issued (19 RESP, 13 APAP, 10 Combined). In total, 203 patients were given CPAP devices, 98 (48%) attended their one-year follow-up, 42 (21%) rescheduled their appointment outside of the data collection timeframe, 55 (27%) did not attend their appointment and 8 (4%) returned their devices before their one-year follow-up (4 RESP, 3 APAP, 1 Combined).

# **Demographic variables**

The sample population was similar across all three groups with average ages of 52±2 years. The percentage of males included was 76% and females made up 24% of the sampled population. The average patient resided in the "obese" category, with a BMI between 30-35kg/m². Patients' mean ESS scores were 13.5±0.5 and the mean severity of OSAHS, based on the number of events/hour, is "severe". On average, the patients' prescribed pressure ranged from 13.1-13.9 and mask leak was acceptable in all categories (less than 0.4L per second). On average, patients were seen at their 1-year follow-up by 355±3 days. The APAP group tended to have the more extreme values, with the highest percentage of males (81%), average BMI (34.4) and mean severity (36.2 events/hour). A summary of this this information

can be seen in table 2. The majority of patients who were on the APAP pathway had severe OSAHS (54%), whilst the most prevalent severity in the RESP group was moderate (34%). Overall, 44% of patients in the study had severe OSAHS (Table 3).

**Table 3** Summary of the demographic variables. All values are reported as means, with the ranges contained in brackets. For both "gender" the values are counts and the figures in brackets are the percentage of the population in the respective column

		RESP	Combined	Total
	APAP (n=43)	(n=32)	(n=23)	(n=98)
Mean Age	53	50	54	52
(years)	(37-74)	(25-74)	(29-82)	(25-82)
Male	35 (81%)	21 (66%)	18 (78%)	74 (76%)
Female	8 (19%)	11 (34%)	5 (22%)	24 (24%)
Mean BMI	34.4	33.5	32.7	33.7
	(22.1-58.00)	(24.2-48.4)	(22.6-42.4)	(22.1- 58.0)
Mean ESS	13	14	13	13
	(4-22)	(5-22)	(2-19)	(2-22)
Mean AHI	36.18	35.07	25.9	35.8
	(5.80-84.00)	(5.40- 133.70)	(5.2-80.0)	(5.20- 133.70)
Mean Pressure	13.6	13.9	13.1	13.8
(cmH2O)	(9.0-18.6)	(9.0-20.0)	(7.8-17.4)	(7.8- 20.0)

A ranking of each groups' device usage was observed within the data collected. This is shown from the average yearly usage hours and percentage usage, were the Combined group used their devices for 5.75 hours a night, 1569 hours a year 76.5% of nights; more than the APAP group (5.19 hours a night; 1280 hour per year; 63.2% of nights), more than the RESP group (4.86 hours per night; 1204 hours per year; 56.1% of nights). All groups increased in weight, with the highest average hourly CPAP users increasing the most (average 3.37kg) in comparison to a 0.87 and 0.2 kg increase for those in the APAP and RESP groups. Only patients in the RESP group had an average pressure increase of 0.25cmH2O, whereas the Combined and APAP group required reductions in pressure of 0.07 and 0.06cmH2O on average. Symptomatically, those in the RESP and Combined group saw the greatest reduction in symptoms (assessed by a reduction in the ESS score) of seven points in comparison to a reduction of six seen by the APAP group. All of this information is summarised in table 3. Those undergoing the APAP pathway took only 40 days to get on to treatment, whereas the RESP group took an average of 100 days, whilst the combined group took an average of 73 days to receive a CPAP device (Table 4).

#### **Primary aims**

The primary outcome was to assess any differences between device usage across the three groups. Normality across the data is required to perform a one-way analysis of variance (ANOVA) test and was assessed via a Shapiro-Wilk test. For the Shapiro-Wilk test, p - values ranged from 0.075 - 0.200, so the ANOVA test could be performed.

The ANOVA test assessed the means of the primary outcome variables for the "APAP", "RESP" and "Combined" groups (nightly usage and total yearly usage). The results of the ANOVA test can be seen in table 4 below. Levene's statistics across all variables were above 0.05. This meant there was equal variance across the groups. The ANOVA test results (p>0.05) indicate that there is no statistically significant difference between any of the primary outcomes' means and so the null hypothesis is retained, a summary of this data can be seen in Table 5 below.

**Table 4** Summary table of outcome variables. The table summarises the results of all three groups. All values are reported as means, with the ranges contained in brackets

Mean	APAP	RESP	Combined	Total
Percentage Percentage	63.2	56.1	76.5	63.9
Usage (%)	(0.3-99.7	(0.0-100.0)	(7.7-100.0)	(0.0- 100.0)
Mean Nightly	5.19	4.86	5.75	5.21
Usage (hours)	(1.8-8.00)	(0.00-8.30)	(2.60-8.50)	(0.00- 8.50)
Mean Yearly	1279.64	1203.67	1569.12	1321.45
Usage (hours)	(10.80- 2803.60)	(0.00- 2987.90)	(139.90- 3116.20)	(0.00- 3116.20)
Mean Weight	0.84	0.2	3.37	1.23
Change (kg)	(-20.00- +22.60)	(-39.5- +17.2)	(-7.400+11.20)	(-39.50- +22.60)
Mean Pressure	-0.04	0.25	-0.07	0.04
Change (cmH2O)	(-2.2-+4)	(-2.00- +4.00)	(-2.00-+2.00)	(-2.20- +4.00)
Mean ESS	-6	-7	-7	-6
Change (/24)	(-14-+2)	(-17-+6)	(-18-+7)	(018-+7)

Moreover, the Kruskal-Wallace H test also showed no statistically significant difference in yearly percentage usage, n=95;  $X^2(2)=3.471$ ;p=0.176; with a mean rank of 46.9 of APAP, 43.02 for RESP and 57.09 for the Combined group.

Table 5 ANOVA Test for primary outcomes. Df=degrees of freedom

Outcome Variable (n=96)	Levene's Statistic	Df	F-value	Sig.
Nightly Usage	2.855	2,93	1.596	0.208
Total Hours Used	1.506	2,93	1.134	0.326

To assess the clinical significance of adding a secondary CPAP initiation technique, the methodology proposed by Wright et al, was used again. For the Combined group's usage to be clinically significant, it would have to exceed the MCID thresholds set by the APAP and RESP group of 1457 and 1401 hours per year of CPAP usage. It did, with 1569 hours usage per year and so the addition of a secondary CPAP initiation technique can be deemed of small clinical significance. This is also seen when using the Effect Size method methodology. An effect size between 0.2-0.5 indicates the addition of a secondary treatment initiation technique results in a small clinically significant improvement in usage (Table 6).

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Table 6 Clinical significance Mean values=mean total yearly usage; this table shows distribution-based methods of assessing clinical significance

	Mean	Effect Size	Threshold
APAP	1279.6	0.326	1457.3
RESP	1203.7	0.26	1400.9
Combined	1569.1		

The speed of CPAP initiation is crucial in the reducing the comorbidities of the sufferer and the effect on the wider community and bed partner. Those in the APAP group were significantly quicker than the other groups, as seen by a further ANOVA test (F=(2,93) =13.1; p< 0.001). Post hoc Tukey's HSD tests showed that usage between RESP and APAP groups was significantly different (p<0.01), and the Combined groups usage lay in between the two, significantly different to the APAP group (p=0.015), but not the RESP group (p=0.082).

### Secondary aims

The secondary aims were to see if any patient characteristic predicted a patient's CPAP usage one-year post issue and assess the cost effectiveness of each route.

Ethnicity has been seen to affect device usage but did not within this study. Results from a Chi-Squared tests (n = 98;df =4;X<sup>2</sup>=4.52;p=0.540) showed no difference of distribution when the usage was modified from an hourly value to a categorical usage (0=unbeneficial, 1=slightly beneficial, 2=highly beneficial. These values were adapted from the methodology used by Zimmerman et al.42 All ethnicities achieved, on average, the NICE target for CPAP therapy of four hours/night but no ethnicity averaged more than six

Previous studies have shown a weak correlation between severity and device usage. A regression analysis comparing the number of events per hour (severity) and average nightly usage suggested a weak correlation between severity and nightly usage. The correlation showed n = 89; df =(1, 85); F=4.185; r=0.217; r<sup>2</sup>=0.047; p=0.044. Using the graph and r<sup>2</sup> value, it suggests the correlation between the two variables is weak and accounts for only 5% of the results, however, the p-value is less than 0.05 (5%) which indicates the more severe the initial OSAHS, the greater the device usage.

In-trial study costs can be seen in table 6. In total, the cost of pursuing the respiratory branch of the pathway would be £1,119 (a Respiratory study, a CPAP issue and a one-year follow-up) whereas the APAP trial pathway would total £456 (an APAP trial, a CPAP issue and a follow-up) and the combined pathway costs £1,271. If using telephone consultations, then this reduces to £333 (an APAP trial, a telephone consultation and a follow-up). The total cost of all respiratory studies included in this project was £35,808 for 32 studies in comparison to £19,608 for 43 APAP trials and £29,233 for 23 combined studies (totalling £84,649). If only APAP trials had been used for the whole sample, then a total cost of £44,688 would have been incurred. The setup cost of an hour's therapy equates to £0.36 for APAP, £0.81 for Combined and £0.93 for RESP. This indicates that the most cost-effective route is the home APAP trial (Table 7).

There is a difference between nightly usage statistics between the RESP and APAP groups. APAP groups used their CPAP devices, on average, for 20 minutes a night more and for 26 nights a year more than the RESP group giving 90 hours of extra usage each year. If the two branches are combined, device usage is once again improved by an average of 365 hours a year in comparison to the RESP group.

Table 7 Cost of various studies/appointments. The cost of each CPAP device was excluded from the total, as all branches requires them

Study Type	Cost (£)
Respiratory Study	815
APAP Trial	152
Face to Face Follow-up	152
Telephone Follow-up	29

Clinically, the differences observed can be categorised as "small" change, however this was difficult to assess as there is limited data on the effects of CPAP usage on comorbidities and physiology of OSAHS patients. Patients use their devices for an average of 5.21 hours/night (>1200 hours/year) which meets the recommended guidelines of  $\geq 4$ hours/night for 70% of nights (1022 hours/year). Only the combined group used their devices for more than 70% of nights. However, the guidelines seem arbitrary measures which require further research.

### **Discussion/conclusion**

This analysis of multiple pathways indicates that there is no statistically significant difference in nightly usage when a patient is initiated on CPAP therapy via inpatient RESP titrations, home-based APAP titrations or a combination of the two. These findings are in correlation with other studies.<sup>24,29,39</sup> However, this research project is unique as it combines both the RESP and APAP pathways, includes patients with a BMI>40kg/m<sup>2</sup>, does not exclude those over the age of 70 and includes patients solely from a tertiary care centre in the UK, allowing the possible extrapolation of data to the general UK population.

One prominent theory explaining why improved usage is seen in the APAP and Combined groups pertains to the positive psychological and behavioural changes associated with patients who take their device home.31

This leads to increased levels of acceptance and usage. Another relates to the "reinforcement" or increased interaction time from the healthcare professionals.<sup>43</sup> However, these studies suggested the first few weeks of usage predict future usage. This is contrary to what has been seen in this study, as the Combined group consists of patients who have had a short experience with CPAP and have not been able to tolerate it, before being initiated again using a different method. This shows that the usage of a device within the first week or first few weeks does not necessarily predict the outcomes one year into treatment, although the more interaction a patient has during the initiation phase of their treatment, the greater the device usage. This suggests that one acclimatisation technique (home APAP trials) could be employed across the OSAHS population to increase each patients' usage. This would save money for sleep centres in the long run and reduce the cost of treatment by up to £663 per patient, and £786 if telephone follow-ups are used instead of face to face consultations. Moreover, home-trials potentially enable the use of psychometric testing during a follow-up consultation.31 This could identify inconsistent users and offer early extra help that may be needed to achieve an effective therapeutic treatment level.<sup>28</sup> Practically, this

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approach is unlikely to succeed. Historically with CPAP therapy, a "best fit" approach has been used for the majority of patients and those who are unable to tolerate therapy are left to struggle through and persist with poor treatment. Additionally, respiratory studies are used to diagnose other sleep disorders such as periodic limb movement and restless leg syndromes. Unlike APAP trials, 57 RESP patients were excluded from the OSAHS pathway in comparison to 0 from the APAP pathway. Respiratory studies therefore maintain an important tool in the exclusion of OSAHS and the diagnosis of more complex sleep disorders and should be reserved for those with borderline OSAHS for other, more complex, sleep disorders.

# Secondary aims

This study has demonstrated a statistically significant difference in usage regarding severity, indicating that the more severe the OSAHS, the more likely a patient is to use their device each night. The ESS did not show the same correlation, highlighting an individual response to CPAP where adherence to treatment may directly relate to the sleep requirements of a patient, which vary across the population. Furthermore, the psychological/behavioural changes that occur in someone who is well established on CPAP may play a role in dampening the perceived severity of their OSAHS.

No statistically significant difference was seen between multiple ethnicities' usages, contrary to previous studies.<sup>36-38</sup> They suggested that the variability was due to socio-economic differences between various ethnic groups. These studies were not performed in the UK, where a variety of with varying socio-economic backgrounds exist. Additionally, since the referenced studies were published, new masks for CPAP devices have been released, allowing for greater adaptability to non-Caucasian facial structures and a more effective fit which could lead to greater adherence to treatment.

Using a combination of techniques is more cost-effective than initiating a patient on to CPAP during a respiratory study and APAP trials can reduce the time taken to get a patient on CPAP therapy. A difference of £0.57 between the least and most costly technique show that APAP trials are cheaper and more effective than respiratory titrations. A controversial issue that this study has brought to light pertains the change in weight across all three groups, which is deemed to be an important process in the treatment of OSAHS.<sup>17</sup> One of the proposed benefits of implementing CPAP is that it enables an overweight OSAHS patient to have a fully functioning day and increase their activity levels and reducing their need to eat. The data from this study suggests that the implementation of CPAP is facilitating an unhealthy lifestyle, with some patients increasing in weight by up to 22kg in just one year. In another study, it was found that although weight reduction is crucial in symptom treatment, the percentage of patients losing weight is typically very low.<sup>44</sup> This poses a crucial dilemma for healthcare professionals; if CPAP users are living unhealthier lifestyles whilst being treated for OSAHS, there may be a need to review prescription criteria

# Potential limitations/weaknesses

A potential limitation to this study pertains to the "Did Not Attend" (DNA) rate of patients and the rescheduling of their one-year followup appointments outside of the designated timeframes. 61 patients did not attend their appointment and 86 rescheduled too far from the initial appointment date. This meant that the results may have been skewed and compliance levels may therefore be overestimated due to the psychological and behavioural influences on the treatment. Although the results of this study can be extrapolated for the population in a

multi-cultural "free at the point of service" healthcare locality, a larger population sample assessed over several years across multiple sleep centres would reduce any disparities that might have been observed. It would also give an even more in-depth analysis into the effects of CPAP acclimatisation techniques and a more accurate picture of CPAP device usage over a longer-term period. Additionally, within this study and other similar ones, patients with significant comorbidities outside of OSAHS were not observed which limits the extrapolation of findings to a single condition cohort.

# Conclusion

In conclusion, the only demographic variable that weakly correlates with device usage is the severity, as measured by the AHI. However, on average, patients increased in weight by 1.23kg. The increase in weight of all groups demonstrates that more effort is needed in encouraging patients to engage in healthy lifestyles, which will ultimately reduce the severity and in some instances, negate the need for OSAHS treatment as well as reduce the prevalence of other comorbidities. If APAP trials are used to initiate patients and weight loss is encouraged, significant cost cuts could be made from a service perspective and time to get on CPAP treatment might also be reduced.

This study shows no statistically significant difference in nightly device usage between any patients initiated to therapy using a home APAP trial, an inpatient respiratory study or a combination of the two. However, those who had a combination of techniques did use their devices more than the lowest scoring single technique, demonstrating that multiple initiation techniques have a clinical improvement on device usage. It is possible that a brief introduction to therapy overnight initiates the psychological changes a patient needs to undergo to effectively acclimatise to a long-term therapy, however more research needs to be done concerning this topic. Further research will facilitate updating guidelines on acceptable and target nightly CPAP usage. The implementation of questionnaires can further investigate CPAP effectiveness, and if added at an early stage it can also help to assign patients to the most appropriate pathways.

# **Acknowledgments**

None.

# Conflicts of interest

The authors declare no conflict of interest.

#### References

- Hirshkowitz M, Whiton K, Albert SM, et al. National sleep foundation's updated sleep duration recommendations: final report. Sleep Health. 2015;1(4):233-243.
- Spiro SG, Silvestri GA, Agusti A. Clinical respiratory physiology. 4th edn. Philadelphia: Elsevier Inc; 2012.
- Sutherland K, Lee RW, Cistulli PA. Obesity and craniofacial structure as risk factors for obstructive sleep apnoea: impact of ethnicity. Respirology. 2012;17(2):213-222.
- SIGN. Management of obstructive sleep apnoea/hypopnoea syndrome in adults. Edinburgh: SIGN; 2003.
- Wu S, Wang R, Ma X, et al. Excessive daytime sleepiness assessed by the Epworth Sleepiness Scale and its association with health related quality of life: a population-based study in China. BMC Public Health. 2012;12(849).
- Nabil M, Lawati A, Patel SR, et al. Epidemiology, risk factors, and consequences of obstructive sleep apnea and short sleep duration. Progress in Cardiovascular Diseases. 2009;51(4):285-293.

- Schwartz AR, Patil SP, Laffan AM, et al. Obesity and obstructive sleep apnea - pathogenic mechanisms and therapeutic approaches. *Proceedings* of the American Thoracic Society. 2008;5(1):185–192.
- Romero CA, Caples SM, Lopez- JF, et al. Interactions between obesity and obstructive sleep apnea. *Chest.* 2010;137(3):711–719.
- Villaneuva AT, Buchanan PR, Yee BJ, et al. Ethnicity and obstructive sleep apnoea. Sleep Medicine Reviews. 2005;9(6):419–436.
- Mohsenin V. Effects of gender on upper airway collapsibility and severity of obstructive sleep apnea. Sleep Medicine. 2003;4(6):523–529.
- Dutt N, Janmega AK, Mohapatra PR, et al. Qality of life impairment in patients of obstructive sleep apnea and its relation with the severity of disease. *Lung India*. 2013;30(4):289–294.
- 12. Ashtyani H, Hutter DA. uCollateral damage: the effects of obstructive sleep apnea on bed partners. *Chest.* 2003;124(3):780–781.
- Naresh DA, Nieto FJ, Somers VK. Intermittent hypoxemia and OSA implications for comorbidities. Chest. 2015;147(1):266–274.
- Cheshire K, Engleman H, Deary I, et al. Factors impairing daytime performance in patients with sleep apnea/hypopnea syndrome. Archives of Internal Medicine. 1992;152(3):538–541.
- Teran SJ, Jimenez GA, Cordero GJ. The association between sleep apnea and the risk of traffic accidents. The New England Journal of Medicine. 1999:240(11):847–851.
- James PM, Lyng PJ. Quality of life in bed partners of patients with obstructive sleep apnea or hypopnea after treatment with continuous positive airway pressure. Chest. 2003;124(3):942–947.
- NICE. Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome. 2008.
- AASM. Clinical guideline for the evaluation, management and longterm care of obstructive skleep apnea in adults. *Journal of Clinical Sleep Medicine*. 2009;5(3):263–276.
- Giles TL, Lasserson TJ, Wright JJ, et al. Continuous positive airway pressure for obstructive sleep apnoea in adults. *Cochrane Database of Systematic Reviews*. 2006(3).
- 20. https://www.resmed.com/in/en/consumer.html
- 21. Fietze I, Glos M, Moebus I, et al. Automatic pressure titration with apap is as effective as manual titraton with cpap in patients with obstructive sleep apnea. *Respiration*. 2007;74(2007):279–286.
- 22. Berry B, Hill G, Thompson L, et al. Portable monitoring and autotitration versus ploysomnography for the diagnosis of obstructive sleep apnea. *Sleep*. 2008;35(6):1423–1431.
- McArdle N, Singh B, Murphy M, et al. Continuous positive airway pressure titration for obstructive sleep apnoea: automatic versus manual titration. *Thorax*. 2010;65:606–611.
- 24. Rosen CL, Auckley D, Foldvary SN, et al. A multisite randomized trial of portable sleep studies and positive airway pressure autotitration versus laboratory-based polysomnography for the diagnosis and treatment of obstructive sleep apnea: the homepap study. Sleep. 2012;35(6):757–767.
- Mulgrew AT, Fox N, Ayas NT, et al. Diagnosis and initial management of obstructive sleep apnea without polysomnography. *Annals of Internal Medicine*. 2007;146(3):157–166.
- Hoy CJ, Vennelle M, Kingshott RN, et al. Can intensive support improve continuous positive airway pressure use in patients with the sleep apnea/ hypopnea syndrome?. American Journal of Respiratory and Critical Care Medicine. 1999;159(4):1096–1100.

- Fletcher EC, Luckett RA. The effect of positive reinforcement on hourly compliance in nasal continuous positive airway pressure users with obstructive sleep apnea. *American Review of Respiratory Disease*. 1991;143(5):936–941.
- Wozniak DR, Lasserson TJ, Smith I. Educational, supportive and behavioural interventions to improve usage of continuous positive airway pressure machines in adults with obstructive sleep apnoea. *Cochrane Databse of Systematic Reviews*. 2014(1).
- Cooksey JA, Balachandran JS. Portable monitoring for the diagnosis of OSA. Chest. 2016;149(4):1074–1081.
- Ballard RD, Gay PC, Strollo PJ. Interventions to improve compliance in sleep apnea patients previously non-compliant with continuous positive airway pressure. *Journal of Clinical Sleep Mediicne*. 2007;3(7):706–712.
- Stepnowsky Jr CJ, Marler MR, Ancoli IS. Determinants of nasal CPAP compliance. Sleep Medicine. 2002;3(3):239–247.
- Wolkove N, Baltzan M, Kamel H, et al. Long-term compliance with continuous positive airway pressure in patients with obstructive sleep apnea. *Canadian Respiratory Journal*. 2008;15(7):365–369.
- Wang Y, Gao W, Sun M, et al. Adherence to CPAP in Patients With Obstructive Sleep Apnea in a Chinese Population. *Respiratory Care*. 2012;57(2):238–243.
- 34. Weaver TE, Maislin G, Dinges DF, et al. Relationship between hours of CPAP use and achieving normal levels of sleepiness and daily functioning. *Sleep*. 2007;30(6):711–719.
- Gordon P, Sanders MH. Sleep 7: Positive airway pressure therapy for obstructive sleep apnoea/hypopnoea syndrome. *Thorax*. 2004;60:68–75.
- Weaver TE, Grunstein RR. Adherence to continuous positive airway pressure therapy. *Proceedings of the American Thoracic Society*. 2008;5(2):173–178.
- Campbell A, Neill A, Lory R. Ethnicity and socioeconomic status predict initial continuous positive airway complaince in New Zealand adults with obstructive sleep apnoea. *Internal Medicine Journal*. 2010;42(6):e95– e101.
- 38. Billings ME, Auckley D, Benca R, et al. Race and residential socioeconomics as predictors of CPAP adherence. *Sleep*. 2011;34(12):1653–1658.
- Masa FJ, Jimenez A, Duran J, et al. Alternative methods of titrating continuous positive airway pressure. *American Journal of Respiratory and Critical Care Medicine*. 2004;170:1218–1224.
- 40. Cross MD, Venelle M, Engleman HM, et al. Comparison of CPAP titration at home or the sleep laboratory in the sleep apnea hypopnea syndrome. *Sleep*. 2006;29(11):1451–1455.
- Wright A, Hannon J, Hegedus EJ, et al. Clinimetrics corner: a closer look at the minimal clinically important difference (MCID). The Journal of Manual and Manipulative Therapy. 2012;20(3):160–166.
- 42. Zimmerman ME, Arnedt JT, Michael S, et al. Normalization of memory performance and positive airway pressure adherence in memory-impaired patients with obstructive sleep apnea. *Chest.* 2006;130(6):1772–1778.
- Weaver TE, Sawyer AM. Adherence to continuous positive airway pressure treatment for obstructive sleep apnea: implications for future interventions. *The Indian Journal of Medical Research*. 2010;131:245–258.
- Sanchez AI, Martinez P, Miro E, et al. CPAP and behavioral therapies in patients with obstructive sleep apnea: Effects on daytime sleepiness, mood, and cognitive function. *Cleep Medicine Reviews*. 2009;13:223–233.