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**OBSTRUCTIVE SLEEP APNOEA AND DAYTIME
DRIVER SLEEPINESS**

by

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ABSTRACT

Driver sleepiness is known to be a major contributor to road traffic incidents (RTIs). An initial literature review identified many studies reporting untreated obstructive sleep apnoea (OSA) sufferers as having impaired driving performance and increased RTI risk. It is consistently reported that treatment with continuous positive air pressure (CPAP) improves driving performance and decreases RTI risk, although most of these studies are conducted less than one year after starting treatment. UK law allows treated OSA patients to continue driving if their doctor states that treatment has been successful.

Despite the wealth of publications surrounding OSA and driving, 6 key areas were identified from the literature review as not fully investigated, the: (i) prevalence of undiagnosed OSA in heavy goods vehicle (HGV) drivers in the UK; (ii) impact of sleep restriction on long term CPAP treated OSA compared with healthy controls; (iii) ability of treated OSA participants to identify sleepiness when driving; (iv) impact of one night CPAP withdrawal on driving performance; (v) individual difference in driving performance of long term CPAP treated OSA participants; (vi) choice of countermeasures to driver sleepiness by two groups susceptible to driver sleepiness, OSA and HGV drivers.

Key areas (i) and (vi) were assessed using questionnaires. 148 HGV drivers were surveyed to assess OSA symptoms and preference of countermeasures to driver sleepiness. All participants completing the driving simulator study were also surveyed. 9.5% of HGV drivers were found to have symptoms of suspected undiagnosed OSA. Additionally the OSA risk factors were more prevalent for HGV drivers than reported in national statistics reports for the general population. The most effective countermeasures to driver sleepiness (caffeine and a nap) were not the most popular. Being part of a susceptible group (OSA or HGV driver) and prior experience of driver sleepiness did not promote effective choice of countermeasure.

Key areas (ii) to (v) were assessed using a driving simulator. Driving simulators present a safe environment to test participants in a scenario where they may experience sleepiness without endangering other road users. Initially, in a repeated measures counterbalanced design, 19 CPAP treated OSA participants, recruited from an OSA

patients association group and 20 healthy controls, recruited by adverts in the local area, completed a two hour afternoon drive following a normal night's sleep (with treatment) and following sleep restriction to 5 hours. OSA participants were then invited to complete a 3rd study day following a normal length of sleep but without CPAP. The control groups was matched to the OSA group for age and driving experience. All drives were recorded and assessed for sleep related incidents, EEG activity was continuously monitored and subjective sleepiness ratings recorded at regular intervals.

Following a normal night's sleep there was no significant difference between driving performance for CPAP treated OSA participants and controls. Both the healthy controls and the OSA participants could safely drive for approximately 90 min. Sleep restriction had a greater impact on OSA than control participants resulting in significantly more driving incidents and shorter safe driving time.

OSA participants were more likely to report sleepiness prior to a major driving incident than control participants. On average, OSA participants experienced 19 minutes of feeling sleepy prior to incident compared with 65 minutes for controls.

Without CPAP, participants started the drive feeling sleepier and therefore experienced incidents earlier than following sleep restriction to 5 h. Participants were less likely to report sleepiness prior to first major incident compared with following sleep restriction.

Approximately a quarter of OSA participants were severely affected by sleep restriction; others showed no significant difference to controls. These affected OSA participants were more likely to report sleepiness prior to major incident than those not affected.

Following the completion of the driving simulator work, it became apparent that when compared with younger participants studied in previous publications, older participants; (1) had fewer driving incidents; (2) were less likely to report sleepiness prior to a major incident.

In summary, approximately 10% of HGV drivers surveyed were suspected of having OSA. Survey of countermeasures to driver sleepiness suggests experienced drivers do not make effective choices. Long term CPAP treated OSA patients appear not have driving impairment compared with healthy controls of a similar age, as long as treatment is adhered to and adequate sleep obtained. OSA patients can identify when they are sleepy, although older people appear less able to do this while driving than younger people.

An effective education program is needed to facilitate diagnosis of OSA in HGV drivers, for all drivers to improve choice of countermeasures to driver sleepiness and to promote the importance of a full night's sleep and treatment adherence to OSA patients. Further research is needed to investigate ability to identify sleepiness and individual difference in susceptibility to sleep restriction in treated OSA patients.

Key words

Driving performance, driver sleepiness, obstructive sleep apnoea, perception of sleepiness, countermeasures, individual difference, continuous positive air pressure (CPAP)

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NOMENCLATURE

AHI	Apnoea hypopnoea index
ANOVA	Analysis of Variance
BMI	Body mass index
cm	Centimetre
CPAP	Continuous positive air pressure
DVLA	Driver and Vehicle Licensing Agency
EDS	Excessive daytime sleepiness
EEG	Electroencephalogram
EOG	Electroculogram
ESS	Epworth sleepiness scale
EU	European Union
GB	Great Britain
h	hours
HGV	Heavy goods vehicle
Hz	Hertz
KSS	Karolinska Sleepiness Scale
LGV	Large goods vehicle
LHoFA	Likelihood of Falling Asleep (scale)
LSAPA	Leicester sleep apnoea patient association
min	Minutes
MSLT	Multiple sleep latency test
MWT	Maintenance of wakefulness test
NICE	National Institute for Health and Clinical Excellence
PSG	Polysomnography
PVT	Psychomotor vigilance test
OSA	Obstructive sleep apnoea
OSAS	Obstructive sleep apnoea syndrome
RDI	Respiratory disturbance index
RTI	Road traffic incident
s	Seconds

SDB	Sleep disordered breathing
s.d.	Standard deviation
SDI	Sleep disturbance index
srRTI	Sleep-related road traffic incident
SSS	Stanford sleepiness scale
TST	Total sleep time
UK	United Kingdom
USA	United States of America
VAS	Visual analogue scale
y	Years
ϵ	Epsilon

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PREFACE

**CASES OF SLEEP-RELATED ROAD TRAFFIC INCIDENTS CAUSED BY DRIVERS
WITH OBSTRUCTIVE SLEEP APNOEA**

To establish the real world context for research in this thesis it is important to appreciate the human impact of road traffic incidents (RTIs) caused by obstructive sleep apnoea (OSA) drivers. As set out in the UK Public Records Acts 1958 and 1967, court files are closed to the public until they are a minimum of thirty years old. Therefore it is not possible to assess the prevalence of RTIs where OSA has been identified as a causal factor. However, it is possible to appreciate the situation through newspaper articles.

A search of UK newspapers was conducted using the search terms “sleep apnoea” and “traffic accident”. Presented here is a summary of 4 cases that were identified from the newspaper search, with varying court outcomes. It is recognised that the information may be subjective as it is obtained from newspapers rather than court documents and that these are likely to be higher profile cases considered to be newsworthy.

All 4 of the cases detailed below resulted in fatalities and all were caused by heavy goods vehicle (HGV) drivers and in 3 cases OSA was diagnosed after the crash. This is not intended to be analyses of all cases of OSA sleep related road traffic incidents (srRTIs), but, this information does illustrate the severity of srRTIs, occurrence in both diagnosed and undiagnosed OSA sufferers and demonstrates the varied outcomes of court cases.

Case 1

In 2006 on an A road in Oxfordshire a 61 year old HGV driver fell asleep at the wheel of his 30 tonne truck killing a couple and their two sons aged 16 and 11 years. The HGV driver had been awake since 4.30am and driving from 7am when the incident happened at 3:30pm. The HGV drove into the back of a queue of traffic, the first vehicle it hit was pushed out of the way, the second lifted into the top deck of a car transporter before the HGV drove over the top of the third car crushing the family inside.

Following the incident the driver was diagnosed with OSA. The defence stated that the driver did not remember the incident and that OSA had caused him to pass out

suddenly. Medical experts for the prosecution testified that OSA would not result in being unable to identify increasing sleepiness and that the driver could have taken appropriate measures to avoid falling asleep at the wheel.

The court found the driver guilty and sentenced him to 3 years and 9 months in prison.

Source: A Dawar (2007), Driver who fell asleep, killing family of four, will go to jail .The Times (London),December 8, 2007, p. 35.

A Topping (2007), Lorry driver who fell asleep faces jail for killing family. The Guardian (London), December 8, 2007, p. 19.

Case 2

In 2006 on a motorway in Merseyside a 54 year old HGV driver fell asleep at the wheel of his HGV killing a 25 year old man. The HGV drove into the back of a queue of traffic crushing the victims car and writing off 9 other vehicles.

The driver was initially charged with dangerous driving due to falling asleep at the wheel. OSA was diagnosed after the incident. The defence stated that the driver had sought help from his GP about feeling tired four months before hand and that on the day of the incident he had been feeling fine then started to feel faint and fuzzy before having no memory of events.

The court gave a verdict of accidental death and no sentence was given.

Source: J Narain (2008), Death crash trucker's sleeping illness. Daily Mail (London), August 6, 2008, p. 29.

Case 3

In 2005 on an A road in Scotland a 36 year old HGV driver fell asleep at the wheel of his HGV killing three people aged 25, 44 and 36 years. The HGV drove into the back of a queue of traffic at approximately 50 mph hitting 5 vehicles.

Following the incident the driver was diagnosed with OSA. The expert witness for the defence stated that the driver would not have known that he had a sleep disorder or

how severe it was before hand. The driver stated that he had “blacked out” prior to the incident. An expert witness for the prosecution stated that the driver would have known that he was sleepy even though he didn’t know he had a disorder.

The court found the driver to have no proven guilt and no sentence was given.

Source: R Moore (2007), ‘Sleepy’ driver on death rap. The Mirror (Scots Ed) October 10, 2007, p. 15.

Case 4

In 2000 on a motorway in Kent a 44 year old HGV driver fell asleep at the wheel of his HGV tractor unit killing 2 people aged 24 and 25. The HGV tractor unit first hit a broken down van on the hard shoulder before veering across three lanes and into the oncoming traffic hitting the car carrying both victims.

In court the driver admitted to falling asleep at the wheel 15 times before causing several minor accidents. The driver had been diagnosed with OSA in 1999 at which time the doctor advised him not to drive. Despite the diagnosis he continued to work as a lorry driver and took a second job as a cleaner working 3 hours per night. On the night of the incident he had finished work at 1am having had no more than 4 hours sleep. The driver told the court that he had lied to his doctor about feeling sleepy in 1999 as he wanted to be signed of work to deal with family problems. He stated that as far as he knew he had nothing wrong with him apart from a snoring problem.

The court found the driver guilty and sentenced him to 8 years in prison.



Source: H Studd (2002), Eight years for sleepy lorry driver who killed. The Times (London), January 19, 2002.

Photo. Unaccredited (2002), Driver jailed for couples death. BBC news 18 January 2002

CHAPTER ONE

A REVIEW OF LITERATURE ON DRIVER SLEEPINSS AND OBSTRUCTIVE SLEEP APNOEA

1.1 Introduction

Falling asleep whilst driving can result in serious accidents. Road traffic injuries account for 2.1% of all global deaths, which is the 11th greatest cause of deaths in the world (Peden 2004). With over 34 million licensed vehicles on UK roads in June 2009 (Department for Transport 2009) driver sleepiness has the potential to be a major problem. Driver tiredness has been recognised by the UK Department for Transport THINK campaign as being responsible for around 300 deaths per year. One group of people susceptible to excessive daytime sleepiness are untreated Obstructive Sleep Apnoea (OSA) sufferers. Research into obstructive sleep apnoea (OSA) has increased greatly over the last 30 years reflecting the increased importance in this area of research (Lavie 2008). OSA is important in driver sleepiness as one of the symptoms is excessive daytime sleepiness (EDS) (Phillips 2004). If an OSA sufferer is driving it is possible they may suffer driver sleepiness as a result of their pre-existing condition.

Successfully treated OSA patients are usually free to drive, as daytime sleepiness returns to normal levels. However, little is known about OSA patients and their ability to cope in the long term: How they react to a shorter night's sleep than usual? What happens if they miss a night's treatment? If undiagnosed OSA is prevalent in people driving heavy goods vehicles (HGVs) for work? This thesis aims to address these questions.

To define the context of the problem of OSA driver sleepiness the following chapter uses existing work to explain the disorder OSA, detail the nature of sleep-related road traffic incidents (srRTIs) and discuss the impact of OSA on driving. Finally this chapter contains a review of OSA and driving studies conducted using surveys and simulators, enabling identification of gaps in the literature and research questions to be addressed.

1.2 Obstructive sleep apnoea

OSA is a sleep disorder resulting in the repeated collapse of the airway during sleep. As the airway collapses it blocks the air flow so the body and brain do not get sufficient oxygen (Hardinge 2008). During the collapse the body becomes starved of oxygen, the low oxygen levels are recognised by the brain which responds by waking the person in

order to resume breathing. Sufferers do not always fully wake as breathing can resume in light sleep. However, this repetitive interruption of deep sleep can result in EDS (Hardinge 2008).

An apnoea occurs when air flow ceases for 10 seconds or more, anything less than 10 seconds or a partial reduction in air flow is a hypopnoea (Hardinge 2008). Severity of OSA is quantified by the Apnoea Hypopnoea Index (AHI) which is the average number of apnoeas and hypopnoeas which occur per hour of sleep. It is generally accepted that to be classed as an OSA patient the AHI must be greater than 5 (American Academy of Sleep Medicine Task Force 1999). Respiratory Disturbance Index (RDI) may also be used; this is average respiratory arousal events per hour, which may include more than just apnoeas and hypopnoeas e.g. snoring arousals. Sleep disordered breathing (SDB) describes any disorder characterised by abnormal respiratory patterns; the most common is OSA.

1.2.1 Epidemiology

The exact prevalence of OSA is not known as it is suspected many people have the condition and do not realise. Estimations of prevalence depend on the population assessed and the definition of OSA used. Due to time and money constraints it is often not suitable to use a full polysomnography (PSG) for diagnoses (Bresnitz et al. 1994). Prevalence estimations are important in order to estimate the expected health care cost to an area (Young et al.

The most comprehensive study to day of prevalence found 4% of men and 2% of women have OSA (Young et al. 1993). This formed part of the Wisconsin Sleep Cohort Study, a large population based study. In this case an initial sleep patterns questionnaire was completed by participants including questions on snoring. A high return rate of 82% (3513 participants) returned questionnaires, all respondents who habitually snored and 25% of the sample who were not snorers completed overnight PSG. Participants were considered to have OSA if they had an AHI 5 or over. The prevalence rate within the population was based on having a combination of AHI>5 and reporting daytime sleepiness. A sample of participants completed a repeat PSG to check for consistency. This was a major study covering a large population size, the

only minor limitation is that they did not distinguish true OSA events from possible central events; central events being defined as lack of airflow and cessation of respiratory effort, with obstructive apnoea being lack of airflow with continued respiratory effort (Bresnitz et al. 1994).

Several population studies have shown prevalence to be between 0.3% and 10%, though it should be noted that these studies have predominantly been on Caucasian subjects (Stradling et al. 1991, Bearpark et al. 1995, Bixler et al. 2001). It is likely that somewhere around 5% of a Caucasian middle aged adults would be suffering from OSA (Young et al. 2002). There have been few studies in non Caucasian populations so it is not possible to say with certainty if prevalence varies, however it has been reported that prevalence is higher in African Americans than Caucasians (Ancoli-Israel et al. 1995). In that study all participants were over 65 years and had sleep recordings completed at home, the odds of having an AHI ≥ 30 were 2.5 times higher in African-Americans, this was controlling for BMI.

The prevalence of OSA increases with age and is most common in men aged 40 – 60 years (Hardinge 2008) increasing to a possible prevalence of 24% in over 65s, as measured using a portable home monitoring system on 420 participants (Ancoli-Israel 2009). However, it should be noted that presence of sleep disordered breathing in the elderly does not necessarily mean the person has OSA (Hoch et al. 1990).

Research suggests that there is a gender split of between 2:1 and 3:1 prevalence in males compared to females (Redline et al. 1994, Bixler et al. 2001, Wahner-Roedler et al. 2007). OSA is strongly linked to obesity so it is suggested that as the prevalence of obesity is increasing so will prevalence of OSA (Gibson 2004).

1.2.2 Pathogenesis

OSA occurs in individuals where the airway collapses completely and repeatedly, often causing oxygen desaturation. The pharynx is a soft, the small muscles (pharyngeal dilators) contract during inspiration. During sleep all muscles relax, thus the structure of the pharynx is weaker and liable to collapse (Klawe et al. 2003). OSA will occur in some individuals but not other, this will depend on the initial size of the pharynx, if it is larger partial collapse with muscle weakening can occur with it closing (Fogel et al.

2004). Additional factors also contribute predominantly caused by obesity as excess adipose tissue is excess weight the pharyngeal dilators have to act against (Gibson et al. 2004). The narrowing of the airway impedes ventilation and results in full or partial arousal.

OSA is more likely to occur in men and in people aged over 40, additionally obesity, central body fat distribution and large neck size have been consistently shown to be high risk factors of OSA (Shigeta et al. 2008, Young et al. 2002, Peppard et al 2000, Young et al 2004). A collar size of 43cm (17") in men and 40cm (16") in women has been shown to be highly indicative of OSA (Davies et al. 1992). Smoking is considered to be a possible risk factor as the airway may become inflamed. In the Wisconsin cohort mentioned earlier current smokers were 3 times more likely to have OSA than people who did not smoke at the time of data collection (Wetter et al.1994), association between smoking and OSA is also reported by (Stradling and Crosby 1991). Although there is suggestion of association between smoking and OSA there is less evidence than for obesity (Young et al. 2002).

1.2.3 Diagnosis

Polysomnography (PSG) involves the measurement of brain activity by EEG, eye movements by Electrooculogram (EOG) and muscle activity by Electromyogram (EMG). Electrodes are attached to specific locations on a participant's scalp in accordance with the Rechtschaffen and Kales (1968) international 10-20 system and recorded over a night. The output can be scored using Rechtschaffen and Kales (1968) standard scoring to show each stage of sleep and wakefulness, demonstrating the transition from wake to sleep and distinctive stages during sleep.

PSG is used for the recording of brain activity in sleep, this technique is the gold standard for diagnosing OSA as it can be used to sleep stage and monitor arousals from sleep as well as monitoring air flow at the nose/mouth and blood oxygen concentrations. However, in practice it costly to complete a full over night recording to all patients presenting in clinic. In the UK the most commonly used diagnostic tool is a partial sleep study including oximetry, (which can be set up at a sleep clinic), the patient will then sleep at home in their own bed and come back to the clinic the

following day for diagnosis (Hardinge 2008). At some clinics (or in cases where the home recording is inconclusive, often because of detachment of the equipment at night) a full polysomnography (PSG) is carried out over night in hospital (Gibson 2004). People with an AHI greater than 5 are diagnosed as OSA sufferers.

Overnight recordings are expensive and time consuming, so before they are carried out doctors may assess determine if any reported day time sleepiness is excessive. The most common way to assess EDS is by using the Epworth Sleepiness Scale (ESS). Those scoring over 12 are said to have EDS, as healthy people have been shown to score an average of 5 (Johns 1991, Johns et al. 1997). The ESS measures average sleep propensity, an individual's general level of sleepiness independent of the current situation (Shen et al. 2006). OSA patients usually suffer from various other medical conditions, so when identifying EDS it is important to note if the patient has other conditions which may exacerbate this i.e. depression or diabetes (Koutsourelakis et al. 2008). ESS is a valid tool for assessing sleepiness in OSA patients as it improves once treatment is started (Engleman et al. 1996). However, some studies have not found significant correlation between ESS and OSA severity as measured by AHI and how quickly they can fall asleep (Chervin et al. 1997, Olson et al. 1998). A full explanation of the ESS can be found in section 3.5.3.1.

1.2.4 Symptoms

The presenting symptom of OSA is often first reported by the bed partner of the sufferer, most commonly loud snoring and "holding their breath" while asleep (Phillips 2004). In contrast, the most common complaint from the patient is excessive day time sleepiness (EDS) interfering with daytime activities, this is extreme, often unexplained sleepiness during the day which is frequently quantified by an ESS over 12. However, not all sufferers will have EDS (Gibson 2004). OSA patients who have EDS are often referred to as having obstructive sleep apnoea syndrome (OSAS). Patients may be unaware of the apnoeas, believing they are getting a full night's sleep (Hardinge 2008). They may report feeling un-rested when they wake but will not know why. Sufferers also report morning headaches and a dry mouth on waking (Bresnitz et al. 1994).

1.2.5 Complications and associations with OSA

Beyond the symptoms reported specifically to OSA;

Stopping breathing in their sleep

EDS

Loud snoring

Morning headaches

Dry mouth on waking

There are other complications which have been associated with OSA, where links have been shown although not conclusively proven. Outlined below are those complications and associated risks not relevant to driving. Possible cognitive function decline and the symptom of day time sleepiness are relevant to driving and are detailed in section 1.4.

1.2.5.1 Mortality

OSA is a chronic disease which is now routinely treated, as such no recent study has followed patients without treatment. He et al. (1988) monitored 385 male patients with OSA over 8 years, 22 died in this period giving a 0.78 probability of survival. The authors report that in untreated patients aged over 50 the probability of death was significantly higher among those with an AHI ≥ 20 . Although this study is limited to one sleep centre in Canada which limits the generalisation of the findings, it does demonstrate mortality rates to be higher in sufferers with elevated AHI.

1.2.5.2 Type 2 diabetes

It is possible that OSA is associated with diabetes, as many OSA patients also suffer from diabetes, however, as yet there has been no firm evidence that OSA causes diabetes as most studies are observational rather than experimental (Punjabi et al. 2009). A suggested mechanism is that the repeated arousals during the period before treatment decrease insulin sensitivity (Stamatakis and Punjabi 2010). CPAP treatment does not appear to reverse the associated adverse effects with diabetes as reviewed by Punjabi et al. (2009), they suggest a strong confounding factor is BMI as CPAP can treat OSA without the patient being required to lose weight. However, it is then not clear if the diabetes is a risk factor for OSA or if OSA is a risk factor for diabetes (West et al. 2006).

1.2.5.3 Cardiovascular disease and stroke

Apnoea episodes result in the body being exposed to hypoxia and negative intrathoracic pressures on the cardiovascular system. The added pressure to the heart can result in raised blood pressure, heart rate and impair function. There is an independent association between OSA and hypertension, coronary artery disease, arrhythmias, heart failure and stroke, as reviewed in Bradley and Floras (2009), Young et al (2002) and Malhotra and White (2002). In particular there is strong evidence that OSA is a risk factor for stroke (Yaggi and Mosenin 2004). CPAP treatment has been shown by randomised control trials to lower blood pressure and improve cardiac function, however, as yet large trials have not been conducted (Bradley and Floras 2009).

1.2.5.4 Quality of life

The SF-36 health related quality of life measure has been used in OSA samples. The two largest are the Wisconsin Sleep Cohort Study (Finn et al 1998) and the Sleep Heart Health Study (Baldwin et al. 2001). Both studies show a linear association of OSA severity and decline in the SF-36 scales, although not always significantly so. In Baldwin et al. (2001) the association was significant for all scales if OSA was defined as AHI>30, so it appears that severe OSA is highly likely to have an impact on quality of life. Co-morbidities present a confounding factor in any OSA and quality of life study as OSA is common in older adults and has been linked to cardiovascular disease. It can be difficult to clearly distinguish what is the cause of any reduced quality of life. Treatment with CPAP has been found to improve health related quality of life (Moyer et al. 2001). Literature on quality of life and OSA is reviewed by Moyer et al. (2001) and Young et al. (2002).

1.2.6 Treatment

In the UK the National Institute for Health and Clinical Excellence (NICE) guidelines for treatment available on the NHS state that moderate to severe OSA patients are to be treated with continuous positive air pressure (CPAP). This treatment is also recommended for mild sufferers if life style advice (losing weight) has not been effective (NICE 2008). Other possible treatments include oral appliances and uvulopalatopharyngoplasty surgery; these were evaluated by the NICE 2008 report

along with CPAP, the report concluded CPAP to be the most effective treatment. As CPAP is the recommended treatment in the UK the other two treatment options will not be considered in this work.

CPAP works as the increased air pressure prevents the airway collapse (Phillips 2004, Abbey et al. 1989). CPAP treatment entails wearing a mask over the nose and (if needed) mouth during sleep, through which a constant pressure of air is pumped from an electrical box which sits at the side of the bed (Hardinge 2008). The pressure required to maintain the airway varies between individuals so the machine has to be calibrated for each patient (Gibson 2004).



Figure 1.2-1 CPAP machine. ResMed (2008)

CPAP treatment should be used for more than 7 hours each night to ensure maximum reduction in OSA symptoms (Phillips 2004) but in practice compliance is a problem. One study found only 46% of CPAP users used the machine for at least 4h on 70% of days (Kribbs et al. 1993b). Common complaints with the machine are that air can sometimes leak through the mouth which results in the patient having a dry mouth which can feel uncomfortable (Phillips 2004). Claustrophobia with the mask over the face at night and the noise of the machine inhibiting sleep are also reported causes of non compliance with treatment. Generally level of adherence is determined in the early stages of treatment but it is important to follow up after 6 months as some patients will increase or decrease adherence (Aloia et al. 2008). Patients with severe

cases of OSA have been shown to be more compliant than patients with moderate OSA (Yetkin et al. 2008).

CPAP has been shown to improve ESS and MWT scores (Jenkinson et al. 1999, McDaid et al. 2009), however, MSLT do not improve, suggesting OSA patients may retain high sleep ability. It has generally been shown that CPAP improved both objective and subjective sleepiness in moderate to severe cases of OSA (Davies et al. 2000). Not all research supports the use of CPAP; compliance rates are so low that it is more effective to recommend weight loss (Wright et al. 2000). In the case of mild OSA the NICE guidelines state that CPAP should only be used if weight loss fails (NICE 2008).

CPAP treatment has been shown to be cost effective (NICE 2008). One study compared 181 OSA patients and 181 matched controls looking at health care services used in the 10 years prior to OSA diagnosis. They found that OSA patients use approximately twice as many health care services during this time than the controls (Ronald et al. 1999) and results in decreased hospitalisation costs (Bahammam et al. 1999). There is also the decreased cost to society in road traffic incidents (George 2001) and improved quality of life resulting in increased work performance (Findley et al. 2001). Within the NICE guidelines CPAP is recognised as the most cost effective method of treatment for OSA, where it was compared to oral appliances and lifestyle management. Subjects were monitored for 1 year and monitored for health events, RTI, ESS and quality of life by the assessment group. Additionally a CPAP manufacturer also submitted a report on cost effectiveness. Very few participants had an RTI in the year so the impact on RTIs was not firmly established and some of the evidence came from a CPAP manufacturer, however, it remains that the NHS acknowledged CPAP as the most cost effective treatment. Cost effectiveness is very important to the NHS who work from a limited budget (NICE 2008).

1.3 Driver sleepiness

Driver sleepiness is feeling sleepy or drowsy while in control of a motor vehicle. This will result in impaired driving performance and is as a result of inadequate prior sleep, one possible cause of inadequate prior sleep is OSA.

1.3.1 Prevalence of road traffic incidents

Traffic injuries were the 9th leading cause of death and disability in the world in 1990, and have been predicted to be the 3rd leading cause by 2020 (Murray et al. 1997). In 2007 there were 247 780 road casualties and 2 946 people killed on roads in Great Britain (GB) (Department for Transport 2008).

Research has shown that 16 - 20% of road traffic incidents (RTIs) on major roads are as a result of sleep-related crashes (Horne et al. 1995). In the UK Horne et al. (1995) found sleep related road traffic incidents (srRTI) to be more likely to result in fatality, here 23% of fall asleep incidents to result in death or serious injury compared with 15% of all other road incidents police were called to in Devon, Cornwall, Leicestershire, Staffordshire, Northamptonshire, Warwickshire, and West Mercia on motorways and A roads over a 5 year period. This is likely in part due to the high speed of such incidents, an American study found 62% of srRTIs to be at excess of 50mph (Pack et al. 1995). In the American study of 4333 RTIs judged to be caused by the driver falling asleep 1.4% resulted in fatality which is less than the 2.3% of alcohol related RTIs reported as resulting in fatality (Pack et al. 1995). It is not possible to compare the numbers in the UK and USA study as the UK study does not separate for death and serious injury, also the USA study reports in comparison to fatality in alcohol related RTIs only whereas the UK study compares with all other causes of RTI. Also in America using logistic regression driver sleepiness has been reported to directly increase the odds that a RTIs will be fatal (Bunn et al. 2005).

It is likely srRTIs have high fatality and injury rates because drivers who are asleep make no correction to their direction of travel which usually results in head on collisions or running off the road (Pack et al. 1995). If the driver wakes before a crash has occurred it is possible they will suddenly try to correct the direction of travel which could cause them to lose control of the vehicle (Hancock et al. 1997). This has been demonstrated in a driving simulator, where sleepy drivers were less likely to correct steering but their movements were of high amplitude (Thiffault et al. 2003).

1.3.2 Characteristics of sleep-related road traffic incidents

In a suspected drink or drug related RTIs there are definitive tests which will conclude if a driver is under the influence of either. However, with sleep-related RTIs (srRTIs) following the event the drivers are likely to become alert, therefore showing no signs of prior sleepiness. In the UK the following criteria are used by the police and consequently court system to identify srRTIs, this criteria are derived from Horne et al. (1995):

Main Criteria

1. No mechanical defects
2. Good weather and driving conditions
3. Speeding and 'driving too close' excluded
4. Alcohol excluded
5. Medical disorder/medications excluded
6. Vehicle runs off the road or into another vehicle
7. No evidence of braking beforehand
8. Driver could see the impact point clearly for over 7 seconds before the crash
i.e. prolonged inattention, not momentary distraction

Other points:

- A) More likely to occur 02:00h- 06:00 and 14:00 – 16:00h
- B) Usually on a dull road
- C) Driver usually denies sleep/sleepiness

Using the above criteria Horne and Reyner (1995) assessed those RTIs likely to be sleep-related in comparison to the volume of traffic on the roads at the time, reported in figure 1.3-1.

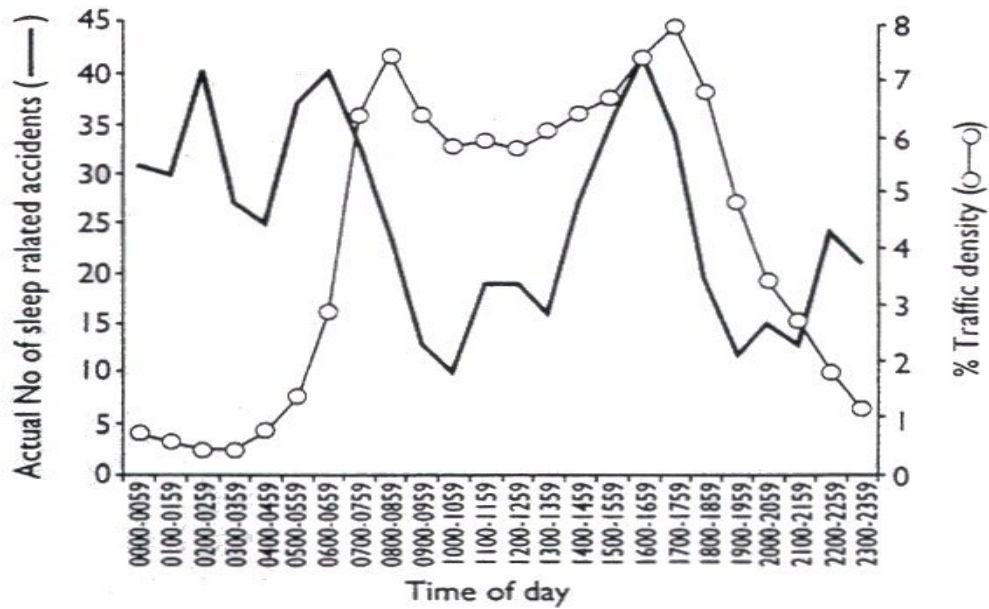


Figure 1.3-1 Number of sleep-related accidents and traffic density, (J. A. Horne et al. 1995)

A clear circadian affect can be seen (solid line of figure 1.3-1); with sleep-related accidents peaking in the early hours of the morning and in the early afternoon in line with circadian rhythm. Traffic density (circles in figure 1.3-1) peaks during the rush hour times of 8-9am and 5-6pm and is at its lowest during the early hours of the morning. Sleep-related RTIs appeared less common at times of the day when traffic density is high.

There is a general trend for younger adults to have sleep crashes in the early hours of the morning and older adults in the afternoon (Summala et al. 1994, Flatley et al. 2004), this is probably due to younger drivers being more likely to be on the roads in the early hours of the morning than older drivers. Research has shown that younger people are more affected by sleep deprivation than older people (Brendel et al. 1990, Lowden et al. 2009), though this does not mean that older people are not affected by sleep deprivation (Sagaspe et al. 2007); added to this inexperienced drivers are more impaired by sleep deprivation than experienced drivers (Lenne et al. 1998). Additionally, women are less likely to have a srRTI than men (Horne et al. 1995). Research has shown that women are better at realising they are sleepy and that their driving is impaired by sleep restriction (Barrett et al. 2004b) and they act on this information.

With all real roads srRTI data there is a strong possibility of under reporting as It can be hard to conclusively identify an RTI as being sleep-related (Horne et al. 1999). As there is no clear test of driver sleepiness the attending police officer may not be willing to report driver sleepiness as a cause of an accident. Therefore, when studying accident data it can be necessary to re-evaluate police reports in order to obtain a more accurate estimate the number of srRTIs (Horne et al. 1995).

1.3.3 Are sleep-related road traffic accidents preventable?

There is now a wealth of research demonstrating that healthy people do not fall asleep whilst driving without experiencing a period of increasing sleepiness beforehand (Reyner and Horne 1998b, Lisper et al. 1986, Otmani et al. 2005, Horne et al. 2004) . However, the problem comes when drivers fail to take signs of sleepiness as signs of increasing risk of falling asleep (Kaplan et al. 2007). The following section discusses if people are aware of sleepiness and therefore able to stop driving before an incident occurs, the implicating factors resulting in srRTIs.

1.3.3.1 Insight into sleepiness

It has long been recognised that people have a legal responsibility to be fit to drive; but opinion on falling asleep at the wheel has changed over the years. McCutcheon (1998) reports a case in Scottish law of H.M. Advocate v. Ritchie (a driver who fell asleep) in 1926, which stated “that a person is obliged to take account of the risk of falling asleep when driving”. The same paper reports this decision being rejected in 1963, and then approved in 1991. From the legal perspective it makes a lot of difference whether a driver is able to fall asleep without any warning or if drivers consciously decide to continue driving while knowing that they are sleepy. Examples of different court outcomes are reported in the preface of this thesis.

There is evidence that people are aware of sleepiness prior to having a srRTI as If people who have fallen asleep while driving are asked what happened prior to the incident they are able to identify and recognise known warning behaviours. These behaviours include: struggling to keep eyes open, yawning, difficulty connecting to driving, slower response to traffic change and an increased variation in speed (Lisper et al. 1986, Nordbakke et al. 2007).

Further evidence of ability to recognise sleepiness is apparent in the correlation between subjective sleepiness scores and driving simulator performance. Here, when sleep restricted participants rate themselves feeling sleepy at times when srRTIs occurred (Horne et al. 2004, Biggs et al. 2007). In a study of young healthy drivers it was found that participants had an average of 45 minutes from when they felt sleepy until a driving incident occurred (Reyner and Horne 1998b). This time interval would be sufficient to implement a countermeasure before a RTI occurs. However, it was found that some drivers although knowing they were sleepy did not feel they were likely to fall asleep and therefore may not use a countermeasure. The correlation between subjective sleepiness ratings and driving performance has also been noted in healthy participants during 24h sleep deprivation (Baranski 2007).

Additionally subjective (KSS) scores have also been shown to correlate to EEG measures of sleepiness (Horne et al. 2004, Kaida et al. 2006), demonstrating that participants have awareness of their underlying sleepiness. As it has been shown experimentally that subjective sleepiness as rated on the KSS is linked driving incidents it can also be expected to do so on real roads. When reporting KSS 9 participants report they are fighting sleep; if someone is fighting sleep it is likely they will be doing something to “fight” it using a countermeasure such as open a window. If a person has taken any action in this manner it can be said that they knew they were sleepy (Horne et al. 2004).

All studies of awareness of sleepiness reported above have been conducted under laboratory conditions, where participants are repeatedly asked to report a subjective sleepiness rating. It should be acknowledged that when on real roads, without this prompt drivers may not regularly assess how sleepy they are so could miss early signs of sleepiness and continue to drive.

The research reported here has been completed using healthy participants; similar research has not been conducted with older drivers or OSA participants, consequently there is no evidence of awareness of sleepiness in these groups.

1.3.3.2 Factors affecting sleep related incidents

Below is a brief outline of the factors which can contribute to srRTIs this is to demonstrate that despite one underlying cause (the driver being too sleepy to drive) there are many contributing factors resulting in increased likelihood of a srRTI occurring.

Prior sleep

Having inadequate sleep prior to driving has been shown to be a major cause of sleep-related accidents (Fell et al. 1997, Connor et al. 2002).

Time of day

As detailed in section 1.2.2 a greater number of sleep-related accidents happen in the early hours of the morning and in the early afternoon when sleep pressure is at its highest (Horne et al. 1995, Pack et al. 1995). The effect of time of day is exacerbated in shift workers driving home in the early hours of the morning (Horne et al. 1999, Akerstedt et al. 2005).

Type of road

Analysis of RTI data has shown sleep-related accidents to be more common on major roads, such as motorways (Horne et al. 1995). It is likely that the monotonous conditions of this type of road facilitate sleepiness (Horne et al. 1999). It is thought that a road with little variation leads to lower arousal and therefore increased sleepiness (Thiffault et al. 2003). In line with this, traffic density also has an effect, as sleep-related accidents on motorways are more likely when there is low traffic density (Flatley et al. 2004), in situations with greater traffic density drivers may be able to maintain alertness.

General sleepiness levels

Using the Epworth sleepiness scale as a measure of general sleepiness, it has been shown that people who are generally sleepier are more likely to fall asleep while driving (Maycock 1996).

Driving duration

It may be hypothesised that the longer a person drives the more likely they are to fall asleep. However, evidence is conflicting, as using a simulator it has been shown that in healthy participants there is no significant effect of time on task to driving incidents, but that driving performance is worsened by prior sleep restriction (P. Philip et al. 2005). In another study, driving impairment over time was reported and the authors suggested that 80 min is the safe limit for monotonous driving (Ting et al. 2008).

Individual difference

Ability to maintain performance when sleep deprived varies greatly between individuals (Van Dongen et al. 2004). Whilst driving a significant difference in ability to cope with sleep deprivation has been found between individuals (Philip et al. 2006).

Driving experience

It is possible that those drivers who often drive at night or when sleep deprived will be at higher risk of falling asleep at the wheel due to greater exposure. However, there is some evidence to show that it is possible for people to adapt to this situation, such as professional drivers adapting to night time driving (Dalziel et al. 1997). Similarly it has been suggested that inexperienced drivers (holding a licence for less than three years) have greater impairment at a driving task following sleep deprivation than experienced drivers (Lenne et al. 1998).

Sleep disorders

Accident surveys have been used to show obstructive sleep apnoea sufferers to be more likely to have srRTIs than healthy people.

1.3.4 Countermeasures to driver sleepiness

Driver sleepiness is a phenomenon that can affect anyone; not just those with sleep disorders (though the propensity may be higher). A key factor in whether a person falls asleep at the wheel is the nature of the aversive action that they take. If a person feels sleepy when driving the choices they make on how to deal with this can determine the outcome of the journey: arriving safely at their destination or having an RTI.

Countermeasures to driver sleepiness are aversive actions taken by the driver in the hope to maintain alertness; these can be classified as two types; pre-journey and in-transit. Pre-journey countermeasures are activities undertaken to reduce sleepiness on a future journey, an example of a pre-journey countermeasures is getting a good night's sleep. In-transit countermeasures are used at the time sleepiness occurs, for example stopping for a nap. Within both types of countermeasure some options are more effective than others and a driver must have accurate knowledge of what is most effective to make the correct choice based on their current situation to avoid a RTI.

1.3.4.1 Effective counter measures to driver sleepiness

Nordbakke and Sagberg (2007) provide a fairly comprehensive list of possible countermeasures drivers use to combat sleepiness.

Pre-journey countermeasures	In-transit countermeasures
Avoid heavy meal right before the drive	Opening the window
Plan starting time/sleeping habits	Stopping and getting out of the car
Sufficient sleep over a long period	(stretch legs)
Plan stop during the drive	Put on music
Sufficient sleep the night before	Talk to yourself
Avoid/be moderate with alcohol	Eat sweets/drink sodas
	Drink coffee (caffeine containing drink)
	Ask passenger(s) to talk to you
	Drink water
	Stop and have a nap
	Stop to eat
	Drive faster or overtake
	Talking on mobile phone (not applicable in the UK)

Table 1.3-1 Counter measures to driver sleepiness Nordbakke and Sagberg (2007)

Planning for a long journey could reduce the chance of driver sleepiness. It is important to get adequate sleep prior to a journey. For instance it has been shown that in cases of drivers who had had a RTI, those who had had 5 hours or less sleep the previous night had significantly greater risk of injury or death as a result of the RTI (Connor et al. 2002). Drivers involved in sleep-related crashes also report shorter average sleep per night than drivers involved in non sleep-related crashes (Stutts et al. 2003).

Circadian rhythm affects how sleepy a person feels at different times of day, consequently there are times during circadian dip that sleep-related RTIs are more likely to occur, these are between 2am to 5am and 2pm to 4pm (Horne et al. 1995, Connor et al. 2002) as discussed in section 1.3.2 Choosing to complete a long journey in these vulnerable time periods could result in driver sleepiness (Lenne et al. 1997). Time on task is also a factor in RTIs (Folkard 1997), planning regular breaks reduces time spent driving and therefore risk of a RTI.

With pre-journey countermeasures it seems obvious to avoid night driving and get adequate sleep prior to a long journey (Anund et al. 2008). However, choosing an effective in-transit countermeasure may be more difficult as some prior knowledge is required. The two effective in-transit countermeasures are caffeine consumption and having a nap, both significantly improve driving performance, subjective sleepiness and objective sleepiness measured by EEG in sleep restricted drivers and more so in combination (Horne et al. 1996, Reyner et al. 2000, De Valck et al. 2001, Reyner et al. 2002, Biggs et al. 2007, Hayashi et al. 2008). In addition to the experimental work RTI risk has also been shown to be reduced for drivers who have had coffee within the last 2 hours (Cummings et al. 2001). Caffeine has also been shown to improve driving performance in individuals who were not sleep restricted in the first place, thus demonstrating a counteracting effect to a monotonous environment as well as improved alertness in cases of sleepiness (Brice et al. 2001, De Valck et al. 2001).

Countermeasures shown to be ineffective include; exercise/stretching legs during a break from driving (Lisper et al. 1980, Horne et al. 1996). Cold air on the face and loud music have also been shown to have little effect on driving performance at a simulator task and make no significant improvement to objective sleepiness as measured by EEG (Reyner, Horne 1998a). As a result of this increasing body of evidence into effective countermeasures UK Highway Code was changed in 1999, where it previously advised sleepy drivers to stop and stretch their legs it now states drivers should have a high caffeine content drink and a 20 minute nap (Highway Code 2008). Consequently, all UK drivers have access to accurate information in the Highway Code, Figure 1.3-1.

The Highway code - Fitness to drive

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Driving when you are tired greatly increases your risk of collision. To minimise this risk

- make sure you are fit to drive. Do not begin a journey if you are tired. Get a good night's sleep before embarking on a long journey
- avoid undertaking long journeys between midnight and 6 am, when natural alertness is at a minimum
- plan your journey to take sufficient breaks. A minimum break of at least 15 minutes after every two hours of driving is recommended
- if you feel at all sleepy, stop in a safe place. Do not stop on the hard shoulder of a motorway
- the most effective ways to counter sleepiness are to drink, for example, two cups of caffeinated coffee and to take a short nap (at least 15 minutes).

Figure 1.3-2 The Highway Code rule 91

A study of UK drivers prior to the highway code change, reported the most popular countermeasure to be opening a window (68%) followed by stop for a walk (57%), only 14% said to drink coffee (Maycock 1996). This is reflective of the advice at the time however, no similar research has been conducted since the change in advice. All drivers passing their test since 1999 will have learnt to have caffeine and a 20 minute nap if they feel sleepy when driving, to plan their journey not to coincide with the circadian dip and to take a break every 2 hours as part of their theory learning from the Highway Code (Highway code 2008). People who passed their test before 1999 would only be aware of this if they keep up to date with Highway Code changes. Although, it is a requirement to keep up to date with changes in the Highway Code this is done at drivers volition, consequently, there may be UK drivers who still think if they feel sleepy when driving they should stop and stretch their legs.

1.3.4.2 Preference for countermeasures

It is important to note that knowledge and action are two different things. In order to choose an effective countermeasure a person needs to have the knowledge of which measures work and additionally the motivation to act on this knowledge.

Although it may seem obvious to get a good night's sleep before a long drive to a sleep researcher, it is not necessarily the case for the general public. A Norwegian survey of

1513 drivers asked respondents what puts them at risk of driver sleepiness, 79% said several nights bad sleep but only 43% felt one night of bad sleep prior to a drive would have an effect (Nordbakke et al. 2007). The circadian effect was even less acknowledged in the Norwegian survey as only 20% of the respondents thought that the time of day they started a journey would have an effect on driver sleepiness. Length of driving time is also not always recognised as a problem; in a UK study only 35.1% of respondents would take a break every 2 hours or less, 23.9% of people being happy to drive for 4 hours or more (Maycock 1996). Those who are happy to drive for longer were more likely to have fallen asleep while driving (Maycock 1996, Nordbakke et al. 2007). If people do not have accurate information about causes of driver sleepiness it is unlikely they will take appropriate pre-transit precautions.

Training in effective countermeasures could be aimed at new drivers and high risk drivers, such as those with sleep disorders and professional drivers. Providing such training has been shown to improve knowledge (Gander et al. 2005). In this case professional heavy vehicle and light vehicle drivers were trained to improve awareness of driver sleepiness and effective countermeasures. In a 2 year follow up participants were asked if they had changed their driving and choices as a result of the training. Approximately half the drivers had done so, highlighting that individual choice plays a large part in countermeasure use, not just knowledge.

When asked which in-transit countermeasures are most effective 70% of people in the Norwegian study said stop and have a nap and 34% said open a window. But when asked which countermeasure they would use the most popular choice was open a window (52%) with stop and nap chosen by only 8% (Nordbakke et al. 2007). This is a clear example of people having accurate knowledge of an affective countermeasure and choosing to ignore it. Though not all knowledge was accurate as 80% of people thought stretching their legs was a highly effective countermeasure whereas only 22% chose drinking coffee.

Age has been shown to be a factor in choice of countermeasure, older drivers have been shown to be more likely to use an effective countermeasure (Anund et al. 2008). In particular, older drivers have been found more likely to stop driving to stretch their

legs or have a nap, whereas young drivers are more likely to continue their journey and use in-car countermeasures such as opening a window (Nordbakke et al. 2007).

In a Swedish survey of 1886 drivers, logistic regression showed that people who had experienced driver sleepiness and professional drivers were more likely to choose having a nap and having caffeine (both effective countermeasures) (Anund et al. 2008). The same survey found that snorers and people with disturbed sleep were no more likely to choose an effective countermeasure than non snorers and people with good sleep. This is surprising as it would be expected that this subgroup of people would be likely to experience some driver sleepiness and therefore have some sort of information on how to cope with this. Nordbakke and Sagberg (2007) asked people in Norway who had fallen asleep while driving what they did afterwards: 26% continued to drive without having a break while only 23% stopped for a nap (Nordbakke et al. 2007). It is possible that as these people did not crash when they fell asleep they did not perceive themselves to be in danger so continued to drive.

Use of countermeasures depends on an individual and their perception of the risk of driver sleepiness. If a driver does not feel they are at risk of becoming sleepy they may not feel the need to get a good night's sleep prior to a long drive. UK motorway drivers are likely to have come across "Tiredness kills take a break" signs, which aim to promote awareness amongst drivers of the advice in the Highway Code. If these are effective it could be expected that UK drivers know that driving when tired is dangerous and would therefore seek out effective countermeasures.

1.4 OSA and driver sleepiness

1.4.1 OSA and driving Law

Certain medical conditions impact a person's legal entitlement to hold a driving licence. In the UK there are two categories of driving licence group 1 car drivers and group 2 HGV drivers. This section outlines the law in regards to both types of licence and suffering from OSA.

1.4.1.1 Car drivers Law

The UK law must follow the European Union (EU) directive 91/439/EEC annex III (European Union 1991) which details the minimum standards of physical and mental fitness for holding a driving licence in the EU, in which there is no mention of sleepiness or sleep apnoea. The final paragraph states:

“As a general rule, where applicants or drivers suffer from any disorder which is not mentioned in the preceding paragraph but is liable to be, or to result in, a functional incapacity affecting safety at the wheel, driving licences shall not be issued or renewed unless the application is supported by authorized medical opinion and, if necessary, subject to regular medical check-ups”

Figure 1.4-1 Paragraph 18 EU Directive 91/439/EEC

This gives some scope for other conditions such as OSA which are not mentioned to result in sufferers being deemed ‘unfit to drive’.

The majority of the EU countries driving licence laws state the EU directive. However, 10 out of 25 surveyed countries do mention sleepiness or OSA in their local law; this includes the UK (Alonderis et al. 2008). Across the EU countries which mention OSA all agree that if untreated patients should stop driving, but once successfully treated driving may resume.

In practice in the UK most patients diagnosed with OSA receive treatment very soon after diagnosis. They will then inform the Driver and Vehicle Licensing Agency (DVLA) that they have the condition and present a letter from their doctor saying they are receiving satisfactory treatment, as such there is rarely a period of time when driving ceases.

1.4.1.2 Heavy goods vehicle law

EU law governs working practice for all HGV drivers across the EU. The law states that:

- Driving time is limited to 9 h per 24h (this may be extended twice a week to 10 h per 24h period).
- Drivers may be on duty for a maximum of 11 h per 24h.

- Maximum weekly drive time is 56 h but must not exceed 90 h in a two week period.
- Drivers can drive a maximum of 4.5 h without a break. For every 4.5 h driving a driver must have 45 min break.

(Official Journal of the European Union 2006) (EC) 561/2006

In the UK, to drive a HGV, a group two, large goods vehicle (LGV) licence is required; applicants for this licence must be aged 18 or over. From the granting of the licence until the licence holder is 45 no medical checks are required. When the licence holder is aged 45 to 65 they must pass medical examinations every 5 years, and when over 65 pass a medical every year. The DVLA issues information regarding the medical which includes a description of symptoms of OSA and advises applicants to contact a doctor if they feel they have any of the symptoms. The information clearly states “Even if a medical condition is the cause of falling asleep at the wheel, it is not an excuse in law” (DVLA 2009). So holders of group two licences receive some, all be it not much, information about OSA and the dangers of driving whilst sleepy when they reach the age of 45.

As with car driving licence holders it is the duty of the licence holder to report any medical conditions to DVLA, this includes OSA. To continue holding a licence group two licence holders must visit a medical practitioner who is required to both confirm receipt of treatment and confirm ongoing compliance with treatment. It is therefore possible that a diagnosed HGV driver may have to stop professional driving for approximately three months during treatment in order to prove compliance.

1.4.2 Risks associated with OSA

In sections 1.2.4 and 1.2.5 the symptoms and risk factors associated with OSA were presented. The risk factor of impaired cognitive function and the symptom of excessive daytime sleepiness both may have a direct impact on driving, because of this these two have been further discussed below.

1.4.2.1 Impaired cognitive function

There are many studies investigating the impact of OSA on cognitive function, but there are no definitive conclusions to the question 'do OSA patients have impaired cognitive function?', and 'does CPAP treatment improve cognitive performance?' In general review papers have suggested that it is likely that there is some cognitive impairment in OSA participants and often some improvement in some areas is seen with CPAP treatment (Aloia et al. 2004, Decary et al. 2000, Engleman and Joffe 1999, Saunamaki et al 2007). Due to the conflicting nature of findings a summary of the studies referenced can be found in Table 1.4-1 to greater detail than other reference tables in the current work. Here follows a discussion of the major points.

In papers reporting impaired cognitive performance in OSA patients the most commonly reported areas of deficit are working memory, phonological fluency, cognitive flexibility and planning (Saunamaki et al. 2007). It has been suggested that this impairment is linked to intelligence: one study showed that cognitive impairment measured by attention tasks compared to healthy controls is only seen in OSA patients with normal intelligence, those with high intelligence show no impairment compared to healthy controls also of high intelligence. Quan et al. (2006) compared 67 untreated OSA participants and 74 controls at a battery of cognitive tests and found no significant difference between the groups. The authors do note that the participants had mild to moderate OSA and that impairment maybe apparent in more severe cases of OSA, none the less, no significant differences were found.

In general CPAP treatment has been shown to improve the specific areas of attention and vigilance as reviewed by Aloia et al. (2004). For example, Bardwell et al. (2001) studied 36 OSA participants receiving 1 week of real or sham CPAP the authors report overall cognitive improvement with the real CPAP. However, this study only compared treatment for 1 week, this is not long enough as participants would not have had time to get used to using the mask. Also performance at the specific tasks did not significantly improve with real CPAP it was only when results for all were combined that the improvement was concluded. CPAP has also been found to improve cognitive performance by Barnes et al. (2002) who report an improvement in cognitive function with 28 OSA participants receiving treatment for 8 weeks. In this case it is not clear

how much improvement is due to the CPAP or placebo effect as in some tests there was significant improvement under the placebo condition. In another treatment intervention study 20 OSA participants were found to have significantly improved cognitive function after 3 months of treatment which was still apparent 1 year into treatment (Bork et al. 1996). Although CPAP may improve cognitive impairment it has been reported that it does not normalise it, in a review Engleman and Joffe (1999) identified that even in cases of improvement treated patients did not always reach baseline levels of controls.

Although on the whole improved cognitive performance is reported following treatment of OSA participants it is not the case for all studies. Testing 47 OSA participants at baseline and following one year of CPAP treatment no change in cognitive impairment was found by Alchanatis et al. (2005). Barbe et al. (2001) tested 55 OSA participants at baseline and following 6 weeks of either CPAP or sham CPAP and found no significant difference of any cognitive measure between groups post treatment. This particular study was with OSA participants who did not have EDS so that maybe a confounding factor as the majority of OSA patients will have EDS. Henke et al. (2001) completed a randomised control trial with 46 OSA patients using CPAP and sham CPAP in this case both groups showed some improvement following treatment but the real CPAP did not result in greater improvement than the sham CPAP.

Although still not conclusive, increasingly papers are reporting that some degree of cognitive impairment is apparent in OSA patients. Additionally authors are stating theories as to what is the cause of this impairment. Two strong hypotheses are i) impairment is caused by sleep deprivation ii) impairment is caused by permanent brain damage as a result of hypoxia.

If there is impairment in cognitive ability in OSA patients which is due to sleep deprivation it would be expected that following successful CPAP treatment cognitive ability will improve because sleep deprivation has been removed. This has been shown by Borak et al. (1996), and even at adherence to CPAP of only 3.4 hours per night improvement is reported (Engleman et al. 1994).

In their highly controlled study of cognitive function across the day Lis et al. (2008) demonstrated untreated OSA patients to be slower and less accurate at cognitive tasks and that performance deteriorated as daytime sleepiness increased. The authors equate performance to be similar to that of healthy people who have been sleep deprived, suggesting it is the sleep fragmentation causing the impairment rather than hypoxia. These findings are supported by Verstraeten et al. (2004) who compared 36 OSA participants with 32 controls they reported significantly worse performance at tasks by the OSA participants but noted it to be similar to the cognitive decline found after sleep loss in healthy people. Both sleep fragmentation and hypoxia are correlated to RDI so it might be expected that those with greater sleep disturbance i.e. a higher RDI would have a greater impairment of cognitive function, but RDI has been shown to be unrelated to cognitive function (Boland et al. 2002, Lojander et al. 1999).

Similarly, decreased brain activation has been seen using fMRI on a 'Go no Go' task with untreated OSA patients compared with controls. Here, higher AHI was associated with slower reaction time, however, AHI was not related to changes in cerebral response. Suggesting that impairment was due to the sleep disruption caused by increased AHI rather than hypoxia (Ayalon et al. 2009). It should be noted that there was greater variability between OSA participants than between control participants, a larger sample size than 14 in each group may be necessary for a firm conclusion. Changes in grey matter are also reported between untreated OSA and control participants however, this has not been linked to any impairment in cognitive function (Yaouhi et al 2009).

Not all studies show significant improvement following CPAP treatment (Knoepke and Aloia 2009, Henke et al. 2001), suggesting the underlying cause of impairment may not be due to sleep deprivation itself. Comparing pre and post treatment patients, Aloia et al. (2004) found psychomotor to be the most likely cognitive function to still be impaired following treatment. The authors hypothesise this to be due to permanent damage of the brain caused as a result of hypoxemia. Noting that the brain regions associated with fine motor control may be more susceptible to hypoxemia, whereas attention, which is impaired by both sleep fragmentation and hypoxemia generally improve when sleep fragmentation is eliminated.

A further suggestion is that cognitive impairment is caused due to a decline in white matter. Brain imaging studies have shown structural abnormalities in white matter in untreated OSA patients (Macey et al. 2008) which could affect performance at cognitive tasks. In this study Macey et al. (2008) made a direct comparison between brain scans of 41 untreated OSA patients and 69 controls. Untreated OSA patients suffer sleep deprivation as a result of a fragmented night's sleep. In healthy subjects white matter has been implicated in a person's ability to function when sleep deprived (Rocklage et al. 2009). As such OSA participants who may have damaged white matter due to hypoxia may have a reduced capacity to cope with the sleep deprivation they experience due to fragmented, this may explain reduced cognitive function.

A major problem when deciding if CPAP treatment reverses any cognitive impairment is variation in compliance to treatment and treatment duration (Decary et al. 2000, Yaouhi et al. 2009). Additionally lack of standardised testing makes it hard to compare results between studies (Decarey et al. 2000). It has also been suggested that tests of higher sensitivity are needed (Lee et al. 1999).

In cases where no improvement has been seen it is possible that patients are not using their machine for long enough and therefore still have some sleep deprivation problems resulting in conflicting findings. For example, when comparing real and sham CPAP Barbe et al. (2001) found no improvement in cognitive performance; whereas Bardwell et al. (2001) reported improvements after just one week's treatment for real compared with sham CPAP. Additionally, not controlling for learning effect is particularly key problem if you consider improvement can be found with sham CPAP as well as real CPAP (Henke et al. 2001) and with placebo tablet as well as CPAP (Barnes et al. 2002).

Alternatively, apparent cognitive difficulty may in fact be an adaptation to new tasks problem rather than a genuine cognitive deficit. In a procedural learning task a sub group of OSA patients were found to have marked difficulty with the task initially when compared to controls and other OSA patients, suggesting adaptive skills problems. After practice there was no significant difference between the OSA participants as a whole and the control group suggesting OSA participants don't have

general cognitive impairment but do struggle with novel tasks, showing normal learning following initial adaptation difficulties (Rouleau et al. 2002). It is also noted that all OSA patients showing this initial impairment were aged over 40 years old, so perhaps age of participant should also be considered when comparing findings.

There has been a large individual difference in cognitive ability reported in untreated OSA participants; however, when considering these results it is important to determine if any deficit is clinically important. It has been suggested that improvement in cognitive performance following CPAP can only be assessed if people are below average to start with; otherwise tests are not of sufficiently sensitivity (Lojander et al. 1999, Alchanatis et al. 2005). Alchanatis et al. (2005) found no difference in cognitive ability between OSA and control participants of high intelligence however, those with normal intelligence did show impairment in comparison to controls. The authors conclude that high intelligence by protect against cognitive decline. No other studies distinguishing IQ were identified so it is not possible to know if this was a one off finding. This suggests that not all OSA patients will experience cognitive impairment.

In summary, it is highly likely that some untreated OSA patients will have some degree of cognitive impairment though the underlining cause of this is not yet known. CPAP has been shown to improve some cognitive functions but not all; it is unclear whether this would be due to permanent brain damage or poor treatment compliance. There is also the possibility of insufficient sensitivity of cognitive measures, and that small sample sizes may be affected by high degrees of individual difference. No studies were identified directly assessing cognitive function and driving ability, however, it is possible that impaired cognitive function may affect driving ability and is an area of research that should be investigated.

Table 1.4 – 1 Summary of cognitive function in OSA patients’ studies

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Alchanatis et al.	2005	Case control	47 OSA before treatment and after 1 year of CPAP 36 controls	Neuropsychological battery test assessing attention and alertness. All participants were divided into high-intelligence group (IQ ≥ 90th percentile) and a normal-intelligence group (50 ≤ IQ < 90 percentile).	No significant difference between patient groups by IQ regarding OSA severity or sleepiness. High-intelligence patients showed the same attention/alertness performance compared with the high-intelligence controls. Patients with normal-intelligence showed attention/alertness decline compared with the normal-intelligence control group. Neither group of patients showed any difference with 1 year of CPAP	High-intelligence may have a protective effect against OSA-related cognitive decline. Cognitive function does not improve with CPAP.
Aloia et al.	2004	Review	37 articles	Articles published from 1985 – 2002	findings were vague for most cognitive domains. Treatment, however, was noted to improve attention, vigilance in most studies and consistently did not improve constructional abilities or psychomotor functioning	Potential cognitive impairment in OSA patients has not been conclusively proven. Treatment can improve the specific areas of attention and vigilance.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Ayalon et al.	2009	Case control	14 OSA 14 Control	Go no go task completed in an fMRI scanner.	Patients with OSA showed decreased brain activation in cingulate, frontal, and parietal regions which are typically involved in attention tasks. Increasing AHI was associated with slower mean reaction time and with decreased brain activation in areas involved in arousal and attention, response	The association of AHI with slow reaction times and brain activation suggests that alertness and reaction times show greater correlations with measures of sleep disruption than with measures of hypoxia.
Barbe et al.	2001	Randomised control trail	55 OSA patients without EDS	Patients received real or sham CPAP for 6 weeks post diagnosis. Quality of life, cognitive function, MSLT and blood pressure were recorded.	All variables were similar (nsd) between groups at the start. There was no significant different to any variables following treatment or sham.	In patients who do not have EDS CPAP does not modify quality of life, objective sleepiness, vigilance, attention, memory, information processing, visuomotor coordination, or arterial blood pressure.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Bardwell et al.	2001	Random control trail	36 OSA patients	Patients received 1 week of CPAP or sham CPAP. Tests completed pre- and post treatment	Digit Vigilance-Time significantly improved with real CPAP. All results were rank summed together The rank-sum test revealed that the CPAP group had significantly better overall cognitive functioning post treatment than the placebo group	There is suggestion that overall cognitive improvement may be due to CPAP, no beneficial effects in any specific cognitive domain were found
Barnes et al.	2002	Random control trail – repeated measures	28 Mild OSA (AHI 5 – 30)	Measures were taken at base line then after 8 wk of treatment with CPAP, and after 8 wk of treatment with an oral placebo tablet	CPAP improved self-reported symptoms of OSA, including snoring, restless sleep, daytime sleepiness, and irritability more than did placebo However, the placebo tablet resulted in a significant improvement in a wide range of functional variables compared with baseline	Placebo effect may account for some of the treatment responses to CPAP observed previously in patients with mild OSA.
Boland et al.	2002	Case control	1700 participants not diagnosed with OSA	PSG completed and RDI scored and cognitive measures taken	There was no consistent association between the RDI and any of the cognitive function measures.	There is no evidence of a dose response relationship between the RDI and cognitive function scores.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Borak et al.	1996	Treatment intervention	20 severe OSA	Psychological tests were performed before, after three, and after twelve months of CPAP treatment.	At baseline the most disturbed cognitive functions were concentration and recent memory. CPAP treatment resulted in significant improvement in cognitive function; concentration, recent verbal, visual and spatial memory were already seen at three months.	In patients with severe OSA CPAP treatment results in a significant early improvement in cognitive function but not in emotional status.
Decary et al.	2000	Review	NA	review paper is to propose a standardized test battery for the neuropsychological evaluation of OSAS patients	Overall performance is found to be impaired in OSA participants but it is hard to compare between studies due to a variety of tests used.	A standard test battery is proposed to cover attentional and executive functioning, short-term and long-term memory, and provide a global evaluation of intellectual functioning.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Engleman et al.	1994	Randomised control trial	34 mild OSA patients	4 weeks on CPAP, 4 weeks on placebo tablet in a randomised order	Compared with placebo, CPAP improved ESS but not objective MWT performances on 2 of 7 cognitive tasks and, depression score.	Confirms benefits for daytime function after CPAP treatment for mild SAHS, but highlight poor compliance of CPAP in many such patients
Engleman and Joffe	1999	review	10 selected articles	Review cognitive impairment in OSA from selected relevant articles.	Cognitive performance on tests of attention and concentration ability, visual motor and constructional skills, verbal fluency, planning and problem solving, memory and executive function may be mildly to moderately impaired in OSA patients. The daytime impairments associated with OSA are improved by CPAP, although it does not normalise The severity of sleepiness and cognitive impairments show weak and moderate correlations with frequency of sleep-disordered breathing in clinical and epidemiological studies.	Experimental and clinical evidence supports a role for nocturnal physiological events of OSA, arousals and hypoxaemia, in directly or indirectly producing neuropsychological deficits, particularly those of sleepiness and cognitive deterioration.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Henke et al.	2001	Randomised control trial	46 OSA patients	Therapeutic and sub therapeutic CPAP. Tested before and after treatment	Significant improvements in Digit Symbol, Digit Span Backward, and Complex Figure tests. However, there were no group differences in changes in test results during the period when one group was on effective CPAP and the other on ineffective CPAP	No difference in improvement depending on if on real or sham CPAP.
Knoepke and Aloia	2009	Review	NA	Review of literature to propose a model for cause of cognitive impairment in OSA	Evidence indicates that hypoxia is partially responsible for this impairment and that its effects are not responsive to treatments for OSA.	Cognitive impairment is apparent in OSA patients. A proportion of the clinical impairment seen can be attributed sleep fragmentation. There is some evidence that some is caused by hypoxia
Lee et al.	1999	Case control	17 OSA patients 16 controls	neuropsychological tests of executive functions	OSA had greater deficits in the retrieval of information from semantic memory and in shifting responses in the face of error but differences in working memory were not.	More sensitive measures than are typically used in neuropsychiatric research are required.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Lojander et al.	1999	Randomised control trial	27 OSA participants with CPAP 23 OSA participants had UPPP surgery	Cognitive function tested at baseline, month 3 and 1 year after treatment	Cognitive function did not correlate importantly with daytime sleepiness or severity of OSAS Success in treatment of OSAS did not affect neuropsychological outcome.	The standard cognitive test battery is insufficiently sensitive to identify positive changes in patients with OSAS,
Macey et al.	2008	Case control	41 untreated OSA patients 69 controls	Brain scan	White matter is extensively affected in OSA patients	Alterations in white matter include axons linking major structures within the limbic system, pons, frontal, temporal and parietal cortices, and projections to and from the cerebellum.
Quan et al.	2006	Case control	67 OSA participants 74 controls	A battery of neuropsychological tests	No significant differences in any individual neuropsychological test or composite variable between the OSA and control groups	Mild to moderate OSA has little impact on the selected measures of attention, executive function, motor speed and processing speed.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Rocklage et al.	2009	Case control	32 students aged 19 – 25 separated to those affected by sleep deprivation and those not	Total sleep deprivation, visual motor task and MRI scan	Participant susceptibility to sleep deprivation was correlated with lower fractional anisotropy values in multiple regions of white matter, Significantly higher values in those less vulnerable to sleep deprivation.	Differences in distributed white matter pathways reflect, and may contribute to, a person's ability to function effectively when sleep deprived.
Rouleau et al.	2002	Case control	28 OSA 18 controls	Mirror Tracing and Rotary Pursuit skill learning tasks. Subjects also completed a comprehensive neuropsychological test battery	No significant differences in learning rates were observed between the groups However, there was a subgroup of OSAS subjects (n=11) who showed marked difficulties in the initial acquisition of the Mirror Tracing Performance of subjects who had difficulty with initial adaptation on the Mirror Tracing was also significantly lower on tests of frontal executive function but not in those <40 years.	OSAS patients did not show procedural skill learning deficits however, did show deficits in initial skill adaptation and difficulties on other neuropsychological tests

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Saunamaki et al.	2007	Review	40 articles	Review of papers from 1990 to 2005	The most defected domains of executive functions were working memory, phonological fluency, cognitive flexibility, and planning. CPAP improved performance times, cognitive flexibility, and planning. Deficits in working memory and phonological fluency persisted.	Performance impaired Executive functions in OSAS should be assessed with a standardized neuropsychological test battery More research is needed on the efficiency of CPAP treatment on executive dysfunctions
Verstraeten et al.	2004	Case control	36 OSA patients 32 controls	Neuropsychological tests included Trail Making part A and B, Symbol Digit Modalities (SDMT), Digit Span forward and backward, Stroop Color-Word, Five-Point design fluency, and an Attention Flexibility task	Performance was significantly reduced on the SDMT, the Digit Span forward task , the number of errors on the basic 2-choice reaction time subtest of the Attentional Flexibility task and the mean RT on the actual Attentional Flexibility subtest. No other performance differences were found between patients and healthy controls.	No specific clinical indications for executive attention deficits or an impaired central executive of working memory are found in patients. Cognitive performance seems very similar to the cognitive decline found after sleep loss

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Yaouhi et al.	2009	Case control	16 OSA untreated 14 controls	Neuropsychological test battery to investigate attention and vigilance, executive functions, episodic memory and motor domains and brain imaging by MRI.	Little impairment in memory and motor domains. No impairment at all other tests. Gray matter loss in the frontal and temporo-parieto-occipital cortices	Not impaired despite the presence of only minor memory and motor impairments, patients displayed significant cerebral changes in terms of both gray matter density and metabolic levels

1.4.2.2 Excessive Daytime Sleepiness and sleep restriction

As EDS is a known symptom of OSA, it is the EDS which can result in OSA sufferers having difficulty to maintain alertness during a monotonous task such as long distance driving. EDS can lead to poor memory, poor sustained attention, irritability, learning problems, cognitive difficulty and ultimately depression (Engleman and Joffe 1999, Engleman et al. 1999), all of which could contribute to increase risk of RTI. The most widely used measure of EDS is the Epworth Sleepiness Scale (ESS) (Johns 2001), this is shown in section 3.5.3. The key papers discussing excessive daytime sleepiness and the few investigation the impact of sleep restriction can be found in table 1.4-2.

Specifically it has been demonstrated that OSA patients have a reduced ability to maintain concentration during monotonous situations (Mazza et al. 2005). It is therefore plausible that if faced with a monotonous motorway drive OSA patients may find it harder than non sufferers to remain alert. Using ESS in the context of driver sleepiness is problematic because it is a subjective measure and people may be unwilling to answer truthfully in fear of having their licence revoked. Engleman et al. (1997) asked 99 OSA patients for ESS scores prior to starting CPAP. Once people were treated they were asked again to rate their ESS score from before treatment, prompting a retrospective assessment of sleepiness. They found that 67% of people gave a higher ESS the second time around. This would suggest that the problem of EDS in OSA is worse than most studies report due to the underreporting by the participants. However, it should be noted that patients were surveyed up to 70 weeks into treatment so some may have found it hard to recall how they were feeling over a year ago.

Many studies have shown that CPAP treatment can improve the performance of OSA patients at various tasks, sometimes to the level of healthy individuals (Hack et al. 2000, Munoz et al. 2000, Yamamoto et al. 2000, George 2001) and therefore it may be supposed that all treated OSA patients are fit to drive. Although, there are a few studies showing some evidence that CPAP does not relieve EDS (Dinges et al. 2003, Santamaria et al. 2007) which may mean driving could remain impaired, there is strong evidence that ESS of treated OSA patients is no worse than the general population. Stradling et. al. (2007) have reviewed this by comparing ESS of over 500 patients with

500 controls, they found the prevalence of scores over 10 to be similar in both groups indicating the patients with EDS using CPAP are still within healthy norms. Another study points out that the range of estimates of increased accident rates due to EDS varies greatly, so more research is needed in this area. The author also states EDS in OSA patients is not a major public health risk (Douglas 2001).

It is generally accepted that treated OSA patients are fit to drive because EDS is controlled and this is reflected in the laws of many countries (Alonderis et al. 2008). An area of interest examined in very few studies of OSA participants relating to driving is the effect of sleep deprivation. It is known that sleep deprivation of healthy individuals can impair driving performance (Horne et al. 2004) and that OSA patients on CPAP treatment can show driving performance the same as healthy individuals (e.g. Findley et al. 1989). So how does sleep deprivation affect the driving of these treated OSA patients? Only two studies which looked at the effect of sleep deprivation on untreated OSA patients were identified, they found that the lack of sleep created the same level of impairment for OSA patients as controls using the psychomotor vigilance task (PVT) (Desai et al. 2006). Interestingly the sleep deprivation did not increase the subjective sleepiness scores of the OSA patients as much as the controls (Desai et al. 2006). This may suggest some impairment in self recognition of sleepiness.

The only sleep restriction study in OSA participants when driving used a driving simulator. Vakulin et al. (2009) compared 38 untreated OSA sufferers with 20 controls at a 90min driving task. The OSA participants were found to have greater vulnerability to the sleep restriction (4h) resulting in larger standard deviation of lane position. Additionally OSA participants had a 40% greater impairment in recognising self sleepiness following sleep restriction than healthy controls. The greater susceptibility to sleep restriction is interesting, but as it is already generally accepted that untreated OSA sufferers are not fit to drive of greater interest is whether this increased vulnerability persists with treatment.

Table 1.4 – 2 Summary of Excessive Day Time Sleepiness in OSA patients’ studies

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Desai et al.	2003	Case control	13 OSA 16 controls	Full PSG after a normal sleep and after 36h sleep restriction.	OSA participants had lower minimum oxygen saturation following sleep deprivation but no difference in AHI.	Sleep deprivation does not worsen OSA parameters measured by PSG.
Desai et al.	2006	Case control	13 OSA 16 controls	Neurobehavioural assessment test after normal sleep and 36h sleep restriction.	OSA participants were less aware of their sleepiness and on 1 occasion showed greater impairment than controls.	OSA react the same to sleep deprivation as controls, but are less able to perceive daytime sleepiness.
Dinges et al.	2003	Case control	77 CPAP treated OSA receive madafonil 80 CPAP treated OSA receive placebo	Reaction time and functional outcomes of sleep (FOS).	Those taking modafonil had better reaction times, less lapses and better FOS results.	Modafonil can help improve alertness in CPAP treated OSA patients.
Douglas	2001	Review			There is great variation in estimates of increase risk of RTI in OSA. Which can be used to suggest between 1% and 50% of RTI deaths are caused by OSA.	Figures are very speculative and more research is needed, it has not been proven that EDS in OSA is a major public health risk.
Engleman et al.	1997	Intervention	99 OSA patients	ESS and questions on driving impairment taken prior and post to CPAP treatment	ESS significantly rose and more driving impairment was reported.	Patients underestimate the problems associated with OSA prior to treatment.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Engleman et al.	1999	Randomised controlled trial	34 OSA patients 4 weeks on CPAP, 4 weeks on oral placebo	ESS, MWT, psychological function and quality of life assessments.	CPAP improved ESS but not MWT, psychological well being and quality of life also improved.	CPAP improves daytime functioning but adherence can be low.
Engleman and Joffe	1999	Review		Daytime sleepiness, cognitive deficits, driving ability and psychosocial well being.	OSA patients generally report severe daytime sleepiness; mild problems are identified with attention, concentration, verbal fluency and problem solving.	Severe daytime sleepiness and mild cognitive function problems may contribute to RTIs making them 7 times more likely than in healthy people. In general CPAP improves all problems.
Findley et al.	1989	Case control	6 untreated OSA 7 controls	Driving simulator	OSA performed worse than controls. Following treatment OSA participants repeated the simulation and made less errors.	Driving simulator performance is impaired in OSA patients and improves with CPAP treatment.
George	2001	Case control	210 OSA treated with CPAP for 3 years	Compared official accident reports for the 3 years before and after CPAP treatment and controls for same period	Untreated OSA had more RTIs than controls, following CPAP the number fell to normal.	Risk of RTI due to OSA is removed by treatment.
Hack et al.	2000	Repeated measures	59 OSA on real and sham CPAP	Driving simulator	Standard deviation of steering improved with real CPAP, daytime sleepiness also improved.	OSA impairs driving and performance improves following treatment.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Mazza et al.	2005	Case control	20 OSA 40 controls	MWT, sustained attention and divided attention tasks.	95% of patients had vigilance and/or attention impairment.	For OSA patients ability to remain awake in monotonous situations is impaired. Using only a single test may underestimate the problem.
Munoz et al.	2000	Case control	80 OSA 80 controls	ESS, anxiety, Steer clear simulator and PVT	Steer clear performance and mood improved with treatment. Reaction time showed little change.	CPAP is a good treatment for OSA.
Santamaria et al.	2007	Review			CPAP is effective for most patients but some continue to complain about sleepiness after CPAP.	CPAP compliance should be monitored and diagnosis checked. Modafinil could be tried.
Stradling et al.	2007	Case control	572 OSA 525 Control	ESS	No difference in the % of each group with an ESS>10.	Some people on CPAP will still be sleepy but no greater prevalence than the general population.
Vakulin et al.	2009	Case control	38 OSA 20 controls	Driving simulator	OSA had higher steering deviation than controls and greater deterioration over time.	OSA are more vulnerable to sleep restriction.
Yamamoto et al.	2000	Retrospective	47 OSA	Driving history, ESS and mood	Reports of more accidents prior to starting CPAP than once on treatment and improved ESS.	CPAP reduces the rate of RTI and improves daytime sleepiness.

1.4.3 Heavy Goods Vehicles

The prevalence of OSA increases with age and is most common in men aged 40 to 60 years (Hardinge, 2008). It has been suggested that HGV drivers as a cohort may be at higher risk of OSA as a result of general characteristics associated with their work e.g. sedentary job and irregular meal patterns which may result in obesity. There is no UK national screening for OSA in HGV drivers and therefore many people may be driving these large vehicles for prolonged periods over many miles whilst suffering from undiagnosed OSA.

1.4.3.1 HGV statistics

The number of HGV licensed drivers in GB in 2007 was 528 000, this is in comparison to over 28 million cars (Department for Transport 2008). In 2007, 461 HGVs were involved in fatal accidents compared to 3141 cars. However if this is looked at in rate per 100 million vehicle kilometres, HGVs have a fatal accident rate of 1.6 compared to 0.8 for cars (Department for Transport 2008). That is to say there are fewer HGV licensed drivers in GB than cars, yet the rate at which they are involved in fatal accidents is twice as high. It should be noted that these figures are for HGVs licensed in Great Britain and does not include foreign registered vehicles on GB roads, meaning that actual figure could be higher.

In 2006 in the USA there were 8 819 000 large trucks registered, 4,732 of these were involved in fatal crashes resulting in a total of 4,995 deaths; this is despite the fact that large trucks only account for 4% of all registered vehicles (NHTSA's National Center for Statistics and Analysis 2008). If this figure is calculated as rate per 100 million vehicle miles travelled there is a fatal accident rate of 2.12, far worse than in Great Britain.

Two USA reports have suggested sleepiness accounts for 31 – 41% of major crashes of commercial vehicles (Transport Research Board 1985, National Transportation Safety Board 1990). This higher figure for HGV srRTIs is supported by a particularly worrying report from a roadside survey of truck drivers in the USA, stating 47.1% of drivers admitting to having fallen asleep at the wheel (McCartt et al. 2000). It is unclear if the problem is as severe in other countries; a study focusing on the Australian state of

Victoria estimated that fatigue of HGV drivers contributes to 9.8 % of fatal HGV crashes (Haworth et al. 1989).

An additional problem for HGV drivers is that in periods of time not driving, drivers may be engaged in loading and unloading of the vehicle. This means that time “resting” from driving is not actually spent at rest.

1.4.3.2 HGV drivers and OSA

HGV drivers have been recognised as appropriate targets for OSA screening (Gurubhagavatula et al. 2004) as they have been identified as often being male, middle aged and obese (Caples et al. 2005), all factors which put people more at risk from OSA. HGV drivers as a population have been targeted in OSA research in order to estimate prevalence both objectively and subjectively. The key findings are summarised in table 1.4-3.

1.4.3.2.1 Objective measures of OSA in HGV populations

The most accurate way to diagnose OSA is with over night polysomnography (PSG). Objective measures give definitive diagnosis of OSA but as they are costly to carry out there are very few studies of this nature. A large study of objective measures recorded truck drivers sleeping at a truck stop and reported 78% having sleep disordered breathing (Stoohs et al. 1995). This suggests the problem of undiagnosed OSA maybe very greatly within the HGV driver population. Overnight sleep recordings have also been completed on HGV drivers in Sweden and Australia, here undiagnosed OSA was less frequent at 17% and 15.8% respectively (Carter et al. 2003, Howard et al. 2004).

To get the most accurate picture of how many HGV drivers have undiagnosed OSA all HGV drivers would be required to undergo PSG. An American study has investigated the cost effectiveness of screening all HGV drivers for OSA and found that this was not cost effective, in comparison to the cost incurred from RTIs of undiagnosed OSA sufferers. However if drivers were first identified as high or low risk using BMI, gender and age and only the high risk drivers were tested with PSG the authors suggest it would cost 50% less than the cost that these drivers could incur on the road while at risk from their undiagnosed OSA (Gurubhagavatula et al. 2008). It must be noted that these values were based on a mass mailing survey of truck drivers with only a 32%

response rate. But still results are promising and give strong argument to implement a basic screening process.

1.4.3.2.2 Subjective measures

For research less accurate and cheaper methods are often used to investigate prevalence of OSA. The majority of research into HGV drivers and OSA uses some form of questionnaire, though there are a few driver simulator studies. Existing studies using subjective measures have shown OSA to be highly prevalent among commercial drivers ranging from between 16% and 78% being affected; measures include questionnaire, ESS, and BMI though none of these studies were conducted in the UK (Stoohs et al. 1995, Carter et al. 2003, Gurubhagavatula et al. 2004, Canani et al. 2005). Questionnaire screening is cheaper than PSG, and recording BMI combined with OSA symptom reporting has been shown to be 81% sensitive at identifying undiagnosed OSA sufferers when checked with PSG (Gurubhagavatula et al. 2004). However, it will always be the case that not all OSA sufferers will be identified. Questionnaire studies have also been used to successfully assess driver sleepiness in HGV drivers, such as in Finland in which 20% of long haul drivers reported falling asleep at the wheel (Häkkinen et al. 2000).

A road side questionnaire survey in the USA looked for predictors of falling asleep at the wheel in long distance drivers who were covering more than fifty thousand miles per year: they found that an arduous work schedule (> 10 hours driving), poor self reported sleep on work nights, daytime sleepiness, symptoms of OSA (snoring, BMI, stopping breathing), night time drowsiness and age were all significant predictors of falling asleep at the wheel (McCartt et al. 2000). However, in this study 47.1% reported falling asleep at the wheel so this is a particularly biased group when compared with the healthy population. Though it does demonstrate the vulnerability of this cohort and is strong evidence for the dangers of OSA.

An alternative approach to HGV driver survey is to question those who have had an accident regarding the hours leading up to it. One New Zealand postal survey asked HGV drivers recently involved in an RTI questions about the 72 hours preceding the incident (Gander et al. 2006). This study suggested that the number of hours of

previous driving is of greater significance than the number of hours prior wakefulness. Suggesting time on task to be a big influencing factor, this is controlled for in the EU as HGV drivers are only allowed to drive 4.5h without a break. It was estimated that 17.6% of the crashes were fatigue related, adding to evidence from studies in many countries that driver sleepiness is a constant problem in this cohort.

A large proportion of HGV drivers recognise sleepiness as a problem in their industry, but the majority do not report this being a problem for them as an individual (Feyer et al. 1995, Arnold et al. 1997). This suggests that if voluntary screening for OSA was offered drivers would not take it up because they don't perceive themselves to have a sleepiness problem. If screening is introduced it is likely to be most effective if it is enforced.

The vast majority of research in this area has been conducted abroad, but there is one UK specific study from 1995; a postal survey of HGV drivers and male car drivers. This study found that there was no significant association between number of miles driven in a year and previous accidents for HGV drivers, although for car drivers people with higher annual millage were more likely to report having had an accident. In this study the HGV drivers were not asked if they had ever fallen asleep at the wheel and the interviewer made a subjective decision as to whether each HGV driver was obese or had a large collar size. The study found that those categorised as obese or large collar size were more likely to have EDS, and those with high EDS who were also classed as having a large collar size were more likely to have had an accident in the last three years (Maycock 1995). This study does suggest that there may be a problem with undiagnosed OSA in UK HGV drivers similar to that identified in the studies about, but as the main classification measures were subjective it is possible not all obese drivers were recognised or some drivers were classified as obese when they were not.

A further UK study has been conducted by a commercial CPAP provider. Their website gives details of a large survey of UK HGV drivers which found 16% percent to be suffering from OSA and needing immediate treatment. Obviously there is a conflict of interest in a CPAP manufacturer conducting this type of study, but to date no equivalent has been carried out (Moylan 2005). Both UK studies would suggest that

there may be a problem with undiagnosed OSA in HGV drivers but the subjective classification of the Maycock study (1995) and the conflict of interest in Moylan (2005) mean that no firm conclusions can be reached.

As a related side line, Edinburgh bus drivers have also been shown to have a high prevalence of driver sleepiness, with 12% of respondents reporting having fallen asleep at the wheel and 9% reporting falling asleep while at work at least once a month. Using a questionnaire assessment this study suggest that prevalence of OSA to be 10% in this population, the authors report inviting participants for a sleep study but with very low acceptance rate the results were not reported (Vennelle et al. 2010). This further demonstrates the difficulty in screening commercial drivers for OSA if it is not compulsory; it is probable that many participants will refuse the overnight sleep study for fear of implications about their legal driving status.

Within sleep research PSG is the accepted gold standard to diagnose OSA however, in the context of HGV driver screening, blanket PSG has been shown not to be cost effective (Gurubhagavatula et al. 2008). As such objective measures alone are not appropriate for this cohort. Instead target PSG recordings to those most at risk are desirable. However, before any government/company policy for targeted screening would be introduced research evidence is needed to prove that the problem of undiagnosed OSA is a large enough problem to be tackled. The best way to do this is anonymous subjective questionnaire and BMI calculation as drivers will be more likely to participate if it is anonymous as they will not feel their job is a risk. If BMI can be objectively calculated this would add strength to the potential diagnosis as BMI is strongly linked to OSA. However, as with all subjective measures it must then be recognised that this is an estimation as not all participants will answer honestly.

Table 1.4 – 3 Summary of Key HGV and OSA studies

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Canani et al.	2005	Cross sectional	438 male HGV drivers	Questionnaire on sleep, driving habits and ESS	45% had loud snoring, 7.6% witnessed apnoeas. 22% had fallen asleep at the wheel . 39% had been involved in an RTI with 16.4% stating sleepiness as possible contributing factor.	Sleepiness is a common problem probably relating to RTIs
Carter et al.	2003	Survey case control	40000 drivers 1389 professional drivers	Survey and 161 drivers had a sleepy study.	Greater proportion of accidents in professional drivers. 17% of professional drivers having the sleep recording were diagnosed with OSA.	Professional drivers had a greater self perceived sleep debt.
Gander et al.	2006	Survey	130 completed questionnaires which could be linked to a crash report.	Anonymous questionnaire on sleep and duty history 72h before incident	17.6% of crashes were identified as fatigue related. In 511 official crash reports 5.1% were identified as fatigue related.	Current methods of assessing fatigue crashes only identify 41-71%
Gurubhagavatula et al.	2004	Survey	247 HGV drivers	Predicting OSA from symptoms and BMI, confirmation by PSG	Using symptoms and BMI was 81% sensitive which is comparable to oximetry.	Two stage screening is viable to exclude OSA from commercial drivers.
Gurubhagavatula et al.	2008	Case control	247 HGV drivers at high risk of OSA, 159 at low risk.	3 screening methods, PSG, PSG only of those at high risk, no screening	PSG is not cost effective as it is more expensive than cost incurred from OSA related crashes. Screening for age, gender and BMI prior to PSG is cost effective.	Strategies to eliminate blanket PSG are more cost effective than not screening high treatment acceptance is needed.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Häkkinen et al.	2000	Survey	184 long haul drivers, 133 short haul drivers	Questions on OSA symptoms and driver sleepiness.	40% of long haul and 21% of short haul had difficulty staying alert on 20% of driving occasions. 20% of long haul reported falling asleep while driving. 4% of long haul showed signs of OSA.	Driver sleepiness is common even if few drivers have OSA.
Haworth et al.	1989	Review			9.1% of fatal accidents involving trucks are sleep related. Accident risk is highest during the night. In vehicle countermeasures are popular.	Sleep related crashes are a recognised problem and in vehicle alerting devices should be tested.
Howard et al.	2004	Survey	2342 HGV drivers, 161 having PSG	Questions on daytime sleepiness and OSA symptoms	Of those having PSG 60% had SDB and 15.8% OSA. 24% of all drivers had EDS. The sleepest 5% of drivers had increased accident risk.	EDS and SDB are common in HGV drivers. Accident risk is related to sleepiness.
Maycock	1995	Survey	996 HGV drivers	Questions on accidents in last 3y, ESS and OSA symptoms.	Accident rate was not linked to time spent driving. Over 55y had more accidents. 37% snored or were judged by the interviewer to have large collar size and had ESS>12.	Those with signs of OSA had an accident liability twice that of the remainder.
McCartt et al.	2000	Survey	593 HGV drivers	Questionnaire on typical work and rest patterns, drowsiness and sleep disorders.	47.1% had ever fallen asleep while driving, 25.4% in the past year. Underlying independent factors of falling asleep while driving were, daytime sleepiness, arduous schedule, older, short and poor sleep and symptoms of sleep disorder.	Identifying drivers with sleep disorders would reduce sleep related driving incidents.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Stoohs et al.	1995	Survey	388 HGV drivers 159 had sleep monitored	Oxygen desaturation index (ODI) , BMI	10% had ODI>30 per h. BMI was significantly different between those with ODI>30 and <5. 20% showed symptoms of regular sleep disturbance.	The combination of potential OSA and difficult shift patterns impacts on daytime alertness.

1.4.4 Review of OSA research with survey/accident studies

Looking at accident records from the police or insurance companies and self reported accidents are also a good way to compare OSA patients and controls or to compare OSA patients' pre and post treatment. However, a major limitation of most of these studies in this area is that they are cross-sectional.

A review of accident survey studies with non commercial drivers found in 23 out of 27 papers untreated OSA drivers were at significantly higher risk of having had an accident than controls (this did include 8 simulator studies) with a median odds ratio of 3:1 (Ellen et al. 2006). In one retrospective study with a large sample size it was suggested that the difference between accident rate in untreated OSA and controls is largely due to those with an AHI over 40 (George et al. 1999). It appears that OSA drivers are at a significantly greater risk of RTI although the difference may be due to severe OSA sufferers being at particularly high risk.

CPAP has been found to be very effective at reducing RTIs. One study surveyed CPAP users, of which 39.39% self reported RTIs in the 2 years prior to CPAP, yet none of them reported RTIs during the first 2 years of treatment (Yamamoto et al. 2000). Another study of CPAP patients in comparison to a control group found the patients were significantly more likely to have had an accident in the 3 years prior to treatment but in the first 3 years of CPAP the chance of an RTI occurring was the same as for controls (George 2001).

In one accident survey study it was found that controls had more accidents than untreated OSA patients during a 3 year period, though the OSA patients self reported a greater percentage of their accidents to be sleep-related (Aldrich 1989). It has been shown that sleepy drivers have more RTIs but sleepy drivers are not necessarily suffering from undiagnosed OSA (Masa et al. 2000). Here respondents were classified in to subgroups by level of sleepiness, when assessed for OSA 24% of total respondents were positively diagnosed with 14% of these in the non sleepy driver's category. Similarly in Horstmann et al. (2000) 32% of OSA patients had an ESS >15 but only 12% of the patients reported having had a sleep-related crash, suggesting EDS

does not necessarily result in a RTI. The same study did however, find that those with an AHI >34 had more accidents than the control, so severe OSA may lead to accidents.

Relying on self reported accidents means there may be some bias as participants may not want to admit to having had an accident. Another approach is to look at insurance company or government records of RTIs, though again any unreported RTIs will not appear. Several studies have found untreated OSA patients to have more accidents than controls to various odds ratios, 2.3 (Barbe et al. 1998), 3.4 (T. Young et al. 1997), 6.3 (Teran-Santos et al. 1999).

A different approach is to survey drivers who have had RTIs to look for commonalities. It has been found that OSA is more prevalent in RTI drivers than matched controls (Teran-Santos et al. 1999). Though in another study the prevalence of sleep disordered breathing (SDB) was found to be similar between the two groups (Kingshott et al. 2004). Also of note in the latter study there was no correlation between ESS and RTI and those who answered yes to the question "Have you ever felt sleepy while driving?" were more likely to have had an RTI. Other studies have also demonstrated that self reported sleepiness while driving was a predictor of accidents (Young et al. 1997, Lloberes et al. 2000, Masa et al. 2000). However, it should be considered that the people who have had an RTI may be more aware of sleepiness while driving as they have experienced a crash; because of this they may have heightened awareness of anything which may result in RTI and over report it.

It is acknowledged that not all OSA patients will have an RTI (George 2001) and although various methods have been tried, it has not been possible to identify a predictor of which patients are more likely to have an incident. Daytime sleepiness, anxiety, depression, level of vigilance and driving simulator performance have all been unsuccessful at predicting which patients will have accidents (Young et al. 1997, Barbe et al. 1998).

1.4.5 Review of OSA and driving simulator studies

The current research to investigate the impact of OSA on driving will be conducted predominantly using a driving simulator. The following is a review of existing literature in the specific area of OSA and driver sleepiness (key findings are summarised in table

1.4-4), subdivided by the type of simulator used for the investigation. To aid understanding, initially an introduction to driving simulators is included.

1.4.5.1 Driving simulators

When experimentally assessing driver sleepiness the ethical implications of putting a known sleepy driver in charge of a vehicle on real roads means that in practice most research is carried out using a driving simulator.

1.4.5.1.1 Types of simulator

The simulators used in this type of research can be split by the three main sub groups; steer clear, divided attention driving task (DADT) and advanced simulators.

- The steer clear task typically lasts for 20 minutes where subjects are shown a computer generated dual carriageway road, they are instructed that if they need to change lane because of an obstacle in the road they should press a computer key. The outcome of the test is measured by how many collisions occurred. The steer clear is a vigilance test which has not been shown to relate to actual crashes (George 2004).
- DADT is more advanced than the steer clear task. This simulator typically has a steering wheel, brake and accelerator pedal, usually set up in front of a computer screen. Participants are asked to drive in the centre of a computer generated winding road. The test measures standard deviation from the centre of the road; and therefore ability to stay on course. In the corners of the screen numbers are shown, these change through the drive, before the start the participant is instructed which of these stimuli they should respond to, when they see this number they should press a button on the steering wheel as quickly as possible. Reaction times are calculated from this.
- Advance simulators vary greatly but all typically have a real immobilised car (or half a car) which the participant sits in to drive on a computer generated road. Some simulators vibrate to suggest movement; others play road noise into the car to give the illusion of movement. The road set up used varies between research centres, with some favouring a winding road similar to the DADT while others have a monotonous dual carriage way. Some have reaction time

tasks as in the DADT others do not. Advanced simulators provide the most lifelike driving experience.

- Real car on road driving. A few research centres conduct trials using instrumented dual controlled cars, such as those at Maastricht and Utrecht universities in the Netherlands. In these studies, participants drive on real roads with the investigator in the passenger seat to take over control of the car if required. Sensors within the car can monitor the real world environment and records deviation from central lane position on major roads. To date these cars have predominantly been used to investigate the effect of drugs and alcohol on driving and never in the area of OSA (e.g. Verster et al. 2004, Wingen et al. 2005).

1.4.5.1.2 Advantages and limitations to simulator studies

As well as being safer than on-road testing simulators also allow tight experimental control by reducing the number of uncontrolled variables (George 2004). It is also harder to monitor lane position on a real road than in a simulator.

Using driving simulators to assess driver sleepiness have shown comparable results to real life driving, however, lane drifting is elevated in a simulator and participants may feel sleepier (Philip et al. 2005). Driving tasks have been shown to be highly correlated to the Maintenance of Wakefulness test (Philip et al. 2005, Pizza et al. 2009). Suggesting that the MWT could be used as an assessment of fitness to drive (Banks et al. 2005, Pizza et al. 2009). In the MWT subjects are required to stay awake as long as they can in an un-stimulating environment.

It is acknowledged that motivation while driving a simulator is different than on the road as a crash does not have the same consequence; the driver has no need to fear for their safety or the safety of other road users (George 2004). It is possible to increase the suggestion of a “real life” situation particularly with sleepy participants by using a real car and recreating a standard driving environment such as wearing a seat belt.

1.4.5.1.3 Performance measures

Various outcome measures can be used to assess driving ability: acceleration, braking, following distance, maintaining speed, lane position, and maintain driving while completing a secondary task (George 2003). Sleep related road traffic incidents (srRTIs) are characterised by drivers drifting off the road or into another lane (Pack et al. 1995) so assessing lane drifting may provide the most accurate measure of sleep impaired driving performance. Driving simulators have shown that with sleepiness, deviation within a lane and collisions with lane demarcation lines increases (Philip et al. 2005). The other measures may also be affected by sleepiness so should be considered, however lane drifting is the primary outcome.

Previous work at Loughborough University has used an advanced simulator, stationary real car simulator to assess driver sleepiness predominantly by inappropriate lane crossing as scored manually from video recordings of drives (Horne et al. 1996, Reyner and Horne 1998a, Reyner and Horne 1998b, Baulk et al. 2001, Horne et al. 2003, Barrett et al. 2004b). This simulator set up has been validated to real road conditions (Baulk et al. 1998), a full description of the simulator can be found in chapter 3.

1.4.5.2 Obstructive sleep apnoea participants at steer clear task

The steer clear simulator is a simple design but has been demonstrated to effectively distinguish between OSA patients and a control group in various studies. It has also been shown that this impaired performance can be overcome by CPAP treatment. This suggests that prior to treatment OSA sufferers may pose a danger on the roads however with effective treatment this risk is reduced.

The earliest of these studies was Findley et al. (1989). This American study compared performance in a steer clear simulator of untreated severe OSA patients with controls. The drive only lasted for 30 minutes so although it was monotonous it is possible that the participants may have been able to sustain attention for this time though would have impaired performance had the test been longer. The OSA patients hit significantly more road obstacles than the controls. After CPAP treatment performance improved and was no longer significantly different to the controls.

However, the small sample size of 12 in each and the fact that only 6 of these completed the task again after CPAP means only limited conclusions can be drawn.

Other driving simulator studies have also shown CPAP to improve performance of OSA sufferers at the steer clear task both in the UK (Kingshott et al. 2000) and in Spain (Munoz et al. 2000). Amongst other tests, participants completed ESS, steer clear and PVT before treatment, 3 months and 12 months into CPAP treatment. ESS and steer clear performance had improved by 3 months and this was sustained up until the 12th month of treatment at the end of this study. These studies all show that any impairment at a steer clear task which is present in OSA patients is greatly reduced and often eliminated after treatment with CPAP.

It is important to note the great variability at steer clear performance amongst OSA patients. One study suggests that as many as 15% of untreated or undiagnosed OSA sufferers do not pose any greater risk on the roads when compared to people of a similar age without the condition (Findley et. al. 1995). The worst performers of the OSA group were significantly worse than the OSA participants who performed at the level of the control group, but nothing was attributed as the cause of this difference. It should be noted that participants only had one minute to practice before the task started so it is possible that a learning effect had an impact on the results of this 30 minute drive.

It has to be questioned how accurate steer clear is at predicting real life situations, the task involves pressing a computer key when you see an obstacle in the road often over a short period of time. For example Findley et al. (1999) used a longer, one hour steer clear task in conjunction with a reaction time task (creating a divided attention driving task) they compared 31 untreated OSA patients and 14 controls over an hour drive. The OSA hit significantly more obstacles, as previous research would predict, but what is interesting is that there was a difference in the time on task effect. The OSA group showed a trend to increased incidents with time on task which was not apparent in the control group. This suggests that it may be appropriate to have a shorter recommended driving time for people with OSA. Another interesting finding of this study is the variability amongst people with OSA, the variability of performance within

the OSA group was 27 times greater than the variability within the control group. This difference may be partially attributed to the control group being smaller than the OSA group, but it is important to note that there may be a heightened difference in ability to drive within OSA patients and therefore it may not be appropriate to consider all OSA patients in the same way. Further investigation is needed to see if there are any predictors of driving performance and also if performance changes with increased driving length

It is possible to describe the steer clear task as a reaction time test within the context of driving. When participants complete a driving simulator task it is important that it gives them the perception of driving. Pressing a button is not representative of driving so participants may not take the simulation as seriously as they would actual driving.

1.4.5.3 Obstructive sleep apnoea participants at a Divided attention driving tasks (DADT)

DADT can be considered more advanced than steer clear as they require participants to use a steering wheel to govern the direction of their vehicle, whilst performing a reaction time test. Participants are required to actively steer to keep the car on the road as well as respond to target numbers. The DADT is traditionally a winding road which participants have to actively steer to stay on, this is not typical of the roads where sleep crashes usually occur. The task is usually short, 20 or 30 minutes, which is not a long time when you consider that the UK Highway Code recommends drivers should take a break every 2 hours and therefore expects long drives to be in excess of this time.

Despite its shortcomings the DADT has been used to show that OSA does cause some driving impairment and that CPAP treatment can reduce this. There is also the suggestion that OSA sufferers are aware of how tired they are so would be able to stop before an incident occurred. DADT have also been used to demonstrate that the ESS and AHI may not be sensitive enough measures to predict driving performance for OSA patients.

The first DADT studies with OSA patients were conducted in Canada (George et al. 1996a). They found that on average OSA patients were worse at staying on track than

the control group, although in practice this was only half of the OSA group performing at a lower level than the control. The investigators took other measures to try to identify what could be causing the impairment in some of the OSA patients tracking and not others. Linear regression analysis showed that less than 25% of the variance in tracking error could be accounted for by AHI or MSLT score. The steering was the main measure of sleepiness, it was assumed that no steering movement for 30 seconds was because of sleep, however, without EEG it is not possible to know if this was the case.

More recently, in the UK a DADT was carried out (Juniper et al. 2000). The view of the road was varied to form three conditions, one when the total road was visible, one condition only the near road was visible and the final condition only the far road was visible. The untreated OSA group performed significantly worse on all conditions at tracking and reaction time in comparison to controls. They were particularly worse when only part of the road was visible, which may suggest that OSA patients need more visual cues to maintain driving performance. As with other studies the drive time was only 30 minutes so it is still not known what performance would be like with prolonged driving.

It is known that sleep deprivation and alcohol can impair driving performance (Horne et al. 2003). The impairment due to OSA has been shown to be similar to that of sleep deprivation and not like that of alcohol over three 30 minute drives (Hack et al. 2001). Alcohol impaired steering equally throughout the drive; sleep deprivation resulted in increased impairment as the drive went on. The OSA group showed steering impairment more characteristic of the sleep deprived group than the alcohol group. However, the OSA group were in their fifties and the other two groups were in their twenties so there may have been a degree of age related change not accounted for. Another limiting factor is that each group drove at a different time in the day so it is not fair to compare them as they would have been under different circadian influences.

The DADT has also been compared to real life RTIs (Turkington et al. 2001) assessing people who attended a hospital clinic with expected OSA who were tested on a 10 minute DADT, they were also asked to report any accidents, near misses or sleeping at

the wheel in the last 3 years and fill in a questionnaire about driving habits such as miles driven a year. No predictor of accident in the previous 3 years was identified. Age, sex and alcohol consumption were the best predictors of simulator performance, ESS was related to the reported near misses and sleeping at the wheel but did not correlate to simulator performance. However, Turkington et al (2001) relied on self reporting accidents; people may have been unwilling to disclose this information, particularly in a hospital setting, if they felt their driving licence was at risk.

Mazza et al (2005) looked at ability at reaction time tests, ability to remain awake and DADT. They found that OSA patients were more likely to fall asleep while trying to remain awake than the control group and that although reaction time was similar the patient group were more likely to make mistakes. They also noted that the OSA patients who remained awake during the task still showed impaired performance at the other tasks. This is a concerning conclusion as it suggests that even if OSA patients appear alert they may still have impaired performance at tasks such as driving. The question then is how to measure this alertness; it has been found that the ESS is not sensitive enough to detect impaired performance (Mazza et al. 2005, Walter et al. 2002a, Kingshott et al. 1998, Orth et al. 2005). It is also of note that Mazza et al. (2005) had only 1 female in the patient group but 12 in the controls which may have affected the comparison. Another study comparing ability to stay awake and DADT performance found ability to stay awake was correlated with simulator performance but this was not significant (Sagaspe et al. 2007b). This study also found that ability to stay awake was linked to AHI which Mazza et al. (2005) did not.

A further study found no difference in ability to remain awake between OSA patients and controls (Mazza et al. 2006). The results of this existing research suggest it is unclear whether OSA patients have an impaired ability to remain awake in monotonous situations or not. It is possible the conflicting results between studies are due to great individual variation between OSA patients.

Recently the DADT has been developed by Pizza et al (2008) so that the drive is a dual carriageway, as this is more reflective of the type of road sleep crashes tend to occur on. In this study OSA patients were tested on the simulator and subjective (Stanford

Sleepiness Scale and ESS) and objective (MSLT) sleepiness measures were taken. These measures all correlated to driving errors, the authors suggest that OSA sufferers are aware of their tiredness so would be able to stop before an incident occurred. However, the study does not state if the patients were receiving treatment or not, it is assumed that they were not in which case it would be interesting to see if the same results were found following CPAP. Secondly the SSS scores were taken before the drive was started but not monitored throughout the drive. It would be useful to know how this changed through the drive as a predictor of incidents to see if OSA patients were truly identifying when they were getting tired. Finally the drive itself was designed to be monotonous but the test was only 30 minutes long so it has to be questioned if this really simulates a monotonous drive.

The most comprehensive investigation into the effects of CPAP using a DADT was a UK study conducted by Hack et al (2000). This study was a double blind randomised control trial with 59 males aged 30 to 75, participants either received a working CPAP machine or a machine which appeared to work but did not blow air out at a positive pressure. DADT was completed for 30 minutes before and after treatment. The real CPAP resulted in significantly improved steering performance and reaction time and the sham CPAP did not. ESS scores were also taken, these significantly improved under both real and sham CPAP though to a greater extent with real CPAP. This study clearly shows the effectiveness of CPAP as a treatment for OSA and also shows that untreated OSA sufferers have some driving impairment (Hack et al. 2000). This is supported by Turkington et al (2004), who tested severe OSA patients in a driving simulator; half were then given CPAP treatment and tested on day 1, 3, 7 and 14. Treatment was then stopped for 7 days but simulator testing continued. The results were compared to the other 18 patients who did not receive treatment. They found the CPAP improved both tracking position and reaction time, the same as Hack et al (2000). However, interestingly Turkington et al (2004) found that stopping treatment did reduce performance but, 7 days after stopping treatment this group were still performing better than the OSA patients who had never received treatment. As performance was not sustained without the treatment it would not be wise to recommend breaks in

treatment though this suggests that if treatment is missed for unavoidable reason patients may still be able to drive safely.

1.4.5.4 Obstructive sleep apnoea participants at advanced simulator studies

There are fewer advanced simulator studies than DADT or Steer Clear as they are more costly and time consuming to administer. They also tend to be longer drives as they are usually the main focus of testing unlike Steer Clear which can be administered as part of a battery of tests. Advanced simulators have been used to show impairment in ability of OSA drivers compared to controls and improvement following CPAP treatment. As with simpler simulator designs, no predictor of driving ability has been identified. These studies tend to be of longer duration than the simpler simulations. This may increase reliability at identifying impairment during monotonous driving as it has been reported that testing OSA drivers for 30 minutes on a simulator cannot identify impairment shown on the same simulator after a 90 minute drive (Vakulin et al. 2009). Impaired ability to recognise sleepiness and a lower capacity to cope with sleep restriction have been demonstrated compared to control groups.

Advanced simulators have been used to demonstrate the effectiveness of CPAP treatment (Orth et al. 2005). In this case OSA patients were tested before and after receiving CPAP treatment, the results of which found an improvement in driving performance after treatment. The investigators also looked for predictors of simulator performance, as doctors are required to state if they think people are unfit to drive it would be useful if a measure could be found on which to base this decision. A number of psychological tests including ESS were looked at as well as features of an overnight PSG recording, but no links were found. This simulator did have a driving 'cab' for participants to sit in but it was not a real car, the 'cab' appears similar to that of racing games found in arcades. The drive was for 60 minutes following the format of the DADT.

A 60 minute advanced driving simulation comparing OSA sufferers and controls found OSA sufferers had worse lane deviation than controls (Risser et al. 2000). This study also took continuous EEG recording to measure attention lapses – alpha or theta activity lasting 3 seconds was counted as an attention lapse. This study is one of only 2

driving simulator studies using EEG during the drive recording, the other being Vakulin et al. (2009), described below. The OSA group had more extended and an increased number of attention lapses. Subjective sleepiness on a VAS was taken immediately before and after the drive showing the control group to be more alert. The subjective scores did not increase as much for OSA sufferers as they did for control participants suggesting impairment in ability to recognise sleepiness. Subjective scores were not taken throughout the drive so it is unknown how the groups relate to each other at this time. The authors state there were 15 controls and 15 OSA patients who completed the drive but it is unclear how many participants were included in analysis. After the drive the OSA participants then completed over night PSG and if their AHI was below 20 they were excluded from the analysis. It is also not stated if the OSA participants were receiving CPAP or not (Risser et al. 2000).

Vakulin et al. (2009) used a dual carriage way simulation for 90 min on 3 occasions with OSA sufferers and control drivers after, normal sleep, sleep restriction (4 hrs) and alcohol consumption. With main outcome measures of steering deviation and 'crashes' the untreated OSA group were found to have more impairment at the driving task than the control group at base line. The OSA group had significantly more impaired driving than the control group after sleep restriction though not after alcohol consumption. Many studies have also shown untreated OSA participants to have impaired driving compared to controls but it is interesting that sleep restriction has a greater effect on OSA participants. Using untreated OSA participants means it is not clear if the sleep restriction itself is the cause of impairment or rather by restricting people who already have poor sleep it might be expected that they be sleepier than controls.

All the advanced simulator studies discussed here have been using monotonous road conditions in order to represent the type of road where sleep-related crashes are most likely to occur. However, if medium traffic density is presented it has been shown that untreated OSA drivers perform at the same level as controls (Tassi et al. 2008). Interestingly the authors report increased theta and beta activity in OSA participants EEG and greater caution when overtaking than controls, suggesting possible compensation mechanisms to achieve the same performance outcome.

A real car study was used to investigate reaction times of OSA sufferers compared with controls (Mazza et al. 2006). Participants drove down a 150 metre track, when the car reached 40 km/hr a jet of water was pumped on to the road forming a wall about 40 meters in front of the car. Participants then had to brake and reaction time was measured. There were three conditions, the participant didn't know when the water would appear, the participant was distracted at the time the water appeared and the participant was told to put their foot over the brake pedal just before the water appeared. OSA patients had slower reaction times than controls in each condition, though on average this was only 0.5 seconds. Following CPAP treatment the average reaction time became the same as for the controls.

Table 1.4 – 4 Summary of OSA and driving simulator studies key findings

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Findley et al.	1989	Case control	12 untreated OSA 12 controls	30min Steer clear, obstacle hit rate	OSA participants hit more obstacles than controls. Follow up of 6 patients post treatment showed improved performance.	Driving simulator performance is impaired in untreated OSA and improves with CPAP.
Findley et al.	1995	Case control	62 untreated OSA, 12 controls, 10 patients with narcolepsy	30min Steer clear	Poor performance at steer clear was associated with higher accident rate in the preceding 5 y. Patients had worse performance than controls.	Impaired vigilance on Steer Clear is associated with high automobile accident rate in OSA patients.
Findley et al.	1999	Case control	31 untreated OSA, 14 controls , 16 narcolepsy	6*4min Steer clear	Patients had significantly more collisions than controls. There was greater inter-participant variability between OSA then controls. OSA participants showed greater decrease in performance with time on task than controls.	In participant assessment tasks need to be of long enough duration to show time on task effects.
George et al.	1996a	Case control	21 untreated OSA, 21 controls, 16 narcolepsy	20min DADT and MSLT	Tracking error was worse for OSA than controls. But half the patient group were as good at tracking as controls. MSLT did not predict DADT performance.	OSA participants have worse DADT performance than controls, MSLT does not predict this.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Hack et al.	2000	Randomised control trial	59 OSA 1 month of CPAP or sham CPAP	3*30min DADT	DADT improved in both conditions but more in real CPAP. Reaction time was faster following real CPAP	CPAP improves steering and reaction time showing untreated OSA to have impaired driving performance.
Hack et al.	2001	Case control	26 untreated OSA, 12 control. 24h sleep deprived and alcohol consumption.	3*30min DADT	Untreated OSA performed between alcohol consuming controls and sleep deprived controls. OSA was more like sleep deprivation than alcohol consumption.	OSA impairment is more comparable with sleep deprivation than abnormal cognitive or motor skills.
Juniper et al.	2000	Case control	12 untreated OSA, 12 control	3*30min DADT part of road visible	OSA performed worse than controls particularly when not the entire road was visible.	OSA patients may be more disadvantaged than controls when the view of the road is limited such as in fog.
Kingshott et al.	2000	Intervention	62 OSA at baseline and 6 months into CPAP	30min Steer clear	Task performance improved with CPAP treatment. AHI was a poor predictor of performance.	CPAP improves daytime functioning in OSA patients.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Mazza et al.	2005	Case control	20 untreated OSA, 40 control	DADT	Vigilance was impaired in OSA compared with control at a range of vigilance tasks including DADT.	It is not just ability to remain awake in monotonous situations but also in for stimulating conditions. A single test is not sufficient to identify impaired vigilance.
Mazza et al.	2006	Case control	OSA before and after CPAP, controls	Real car, reaction time.	OSA had slower reaction times than controls, with twice the number of collisions. Following CPAP there was no difference between OSA and controls.	Driving ability is significantly impaired in OSA. After CPAP deficits normalise even in non sleep patients.
Munoz et al.	2000	Intervention, case control	80 OSA before and after 1y CPAP. 80 Controls	Steer clear	Prior to treatment task performance was significantly worse in OSA compared with controls. Performance improved with CPAP.	CPAP is a valid treatment for OSA patients.
Orth et al.	2005	Intervention	31 OSA patients before and after 2 and 42 days of CPAP.	DADT advanced simulator	Attention and alertness improve with CPAP but vigilance remained the same. No relationship between ESS and DADT	DADT is a possible bench mark for driving performance in OSA patients.

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Risser et al.	2000	Case control	15 untreated OSA, 15 controls	1h Advanced simulator with EEG	OSA had impaired driving performance compared with controls and more EEG attention lapses. Attention lapses were correlated with driving performance.	OSA driver impairment increases over task duration. RTIs are not just due to sleep disturbance but also inattention due to sleepiness.
Sagaspe et al.	2007b	Cross sectional	30 untreated OSA	1h DADT, MWT	MWT correlated with DADT performance. The sleepest group had the worse performance. ESS and AHI did not predict DADT performance.	MWT 0-19min is associated with DADT performance impairment.
Turkington et al.	2001	Cross sectional	150 untreated OSA	20min DADT	Participant characteristics – older age, female and alcohol consumption had greatest influence on DADT performance. Self reported near miss accidents were also associated with DADT performance. ESS is associated with falling asleep at the wheel.	There is an independent relationship between DADT performance and driving ability in OSA patients.
Turkington et al.	2004	Intervention	18 OSA tested at baseline, 1,3,7 days and 2 weeks into CPAP. Then discontinued for 7 days.	DADT	At 7 days of treatment DADT performance was significantly better than baseline. Following 7 days of stopping treatment significant improvement compared to baseline was still reported.	DADT performance improves within the first few days of starting CPAP. Improvement is sustained for up to 1week without

Author	Year	Type of study	Sample	Measures	Results	Conclusions
Vakulin et al.	2009	Case control	38 untreated OSA, 20 controls	Advanced simulator, sleep restriction and alcohol condition	OSA had worse driving performance than controls. Increase in driving impairment was significantly greater in OSA than controls following sleep restriction and alcohol. Prolonged eye closure and microsleeps predicted driving performance.	Untreated OSA are more vulnerable to sleep restriction than healthy controls.

treatment.

1.5 Research aims and hypotheses

The aim of this research is to investigate the impact of OSA on driving in two key subgroups.

- A) HGV drivers on UK roads
- B) OSA patients treated long term with CPAP

From the literature review 7 areas were identified as needing further investigation. The following aims and hypotheses were then developed. This thesis has been designed with the hope of addressing them.

AIM 1: To evaluate the prevalence of undiagnosed OSA in HGV drivers on UK roads.

The literature has shown that driver sleepiness is a problem to HGV drivers. It can be exacerbated by hours spent driving, lack of quality sleep, inadequate rest and sleep disorders. OSA has been shown to be more prevalent in HGV driver populations than in the general population (Stoohs et al. 1995, Carter et al. 2003, Gurubhagavatula et al. 2004, Canani et al. 2005). However, results have been conflicting as some studies use more robust assumptions for undiagnosed OSA than others, as it is not cost effective to screen every driver using PSG. The majority of HGV and OSA studies have been conducted outside of the UK. The key study in the UK was conducted 15 years ago and results were based on the investigators perception of if participants were obese (Maycock 1995) as such there is a gap in the research to investigate if international findings are also applicable in the UK.

Hypotheses addresses in Chapter 2:

To test the hypothesis that undiagnosed OSA will be prevalent in HGV drivers on UK roads.

To test the hypothesis that OSA risk factors and symptoms can be used to predict self reported likelihood of falling asleep at the wheel in HGV drivers on UK roads.

To test the hypothesis that those with suspected OSA will have greater EDS and fall asleep incidents.

To test the hypothesis that high ESS will be associated with reports of falling asleep at the wheel and risk factors of OSA.

To test the hypothesis that OSA symptoms and risk factors will be of greater prevalence than in the general population.

AIM2: To evaluate the effect of sleep restriction in OSA-CPAP compliant patients compared with controls at a simulated driving task.

The literature has shown performance at driving tasks improves in OSA participants following up to 1 year of CPAP treatment also to levels comparable with controls, (Findley et al. 1989, George et al. 1997, Hack et al. 2000, Kingshott et al. 2000, Munoz et al. 2000, Mazza et al. 2006). However, the research showing improvement in performance following CPAP treatment has predominantly been conducted using short duration tests. It is unknown if CPAP treated patients will have similar performance to controls at a long monotonous task, such as simulated motorway driving.

With untreated OSA participants total sleep deprivation (Desai et al. 2006) and sleep restriction to 4 hours (Vakulin et al. 2009) have been found to cause greater impairment at driving tasks than in healthy controls

CPAP treatment has also been shown to improve daytime sleepiness in OSA patients (Hardinge et al. 1995, Ballester et al. 1999). It would therefore be expected that when OSA patients use their CPAP and have a full night's sleep they would feel no sleepier than control participants at the start of a task and progress in sleepiness during the task in the same manner as controls.

Subjective driver sleepiness is most commonly investigated by recording subjective sleepiness before and after a driving task. However, this methodology means that sleepiness is not reported when the participant is completing the task, as such alertness may have improved or worsened since the task environment has been

removed. The current work will record sleepiness throughout the driving task to address this.

In two studies investigating subjective sleepiness following sleep deprivation in untreated OSA participants and increase in subjective sleepiness has been reported, however not to the same magnitude as control participants despite the OSA group having worse task performance (Desai et al. 2006, Risser et al. 2000).

Combined alpha and theta power has been demonstrated to be most representative of the transition between wake and sleep in healthy young participants during a driving simulator task (Horne et al. 1996). Beta activity occurs with increased effort to remain alert and has been shown to decrease with prolonged attention tasks (Jap et al. 2009).

Beta activity in untreated OSA participants has been reported to be higher during a driving task of medium traffic density compared with controls (Tassi et al. 2008). Higher activity in the beta and theta power spectrum has also been observed during total sleep deprivation in untreated OSA participants compared with controls, suggesting greater sleepiness and greater effort to remain alert (Greeneche et al. 2008).

Only one study was identified in the area of OSA and driver simulation. Risser et al. (2000) completed a driving simulator study for 60 min including EEG recording of untreated OSA participants compared with control participants. OSA participants were found to have more “attention lapses” in EEG activity than controls and these lapses became longer in duration as the task progressed for the OSA participants, compared with controls. This indicates that the EEG activity of untreated OSA participants differs to that of controls during a driving task, however, this driving task was only 60 minutes so it is unknown if the same result would be found with a longer task or treated OSA participants.

No studies with treated OSA participants were identified to assess if the increased vulnerability to the effects of sleep restriction in relation to task performance, subjective sleepiness and EEG activity persists into treatment.

Hypotheses addressed in Chapter 5

To test the hypothesis that OSA CPAP compliant participants will show no difference in driver performance at a driving simulator task as reflected by increased lane deviation after a normal night of treated sleep.

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by increased lane deviation and shorter time to first incident after sleep restriction to 5h of treated sleep.

Hypotheses addressed in Chapter 6

To test the hypothesis that OSA CPAP compliant participants will show no difference in driver performance at a driving simulator task as reflected by subjective sleepiness measures (KSS and LHoFA) after a normal night of treated sleep.

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by subjective sleepiness measures (KSS and LHoFA) after sleep restriction to 5h of treated sleep.

To test the hypothesis that in both groups subjective measures of sleepiness will be correlated to each other (KSS vs LHoFA and KSS vs ESS).

Hypotheses addressed in Chapter 7

To test the hypothesis that OSA CPAP compliant participants will show no difference in driver performance at a driving simulator task as reflected by increased beta and combined alpha theta activity after a normal night of treated sleep.

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by increased beta and combined alpha theta activity after sleep restriction to 5h of treated sleep both overall and at the specific time of first incident for the OSA group.

AIM 3: To evaluate the ability of OSA-CPAP compliant patients compared with controls at recognising sleepiness during a simulated driving task.

The literature shows that participants in their early twenties are able to recognise sleepiness while completing a driving task and do so with an average of 45.5 min notice before first major incident (Reyner and Horne 1998b, Horne et al. 2004). The current research allows for the same analysis to be completed on older healthy and OSA participants aged 50 to 75.

Increase in sleepiness from the full night's sleep of sleep deprivation has been reported to be significantly greater for controls than untreated OSA participants (Desai et al. 2006), from which the authors suggest the OSA participants are not as good at recognising sleepiness as controls. However, this may not be certain as in practice the difference was small, with an increase just of 1.3 (SSS) for OSA sufferers, compared to 1.9 for controls. Additionally, Pizza et al. (2008) used a divided attention driving task periodically through the day to demonstrate that times where task performance was most impaired coincided with when OSA participants rated themselves as most sleepy, therefore suggesting OSA participants can recognise sleepiness.

A previous driving simulator study with young participants has found EEG activity to be correlated with subjective sleepiness (Horne et al. 2004). Greneche et al. (2008) also investigated correlation of EEG and subjective sleepiness; here during 24 h sustained wake in older participants. EEG was found to closely correlate to subjective sleepiness in control participants but not in untreated OSA participants, suggesting OSA participants do not know when they were sleepy. This study was not associated with a performance task, so is not directly comparable to the current work as the perception of task performance may influence perception of sleepiness. However, it is of interest that the correlation was not identified in OSA participants.

No studies identifying perception of sleepiness during a performance task with treated OSA participants were identified.

Hypotheses addressed in Chapter 8

To test the hypothesis if OSA CPAP compliant participants show impaired ability to subjectively identify sleepiness at a driving simulator task as reflected by greater

number of driving incidents while reporting not being sleepy, reporting feeling sleepy prior to first driving incident after sleep restriction to 5h.

To test the hypothesis that EEG will correlate to KSS in both treated OSA and control participants after sleep restriction to 5h.

To test the hypothesis that fleeing sleepy will be associated with being likely to fall asleep for OSA CPAP treated patients during a driving task following sleep restriction to 5h.

AIM 4: To evaluate the ability of OSA-CPAP compliant patients during a simulated driving task following CPAP withdrawal for one night compared with after a normal night on treatment and treated sleep restricted to 5h.

The literature shows withdrawal of CPAP in compliant long term users results in immediate resumption of sleep disordered breathing and when treatment is resumed there is immediate recovery, as measured by PSG (Grunstein et al. 1996, Yang et al. 2006a).

Three previous studies were identified as investigating the impact of CPAP withdrawal on task performance and subjective sleepiness; all have been with participants on CPAP for one year or less and results are conflicting.

Turkington et al. (2004) used a divided attention driving task, CPAP was found to improve task performance compared to prior treatment performance. Following two weeks of CPAP the treatment was stopped, although task performance decreased it never returned to the same level as before treatment. Yang et al. (2006) also withdrew CPAP from compliant users; here participants felt sleepier after one night of withdrawal but were able to maintain performance at a battery of cognitive tasks including PVT. The residual effect of treatment after it had been withdrawn is unexpected as sleep disordered breathing is likely to have returned. However, it is possible that participants were able to maintain performance despite the increased sleepiness due to the simple nature of the task. The PVT is a short duration test and

the divided attention driving task used in Turkington et al. (2004) was only 20 minutes in duration. This is too short to give an indication of ability to drive.

In contrast Kribbs et al. (1993a) also withdrew CPAP treatment for 1 night but reported that all participants had impaired subjective sleepiness and PVT performance compared with when undergoing treatment.

No studies investigating perception of sleepiness following CPAP withdrawal were identified.

Hypotheses addressed in Chapter 9

To test the hypothesis that sleep quality will be impaired with CPAP withdrawal in OSA CPAP compliant participants.

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by increased lane deviation, subjective sleepiness, EEG activity, successful drive completion and shorter time to first incident after treatment withdrawal than either normal treated sleep or sleep restriction to 5h of treated sleep.

To test the hypothesis that treatment withdrawal from OSA CPAP compliant participants will not affect ability to recognise sleepiness as reflected by KSS at first major incident and reporting feeling sleepy prior to first driving incident (KSS6+, LHoFA 4+).

AIM 5: To evaluate the individual difference of the effect of sleep restriction in OSA-CPAP compliant patients at a simulated driving task.

The literature shows that ability to maintain performance when sleep deprived varies greatly between healthy individuals (Van Dongen et al. 2004). Some degree of variability at the driving simulator task, when sleep restricted, would therefore be expected in both the control and treated OSA group.

Driving simulator studies have shown there to be great individual difference between untreated OSA participants, with many studies showing an overlap with performance of the control group (George et al. 1996b, Findley et al. 1999, Juniper et al. 2000, Findley 1995, Ayalon et al. 2009). This greater variability appears to be maintained following CPAP treatment (Findley et al. 1989, Hack et al. 2001).

With large individual difference it is important to find out what the predictor of driving impairment is. So far this has not been achieved, ESS, AHI and MWT have all been unsuccessful at consistently predicting poor task performance (Mazza et al. 2005, Kingshott et al. 1998, Orth et al. 2005, Sagaspe et al. 2007b, Turkington et al. 2001).

Many of the studies mentioned use short duration driving performance tasks. It is therefore not known if the same variability cross over in performance level with controls will be apparent during a long duration driving task or in those OSA participants treated for a long period of time.

Hypotheses addressed in Chapter 10

To test the hypothesis that there will be great individual difference in OSA CPAP compliant participants driver performance at a driving simulator task as reflected by lane deviation incidents in comparison to controls after sleep restriction to 5h.

To test the hypothesis that those OSA CPAP compliant participants with greater vulnerability to sleep restriction will have impaired driver performance at a driving simulator task as reflected by lane deviation incidents, time to first incident, greater subjective and EEG sleepiness in comparison to OSA CPAP compliant participants not vulnerable to sleep restriction.

To test the hypothesis that those OSA CPAP compliant participants who are older and those with higher ESS will have greater impaired driver performance at a driving simulator task.

To test the hypothesis that in those OSA CPAP compliant participants who have greater vulnerability to sleep restriction there will be no difference in insight into

sleepiness than those who are not vulnerable, as reflected by subjective score at first major incident.

AIM 6: To evaluate the ability of OSA-CPAP compliant patients at a hazard perception test specifically related to driving compared with healthy controls.

The literature shows that experienced drivers perform better at hazard perception tests than inexperienced drivers (Smith et al. 2009), with age and annual mileage being strong predictors of hazard perception test performance (Grayson et al. 2002).

Hazard perception will be presented as a novel task for all participants. Untreated OSA participants have been reported to have poorer cognitive task performance on initial exposure to a task (Rouleau et al. 2002); it is not known if this is still the cases when treated with CPAP.

Hazard perception is cognitively demanding (Horswill et al. 2004, Smith et al. 2009). OSA patients have been shown to be at greater risk of RTI (Ellen et al. 2006) and to have reduced cognitive function (Mathieu et al. 2008). It is therefore possible that one factor causing the increased RTI risk in OSA patients is poor hazard perception.

Hypotheses addressed in Chapter 11

To test the hypothesis that OSA CPAP compliant participants will show no difference in hazard perception performance at a computer based task compared with controls, following a normal treated night's sleep, as reflected by test score and pass rate.

To test the hypothesis that ESS and Age will be negatively correlated with hazard perception score in both OSA CPAP compliant participants and controls.

To test the hypothesis that driving experience will be positively correlated with hazard perception score in both OSA CPAP compliant participants and controls.

AIM 7: To evaluate the choice of countermeasure to driver sleepiness in two groups susceptible to driver sleepiness, HGV drivers and OSA drivers.

The literature shows that in general people have reported good awareness of the dangers of driver sleepiness and generally good knowledge of effective countermeasures, however, despite this knowledge appropriate measures are not necessarily utilised (Nordbakke et al. 2007, Anund et al. 2008). The only similar UK study identified was conducted prior to the change in advice for sleepy drivers in the UK Highway Code, the survey results for “choice of countermeasure” reflected the advice published at the time (Maycock 1996).

The UK Highway Code currently offers good advice in dealing with driver sleepiness stating to take a break every 2 hours and if a driver feels sleepy to stop for a caffeinated drink and a nap, see Figure 1.3-1. Prior to 1999 stopping to stretch legs was advised. All new drivers in the UK are required to be familiar with the Highway Code; however, experienced drivers are required to keep up to date on their own volition. It is possible therefore, that drivers passing their test before 1999 would choose to stretch their legs if they felt sleepy while driving as this was the advice at the time.

As a subgroup, professional drivers and OSA may be more likely to experience driver sleepiness than control car licence holders. As these groups may have actively sought out advice on driver sleepiness countermeasures or received it from their employer or doctor, which may result in making effective choices.

Hypotheses addressed in Chapter 12

To test the hypothesis that HGV and OSA drivers will be more likely to choose appropriate countermeasures to driver sleepiness than controls.

To test the hypothesis that participants who have prior experience of falling asleep at the wheel will be more likely to choose appropriate countermeasures than those that have not.

To test the hypothesis that the countermeasures listed in the highway code (caffeine, nap and break from driving every 2h) will be most popular for all respondents.

To test the hypothesis that OSA CPAP treated participants will be more likely to identify driver sleepiness as a problem than controls.

CHAPTER TWO

THE PROBLEM IN CONTEXT: A SURVEY OF HEAVY GOODS VEHICLE DRIVERS

2.1 Introduction

Recently the media have drawn attention to HGV drivers falling asleep at the wheel who have OSA or are later diagnosed with OSA. Awareness in this topic area may suggest that HGV drivers are a main problem group for OSA. The stereotype of a HGV driver is one who is overweight and sedentary. If this is true it is suggestive of a sub-population likely to have greater risk of OSA than the general population. Due to the nature of the job these drivers spend a lot of time on the road covering many miles, thus it could be hypothesised that there is an increased risk of an undiagnosed OSA srRTI in this sub-group of the population. The damage done by HGVs has greater consequences than a car if the driver falls asleep due to the vast difference in the mass of the vehicle. As detailed in chapter one, untreated OSA drivers appear to be at a greater risk on the roads than healthy people. Therefore, HGV drivers are an important research group as the prevalence of undiagnosed OSA may be higher in HGV drivers than in the general population.

2.1.1 Key points from the literature review

A comprehensive literature review of HGV drivers and OSA can be found in section 1.4.3; the main points are highlighted here.

Studies of HGV drivers tend to focus either on looking for predictors of driver sleepiness; work demands, personal health, quality of prior sleep, OSA or recording an overview of HGV drivers characteristics; age, average hours driven.

Overall, existing research suggests that driver sleepiness is a problem to HGV drivers. It can be exacerbated by hours spent driving, lack of quality sleep, inadequate rest and sleep disorders. OSA has been shown to be more prevalent in HGV driver populations than in the general population (Stoohs et al. 1995, Carter et al. 2003, Gurubhagavatula et al. 2004, Canani et al. 2005). However, results can be conflicting as some studies use more robust assumptions for undiagnosed OSA than others, as it is not cost effective to screen every driver using PSG.

Although there is a growing body of international research in OSA and HGV drivers only two studies have been carried out in the UK; one which was 15 years ago and

required the investigators to estimate if they thought participants were obese, rather than objective measures and the other was conducted by a CPAP manufacturer.

2.1.2 Research Aim and Hypotheses

AIM : To evaluate the prevalence of undiagnosed OSA in HGV drivers on UK roads.

Hypotheses :

To test the hypothesis that undiagnosed OSA will be prevalent in HGV drivers on UK roads.

To test the hypothesis that OSA risk factors and symptoms can be used to predict self reported likelihood of falling asleep at the wheel in HGV drivers on UK roads.

To test the hypothesis that those with suspected OSA will have greater EDS and fall asleep incidents.

To test the hypothesis that high ESS will be associated with reports of falling asleep at the wheel and risk factors of OSA.

To test the hypothesis that OSA symptoms and risk factors will be of greater prevalence than in the general population.

2.2 Methodology

Study design: Cross sectional questionnaire.

Setting: A UK HGV rest stop;

“J23 Truck Stop” Junction 23 Lorry Park Ltd, Ashby Road, Shepshed, Loughborough, Leicestershire, LE12 9BS

The HGV stop is a safe place for drivers to park and spend their break or to stop over night, facilities include a café and bar. Two investigators (the author and one other) were based in the café between 6pm and 9pm (the busiest period) over several weeks in June 2009.

2.2.1 Participants

148 HGV drivers completed the questionnaire, average age 47.25 years ranging from 21 to 68 years. All participants were male.

2.2.2 Protocol

Investigators set up anthropometric measurement apparatus in a quiet corner of the café. The investigators approached participants in the café, either after they had finished eating or while they were waiting for their food to arrive. An explanation of the purpose of the study was given to all participants before completing the questionnaire. Questionnaires were self-administered but the interviewers were present to answer questions if they arose. The only inclusion criterion was that participants had a HGV licence and were willing to take part. This was regardless of any other variables such as age, race or sex etc. The main reason given for drivers not participating was that they did not have enough time to complete it.

92 participants agreed to the anthropometric measurements being taken, 56 participants provided an estimation of their own weight, height and collar size, all but one volunteered an estimation of each measurement.

This study was approved by the Loughborough University Ethics Committee.

2.2.3 Measures

Three categories of measures were taken.

1. Anthropometric measurements
2. Questionnaire
3. Epworth sleepiness scale

Anthropometric measurements

Collar size and BMI are indicators of risk of OSA. People who have a BMI over 28 and a collar size greater than 43cm (men) are at greater risk of having undiagnosed OSA (NHS 2009). The below measures were taken from the HGV study population to assess prevalence of OSA risk.

Height and weight measures can be used calculate BMI using the following formula.

$$\text{BMI} = \frac{\text{weight in kilograms}}{\text{height in meters}^2}$$

(kg/m²)

BMI is a widely used calculation to assess for obesity, as it assesses weight independently of height (Deurenberg et al. 2007). A BMI of 25 kg/m² is the overweight threshold, with obesity being classified from 30 kg/m².

Height: This was recorded using a portable height measure attached to the wall. Participants were asked to remove their shoes and stand with their backs to the wall while the investigator took a height reading.

Weight: With shoes off, participants were asked to stand on portable scales (Hanson). The portable scales were accurate to within 0.6 kg. No adjustments were made for clothing. Clothing was fairly constant with participants often wearing jeans and a T-shirt. It is expected this clothing would weigh approximately 1.5 kg.

Height and weight measures were used by the investigator to calculate BMI.

Collar size: A standard material tape measure was passed around the neck of each participant; the investigator recorded the measurement in centimetres.

Questionnaire

The questionnaire comprised of 18 questions over two pages. The questions were in 4 main themes. The full questionnaire can be seen in appendix 1.

- Those relating to the professional information (Q 1, 2, 3, 10, 11)
Drivers were asked how long they had held a HGV licence, how many hours they drove for a week, how many miles they covered a year and how long they would drive for before taking a break.
- Those identifying risk factors or symptoms of OSA (Q 4, 5, 6, 7, 8, 18)
This included declaring previous diagnosis with OSA, smoking, caffeine consumption and if bed partners report any signs of OSA during sleep i.e. snoring or witnessed apnoeas.

- Those relating to sleep habits (Q 9, 16, 17)
These included information on napping, sleep onset latency and total sleep time on work and non work days.
- Those relating to driver sleepiness (Q 12, 13, 14, 15)
Drivers were asked had they ever felt sleepy while driving or if they had fallen asleep at the wheel. They were also asked if they felt being drowsy whilst driving was a problem and what countermeasures they would take to avoid this. These questions will be discussed in chapter 12.

Questionnaires were self administered and returned immediately to the investigator. The majority of the questions had set answers with tick boxes, this reduced the time taken to complete the questionnaire.

For the purpose of this study the following will be accepted as risk factors of OSA, as detailed by the NHS (NHS 2009):

- Male sex
- Obesity
- Aged over 40
- Neck circumference of 43 cm or more
- Smoking (suspected risk factor)

For the purpose of the current study the following will be recognised as being associated with OSA

- Feeling excessively sleepy during the day (ESS 12 or over)
- Having to drink caffeine often with the sole purpose to remain alert
- Having a bed partner reporting witnessed apnoeas (either choking or holding breath)
- Having a bed partner report frequent loud snoring (suspected risk factor)

Questions relating to countermeasures to driver sleepiness will be discussed in chapter 12.

Epworth Sleepiness Scale

The Epworth Sleepiness Scale (ESS) (Johns 2000a) is a widely used and validated eight item self rating scale. Participants indicate the probability of them falling asleep under different set circumstances, see appendix 2. The resulting scores are totalled with a range from 0 to 24. A score of below 10 is considered normal. Any participant scoring 12 or higher is considered to have some degree of excessive daytime sleepiness (EDS).

2.2.4 Statistical analysis

Analysis was completed using Statistical Package for Social Science (SPSS 16.02 for Windows, Rel 10/4/08. Chicago: SPSS Inc). Results are expressed as mean \pm standard deviation or as percentages.

Chi-squared tests were used to assess for association between categorical data. In all cases the assumptions of independence of data and expected frequencies being about 5 were met. In the event of a significant Chi-squared result the odds ratio was calculated by hand and reported.

Spearman's Rho was used to identify any significant correlations between risk factors of OSA and the ESS (scale data).

2.3 Results

2.3.1 Prevalence of possible undiagnosed OSA

Hypotheses:

To test the hypothesis that OSA risk factors and symptoms can be used to predict self reported likelihood of falling asleep at the wheel in HGV drivers on UK roads.

To test the hypothesis that those with suspected OSA will have greater EDS and fall asleep incidents.

9.46% of the study population are suspected of having OSA, 2.7% of the study population reported previous diagnosis of OSA. The main criteria for suspected OSA was bed partner reports of holding breath or choking while asleep, 7.43% of participants fit this criteria. Additionally participants were suspected of having OSA if

they matched all of the risk criteria; ESS \geq 12, obesity, collar size \geq 43 cm, aged over 40 years and occasional or frequent snoring, 2.03% of participants matched these criteria.

43.86% of the suspected OSA cases consented to anthropometric measures being taken. Average age of these participants was 46.5 years with 35.71% of them under the age of required regular medicals (Figure 2.3-1). 71.43% were obese, with only one person in the normal weight category (Figure 2.3-2). All participants who consented to the anthropometric measurements were obese. 21.43% had fallen asleep at the wheel (Figure 2.3-3) with 57.14% having EDS (Figure 2.3-104).

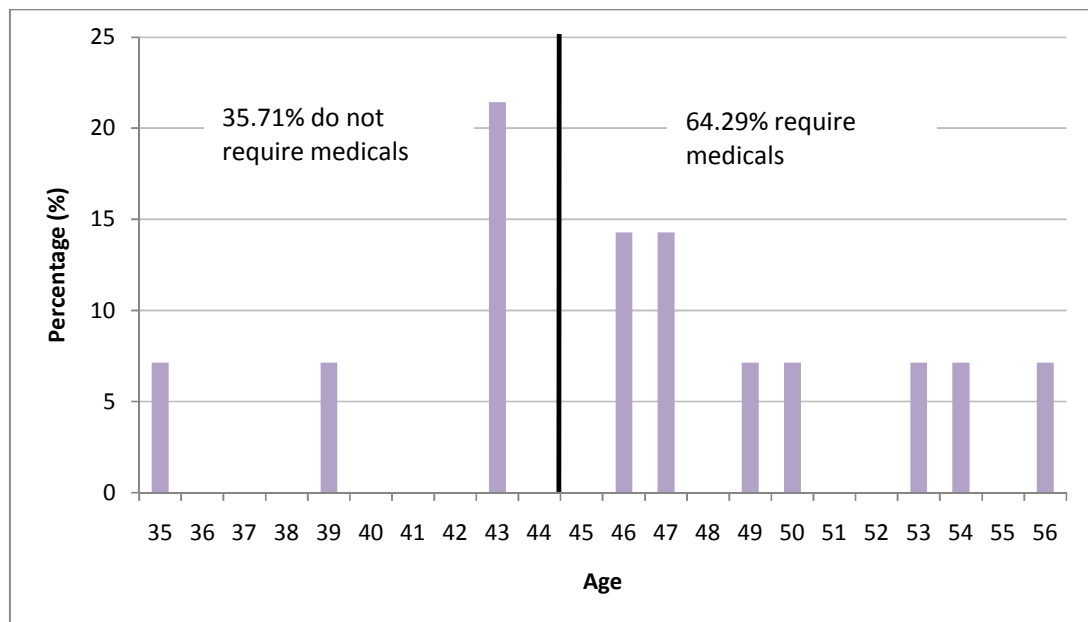


Figure 2.3-1 Age distribution of participants with suspected OSA

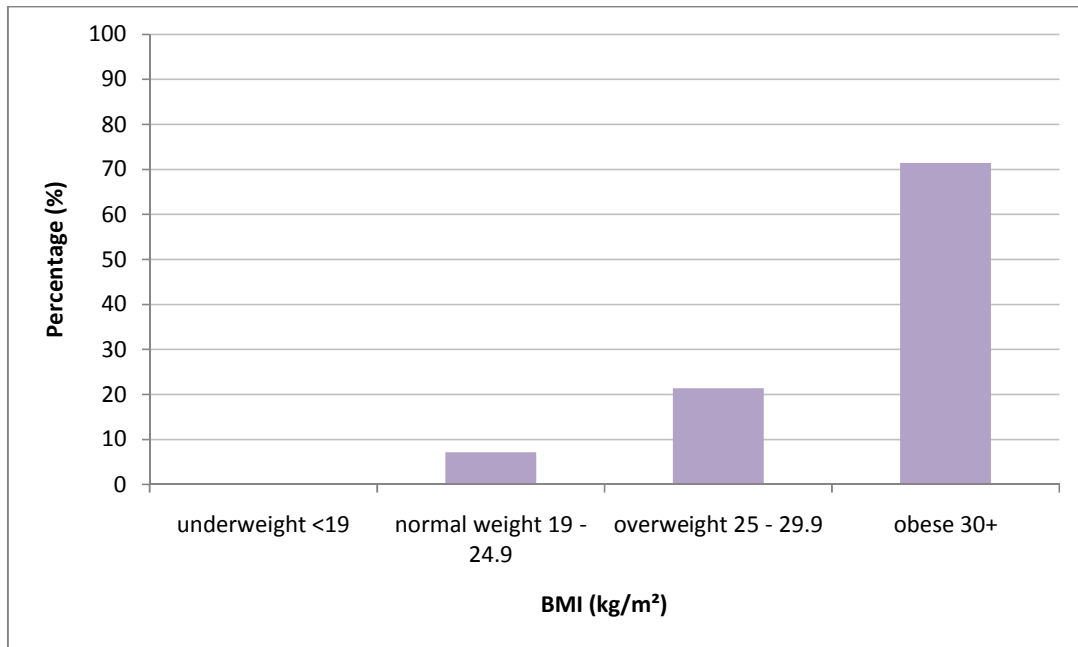


Figure 2.3-2 BMI classification of participants with suspected OSA

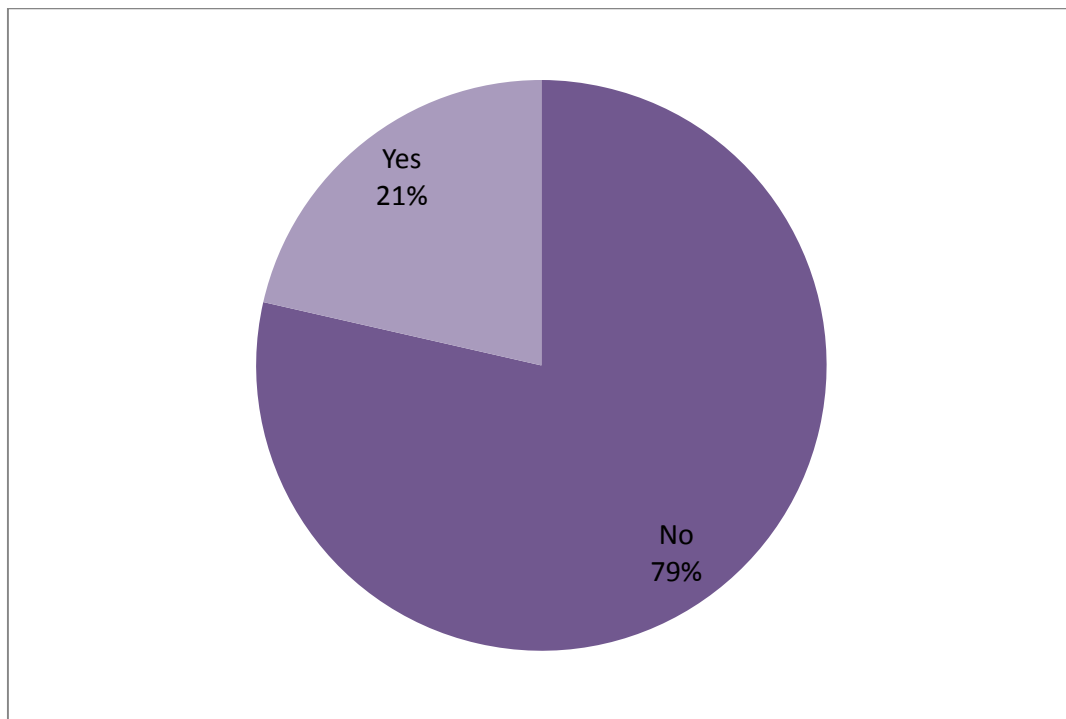


Figure 2.3-3 Reports of falling asleep at the wheel for participants with suspected OSA

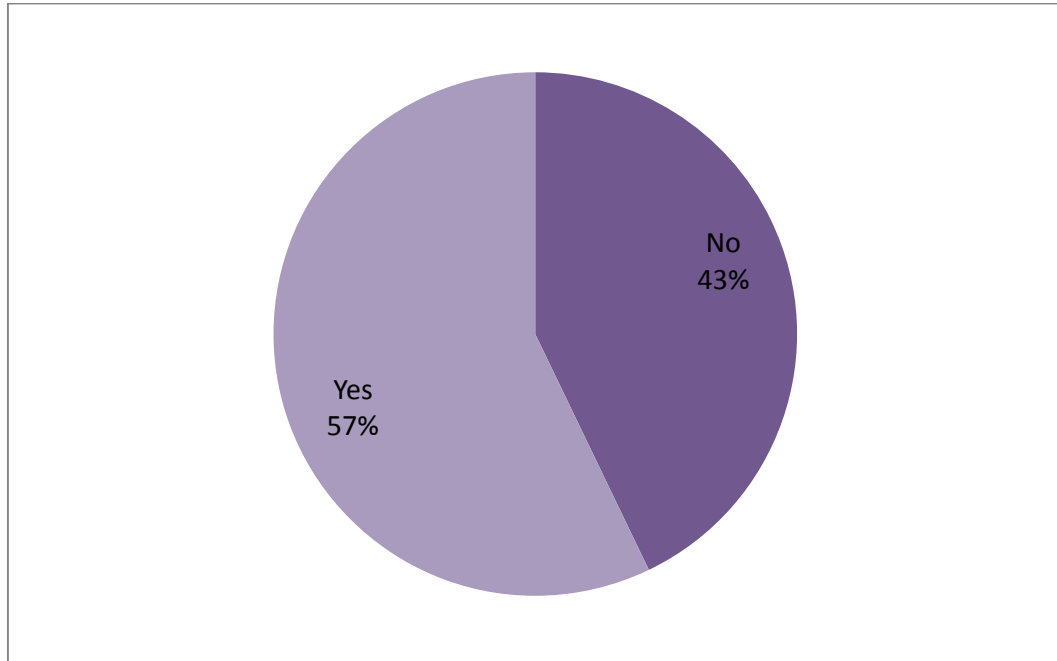


Figure 2.3-4 Excessive daytime sleepiness in participants with suspected OSA

Chi-squared test compared characteristics of the suspected cases with the rest of the study population, see Table 2.3-1. The only significant finding was for EDS where 57.1% of those with suspected OSA had EDS compared to 8.3% of those who were not suspected of having OSA. Based on the odds ratio, the odds of having EDS are 14.78 times higher for the people with suspected OSA.

	Chi-Squared value	Degrees of freedom	significance
BMI classification	3.641	2	0.162
Age ≥40 yrs	0.088	1	0.767
Neck ≥ 43 cm	1.587	1	0.208
Smoker	2.671	1	0.102
ESS ≥ 12	26.638	1	0.000*
Fallen asleep at the wheel	0.089	1	0.766

Table 2.3-1 Chi-squared results for those who reported apnoeas (* denotes significance)

2.3.2 Prevalence of OSA risk factors and symptoms in the whole study population

Hypotheses:

To test the hypothesis that undiagnosed OSA will be prevalent in HGV drivers on UK roads.

In the total sample all participants were male, 46.62% were obese, 82.43% were aged over 40, 41.89 % had a neck circumference of 43 cm or more and 31.08% were smokers, see Figure 2.3-5, Figure 2.3-6, Figure 2.3-7 and Figure 2.3-8. These are all risk factors which could contribute to OSA.

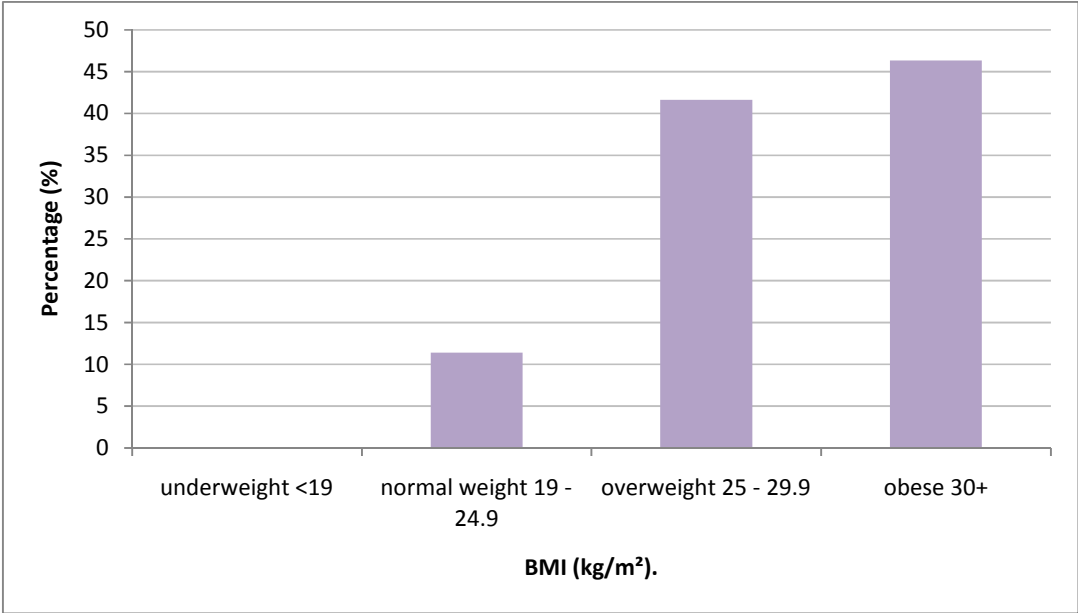


Figure 2.3-5 BMI classifications of the total study population

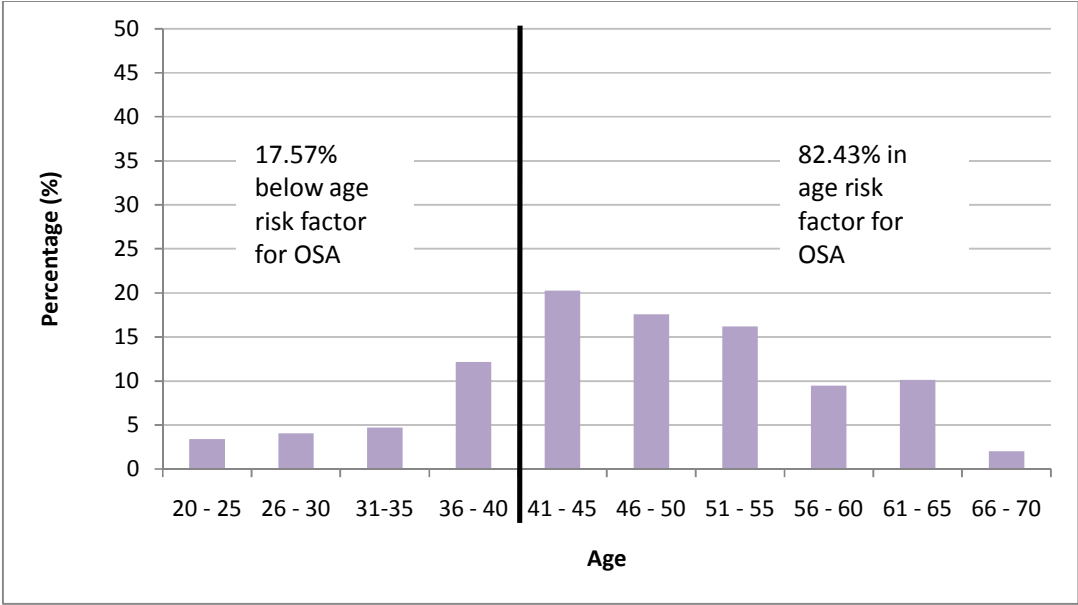


Figure 2.3-6 Age distribution of the total study population

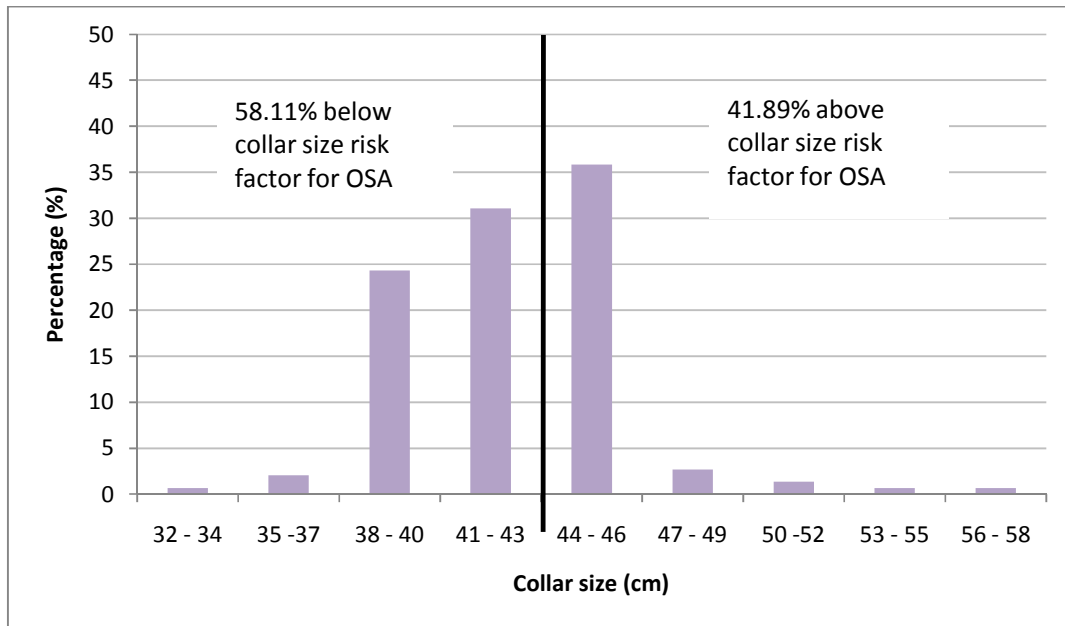


Figure 2.3-7 Collar size distribution of the total study population

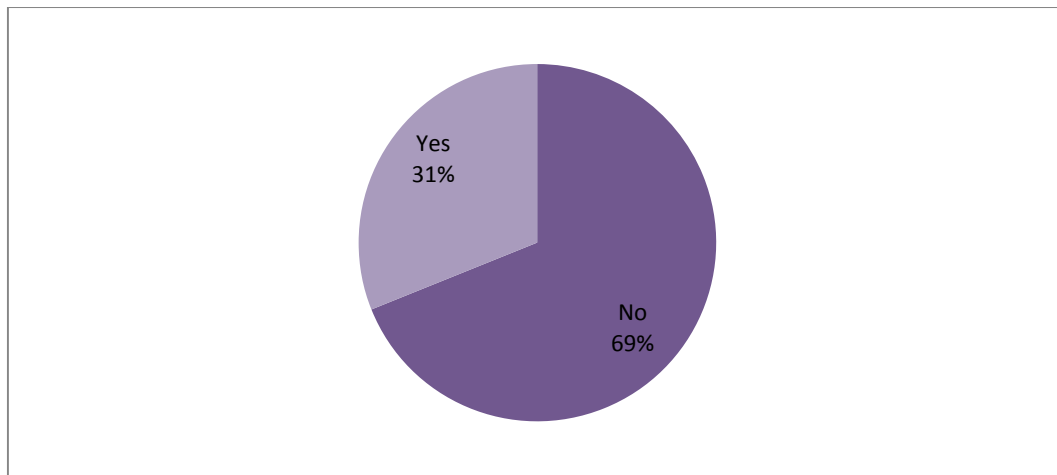


Figure 2.3-8 Percent of smokers in the total study population

22.3% of participants had an ESS score of 10 or over. An ESS of 10 indicates there may be some cause for concern. 12.85% of participants had an ESS of 12 or over, therefore these people have excessive daytime sleepiness (EDS), Figure 2.3-10. Reliance on caffeine to stay alert was not found and 72.11% said they never drink a caffeine content drink with the sole purpose to remain alert, Figure 2.3-11. 14.86% reported frequent loud snoring and 41.89% reported occasional snoring. 7.43% reported a bed partner witnessing an apnoea (holding breath or choking in sleep). None of the apnoea

witness reports were from those already diagnosed with OSA and who were presumably being treated at the time of the survey, see Figure 2.3-9.

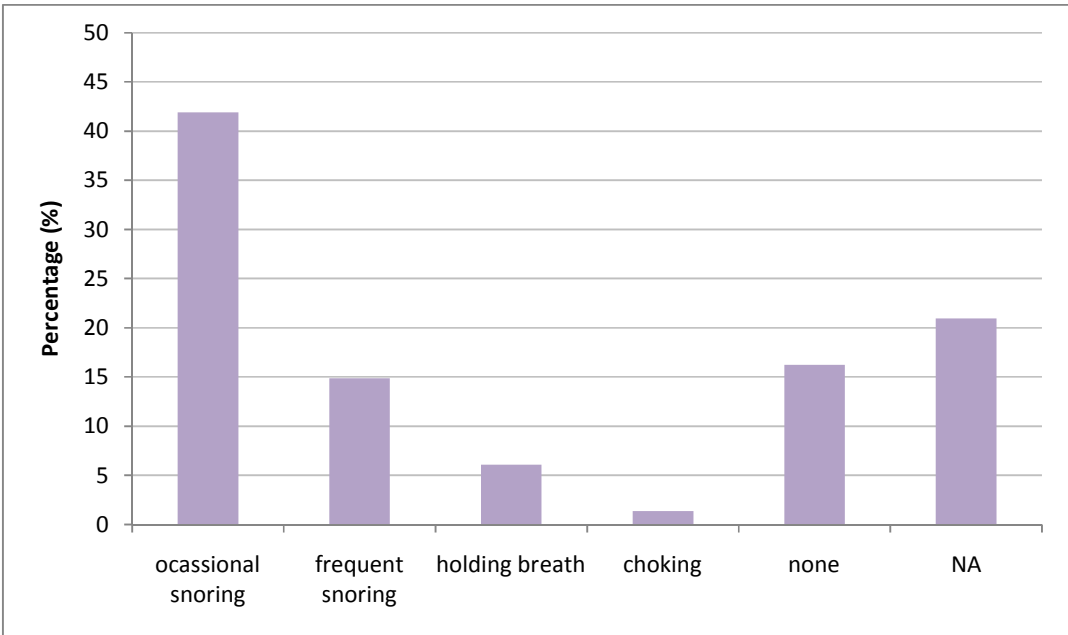


Figure 2.3-9 Reports from bed partners of the whole study population

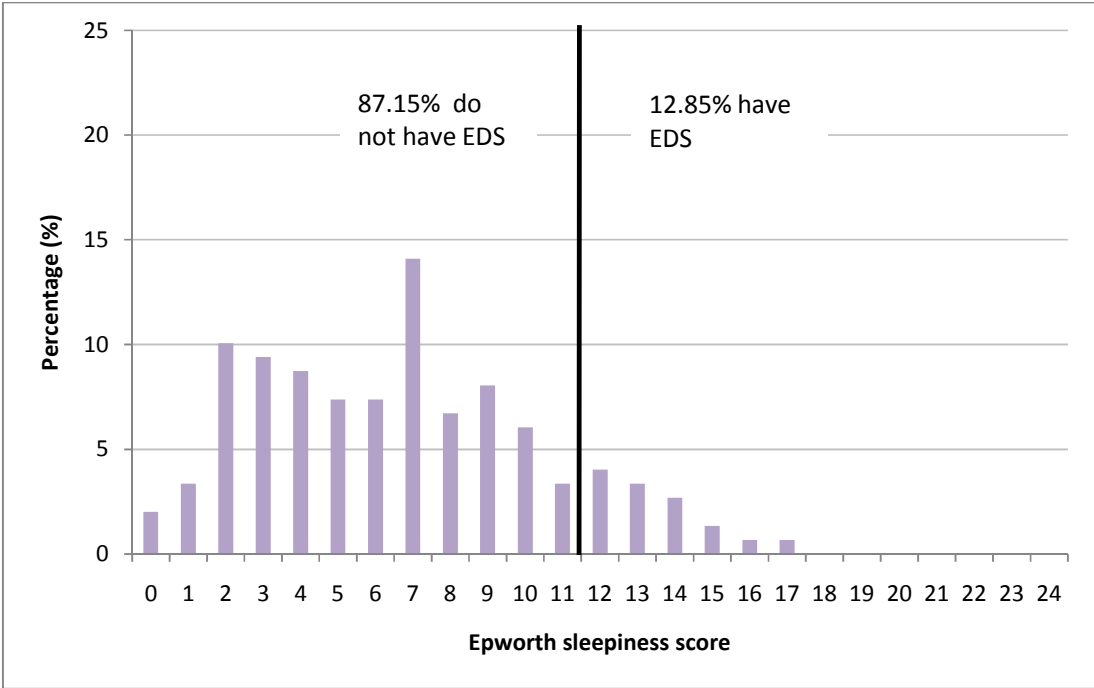


Figure 2.3-10 ESS distribution and Excessive daytime sleepiness of the whole study population

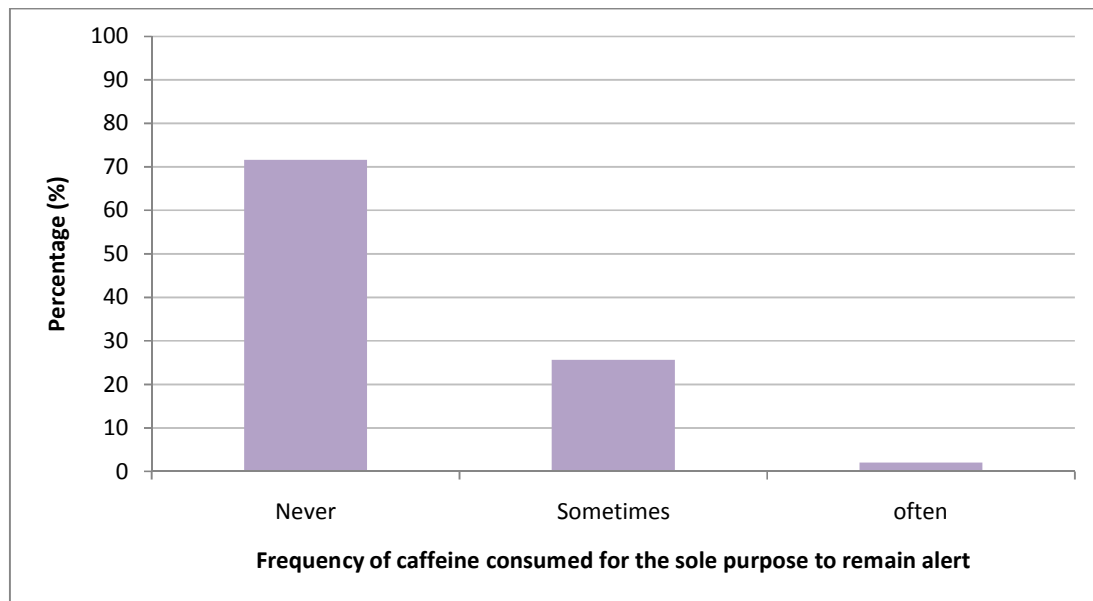


Figure 2.3-11 Graph to show how often caffeine is used with the sole purpose to remain alert

2.3.3 Characteristics of the study sample and professional information

Hypotheses: To test the hypothesis that undiagnosed OSA will be prevalent in HGV drivers on UK roads.

On average, participants had held a HGV licence for 20.84 years (s.d. 11.12). Average BMI was 29.93 kg/m² (s.d. 4.64) and ranged from 20.60 kg/m² to 47.90 kg/m². 88.5% of participants were overweight or obese. Average collar size was 42.13 cm (s.d. 3.23), 40.82% of participants having a collar size of 43 cm or more. They drove on average 43.07 (s.d. 7.15) hours a week, (3 participants drove less than 30 hours per week) covering an average of 85,160 miles a year (s.d.40.70). Participant characteristics are detailed in Table 2.3-2.

	Mean	S.d.
Age (years)	47.25	10.30
Years held group 2 licence	20.84	11.12
BMI (kg/m²)	29.93	4.64
Collar size (cm)	42.13	3.23
Hours driven per week	43.07	7.15
Miles driven per year	85 160	40 700

Table 2.3-2 Participant characteristics

68.24% of participants reported no difference in the amount of time they actually drove for and how long they would be comfortable driving for. 6.08% said they drove

for longer than they were happy to and 25.68% would be happy to drive for longer than they currently do, see Figure 2.3-12. 33.11% of people slept for the same amount of time on work and non work nights. 8.58% slept for longer on work nights than non work nights. Of the 58.12% getting less sleep than they would on a non work night the average sleep loss was 2.02 hours.

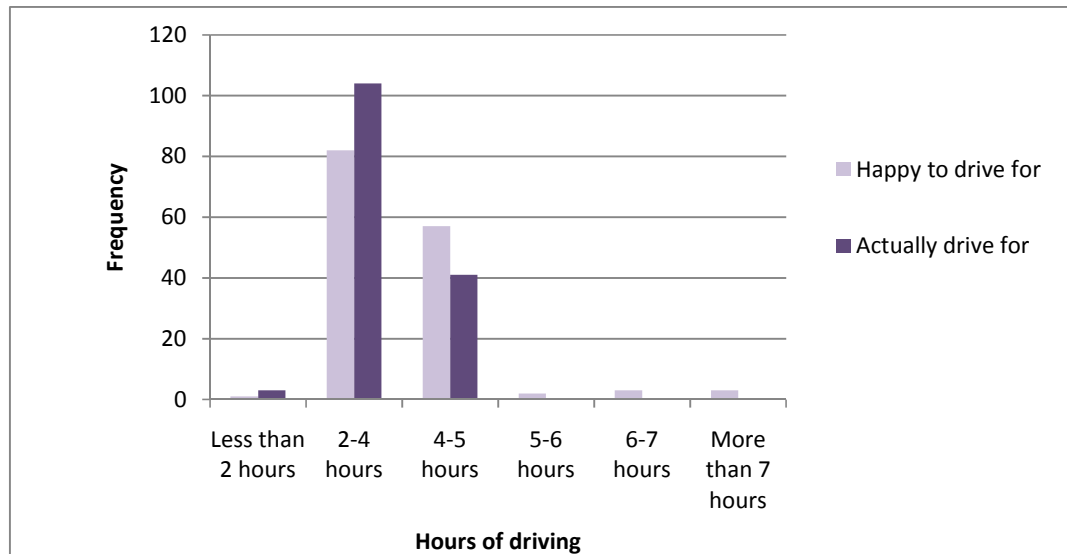


Figure 2.3-12 Number of hours participants would be happy to drive for before taking a break and number of hours participants actually drive for before taking a break

2.3.4 Associations falling asleep at the wheel and EDS

Hypotheses:

To test the hypothesis that OSA risk factors and symptoms can be used to predict self reported likelihood of falling asleep at the wheel in HGV drivers on UK roads.

To test the hypothesis that high ESS will be associated with reports of falling asleep at the wheel and risk factors of OSA.

BMI classification, age over 40 years, neck circumference of 43 cm or over, smoking and having EDS (ESS of 12 or over) were compared between those reporting having fallen asleep at the wheel and those not having fallen asleep at the wheel using Chi-squared test. None were significantly different, see Table 2.3-3 Chi-squared results with having fallen asleep at the wheel, see Table 2.3-3.

	Chi-Squared value	Degrees of freedom	significance
BMI classification	0.804	2	0.669
Age ≥40 yrs	0.167	1	0.683
Neck ≥ 43 cm	2.147	1	0.143
Smoker	0.597	1	0.440
ESS ≥ 12	1.001	1	0.317

Table 2.3-3 Chi-squared results with having fallen asleep at the wheel

BMI classification, age over 40 years and neck circumference of 43 cm or over were compared between those having EDS and not having EDS using Chi-squared test. Only smoking showed a significant relationship with EDS. 23.9% of smokers scored an ESS suggestive of EDS compared to 7.8% of non smokers.

	Chi-Squared value	Degrees of freedom	significance
BMI classification	0.319	2	0.853
Age ≥40 yrs	1.379	1	0.240
Neck ≥ 43 cm	0.388	1	0.533
Smoker	7.316	1	0.007*

Table 2.3-4 Chi-squared results with having excessive daytime sleepiness (* denotes statistical significance)

2.3.5 Correlation between risk factors and ESS

Hypotheses:

To test the hypothesis that OSA risk factors and symptoms can be used to predict self reported likelihood of falling asleep at the wheel in HGV drivers on UK roads.

To test the hypothesis that high ESS will be associated with reports of falling asleep at the wheel and risk factors of OSA.

Using Spearman's Rho, BMI, age, collar size, weight, hours driven per week and miles driven per year were assessed for correlation to ESS. The only significant result was with age, this was a very slight negatively correlated.

	Spearman's rho	N	significance
BMI	0.700	148	0.199
Age ≥40 yrs	-0.171	148	0.019*
Neck ≥ 43 cm	0.108	147	0.096
Weight	0.110	147	0.092
Hours driven per week	-0.107	146	0.100
Miles driven per year	0.028	141	0.373

Table 2.3-5 Spearman's rho correlations to ESS (* denotes statistical significance)

2.3.6 Opinions on drivers sleepiness

62.56% reported having felt sleepy at some time whilst driving. 18.92% admitted having fallen asleep at the wheel, Figure 2.3-13. 12.84% of respondents didn't feel that driving whilst drowsy affects their ability to drive safely, Figure 2.3-14.

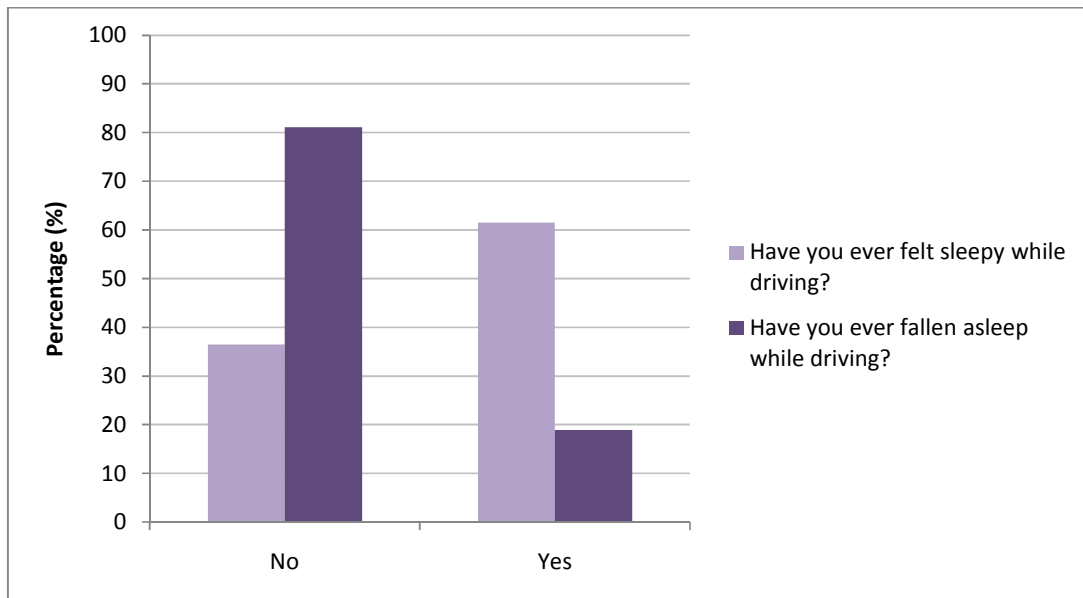


Figure 2.3-13 Percent of participants who have felt sleepy while driving and fallen asleep while driving

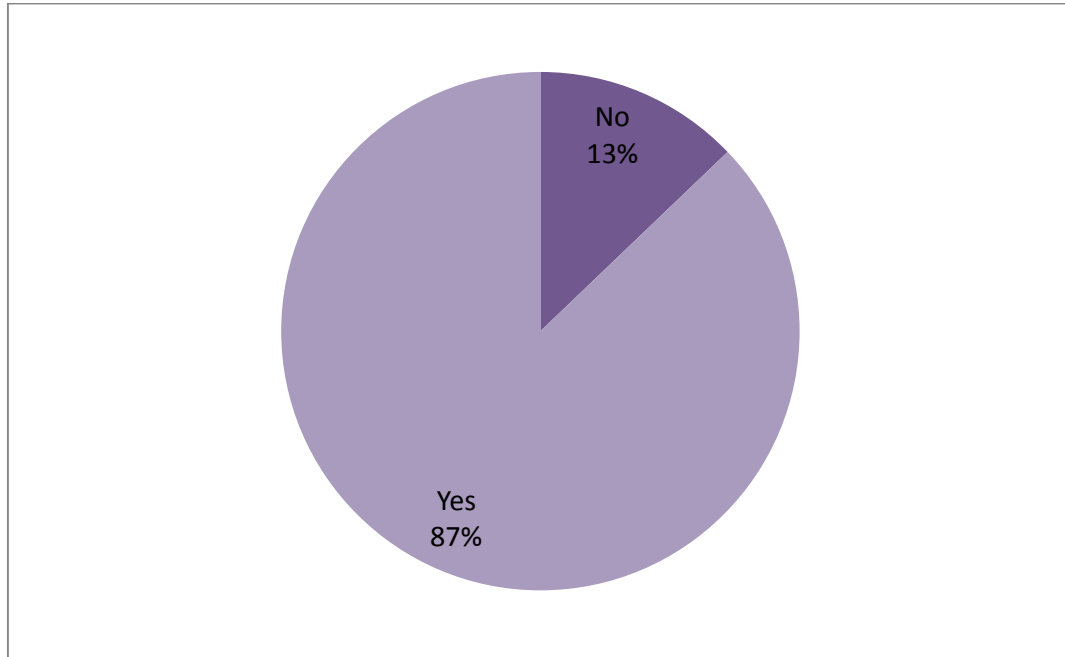


Figure 2.3-14 Percept split of opinion on whether driving while drowsy affects ability to drive safely

2.3.7 Comparison of HGV results to population statistics

Hypotheses:

To test the hypothesis that OSA symptoms and risk factors will be of greater prevalence than in the general population.

	Study population	General public
Male	100%	49.06% a
Obesity prevalence	46.62%	23.1% b
Aged over 40	82.43%	56.14% c
Average neck circumference	42.13 cm	38 cm d
Smoking prevalence	31.08%	21% e
Average ESS	6.7	4.6 f
Bed partner reporting witnessed apnoeas	7.43%	3.8% g
Bed partner reporting snoring	56.75%	40.3% g

Table 2.3-6 Comparison of HGV results and population statistics

a UK population as a whole 2007 (Office for National Statistics 2007)

b UK male adult population 2005 (NHS Information Centre 2006)

c UK adult males (aged 21 – 65) 2007 (Office for National Statistics 2007)

d UK male general population (Martin et al. 1997)

e UK total population aged ≥ 16 2007 (National Statistics Online 2009)

f Australian 1997 general population (Johns et al. 1997)

g UK general population telephone interview (Ohayon et al. 1997)

Table 2.3-6 compares the prevalence of OSA risk factors in the HGV driver sample to the general population. Data for the general population were obtained from the office of national statistics where possible. Where this was not possible relevant published journal articles have been used. Of the adult male population aged 21 – 65 in the UK 56.14% are aged over 40 year olds (Office for National Statistics 2007), in the HGV sample 82.43% are aged 40 – 65 years. Smoking rates are also higher than the general public. ESS is found to be on average 2.1 higher than a sample of the general population. 56.75% of the HGV population reported snoring compared to 40.3% of the general population (Ohayon et al. 1997). 7.43% of HGV drivers reported apnoeas in comparison to 3.8% of the general public (Ohayon et al. 1997).

2.4 Discussion

This is the most recent study of its kind that we know of in the UK; similar studies have been conducted in the USA, Brazil, Australia, France, New Zealand and Greece. Previous UK studies have been conducted by a CPAP company, creating a conflict of interest (Moylan 2005) and a survey in which investigators classified BMI categories without taking measurements (Maycock 1995).

A main aim of the current work was to identify what percentage of HGV drivers in a sample study population have suspected OSA and to see how they differed to the rest of the study population. 9.46% were identified as having suspected OSA. The suspected OSA cases are much more than the estimated 4% prevalence in the general male population (Young et al. 1997), although less than in a Swedish and Australian studies using overnight PSG in HGV drivers at 17% and 15.8% respectively (Carter et al. 2003, Howard et al. 2004). The main basis for suspicion of OSA in the current study was reports of witnessed apnoeas by bed partners; however, 20.27% of drivers did not have a bed partner so cases of suspected OSA may be under reported. 2.70% of the total sample reported prior diagnosis of OSA, as they were all currently employed as

professional HGV drivers and did not show EDS it is assumed they were all successfully treated.

Those with suspected OSA were significantly more likely to be suffering from EDS than the remainder of the study population, the odds of having EDS being 14.78 times higher for this subgroup than the study population as a whole. Elevated EDS puts a person at greater risk of falling asleep at the wheel and suggests they should ideally be tested for OSA. Of those participants with suspected OSA, 35.7% were younger than 45 years old so will not yet require a medical examination to retain their licence. The remainder were aged between 45 and 65 years so were subject to medical examinations every 5 years. It is possible that the current required medicals are not picking up all cases of OSA.

One of the key risk factors for OSA is obesity, 88.5% of the study population were found to be either over-weight or obese, this is comparable with Gurubhagavatula et al. (2004) a USA study which found a prevalence of 88% overweight or obese HGV drivers. Additionally, overweight men have been found likely to underestimate their weight (Kuchler et al. 2003) as a result it is probable that the BMI maybe artificially lower than it would have been if all participants consented to anthropometric measurements being taken.

Overall it has been found that there is a higher prevalence of risk factors and symptoms of OSA in a sample of HGV drives on UK roads, than in the general population. In comparison to the general public population statistics this sample of HGV drivers demonstrate a male dominated environment (Office for National Statistics 2007) with higher prevalence of obesity (NHS Information Centre 2006) and greater average neck circumference (Martin et al. 1997). EDS is a common symptom of OSA and although the average ESS for the HGV drivers surveyed was not at a critical level it is 2.1 higher than a sample of the general public (Johns et al 1997). Another common symptom of OSA is snoring and again this is more prevalent in HGV drivers than the general population (Ohayon et al. 1997), suggesting that OSA may be more prevalent in HGV drivers than the general public. However, not all snorers have OSA so this is only an indication of a likely higher prevalence. A more reliable indicator of OSA is

reports of witnessed apnoeas, which were reported almost twice as much as in a sample of the general population (Ohayon et al. 1997). The HGV driver population appears to be at greater risk of OSA than the general population.

From the survey completed none of the factors assessed were significantly associated with reports of drivers having falling asleep at the wheel. Smokers were significantly more likely to have an ESS \geq 12 than non smokers, but no other factors were significantly associated with EDS. It is not possible to know if one causes the other as smoking may result in greater daytime sleepiness or it is possible that individuals may decide to smoke because they are sleepy and nicotine, as a stimulant, increases their alertness.

Participants in the current study had an average age of 47.3 y which is older than found in similar studies in other countries where average age in late 30s is more common (Stoohs et al. 1995, Philip et al. 2002, Gurubhagavatula et al. 2004, Canani et al. 2005, Tzamalouka et al. 2005, Gander et al. 2006, Hanowski et al. 2007). Having an older HGV driving population in the UK may increase the number of HGV drivers suffering from OSA as the condition is more prevalent in those aged over 40.

The majority of participants were driving for the maximum time period allowed under EU law before taking a break. These truck drivers appeared generally happy with the requirements of the job and the majority were not unwilling to drive these hours, 25.68% even said they would be happy to drive for longer before taking a break. The average driving week was reported as 43.07 hours which is less than the 56 hours per week allowed by law (EU law).

In comparing self reported sleep time on work nights and non work nights almost 60% reported a difference. However, approximately 40% of those losing sleep only have an hour or less difference in sleep time between work and non work nights, so this is likely to have minimal impact. More worryingly approximately 13% those reporting sleep loss on work nights recorded a difference of 4 to 6 hours; this is a large difference in sleep time and may result in impairment at work.

HGV drivers cover approximately 81 489 miles more per year than the average car driver (comparing millage reports in the current study and car driving mileage (Department for Transport 2009). Additionally they appear to be at greater risk of OSA (as suggested by prevalence of symptoms and risk factors in this sample) than the general public. It is therefore very important that HGV drivers are able to recognise sleepiness as a hazard to driving and be able to take effective counter measures. The majority of the HGV drivers in this sample reported having felt sleepy whilst driving and the majority recognised that driving whilst drowsy could affect their ability to drive safely. However, 12.8% felt driving whilst drowsy did not affect their ability to drive safely and this was despite 36.8% of these drivers reporting that they had fallen asleep at the wheel. It is possible that they have this response because they have fallen asleep while driving in the past and there have been no consequences.

18.9% of drivers admitted to having fallen asleep at the wheel in the past, this is a lower percentage than in some other studies which have found 22% (Canani et al. 2005), 23% (Tzamalouka et al. 2005), and 47.1% (McCartt et al. 2000). However, admitting to falling asleep at the wheel is admitting to dangerous driving and even though the questionnaire is anonymous some drivers may have been unwilling to admit if they had fallen asleep at the wheel.

This survey has shown that prevalence of undiagnosed OSA in a sample of UK HGV drivers is potentially higher than in the general population. It suggests that there are HGV drivers who are driving long distances for prolonged periods of time whilst having undiagnosed OSA. This will predispose them to EDS which may increase the chance of them having an accident. Offering screening and treatment is likely not to be enough, the industry as a whole needs to show acceptance towards treated OSA drivers or people will not be willing to come forward and be tested. In order for the industry to be accepting it is important to know that the treatment is effective and that driving performance is equivalent to healthy drivers both at the onset of treatment and in the long term.

Screening for high risk factors of OSA then testing this subgroup of high risk drivers using PSG could be a cost effective way to identify patients (Gurubhagavatula et al.

2008). However, as we have found, drivers who are subject to medicals are still falling into the high risk group of suspected OSA. It is unclear if this is because GPs carrying out current medicals are not recognising the symptoms of OSA or that the frequency of medicals at five years is not sufficient.

Another problem is even if drivers are diagnosed with OSA it can be difficult to get them to accept and regularly use treatment. One USA study surveyed 456 HGV drivers and identified 53 as showing signs of OSA, these were all invited for PSG but only 20 turned up to be tested. All 20 had OSA but in a follow up only 1 patient reported using their treatment (Parks et al 2009). There is a problem with adherence to CPAP treatment for all OSA patients (Weaver et al. 2008) but the issue of unwillingness to seek help may be exacerbated by fear of losing their driving licence and job.

2.4.1 Limitations

The sample size of 148 is adequate for the purpose of this study, however there are 528, 000 licensed heavy goods vehicles in the UK, so to get a more detailed picture of the HGV drivers in the UK, a larger sample size would be required. In order to achieve this, more than one survey site would be needed. The current study was limited to one local survey site and data was collected over several weeks. It was noted that by the end of the data collection investigators were encountering customers of the café who had already completed the survey on a previous occasion. Encompassing more HGV stops would allow a larger sample size to be collected; unfortunately the current study did not have the resources to do this. Another way to reach a larger potential study population would be to conduct a postal survey. However, this would mean that anthropometric measurements would not be taken by the investigator and results would be reliant on accurate reports from participants.

The most feasible way to get contact details of large numbers of HGV drivers would be through large national employers. However, even if a questionnaire remained anonymous people may be unwilling to answer questions such as “Have you fallen asleep at the wheel?” honestly if they think that their employer may find out. A postal survey would allow participants to fill the questionnaire in at a time appropriate to them and would not impose on their meal time. Conducting research in a café may

also bias the type of person who fills in the survey as by nature of a truck stop anyone in it has “stopped” driving, those wishing to keep going will not be represented. Also any drivers who had brought their own meal may have been eating in their HGV and will not have been represented.

The questionnaire was designed to take 5 minutes to complete in the hope that a large number of people would complete it. More accurate identification of suspected OSA could have been obtained by using additional questionnaires specifically designed for diagnosis of OSA. However, because drivers were there to eat, the focus was on keeping the survey short. An area of questioning not included was the pattern of working hours; it is not possible to tell from this survey if drivers worked at night or during the day. This may have an effect as sleep-related crashes are more likely to occur in the early hours of the morning than at any other time (Horne et al. 1995). PSG recordings were not carried out so a conclusive diagnosis of how many drivers had OSA is not known. Due to time and cost this was not feasible to complete.

No questions were asked about drinks containing small amounts of caffeine such as tea and cola. In small quantities the amount of caffeine received in these drinks is not enough to promote alertness. It would have been useful to know if they had been consumed in quantities large enough that may have impacted alertness.

The ethnicity and country the driving licence was not recorded. UK drivers are subject to medical checks from the age of 45 but foreign drivers may not be. This meant it was not possible to distinguish if the OSA with suspected OSA had received a medical check or not.

2.5 Conclusions

- Almost 10% of the HGV population have suspected undiagnosed OSA. These suspected OSA sufferers have significantly more EDS than the rest of the study population.
- The UK HGV driving population appears to be slightly older than in other countries and over half are old enough to require medicals in order to maintain their licence.

- The HGV driver population has higher incidence of both risk factors and symptoms of OSA than the general public, suggesting that occurrence of OSA maybe higher in this subgroup than the population as a whole.
- The majority of HGV drivers have felt sleepy whilst they are driving
- No identifier of which drivers would have EDS or have fallen asleep at the wheel was identified.

2.6 Further work

The knowledge gained from this survey study provides a context for the problem of OSA and driver sleepiness on UK roads. As such it is important to determine if treated OSA drivers have any impairment compared to the general population. A driving simulator will be used so that this issue can be investigated further (chapters 3 – 10) in a safe environment.

Acknowledgements

Thank you to Carina McKnight for her assistance with the data collection from the HGV drivers reported in this chapter.

CHAPTER THREE

Methodology for driving simulator studies

The following chapter details the methodology for the driving simulator studies used to collect data presented in chapters 5 to 10. This chapter presents an overview of procedures applicable to recruiting participants; study protocol for both screening and test days; details of the driving simulator used and the different measures recorded. Specifics will be detailed in the relevant chapters.

3.1 The Driving Simulator

The driving simulator comprised of a Ford Fiesta car with a fixed base (Figure 3.1-1). A large screen was located in front of the car so that it could be viewed through the windscreen, with a road projected onto the screen. A video camera with infra-red light was positioned to the side of the car to film the driver's face. The camera could be seen by the driver but did not disrupt the view of the road. All mirrors in the car were blacked out. There was an unobtrusive microphone in the car to record participant's responses to the subjective sleepiness questions.

The steering, accelerator and brake were electronically connected to a computer system at the back of the lab, from which the road was generated. Changes in steering and speed were picked up by the computer which adjusted the position on the road accordingly.



Figure 3.1-1 Loughborough University Sleep Research Centre driving simulator

The road projected was a computer generated dual carriageway in the daytime, with a hard shoulder to the left and a central reservation in the middle (see Figure 3.1-2). Rumble strips were present either side of the carriageway resulting in a change of audio if they were driven on. The road generated had no sharp corners but had gentle bends; there were an equal number of gentle bends to the right as to the left. The road was designed so that it must be 'actively' driven; there were sufficient bends so that participants would not be able to stay in the left hand lane unless they were driving attentively. During the two hour drive three slow moving cars were presented in the left hand lane. Participants had to overtake the car then return to the left hand lane. The laboratory lights were switched off during testing.



Figure 3.1-2 Road view, seen by participants, showing a slow moving vehicle to be overtaken

During the drive the image from the video camera and the road as seen by the participant were recorded on to DVD with the road scene appearing in the top right hand corner (Figure 3.1-3). The recordings were later analysed to assess sleep-related incidents.



Figure 3.1-3 Freeze frame from a recording of a participant driving

A comparison of performance in this simulator with performance on a closed-circuit track in a dual controlled car following sleep restriction to 5 h demonstrated similar trends in driving performance and subjective sleepiness were found in both situations (Baulk 2002).

3.2 Participant Recruitment

As discussed in chapter 2 HGV drivers are a susceptible group to OSA and further research into their driving ability when treated for OSA is needed. However, the nature of simulator studies means that they are time consuming so it is unlikely that full time employed people would volunteer to take part, particularly HGV drivers who may often be away from home. A way of allowing HGV drivers to participate may have been to approach employers to ask for their drivers to be allowed to participate during work time. However, it was suspected that drivers would be unwilling to participate if their employers were involved for fear of jeopardising their jobs.

Due to the suspected restricted availability of HGV drivers, simulator studies will be carried out on members of the general driving public with a group 1 licence.

3.2.1 OSA participants

All participants were recruited from Leicester Sleep Apnoea Patients Association (LSAPA). When people are diagnosed with OSA at Leicester General Hospital they receive CPAP treatment and are invited to join LSAPA, a voluntary support network.

To maintain patient confidentiality letters detailing the study and questionnaires were sealed in unaddressed envelopes and delivered to LSAPA. The association mailed the letters to their members requesting completed questionnaire to be sent to the researchers. At the end of the questionnaire participants were invited to state if they would like to be contacted in regards to a driving simulator study.

170 recruitment letters were sent out, 103 completed questionnaires were returned, of which 70 people were interested in the simulator studies. 32 participants were invited in for screening following exclusion of 38 potential participants due to reports of ill health, driving less than three hours a week or living more than 30 miles from Loughborough University. 20 participants were selected for the final study.

It was desirable that the OSA study population were reflective of the responses received from the questionnaire sent to the LSAPA. Only 14% of LSAPA respondents were female, due to this small number and the findings in chapter 2 where no HGV drivers were female, it was decided that the final study population would be all male. The average age of the male questionnaire respondents was 63.64 years. In order for the study population to represent this group those aged below 50 and over 75 were excluded. The control group were then recruited to fit the same criteria.

3.2.2 Control Participants

To compare the 20 OSA participants a healthy control group of the same sex and similar age were recruited. Advertisements for control participants were put up in the form of posters at Loughborough University notice boards, local community centres, leisure centres, bowls clubs, local libraries, churches and the town hall. An advertisement was placed in a local newspaper and a news story about the simulator studies was published in the following edition. Finally letters were sent to the secretaries of 5 local Rotary Clubs.

Following these advertisements and a screening phone conversation to exclude people with ill health, driving less than 3 hours a week or living more than 30 miles from Loughborough University, 30 people agreed to attend a screening day.

3.3 Screening

For both the OSA and control participants initial screening was conducted by telephone to ensure potential participants were only invited to the laboratory screening day if they met the following inclusion criteria:

- Held a current UK driving licence
- Not a commercial driver
- Drove for at least three hours a week
- Lived no further than 30 miles from the university (Due to budget limitations, as taxis were to be provided)
- Self reported general health as good to excellent (not suffering from epilepsy or severe migraines which may be affected by the simulator)

- Male
- Aged 50 to 75

All participants were sent a participant information sheet (appendix 3) with details of the study prior to agreeing to participate.

The same screening day protocol (seen in Table 3.3-1) was observed for both OSA and control participants. As well as to exclude people who were not suitable for the study, screening also introduced the participant to the researcher and the simulator in order to reduce anxiety on the study days.

1000h – 1015h	Explanation of studies and completion of consent forms
1015h – 1100h	Completion of structured interview
1100h – 1110h	Anthropometric measures taken
1110h – 11130h	Hazard perception test completed
1130h – 1200h	Test drive of simulator

Table 3.3-1 Screening day schedule

During the screening day the studies were explained in full to participants and an informed consent form (appendix 4) was completed. A media consent form (appendix 5) was also completed stating whether or not participants agreed to their video or photograph being used for scientific or media purposes.

All participants were interviewed when they attended a screening day. The interviews were conducted in the form of a structured questionnaire; the investigator read the questions aloud to enable the participant to expand on the answers if they felt there was more to say than could be conveyed in the questionnaire tick boxes. The interview consisted of 39 questions for the OSA participants (appendix 6) and 27 questions for the control participants (appendix 7) taking 45 to 60 minutes to complete. This was followed by anthropometric measurements of height, weight and percentage body fat. Percentage body fat was calculated using TANITA body composition analyzer TBF-300.

Participants all completed a computer based hazard perception test (Driving Test Success 2007) designed to simulate the hazard perception test forming part of the current UK driving test. This test takes approximately 20 minutes to complete and consists of 14 video clips, requiring participants to press the mouse button as soon as they see a hazard in each clip. The test was explained to participants and they were

shown an example clip. The investigator remained in the room while participants completed the first clip to check that they understood the test. The investigator then left the room while participants completed the remaining video clips.

Finally a 30 min test drive in the simulator was completed by each participant. During the test drive the car was set up in the same manner as the study days with the exclusion of EEG recording. 10 cars were presented in order for participants to practice overtaking.

Participants were excluded from the main studies if they were found to have:

- Uncontrolled medical conditions
- Irregular sleep patterns
- Discomfort at driving the simulator
- A BMI over 28 (control participants only as this would put them in a high risk category for undiagnosed OSA)

3.4 Study Protocol

All studies were approved by Loughborough University Ethics Advisory Committee, and protocol established following advice from Dr C. Hanning, see appendix 7.

3.4.1 Sleep restriction study

The sleep restriction study consists of two study days, completed in a counter balanced design. These were:

1. Following normal sleep
2. Following sleep restriction to 5 h

The protocol for both study days was the same except for the amount of sleep obtained the night before. Actimeters and sleep diaries (appendix 8) were sent out in advance to be worn/completed on the three nights prior to the study day. Participants were asked to refrain from drinking alcohol or caffeine from 2200h the night before the study day and to not eat anything after 1000h on the study day.

1200h – 1250h	Taxi transports participant from home to the Sleep Research Centre
1300h	Participant lunch
1300h	Investigator checks actiwatch data for compliance
1315h – 1345h	Electrodes applied
1345h – 1400h	Participant settled in car
1400h – 1600h	Simulator drive
1600h – 1615h	Electrodes removed
1600h	Taxi to take participant home

Table 3.4-1 Study day schedule

A taxi was provided to bring the participants to the laboratory. On arrival at 1300h participants were given a light lunch of two cheese rolls and a glass of water and the actimeter data was downloaded to check compliance. At 1315h electrodes were applied and driving commenced at 1400h. This time was chosen to coincide with the natural circadian dip.

Participants were instructed to drive in the left hand lane (unless overtaking), at a speed appropriate for the road and at which they were able to maintain control of the vehicle. During the drive the investigator was in the room at all times in case of a problem but there was no communication between investigator and participant once the drive began. Every 200 seconds subjective sleepiness was measured, a recorded voice would ask “sleep check?” and the investigator recorded the participant’s verbal response. During the two hours there were three cars to overtake at regular intervals. At 1600h the simulator program stopped so that participants did not have to pull over and stop the car. The electrodes were removed and participants went home in a prepaid taxi. Participants returned for the second of their study days at least three days later.

3.4.2 CPAP withdrawal

Following completion of the sleep restriction study all OSA participants were invited to participate in a CPAP withdrawal study, 11 accepted. This study comprised of one study day. The night before this study day participants slept for their normal length of sleep but did not use their CPAP machine. All participants discussed the procedure for this study thoroughly with the investigator ensuring that participants were aware of the following:

- There was no obligation to participate in this study.
- They should only agree if they were fully aware of the study protocol and participant requirements.
- It was possible that they may feel some additional sleepiness in the day following not using the CPAP, so this study day is to be organised for a date convenient to them on which they have no other commitments.
- If any problems occurred in the night as a result of not using CPAP they should resume CPAP use immediately and contact the investigator in the morning to cancel the afternoon simulator drive.

The protocol on the study day itself was exactly the same as for the sleep restriction study, Table 3.4-1.

3.5 Measurements

3.5.1 Screening day measures

On the screening day all participants completed a structured interview style questionnaire with the researcher detailing general health, general sleep, driving habits and OSA if applicable. The questionnaire (appendix 5 and 6) was used to exclude participants who were not suitable to participate and to determine participant characteristics. These are detailed in chapter 4.

Anthropometric measurements, BMI and percentage body fat were also taken. BMI as a technique is detailed in section 2.2.3. BMI is highly correlated to percentage body fat so generally provides a good indication of obesity, however, in muscular people obesity can be over estimated as muscle mass is not distinguished from fat mass (Aronne 2002). It is therefore preferable to calculate percentage body fat as well. A man of average weight would be expected to have 15 – 20 % body fat (Seidell et al. 1997). It was not possible to calculate % body fat of HGV drivers as the survey was conducted outside of the University. For participants in the driving simulator study it was possible to take this measure the TANITA body composition analyzer TBF-300 was used.

There are various techniques to measure percentage body fat; those with the greatest accuracy are more time consuming to carry out e.g. under water weighting. Bio-electrical impedance provides a quick and simple way of calculating percentage body fat from total body water content. Participants are asked to stand bare foot on a set of scales similar in size to standard bathroom scales. A small alternating current is applied; the calculation is based on the assumption that only body water will conduct the current. Total body water content can then be predicted, and therefore fat free mass (Deurenberg et al. 1999).

3.5.2 Driving performance

Driving incidents

Lane drifting is indicative of driver sleepiness, and was noted as a driving incident. Two types of driving incidents were recorded:

- Minor – when the wheels of the car touched a lane demarcation line.
- Major – when the car came out of the left hand driving lane.

At the end of the drive a computer printout detailed where the car was positioned on the road for each second of the drive. All incidents were then identified by the researcher. The incidents were identified on the video footage and classified visually by the investigator as one of two types:

- Sleep-related – i.e. the driver's eyes were rolling, closed or staring vacantly.
- Non-sleep related – i.e. driver distraction, fidgeting or looking around

Only sleep-related incidents are considered in this thesis, when driving incidents are referred to in the context of the current work this should be taken to mean sleep-related incidents.

Standard deviation of road position

As well as departure from the driving lane, the simulator also records road position within the left hand driving lane. In some occasions of drifting due to sleepiness the participant will make corrections before a driving incident occurs. This behaviour can

be identified by calculating the standard deviation of road position; the greater the standard deviation, the greater the level of driver sleepiness.

3.5.3 Subjective sleepiness

Subjective measures of sleepiness are used to assess the perceptions of participants of their own sleepiness levels. These measures can be divided into two categories:

- 1) Trait sleepiness, how sleepy a person feels in general
- 2) State sleepiness, how sleepy a person feels at a specific time point

In the context of driver sleepiness trait sleepiness is important because if a person is consistently sleepy they may have greater difficulty maintaining alertness whilst driving than someone who is not. State sleepiness is important because people continue to drive based on their own perceptions of how sleepy they are and use this information to decide when they should stop.

3.5.3.1 Trait sleepiness

Trait sleepiness is most commonly quantified using the Epworth Sleepiness Scale (ESS). The ESS measures average sleep propensity, an individual's general level of sleepiness independent of the current situation (Shen et al. 2006).

The ESS is a widely used 8 item self rating scale. Participants indicate the probability of them falling asleep under different set circumstances. In each circumstance participants can choose

- 0 = no chance of dozing
- 1 = slight chance of dozing
- 2 = moderate chance of dozing
- 3 = high chance of dozing

The Epworth Sleepiness Scale

How likely are you to fall asleep in the following situations? Please indicate, using the following scale, which is most appropriate given the situation.

0 = Would never doze

1 = Slight chance of dozing

2 = Moderate chance of dozing

3 = High chance of dozing

<u>Situation</u>	<u>Chance of Dozing</u>
Sitting and Reading
Watching TV
Sitting inactive in a public place (e.g. theatre/meeting)
As a passenger in a car for an hour without a break
Lying down in the afternoon when circumstances permit
Sitting and talking to someone
Sitting quietly after lunch without alcohol
In a car, while stopped for a few minutes in the traffic

Figure 3.5-1 Epworth Sleepiness Scale

The resulting scores are totalled ranging from 0 to 24 with scores over 12 suggesting excessive daytime sleepiness (Johns 1991).

This scale is quick and easy to use so it popular in a clinical setting to assess for EDS in OSA patients. It has been shown to correlate with RDI (Johns 1993) and improves in OSA patients once started on CPAP treatment (Engleman et al. 1996). It is generally accepted as a good tool to identify OSA. However, some studies have not found significant correlation between ESS and OSA severity as measured by AHI and MSLT

(Chervin et al. 1997, Olson et al. 1998). Despite criticism; some studies have found correlations between ESS and MSLT (Johns 1991) though Johns does argue that the MSLT should not be considered the 'gold standard' measure of sleepiness (Johns 2000a, Johns 2000b, Johns 1991). ESS has been found to correlate to inappropriate line crossings on a dual carriageway in OSA drivers and controls (Philip et al. 2008).

The ESS relies on honest self reporting of symptoms; as such it may be subject to misinterpretation and untruthful responses (Shen et al. 2006). An example of these problems can be demonstrated by asking people to complete an ESS about their spouse, as one study has found bed partners give a higher ESS than the patients themselves (Walter et al. 2002b). However, another study has found close agreement between scores of spouses (Olson et al. 1998).

In comparison to the equivalent objective measures, MSLT and MWT, the ESS is easier to use and much more cost effective. During the screening day, participants completed the ESS (appendix 2).

3.5.3.2 State sleepiness

The Karolinska Sleepiness Scale (KSS) is a widely used Likert scale to record sleepiness at a set time point (Akerstedt et al. 1990). It is quick and simple to complete allowing a participant to give an instant uniformed response to the question 'How sleepy do you feel?' Response is given as a number on a scale from 1 to 9.

The Karolinska Sleepiness Scale

1. Extremely alert
2. Very alert
3. Alert
4. Rather alert
5. Neither alert nor sleepy
6. Some signs of sleepiness
7. Sleepy, but no effort to keep awake
8. Sleepy, some effort to keep awake
9. Very sleepy, great effort to keep awake, fighting sleep

Figure 3.5-2 Karolinska Sleepiness Scale

The KSS has been validated to EEG activity showing that EEG activity changes when a KSS of 7 is given by healthy individuals; this is predominantly linked to an increase in theta and alpha power (Akerstedt et al. 1990, Baulk et al. 2001, Kaida et al. 2006). KSS has also been found to correlate to actual inappropriate line crossings on a dual carriageway with both OSA drivers and controls (Philip et al. 2008).

KSS is a subjective measurement so it is possible that participants may not answer honestly, to try to eliminate this, the investigator built up a good relationship with participants during the approximately three hours spent with each participant before they completed a study drive. The KSS has been validated against EEG, which has shown participants scoring 7 or higher on the KSS coinciding with EEG activity suggests sleepiness (Akerstedt et al. 1990).

An alternative to the KSS is a Visual Analogue Scale (VAS). VAS requires participants to indicate on a line where their subjective sleepiness falls. It is suggested that VAS is more sensitive than KSS (Shen et al. 2006) but for the purpose of a driving simulator it is more practical to use a scale with a verbal response.

Validation of the KSS to EEG shows that healthy people are able to tell when they are sleepy; in the case of driver sleepiness it is important that people recognise this and take action. They will only do this if they feel the sleepiness may impact on their

chance of actually falling asleep. In order to assess this, a Likelihood of Falling Asleep (LHoFA) scale can be used in conjunction with the KSS (Reyner and Horne 1998b). Whereas the KSS can show if someone has insight into their level of sleepiness the LHoFA demonstrates if they perceive this to be a problem. For example if someone rates 9A they suggest they know they are very sleepy (very sleepy great effort to keep awake) but they believe they are very unlikely to fall asleep.

Likelihood of falling asleep in the next 5 minutes	
A	Very unlikely
B	Unlikely
C	Neither
D	Likely
E	Very likely

Figure 3.5-3 The Likelihood of Falling Asleep scale

On all test days state sleepiness was recorded throughout the drives using the KSS and rating the Likelihood of falling asleep in the next 5 minutes (LHoFA). The scales were explained to participants at the screening day and they practiced using it during the test drive. Every 200 seconds of the drive is marked as a sleep check because a recorded voice asked “sleep check?” at these times, to which participants responded with a number from the KSS and a letter from the LHoFA scales. Responses to both these scales are reflective of how the participant is feeling at that particular point in time. 36 responses were collected for each participant in each 2 h drive. The scales were constantly visible, presented on the dashboard of the car.

Whereas the KSS can show if someone has insight into their level of sleepiness the LHoFA demonstrates if they perceive this to be a problem. For example if someone rates 9A they suggest they know they are very sleepy but they believe they are very unlikely to fall asleep.

For analysis subjective sleepiness scores are taken to represent the 100 seconds prior and post a “sleep check?”.

3.5.4 Sleep diary and actigraphy

Actigraphy is a technique used for measuring sleep quality based on movement during sleep. Participants were required to wear an actimeter © (CNT) for three nights prior to attending a study day. An actimeter is a movement sensor worn around the wrist. The actimeter was programmed to start recording 72 hours before the participant was due to arrive in the lab. Participants were instructed to put the actimeter on one hour before they intended to go to bed and take it off one hour after they woke in the morning. Participants were also instructed to remove it in situations where it may get wet, such as having a shower. Movement data was stored every 30 seconds. The more a person moves in their sleep the more fragmented and light the sleep is deemed to be. Actigraphy is recognised as an accurate way to detect sleep in normal healthy populations (Littner et al. 2003), and can also be used as an indicator of OSA (Morgenthaler et al. 2007).

Participants were also required to keep a sleep diary (appendix 8). This detailed: the time they went to bed, how long they thought they took to fall asleep, if they woke in the night and what time they got up in the morning. They were asked to write on the sleep diary times they had removed the actimeter.

When participants arrived in the laboratory the actimeters were downloaded and the data visually inspected to verify that participants complied with the sleep requirements for the previous night. The data can be analysed using an algorithm which automatically scores the actigraph record (Sadeh et al. 2002).

Actimeters are small, light weight, portable devices which make them easy to use and appropriate for cases like this when sleep quality is assessed on a high level. Data collected from actimeters is of movement alone and cannot substitute the detailed recording of PSG. If details of sleep architecture are required PSG is a more appropriate measure to use.

3.5.5 Electroencephalography

Sleepiness can be measured by examining brain activity, recorded using electrodes attached to the scalp. These measure changes in electrical potential resulting from synaptic excitations of the dendrites in large populations of pyramidal neurons in the cerebral cortex. These are weak signals which need to be amplified for analysis (Teplan 2002).

EEG can also be recorded during wakefulness and spectrally analysed. EEG shows brain activity in terms of amplitude (voltage between the highest and lowest points of a wave, in microvolts) and frequency (the number of waves per second, in hertz). Spectral analysis describes the frequency of signal based on a set of criteria. The power spectrum displays the distribution of power over the particular frequency component of the signal. Differing frequencies have been found to correspond to differing sleepiness states:

<4 Hz = Delta, occurs during deep sleep

4 – 7 Hz = Theta, occurs in drowsiness and light sleep

8 – 11 Hz = Alpha, occurs in relaxed wakefulness

13 – 20 Hz = Beta, occurs when alert or anxious

Driver sleepiness is concerned with the transition from wake to sleep; as such it is power in alpha (8-11 Hz) and theta (4 – 7 Hz) bands that is of interest. The amount of alpha or theta a participant displays varies from person to person; therefore combined alpha and theta activity (4-11Hz) can be used to reflect increasing sleepiness (Horne et al. 1996, Reyner et al. 2000, Eoh et al. 2005).

Although generally Beta activity has been shown to decrease with a prolonged attention task e.g. (Jap et al. 2009) it may also be of particular interest in the area of OSA and driver sleepiness. A recent driving simulator study comparing drivers with OSA and controls found beta activity to be higher in OSA group, which the authors suggest may be due to an increased effort on the part of the OSA drivers to remain

alert (Tassi et al. 2008). Beta activity has also been shown to increase with increased sleep deprivation in OSA patients (Greeneche et al. 2008).

Daytime EEG equipment takes about 20 – 30 minutes to apply prior to the drive, so participants are required to be in the lab for longer than the drive period itself. Electrodes can be uncomfortable and are an additional variable which is not present in real life driving. It is also possible to accidentally pull an electrode off thus interrupting the signal.

In the current work Electroencephalography (EEG) signals were recorded using silverchloride coated electrodes for one channel of EEG (C3-A1 with C4-A2 as a backup; International 10-20 system; Rechtschaffen and Kales, (1986). Electrooculography (EOG) was recorded for both eyes to identify “eye rolling”. Electrodes were placed 1cm lateral to and 1cm below the left outer canthus and 1cm lateral to and 1cm above the right outer canthus, both were referenced to the forehead. Electrode resistance was measured using an impedance meter at application of the electrodes, resistance was <10kΩ for EOG and <5kΩ for EEG. Both EEG and EOG were collected using the Embla ambulatory system and recorded and analysed using Somnologica (flaga.hf).

The EEG data was subject to high and low bandpass filtering at 20 and 4 Hz to remove slow eye movements and muscle artefact. All EEG was spectrally analysed using Somnologica (flaga.hf) in 4 second epochs for combined alpha and theta (4-11Hz) and beta (13-20Hz). EEG power in these ranges was averaged into 1 min epochs (after manual removal of any artefact) and standardised to the first 30 min of each individual’s normal sleep drive, thus removing individual difference in mean EEG power levels.

Standardised value = $\frac{\text{difference from the mean of the first 30 minutes}}{\text{standard deviation of the first 30 minutes}}$

Individual standardised values were then averaged for all participants in each condition.

3.6 Statistical Analysis

The statistical analyses used in each chapter and noted in their individual method sections and which research questions they are addressing. Statistical analysis in all cases was completed in SPSS 16.02 for Windows, (Rel 10/4/08. Chicago: SPSS Inc).

For chapters 5 to 10 the main statistical analysis technique used was analysis of variance (ANOVA). In all cases driving incidents, KSS, EEG and LHoFA results were averaged into 30 min epochs per participant per condition. In cases where control and OSA participants were compared a mixed repeated measures analysis of variance (ANOVA) was completed, with two within subject factors:

Condition – 2 levels: normal sleep and sleep restriction

Time – 4 levels: 0-30 min, 30-60min, 60-90min and 90-120min

Additionally one between subjects factor:

OSA diagnosis – 2 levels: OSA patient and healthy control

Where only one group was investigated a two way (condition x time) repeated measures ANOVA was applied. To clarify terminology used, groups, refers to OSA and control and conditions refers to normal night's sleep and sleep restriction.

In all cases data were first visually examined as hectograms to check the assumption of normal distribution was not violated. In the case of driving incidents this assumption was violated and a square root transformation was completed to correct for the skewed raw data. Huynh-Feldt (ϵ) adjustment was used if sphericity (Homogeneity of variance) could not be assumed. ϵ will always fall between 0.33 and 1, the higher the number the closer the data are to being spherical. All significance findings are reported at $p < 0.05$.

Additionally Chi-Squared, Pearsons correlation, Spearman's rho correlation and T tests are also used throughout the thesis and will be identified and explained at the relevant points.

Throughout this thesis means will be presented with standard deviation rather than standard error of the mean, as the variability within the study sample is considered to be of greater interest than level of uncertainty of how the study sample represents the underlying population (Hassani et al. 2010). Visualising standard deviation is important to understand the magnitude of variation within a group and how this variation differs between groups (OSA compared with control). Standard error is not appropriate as inferential statistics are not used (Nagele 2003).

3.7 Pilot Work

The simulator set up used in the current work at Loughborough University is well tested with the method having been used previously under numerous different study protocols (Horne et al. 1996, Reyner and Horne 1998a, Reyner et al. 2000, Reyner et al. 2002, Horne et al. 2003). The simulator has also been validated as representative of driving a real car, demonstrating it is a valid method of detecting driver sleepiness (Baulk 2002). All of the previous studies have been completed by participants aged less than 30 years old. As the current work with OSA drivers would involve drivers aged over 50 it was necessary to assess the appropriateness of the simulator set up for this age group. Pilot drives were completed: three participants aged 63, 61 and 62 completed the full study protocol as set out for the sleep restriction study.

3.7.1 Screening day measures

The screening day required participants to complete a questionnaire, hazard perception test and have anthropometric measurements taken. These measures were novel to the current research. There were no problems with the anthropometric measurements taken or the hazard perception test but feedback from the first pilot participant led to the alteration of wording of one question and the addition of another question.

3.7.2 The simulator

Initially, pilot participant 1 carried out a 30 minute test drive in the simulator where 3 cars were presented to overtake (as is the case in the 2 hour drives of the study). At the end of the test drive the participant was proficient at maintaining road position in the left hand lane so progressed to the main study day. During the 2 hour afternoon

drive it was noted that the participant was still experiencing a learning curve of how to complete the overtaking manoeuvres. In response to this 10 cars were presented to overtake during the 30 minute test drive for pilot participants 2 and 3, allowing more practice at this aspect of the drive. Neither participant 2 or 3 had problems or showed a learning curve response with overtaking during the 2 hour drive. As such pilot participants 2 and 3 were included in the final data set and participant 1 excluded.

Protocol was finalised and is described in section 3.4.

3.7.3 Electroencephalogram (EEG) analysis

In the previous studies (Horne et al. 1996, Reyner, Horne 1998a, Reyner et al. 2000, Reyner et al. 2002, Horne et al. 2003) using the simulator, EEG was spectrally analysed in combined alpha and theta bands 4 – 11 Hz, an increase in power at this frequency was found to reliably represent increased sleepiness. The participants in the current study differed from those in previous studies as they were older and half had OSA. Therefore on completion of the sleep restriction data collection, explorative analysis was conducted with the EEG recordings to investigate if 4 – 11Hz was most appropriate frequency band to complete spectral analysis on with this group. 5 analysis sets were conducted at different hertz bands and compared to see which bands reliably indicated the increased sleepiness caused by sleep restriction.

A bypass filter below 4 Hz and above 20 Hz was run over the EEG activity of 8 OSA and 8 control participant's EEG recordings before spectral analysis was conducted. In all cases EEG was standardised as described in section 3.5.5

Analysis was completed for Alpha (8 - 11Hz) and Theta (4 – 7 Hz) activity independently and combined (4 – 11 Hz). Alpha activity was also analysed in a narrower band width of 8.5 – 9 Hz as alpha activity frequency changes with age (Greeneche et al. 2008) and it has been suggested that in older people alpha activity falls in this specific narrower range and using the traditional 8 – 11Hz, therefore results in the analysis are missing most of the 'real' alpha (Klimesch 1999). Beta activity (13 – 20 Hz) was also analysed as this has been shown to be higher in untreated OSA participants than controls (Tassi et al. 2008).

The different analyses results for each group individually (control n = 8 and OSA n = 8) were then used to compare the normal night sleep and sleep restriction condition, in order to identify the hertz band which most consistently distinguished between the two conditions.

- Theta activity alone did not give clear results as there was an observable difference between conditions for some participants but not for others.
- There was little difference between the narrower and wider alpha ranges. In both OSA and control participants both measure of alpha activity were greater following sleep restriction.
- For both the OSA and control group alpha and theta combined together (4 – 11 Hz) showed the clearest difference between conditions. For this reason alpha and theta combined, 4 – 11 Hz will be used for the final analysis.
- Beta activity did not increase as expected during the sleep restriction condition but it was higher in both conditions for the OSA group than the control group. Due to this disparity beta activity will also be used for the final analysis.

In conclusion of this explorative analysis it was confirmed that combined alpha and theta activity (4-11 Hz) is the most appropriate frequency for assessing sleepiness with spectral analysis and that beta activity (13 – 20hz) may be of interest in comparing OSA and control participants.

CHAPTER FOUR

Participant characteristics for the main driving simulator studies (not pilot work)

4.1 Method

Following screening 40 participants were selected to complete the sleep restriction study. The following chapter outlines the characteristics of the total study population, OSA n = 20, control n = 20. It is not designed to answer any hypothesis or research questions but provides back ground information of the two groups (OSA and control) being investigated by the simulator studies.

4.1.1 Statistical analysis

Analysis is designed to identify any difference between the two experimental groups. Any differences found may be an underlying factor for differences at the driving simulator tasks.

A Two tail independent T tests was used to compare the ages and total sleep time and sleep disturbance index of each group. Data were visually checked in histograms that the assumption of normal distribution was not violated. The assumption of homogeneity of variance was assessed using Levenes test and was not violated.

BMI and % body fat are reported but not statistically compared as the control group was artificially selected to have a BMI under 28.

4.2 Physical characteristics

	Mean	S.d.
OSA Age	63.8	7.7
Control Age	66.6	6.1
OSA BMI	34.5	6.5
Control BMI	25.5	1.7
OSA % body fat	32.4	5.5
Control % body fat	23.9	3.8

4.2-1 Age, BMI and percentage body fat of OSA and control groups

All participants were aged between 50 and 75, there was no significant difference between groups [$t(37) = 1.22, p = 0.269$]. As expected both BMI and percentage body fat were higher in the OSA group. The average BMI in the OSA group was obese at 34.5; the average BMI in the control group was slightly overweight at 25.5. Control participants were screened not to have a BMI over 28 as there would then be at risk of

then having undiagnosed OSA. BMI distribution can be seen in Figure 4.2-1. A man of average body weight would be expected to have 15 – 20% body fat, healthy range for 50 – 75 years old is considered to be 13 – 25 %. 9 control and 18 OSA participants had a percent body fat above 25%.

All participants were included in the study. Due to work commitments one OSA participant withdrew from the study before completion. The time commitment required for the study resulted in no other suitable participant volunteering. It is therefore stated in the methodology section of each chapter whether this participant is included (OSA n =20) in analysis for that chapter or not (OSA n = 19).

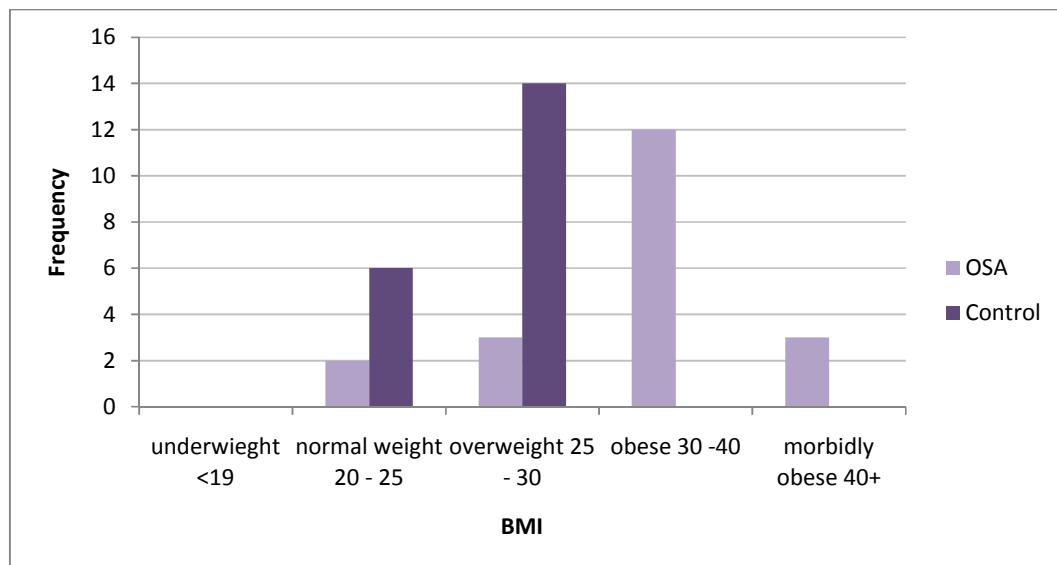


Figure 4.2-1 BMI distribution

4.3 OSA

All of the OSA participants were being treated using CPAP from Leicester General Hospital and attend once a year for check up appointments. They had all been receiving CPAP since their diagnosis. For between 1 and 19 years (average = 7.46 years). When asked if they ever slept without their CPAP 16 said they never would, 1 person said they sleep without it once a month, 2 people once every two to three months and 1 person very occasionally. These participants reported not using their CPAP on occasion if they were away from home and there was no facility to plug it in, if they have a sore throat/nose they chose not to wear it, or if they fall asleep before

putting it on. However, one person who reported falling asleep before putting it on did comment that in this scenario they would then wake in the night and apply the mask.

All the participants were happy with the CPAP and felt it was improving their quality of life. When asked what life was like before having a CPAP machine the most common complaints were falling asleep during the day, feeling stressed at work, struggling when driving and having a reduced social life, examples include:

“I had a restricted social life as I found it hard to go out in the evenings because I felt sleepy.”

“I was embarrassed to go on holiday with groups of people as my snoring would disturb them.”

“My performance at work was badly affected; I thought I couldn’t sleep well because I was stressed. It turned out I was stressed because I wasn’t sleeping well.”

“I left my job as I thought I was stressed so was unable to sleep properly.”

“I used to fall asleep in the daytime when I sat down.”

“I struggled to stay alert when driving long distances.”

“I was tired during the day and wanted to sleep all the time.”

4.4 Driving

OSA participants had held a UK driving licence for an average of 44.6 years, s.d. 7.2, with the least experienced driver having 32 years experience. Control participants had held a UK driving licence for an average of 45.2 years, s.d. 6.9, with the least experienced driver having 30 years experience. No participants were professional drivers. All participants drove for a minimum of 3 hours per week, the modal number of hours driven per week was 3- 5 hours (55% of OSA, 40% of controls). All participants drove at least 1000 miles per year with the modal response being 5000 – 10 000 miles (65% OSA, 40% control).

4.5 Trait sleepiness

All participants completed the Epworth Sleepiness Scale to assess for excessive daytime sleepiness (ESS >12). On average the OSA group had a slightly higher ESS (5.3 s.d. 3.36) compared with controls (4.7 s.d. 2.56). One OSA participant reported EDS, during the 30 minute test drive of the simulator participants rated how sleepy they felt on the KSS every 200 seconds, and a mean over the 30 minutes was calculated. The OSA participant with EDS had an average KSS of 1 during the test drive and was included in the final study population.

4.6 Habitual sleep

During screening participants were asked how long it took them to fall asleep in order to exclude anyone with insomnia. They were also asked if their bed partner currently reported anything unusual about their sleep. All control participants reported no loud snoring, choking or waking with a jolt in their sleep; all these signs would suggest undiagnosed OSA.

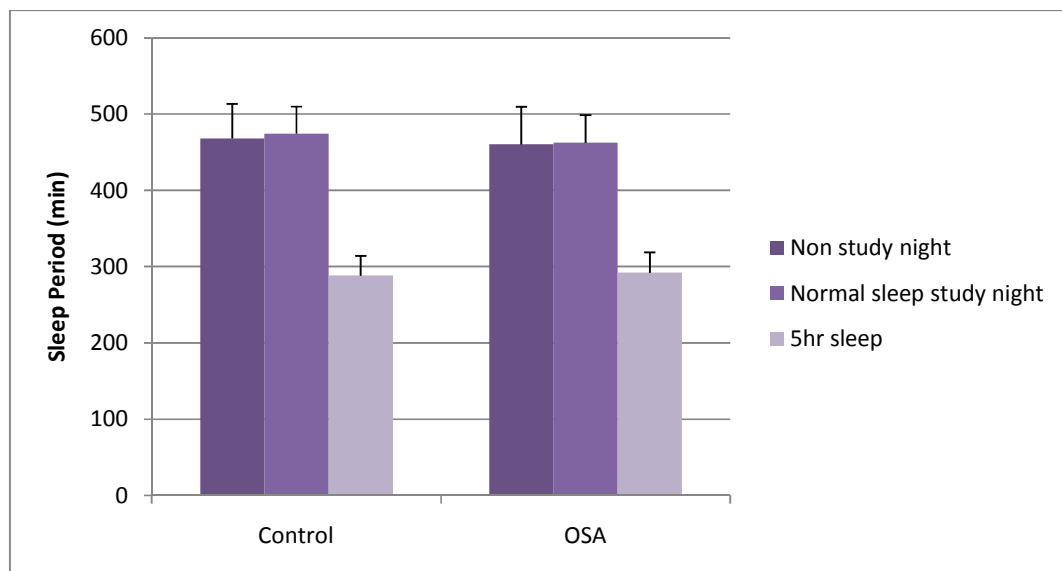


Figure 4.6-1 Total sleep time with standard deviation

Each participant completed a sleep diary and wore an actiwatch to assess for compliance to sleep criteria prior to the study days. Four nights of baseline actiwatch data were collected as non study nights. Sleep diary and actimeter data were combined (Copyright Cambridge Neurotechnology Ltd. Version 7.22) and mean total

sleep time (TST) was calculated as time from initial sleep onset until final awakening for each participant, see Figure 4.6-1. On average both groups habitually slept a similar length (on non study days), controls slept for 7h 50min and OSA participants slept 7h 37 min on average. There was no significant difference between the two groups average non study night SP [t (37) = 0.931, p = 0.358, two tailed].

The TST calculated for non study nights was used to assess if participants were compliant in the study conditions having either their usual night's sleep or 5 hours sleep as appropriate.

4.7 Actiwatch compliance check for the sleep restriction study

4.7.1 Total sleep time

Participants slept for the night before the study in their own homes, where actigraphy was used to assess their normal sleep behaviour and compliance to the 5 hours sleep restriction.

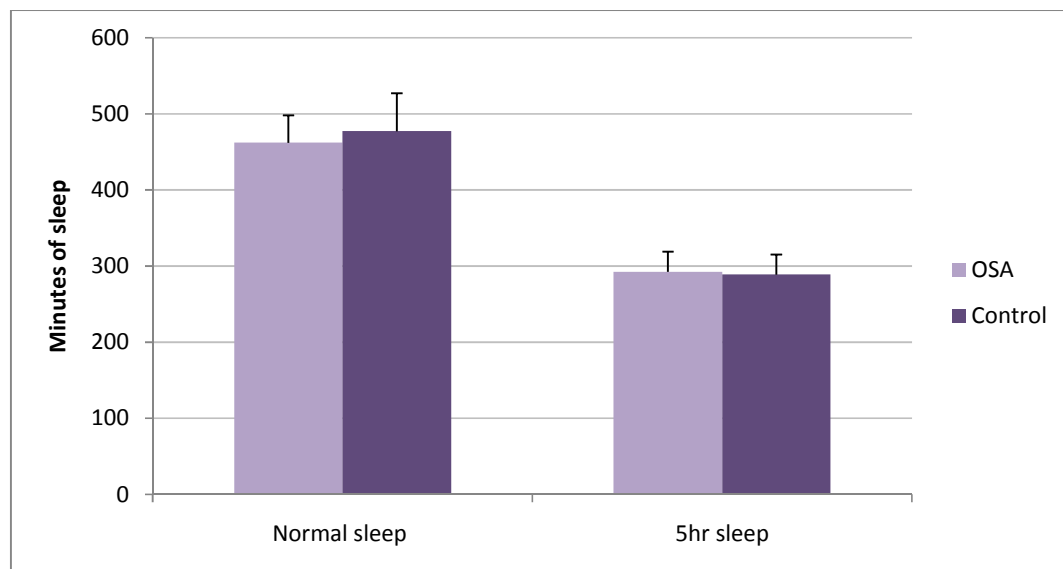


Figure 4.7-1 Mean assumed sleep length in minutes, with standard deviation

All participants were compliant. The assumed sleep length, as calculated from the actiwatch software, sleep analysis 5 (Copyright Cambridge Neurotechnology Ltd. Version 7.22)

$$\text{Assumed sleep} = \text{total sleep time} - \text{awake minutes}$$

This was compared for each condition (normal and restricted sleep) between the groups, Figure 4.7-1. There was no significant difference between sleep length after normal sleep; OSA (n=19) patients slept for 462.1 min, control (n=19) group slept 477.3 min [t (36) = 1.09, p = 0.29, two tailed] and for sleep restriction the OSA group (n=19) slept 292.4 min and the control (n=20) 288.9 min [t (37) = 0.43, p = 0.67, two tailed]. n = 19 for control normal sleep due to a failure of one actiwatch recording. Any subsequent differences in performance during the driving task between groups is not because of differing sleep time.

4.7.2 Sleep disturbance index

Sleep quality as well as sleep length can impact how sleepy a person feels during the day. Sleep disturbance index (SDI) can be calculated from actiwatch data using the following equation

$$SDI = \frac{\text{number of wake minutes}}{\text{assumed length of sleep}}$$

The higher the SDI the poorer the sleep quality, therefore the sleepier a person may feel during the day. SDI was compared between groups for both conditions, and no significant difference was observed, Figure 4.7-2.

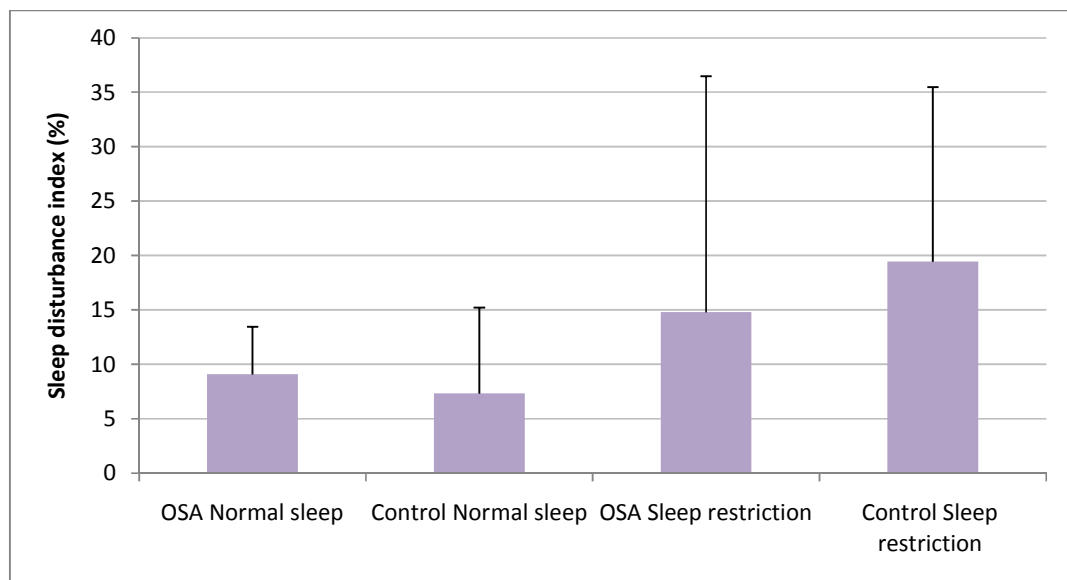


Figure 4.7-2 Mean sleep disturbance index with standard deviation bars

Following a normal night's sleep the mean SDI was 9.08% for OSA participants and 7.32% for control participants, showing no significant difference [$t(36) = 0.846$, $p = 0.403$, two tailed]. Following sleep restriction to 5 hours, sleep was more disturbed for both groups, the mean SDI was 14.81% for OSA participants and 19.45% for control participants, again showing no significant difference [$t(37) = 0.762$, $p = 0.451$, two tailed]. Any difference in performance during the task cannot be attributed to differing sleep quality the night before.

CHAPTER FIVE

Impact of sleep restriction on driving task performance

5.1 Introduction

It has repeatedly been reported that an OSA patient's performance at driving tasks improves following CPAP treatment; however the majority of studies follow up after less than one year of treatment. It has not been demonstrated if performance at a driving task is still comparable to controls following long term treatment. Additionally, previous research has not considered the ability to perform a driving task under the added pressure of sleep restriction. This chapter aims to address both of these issues by comparing performance at a driving simulator task using the primary outcome measure of task performance as assessed by driving incidents and standard deviation of road position. A comparison will be made between OSA participants treated with CPAP for a minimum of one year with healthy controls of a similar age, following their normal night's sleep and sleep restriction to 5h.

5.1.1 Key points from the literature review

Following the start of CPAP treatment the risk of RTI reduces in OSA patients to that of controls (George 2001). Improvement at driving tasks has been reported in OSA participants following CPAP treatment also to levels comparable with controls, (Findley et al. 1989, George et al. 1997, Hack et al. 2000, Kingshott et al. 2000, Munoz et al. 2000, Mazza et al. 2006). In general these studies are carried out before and after the start of treatment: as such follow up periods tend to be within one year of starting treatment. Additionally the research showing improvement in performance following CPAP treatment has predominantly been conducted using short duration tests. It is unknown if CPAP treated patients will have similar performance to controls at a long monotonous task, such as simulated motorway driving.

Sleep restriction is known to impair driving performance in healthy individuals, resulting in a greater number of driving incidents over a monotonous two hour drive (Horne et al. 2004); it is not known if this effect differs with treated OSA participants. With untreated OSA participants total sleep deprivation (Desai et al. 2006) and sleep restriction to 4 hours (Vakulin et al. 2009) have been found to cause greater impairment at driving tasks than in healthy controls. No studies with treated OSA participants were identified to assess if this increased susceptibility to the effects of sleep restriction persists into treatment.

5.1.2 Research aim and hypotheses

Aim: To evaluate the effect of sleep restriction in OSA-CPAP compliant patients compared with controls at a simulated driving task.

Hypotheses:

To test the hypothesis that OSA CPAP compliant participants will show no difference in driver performance at a driving simulator task as reflected by increased lane deviation after a normal night of treated sleep.

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by increased lane deviation and shorter time to first incident after sleep restriction to 5h of treated sleep.

5.2 Method

Design: Repeated measures counterbalanced. Completing a 2h afternoon drive following a normal night's sleep and following sleep restriction to 5h. Comparing treated OSA participants and healthy controls.

Setting: Driving simulator

5.2.1 Participants

Participant characteristics can be found in chapter 4. 20 control participants and 19 OSA participants are represented in the following chapter.

5.2.2 Protocol

Study protocol was followed as detailed in chapter 3. The data presented here is for the simulator measures only, resulting from the repeated measures counterbalanced design comparing performance following a normal night's sleep and sleep restriction to 5 h.

5.2.3 Measures

Sleep-related minor and major driving incidents were scored from the driving simulator and video recording as detailed in chapter 3 and analysed in 30 min epochs. The standard deviation of road position was generated by the driving simulator. The

standard deviation for the road position was calculated for each participant for each 2 hour drive. The average of which was then compared between groups.

5.2.4 Statistical analysis

Incidents were analysed in three groups: minor incidents, major incidents and total incidents (minor + major). Incidents were totalled per participant then a mean taken for each group. As described in section 3.6, incidents were calculated in four 30 minute epochs and analysed using a mixed measures ANOVA, with two within subject factors: condition (2 levels) and time (4 levels), and one between subjects factor, having OSA or not.

A mixed measures ANOVA with one within subject factor, condition (2 levels) and one between subjects factor, having OSA or not, was used to analyse time to first incident and standard deviation of road position.

In all cases raw data were visually examined in histograms to check the assumption of normal distribution, standard deviation of road position and time to first major incident were normal. Number of driving incidents (Minor, major and total) were not, to correct for this skewed data a square root transformation was completed prior to analysis. Huynh-Feldt (ϵ) adjustment was used where the assumption of homogeneity of variance was not met.

5.3 Results

5.3.1 Frequency of driving incidents

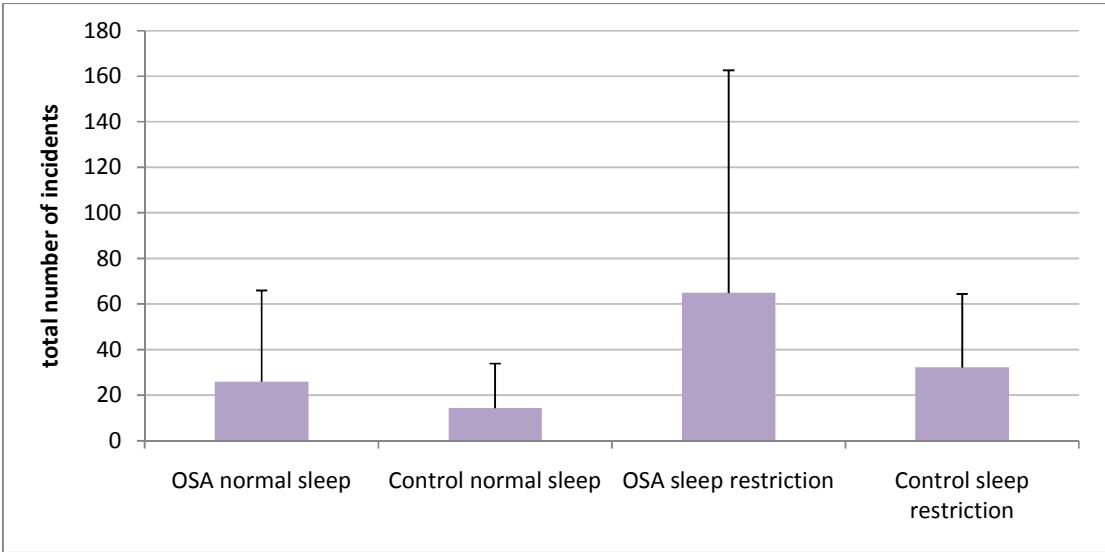


Figure 5.3-1 Mean number of total incidents occurring in 2 hours driving with standard deviation

Both groups experience more driving incidents following sleep restriction. In both conditions the OSA participants had more incidents than the controls, see Figure 5.3-1.

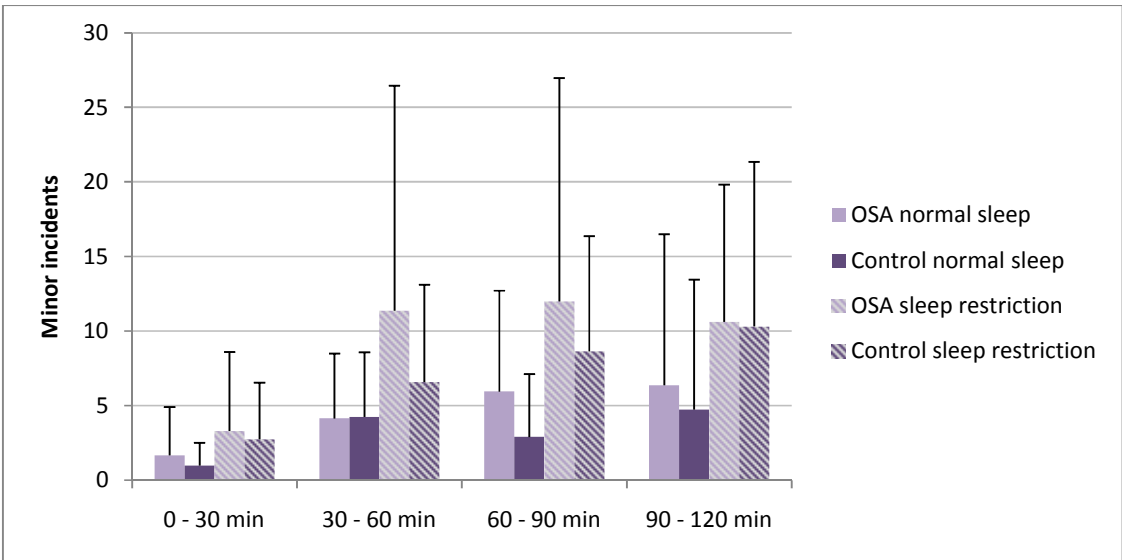


Figure 5.3-2 Minor incidents in 30 minute epochs with standard deviation

The number of minor incidents occurring is displayed in 30 minute epochs in Figure 5.3-2. ANOVA demonstrates a significant effect of condition [$F(1,37) = 22.29, p < 0.001, \epsilon = 1$], with both groups having more minor incidents following sleep restriction

than a normal night's sleep. There is a significant effect of time [$F(2.03, 75.16) = 26.92$, $p < 0.001$, $\epsilon = 0.68$] in general demonstrating an increase in incidents as the drive progressed. There was no significant difference between OSA and controls.

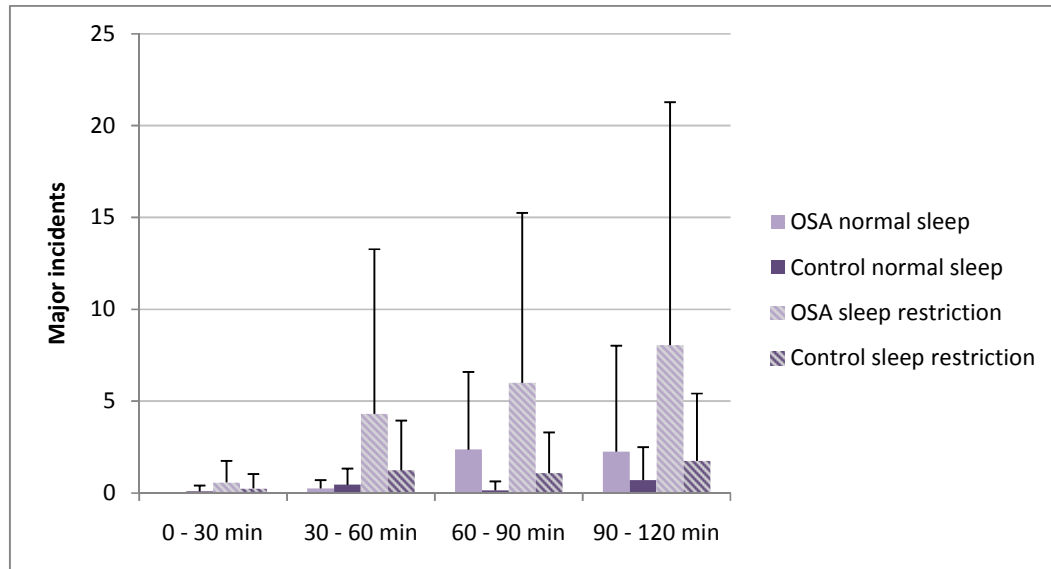


Figure 5.3-3 Major incidents in 30 minute epochs with standard deviation

The number of major incidents in each 30 minute epoch is shown in Figure 5.3-3 . For the first 30 min there is little difference in major incidents between groups; however for the following hour and a half the sleep restricted OSA participants had a greater number of incidents than the sleep restricted controls.

There is a significant effect of condition on the number of major incidents [$F(1, 37) = 20.78$, $p < 0.001$, $\epsilon = 1$] as both groups had more major incidents following sleep restriction. There is a significant effect of time [$F(1.7, 63) = 15.01$, $p < 0.001$, $\epsilon = 0.57$] demonstrating a general increase in number of incidents across the drive. Sleep restriction affected OSA participants differently than controls as there is a significant condition, group interaction [$F(1, 37) = 9.37$, $p = 0.004$, $\epsilon = 1$]. This is demonstrated by the interaction graph Figure 5.3-4, showing sleep restriction to have a greater effect on OSA participants than would be expected if sleep restriction resulted in the same increase in impairment as it does to control participants. The dotted line denotes the results that would be expected from OSA participants had they been affected by the intervention in the same way as the control group.

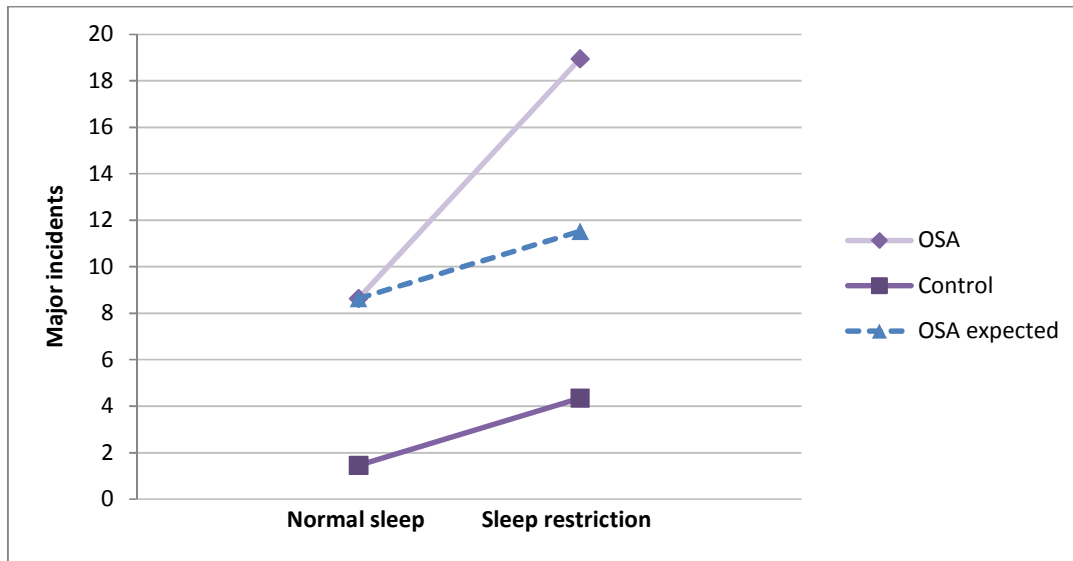


Figure 5.3-4 Interaction condition and group for number of major driving incidents

5.3.2 Time to first major incident (safe driving time)

In a real road driving situation if a person drives out of their driving lane on any occasion it could result in serious consequences. To investigate this scenario the average time to first major incident was calculated. Those completing the drive without major incident were recorded as driving 120 minutes. Results are shown in Figure 5.3-5

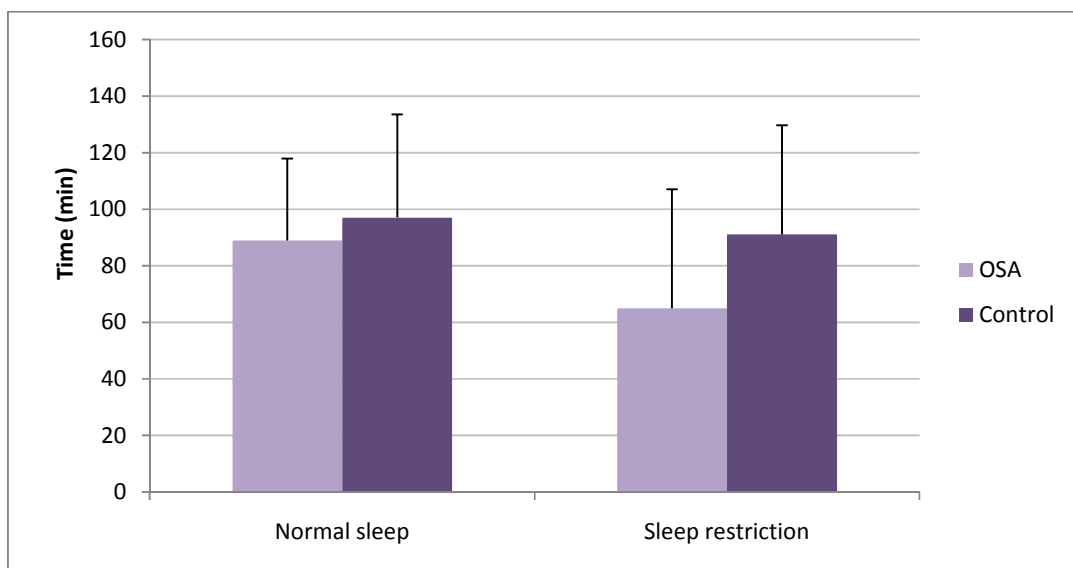


Figure 5.3-5 Safe driving time with standard deviation

After a normal night's sleep the control participants successfully drove for a mean (s.d.) of 97.1 minutes (36.5) and the OSA group 88.9 minutes (29.0). Following sleep restriction this decreased to 91.1 minutes (38.6) for control and 65.0 minutes (42.0) for OSA. The effect of condition is close to significance [$F(1,37) = 4.04, p = 0.052, \epsilon = 1$], suggesting that following sleep restriction both groups drove for a shorter time before having their first major incident. There is a significant condition, group interaction [$F(1,37) = 4.16, p = 0.049, \epsilon = 1$], displayed in Figure 5.3-6, suggesting that sleep restriction has a greater impact in OSA participants safe driving time than would have been expected if sleep restriction resulted in the same difficulties experienced by controls.

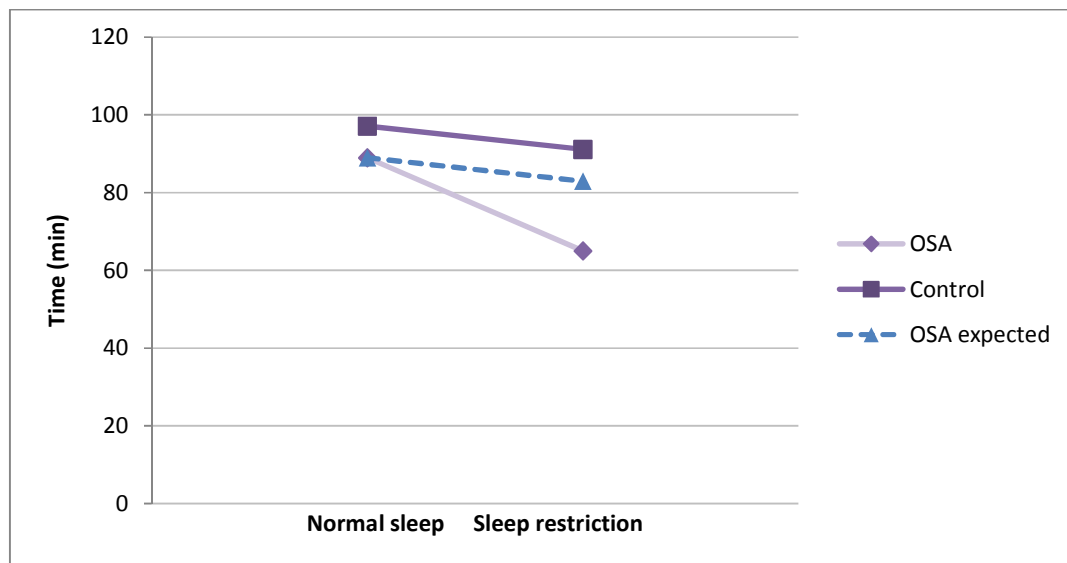


Figure 5.3-6 Interaction of condition and group for safe driving time

5.3.3 Standard deviation of road position (drifting within the driving lane)

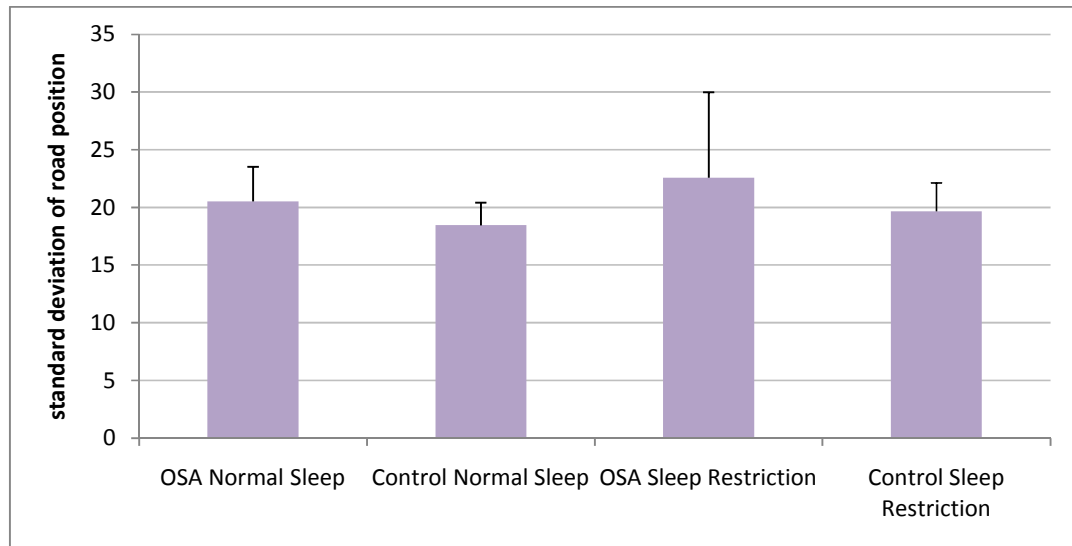


Figure 5.3-7 Standard deviation of road position for both groups in both conditions with standard deviation

The larger the standard deviation of road position the greater the movement of the vehicle from the required “straight” driving position; defined as ‘drifting within the driving lane’. Movement within driving lane is an indication of drowsiness, as alert drivers are expected to have better control and more accurately maintain driving position. There is a significant effect of condition [$F(1,37) = 6.91, p = 0.012, \epsilon = 1$], with both groups showing greater standard deviation of road position following sleep restriction. The impact of sleep restriction on road position was no different for the OSA group than controls as the group.

5.4 Discussion

OSA participants have been found to be more affected by sleep restriction than controls. For both number of driving incidents and safe driving time the OSA participants were significantly more impaired after sleep restriction compared with the controls. When considering the total number of incidents over two hours, sleep restriction resulted in an increase of incidents of OSA participants more than twice that for controls. A significant condition and group interaction for safe driving time demonstrates the differing effect of sleep restriction of OSA participants. If sleep restriction had the same effect on OSA participants as it did for controls it would be expected that they could drive safely for 18 minutes more than they actually did.

Major incidents demonstrate the strongest evidence for the impact of sleep restriction, where the significant condition and group interaction shows the total number of major incidents to be considerably higher than would be expected if the OSA participants had responded in the same manner as controls to the sleep restriction. The sleep restriction did significantly affect both groups resulting an increase in driving incidents and a near significant reduction in safe driving time.

When interpreting these results it is important to consider the nature of driving as a task. The question 'should OSA patients drive when sleep restricted?' does not have a simple yes/no answer. Although it is clear that OSA participants would suffer impaired driving performance if undertaking a long drive, for the first 30 minutes of driving the number of incidents is similar for the OSA and control groups. In fact OSA participants were able to drive without major incident for an average of 65 minutes following sleep restriction. It appears that OSA patients may only experience greater impairment from sleep restriction in a long duration task. No difference in sleep deprivation impairment between OSA and control participants was found in Desai et al. (2006): here the battery of tests completed were all short in duration, so it is likely the OSA participants were able to maintain performance to the level of controls in these short tests. However, had they been longer a difference in impairment severity would have been noted.

No significant difference was found with standard deviation of road position. In real life, major driving incidents are more likely to result in RTI's than minor incidents, and standard deviation of road position could represent movement within the designated driving lane. Therefore, major incidents are considered most important in assessing driving task performance and form the focus of the discussion.

After a normal night's sleep OSA participants had no significant difference in the number of either major or minor incidents compared to controls. There was also no significant difference in safe driving time. These results add to the evidence from many previous publications in finding no significant difference between the driving performances of CPAP treated OSA participants and healthy controls. (Findley et al. 1989, George et al. 1997, Hack et al. 2000, Kingshott et al. 2000, Munoz et al. 2000,

Mazza et al. 2006). In addition, the current research provides unique confirmation that these results are still found in long term treated OSA participants. With OSA participants demonstrating greater difficulty in the later stages of the drive it suggests that they had greater difficulty with time on task than the control group.

Previous research has found untreated OSA participants to be more susceptible to the effects of sleep restriction (4h) than control drivers, (Vakulin et al. 2009). The current study is interesting compared with Vakulin et al. (2009) as it is a similar study design (though with different simulator) and with treated OSA participants. Commonly both the treated and untreated OSA participants suffered more from the sleep restriction than the control group, having more sleep-related incidents. Vakulin et al. (2009) found the standard deviation of road position to be 40% higher in OSA participants after the sleep restriction than the controls. No difference was found in the current work for this measure; this is possibly because of differing simulator set up, but a significant difference was found in the number of major incidents. It is possible that because of CPAP treatment sleep restriction related impairment is more manageable than in untreated sufferers. This enables participants to maintain their road position for the majority of the drive until the point they can't maintain wakefulness any longer, having a major incident. CPAP treatment has been shown by many studies, including the current work, to result in driving performance of OSA participants to be no different from controls. It is interesting that the increased susceptibility to sleep restriction reported in untreated OSA participants is still apparent in the long term treated OSA participants.

It is possible that untreated OSA participants are already sleep deprived so by reducing sleep length participants will experience greater sleep restriction than controls, putting them at a greater disadvantage. In the current research all OSA participants are successfully treated with CPAP, theoretically putting them at the same starting point as controls; demonstrated by a similar performance between groups following a normal night's sleep. It is not possible to ascertain why OSA participants were less able to cope with sleep restriction than the control group from the current work, but it is possible that the time spent with untreated OSA may have resulted in some permanent brain damage. Imaging studies have found differences in grey matter in

untreated OSA sufferers and differences in some cognitive function studies between untreated OSA patients and controls (Joo et al. 2010). This may offer a possible explanation for being less able to cope with sleep restriction. To investigate this further it would be necessary to complete a longitudinal study investigating sleep restriction prior and post treatment with brain imaging.

The UK Highway Code recommends taking a break from driving every 2 hours to avoid driver fatigue. In the current work the average safe driving time was approximately 90 minutes for both the control and OSA participants following a normal night's sleep. Even the healthy controls were not able to maintain performance for 2 hours, with 35% of them unable to complete the drive without major incident. It may be more appropriate to recommend taking a break from driving every 90 minutes to avoid driver fatigue as this was the approximate safe driving time reached by both groups following a normal night's sleep. All the participants were aged between 50 and 75 years old so it may be that a short safe driving time is a reflection of age. If this were the case it might be expected that the over 50s would feature highly in sleep-related crash statistics. In fact the most likely group to have srRTIs are the under 30s (Horne et al. 1995). This is likely due to the fact that older drivers will demonstrate less risky behaviour, i.e. less likely to drive without adequate prior sleep or in the early hours of the morning. It is also possible that older drivers would be taking breaks more frequently than 2 hours for reasons other than sleepiness, such as bathroom breaks, to stretch legs, or because they feel less pressure to complete their journey at speed (Bhatti et al. 2008). Ultimately this reduces their sustained driving time and pre-empts any difficulty due to driver sleepiness.

The simulated road presented was designed to represent the type of driving condition where srRTIs are most likely to occur (Horne et al. 1995). It was therefore the intention of this study to present a 'worst case scenario' of a dull monotonous drive. As such it is acknowledged that in a 'real world' scenario participants may have been able to drive safely for longer than was found with the simulator. It is also possible that a larger volume of traffic on the road would have reduced the difference in performance between the OSA and control groups, as was found in a simulator of high traffic density in Tassi et al. (2008).

A greater variation in performance within the OSA group was found compared with control group. For both total major and minor incidents the standard deviation is larger for the OSA group than the control group. This is true for both conditions but the difference is larger following sleep restriction, Table 5.4-1

	Normal sleep		Sleep restriction	
Total minor incidents s.d.	OSA	Control	OSA	Control
	20.03	17.02	40.20	25.13
Total major incidents s.d.	OSA	Control	OSA	Control
	9.89	2.91	31.07	8.77

Table 5.4-1 Standard deviation for total number of driving incidents in 2 hours

The greater individual difference within the OSA participants is of particular interest and will be investigated further in chapter 10.

Primarily this study demonstrates the importance of getting a full night’s sleep before embarking on a long motorway journey, for both OSA drivers and healthy drivers. Advice should be aimed at this older age group in general, advising them to take a break from driving at least every 90 minutes and more often if they have had a poor night’s sleep. Health practitioners should emphasise to OSA patients that although they are safe to drive if using their CPAP correctly they should be aware that they may suffer greater impairment following sleep restriction than they would if they did not have OSA. It is now important to investigate if OSA participants know that they are sleepy as this would enable them to take appropriate action. Being sleepy while driving itself does not cause RTIs it is the inability to recognise or unwillingness to act on it that results in srRTIs; the ability to recognise sleepiness will be investigate in chapter 8.

5.5 Conclusions

- Following a normal night’s sleep with CPAP treatment OSA participants’ performance at a simulated driving task is not significantly different to that of healthy controls.
- Sleep restriction has a significantly greater impact on driving task performance for CPAP treated OSA participants than healthy controls.

- Older drivers may benefit from taking a break from driving at least every 90 minutes. This is more often than the 2 hours recommended in the Highway Code.

CHAPTER SIX

Impact of sleep restriction on subjective sleepiness while completing a driving task

6.1 Introduction

The focus of this chapter is state sleepiness while completing a simulated driving task. The previous chapter has shown OSA participants to have greater impairment due to sleep restriction compared with controls in terms of driving incidents; the current chapter assesses if this is reflected in subjective sleepiness.

6.1.1 Key points from the literature review

Subjective sleepiness will increase with time on task, particularly if the task is monotonous; even after a full night's sleep participants may feel sleepier as the task progresses (Thiffault et al. 2003). Subjective driver sleepiness is most commonly investigated by recording subjective sleepiness before and after a driving task. However, this methodology means that sleepiness is not reported when the participant is completing the task, as such alertness may have improved or worsened since the task environment has been removed. Also, any changes in alertness during the task will not be identified. The current study will record subjective sleepiness at regular intervals throughout a task to monitor changes while the task is being completed. The more often ratings are taken, the more detail of change in subjective state is obtained, however, the act of asking participants for a subjective rating itself has an alerting effect as it can produce stimuli in an otherwise monotonous environment. This is similar to the effect noted by conducting a reaction time test during a monotonous task (Baulk et al. 2001).

CPAP treatment has been shown to improve daytime sleepiness in OSA patients (Hardinge et al. 1995, Ballester et al. 1999). It would therefore be expected that when OSA patients use their CPAP and have a full night's sleep they would feel no sleepier than control participants at the start of a task and progress in sleepiness during the task in the same manner as controls. Previous research investigating subjective sleepiness in untreated OSA participants has recorded sleepiness periodically using the Stamford Sleepiness Scale, after total sleep deprivation compared with following a normal night's sleep. Both groups reported feeling sleepier during total sleep deprivation but the untreated OSA participants did not report an increase in sleepiness to the same magnitude as control participants. (Desai et al. 2006). A similar finding has been reported using a visual analogue scale (Risser et al. 2000); here untreated OSA

and control participants rated sleepiness before and after completion of a 60 minute driving simulation. Both groups showed increased sleepiness at the end of the task, however, the OSA group had worse performance at the task but did not rate themselves as sleepier than controls. In both of these studies untreated OSA participants did not rate themselves as sleepy as would be expected from the magnitude of task performance impairment compared with controls. The current research will investigate if this is also apparent in treated OSA participants.

6.1.2 Research aim and hypotheses

AIM2: To evaluate the effect of sleep restriction in OSA-CPAP compliant patients compared with controls at a simulated driving task.

Hypotheses:

To test the hypothesis that OSA CPAP compliant participants will show no difference in driver performance at a driving simulator task as reflected by subjective sleepiness measures (KSS and LHoFA) after a normal night of treated sleep.

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by subjective sleepiness measures (KSS and LHoFA) after sleep restriction to 5h of treated sleep.

To test the hypothesis that in both groups subjective measures of sleepiness will be correlated to each other (KSS vs LHoFA and KSS vs ESS).

6.2 Method

Design: repeated measures counter balanced. Completing a 2h afternoon drive following a normal night's sleep and following sleep restriction to 5h. Comparing treated OSA participants and healthy controls.

Setting: driving simulator

6.2.1 Participants

Participant characteristics can be found in chapter 4. 20 control participants and 19 OSA participants are represented in the following chapter.

6.2.2 Protocol

Study protocol was followed as detailed in chapter 3. The data presented here is for the subjective sleepiness measures only, resulting from the repeated measures counterbalanced design comparing performance following a normal night's sleep and sleep restriction to 5 h.

6.2.3 Measures

During each 2 hour drive state sleepiness was recorded throughout using the KSS and rating the Likelihood of falling asleep in the next 5 minutes (LHoFA). The scales were explained to participants at the screening day and they practiced using it during the test drive. Every 200 seconds of the drive is marked as a sleep check because a recorded voice asked "sleep check?" at these times, to which participants responded with a number from the KSS (out of 9) and a letter from the LHoFA (out of 5) scales. Responses to both these scales are reflective of how the participant is feeling at that particular point in time. 36 responses were collected for each participant in each 2 h drive. The scales were constantly visible, presented on the dashboard of the car.

All participants had previously completed an ESS measure of trait sleepiness at their screening day.

Full details of both scales can be found in chapter 3. Both scales were presented in clear view to participants throughout the drive.

For analysis subjective sleepiness scores are taken to represent the 100 seconds prior and post a "sleep check?".

6.2.4 Statistical analysis

The 36 subjective ratings taken in each drive were averaged across the participants in each group, for each condition. The mean response for each group in each condition was averaged into 30 minute epochs for statistical analysis using mixed measures ANOVA with two within subject factors; condition (2 levels) and time (4 levels), and one between subject factor, having OSA or not, as described in section 3.6

In all cases raw data were visually examined in histograms to check the assumption of normal distribution, KSS, LHoFA and the mean change in KSS (see below) showed

normal distribution. Huynh-Feldt (ϵ) adjustment was used where the assumption of homogeneity of variance was not met.

The relationship between subjective sleepiness ratings was analysed with Spearman's correlation coefficient (r_s) comparing the mean KSS with LHoFA score for each participant over the 2 hours and KSS with ESS.

The mean percentage of the drive spent in each subjective score was calculated for both groups in both conditions and compared on percentage graphs.

To assess change in state sleepiness over the drive the difference between the first and last KSS score was calculated for each participant determining the change in sleepiness state.

Change in sleepiness state = KSS second 7100 – KSS second 200

This was calculated to make comparisons to previous publications who recorded subjective sleepiness before and after a driving task. The mean change was calculated compared between groups using a repeated measures ANOVA, with one within subject factor, condition (2 levels) and one between subjects factor, having OSA or not.

6.3 Results

6.3.1 KSS

To test the hypothesis that OSA CPAP compliant participants will show no difference in driver performance at a driving simulator task as reflected by subjective sleepiness measures (KSS and LHoFA) after a normal night of treated sleep.

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by subjective sleepiness measures (KSS and LHoFA) after sleep restriction to 5h of treated sleep.

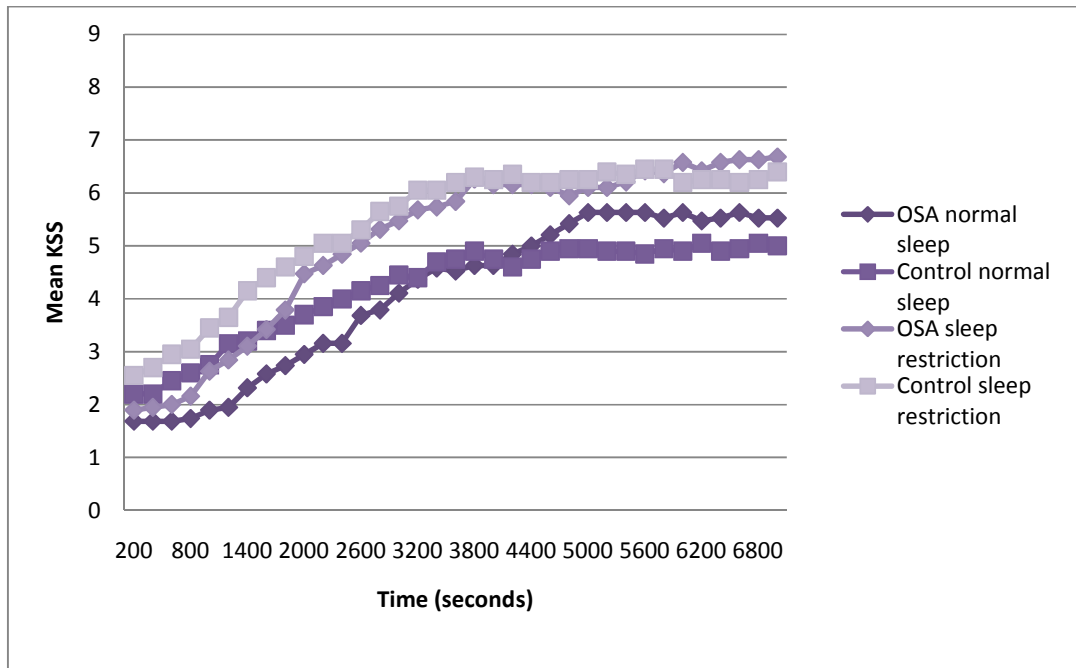


Figure 6.3-1 Mean KSS every 200 seconds for OSA and Control participants following normal sleep and sleep restriction

The mean KSS scores are shown in Figure 6.3-1. In all cases KSS increased linearly from the beginning of the drive then plateaued after one hour. Both groups reported feeling sleepier following the sleep restriction.

For statistical analysis scores were averaged to 30 minute epochs, Figure 6.3-2.

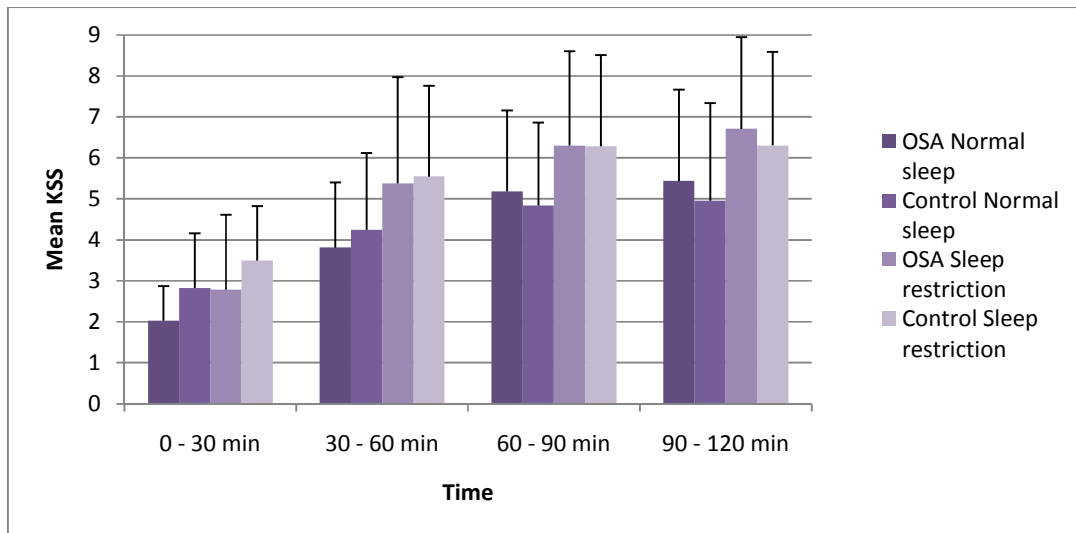


Figure 6.3-2 Mean KSS in 30 minute epochs with standard deviation

The effect of condition is significant [$F(1,37) = 19.94, p < 0.001, \epsilon = 1$]. The effect of time was also significant, participants got sleepier as the drive went on [$F(1.9, 72.1) = 69.99, p < 0.001, \epsilon = 0.649$]. There was no group interaction effect.

6.3.2 Change in sleepiness state

To test the hypothesis that OSA CPAP compliant participants will show no difference in driver performance at a driving simulator task as reflected by subjective sleepiness measures (KSS and LHoFA) after a normal night of treated sleep.

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by subjective sleepiness measures (KSS and LHoFA) after sleep restriction to 5h of treated sleep.

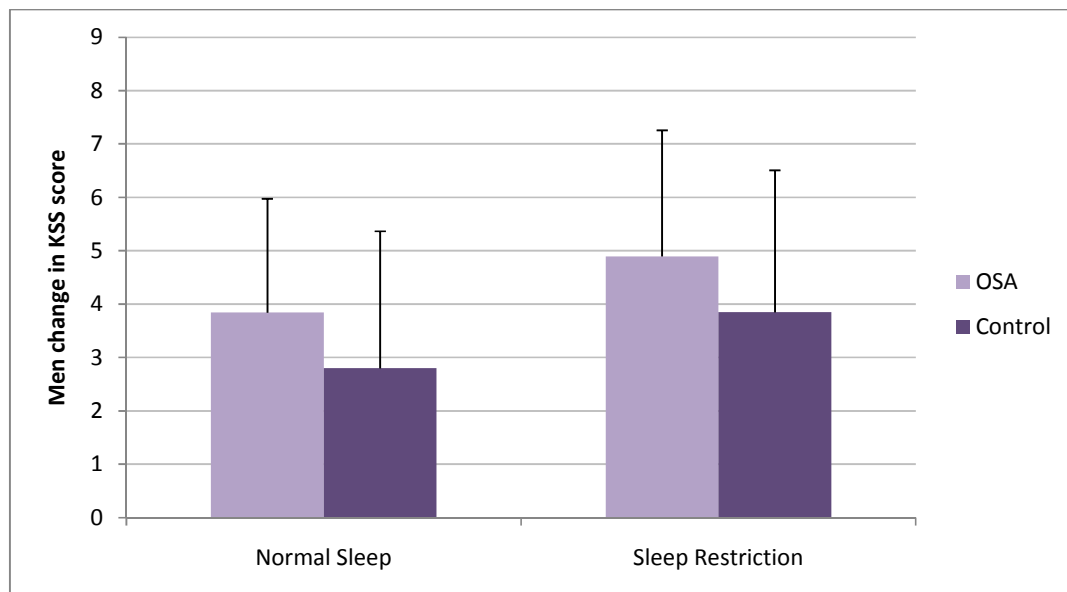


Figure 6.3-3 Mean change in KSS score from second 200 to second 7000 with standard deviation

The change in reported sleepiness state is shown in Figure 6.3-3. There was a significant effect of condition [$F(1,37) = 9.27, p = 0.004, \epsilon = 1$], both groups showing a greater change in subjective sleepiness from the beginning to the end of the task following sleep restriction. There was no significant group interaction; the sleep restriction did not affect the OSA participants any differently from the control participants.

6.3.3 LHoFA

To test the hypothesis that OSA CPAP compliant participants will show no difference in driver performance at a driving simulator task as reflected by subjective sleepiness measures (KSS and LHoFA) after a normal night of treated sleep.

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by subjective sleepiness measures (KSS and LHoFA) after sleep restriction to 5h of treated sleep.

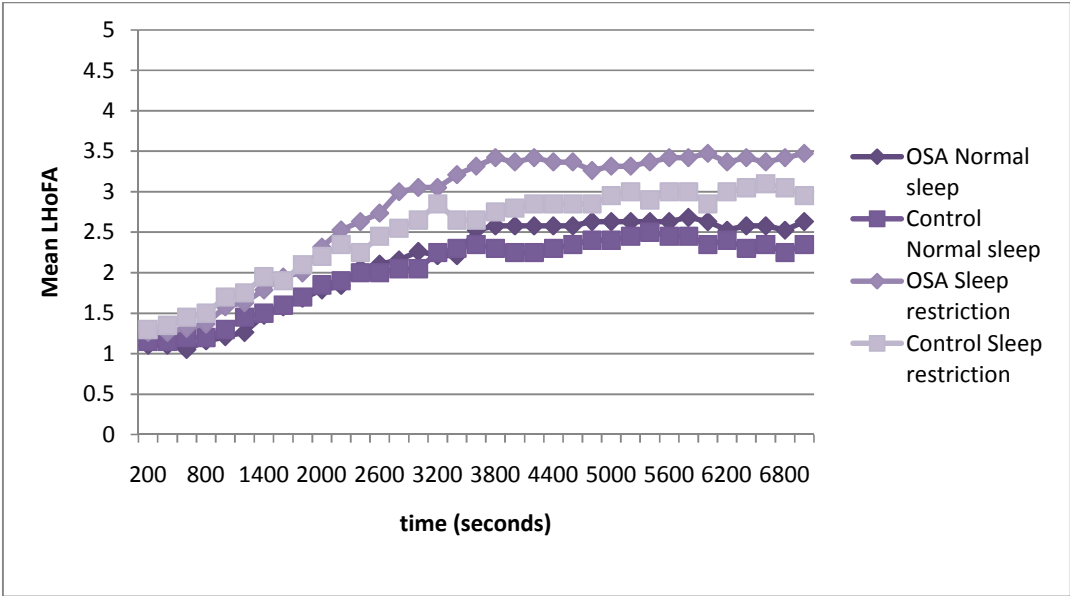


Figure 6.3-4 Mean LHoFA score every 200 seconds for OSA and control participants following normal sleep and sleep restriction

LHoFA is displayed in Figure 6.3-4, the same trend is apparent as for KSS. Participants felt more likely to fall asleep following sleep restriction than following normal sleep, in all cases likelihood for falling asleep increased for the first hour then plateaued. Scores were averaged into 30 minute epochs for statistical analysis, Figure 6.3-5.

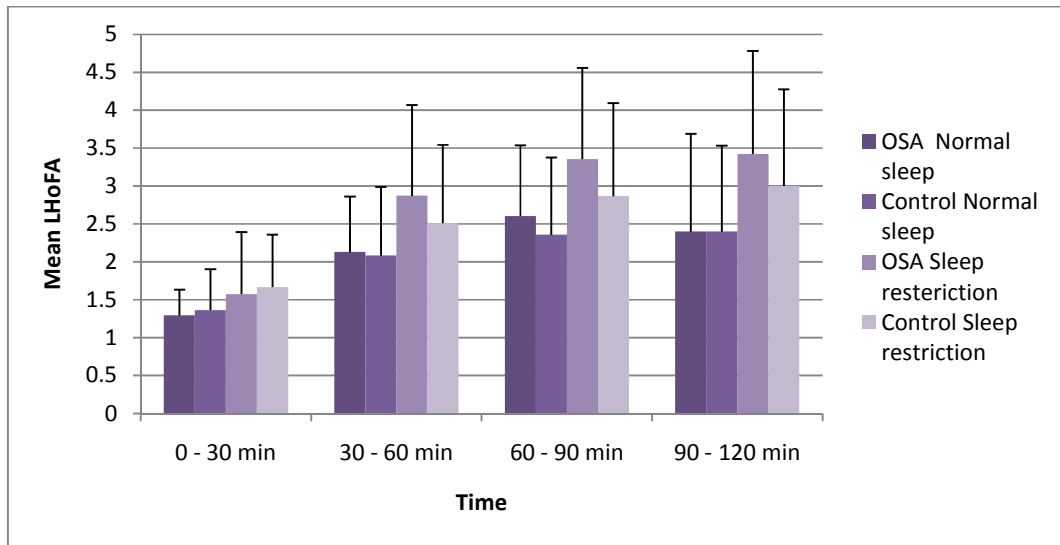


Figure 6.3-5 Mean LHoFA scores in 30 minute epochs with standard deviation

There is a significant effect of condition, participants felt more likely to fall asleep following sleep restriction [F (1,37) = 30.92, $p < 0.001$, $\epsilon = 1$]. The effect of time was also significant as participants felt more likely to fall asleep as the drive progressed [F (1.8, 66.4) = 50.73, $p < 0.001$, $\epsilon = 0.60$]. There was no significant interaction of group.

6.3.4 Correlations between scales

To test the hypothesis that in both groups subjective measures of sleepiness will be correlated to each other (KSS vs LHoFA and KSS vs ESS).

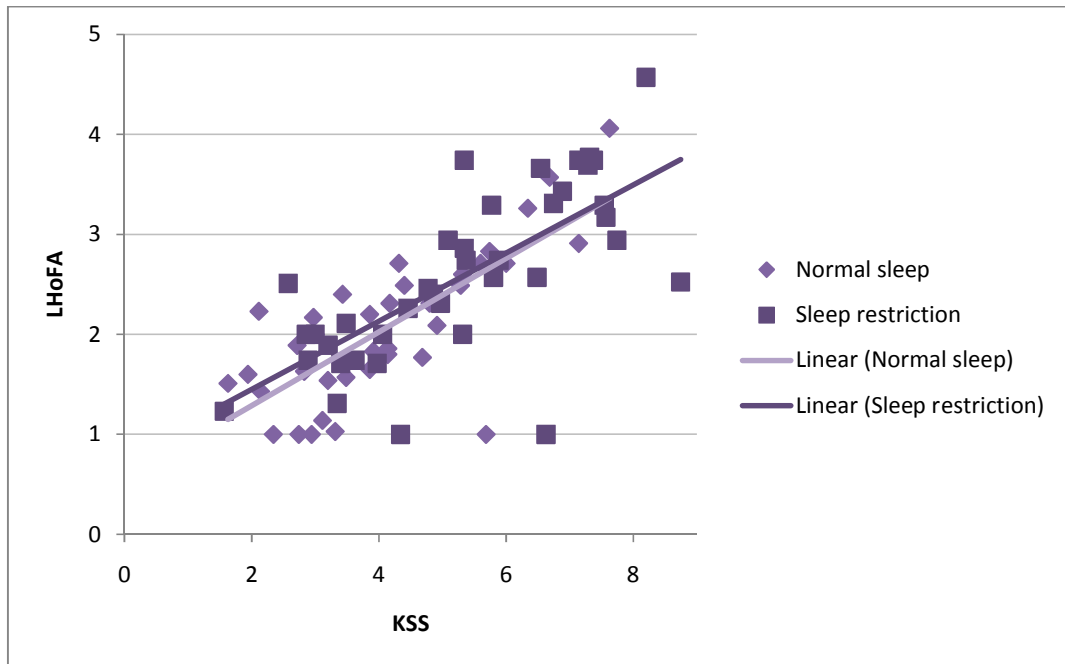


Figure 6.3-6 Subjective sleepiness, LHoFA and KSS

Spearman's correlation coefficient demonstrates that KSS and LHoFA have a significant positive relationship see in Figure 6.3-6, following both normal sleep [$r_s = 0.727$, $p < 0.001$] and sleep restriction [$r_s = 0.748$, $p < 0.001$].

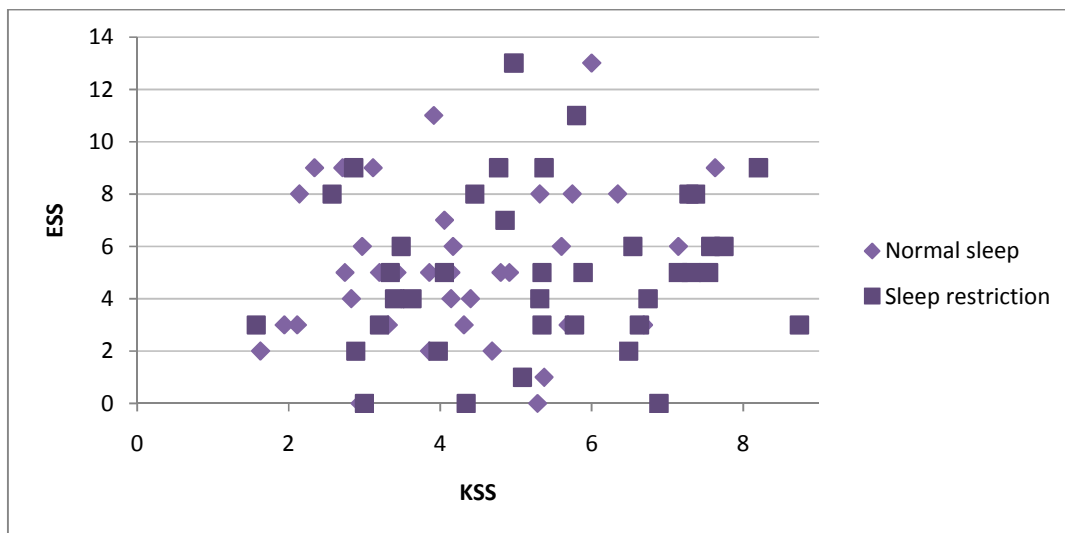


Figure 6.3-7 Subjective sleepiness, ESS and KSS

There was no correlation between ESS scores and KSS following a normal night's sleep, shown in Figure 6.3-7 [$r_s = 0.153$, $p = 0.352$] or sleep restriction [$r_s = 0.016$, $p = 0.331$].

The state sleepiness experienced during the task was not significantly related to trait sleepiness.

6.3.5 Prevalence of subjective sleepiness ratings

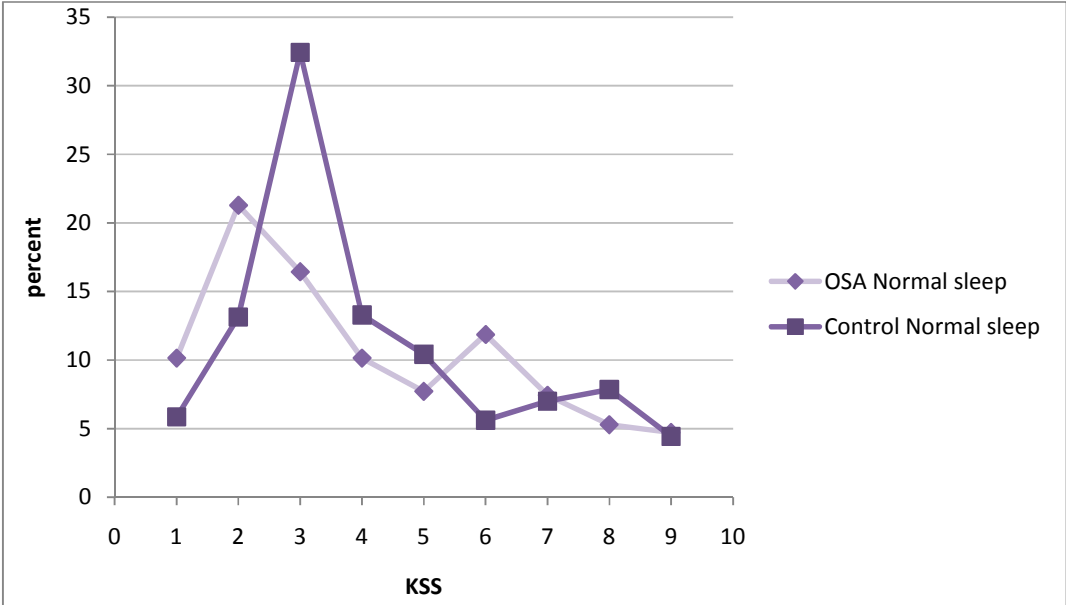


Figure 6.3-8 Mean percentage of the drive spent in each KSS score following a normal night’s sleep

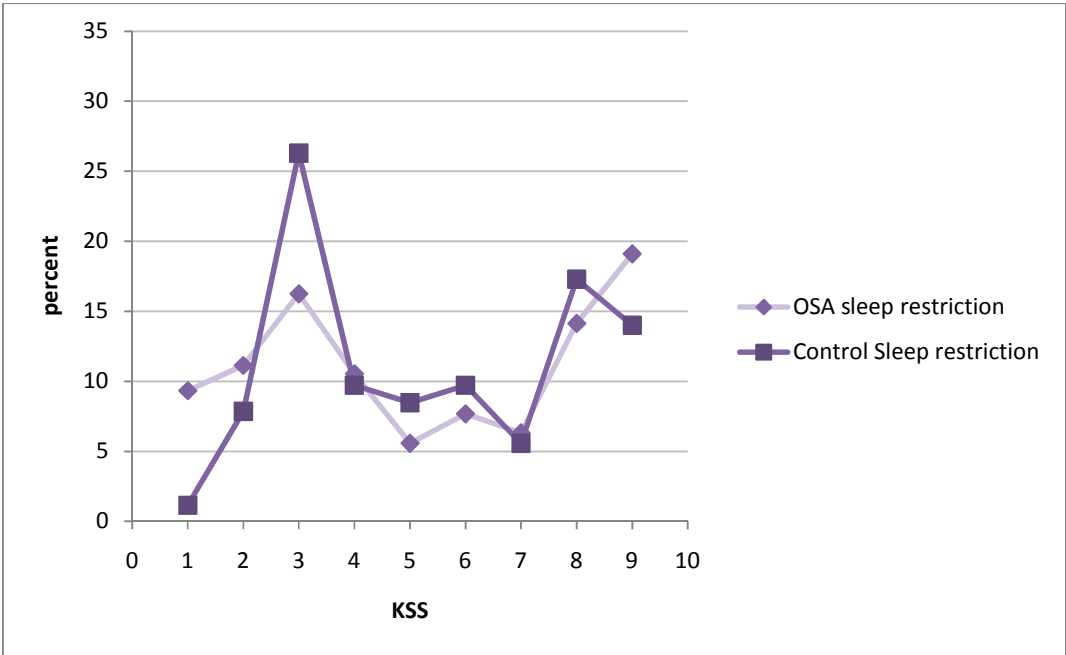


Figure 6.3-9 Mean percentage of the drive spent in each KSS following sleep restriction

36 subjective sleepiness ratings were recorded for each participant in each drive, resulting in 720 data points per condition for control participants and 684 data points

per condition for OSA participants. The frequency of a particular subjective score was recorded per participant and a mean taken across participants for each point on both scales, displayed in Figure 6.3-8, Figure 6.3-9, Figure 6.3-10 and Figure 6.3-11. Following a normal sleep KSS 2 was most frequently reported by OSA drivers and KSS 3 by control drivers. Following sleep restriction KSS 3, 8 and 9 were most frequently reported for both groups.

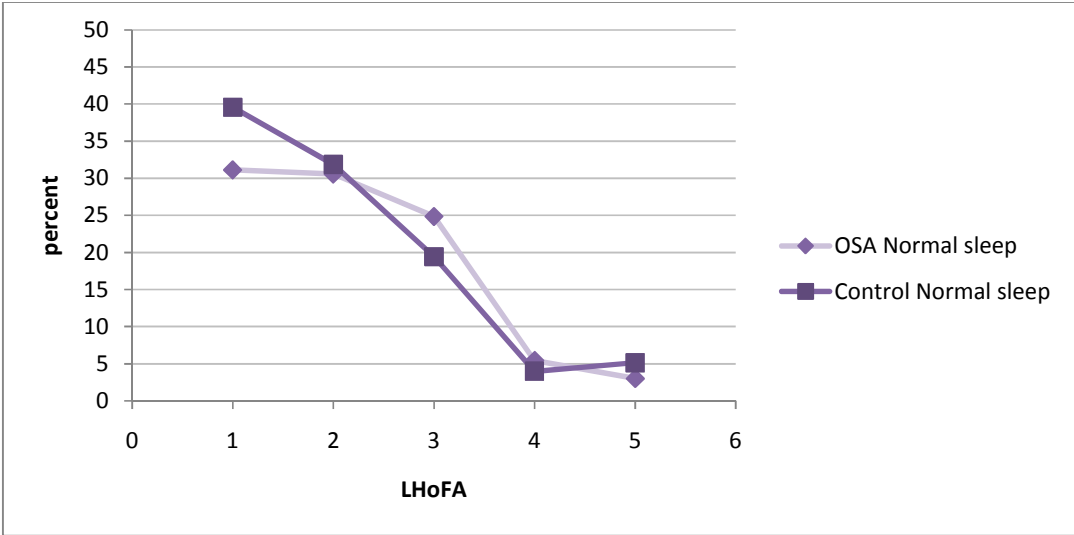


Figure 6.3-10 Mean percentage of the drive spent in each LHoFA score after a normal sleep

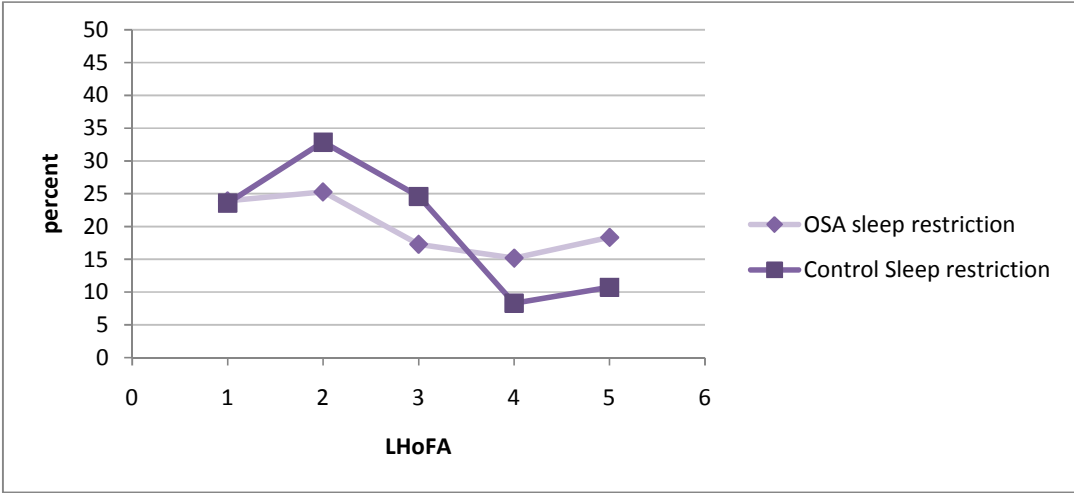


Figure 6.3-11 Mean percentage of the drive spent in each LHoFA score after sleep restriction

After a normal sleep LHoFA 1 was the most frequently reported score by both OSA and control participants, with frequency of reporting decreasing up the scale, shown in Figure 6.3-10. Following sleep restriction LHoFA 2 was most frequently reported for

both groups. The variability between popularity of LHoFA scores after sleep restriction was less for OSA participants than control participants, displayed in Figure 6.3-11.

6.4 Discussion

Subjective sleepiness was recorded on the KSS and LHoFA scales throughout the drive, there was no significant group interaction for either scale in either condition. The OSA and control participants experienced comparable levels of sleepiness and likelihood of falling asleep in both conditions. For both groups participants felt significantly sleepier and significantly more likely to fall asleep following sleep restriction and in all cases the effect of time was significant.

Sleep restriction had a significantly greater effect on driving task performance of the OSA participants than controls; therefore it would have been understandable for the OSA participants to feel significantly sleepier following sleep restriction than controls. However, the non significant difference in subjected sleepiness despite a significant difference in task performance is consistent with previous research, (Risser et al. 2000). In that study untreated OSA participants reported subjective sleepiness on a VAS before and after a 60 min simulated drive, no difference was found between OSA and control participants in the magnitude of sleepiness increase, despite worse performance by the OSA participants. Risser et al. (2000) recorded two subjective sleepiness scores and compared the difference between them, for comparison in the current work the mean change in KSS was also reported, again there was no significant difference between groups, despite the greater number of incidents by the OSA participants. Not feeling sleepier even though task performance is impaired may be indication of a lack of ability to identify sleepiness by the OSA participants; this is an area requiring further investigation and will be assessed in chapter 8.

Ability to sustain attention has been shown to be impaired in untreated OSA sufferers and to improve to the same level as controls following 4 months of CPAP (Ferini-Strambi et al. 2003). Subjective alertness over the two hours in the current work also shows the effect of time to be the same on controls and long term treated OSA participants. The OSA group did not show any more increased sleepiness with time on task than the controls, demonstrating this positive effect of CPAP to be sustained.

Analysis of RTI data depicts a small peak in srRTIs during the early afternoon despite this being a period of time with fewer cars on the roads (Horne et al. 1995). These afternoon srRTIs are more likely to be caused by older drivers, whereas early morning srRTIs are more likely to be caused by younger drivers (Horne et al. 1995). The current study was conducted during the early afternoon, which, as a time noted for older drivers to have srRTIs it could be expected that these participants would experience day time sleepiness. However, it is noted that when compared with previous publications using this simulator the current participants felt more alert at the start of each drive than younger participants completing the same study protocol. The participants in the current study reporting an initial KSS of 2.6 after sleep restriction compared to KSS of 5 (Reyner et al. 2002), KSS of 4 (Horne et al. 2004) or KSS of 3 (Horne et al. 2003) for younger participants. This was an unexpected difference and is further discussed in chapter 13.

Following sleep restriction it was expected that the KSS scores denoting sleepiness (6-9) would be more frequently reported than following normal sleep. However, KSS 6 and 7 were less frequently reported following sleep restriction by both OSA and control participants than after normal sleep. Following sleep restriction both groups most frequently reported KSS 3, 8 and 9. The low frequency of reporting KSS 6 and 7 is reflective of a fast transition from alert (KSS 1-4) to very sleepy (KSS 8-9). With a short transition time from alert to sleepy there is a smaller window for participants to identify increasing sleepiness, as such it may be difficult to recognise if they are sleepy prior to a driving incident, and this will be investigated in chapter 8.

It is beneficial to collect subjective sleepiness reports throughout the drive to reflect changes in sleepiness as they occur, yet, it is recognised that the act of asking “sleep check?” may promote artificial alertness in participants. Completing a secondary task during a monotonous main task has been shown to artificially increase alertness (Baulk et al. 2001) and the repeated request “sleep check?” may have had a similar effect.

The KSS and LHoFA scales were found to be significantly correlated in both conditions, with approximately 85% of variance explained. It should be expected that as participants felt sleepier they would also feel more likely to fall asleep; nevertheless,

some younger drivers do not demonstrate this relationship (Reyner, Horne 1998b). It has been reported with younger participants that some will identify themselves as fighting sleep but not acknowledge any likelihood of falling asleep. Younger drivers are known to take more risks and have a greater sense of invincibility (Finn et al. 1986); the high correlation between the two measures may be a reflection of the age of the participants.

There was no correlation between the state sleepiness measured by KSS and trait sleepiness measured by ESS. The ESS is commonly used in medical practice to monitor EDS in OSA patients. Having an ESS of less than 12 is an indication that patients have no EDS and may be used by a doctor as a basis for assessing fitness to drive. In the current study all participants had an $ESS \leq 13$ (one participant scored over 12) therefore none would be considered to have serious EDS. Even without EDS, it would be expected that trait sleepiness would be related to state sleepiness. Though it is possible that if participants with a wider range of ESS scores were studied a correlation maybe found with KSS, as it stands the higher end of the ESS scale is not represented. The lack of correlation between the trait sleepiness and state sleepiness whilst driving suggests that ESS may not be a reliable tool to assess fitness to drive.

In chapter 5 larger standard deviation of number of driving incidents was reported within OSA participants compared with controls. This greater variation was not found with KSS and LHoFA scores, Table 6.4-1.

	Normal sleep		Sleep restriction	
Total KSS s.d.	OSA	Control	OSA	Control
	1.46	1.56	1.97	1.69
Total LHoFA s.d.	OSA	Control	OSA	Control
	0.69	0.78	0.83	0.91

Table 6.4-1 Standard deviation of subjective scores

Sleep restriction resulted in larger standard deviations than normal sleep, reflecting individual difference in the ability to cope with sleep restriction. KSS following sleep restriction was the only measure showing a larger standard deviation in OSA than control participants. Overall this also shows that there is little difference in subjective experience within treated OSA and control participants.

6.5 Conclusions

- Treated OSA drivers do not show the increase in subjective sleepiness that would be expected following sleep restriction when the increase in number of driving incidents is considered.
- Both treated OSA participants and control participants feel sleepier and more likely to fall asleep while completing a driving task following sleep restriction compared to after a normal night's sleep.
- Increasing time on task significantly increases subjective sleepiness for both treated OSA and control participants following normal sleep and sleep restriction.
- It is possible that older drivers experience a quick transition from alert to very sleepy.
- KSS and LHoFA are highly correlated; older drivers recognise that if they feel sleepy they are likely to fall asleep.

CHAPTER SEVEN

Impact of sleep restriction on EEG sleepiness while completing a driving task

7.1 Introduction

The current chapter compares the EEG spectral components between treated OSA participants and control participants as they complete a two hour driving simulator task following a normal night's sleep and sleep restriction (5h). It has already been shown that OSA participants have greater task impairment following sleep restriction (chapter 5) but suffer no higher subjective sleepiness compared with controls (chapter 6). EEG spectral analysis provides a physiological indication of sleepiness which can be compared between groups.

7.1.1 Key points from the literature review

Increasing combined alpha and theta power has been demonstrated to be most representative of the transition between wake and sleep in healthy young participants during a driving simulator task (Horne et al. 1996). Beta activity occurs with increased effort to remain alert and has been shown to decrease with prolonged attention tasks (Jap et al. 2009).

Beta activity is of particular interest in OSA participants as it has found to be higher in untreated patients during a driving task of medium traffic density compared to controls, suggestive of increased effort to remain alert (Tassi et al. 2008). Higher activity in the beta and theta power spectrum has also been observed during total sleep deprivation in untreated OSA participants compared with controls, suggesting greater sleepiness and greater effort to remain alert (Greeneche et al. 2008).

Very few EEG studies have been carried out in the area of OSA and driver simulation and in particular none of longer duration. Risser et al. (2000) completed a driving simulator study for 60 min including EEG recording of untreated OSA participants compared with control participants. OSA participants were found to have more "attention lapses" in EEG activity than controls and these lapses became longer in duration as the task progressed for the OSA participants. Participants were asked to rate sleepiness subjectively before and after the task. Despite the greater amount of "attention lapses" in EEG, OSA participants showed parallel increase in subjective sleepiness to controls. This indicates that the EEG activity of untreated OSA participants differs to that of controls during a driving task, and that subjective

sleepiness in OSA may not be linked to EEG activity, however, this driving task was only 60 minutes so it is unknown if the same result would be found with a longer task. No similar studies were identified with treated OSA participants.

7.1.2 Research aim and hypotheses

Aim: To evaluate the effect of sleep restriction in OSA-CPAP compliant patients compared with controls at a simulated driving task.

Hypotheses:

To test the hypothesis that OSA CPAP compliant participants will show no difference in driver performance at a driving simulator task as reflected by increased beta and combined alpha theta activity after a normal night of treated sleep.

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by increased beta and combined alpha theta activity after sleep restriction to 5h of treated sleep both overall and at the specific time of first incident for the OSA group.

7.2 Method

Design: repeated measures counter balanced. Completing a 2h afternoon drive following a normal night's sleep and following sleep restriction to 5h. Comparing treated OSA participants and healthy controls.

Setting: driving simulator

7.2.1 Participants

Participant characteristics can be found in chapter 4. 20 control participants and 19 OSA participants are represented in the following chapter.

7.2.2 Protocol

Full study protocol can be found in chapter 3.

7.2.3 Measures

Two channels of EEG activity were recorded, C3-A1 for analysis and C4-A2 as a backup. Resulting from exploratory analysis described in chapter 3, combined alpha and theta (4-11 Hz) and beta (13 – 20 Hz) bands were used for the final analysis.

EEG data was recorded in 4 second epochs, power in the specific hertz bands was averaged into 1 minute epochs for each participant and standardised to the first 30 minutes of the normal sleep drive, full details can be found in chapter 3.

7.2.4 Statistical analysis

EEG activity is visually displayed in 1 minute epochs to show change in activity across the drive, each data point represents a mean for participants at that time point. These results were averaged into 30 minute epochs for statistical analysis using a mixed measures ANOVA, with 2 within subject factors; condition (2 levels) and time (4 levels), and the between subjects factor, of having OSA or not, as described in section 3.6.

In all cases raw data were visually examined in histograms both spectral analysis of EEG were slightly skewed, square root transformation of the data was completed but as this did not affect statistics the original data is presented here. Huynh-Feldt (ϵ) adjustment was used where the assumption of homogeneity of variance was not met.

EEG at minute 65 of the drive is compared between groups using a 1 tail independent t test. This data is normally distributed, the assumption of homogeneity of variance was also met, tested using Levenes.

7.3 Results

7.3.1 Combined alpha and theta activity

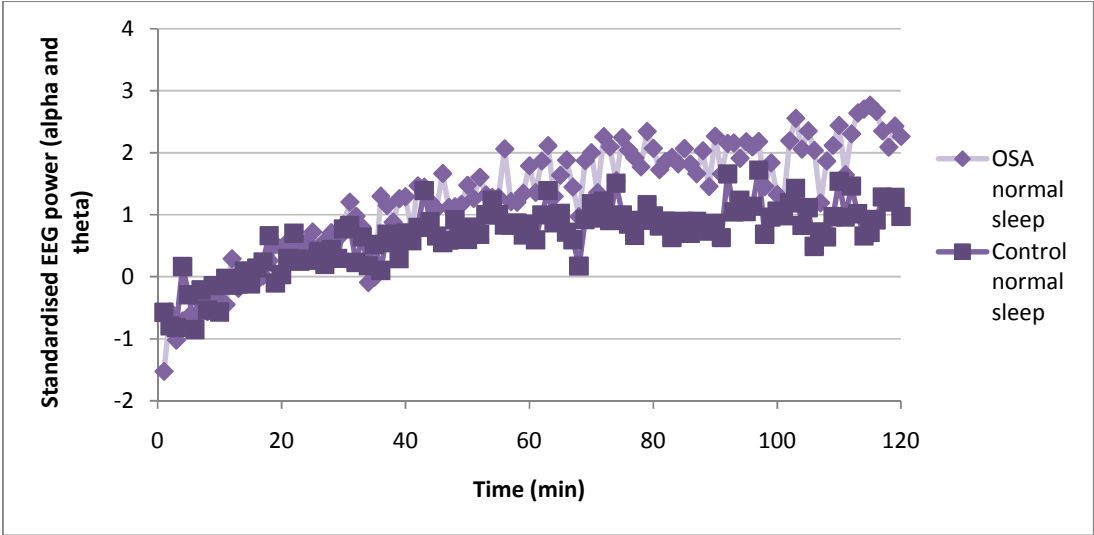


Figure 7.3-1 Mean standardised EEG power (4 - 11Hz) in 1 min epochs, for both groups following normal sleep

Following a normal night’s sleep both control and OSA participants demonstrated an increase in alpha and theta power for the first hour of the drive before reaching a plateau in the second hour, see Figure 7.3-1.

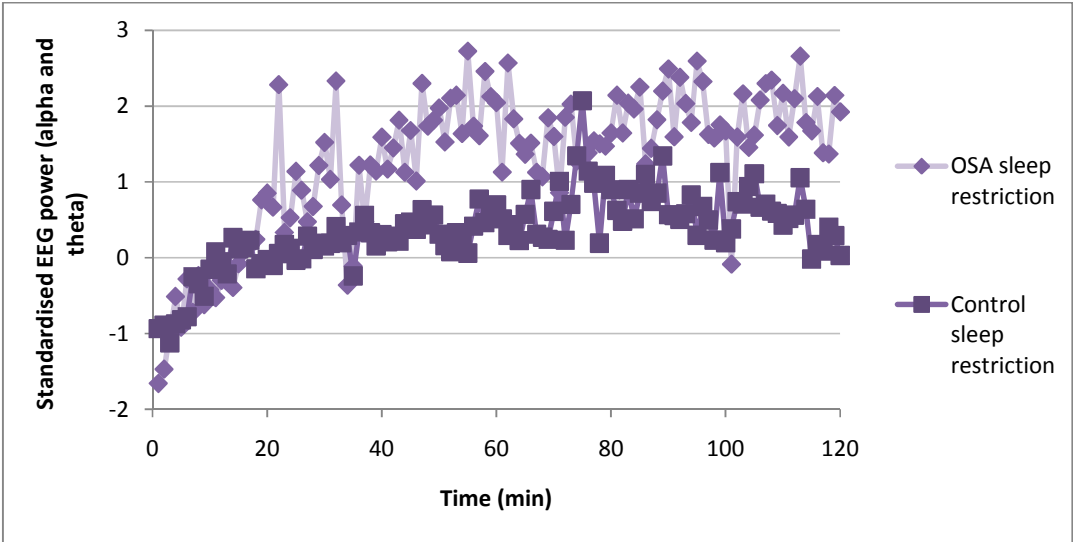


Figure 7.3-2 Mean standardised EEG power (4 - 11Hz) in 1 min epochs, for both groups following sleep restriction

Following sleep restriction OSA participants show similar alpha and theta power to controls for the first 20 minutes. For the rest of the drive EEG power is higher for OSA participants.

For statistical analysis scores were averaged to 30 minute epochs, see Figure 7.3-3.

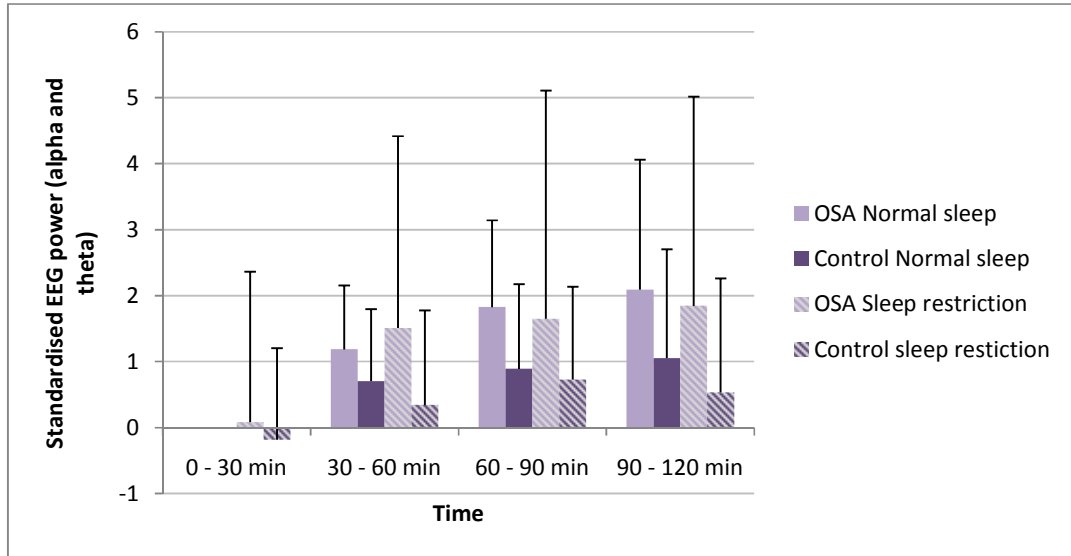


Figure 7.3-3 Mean EEG power (alpha and theta) in 30 min epochs with standard deviation

Following one night sleep restriction to 5 hours there was no significant effect of condition [$F(1,37) = 0.339, p = 0.635, \epsilon = 1$], participants showed no difference in EEG sleepiness despite feeling significantly subjectively sleepier and demonstrating significantly worse performance at the task. Although OSA participants showed greater EEG sleepiness than controls, the group interaction was not significant [$F(1,37) = 0.221, p = 0.641, \epsilon = 1$].

There was a significant effect of time [$F(1.74, 64.23) = 35.05, p < 0.001, \epsilon = 0.58$] showing an increase in EEG sleepiness as the drive progressed. There is also a significant time, group interaction [$F(1.74, 64.23) = 4.27, p = 0.023, \epsilon = 0.58$] visualised in Figure 7.3-4. The OSA participants showed significantly greater alpha and theta power in the later 90 minutes of the drive than would be expected if time of task had the same effect as it did on controls.

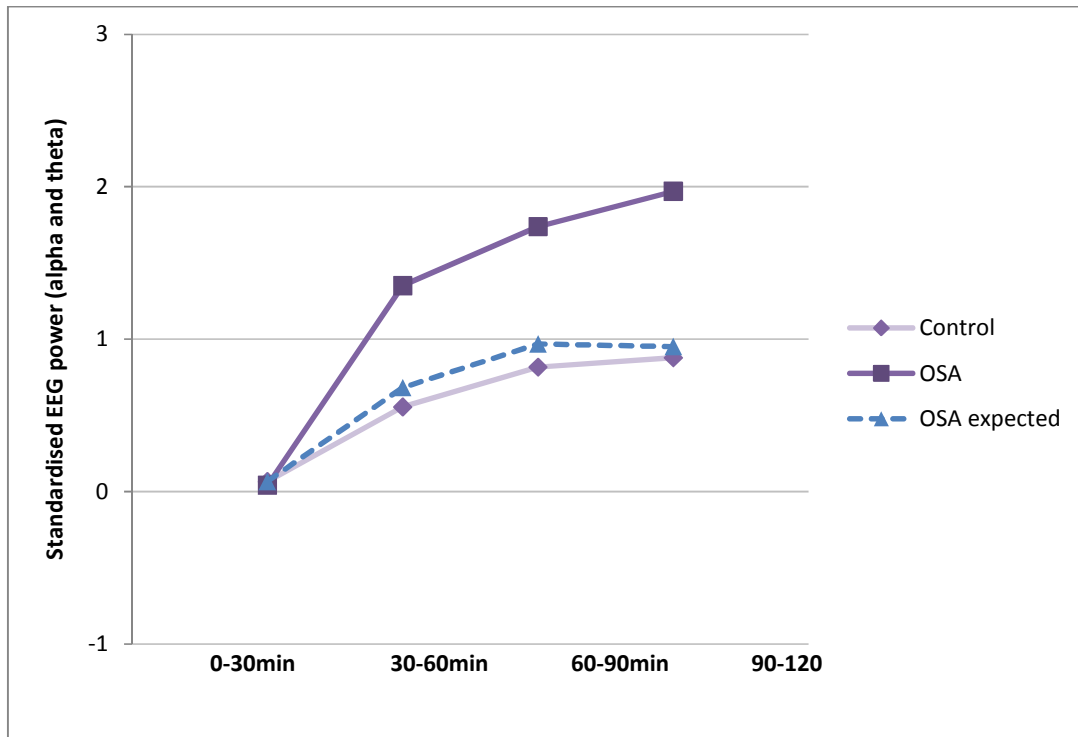


Figure 7.3-4 Mean standardised EEG power (4-11Hz) across both conditions, for each group over time, in 30 minute epochs

7.3.2 Beta activity

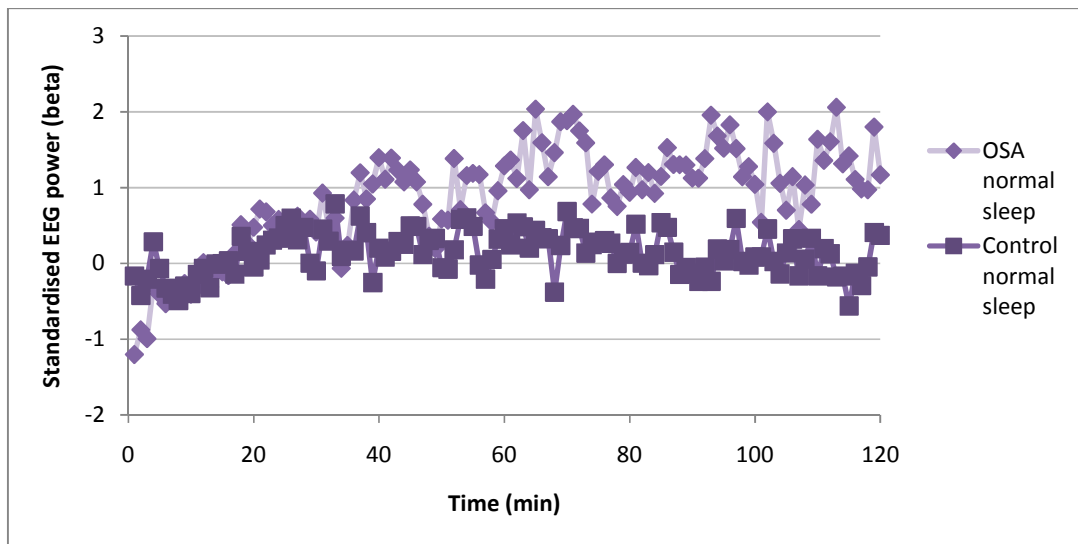


Figure 7.3-5 Mean standardised EEG activity (13-20Hz) in 1 min epochs, for both groups after a normal sleep

Following a normal night's sleep beta activity was similar for both groups for the first 40 minutes activity slightly higher in OSA participants than control participants for the remainder of the drive, see Figure 7.3-5.

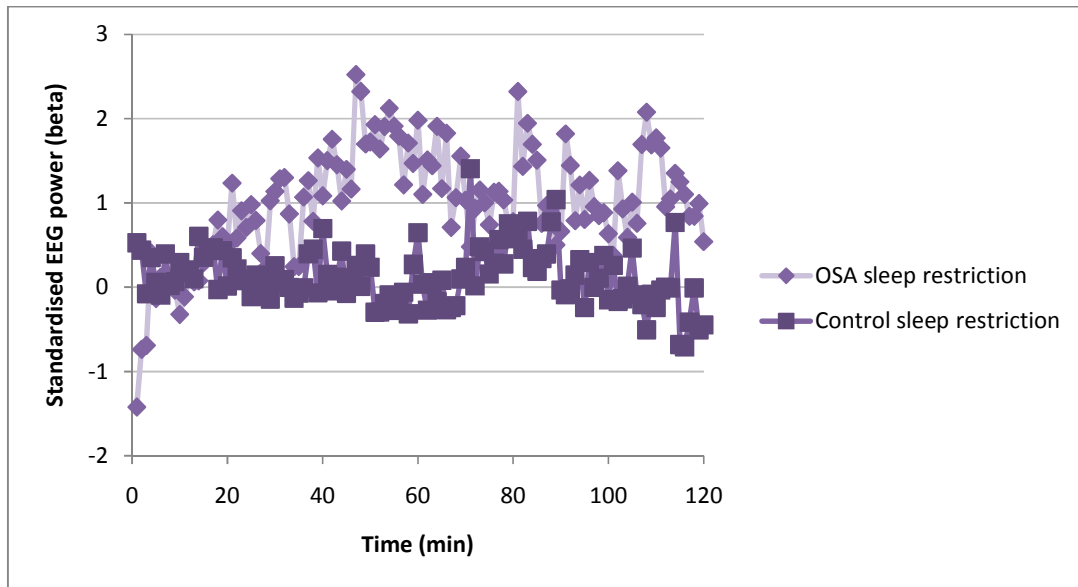


Figure 7.3-6 Mean standardised EEG power (13 - 20Hz) in 1 min epochs, for both groups following sleep restriction to 5 hours

Following sleep restriction EEG power in the beta spectrum was higher for most of the drive for the OSA participants compared with controls.

For statistical analysis scores were averaged to 30 minute epochs, see Figure 7.3-7

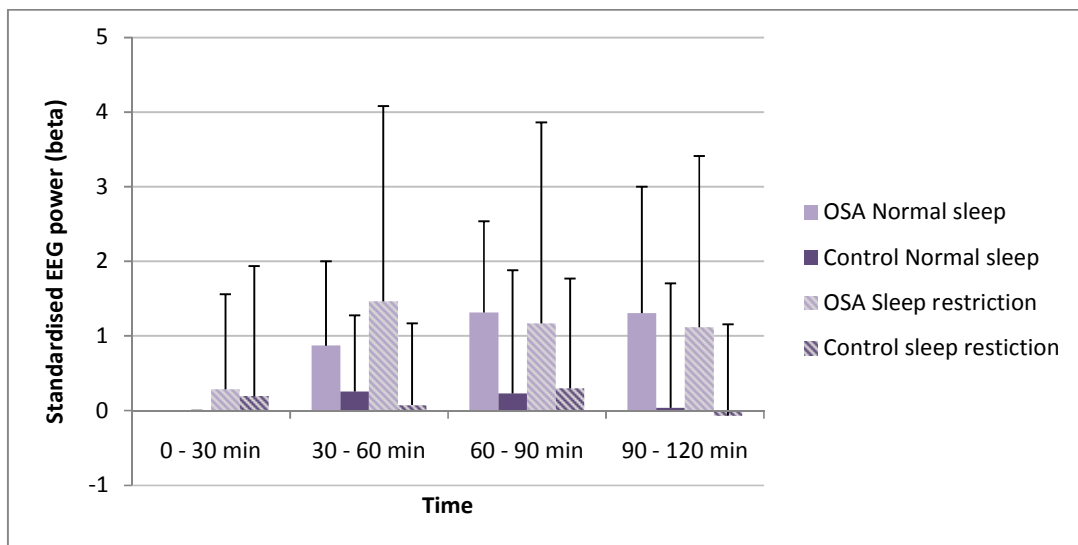


Figure 7.3-7 Mean EEG power (beta) in 30 minute epochs with standard deviation

Condition had no significant effect on power in the beta range [F (1,37) = 0.08, p = 0.777, $\epsilon = 1$]. There was a significant effect of time, as beta power increases as the drive progressed [F (1.8, 65.6) = 5.8, p = 0.006, $\epsilon = 0.59$].

There was again a significant time, group interaction [$F(1.78, 65.6) = 4.91, p = 0.013, \epsilon = 0.59$]. The OSA group have significantly more power in the beta range in minutes 30 to 120 than would be expected if beta activity followed the same pattern as for control participants, suggesting a greater effect of time on task on the OSA participants, this is visualised in Figure 7.3-8

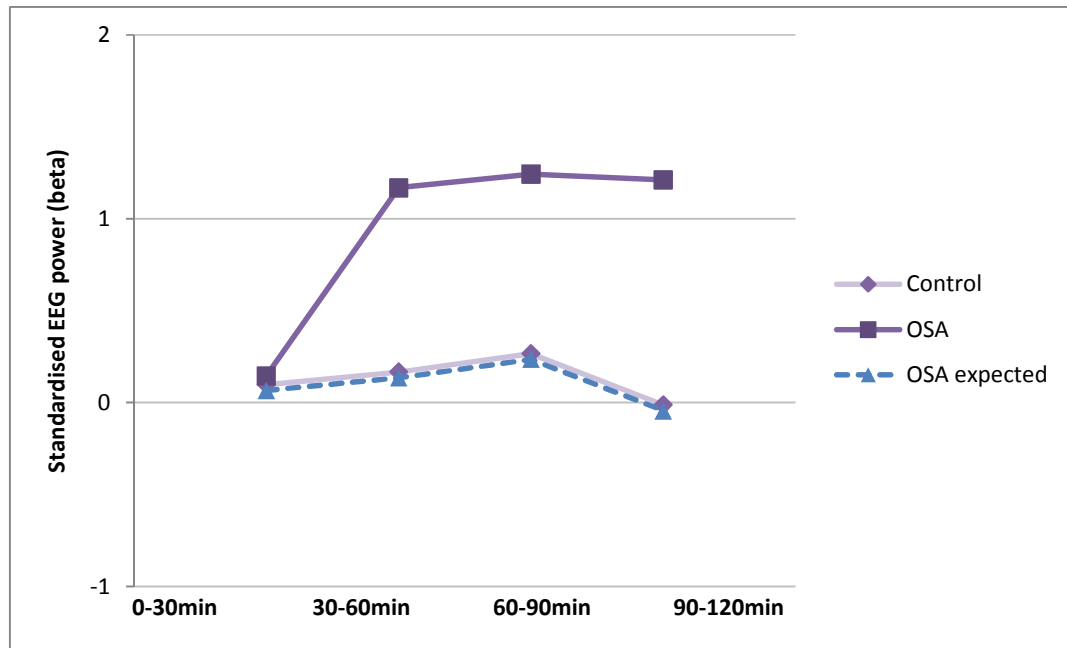


Figure 7.3-8 Mean standardised EEG activity (13 -20Hz) combined for both groups over time for both conditions and expected power following sleep restriction, in 30 minute epochs

7.3.3 Sleep restriction: time at first major incident

Following sleep restriction control participants could drive for significantly longer before having their first major incident than OSA participants, 91.1 minutes (s.d. 38.6) compared to 65.0 minutes (s.d. 42.0), reported in chapter 5. The EEG activity at minute 65 of the sleep restriction condition was selected to represent the time point where OSA participants were struggling with sleepiness and control participants were not (as measured by task performance). Comparison between the two groups at this point was completed using an independent t test (1 tail).

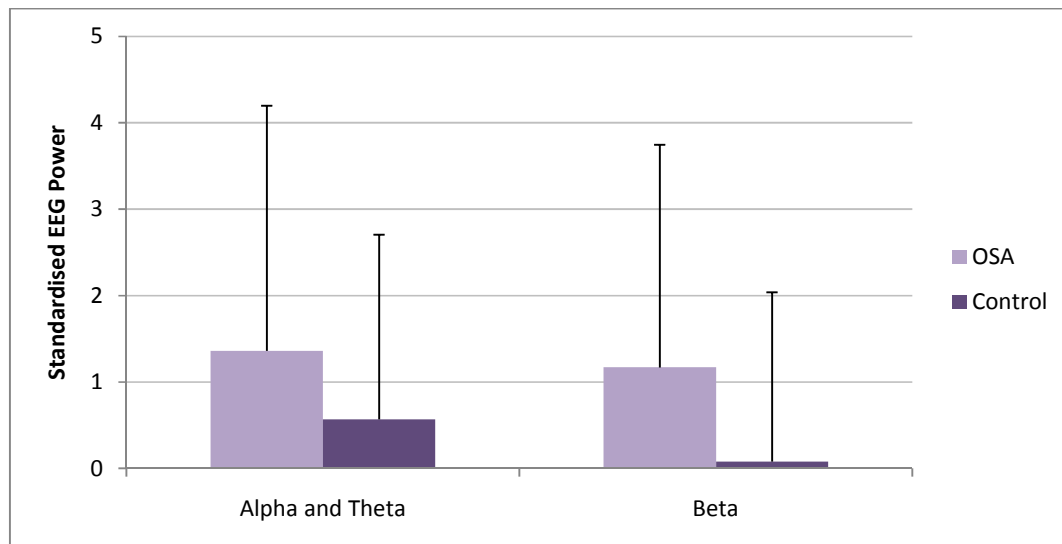


Figure 7.3-9 Mean standardised EEG power at minute 65 of the sleep restriction condition, for both groups with standard deviation

At minute 65 of the sleep restriction condition there is a near significant trend for OSA participants to have higher beta power than the control group, suggesting greater effort to maintain alertness [$t(37) = 1.49, p = 0.07$]. There is a no significant difference between alpha and theta power between groups [$t(37) = 0.97, p = 0.17$].

7.4 Discussion

There was no significant effect of condition on either combined alpha theta EEG power (indicative of sleepiness) or beta EEG power (indicative of effort to remain alert). This was unexpected as sleep restriction had resulted in significantly more driving incidents and significantly greater subjective sleepiness, also sleep restriction has been reported to effect EEG activity in previous studies (Horne et al. 1996, Greneche et al. 2008). The lack of significant difference despite the trends in EEG activity is due to variation between participants. Large individual differences in EEG spectral activity are to be expected due to factors such as thickness of the skull, slight variation in electrode placement at study repetition and artefact due to muscle activity. For each participant recordings were standardised to the first 30 minutes of the drive following normal sleep to try to control for this variation. However, because driving (even under monotonous conditions) is not a constant experience, such as staring at a blank wall, fluctuation within the EEG signal is unavoidable. Individual difference as a topic is discussed in chapter 10.

It is also possible that significance was not found between conditions because participants did not reach a great enough sleepiness level to be apparent in the EEG. In the current study the average KSS score for both groups was less than 7 following sleep restriction, showing participants were not feeling sleepy and EEG activity has been shown to represent physiological changes due to sleepiness specifically when extreme sleepiness is encountered (Akerstedt et al. 1990), sleepiness may not have been extreme enough to effect EEG activity.

Sleep restriction was found to result in significantly more driving incidents for OSA participants than controls. Although there is no significant effect of group on EEG activity, the sleep restriction showed a trend for greater impact on OSA participants. Both combined alpha/theta and beta activity was similar between groups for the first 30 minutes, then higher for OSA participants for the rest of the drive. Higher alpha/theta and beta activity has also been reported in untreated OSA participants compared with controls during sustained wake (Greeneche et al. 2008), this is still apparent in treated OSA participants in the current study although not significant. The higher alpha/theta activity suggests the OSA participants were sleepier, and higher beta suggests they were putting in more effort to remain alert than controls. This would explain the significant difference in driving incidents between OSA and control participants.

There was a significant effect of time on both beta and combined alpha and theta power, with participants getting sleepier and putting in more effort to remain alert as the drive progressed. In both cases the significant time, group interaction shows the OSA participants to be more affected by time on task than the control participants. This effect has also been demonstrated previously in (Eoh et al. 2005) but in this case the driving simulation task was only 50 minutes in duration which is short when investigating the effect of time on task. In the context of driving, treated OSA drivers may need to break from driving more often than control drivers, as they feel significantly sleepier with time on task.

Previous research has shown untreated OSA participants to have greater EEG sleepiness during a driving task than controls (Risser et al. 2000); no significant

difference was identified in the current work between treated OSA participants and controls. It is possible that the CPAP treatment has eliminated any difference in EEG sleepiness between groups; however, these studies differ in their approach to EEG analysis.

After sleep restriction the OSA participants were on average able to drive for 65 minutes before having their first major incident, compared to 91 minutes for controls. EEG activity at minute 65 after sleep restriction showed OSA participants to have slightly higher EEG sleepiness than control participants (nsd) and putting in more effort to remain alert (nsd). Unfortunately, this effort was not effective as major driving incidents still occurred. A greater effort to remain alert by OSA participants than controls was also reported by Tassi et al. (2008). Here untreated OSA patients and controls completed 6, 25 min, driving simulations over 24 hours of sustained wake. The authors suggest the increase in beta activity can be used to maintain performance so long as the activity is not too monotonous or boring. The monotonous nature of the current task might explain why despite indication of higher beta activity task performance was not maintained.

	Normal sleep		Sleep restriction	
Total Alpha and theta s.d.	OSA	Control	OSA	Control
	0.93	0.52	0.95	0.48
Total Beta s.d.	OSA	Control	OSA	Control
	0.68	0.28	0.66	0.34

Table 7.4-1 Standard deviation of 1 min epoch EEG activity

For both of the EEG bands analysed in both conditions there is greater standard deviation within the OSA participants than the control participants, see Table 7.4-1. This greater variability within the OSA participants was also apparent in the number of driving incidents and will be discussed in chapter 10.

7.5 Conclusions

- Sleep restriction did not significantly affect EEG alpha and theta power or beta power in either group.
- Time on task resulted in significantly greater sleepiness and effort to remain alert in OSA participants compared with controls.

- OSA participants were sleepier than control participants as measured by alpha and theta EEG activity (nsd). Both after a normal night's sleep and following sleep restriction.
- OSA participants appeared to put more effort into staying alert than control participants, as measured by beta activity (nsd). There is no difference in the amount of effort put in with and without sleep restriction.

CHAPTER EIGHT

Insight into sleepiness, the ability to recognise sleepiness prior to a major driving incident

8.1 Introduction

The following chapter investigates if treated OSA participants and older healthy controls can identify when they are sleepy (have insight into their sleepiness). It is known that young participants have insight into sleepiness (Horne et al. 2004) with typically 45 minutes of feeling sleepy prior to a major driving incident occurring (Reyner and Horne 1998b). This has legal implications because drivers have prior warning of their sleepiness and therefore can be held responsible if a sleep-related incident occurs. In the situation of an OSA driver falling asleep at the wheel it has been argued that OSA renders the driver unable to identify sleepiness and will have no opportunity to cease driving prior to srRTI therefore they are not responsible.

8.1.1 Key points from the literature review

Participants for Reyner and Horne (1998b) and Horne et al. (2004) were in their early twenties and were able to recognise that they were sleepy, with an average of 45.5 minutes of declaring some level of sleepiness until first major incident, with 83% of major incidents happening in KSS 8 or 9. The current research allows for the same analysis to be completed on older healthy and OSA participants aged 50 to 75.

The current research has shown treated OSA participants to be more affected by sleep restriction than controls in terms of total driving incidents and safe driving time. However, following a normal night's sleep there is little difference in driving ability (measured by driving incidents) and no evidence that treated OSA patients should cease driving. The significant difference in safe driving time following sleep restriction is concerning, raising the question do OSA patients know when they are sleepy? If treated OSA patients are able to recognise sleepiness, they have full opportunity to stop driving and consequently should be held responsible for falling asleep at the wheel in the same manner as other road users.

Previous research investigating the ability to recognise sleepiness has been undertaken with untreated OSA sufferers. Desai et al. (2006) took subjective sleepiness ratings on the Stamford Sleepiness Scale periodically through the day comparing OSA and control participants during total sleep deprivation and then following a full night's sleep. The authors report the increase in sleepiness from the

full night's sleep to sleep deprivation as being significantly greater for controls than OSA participants, from which they suggest the OSA participants are not as good at recognising sleepiness as the controls. However, in practice the difference was small, with an increase just of 1.3 for OSA sufferers, compared to 1.9 for controls. Conversely, Pizza et al. (2008) used a divided attention driving task periodically through the day to demonstrate that times where task performance was most impaired coincided with when OSA participants rated themselves as most sleepy, therefore suggesting OSA participants can recognise sleepiness.

Subjective sleepiness and EEG (combined alpha and theta) sleepiness have been investigated separately in chapters 6 and 7; both increased as a result of sleep restriction (nsd for EEG). The relationship between subjective sleepiness and EEG sleepiness can be used to examine the extent to which drivers are aware of their sleepiness, which is positively correlated in young participants (Horne et al. 2004). Greneche et al. (2008) also investigated correlation of EEG and subjective sleepiness; here during 24 h sustained wake in older participants. EEG was found to closely correlate to subjective sleepiness in control participants but not to OSA participants, suggesting OSA participants do not know when they were sleepy. This study was not associated with a performance task, so is not directly comparable to the current work as the perception of task performance may influence perception of sleepiness. However, it is of interest that the correlation was not identified in OSA participants.

The previous studies with OSA participants identifying sleepiness have all been in untreated cases. Using CPAP has been shown to change an OSA patient's perception of sleepiness (Engleman et al. 1997). In the study participants were asked to rate their sleepiness using the ESS before starting CPAP, then to retrospectively re-rate their ESS following treatment, this resulted in a significant increase in ESS score. This may suggest that the treated OSA participants in the current work will be able to identify sleepiness even though previous studies with untreated OSA patients report difficulties. A possible explanation might be that sleepiness was common place before treatment so the severity was not recognised. Following treatment participants were then at an increased ability to recognise sleepiness and could more accurately re-assess their ESS from before treatment. In this case, OSA patients may be better able

to identify sleepiness having experienced a severe case and subsequently been treated. However, it is also possible that participants were unwilling to admit before treatment how sleepy they actually felt for fear of consequence, e.g. being told they are too sleepy to drive or that they now feel an obligation to demonstrate the CPAP is working.

8.1.2 Research aim and hypotheses

Aim: To evaluate the ability of OSA-CPAP compliant patients compared with controls at recognising sleepiness during a simulated driving task.

Hypotheses:

To test the hypothesis if OSA CPAP compliant participants show impaired ability to subjectively identify sleepiness at a driving simulator task as reflected by greater number of driving incidents while reporting not being sleepy, reporting feeling sleepy prior to first driving incident after sleep restriction to 5h.

To test the hypothesis that EEG will correlate to KSS in both treated OSA and control participants after sleep restriction to 5h.

To test the hypothesis that fleeing sleepy will be associated with being likely to fall asleep for OSA CPAP treated patients during a driving task following sleep restriction to 5h.

8.2 Method

Design: single condition, completing a 2h drive following sleep restriction to 5h. Comparing treated OSA participants and healthy controls.

Setting: driving simulator

8.2.1 Participants

Participant's characteristics can be found in chapter 4. 20 control participants and 19 OSA participants are represented in the following chapter.

8.2.2 Protocol

Study protocol was followed as detailed in chapter 3. The data presented here is the results following the sleep restriction condition only, in order that participants were likely to experience some sleepiness.

8.2.3 Measures

Driving incidents, subjective sleepiness and EEG were recorded and analysed as detailed in chapter 3.

8.2.4 Statistical analysis

Subjective sleepiness ratings were recorded every 200 seconds throughout each drive, resulting in 36 recordings per 2h. Each score was taken to represent the 100 seconds preceding and following the time it was given. The number of major and minor driving incidents coinciding with each subjective score were totalled for each participant and averaged across each group.

The frequency of LHoFA score was reported for each KSS rating. Throughout the drive 36 subjective sleepiness scores are recorded, giving a total of 720 responses for controls (n=20) and 684 responses for OSA (n=19) participants. The frequency of each combination of KSS and LHoFA is displayed as a percentage in area graphs for each group.

In the case of the specific analysis of subjective sleepiness prior to major incidents, only those participants who had a major incident could be included, control n = 9, OSA n = 14. This is presented as a percentage of participants reporting sleepiness prior to major incident.

Mean subjective sleepiness score at first major incident are compared between groups by independent t test. The subjective scores data was normally distributed and met the assumption of homogeneity of variance, assed by Levenes test.

Pearson's r (r) is also reported for EEG and KSS correlation as although the KSS produces categorical data the scale is well validated and widely used with parametric statistics. The correlation of EEG and KSS is compared between participants reporting sleepiness prior to incident and those not reporting sleepiness prior to incident.

Spearman's rho (r_s) is used to assess correlation between EEG and LHoFA in those participants who had a major incident (control n = 9, OSA n = 14).

8.3 Results

8.3.1 Driving incidents per subjective score

To test the hypothesis if OSA CPAP compliant participants show impaired ability to subjectively identify sleepiness at a driving simulator task as reflected by greater number of driving incidents while reporting not being sleepy, reporting feeling sleepy prior to first driving incident after sleep restriction to 5h.

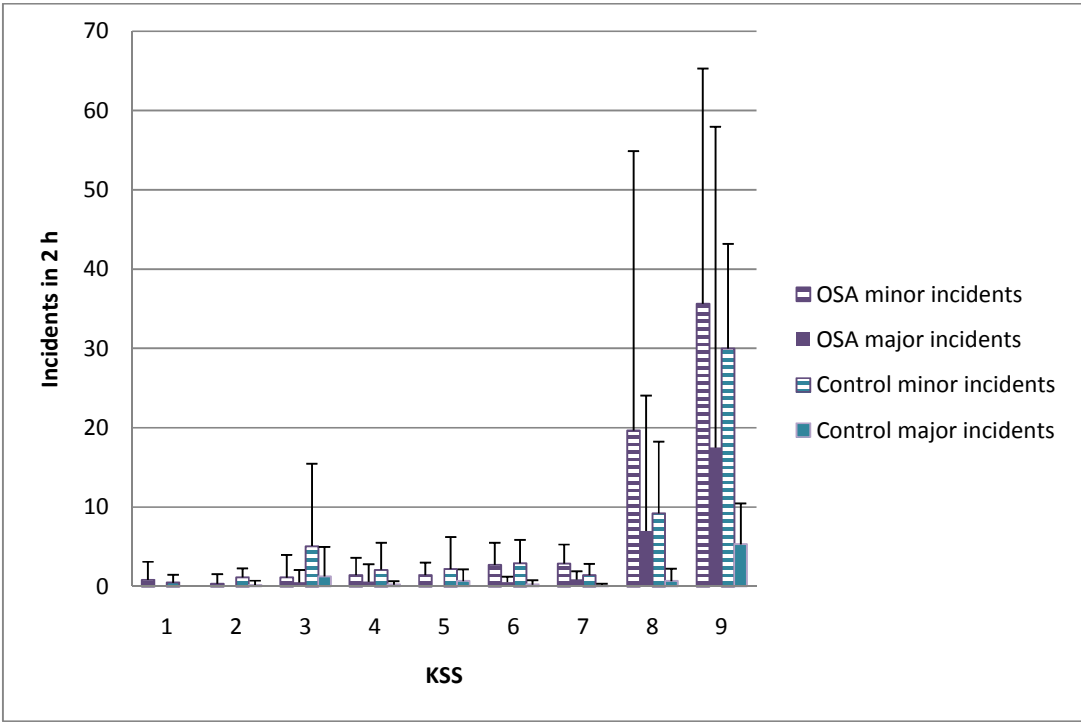


Figure 8.3-1 Mean minor and major driving incidents per KSS for OSA and control participants with standard deviation

Figure 8.3-1 displays major (solid colour) and minor (hatched colour) incidents for the 2 h drive occurring at each KSS rating for control and OSA participants. Few minor and major incidents occur for both groups in KSS ratings 1 to 7, with no increase in frequency at the start of signs of sleepiness (6 to 7). OSA participants had a greater number of driving incidents at KSS 8 than control drivers, but this is a reflection of OSA participants having a total greater number of incidents overall.

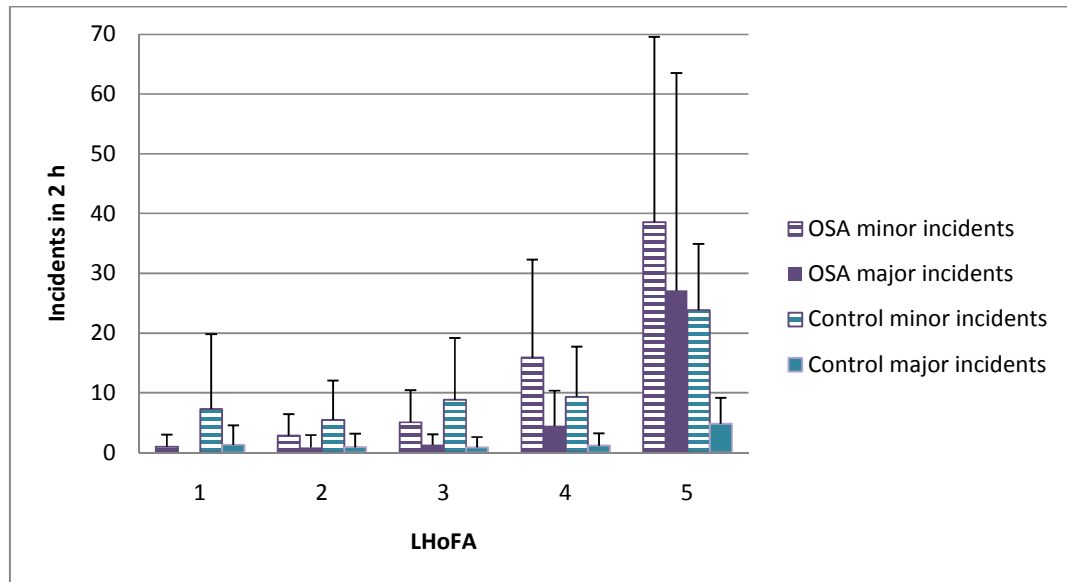


Figure 8.3-2 Mean major and minor incidents for each LHoFA sleep rating in OSA participants with standard deviation

Figure 8.3-2 shows major (solid colour) and minor (hatched colour) incidents for the 2 h drive within each LHoFA rating for control and OSA participants. The OSA participants have few minor and major incidents for LHoFA 1 to 3, followed by an increase for both in LHoFA 4 and 4. Control participants did not show increase in driving incidents until LHoFA 5.

8.3.2 Association of sleepiness with likelihood of falling asleep

To test the hypothesis that fleeing sleepiness will be associated with being likely to fall asleep for OSA CPAP treated patients during a driving task following sleep restriction to 5h.

To assess if feeling sleepy (KSS 8 and 9) is associated with being likely to fall asleep (LHoFA 4 and 5) the percent of LHoFA responses in each KSS was recorded.

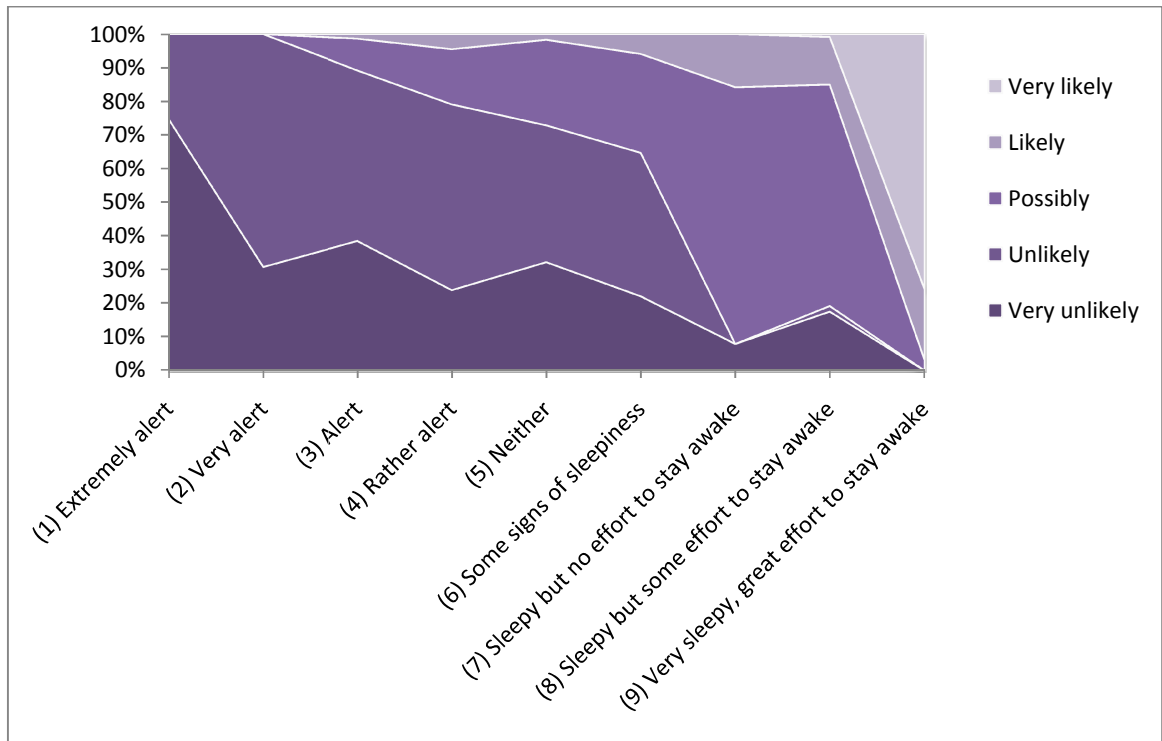


Figure 8.3-3 The percentage of KSS rating spent in each LHoFA score for control participants

	Very unlikely	Unlikely	Possibly	Likely	Very likely
(1) Extremely alert	0.9	0.3	0.0	0.0	0.0
(2) Very alert	4.0	9.1	0.0	0.0	0.0
(3) Alert	8.2	10.8	2.0	0.3	0.0
(4) Rather alert	2.3	5.3	1.6	0.4	0.0
(5) Neither	2.7	3.5	2.2	0.1	0.0
(6) Some signs of sleepiness	2.2	4.2	2.9	0.6	0.0
(7) Sleepy but no effort to stay awake	0.4	0.0	4.2	0.9	0.0
(8) Sleepy but some effort to stay awake	3.0	0.3	11.4	2.4	0.1
(9) Very sleepy, great effort to stay awake	0.0	0.0	0.4	2.9	10.4

Table 8.3-1 Percentage of total time in each KSS rating, subdivided into categories of likelihood of falling asleep for control participants

Figure 8.3-3 and Table 8.3-1 show the percentage of time spent in each KSS and LHoFA combination for control participants. While scoring KSS 8 on 3.3% of occasions control participants did not feel it likely they would fall asleep. 36.5% of total drive time was spent in KSS categories 7 to 9.

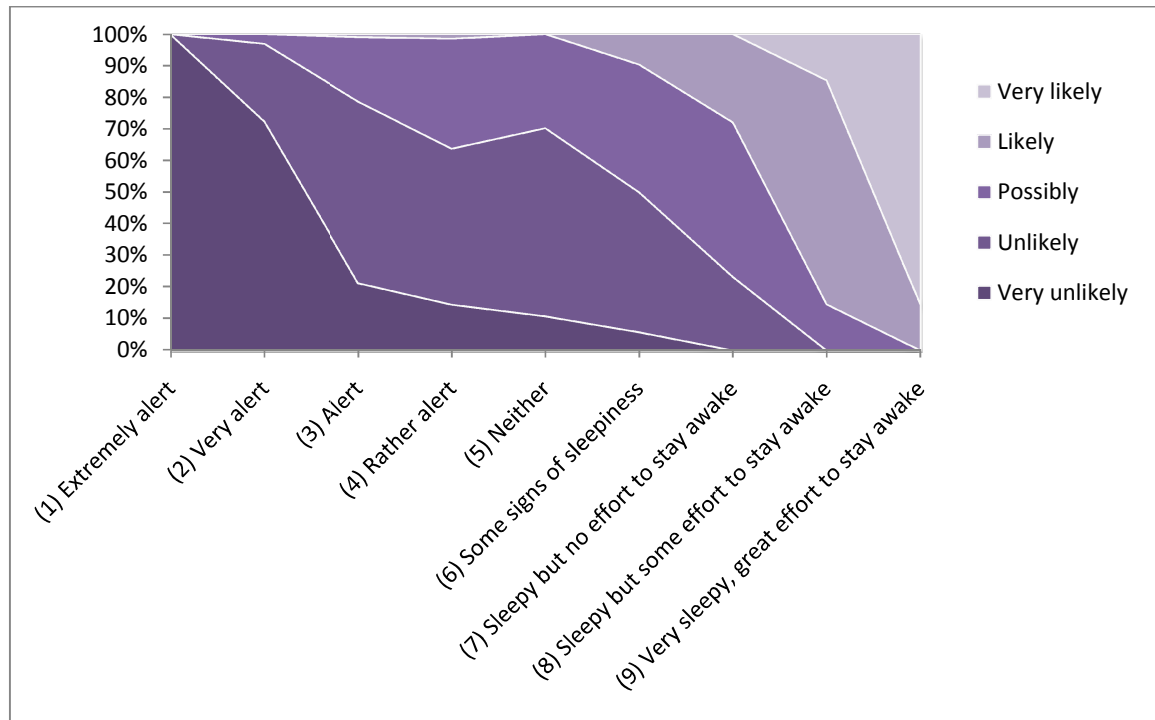


Figure 8.3-4 The percentage of KSS rating spent in each LHoFA score for OSA participants

	Very unlikely	Unlikely	Possibly	Likely	Very likely
(1) Extremely alert	10.8	0.0	0.0	0.0	0.0
(2) Very alert	7.1	2.4	0.3	0.0	0.0
(3) Alert	3.5	9.4	3.3	0.2	0.0
(4) Rather alert	1.5	5.2	3.6	0.2	0.0
(5) Neither	0.6	3.3	1.7	0.0	0.0
(6) Some signs of sleepiness	0.5	3.5	3.2	0.8	0.0
(7) Sleepy but no effort to stay awake	0.0	1.5	3.2	1.8	0.0
(8) Sleepy but some effort to stay awake	0.0	0.0	2.0	9.6	2.0
(9) Very sleepy, great effort to stay awake	0.0	0.0	0.0	2.7	16.2

Table 8.3-2 Percentage of total time in each KSS rating, subdivided into categories of likelihood of falling asleep for OSA participants

Figure 8.3-4 and Table 8.3-2 show the percentage of total time spent in each KSS and LHoFA combination for OSA participants. For OSA participants when scoring KSS 8 falling asleep was always seen as at least possible. 20.8% of drive time was spent in KSS categories 7 to 9.

8.3.3 Major incidents and subjective scores

To test the hypothesis if OSA CPAP compliant participants show impaired ability to subjectively identify sleepiness at a driving simulator task as reflected by greater number of driving incidents while reporting not being sleepy, reporting feeling sleepy prior to first driving incident after sleep restriction to 5h.

Control Participants
<ul style="list-style-type: none"> - 44.4% (4/9) identified sleepiness on the KSS (6+) prior to first major incident: the 4 participants had an average of 65.0 minutes sleepiness prior to incident. - 44.4% (4/9) participants identified some chance of falling asleep on LHoFA prior to first major incident: the 4 participants felt likely to fall asleep an average 34.1 minutes prior to incident. - In total 84 major incidents occurred: 48.8% of these occurred in KSS 8 and 9. 45.2% occurred in KSS 1 – 5. - 45.2% of major incidents occurred in LHoFA 4 and 5.
OSA Participants
<ul style="list-style-type: none"> - 71.4% (10/14) participants identified sleepiness on the KSS (6+) prior to first major incident: the 10 participants had an average of 15.3 minutes sleepiness prior to incident. - 50% (7/14) participants identified some chance of falling asleep on LHoFA prior to first major incident: the 7 participants felt likely to fall asleep an average of 19.2 minutes prior to incident. - In total 323 major incidents occurred, 90.7% of these occurred in KSS 8 and 9. 4.9% occurred in KSS 1 – 5. - 90.7% of major incidents occurred in LHoFA 4 and 5.

Table 8.3-3 Perception of sleepiness

During the drive 9 control participants and 14 OSA participants had a major driving incident. 44.4% of control participants identified sleepiness prior to major incident and did so an average of 65 minutes prior to the major incident. 71.4% of OSA participants identified sleepiness prior to major incident though with less warning, having an average of 15.3 minutes awareness of sleepiness before an incident occurred.

44.4% of control participants felt likely to fall asleep prior to major incident, though for a shorter time (34.1 minutes) than they had felt sleepy for. 50% of OSA participants

reported likelihood of falling asleep prior to major incident giving a longer warning time (19.2 minutes) than KSS.

90.7% of major incidents for OSA participants occurred while reporting KSS 8 and 9 compared with only 48.8% of control participants major incidents occurring in KSS 8 and 9.

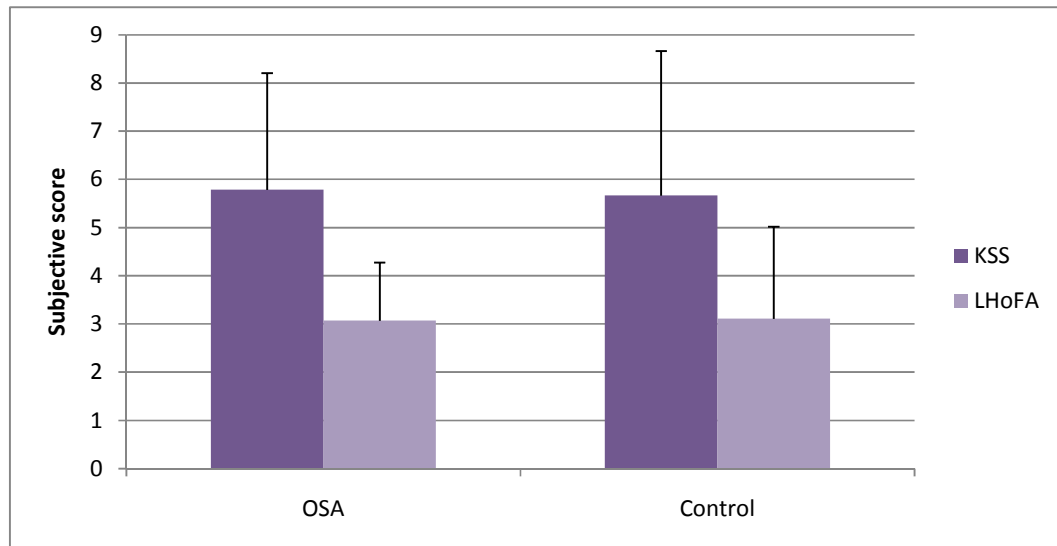


Figure 8.3-5 Mean subjective sleepiness score at first major incident with standard deviation

There was no significant difference between mean KSS or LHoFA score at first major incident for OSA or control participants, see Figure 8.3-5. At the time of first major incident neither group was identifying them self as sleepy or having a possibility of falling asleep.

8.3.4 EEG and subjective sleepiness

To test the hypothesis that EEG will correlate to KSS in both treated OSA and control participants after sleep restriction to 5h.

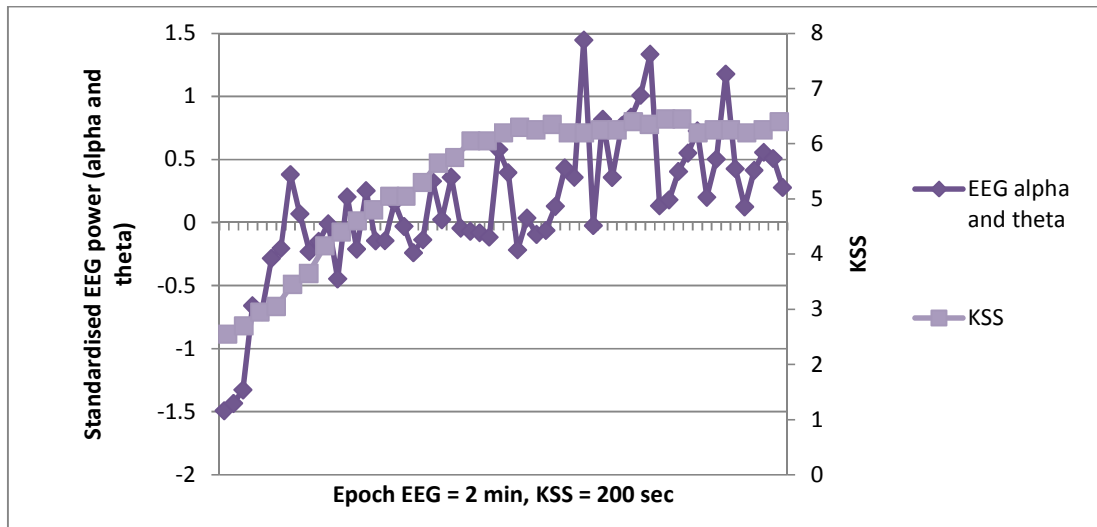


Figure 8.3-6 Mean change in EEG power (4 - 11Hz) in 2 min epochs and KSS in 200 s epochs during a 2 hour drive for control participants

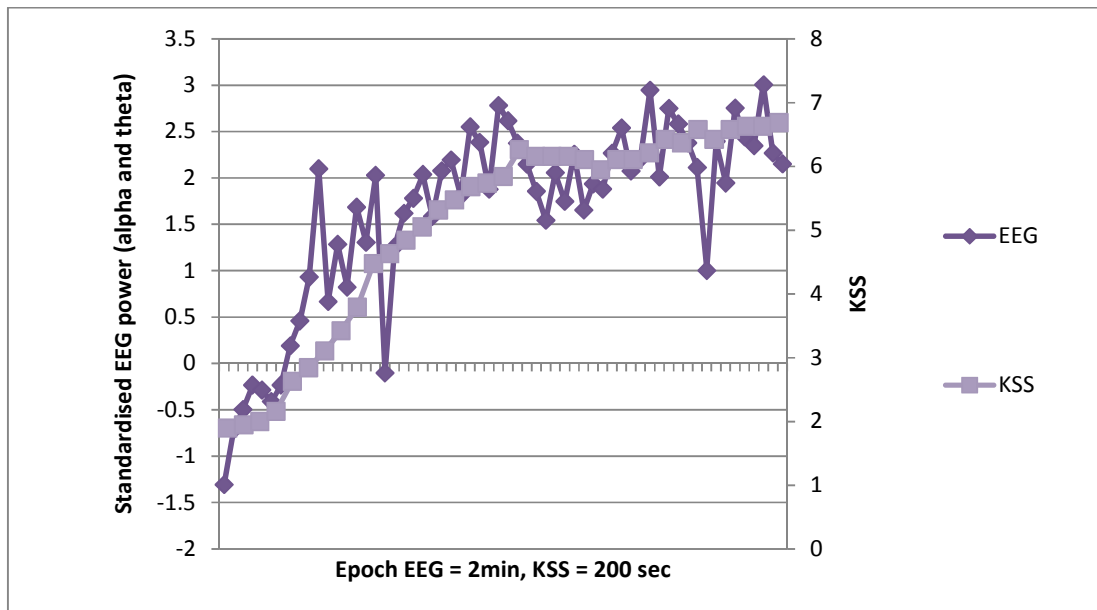


Figure 8.3-7 Mean change in EEG power (4 - 11Hz) in 2 min epochs and KSS in 200 s epochs during a 2 hour drive for OSA participants

Figure 8.3-6 and Figure 8.3-7 display combined alpha and theta power in 2 minute epochs and subjective sleepiness in 200 second epochs for the participants who had major incidents. The two measures are significantly correlated for both groups but a greater amount of variance is explained for OSA [$r = 0.89$, $p < 0.001$] participants compared with controls [$r = 0.75$, $p < 0.001$]. The same can be said for the correlation

between EEG sleepiness and LHoFA for OSA [$r_s = 0.75$, $p < 0.001$] and control participants [$r_s = 0.51$, $p < 0.001$], not graphically displayed.

8.3.5 Comparison of those with and without insight

As detailed above, 44.4% of controls and 71.4% of OSA participants identified sleepiness (by KSS) prior to having a major incident. It can be hypothesised that those who identified sleepiness may be able to do this because they have greater subjective awareness of their physiological sleepiness. If this were the case a stronger correlation between EEG sleepiness and subjective sleepiness would be expected. Those participants reporting sleepiness prior to incident are said to have “insight” into sleepiness.

	KSS Pearsons		LHoFA Spearmans rho	
Control EEG with insight n = 4	.88	$p = < 0.01$.76	$p = < 0.01$
Control EEG without insight n = 5	.19	$p = 0.13$.06	$p = 0.37$
OSA EEG with insight n = 10	.83	$p = < 0.01$.60	$p = < 0.01$
OSA EEG without insight n = 4	.82	$p = < 0.01$.69	$p = < 0.01$

Table 8.3-4 EEG and subjective sleepiness correlation in those with and without insight into sleepiness

In control participants correlation of EEG sleepiness and subjective sleepiness appears to be linked to ability to recognise sleepiness. In those control participants without insight into sleepiness no correlation was found between the two types of measure. Both sub groups of OSA participants showed significant correlation between EEG sleepiness and subjective sleepiness; however, only between 36% and 56% of variability is explained.

KSS at first major incident	With insight	Without insight
Control	8.8	3.2
OSA	7.1	2.5

Table 8.3-5 Mean KSS score at first major incident of those with and without insight into sleepiness

Mean KSS score at first major incident for both groups as a whole suggested that participants did not to feel sleepy at this time. However, when split into those with insight and those without in Table 8.3-5 it is apparent that participants with insight into sleepiness knew they were sleepy prior to first major incident and those without insight did not.

8.4 Discussion

The ability to identify sleepiness while driving gives drivers opportunity to cease driving before having a srRTI. This is an important skill which can mean the difference between life and death. Overall OSA participants were found to be more likely to recognise sleepiness prior to incident, more likely to report feeling sleepy at the time of major incidents and were more likely to acknowledge sleepiness may result in falling asleep than control participants. It is possible that their experience of having and being treated for a sleep disorder improves insight into sleepiness. It has previously been shown that perception of ESS changes following CPAP treatment in OSA patients (Engleman et al. 1997). It is possible that prior experience of extreme sleepiness results in more of the OSA participants being able to accurately identify increasing sleepiness than control participants.

73.7% of participants in the current work identified some sleepiness prior to having a major driving incident; less than the 100% reported in younger participants (Reyner and Horne 1998b). In that study younger participants were reported to have a 45.5 minute window of knowledge of sleepiness prior to their first major incident. In the current study control participants also had a long window of opportunity between identification of sleepiness and first major incident. Although the OSA participants were more likely to identify sleepiness they did so with an average 19 minutes (LHoFA) warning prior to the incident. In relative terms this could make it harder to find a safe place to stop before an incident occurs. In practice 15 minutes travelling at 70 mph on a motorway equates to 17.8 miles travelled, a distance at which it is likely a driver would come across a junction off the motorway in order to find a safe stopping place. On real roads with more traffic and a more stimulating environment it is probable that the window of opportunity to stop would be longer than in the simulator scenario. Greater stimulus from the environment makes the transition from slightly sleepy to very sleepy likely to increase in duration. It is also probable that in this study more incidents occurred than would do on the real roads due to the monotonous environment and a lack of consequence allowing drivers to be more complacent. In a real environment with more traffic on the road and the awareness of danger it is

probable fewer incidents would have occurred. Subsequently the time to first incident from identifying sleepiness is likely to be longer in practice.

Overall, neither group felt sleepy or likely to fall asleep at the time of first incident, despite a major sleep-related incident occurring. However, when both groups are divided into those with insight (reporting sleepiness prior to first major incident) and without insight, those with insight were reporting feeling sleepy prior to the first major incident. It appears if participants can identify sleepiness then they do so well. This has serious connotations in the real world, as although the signs may be there that a person is sleepy if they are unable to recognise them they will not be able to act. Education in identification of sleepiness may help; this could be investigated by repeating the study protocol with another group who had first received training to identify sleepiness.

Recognition of feedback from task performance appears to be particularly important as participants have difficulty identifying when they are likely to fall asleep if completing the MWT (Herrmann et al. 2010). Also correlation between EEG and subjective sleepiness is not apparent with untreated OSA participants during sustained wakefulness and no performance task (Greeneche et al. 2008).

In previous work all young drivers were able to identify sleepiness prior to a major incident (Reyner and Horne 1998b). The lesser ability of these older drivers to identify sleepiness may be explained by a weaker correlation association between subjective sleepiness and EEG alpha and theta power. The correlation between EEG and KSS in young people explains between 77.4 and 86.5% of the variability (Horne et al. 2004) compared to between 56.3% and 79.2% of the variability in the current study, demonstrating that younger participants are more aware of EEG sleepiness changes than the older participants. It should be noted that in Horne et al. (2004) EEG activity was reported in 200 second epochs and in the current work is reported in 120 second epochs. Another consideration is that in the current work all the older drivers are male and the studies of Horne and Reyner with younger drivers had a mix of male and female participants. It has been shown that women are better at identifying increased sleepiness with alcohol consumption (Barrett et al. 2004b); it is therefore possible that

if women are better at identifying sleepiness this would have improved the overall performance of the younger group.

There is a distinct difference between feeling sleepy and recognising the likelihood of falling asleep. The older drivers in the current work were all accurately able to identify that one would lead to another. On the whole, younger participants recognised that being sleepy could result in falling asleep, however, 18% of responses KSS 8 were reported with unlikely to fall asleep (Reyner and Horne 1998b). There is a clear distinction in attitude to sleepiness with only 3.3% of the older control participants reporting KSS 8 believing they were unlikely to fall asleep. The OSA participants appear more willing to accept that sleepiness means a possibility to fall asleep than control's because they all felt likely to fall asleep in KSS 8. With age perception of risk changes (Finn et al. 1986), it is probable that the older drivers are more willing to recognise consequence to feeling sleepy, and not harbour a belief of invincibility. As a result, analysis of LHoFA and KSS produce results similar to each other.

Younger drivers have been reported to spend 60% of the drive time in KSS 7 to 9, completing a similar protocol (Reyner and Horne 1998b) compared to 36.5 % for older control participants and 20.8% for OSA participants. This is likely due to the higher impact of sleep restriction on younger people than older people (Adam et al. 2006). The percentage of major incidents occurring in KSS 8 and 9 demonstrates ability to recognise sleepiness; with this measure the OSA participants again appeared better able to recognise sleepiness than control participants as when 90% of driving incidents occurred OSA participants were reporting KSS 8 and 9.

Having insight into sleepiness is improved by ability to recognise changes in EEG sleepiness in control participants, as those without insight into sleepiness showed a non significant correlation between EEG and subjective scores. These participants were unaware of their physiological level of sleepiness. For OSA participants the correlation between EEG and subjective ratings for those with insight and those without is very similar. Difference in ability to recognise sleepiness here is more subtle; possibly participants are recognising an increase in sleepiness but not quick enough to know that they are sleepy before an incident occurs.

If a participant is reporting KSS 9, defined as fighting sleep, it is probable that in a real life situation they would be performing a countermeasure to “fight” sleep, i.e. opening a window or talking to a passenger. Undertaking any such act demonstrates an awareness of sleepiness, in order to consciously take action. In addition all participants were asked if they had ever felt sleepy when driving, 100% of OSA participants and 85% of control participants said they had (chapter 12). In order to remember having felt sleepy they must have been aware of feeling sleepy at the time. Implementing an effective counter measure at this time is particularly important for OSA patients as in the current work they were found to have a short time period from identifying sleepiness to first major incident. Choice of countermeasure is investigated in chapter 12.

8.5 Conclusions

- The majority of older participants (73.7%) did have insight into sleepiness.
- A greater proportion of OSA participants had insight into sleepiness than control drivers.
- Of participants with insight into sleepiness, control drivers had an average of 65 minutes warning and OSA drivers an average 19.2 minutes warning of sleepiness prior to incident.
- All OSA participants and the majority of control participants associated sleepiness with a likelihood of falling asleep.
- OSA participants were better at identifying sleepiness than control participants as a greater percentage of major incidents for OSA occurred in KSS 8 and 9 than for control participants.
- EEG activity is correlated with subjective sleepiness scores except in control participants who do not have insight into sleepiness.

CHAPTER NINE

Impact of one night CPAP withdrawal

9.1 Introduction

The participants in the sleep restriction study were all compliant CPAP users however, on rare occasions they did report one night withdrawal of CPAP treatment. As part of the characteristics questionnaire given to all participants in the sleep restriction study, OSA participants were asked, “Do you ever sleep without your CPAP?” 4 out of 20 participants said they did very occasionally, stating reasons such as “if I have a cold” and “if I am away from home and there is no plug socket near the bed”.

There is limited existing research in this area; consequently the sleep restriction study was extended and all OSA participants were invited to complete the simulated drive a third time following their normal length of sleep having not used their CPAP treatment for one night.

9.1.1 Key points from the literature review

Withdrawal of CPAP in compliant long term users results in immediate resumption of sleep disordered breathing and when treatment is resumed there is immediate recovery (Grunstein et al. 1996, Yang et al. 2006a). There have been limited studies investigating the impact of CPAP withdrawal on task performance and subjective sleepiness; all have been with participants on CPAP for one year or less and results are conflicting.

Turkington et al. (2004) used a divided attention driving task, CPAP was found to improve task performance compared to prior treatment performance. Following two weeks of CPAP the treatment was stopped, although task performance decreased it never returned to the same level as before treatment. Yang et al. (2006) also withdrew CPAP from compliant users; here participants felt sleepier after one night of withdrawal but were able to maintain performance at a battery of cognitive tasks including PVT. The residual effect of treatment after it had been withdrawn is unexpected as sleep disordered breathing is likely to have returned. However, it is likely that participants were able to maintain performance despite the increased sleepiness due to the simple nature of the task. The PVT is a short duration test and the divided attention driving task used in Turkington et al. (2004) was only 20 minutes in duration. This is too short to give an indication of ability to drive.

In contrast Kribbs et al. (1993a) also withdrew CPAP treatment for 1 night but reported that all participants had impaired subjective sleepiness and PVT performance compared with when undergoing treatment. Similarly the MSLT has been shown to be significantly affected by one night's CPAP withdrawal, although in this case participants did not suffer from greater subjective sleepiness (Sforza et al. 1995).

9.1.2 Research aim and hypotheses

Aim: To evaluate the ability of OSA-CPAP compliant patients during a simulated driving task following CPAP withdrawal for one night compared with after a normal night on treatment and treated sleep restricted to 5h.

Hypotheses:

To test the hypothesis that sleep quality will be impaired with CPAP withdrawal in OSA CPAP compliant participants.

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by increased lane deviation, subjective sleepiness, EEG activity, successful drive completion and shorter time to first incident after treatment withdrawal than either normal treated sleep or sleep restriction to 5h of treated sleep.

To test the hypothesis that treatment withdrawal from OSA CPAP compliant participants will not affect ability to recognise sleepiness as reflected by KSS at first major incident and reporting feeling sleepy prior to first driving incident (KSS6+, LHoFA 4+).

9.2 Method

Design: repeated measures. Completing a 2h afternoon drive following a normal night's sleep, sleep restriction to 5h and a normal length of sleep without CPAP treatment. OSA participants only.

Setting: driving simulator

9.2.1 Participants

All participants had completed the sleep restriction study. Details of recruitment and selection can be found in chapter 3. The 19 OSA participants who completed the sleep restriction study were invited to take part in a CPAP withdrawal night, 11 participated.

There was no significant difference in characteristics between the 11 who participated and the 8 who did not, see Table 9.2-1. However, all those who reported on occasion as not using CPAP treatment declined to participate.

	Participated (n=11)		Did not participate (n=8)	
Age (years)	65.6	(s.d. 7.7)	62.8	(s.d. 7.1)
BMI	33.1	(s.d. 6.1)	36.2	(s.d. 7.5)
Driving experience (years)	45.9	(s.d. 6.6)	44.1	(s.d. 7.8)
CPAP treatment (years)	7.7	(s.d. 5.8)	7.7	(s.d. 4.0)
ESS	5.2	(s.d. 2.3)	5.5	(s.d. 4.8)
Report occasionally missing a night's treatment	0/11		4/8	
Have insight into sleepiness	75% (6/8)		66.6%(4/6)	

Table 9.2-1 Participant characteristics of those who participated and who did not participate in CPAP withdrawal

9.2.2 Protocol

The study protocol was the same as the sleep restriction study detailed in chapter 3. On the additional study night prior to attending the lab, participants slept at home for their usual length of sleep without using the CPAP treatment. Ethical approval was obtained from Loughborough University Ethics Committee following a letter from Dr Chris Hanning, see appendix 7.

As treatment was being stopped there was an additional ethical implication because this is something prescribed by a doctor and a medical doctor was not present during the withdrawal. To address this Dr Chriss Hanning provided a statement for the university ethics committee clarifying that there is no risk to patients with discontinuing treatment for one night and that this is a situation experienced by many patients on occasion. The withdrawal of CPAP was suspected to cause increased day time sleepiness, this issue was addressed by providing transport to and from the university and instructing participants not to drive or operate machinery until they had slept using their CPAP. An additional suspected issue was that participants may have felt uncomfortable in the night when sleeping without the machine. All participants

were informed that if they had any noticeable problems breathing during the withdrawal night they were to resume treatment then phone the investigator in the morning to confirm they were unable to participate. No participants had such a problem.

9.2.3 Measures

As with the sleep restriction study actigraphy was used to verify sleep length and sleep disturbance index (SDI) was calculated using the below formula,

$$\text{SDI} = \text{actual awake time (min)} / \text{assumed total sleep (min)}$$

SDI was compared between OSA participants with CPAP and without CPAP and compared with 11 healthy controls, chosen at random from the 20 who completed the sleep restriction study.

During the simulator task driving incidents, subjective sleepiness and EEG were recorded in accordance with the procedures in chapter 3.

9.2.4 Statistical analysis

SDI was compared between OSA with CPAP and controls using a 2 tail independent T test. OSA participants with and without CPAP were compared using 1 tail repeat measures T test. In all cases data were visually checked in histograms for normal distribution and Levenes test was used to assess for homogeneity of variance.

Driving incidents, subjective sleepiness and EEG were calculated in 30 min epochs and analysed using a factorial repeat measures ANOVA for comparison of OSA participants for condition (3 levels) and time (4 levels). In all cases data were visually checked in histograms for normal distribution. Due to a positive skew on the driving incident data, a square root transformation was completed prior to analysis. EEG data is slightly skewed but the original data is still presented. Huynh-Feldt adjustment was used the assumption of homogeneity of variance is violated.

9.3 Results

9.3.1 Actiwatch

To test the hypothesis that sleep quality will be impaired with CPAP withdrawal in OSA CPAP compliant participants.

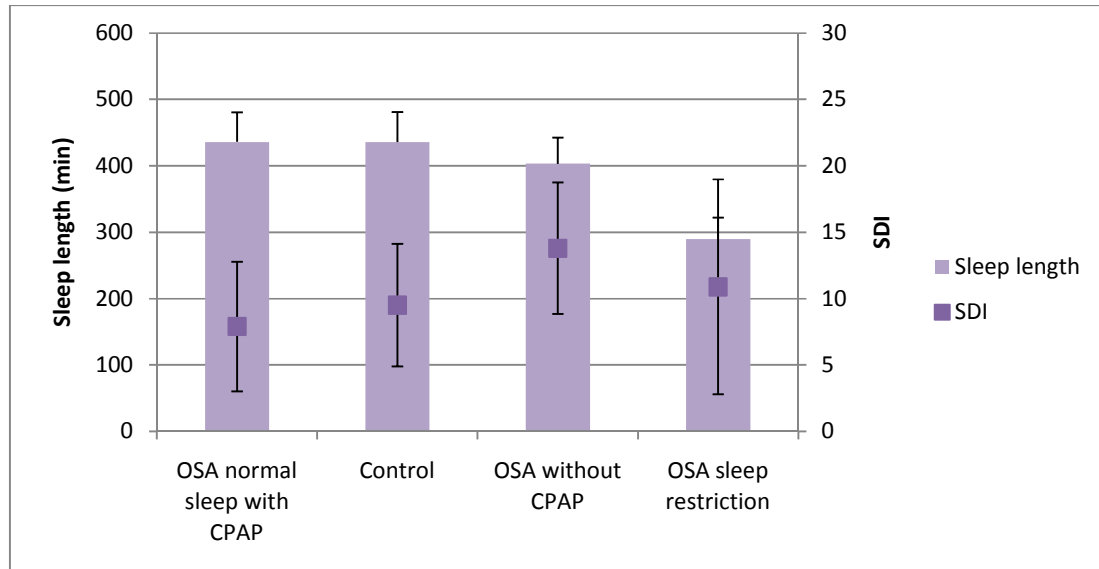


Figure 9.3-1 Mean sleep length (min) and mean SDI for OSA participants with and without CPAP and control participants, with standard deviation

Actigraphy showed no significant differences between mean actual sleep time, OSA with CPAP = 436 min (s.d. 44.6) Control = 435.8 min (s.d. 45.2) OSA without CPAP = 403.1 min (s.d. 39.4). There was no significant difference between SDI of OSA with CPAP (7.9) and controls (9.5) [$t(19) = 0.891, p = 0.423$]. However, withdrawal of CPAP treatment significantly increased SDI in OSA patients, from 7.9 to 13.8 [$t(10) = 3.510, p = 0.003$] see Figure 9.3-1.

9.3.2 Driving Incidents

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by increased lane deviation, subjective sleepiness, EEG activity, successful drive completion and shorter time to

first incident after treatment withdrawal than either normal treated sleep or sleep restriction to 5h of treated sleep.

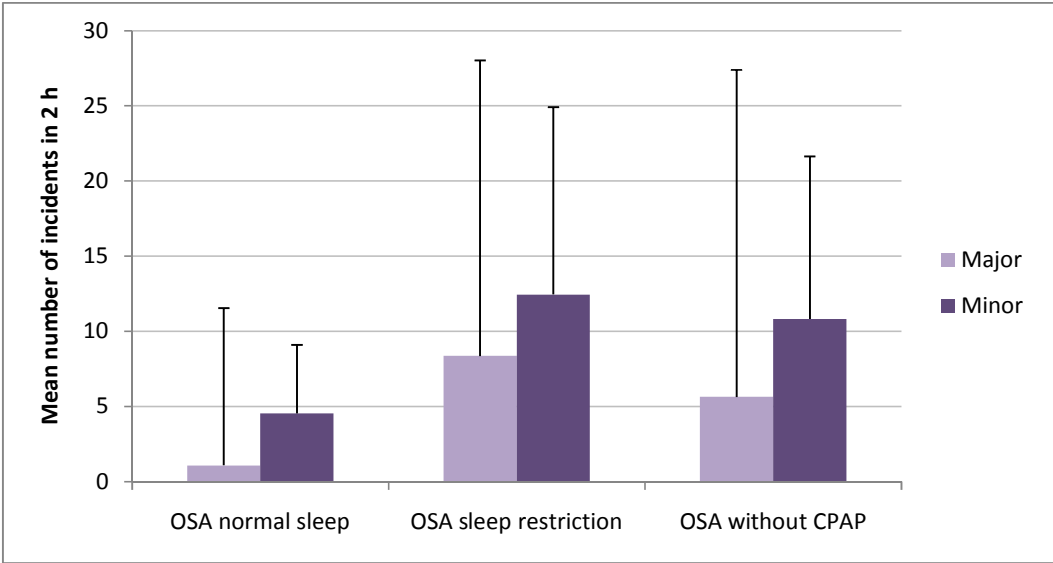


Figure 9.3-2 Mean major and minor incidents in the 2 hour drive with standard deviation

Figure 9.3-2 shows mean incidents over the total drive. Sleep restriction results in increased incidents compared with normal sleep (with CPAP). Withdrawal of CPAP also increases incidents but not to the same extent as sleep restriction.

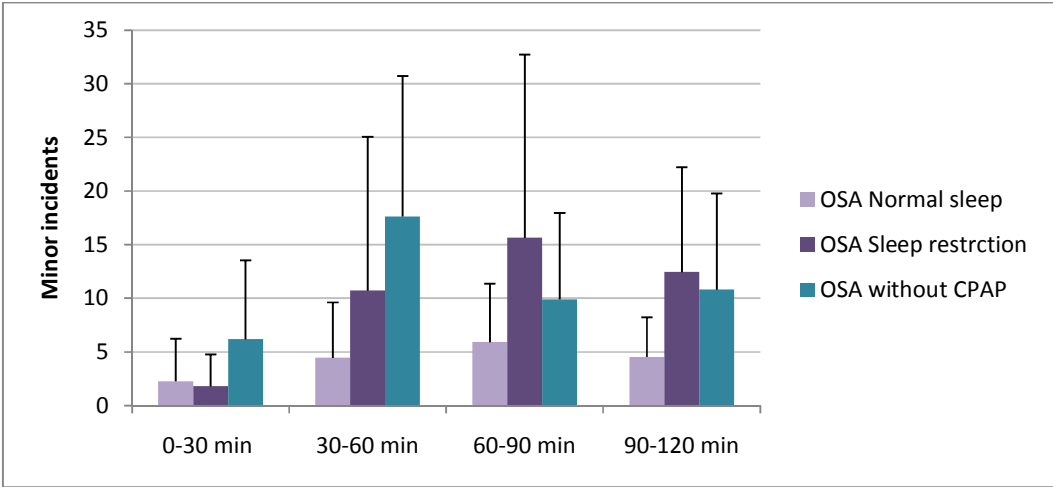


Figure 9.3-3 Mean number of minor incidents in 30 minute epochs with standard deviation

There is a significant effect of condition [$F(2,20) = 7.82, p = 0.003$] and time [$F(3,30) = 15.95, p < 0.001$] on minor incidents. There is also a significant condition, time interaction [$F(6,60) = 2.66, p = 0.02$]. On both occasions using CPAP the number of

minor incidents peaks in minutes 60-90, without the CPAP the peak in minor incidents occurs in minutes 30-60.

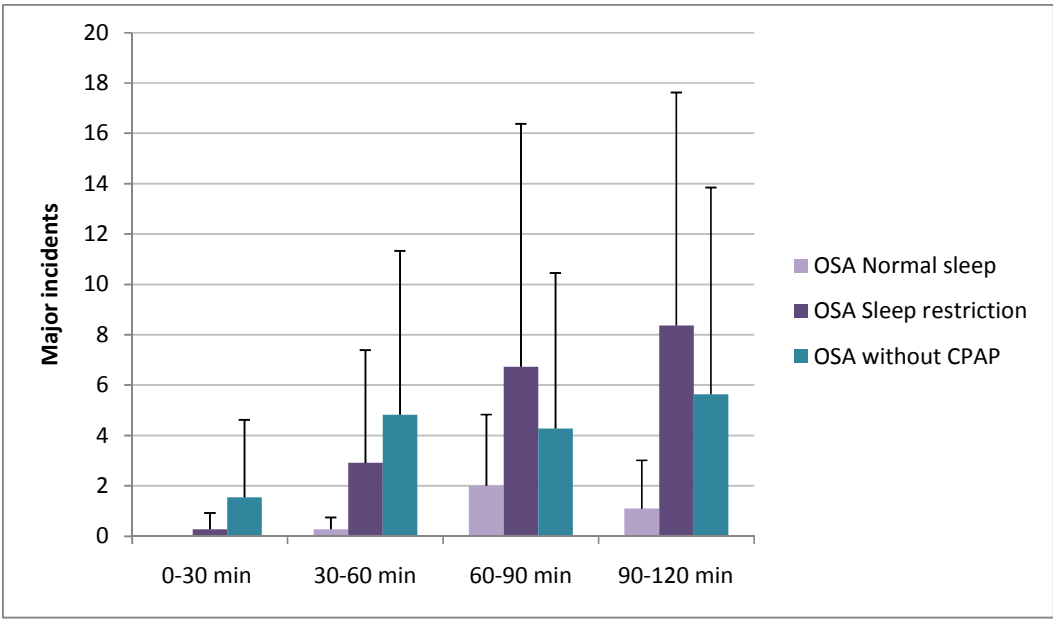


Figure 9.3-4 Mean number of major incidents in 30 minute epochs, with standard deviation

The same significant effects are found with major incidents for condition [F (2,20) = 7.0, p =0.005], time [F (1.5,30.3) = 9.95, p = 0.003, ε = 0.51] and condition, time interaction [F (6,60) = 3.40, p = 0.006]. For the first hour major incidents are more prevalent when CPAP is withdrawn, in the second hour major incidents are more prevalent when sleep is restricted and CPAP is used.

9.3.3 Successful drive completion (without major incident) and time to first major incident

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by increased lane deviation, subjective sleepiness, EEG activity, successful drive completion and shorter time to first incident after treatment withdrawal than either normal treated sleep or sleep restriction to 5h of treated sleep.

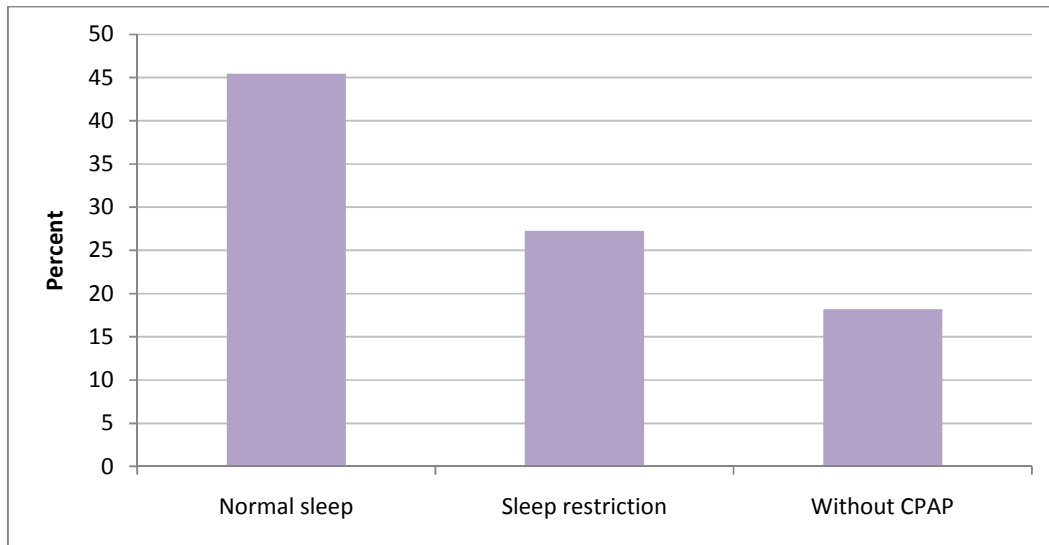


Figure 9.3-5 Percent of successful drive completion (without major incident)

Following a normal night's sleep 45.5% of participants completed the 2 h drive without major incident, 27.3% successfully completed after sleep restriction while only 18.2% of participants successfully completed the drive after CPAP withdrawal.

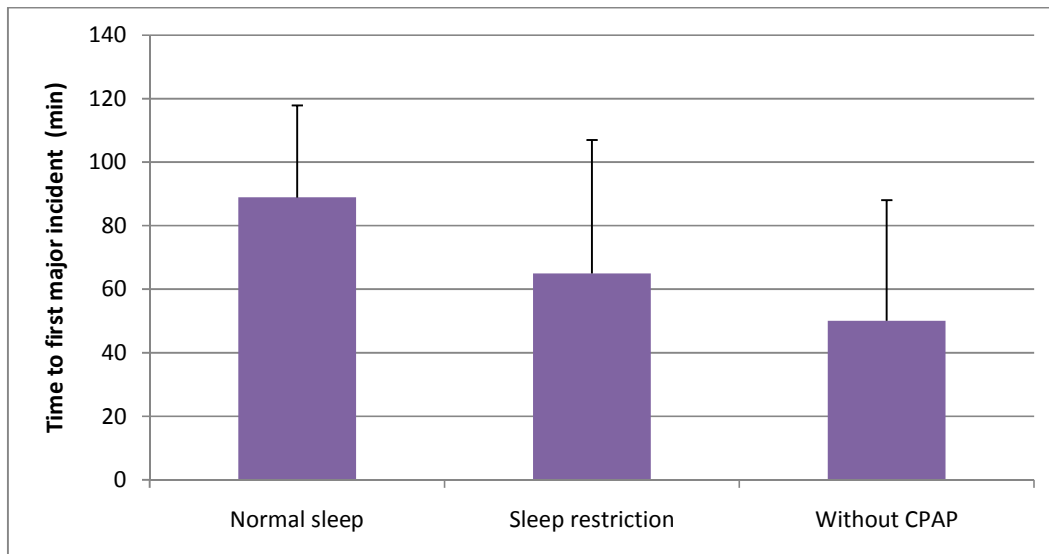


Figure 9.3-6 Average minute driven prior to first major incident with standard deviation

There was a significant effect of condition on safe driving time [$F(2,20) = 8.8, p = 0.002$]. After having the same length of sleep the participants drove without major incident for an average of 38.8 minutes longer when using CPAP than without.

9.3.4 Subjective sleepiness

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by increased lane deviation, subjective sleepiness, EEG activity, successful drive completion and shorter time to first incident after treatment withdrawal than either normal treated sleep or sleep restriction to 5h of treated sleep.

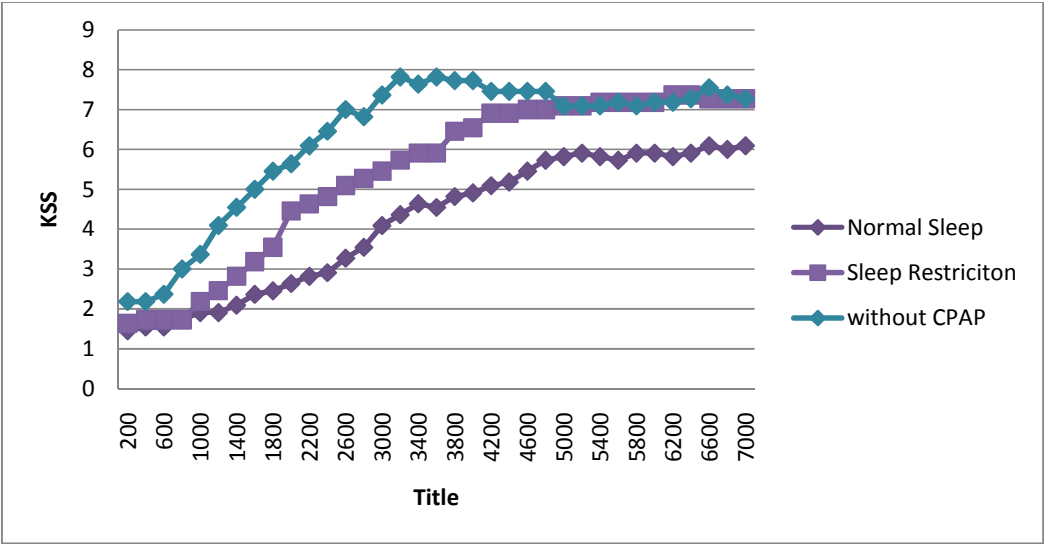


Figure 9.3-7 Mean KSS recorded every 200 seconds for each condition

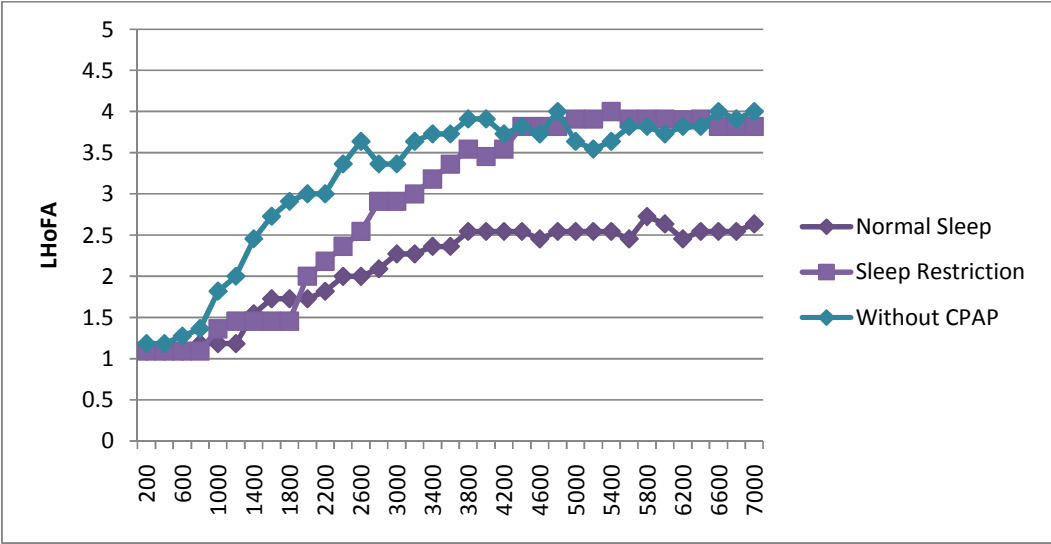


Figure 9.3-8 Mean LHoFA recorded every 200 seconds for each condition

Figure 9.3-7 and Figure 9.3-8 show mean subjective sleepiness across the drive. Without CPAP the participants feel sleepier in the first half of the drive than in the

other two conditions. In the second hour subjective sleepiness is similar to that after sleep restriction, in both cases, greater sleepiness was experienced than after a normal night with CPAP.

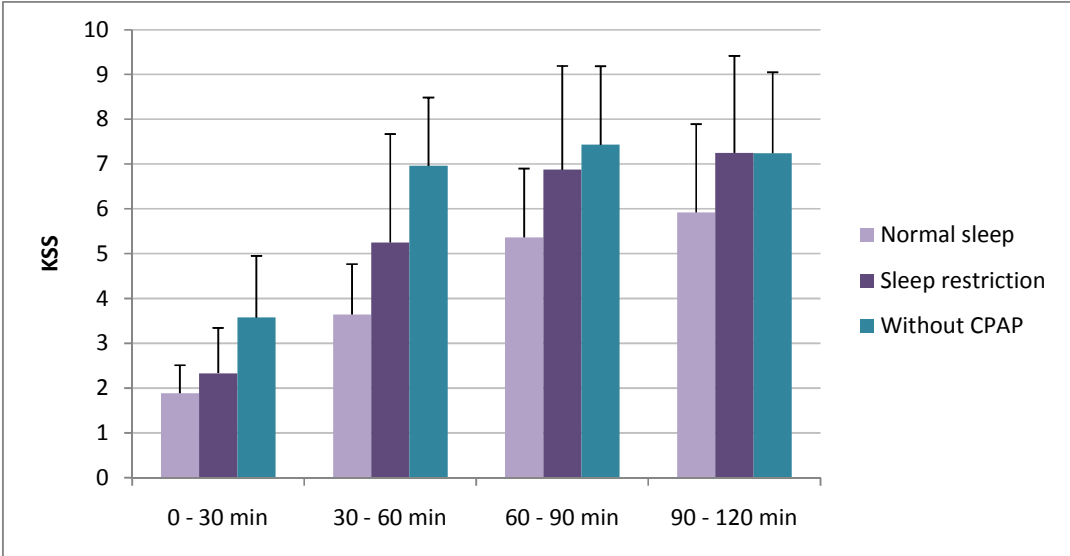


Figure 9.3-9 Mean KSS in 30 min epochs with standard deviation

Figure 9.3-9 shows KSS in 30 min epochs, there is a significant effect of condition [$F(2,20) = 10.04, p = 0.001$], time [$F(1.96,19.58) = 98.31, p < 0.001, \epsilon = 0.65$] and condition, time interaction [$F(3.94,39.41) = 3.39, p = 0.018, \epsilon = 0.66$]. These findings are similar to that of incidents, for the first hour KSS is highest in the condition without CPAP, then similar for without CPAP and sleep restriction in the second hour.

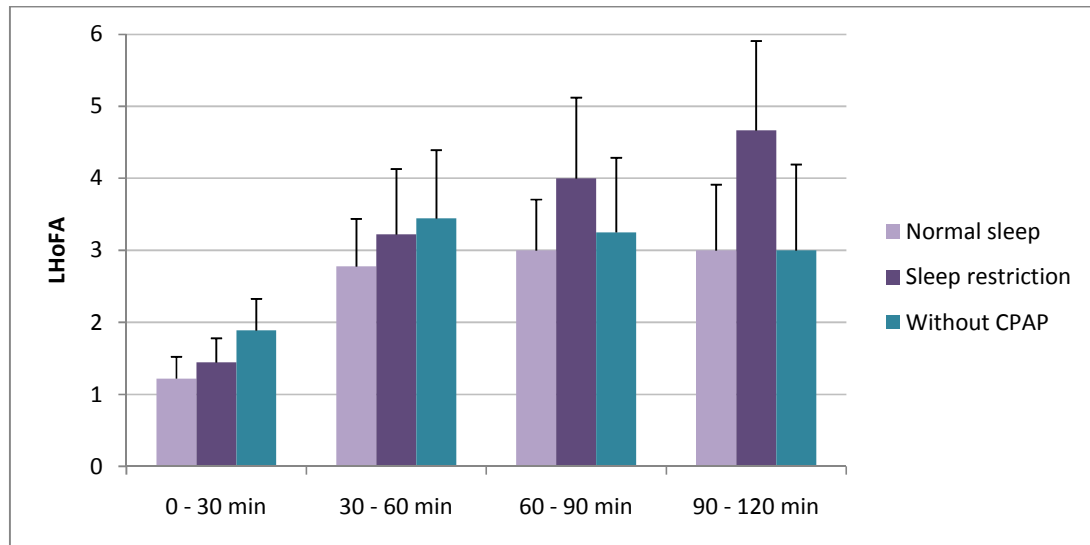


Figure 9.3-10 Mean LHoFA in 30 min epochs with standard deviation

Figure 9.3-10 shows mean LHoFA in 30 min epochs. LHoFA again followed the same pattern as KSS, showing a significant effect of condition [$F(2,20) = 13.16, p < 0.001$], time [$F(2.1, 21.0) = 57.58, p < 0.001, \epsilon = 0.70$] and condition, time interaction [$F(2.8, 20.3) = 6.21, p = 0.003, \epsilon = 0.47$].

9.3.5 EEG

To test the hypothesis that OSA CPAP compliant participants will show impaired driver performance at a driving simulator task as reflected by increased lane deviation, subjective sleepiness, EEG activity, successful drive completion and shorter time to first incident after treatment withdrawal than either normal treated sleep or sleep restriction to 5h of treated sleep.

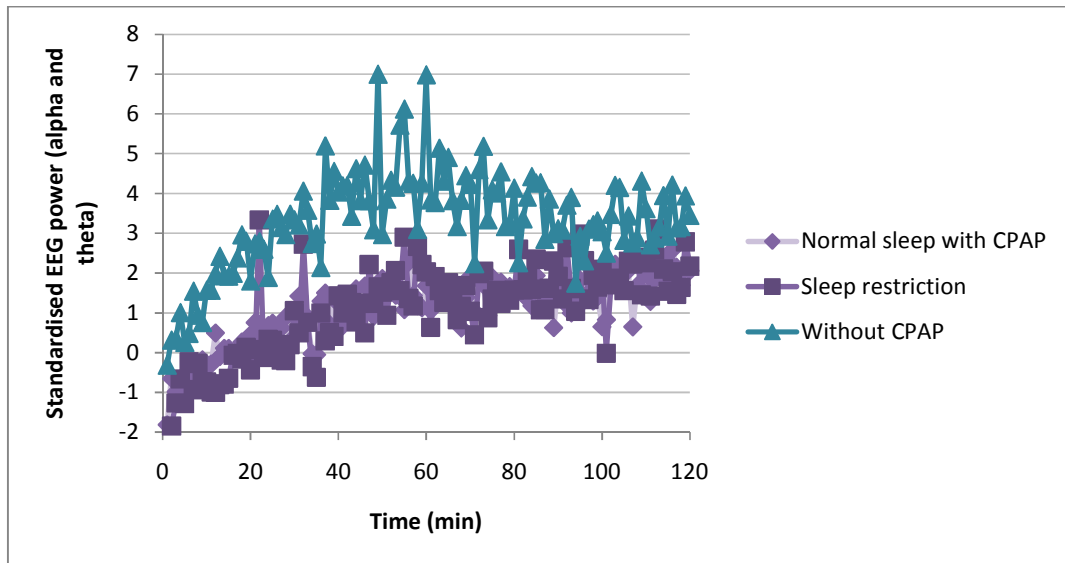


Figure 9.3-11 Standardised EEG power (alpha and theta) over time

Following the CPAP withdrawal EEG alpha and theta power was higher throughout the drive than in either condition with the CPAP, see Figure 9.3-11.

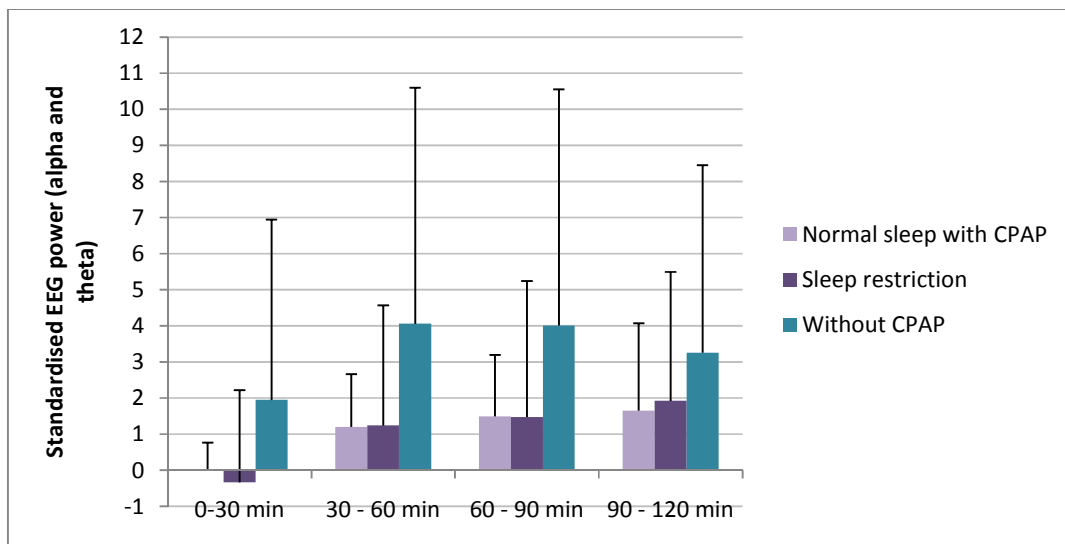


Figure 9.3-12 Standardised EEG power (alpha and theta) in 30 min epochs with standard deviation

Although there is higher EEG activity after CPAP withdrawal there is no significant effect of condition [$F(1.37, 13.71) = 1.76, p = 0.21, \epsilon = 0.69$]. There is a significant effect of time [$F(2.19, 21.84) = 8.18, p = 0.002, \epsilon = 0.73$]. There was no significant condition, time interaction [$F(3.58, 35.81) = 1.71, p = 0.18, \epsilon = 0.60$].

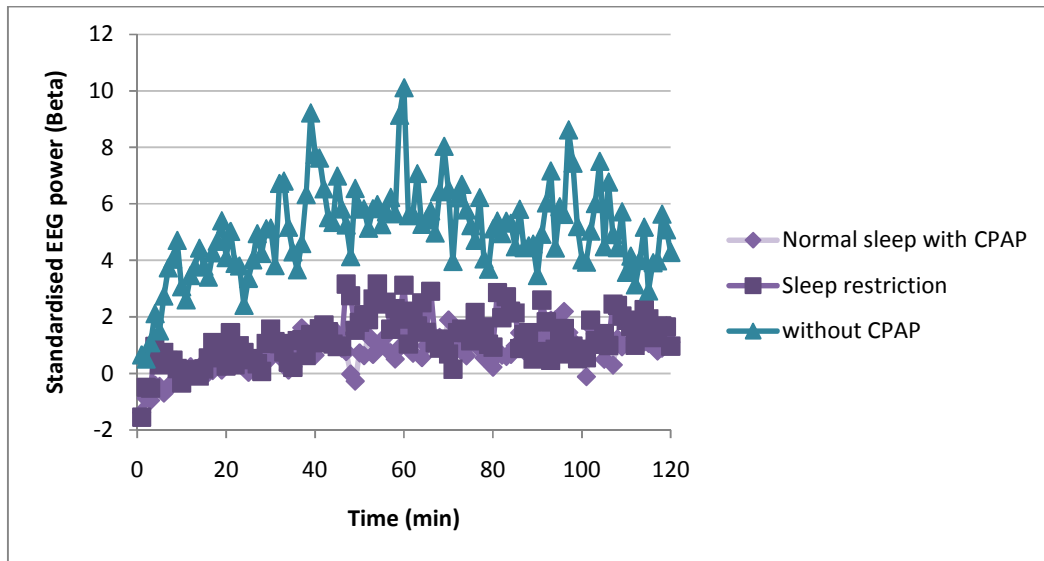


Figure 9.3-13 Standardised EEG power (beta) over time

Beta power to be higher throughout the drive following CPAP withdrawal than for either condition with CPAP, see Figure 9.3-13.

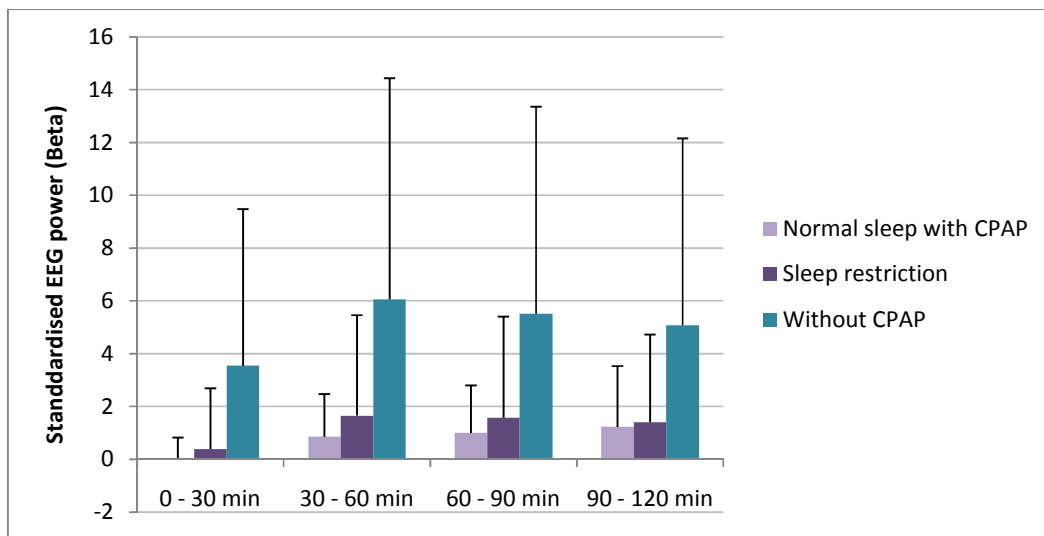


Figure 9.3-14 Standardised EEG power (beta) in 30 min epochs with standard deviation

Figure 9.3-14 shows beta activity in 30 min epochs. There is a near significant effect of condition [$F(1.17, 11.69) = 3.87, p = 0.07, \epsilon = 0.59$], a significant effect of time [$F(1.96, 19.59) = 4.75, p = 0.02, \epsilon = 0.65$] but no significant condition, time interaction [$F(2.45, 24.53) = 0.79, p = 0.491, \epsilon = 0.41$].

9.3.6 Insight into sleepiness

To test the hypothesis that treatment withdrawal from OSA CPAP compliant participants with not affect ability to recognise sleepiness as reflected by KSS at first major incident and reporting feeling sleepy prior to first driving incident (KSS6+, LHoFA 4+).

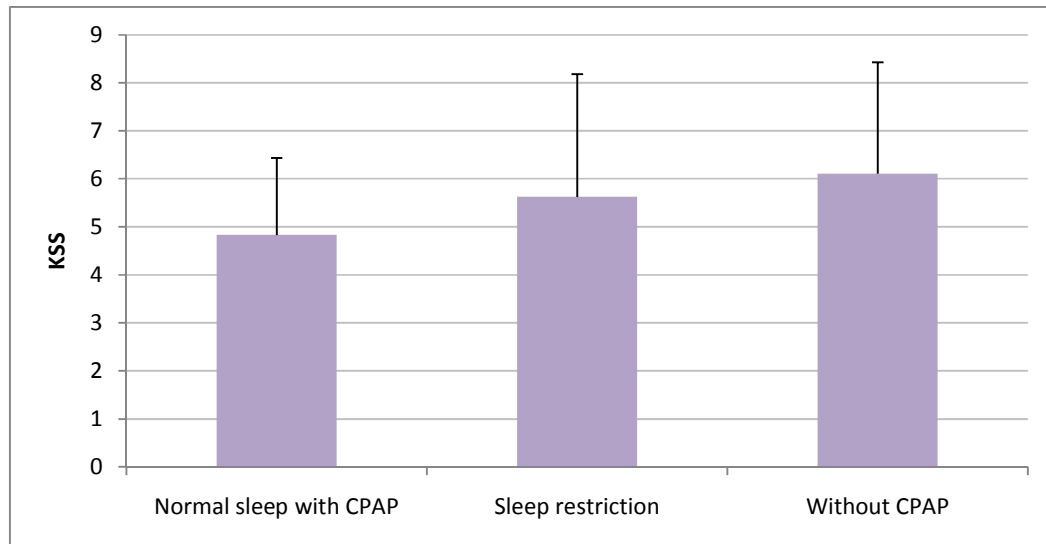


Figure 9.3-15 Mean KSS at first major incident with standard deviation

Without CPAP participants on average were feeling sleepier at the time of first major incident than on either occasion when CPAP had been used (nsd).

OSA Participants normal sleep with CPAP
<ul style="list-style-type: none"> - 50% (3/6) identified sleepiness on the KSS (6+) prior to first major incident - Those who were reported sleepiness prior to incident did so on average 22.14 min prior to major incident. - In total 36 major incidents occurred, 11.1% occurred in KSS 8 and 9. 75% occurring in KSS 6 – 9.
OSA Participants sleep restriction with CPAP
<ul style="list-style-type: none"> - 75% (6/8) identified sleepiness on the KSS (6+) prior to first major incident - Those who were reported sleepiness prior to incident did so on average 20.09 min prior to major incident. - In total 195 major incidents occurred, 91.8% occurred in KSS 8 and 9. 98.9% occurring in KSS 6 – 9.
OSA Participants without CPAP
<ul style="list-style-type: none"> - 55.5% (5/9) identified sleepiness on the KSS (6+) prior to first major incident - Those who were reported sleepiness prior to incident did so on average 19.48 min prior to major incident. - In total 172 driving incidents occurred, 73.8% occurred in KSS 8 and 9. 94.8% occurring in KSS 6 -9.

Table 9.3-1 Perception of sleepiness in each condition

Major incidents occurred for 6 participants after normal sleep; 8 after sleep restriction and 9 after CPAP withdrawal. Participants were most likely to identify sleepiness prior to major incident following sleep restriction. Identification of sleepiness prior to incident was similar after a normal nights' sleep with and without CPAP. In sleep restriction and CPAP withdrawal the majority of major incidents occurred while participants were feeling very sleepy, reporting KSS 8 and 9. When participants have insight into their sleepiness they have approximately 20 min knowledge of sleepiness prior to major driving incident.

9.4 Discussion

Withdrawal of CPAP for just one night with compliant CPAP users resulted in a significant increase in driving incidents and subjective sleepiness compared with the same participants obtaining the same length of sleep using CPAP treatment.

There was a significant condition, time interaction on both incidents and subjective sleepiness where impairment was found earlier in the drive for the CPAP withdrawal night than following sleep restriction. Overall a greater number of incidents occurred following sleep restriction than following normal sleep or CPAP withdrawal suggesting that sleep restriction has greater consequences than missing treatment. However, the significant condition time interaction demonstrates the two scenarios to have differing implications. During the first hour the number of driving incidents were more numerous following CPAP withdrawal than following sleep restriction. Subjective sleepiness was also greater in CPAP withdrawal for the first hour and EEG activity shows a non-significant trend for greater sleepiness and increased effort to remain alert. Additionally, safe driving time before first major incident was shorter following CPAP withdrawal than following sleep restriction.

In terms of driving the differing effect of sleep restriction and CPAP withdrawal is of great importance as any major incident on a real road could be fatal. Following a normal sleep with CPAP OSA participants were safe to drive for approximately 90 min (comparable with controls see chapter 5) but without the CPAP there was a dramatic fall in safe driving time to less than 1h. This is an important message for OSA patients to consistently use CPAP, because even if they are compliant generally, there is no residual effect on driving performance if treatment is missed.

An explanation for these findings is that EEG sleepiness levels are greater following CPAP withdrawal than following sleep restriction. Although not significant, in the first 30 min epoch alpha/theta levels and beta levels are similar following normal sleep and sleep restriction but are notably higher following CPAP withdrawal. Without CPAP, participants start sleepier and therefore have difficulties in task performance earlier on. As the effect of condition on beta power is near significance it is also possible that because of the extra effort participants were putting in following CPAP withdrawal overall incidents were fewer compared with sleep restriction.

Treated OSA patients are obtaining quality sleep when using CPAP and no disparity in sleep quality (SDI) was found compared with healthy controls and as a result task performance and subjective sleepiness are comparable, as detailed in chapters 5 and

6. However, withdrawal of treatment for one night caused sleep quality to deteriorate significantly. Without full PSG it is not possible to say if SDB was resumed but the higher SDI suggests this is likely to have occurred, which would be consistent with existing research (Grunstein et al. 1996, Yang et al. 2006a).

The resumption of sleep disordered breathing in cases of CPAP withdraw is consistently found, but impact on task performance and subjective sleepiness vary between studies from immediate impairment (Kribbs et al. 1993a) to maintained higher than expected performance for up to 7 days without treatment (Turkington et al. 2004a, Yang et al. 2006b). The current study found task performance to be impaired and subjective sleepiness to be increased with one night CPAP withdrawal. This is in contrast to Yang et al. (2006) who found no impairment in a cognitive task battery following 1 night CPAP withdrawal. The tasks used by Yang were fairly short, the current study uses a long sustained attention task, and it is possible that short term concentration is not affected by CPAP withdrawal but longer sustained attention is.

The case of 7 days without treatment reported by Turkington et al. (2004) appears contradictory to the current work where task performance was reportedly maintained. However, the main focus of that study was to investigate improvements in performance when CPAP is started compared with OSA sufferers who do not receive treatment. The maintained task performance with 7 days withdrawal reported is in comparison with those participants who had never received treatment. On inspection of the graphs impairment in performance following 1 nights' withdrawal is shown but this is not commented on by the authors.

There was a significant effect of condition on subjective sleepiness, with CPAP withdrawal resulting in higher KSS scores than sleep restriction in all but the final epoch. However, participants only rated themselves more likely to fall asleep for the first hour (comparing CPAP withdrawal and sleep restriction). Participants were recognising an increased sleepiness but not acknowledging an increased likelihood of sleep. Following sleep restriction 75% of participants recognised they were sleepy prior to having a major incident. Following a normal length of sleep both with and

without CPAP frequency of identifying sleepiness fell to approximately 50% of participants. For both sleep restriction and CPAP withdrawal the majority of major incidents occurred in KSS 8 and 9, so for the most part participants knew when they are sleepy. However, the transition into sleepiness was less frequently identified following CPAP withdrawal. In all conditions those who could identify sleepiness did so with approximately 20 minutes notice prior to major incident, which in practice should allow time to get off the road as long as it is acted on immediately.

As CPAP withdrawal did appear to reduce the occurrence of insight into sleepiness, this study highlights the importance of treatment compliance. It is possible that the act of restricting sleep may increase acceptance of possibility of falling asleep, as in order to restrict sleep a participant must be out of bed at a time when they are usually asleep. This act provides a memory cue as to why it might be possible to fall asleep so participants may be looking out for impaired task performance more. Fewer major incidents occurred while participants were sleepy after a normal sleep than after CPAP withdrawal. Similarly the withdrawal of CPAP is a physical action which may result in actively looking for impairment. With CPAP withdrawal the participant knows they were in bed for an adequate length of time and therefore may perceive themselves to be at less risk of falling asleep than if they have restricted their sleep time, but more at risk than if they have used the CPAP.

The nature of the study design meant that the CPAP withdrawal night was not completed in a counterbalanced routine. However, there is no improvement in task performance so there were no beneficial effects of additional learning time. It is also acknowledged that the 11 participants were self selecting after all 19 participants completing the sleep restriction study were asked. No significant differences in characteristics between those who participated and those who did not were identified. However, Yang et al. (2006) stated "Individuals who are compliant CPAP users may be reluctant to volunteer for this type of research if they have previously experienced marked negative symptoms with CPAP withdrawal." This could be applicable to the current research as all those reporting occasional CPAP withdrawal declined to take part. This is encouraging in terms of compliance to treatment, as

those who have experienced the effects of CPAP withdrawal do not want to repeat it. Also baseline data prior to initial CPAP treatment was not available for comparison.

OSA patients need to know that even short-term non-compliance with CPAP treatment significantly impairs sleep quality, leading to excessive sleepiness and impaired performance at a monotonous task such as driving. Importantly task performance is impaired from earlier on and there is a reduced ability to recognise sleepiness compared with sleep restriction. No residual effects of the CPAP treatment were found.

9.5 Conclusions

- CPAP withdrawal results in impairment earlier in the task than sleep restriction.
- CPAP withdrawal results in a greater number of driving incidents than following a normal night's sleep with CPAP, but less than sleep restriction with CPAP.
- Following CPAP withdrawal participants feel sleepier than following a normal sleep with CPAP and sleep restriction. However, they do not always associate this with being more likely to fall asleep than following sleep restriction.
- One night withdrawal of CPAP results in increased sleep disturbance and reduced sleep efficiency, compared with a night using CPAP.
- Insight into sleepiness was more common following sleep restriction than CPAP withdrawal.

CHAPTER TEN

OSA participants' individual difference in susceptibility to sleep restriction

10.1 Introduction

The standard deviations of the primary outcome measures of the sleep restriction study are reported in the discussions of chapters 5, 6 and 7. Higher standard deviations are found following sleep restriction for the OSA participants compared with control participants for all measures, except LHoFA. In particular the standard deviation for number of driving incidents following sleep restriction was considerably greater in OSA participants than controls. This is of interest as it suggests some OSA participants may not have been as affected by sleep restriction despite the overall results showing greater impairment in the OSA group than controls. This idea is investigated in the following chapter.

10.1.1 Key points from the literature review

The ability to maintain performance when sleep deprived varies greatly between individuals (Van Dongen et al. 2004). Some degree of variability at the driving simulator task, when sleep restricted, was therefore expected in both the control and treated OSA group.

Driving simulator studies have shown there to be great individual difference between untreated OSA participants, with many studies showing an overlap with performance of the control group (George et al. 1996b, Findley et al. 1999, Juniper et al. 2000, Findley 1995, Ayalon et al. 2009). This greater variability appears to be maintained following CPAP treatment (Findley et al. 1989, Hack et al. 2001). With large individual difference it is important to find out what the predictor of driving impairment is, as OSA may not be the only factor affecting driving performance, because some participants appear able to perform driving tasks to the same level as controls and some cannot. Knowing what predicts impaired driving performance would help doctors make the decision about fitness to drive.

With previous studies it has not been possible to demonstrate what factor predicts which OSA participants will have impaired performance. ESS, AHI and MWT have all been unsuccessful at consistently predicting poor task performance (Mazza et al. 2005, Kingshott et al. 1998, Orth et al. 2005, Sagaspe et al. 2007b, Turkington et al. 2001).

Many of the studies mentioned use short duration driving performance tasks. It is therefore not known if the same variability cross over in performance level with controls will be apparent during a long duration driving task.

10.1.2 Research aim and hypotheses

Aim: To evaluate the individual difference of the effect of sleep restriction in OSA-CPAP compliant patients at a simulated driving task.

To test the hypothesis that there will be great individual difference in OSA CPAP compliant participants driver performance at a driving simulator task as reflected by lane deviation incidents in comparison to controls after sleep restriction to 5h.

To test the hypothesis that those OSA CPAP compliant participants with greater vulnerability to sleep restriction will have impaired driver performance at a driving simulator task as reflected by lane deviation incidents, time to first incident, greater subjective and EEG sleepiness in comparison to OSA CPAP compliant participants not vulnerable to sleep restriction.

To test the hypothesis that those OSA CPAP compliant participants who are older and those with higher ESS will have greater impaired driver performance at a driving simulator task.

To test the hypothesis that in those OSA CPAP compliant participants who have greater vulnerability to sleep restriction there will be no difference in insight into sleepiness than those who are not vulnerable, as reflected by subjective score at first major incident.

10.2 Method

Design: repeated measures counter balanced. Completing a 2h afternoon drive following a normal night's sleep and following sleep restriction to 5h. OSA participants only.

Setting: driving simulator

10.2.1 Participants

The focus of this analysis will be on the OSA participants. The 19 OSA participants were classified into 2 subgroups

- More affected by sleep restriction than control participants (affected)
- Affected by sleep restriction the same as control participants (not affected)

The division of the OSA group was based on the average increase in incidents being greater than the mean plus 1 standard deviation of control participants ($17.85 + 29.41 = 47.26$). 5 OSA participants were identified as having been more affected by sleep restriction (highlighted in yellow) than the control group, (Table 10.2-11).

Participant number	Incidents in Normal sleep	Incidents in Sleep restriction	Difference in incidents	Participant number	Incidents in Normal sleep	Incidents in Sleep restriction	Difference in incidents
OSA2	17	72	55	Con1	3	49	46
OSA3	23	76	53	Con2	3	27	24
OSA4	8	28	20	Con3	12	18	6
OSA5	1	0	-1	Con5	5	38	33
OSA7	44	200	156	Con6	20	49	29
OSA8	27	18	-9	Con7	85	57	-28
OSA9	4	45	41	Con8	4	13	9
OSA10	11	28	17	Con9	11	24	13
OSA11	54	54	0	Con10	5	7	2
OSA12	2	6	4	Con11	43	77	34
OSA13	1	2	1	Con13	17	30	13
OSA14	1	2	1	Con14	10	36	26
OSA16	0	0	0	Con15	1	5	4
OSA17	20	13	-7	Con16	22	30	8
OSA18	27	141	114	Con17	17	139	122
OSA19	41	87	46	Con18	18	27	9
OSA20	11	40	29	Con19	1	9	8
OSA6	22	15	-7	Con20	8	6	-2
OSA21	124	242	118	Con21	1	2	1
				Con22	0	0	0
Average			33.21	Average			17.85
S.d.			48.12	S.d.			29.41

Table 10.2-1 Identification of OSA participants affected by sleep restriction by increase in driving incidents.

10.2.2 Participant characteristics

	Affected mean (n=5)	Affected s.d.	Not affected mean (n=14)	Not affected s.d.	Independent t test	p value (2 tail)
Age	59.8	10.13	66.00	5.82	1.68	0.11
ESS	4.40	3.05	5.64	3.63	0.68	0.51
BMI	34.62	8.27	34.31	6.43	0.09	0.93
% body fat	31.08	6.95	33.92	5.37	0.61	0.55
Years of CPAP treatment	5.85	7.42	8.36	3.99	0.96	0.35
Driving experience years	42.20	9.39	46.21	5.98	1.11	0.28
Hazard perception score	55.6	4.28	47.36	8.83	1.98	0.06

Table 10.2-2 Comparison of participant characteristics by independent t test between those who were affected by sleep research and those not affected

Table 10.2-2 shows there is no significant difference between those OSA participants who were affected by sleep restriction and those who were not in terms of age, ESS, BMI, % body fat, years of CPAP treatment and driving experience. Those who were affected by sleep restriction had near significantly higher hazard perception scores, though the mean of both groups is over the 44 pass mark, for more details on hazard perception test please see chapter 11.

10.2.3 Protocol

The results from the 5 OSA participants affected by sleep restriction were compared with the results from the remaining OSA participants (n = 14). Those OSA participants not affected by sleep restriction will then be compared with the control group.

10.2.4 Measures

Number of driving incidents, subjective sleepiness and EEG activity were recorded and analysed as detailed in chapter 3.

10.2.5 Statistical analysis

Results for number of driving incidents, subjective sleepiness and EEG were calculated in 30 min epochs and analysed using a repeated measures ANOVA form comparison of

the two sub types of OSA participants for condition (2 levels), time (4 levels) and 1 between subject level (affected or not affected).

A repeated measures ANOVA was also used to compare OSA participants not affected by sleep restriction and controls also with data in 30 minute epochs for condition (2 levels), time (4 levels) and 1 between subject level (not affected OSA or control).

Due to a positive skew on driving incident data a square root transformation was completed prior to analysis. Subjective sleepiness was normally distributed. EEG is slightly skewed, the original data is presented. Huynh-Feldt adjustment was used where the assumption of homogeneity of variance was violated.

Prevalence of participant characteristics (including total sleep time) was compared between the two OSA sub groups by independent t test (two tailed). Data were normally distributed, visually checked using histograms and did not violate the assumption of homogeneity of variance, assessed by Levenes test. Correlation between increase in total number of driving incidents following sleep restriction with age and hazard perception score were assessed using one tailed Pearson's *r*. Correlation of ESS and annual mileage with increase in driving incidents was assessed using one tailed Spearman's rho.

10.3 Results

10.3.1 Sleep time

Actiwatch data was used to assess total sleep time for non study days, the normal sleep condition and the sleep restriction condition. It would be possible for the difference in driving performance between the two OSA sub groups to be caused by difference in habitual sleep time or difference in compliance to the 5 h sleep restriction. In order to eliminate this as a possible confounding variable, comparison was made between those OSA participants affected by sleep restriction and those not affected to eliminate reduced sleep time as a cause of higher impact of sleep restriction.

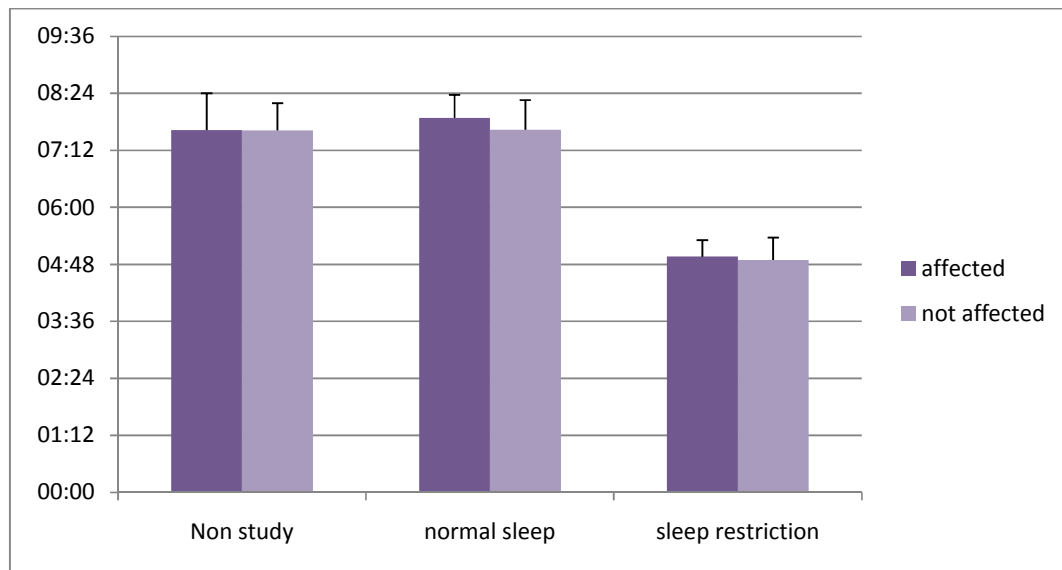


Figure 10.3-1 Total sleep time for OSA participants affected and not affected by sleep restriction

Figure 10.3-1 shows no significant difference in sleep length on either of the study days or on non study days. Comparing total sleep time of the normal nights' sleep and sleep restriction nights showed those affected by sleep restriction lost an average of 2 h 43 min sleep and those not affected lost an average of 2 h 50 min sleep. Therefore, the difference in performance cannot be explained by differing sleep times.

10.3.2 Driving incidents

To test the hypothesis that there will be great individual difference in OSA CPAP compliant participants driver performance at a driving simulator task as reflected by lane deviation incidents in comparison to controls after sleep restriction to 5h.

To test the hypothesis that those OSA CPAP compliant participants with greater vulnerability to sleep restriction will have impaired driver performance at a driving simulator task as reflected by lane deviation incidents, time to first incident, greater subjective and EEG sleepiness in comparison to OSA CPAP compliant participants not vulnerable to sleep restriction.

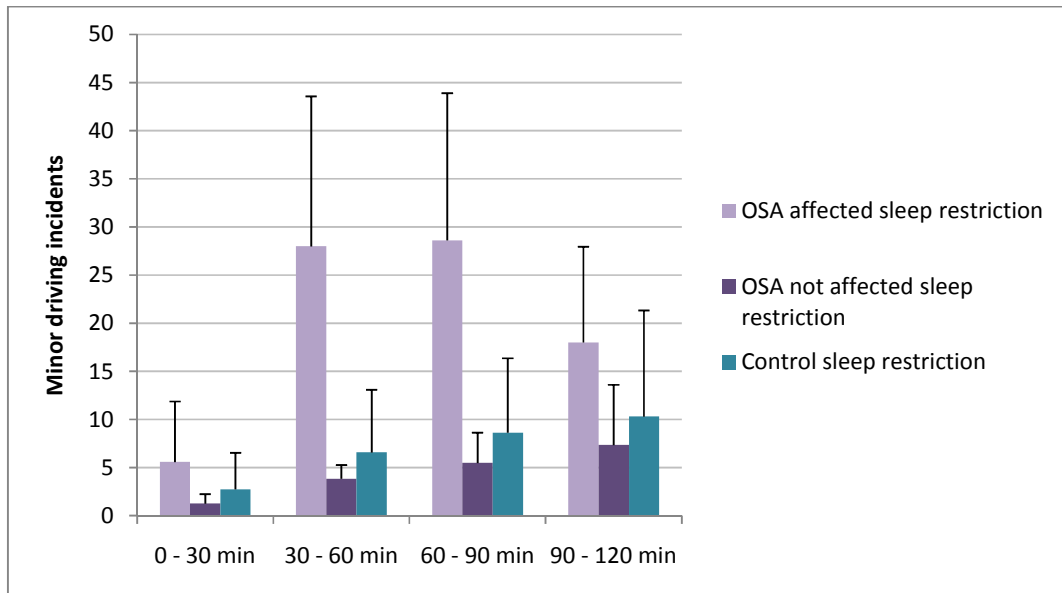


Figure 10.3-2 Minor driving incidents over time with standard deviation

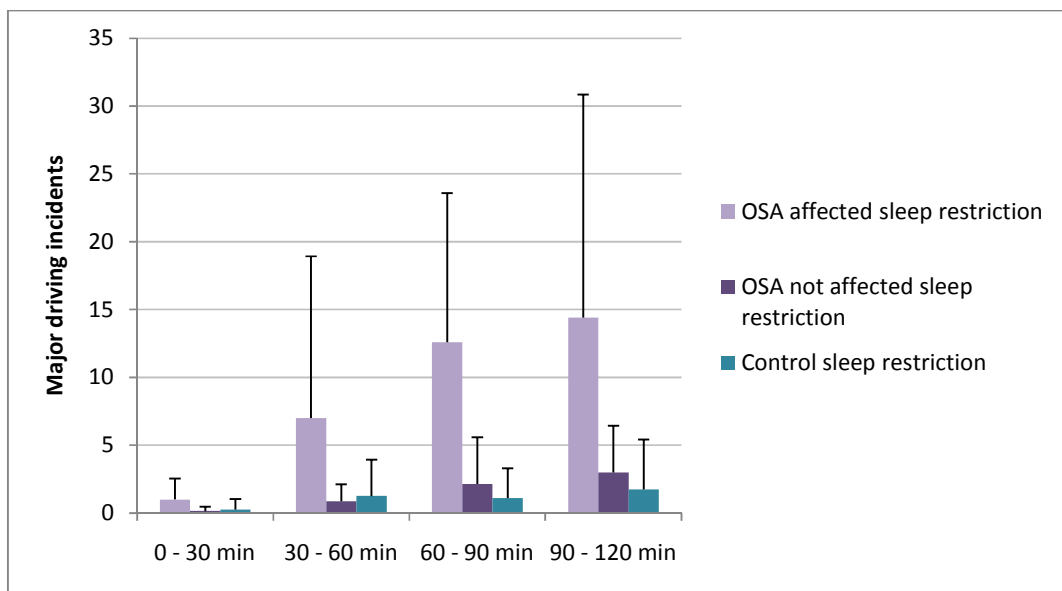


Figure 10.3-3 Major driving incidents over time with standard deviation

Figure 10.3-2 and Figure 10.3-3 show the number of minor and major incidents occurring in 30 minute epochs. The OSA group were sub divided by number of incidents, as expected there was a significant condition, group interaction showing those who were affected by sleep restriction had significantly more minor [$F(1,17) = 17.758, p = 0.001$] and major [$F(1,17) = 25.142, p < 0.001$] incidents than those who were not affected. In comparison with control participants those with OSA who were

not affected by sleep restriction showed no significant difference in major incidents [$F(1,32) = 0.219, p = 0.643$] or minor incidents [$F(1,32) = 3.146, p = 0.086$].

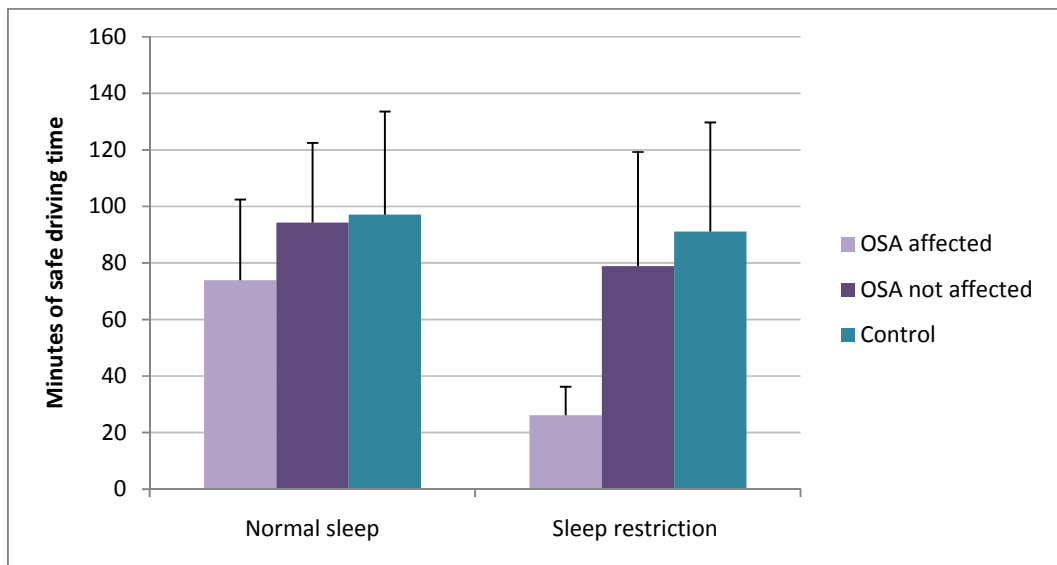


Figure 10.3-4 Mean time driven prior to first major incident with standard deviation

Following sleep restriction those OSA participants who were not affected by sleep restriction could drive safely for significantly longer than those who were affected by sleep restriction [$t(16.309) = 4.516, p < 0.001$] and showed no significant difference in safe driving time to the control participants [$t(32) = 0.890, p = 0.380$], this can be seen in Figure 10.3-4.

10.3.3 Subjective sleepiness

To test the hypothesis that those OSA CPAP compliant participants with greater vulnerability to sleep restriction will have impaired driver performance at a driving simulator task as reflected by lane deviation incidents, time to first incident, greater subjective and EEG sleepiness in comparison to OSA CPAP compliant participants not vulnerable to sleep restriction.

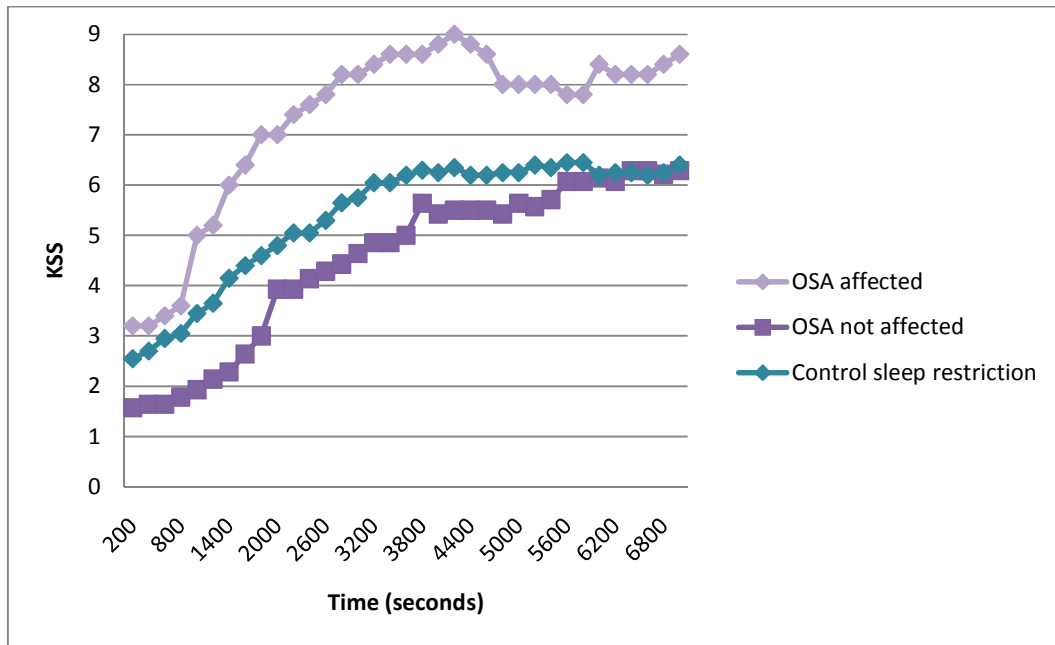


Figure 10.3-5 Mean KSS score over time following sleep restriction

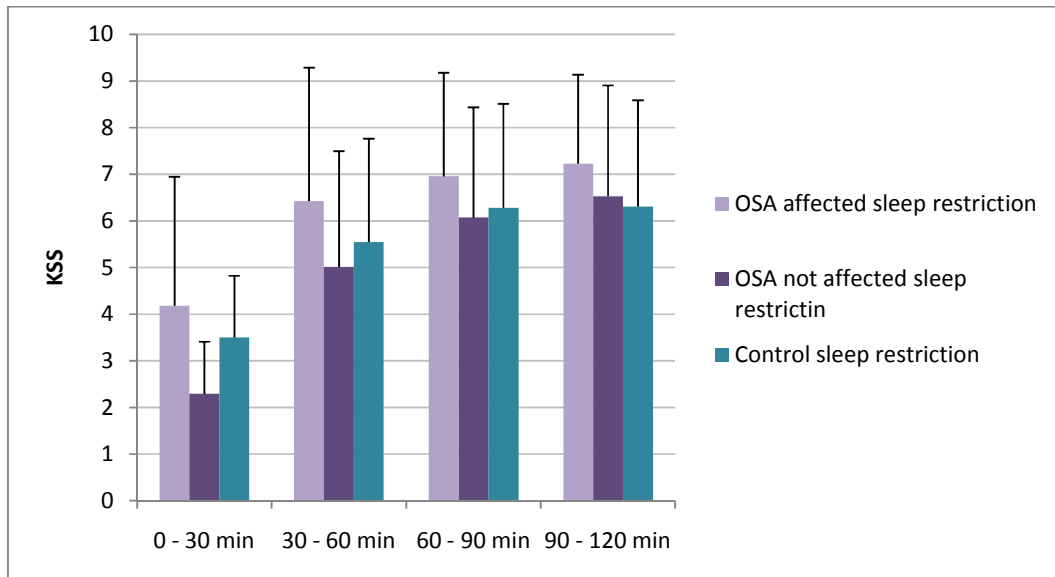


Figure 10.3-6 Mean KSS in 30 min epochs with standard deviation following sleep restriction

KSS can be seen in Figure 10.3-5 and Figure 10.3-6. There was no significant condition, group interaction between OSA participants who were and were not affected by sleep restriction [$F(1,17) = 0.22, p = 0.883$] and the not affected group showed no significant difference to controls [$F(1,32) = 0.004, p = 0.953$].

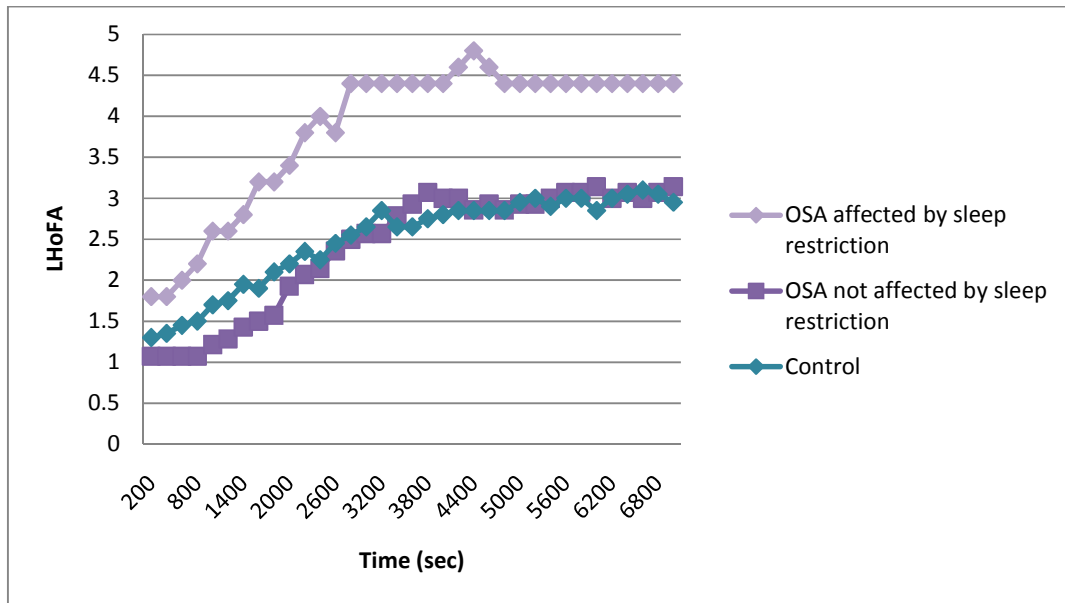


Figure 10.3-7 Mean LHoFA over time following sleep restriction

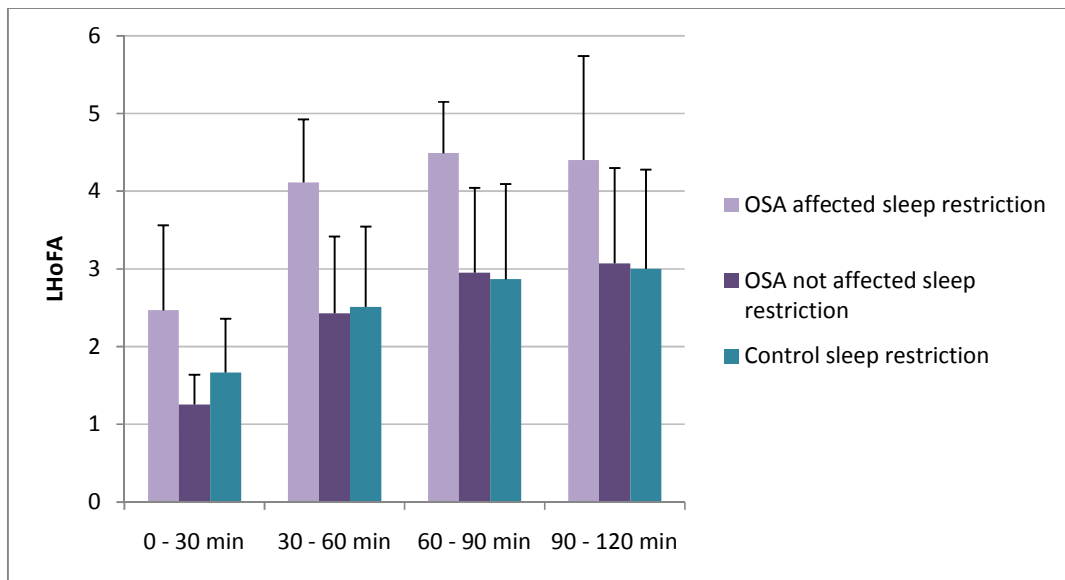


Figure 10.3-8 Mean LHoFA in 30 min epochs with standard deviation following sleep restriction

Using the LHoFA scale (Figure 10.3-7 and Figure 10.3-8) the OSA group who were not affected by sleep restriction felt significantly less likely to fall asleep than those who were affected [$F(1,17) = 6.374, p = 0.022$] and those not affected showed no significant difference to controls [$F(1,32) = 0.015, p = 0.903$]. In all cases participants fell asleep and more likely to fall asleep as the drive progressed.

10.3.4 EEG

To test the hypothesis that those OSA CPAP compliant participants with greater vulnerability to sleep restriction will have impaired driver performance at a driving simulator task as reflected by lane deviation incidents, time to first incident, greater subjective and EEG sleepiness in comparison to OSA CPAP compliant participants not vulnerable to sleep restriction.

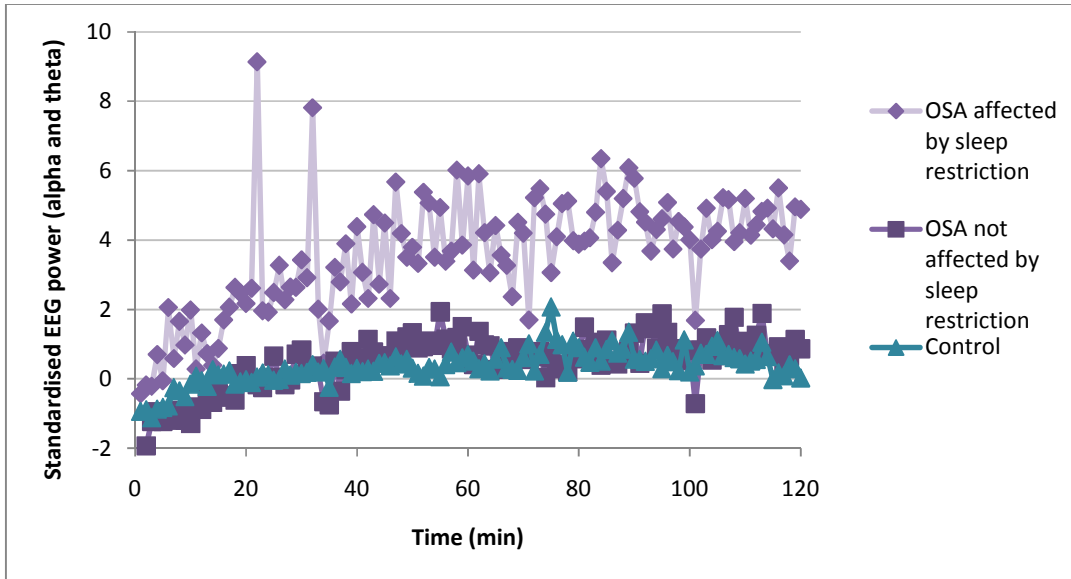


Figure 10.3-9 Standardised alpha and theta EEG power over time following sleep restriction

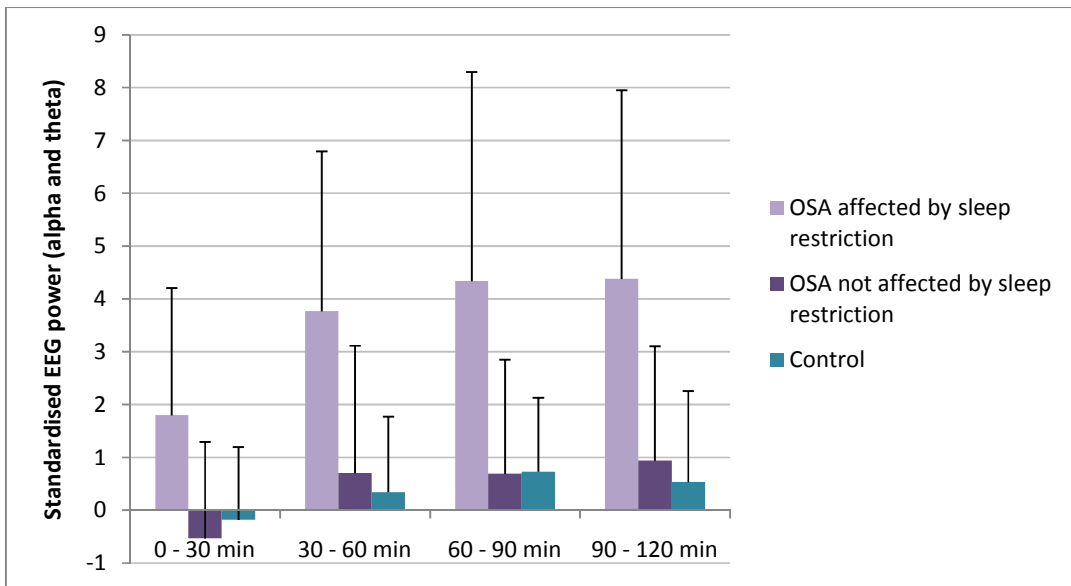


Figure 10.3-10 Standardised alpha and theta EEG power in 30 min epochs with standard deviation following sleep restriction

Combined alpha and theta activity are shown in Figure 10.3-9 and Figure 10.3-10. The OSA participants affected by sleep restriction showed a significantly higher standardised power, suggesting increased level of sleepiness than those not affected, [F(1, 17) = 7.374, p = 0.033]. There is no significant difference between OSA participants not affected by sleep restriction and controls [F (1,32) = 0.436, p = 0.514].

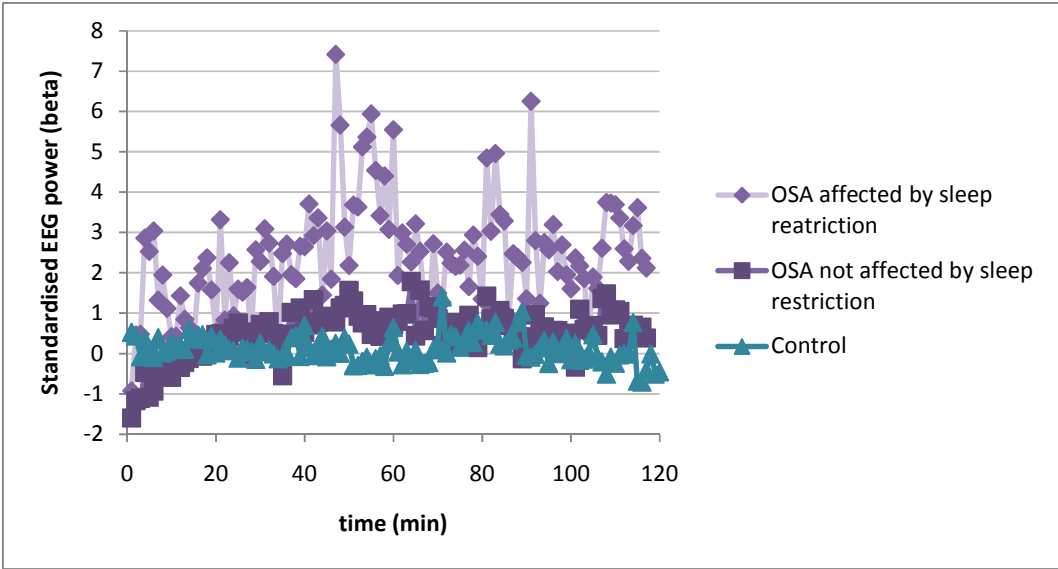


Figure 10.3-11 Standardised beta EEG power over time following sleep restriction

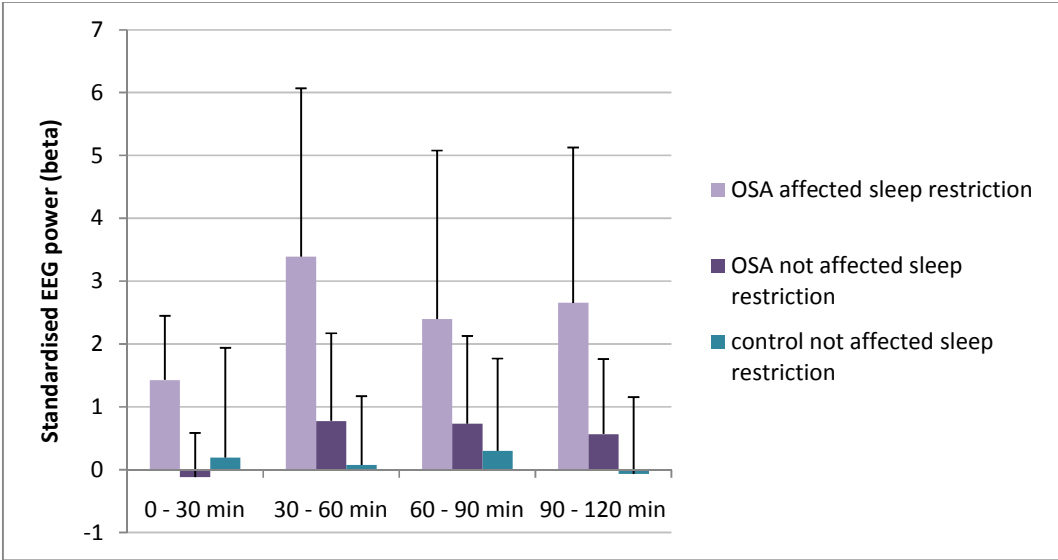


Figure 10.3-12 Standardised beta EEG power in 30 min epochs with standard deviation following sleep restriction

Those OSA participants who were affected by sleep restriction had higher standardised beta power, suggesting that those participants were putting in more effort to remain

alert than those who were not affected, this was a non significant difference [$F(1,17) = 2.399, p = 0.140$]. However there is a significant condition, time group interaction [$F(3,51) = 3.202, p = 0.31$] and again there is no significant difference between those who were not affected and controls [$F(1,32) = 0.230, p = 0.635$].

10.3.5 Correlations

To test the hypothesis that those OSA CPAP compliant participants who are older and those with higher ESS will have greater impaired driver performance at a driving simulator task.

	Pearsons r	P value
Age	-0.54	0.018*
Hazard perception score	0.37	0.122
Years driving experience	-0.43	0.069
	Spearman's rho	P value
ESS	-0.039	0.876
Annual millage	-0.307	0.201

*significant $p < 0.05$

Table 10.3-1 Correlations to increase in driving incidents between a normal nights sleep and sleep restriction

Table 10.3-1 shows the results of correlation between the change in number of driving incidents from the normal sleep to the sleep restriction condition and various participant characteristics. The only significant correlation was age, demonstrated in Figure 10.3-13.

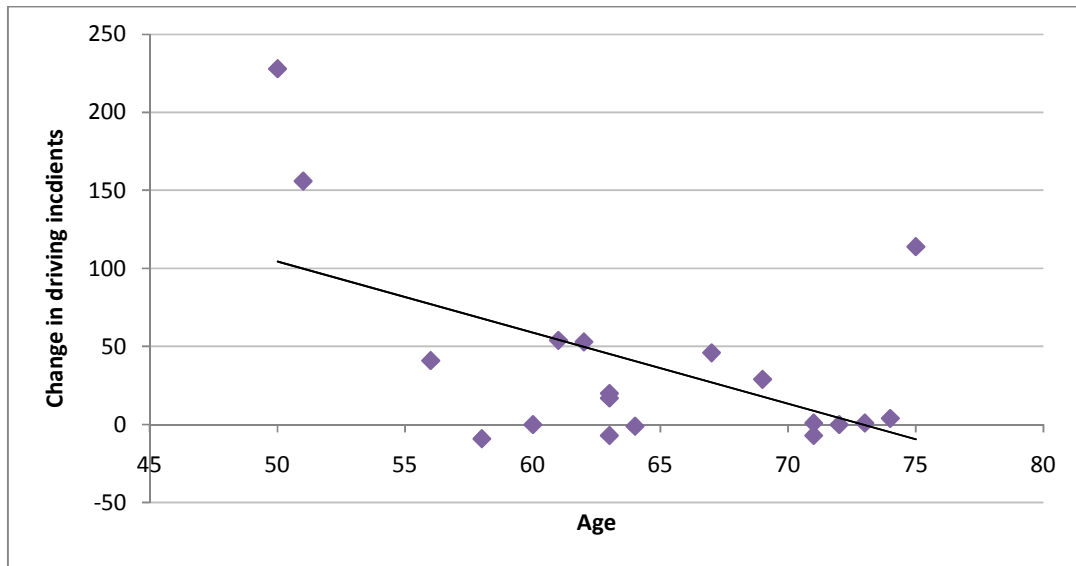


Figure 10.3-13 Change in driving incidents for OSA participants with age

There is a significant negative correlation with older drivers being less affected by sleep restriction. In practice two younger drivers, aged 50 and 51 both had greater than 150 increase in number of incidents; it is likely that the significant correlation is due to these two participants.

10.3.6 Insight into sleepiness

To test the hypothesis that in those OSA CPAP compliant participants who have greater vulnerability to sleep restriction there will be no difference in insight into sleepiness than those who are not vulnerable, as reflected by subjective score at first major incident.

OSA Participants affected by sleep restriction	
-	100% (5/5) identified sleepiness on the KSS (6+) prior to first major incident an average of 7.4 minutes prior to the incident.
OSA Participants not affected by sleep restriction	
-	55.6% (5/9) identified sleepiness on the KSS (6+) prior to first major incident an average of 23.2 minutes prior to the incident.

Table 10.3-2 Perception of sleepiness

All of the participants affected by sleepiness reported feeling sleepy prior to their first major incident. However, they only had 7.4 minutes notice of sleepiness prior to incident. On average the first major incident occurred 26 minutes into driving so there

was not a large opportunity to rate sleepiness. Just over half of those not affected by sleep restriction identified sleepiness prior to first major incident with a longer awareness period of 23 minutes.

10.4 Discussion

Although individual differences in ability to cope with sleep restriction is to be expected (Van Dongen et al. 2004, Philip et al. 2006) the magnitude of variation found was higher within OSA participants than control participants. This is consistent with previous research reporting some OSA participants to have similar levels of performance to controls (George et al. 1996a, Findley et al. 1999, Juniper et al. 2000). Therefore, it may not be appropriate to offer blanket advice on the fitness to drive of all treated OSA patients.

As discussed in previous chapters OSA participants are found to have no significant impairment in driving performance after a normal night's sleep compared with controls. However, if sleep is disturbed by a reduce sleep length or withdrawal of CPAP, driving performance is significantly affected. When driving performance following sleep restriction is analysed in greater depth two distinct groups become apparent within OSA participants. Some OSA participants have impairment (measured by driving incidents) greater than control participants (higher than 1 standard deviation from the mean). These OSA participants were significantly affected by sleep restriction by such a magnitude as to create an overall significant difference in driving incidents between OSA and control groups when the group was considered as a whole, as discussed in chapter 5. Those who are not affected by sleep restriction performed no differently to controls. OSA participants who were affected also appeared to have greater difficulty with prolonged time on task as even after a normal sleep this sub group had a shorter safe driving time than the unaffected OSA sub group and controls.

Interestingly, by creating the two sub groups of OSA participants using driving incidents significant differences are also found between them with subjective sleepiness and EEG. The overall findings between OSA and control participants for subjective sleepiness and EEG reported in chapter 6 and 7 were not significant. However, when separated, these two OSA sub groups are significantly different to

each other and those not affected are no different to controls. This further adds to the evidence in chapter 8 that OSA patients do have insight into their sleepiness as here the group with higher standardised power in alpha/theta (greater EEG sleepiness) reported feeling significantly more likely to fall asleep. In chapter 8, 71.4% of OSA participants were found to have insight into their sleepiness compared with 44.4% of control participants. All of those OSA participants affected by sleep restriction had insight into sleepiness compared with 55.5% of those who were not affected by sleep restriction. Even though some OSA participants were significantly affected by sleep restriction these were the participants who were much more likely to identify when they are sleepy. Providing they act appropriately on this knowledge they should pose no more danger on the road than any other group of drivers.

It is really important that all drivers are aware of how to recognise when they are sleepy and what to do about it, particularly with OSA drivers. Those OSA participants who were affected by sleep restriction only drove for an average of 26 minutes before having a major driving incident and only felt sleepy on average 7 minutes before this incident occurred. Encouragingly, all of the OSA participants affected by sleep restriction were able to identify they were sleepy prior to major incident, so should be able to implement a countermeasure to driver sleepiness as long as they act straight away. Promoting awareness of the dangers of driver sleepiness and what effective countermeasures should be taken if a driver does feel sleepy should enable those most affected to take action before an incident occurs. In particular medical practitioners of OSA patients should explain the increased susceptibility faced by some OSA patients to sleep restriction. Awareness of effective countermeasure to driver sleepiness is discussed in chapter 12.

No difference was found between the total sleep time of those OSA participants affected or not affected by the sleep restriction. As such differences during the day are as a result of two distinct phenotypes: affected and not affected by sleep restriction. As in previous studies no predictor has been found to suggest which OSA participants will be affected by sleep restriction and which will not. A significant negative correlation with age was identified, but in practice two younger OSA drivers had a large increase in number of incidents, if these were removed as outliers the

correlation would probably not be significant. The mean ESS was slightly higher in those who were affected by sleep restriction, but not significantly. This adds to a large number of previous studies finding no predictor of which OSA participants will have impaired driving performance (George et al. 1996b, Kingshott et al. 1998, Turkington et al. 2001, Mazza et al. 2005, Sagaspe et al. 2007a). Those OSA participants affected by sleep restriction did score higher at the hazard perception test than those not affected, perhaps suggesting some ability to compensate for negative effects of time on task and sleep restriction in a stimulating environment.

Without a reliable predictor medical practitioners have nothing to base fitness to drive recommendations on. ESS is often used in a clinical setting to assess fitness to drive, but in the current work the ESS of those participants affected and not affected by sleep restriction were within normal range. As such, it is possible that ESS is an appropriate tool for assessing day time sleepiness under normal sleep conditions because there was no significant difference between driving performance of these OSA participants and controls following normal sleep, but as some OSA participants are susceptible to sleep restriction it would be appropriate for treated patients to undergo a sleep restriction study to assess performance. Those who suffer from a greater susceptibility could then receive targeted advice. The current driving simulator set up would not be appropriate for clinical use due to its long nature; further research in this area is needed to identify a shorter test sensitive to the affects of sleep restriction which could be used in a clinical setting. Hopefully a 30 min test would be appropriate as on average the affected group had the first major incident in 26 minutes.

The clear distinction between the two types of OSA participant can be seen in this study population of 19 OSA participants. With smaller study populations this distinction may not have been identified, because of these findings studies with very small sample sizes should be accepted with caution. When making comparative statements between OSA participants and control participants care is needed as to which sub group of OSA participants are represented.

10.5 Conclusion

- 26.3% of OSA participants were affected by sleep restriction, having significantly more driving incidents and shorter safe driving time than controls.
- OSA participants affected by sleep restriction had significantly higher EEG power in alpha/theta and LHoFA scores than those not affected.
- OSA participants not affected by sleep restriction showed no significant difference compared with controls in terms of driving incidents, subjective sleepiness or EEG activity.
- No predictor as to which OSA participants would be affected by sleep restriction was identified.
- OSA participants who were more affected by sleep restriction were more likely to have insight into sleepiness.

CHAPTER ELEVEN

Hazard perception test

11.1 Introduction

Hazard perception is a skill enabling drivers to identify potentially dangerous situations in time to take evasive action if necessary. Passing (scoring 44 or more out of 75) a hazard perception test has been compulsory for obtaining a UK driving licence since its introduction in 2002. The participants in this research all obtained their driving licence prior to this date so were not required to pass such a test. The hazard perception test provides a specific driving context in which to assess cognitive function.

11.1.1 Key points from the literature review

Despite not having taken this test before it could be expected that as all participants are experienced drivers they would pass. Experienced drivers perform better at hazard perception tests than inexperienced drivers (Smith et al. 2009), with age and annual mileage being strong predictors of hazard perception test performance (Grayson et al. 2002). Poor hazard perception has been linked to increased RTI risk (Grayson et al. 2002) although training in hazard perception has not conclusively been seen to reduce RTI risk (Horswill et al. 2004).

Hazard perception will be presented as a novel task for all participants. Untreated OSA participants have been reported to have poorer cognitive task performance on initial exposure to a task, though improvement can be seen with practice (Rouleau et al. 2002); it is not known if this is still the cases when treated with CPAP.

Hazard perception is cognitively demanding (Horswill et al. 2004, Smith et al. 2009). OSA patients have been shown to be at greater risk of RTI (Ellen et al. 2006) and to have reduced cognitive function (Mathieu et al. 2008). It is possible that one factor causing the increased RTI risk in OSA patients is poor hazard perception.

11.1.2 Research aim and hypotheses

Aim: To evaluate the ability of OSA-CPAP compliant patients at a hazard perception test specifically related to driving compared with healthy controls.

Hypotheses:

To test the hypothesis that OSA CPAP compliant participants will show no difference in hazard perception performance at a computer based task compared with controls, following a normal treated night's sleep, as reflected by test score and pass rate.

To test the hypothesis that ESS and Age will be negatively correlated with hazard perception score in both OSA CPAP compliant participants and controls.

To test the hypothesis that driving experience will be positively correlated with hazard perception score in both OSA CPAP compliant participants and controls.

11.2 Method

Design: each participant completed the hazard perception test once following a normal night's sleep. Comparing OSA and control participants.

Setting: computer based test.

11.2.1 Participants

The data presented in this chapter are for 20 OSA and 20 control participants. Details of recruitment can be found in chapter 3 and participant characteristics in chapter 4.

11.2.2 Protocol

The PC hazard perception test (Driving Test Success 2007) was completed during the screening day following a normal night's sleep. The test consists of a series of video clips requiring participants to click the mouse button when they see a developing hazard. The video is filmed from a camera mounted on the interior windscreen of a car driven in various situations. Participants were alone in a room with no distractions while completing the test.

11.2.3 Measures

The hazard perception test consists of 14 video clips presenting 15 hazards. For each hazard a mark is given from 0 to 5, the earlier the hazard is identified the more points will be scored, if the hazard is missed a score of 0 is given. Tests are scored out of 75, the pass mark is 44.

11.2.4 Statistical analysis

The average hazard perception score of OSA and control participants was compared with independent t test (2 tailed). Data was normally distributed (assessed visually on a histogram) and did not violate the assumption of homogeneity of variance (assessed using Levenes test). Association between having OSA or not and passing the hazard perception test is assessed using chi-square test.

Correlation between age and driving experience with hazard perception score was assessed using one tailed Pearson's r (r). Correlation between ESS and annual mileage with the hazard perception score was assessed using one tailed Spearmans rho (r_s) for each group individually.

11.3 Results

11.3.1 Test score and pass rate

To test the hypothesis that OSA CPAP compliant participants will show no difference in hazard perception performance at a computer based task compared with controls, following a normal treated night's sleep, as reflected by test score and pass rate.

The computer programme automatically graded each video clip giving participants a score out of 75. Overall 72.5% of participants passed the test.

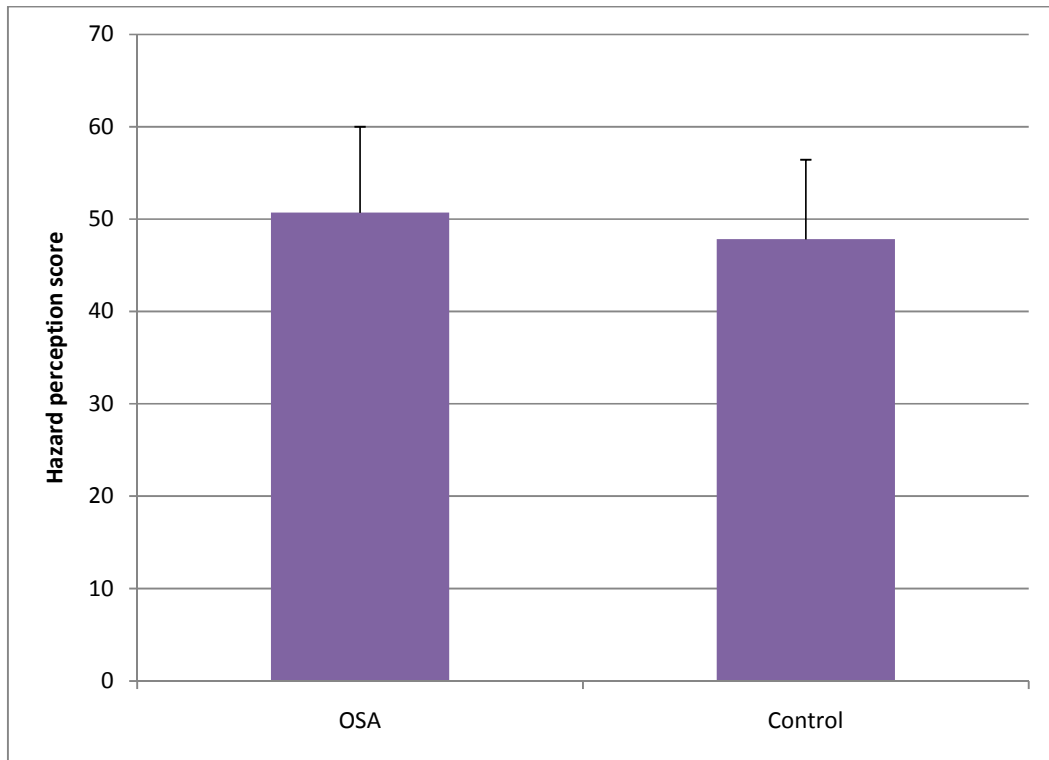


Figure 11.3-1 Mean hazard perception score for the two groups with standard deviation

There was no significant difference between mean score for OSA participants compared with controls [$t(38) = 1.29, p = 0.21$], shown in Figure 11.3-1.

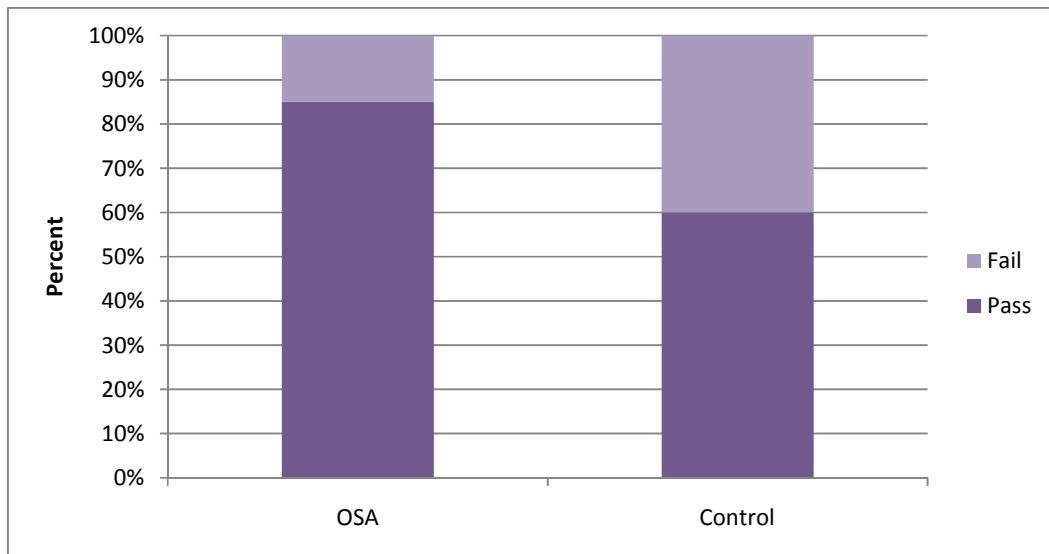


Figure 11.3-2 Hazard perception pass rate by group

85% of the OSA participants passed compared with 60% of controls, pass rate can be seen in Figure 11.3-2. There was no significant association between having OSA and passing [$X^2 (1) = 3.14, p = 0.077$].

11.3.2 Correlations

To test the hypothesis that ESS and Age will be negatively correlated with hazard perception score in both OSA CPAP compliant participants and controls.

To test the hypothesis that driving experience will be positively correlated with hazard perception score in both OSA CPAP compliant participants and controls.

Age, driving experience and annual mileage has no correlation to hazard perception score as shown in Table 11.3-1

	OSA		Control	
	Pearson's r	Significance (one tailed)	Pearson's r	Significance (one tailed)
Age and hazard perception score	-0.25	0.148	-0.29	0.109
Driving experience and hazard perception score	-0.07	0.382	0.08	0.371

Table 11.3-1 Parametric correlation statistics

	OSA		Control	
	Spearman's rho	Significance (one tailed)	Spearman's rho	Significance (one tailed)
ESS and hazard perception score	0.06	0.409	-0.52	0.009**
Annual mileage and hazard perception score	0.07	0.379	0.17	0.237

** signifies significance at 0.001 level

Table 11.3-1 Non parametric correlation statistics

In control participants ESS was negatively correlated to hazard perception score visualised in Figure 11.3-3

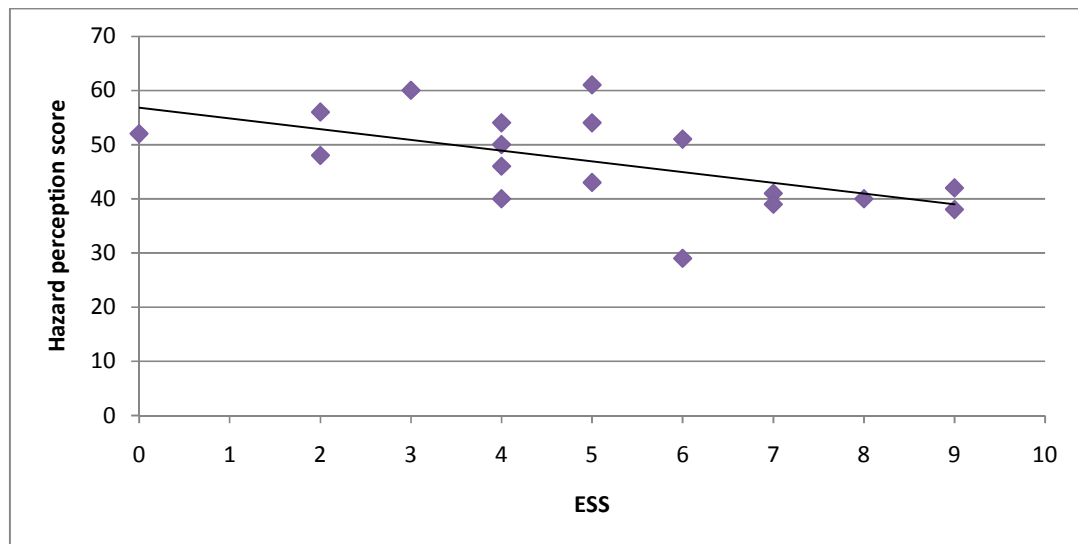


Figure 11.3-3 Hazard perception score by ESS for control participants

11.4 Discussion

There was no significant difference of hazard perception score or pass rate between OSA and control participants and no suggestion that treated OSA drivers are not fit to drive, despite previous studies finding impaired cognitive function in OSA participants. A limitation of cognitive function research is that a wide variety of tests are used, these measure cognitive function in different ways, presenting a problem when comparing them. The hazard perception test is a cognitive function test tailored to assess the very specific skill of identifying hazards while driving. So while there is some evidence of cognitive impairment in OSA participants it is has not been found using this specific test.

One explanation for cognitive impairment in untreated OSA participants is that any impairment found is due to varying tolerance levels to sleep deprivation (Yaouhi et al. 2009) and that treatment with CPAP removes any impairment previously reported (Alchanatis et al. 2005). This would provide an explanation for why no impairment was reported in these treated OSA participants. However, participants did not complete the hazard perception test prior to starting CPAP treatment so it is not possible to tell if CPAP has removed any previous impairment in these particular participants.

It has been reported that untreated OSA participants struggle with novel tasks but given time to practice, any impaired ability is removed (Rouleau et al. 2002). In the

current study the task was novel to all participants and in fact more OSA participants passed the test than healthy controls, indicating no impaired ability in treated OSA participants.

It was expected that as participants had a minimum of 30 years driving experience they would score highly on the test as experienced drivers have been shown to be better at hazard perception tests (Smith et al. 2009). However, 27.5% of participants failed the test, scoring lower than 44/75. This is possibly because participants were given no opportunity to practice prior to completion of the task. Prior to an actual driving test the hazard perception test can be practiced, the PC programme used for this study is a commercially available aid designed for this purpose. The participants in this study are therefore in an unusual situation that they did not get to practice before hand. If they had done the pass rate may have been higher.

The hazard perception test used has been designed specifically to assess fitness to drive in new drivers. Although cognitive function is assessed it has not been designed specifically with this in mind. The focus of the current thesis is not on cognitive function but because this test forms part of the UK driving test it was felt appropriate for participants to complete it, as this is the actual measure used to assess driving ability in the UK.

ESS was significantly negatively correlated to hazard perception score for control participants but not OSA participants. It might be expected that people with trait sleepiness may find it harder to maintain concentration through the 15 minute test and therefore have a lower score. However, Smith et al. (2009) found experienced drivers not to be affected by sleepiness when completing the hazard perception test. Although this correlation is significant in practice only 27% of the variability in hazard perception score of control participants can be explained by ESS.

The test is known to be easier to pass for experienced than non experienced drivers Smith et al. (2009); however in the current work driving experience was not found to correlate to hazard perception score. In Smith et al. (2009) the experienced drivers were aged 28 – 36 years much younger than the 50 – 75 year olds in the current study. This suggests the effect of increasing driver experience is gained from experience in

earlier years of driving. With all participants having over 30 years experience it was not an impacting factor on hazard perception ability. Driving experience in terms of annual mileage was also investigated and again no correlation was found with hazard perception score.

The study population was specifically chosen to be older experienced drivers. The hazard perception test is aimed at inexperienced drivers and therefore may not be sensitive enough to identify any impairment in these experienced drivers. The test is the government standard for the UK so in having the ability to pass a person would be eligible to take their practical driving test to gain their driving licence. It is concerning that not all drivers could pass the test despite them all having a driving licence, but it is possible with further practice they would all pass. Importantly there was no difference between OSA and control participants.

11.5 Conclusion

- There is no cognitive impairment as measured by hazard perception test in CPAP treated OSA patients compared with healthy controls.

CHAPTER TWELVE

Countermeasures to driver sleepiness: is the message getting through?

Findings reported from all groups studied: HGV drivers and OSA car drivers

12.1 Introduction

Any actions taken by a driver to prevent sleepiness occurring or to reduce sleepiness at the time are countermeasures. Whether or not an effective countermeasure is used is dependent on recognition of sleepiness, knowledge of countermeasures and driver choice. Chapter 8 reported that the majority of participants in the simulator study were able to recognise when they are sleepy. Following recognition of sleepiness a driver can only make an appropriate choice if they are educated in which countermeasures are effective and will only make that choice if they are motivated to do so by the perception of the danger to themselves and others.

The data presented in this chapter is from questionnaire responses of the 148 HGV drivers surveyed in chapter 2, the 20 OSA car drivers and 20 Control car drivers who participated in the simulator studies. The chapter is located after the HGV and simulator chapters as it relates to all the participant groups previously studied.

12.1.1 Key points from the literature review

Studies in Norway and Sweden surveying the general public have reported good awareness of the dangers of driver sleepiness and generally good knowledge of effective countermeasures, however, despite this knowledge appropriate measures are not necessarily utilised (Nordbakke et al. 2007, Anund et al. 2008). The only similar UK study identified was conducted prior to the change in advice for sleepy drivers in the UK Highway Code, the survey results for “choice of countermeasure” reflected the advice published at the time (Maycock 1996).

The UK Highway Code currently offers good advice in dealing with driver sleepiness stating to take a break every 2 hours and if a driver feels sleepy to stop for a caffeinated drink and a nap, see Figure 1.3-1. Prior to 1999 stopping to stretch legs was advised.

Young participants know when they are sleepy (Horne et al. 2004) and feel sleepy for approximately 45 minutes before having an incident (Reyner and Horne 1998b). Healthy older participants in the current study reported 65 minutes of sleepiness prior to driving incident. This is sufficient time to implement a countermeasure and avoid an RTI. It is possible that on real roads drivers do not assess their sleepiness levels as

often, as when in a regulated study, so may not realise they are sleepy until they are fighting sleep. The UK motorway signs, “tiredness kills take a break” provide a prompt for people on long journeys to assess their sleepiness, and the accurate information in the Highway Code means UK drivers are well facilitated in making good countermeasure choices. A key question is, now ten years after the change to the Highway Code advice, are experienced drivers choosing effective countermeasures? In particular because OSA participants only had approximately 20 minutes between feeling sleepy and having a major incident it is important that they utilise an effective countermeasure quickly.

All new drivers in the UK are required to be familiar with the Highway Code; however, experienced drivers are required to keep up to date on their own volition. It is possible therefore, that drivers passing their test before 1999 would choose to stretch their legs if they felt sleepy while driving as this was the advice at the time.

As a subgroup, professional drivers (driving long distances for long hours) and OSA patients (with a shorter window on which to act when feeling sleepy) may be more likely to experience driver sleepiness than control car licence holders. As such these groups may have actively sought out advice on driver sleepiness countermeasures or received it from their employer or doctor, which may result in making effective choices.

12.1.2 Research aim and hypotheses

Aim: To evaluate the choice of countermeasure to driver sleepiness in two groups susceptible to driver sleepiness, HGV drivers and OSA drivers.

Hypotheses:

To test the hypothesis that HGV and OSA drivers will be more likely to choose appropriate countermeasures to driver sleepiness than controls.

To test the hypothesis that participants who have prior experience of falling asleep at the wheel will be more likely to choose appropriate countermeasures than those that have not.

To test the hypothesis that the countermeasures listed in the highway code (caffeine, nap and break from driving every 2h) will be most popular for all respondents.

To test the hypothesis that OSA CPAP treated participants will be more likely to identify driver sleepiness as a problem than controls.

12.2 Method

Design: cross-sectional questionnaire, completed once by all participants. Comparing HGV drivers, OSA car drivers and control car drivers.

Setting: HGV drivers - A UK HGV rest stop as described in chapter 2. Participants completed the questionnaire independently with the investigator available to help if required.

Car drivers (OSA and control) – University Sleep Centre. Participants completed the questionnaire with the investigator prior to participating in the simulator studies of chapters 5 – 10.

12.2.1 Participants

Three groups of participants were recruited

- (1) 148 HGV drivers on UK roads surveyed in a truck stop as detailed in chapter 2.
- (2) 20 CPAP treated OSA car drivers who participated in the driving simulator study details of recruitment and participant characteristics can be found in chapter 3 and 4.
- (3) 20 healthy car drivers who participated in the driving simulator study details of recruitment and participant characteristics can be found in chapter 3 and 4.

12.2.2 Protocol

The HGV drivers completed a self administered questionnaire following the protocol in chapter 2, as part of the questionnaire (appendix 1) questions was asked about driver sleepiness and countermeasures to sleepiness, the results of which were not discussed in chapter 2.

The OSA and control drivers completed the screening questionnaires (appendix 6 and 7) with the researcher. These included questions about driver sleepiness and countermeasures to sleepiness.

12.2.3 Measures

The following questions were asked:

Have you ever felt sleepy while driving?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Have you ever fallen asleep while driving?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
How long are you happy to drive for without taking a break?	<hr/>			

If you felt sleepy while driving what are you most likely to do? (you may choose more than one)	Stretch your legs	<input type="checkbox"/>
	Open a window	<input type="checkbox"/>
	Have a caffeine containing drink	<input type="checkbox"/>
	Turn the radio up	<input type="checkbox"/>
	Stop for a nap	<input type="checkbox"/>
	Keep going	<input type="checkbox"/>

12.2.4 Statistical analysis

Responses to each question are reported in percentages.

Comparison is made using chi-squared test for independence between the two groups of car drivers (OSA and Control) and drivers with and without experience of falling asleep at the wheel, separately for professional and non professional drivers. Odds ratios are not reported as no Chi-squared tests were significant.

The two groups of healthy drivers (HGV and Control) were visually compared without statistics due to be large difference in sample size.

12.3 Results

12.3.1 Experience of driver sleepiness

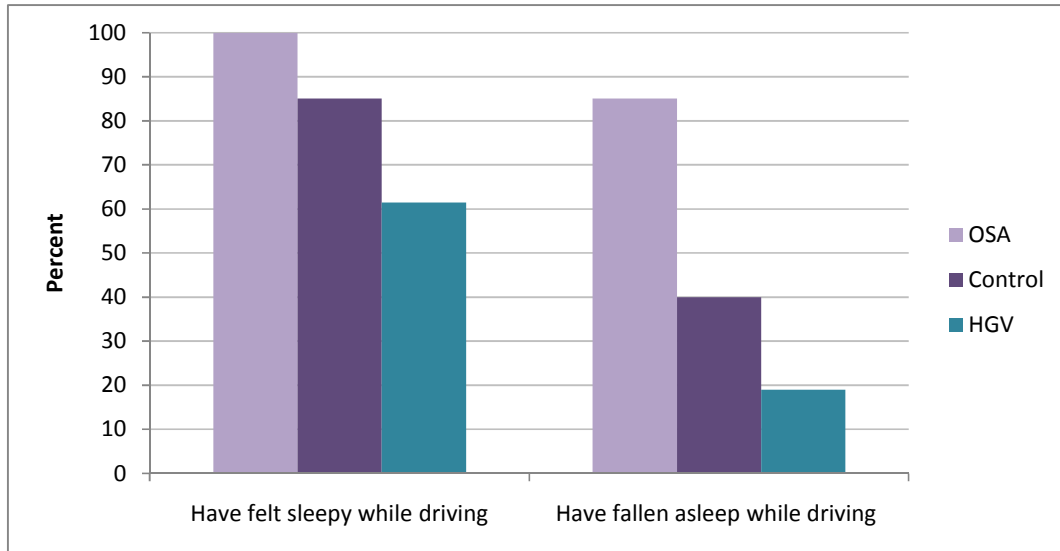


Figure 12.3-1 Percentage of OSA, Control and HGV drivers who have felt sleepy and fallen asleep while driving

All of the OSA participants had prior experience of feeling sleepy while driving compared with 85% of controls (nsd). Significantly more OSA participants (85%) admitted falling asleep while driving compared with controls (40%) [$X^2 = 6.82$, $p = 0.009$].

35% of cases of OSA participants falling asleep at the wheel were reported after having started their CPAP treatment. Following CPAP treatment it might be expected that OSA drivers have the same experience as controls but actually incidence of falling asleep at the wheel is less than controls (40%).

62.56% of HGV drivers reported having felt sleepy at some time whilst driving with 18.92% admitting having fallen asleep at the wheel. This is less in both cases than the control non professional drivers.

12.3.2 Choice of countermeasure

To test the hypothesis that HGV and OSA drivers will be more likely to choose appropriate countermeasures to driver sleepiness than controls.

To test the hypothesis that the countermeasures listed in the highway code (caffeine, nap and break from driving every 2h) will be most popular for all respondents.

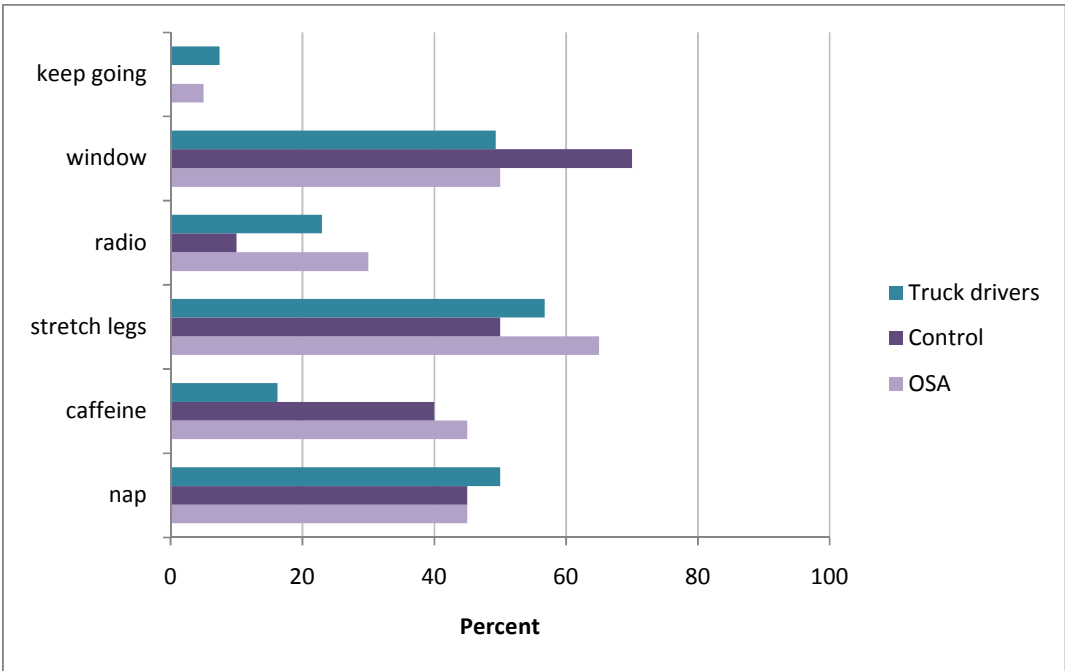


Figure 12.3-2 Preference for driver sleepiness countermeasure for OSA and control drivers

The most popular countermeasure for all three groups was to open a window and stretching legs, in all cases the least popular was to keep going, see Figure 12.3-2.

Having OSA had no effect on preference of any countermeasure compared with healthy controls, keeping going [$X^2 = 1.03$, $p = 0.31$], having a nap [$X^2 = 0$, $p = 1$], turning the radio up [$X^2 = 2.57$, $p = 0.109$], having a caffeine drink [$X^2 = 0$, $p = 1$], opening a window [$X^2 = 0.108$, $p = 0.298$] and stretching legs [$X^2 = 0.450$, $p = 0.502$].

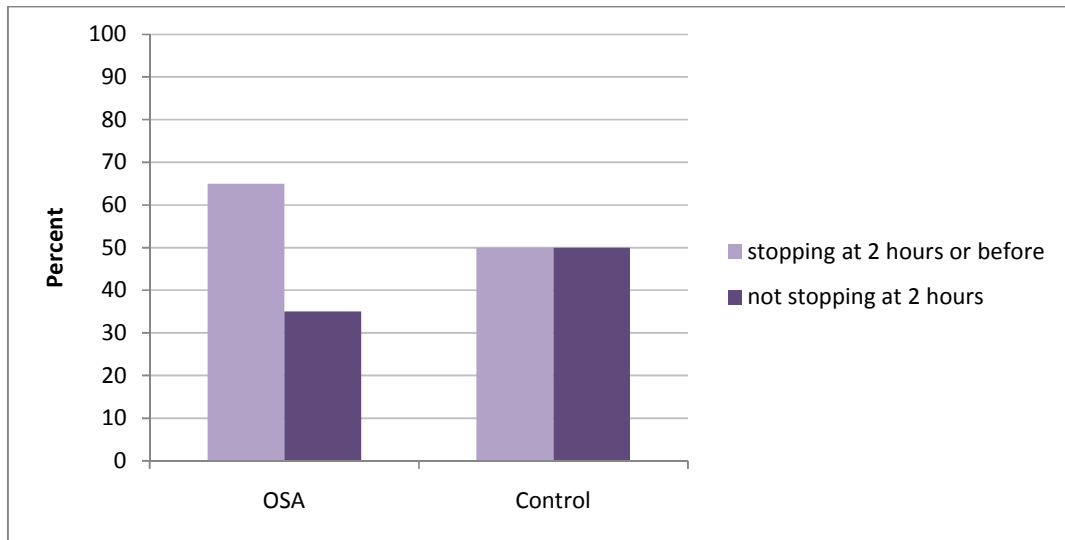


Figure 12.3-3 Percentage of car driving participants preferring to stop driving and not stop driving within the suggested 2 hours

When asked how long they would be happy to drive for without taking a break more OSA drivers responded with an answer of ≤ 2 hours than control participants, [$X^2 = 0.468, p = 0.494$], Figure 12.3-3.

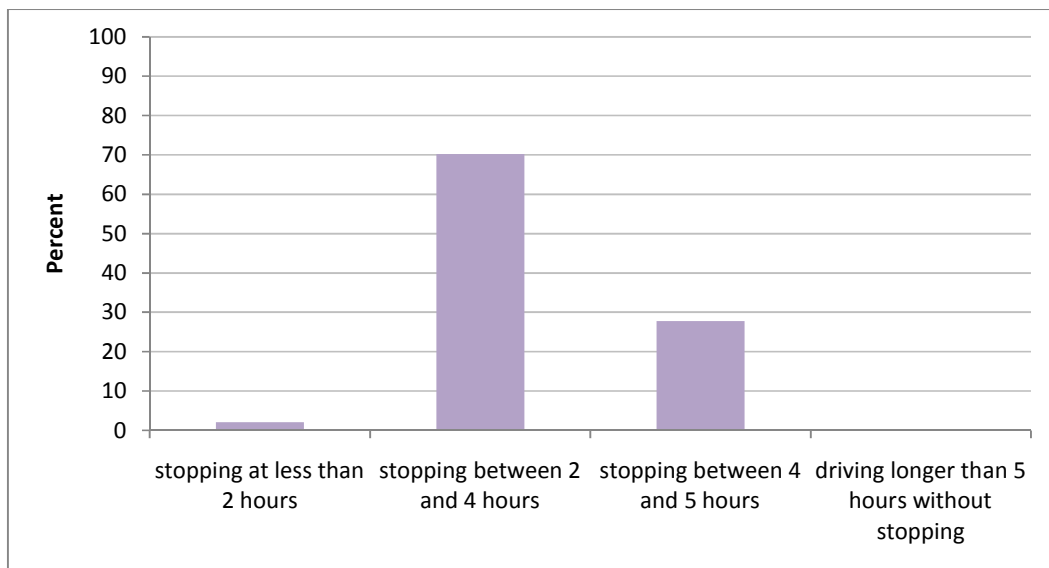


Figure 12.3-4 Preference of driving time for HGV drivers

The majority of HGV drivers are willing to drive for longer than the recommended 2 hours for private drivers in the Highway Code. This is not unexpected as the maximum legal drive time without a break for HGV drivers is 4.5 hours, see Figure 12.3-4.

12.3.3 Prior experience of driver sleepiness and effect on choice of countermeasure

To test the hypothesis that participants who have prior experience of falling asleep at the wheel will be more likely to choose appropriate countermeasures than those that have not.

62.5% of the private car drivers surveyed reported previous experience of falling asleep at the wheel. Data was compared between drivers who had experience of driver sleepiness (n = 25, OSA = 17) and those who had not (n = 15, OSA = 3). 18.9% of HGV drivers reported previously falling asleep while driving, the HGV data was also analysed to compare those with driver sleepiness experience (n = 28) and those without (n = 120). Data was analysed separately for professional and non professional drivers.

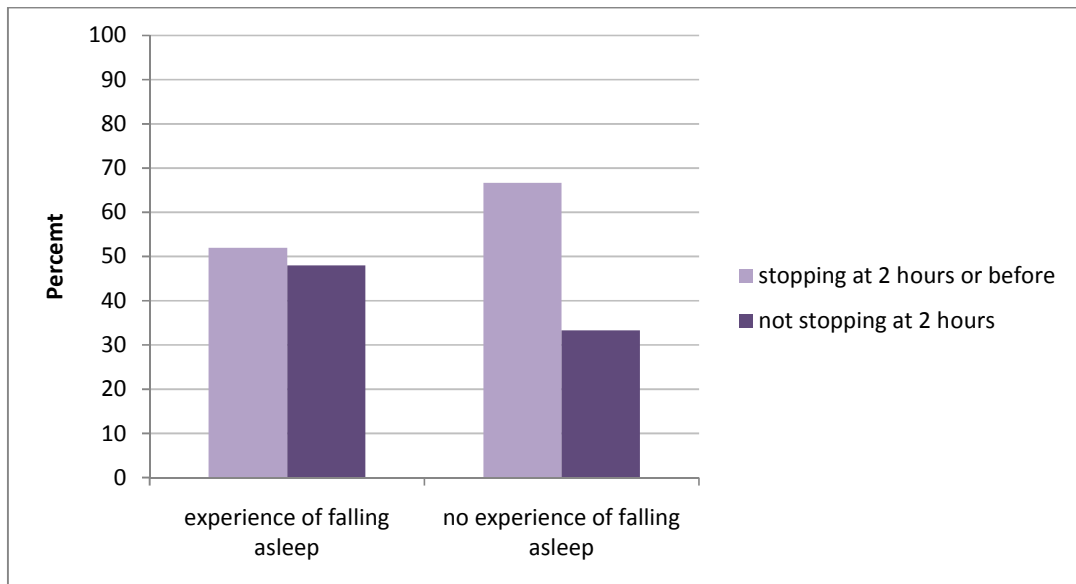


Figure 12.3-5 Percentage of non professional drivers preferring to stop or not stop driving within the suggested 2 hours, split by prior experience of falling asleep at the wheel

Prior experience of driver sleepiness had no significant effect on choice of driving duration for non professional drivers [$X^2 = 0.716$, $p = 0.397$]. More participants who had fallen asleep at the wheel before would drive for longer than the recommended 2 hours (nsd), see Figure 12.3-5.

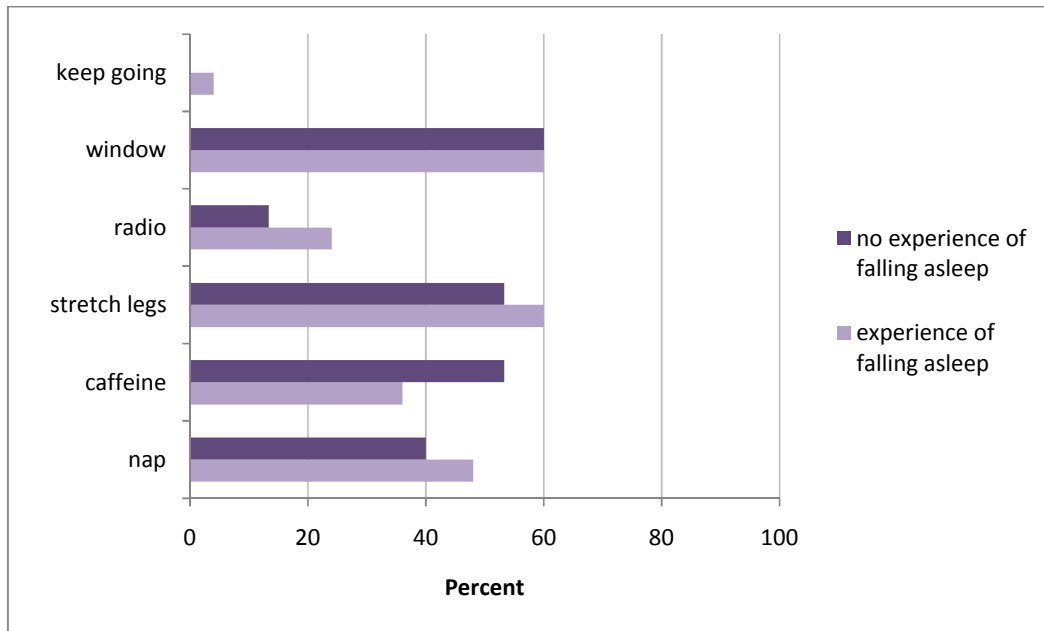


Figure 12.3-6 Preference of countermeasure between non professional drivers who did and did not have prior experience of driver sleepiness

The preferred countermeasure to driver sleepiness for both groups of non professional drivers was opening a window. Having a caffeine containing drink was more popular among those with no experience of driver sleepiness (nsd). Having prior experience of driver sleepiness had no significant effect on choice of any countermeasure, keep going [$X^2 = 0$, $p = 1$], have a nap [$X^2 = 0$, $p = 1$], turn the radio up [$X^2 = 0.2$, $p = 0.887$], have a caffeinated drink [$X^2 = 0.689$, $p = 0.406$], open a window [$X^2 = 0$, $p = 1$], stretch legs [$X^2 = 0.014$, $p = 0.906$], see Figure 12.3-6.

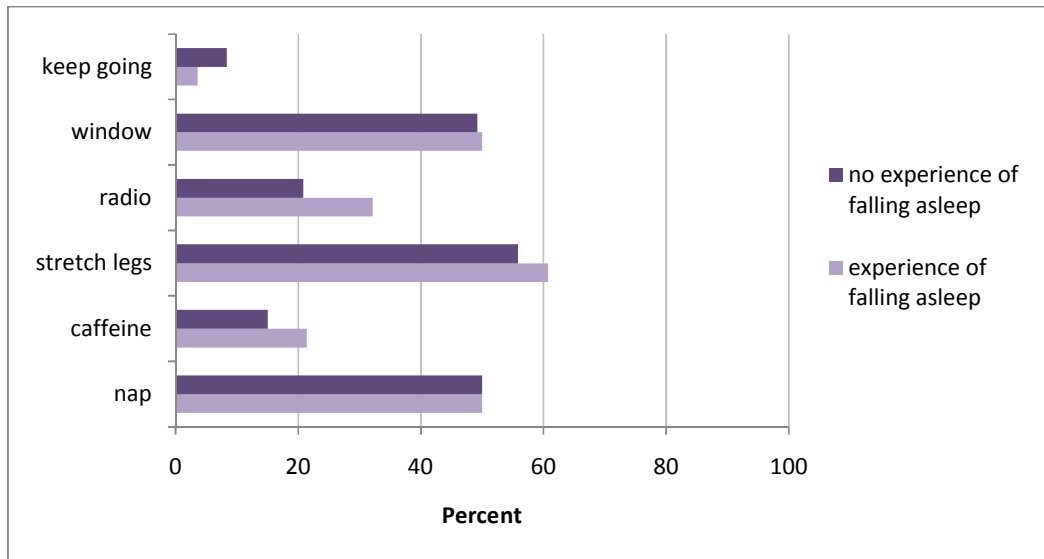


Figure 12.3-7 HGV drivers preference for countermeasure comparing those who do and do not have prior experience of driver sleepiness

The most popular countermeasure for both groups of professional drivers was stretching legs, followed by having a nap and opening a window, see Figure 12.3-7. Prior experience of driver sleepiness has no significant effect on preference of countermeasure for HGV drivers. Keep going [$X^2 = 0.226$, $p = 0.635$], have a nap [$X^2 = 0$, $p = 1$], turn the radio up [$X^2 = 1.016$, $p = 0.313$], have a caffeinated drink [$X^2 = 0.278$, $p = 0.598$], open a window [$X^2 = 0$, $p = 1$], stretch legs [$X^2 = 0.45$, $p = 0.832$].

12.3.4 Attitudes to driver sleepiness

To test the hypothesis that OSA CPAP treated participants will be more likely to identify driver sleepiness as a problem than controls.

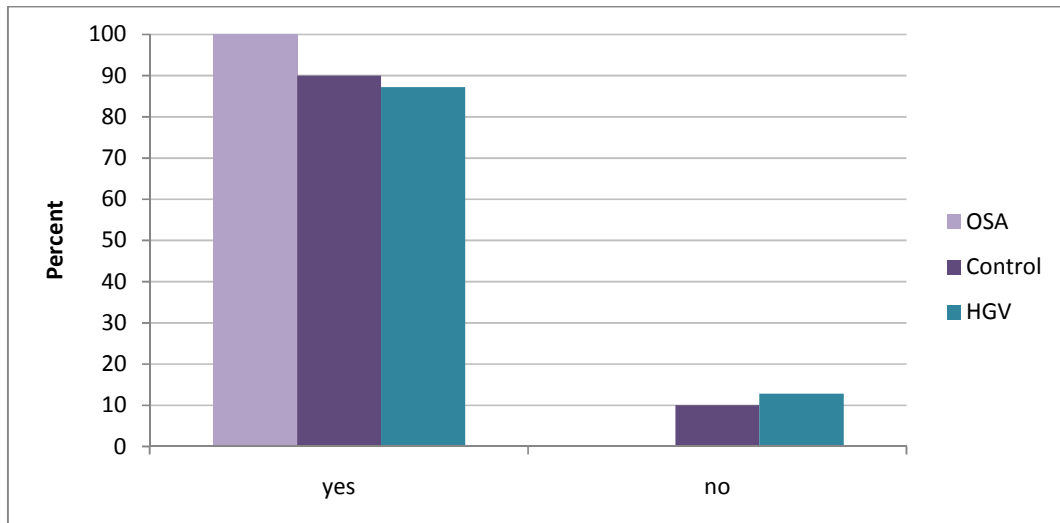


Figure 12.3-8 Percentage of drivers believing sleepiness can affect ability to drive safely

When asked if being sleepy can affect their ability to drive safely all of the OSA drivers thought it could compared with 90% of control drivers and 87.2% of HGV drivers, see Figure 12.3-8.

Perception of ability to drive safely when sleepy may be influenced by prior experience. When the group is split by experience of driver sleepiness, car drivers who had previously fallen asleep at the wheel all thought that sleepiness affected their ability to drive safely. However, 25% of HGV drivers who had prior experience of driver sleepiness did not believe it could affect their ability to drive safely, see Figure 12.3-9.

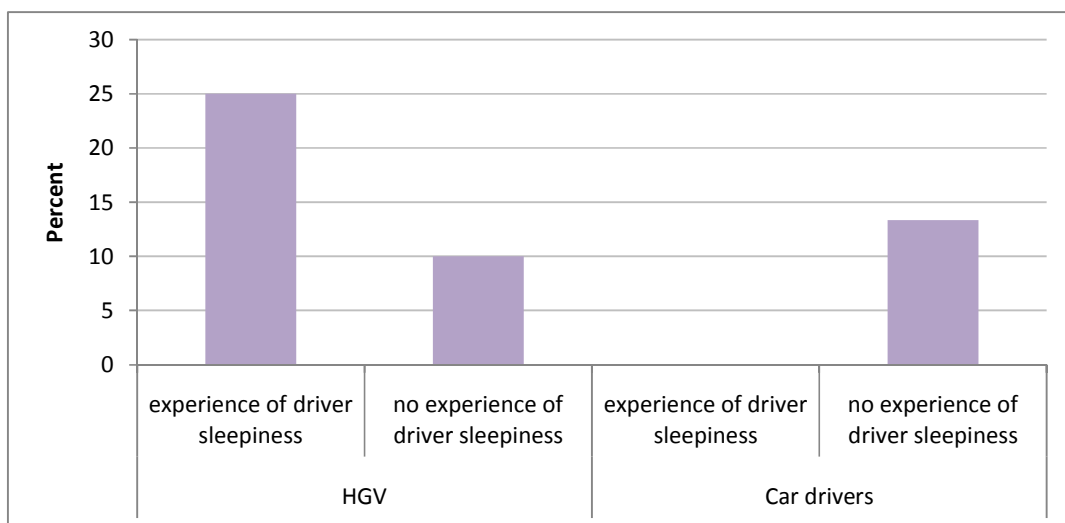


Figure 12.3-9 Percentage of drivers believing driver sleepiness does not affect ability to drive safely by prior experience of driver sleepiness

12.4 Discussion

The UK government is providing valid advice on counteracting driver sleepiness. Despite being introduced in 1999 this advice is not being followed; instead of selecting caffeine and a nap drivers are still choosing to open a window and stretch their legs which follows the advice in the “Highway Code” before 1999, when all participants took their driving tests. Two groups of drivers at increased susceptibility to driver sleepiness, HGV drivers and OSA patients, are no better at choosing effective countermeasures to driver sleepiness than controls. Having previously fallen asleep while driving does not result in increased likelihood of choosing an effective countermeasure.

Significantly more OSA participants had fallen asleep while driving than control participants. This is likely to be due to driver sleepiness prior to starting treatment as the number of OSA participants reporting falling asleep while driving post treatment is very similar to reports from control participants.

It might be expected that OSA and HGV participants would be more likely to choose effective countermeasures than controls because they would have had access to accurate information about driver sleepiness from either their company, occupational health or medical practitioner, however, there was no difference in preference for each countermeasure option. Having a nap was rated more highly by HGV drivers than non professionals, this is possibly because many HGVs are designed for drivers to sleep in them overnight whereas cars are not. Despite this, only half of the HGV drivers stated a nap was a countermeasure they would use if they felt sleepy.

The majority of drivers would take some action, with only 5% of OSA drivers and 7% of HGV drivers saying they would keep going. The low popularity of keeping going may be a reflection of participant age, as it has been shown that older drivers (aged > 45) are more likely to sacrifice journey time for a sleepiness countermeasure than young drivers (Anund et al. 2008). However, the HGV drivers were surveyed in a truck stop so by the nature of the experimental protocol any drivers choosing to keep going would not be available for survey.

The most popular choices are not effective at reducing sleepiness and are not in line with government advice. The most popular countermeasure for OSA and HGV drivers was to stretch their legs and for control drivers was to open a window. These findings are comparable to large studies in Sweden and Norway (Nordbakke et al. 2007, Anund et al. 2008). In Sweden a survey of 3135 drivers reported their most popular countermeasures as stop for a walk (54%), turn on the radio (52%) and open a window (47%) (Anund et al. 2008). In Norway 1513 drivers reported their most popular countermeasures as open a window (52%), stop to get out of the car (50%) and put music on (36%) (Nordbakke et al. 2007). Stopping for a walk and opening a window are in all cases popular choices of countermeasure despite being ineffective (Reyner et al 1998a, Horne et al 1996). It is likely opening a window is particularly popular because it does not increase journey time.

Previous research in the UK prior to the change in Highway Code advice reported only 35.1% of people to take a break from driving every 2 hours (Maycock 1996). The current research reports nearly 60% of non professional drivers stating that they would take a break from driving every 2 hours. This greater percentage is encouraging and could suggest an improvement in public awareness. However, Maycock (1996) had a much larger sample size of 4621 and a younger average age of 47.7 years compared to the average age of participants in this study, 65 years. Being willing to take a break may be influenced by age.

It was hypothesised that previous experience of falling asleep while driving may cause a person to seek out accurate information on how to deal with driver sleepiness there by putting themselves in a position better equipped to deal with the situation should it happen again. A larger proportion of non professional drivers had previously fallen asleep at the wheel than HGV drivers. Drivers who had not fallen asleep while driving were more likely to report taking a break from driving at least every 2 hours (nsd). The act of regularly stopping may be why these participants were less likely to have fallen asleep while driving. There was no effect of prior experience of driver sleepiness on any countermeasure choice, with the most popular for both sub groups being open a window and stretch legs. Those who had experienced falling asleep were no more likely to choose a nap and caffeine than those who had.

A factor in choice of countermeasure is whether a person perceives driver sleepiness to be a problem. All drivers were asked if they think driving while sleepy affects their ability to drive safely. This demonstrated that the majority of respondents do know that sleepiness affects ability to drive safely, so initial recognition of the problem is there, along with the desire to do something (keeping going being the least popular countermeasure). One particular subset of interest are HGV drivers who had fallen asleep while driving, 25% of these drivers reported driver sleepiness not to affect their ability to drive safely. It is possible that if they have fallen asleep and there have been no consequences they do not perceive the possible danger. This group in particular may benefit from targeted advice because they have got away with it once. They are less concerned and therefore may not bother to implement any countermeasures.

This current study has a small sample size, but despite this a consistent preference for opening a window and stretching legs has been reported, which is in line with research in other European countries (Nordbakke et al. 2007, Anund et al. 2008). The question of 'why?' cannot be answered from the data here, but participant response follows outdated advice in the Highway Code so it is possible that experienced drivers are not aware of the new advice.

The choice of countermeasures question used in this survey asked drivers what they would do if they felt sleepy, it does not ask what they think is most effective countermeasure. Nordbakke and Sagberg (2007) in Norway found that 70% of respondents thought that a nap would be the most effective countermeasure but when asked what they do only 8% said they would nap. It would be interesting to see if there was similar disparity in the UK. The current work could be extended to investigate if non professional drivers and professional drivers who passed their driving test after 1999 were better at identifying effective countermeasures.

An awareness campaign is needed to provide experienced drivers with accurate information on how best to deal with sleepiness. Key dissemination points could be HGV employers and OSA medical practitioners. However, although training in driver sleepiness is known to improve knowledge, this knowledge is not necessarily followed (Gander et al. 2005). UK drivers currently have access to accurate information about

countermeasures to driver sleepiness but the message does not appear to be getting through.

12.5 Conclusion

- The most effective countermeasures to driver sleepiness (caffeine and a nap) are not the most popular choice for UK drivers.
- Prior experience of driver sleepiness does not promote effective choice of countermeasures.
- Being part of a susceptible group (OSA and HGV drivers) does not result in more effective choice of countermeasure.

CHAPTER THIRTEEN

Comparison of driving simulator performance of the current older participants with previous publications of young participants

13.1 Introduction

Years of driver sleepiness research at Loughborough University have shown that driving performance is impaired following sleep restriction and that participants are aware when they are sleepy (Reyner, Horne 1998b, Horne et al. 2004). It has been shown that caffeine and a 20min nap combined are the most effective countermeasures to driver sleepiness (Horne et al. 1996, Reyner et al. 1997, Reyner and Horne 1998a, Reyner et al. 2000, Horne et al. 2001, Reyner et al. 2002) and low levels of alcohol worsen performance when combined with sleep restriction (Horne et al. 2003, Barrett et al. 2004a, Barrett et al. 2004b, Barrett et al. 2005).

All of these previous studies have been conducted in young (under 30 years) healthy participants. The current research uses healthy older participants (aged 50 – 75 years) as a control group for comparison with OSA participants in the same age range. Although not the focus of this research it was observed that sleep restriction affects task performance of young people in the previous publications than for the older participants in the current work. Interestingly, as shown in chapter 8, it was also identified that these older participants did not show as great frequency of insight into sleepiness as younger participants (Reyner and Horne 1998b, Horne et al. 2004).

In order to put these findings of the current work into context this chapter provides a brief comparison between the current research and previous results with younger participants using the same simulator set up as previous publications by Loughborough University.

13.1.1 Research questions

- Do older participants differ in ability at a driving simulator task, in terms of driving incidents compared with younger participants?
- Do older participants show the same pattern of increasing sleepiness as younger participants during a driving simulator task?

13.2 Method

Design: Repeated measures counterbalanced. Completing a 2h afternoon drive following a normal night's sleep and following sleep restriction to 5h. Comparing healthy older (50 – 75y) and younger (<30y) participants.

Setting: driving simulator

13.2.1 Selection of younger participants

All driving simulator publications from Loughborough University were assessed to identify those most relevant for comparison with the current work. The most relevant for comparison was:

Horne JA, Reyner LA, Barrett PR (2003) Driving impairment due to sleepiness is exacerbated by low alcohol intake.

This paper was selected because it matched the current study in that;

- The study contained 2 h drive times between 2pm and 4pm
- All participants were male, n = 12 (aged under 30)
- Results reported a baseline (normal night's sleep) condition and a sleep restriction to 5 h condition.

Although insight into sleepiness has already been discussed in chapter 8, in the current chapter comparison will be made between the older control group and the unpublished data from the younger participants in Horne et al. (2003).

13.2.2 Protocol

Details of full study protocols can be found in chapter 3 of this thesis and in the publication of Horne et al. (2003).

13.2.3 Measures

The number of major driving incidents and KSS were recorded and analysed as detailed in chapter 3. EEG activity was not compared as age related changes to the signal present a confounding variable. Minor incidents and LHoFA were not recorded in Horne et al. (2003).

13.2.4 Statistical analysis

Results for the number of driving incidents and subjective sleepiness were calculated in 30 minute epochs and compared between the younger participants and older control group using a repeated measure ANOVA for 2 within subject factors, condition (2 levels), time (4 levels) and 1 between subjects factor (age group) as described in section 3.6.

In all cases raw data were visually examined in histograms to check the assumption of normal distribution, standard deviation of road position and time to first major incident were normal. Number of driving incidents were not normally distributed, to correct for this skewed data a square root transformation was completed prior to analysis. Subjective sleepiness data was normally distributed. In all cases the assumption of homogeneity of variance was met so Huynh-Feldt (ϵ) adjustment was not used.

Results from OSA participants are presented for visual comparison on the same graph but are not included in the ANOVA as they have been compared with the control group.

13.3 Results

13.3.1 Major driving incidents

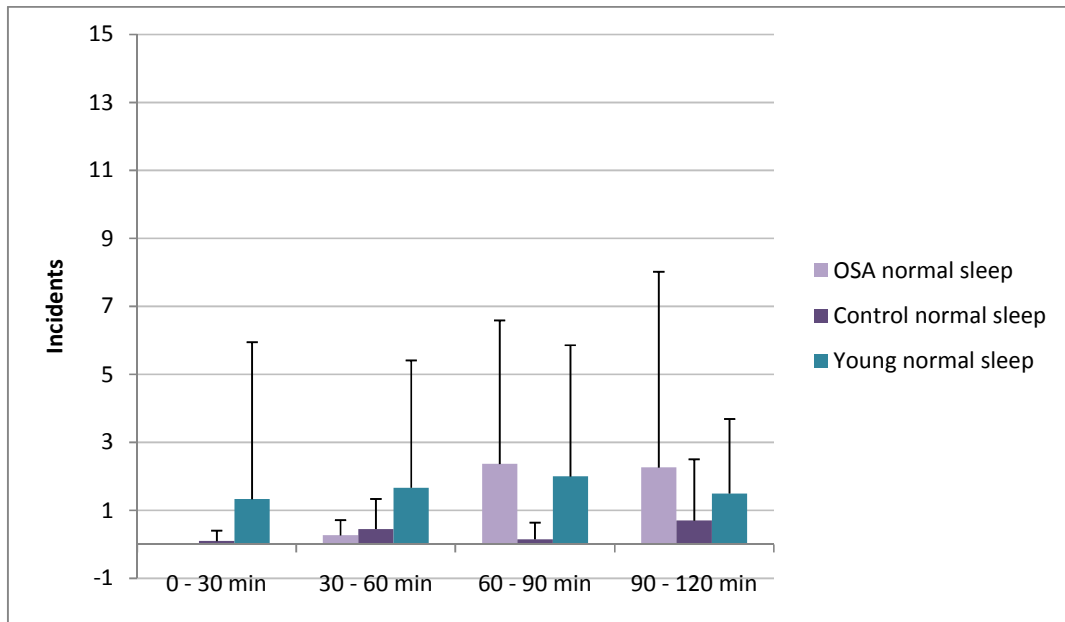


Figure 13.3-1 Major driving incidents after a normal night's sleep with standard deviation

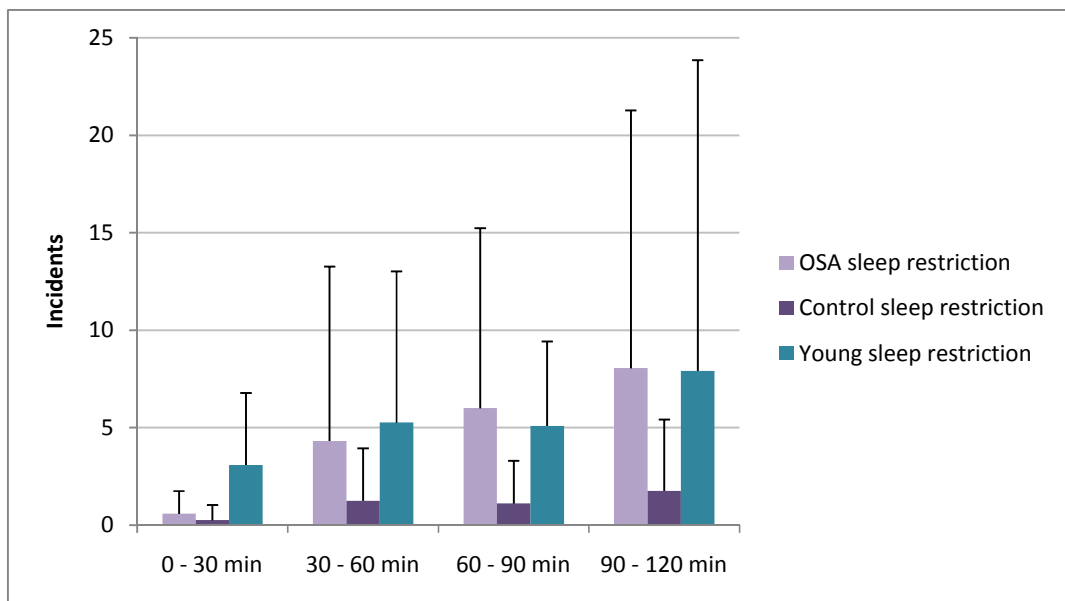


Figure 13.3-2 Major driving incidents after sleep restriction with standard deviation

Figure 13.3-1 and Figure 13.3-2 shows major driving incidents in young healthy controls and both older groups following a normal night's sleep and sleep restriction to 5 hours. There is a significant condition, group interaction, in both conditions the control older participants had less driving incidents than the younger participants [F

(1,30) = 8.38, p = 0.007]. OSA participants appear more similar to young participants during the later stages of both drives than older control participants.

13.3.2 Subjective sleepiness

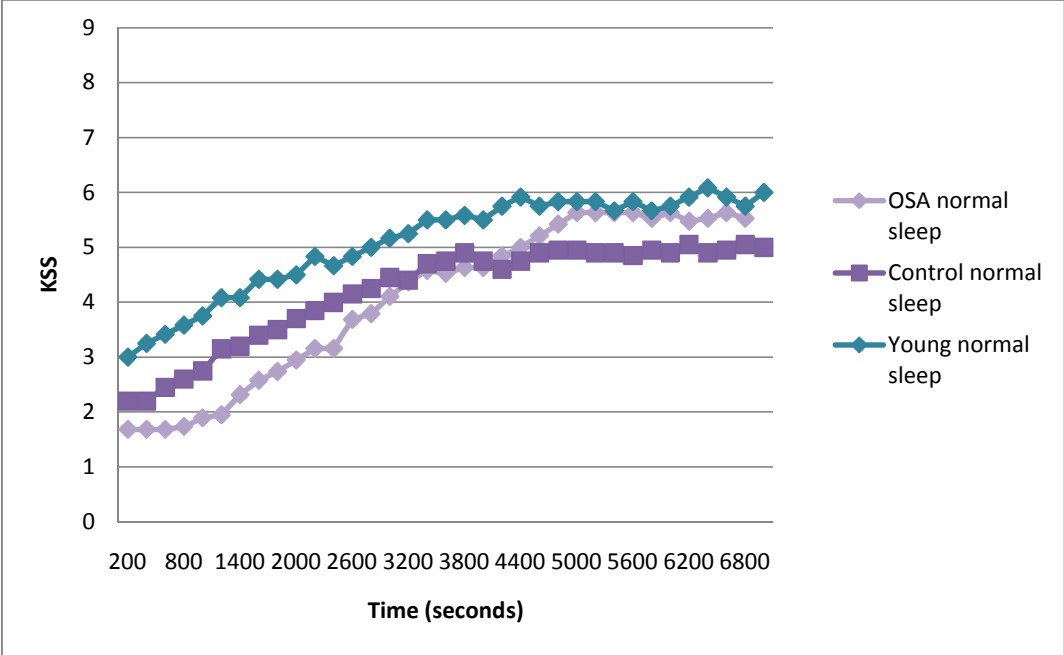


Figure 13.3-3 Mean KSS following a normal night's sleep for all three groups

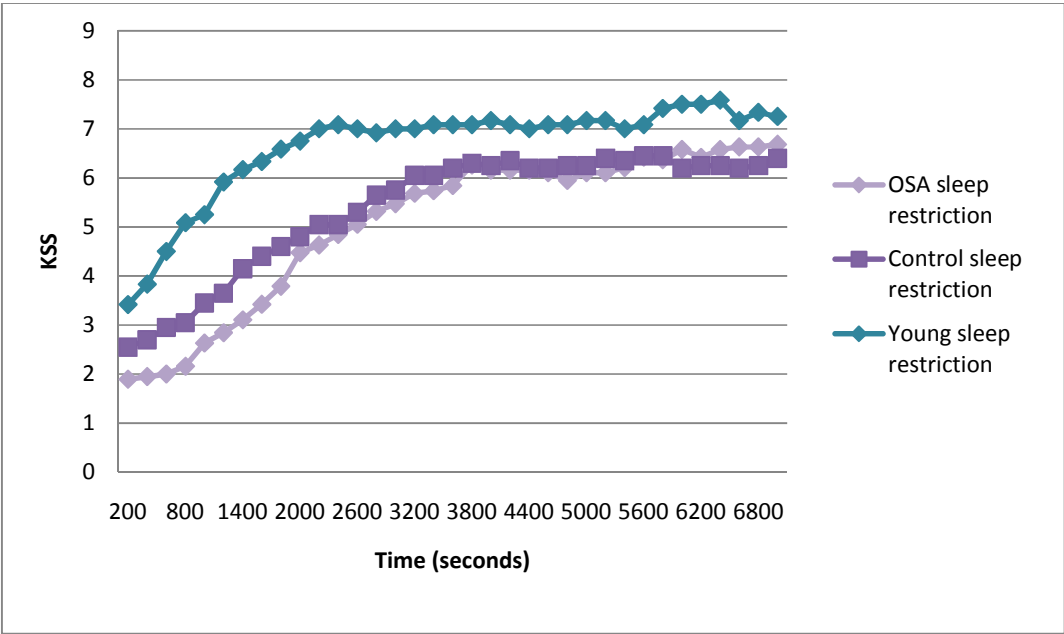


Figure 13.3-4 Mean KSS following sleep restriction for all three groups

Figure 13.3-3 and Figure 13.3-4 show mean KSS over a 2 h drive for young participants, older control participants and OSA participants. For both conditions the younger participants start the drive feeling sleepier than the older participants. For statistical analysis results were averaged to 30 minute epochs, shown in Figure 13.3-5 and Figure 13.3-6.

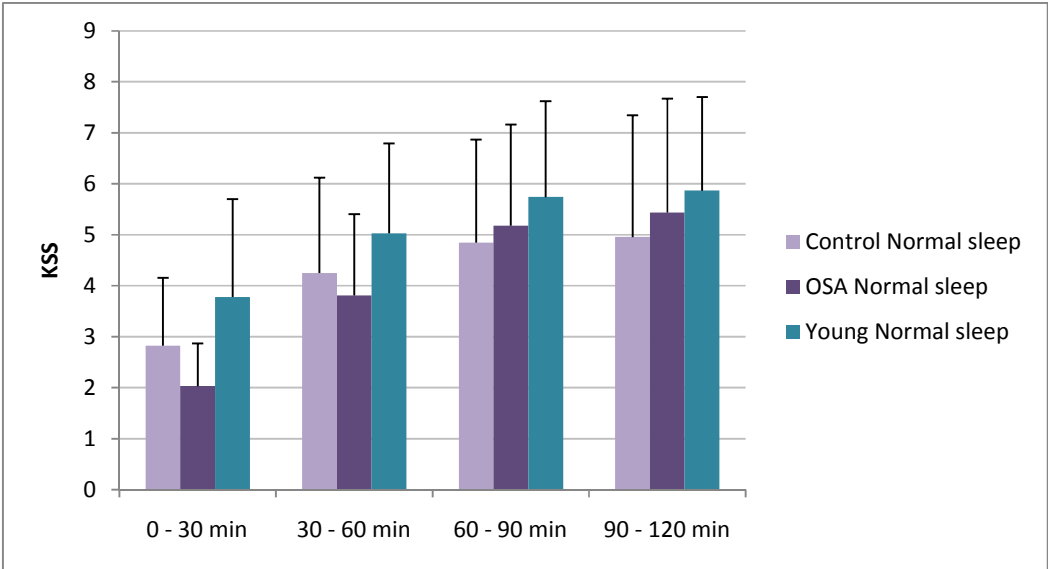


Figure 13.3-5 KSS in 30 min epochs following a normal night's sleep with standard deviation

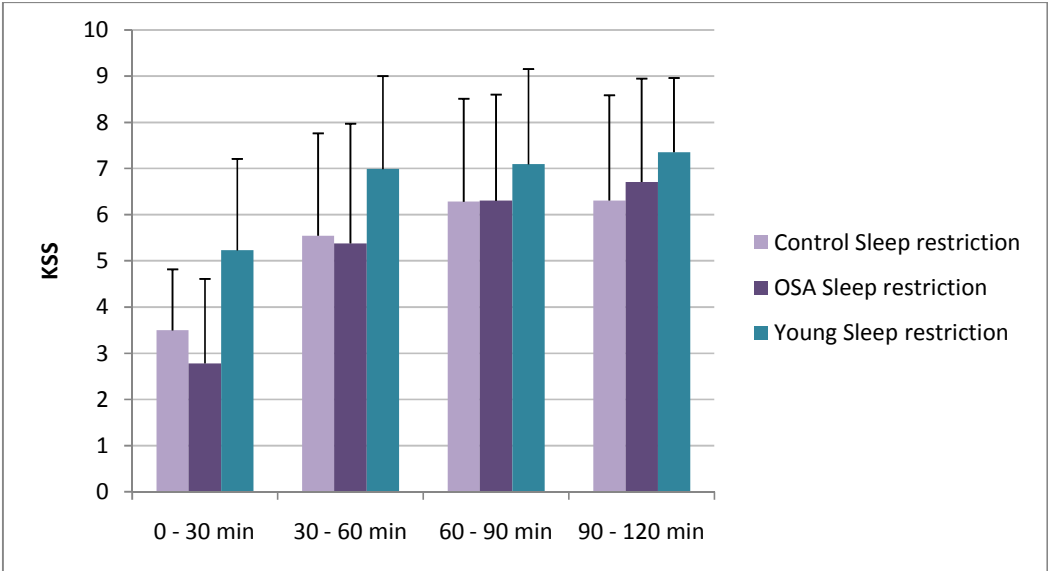


Figure 13.3-6 KSS in 30 min epochs following sleep restriction with standard deviation

There was no significant condition, group interaction [F (1, 30) = 0.73, p = 0.397] or condition, time interaction [F (2.05, 61.34) = 0.27, p = 0.767] between the younger and older healthy participants.

13.3.3 Insight into sleepiness

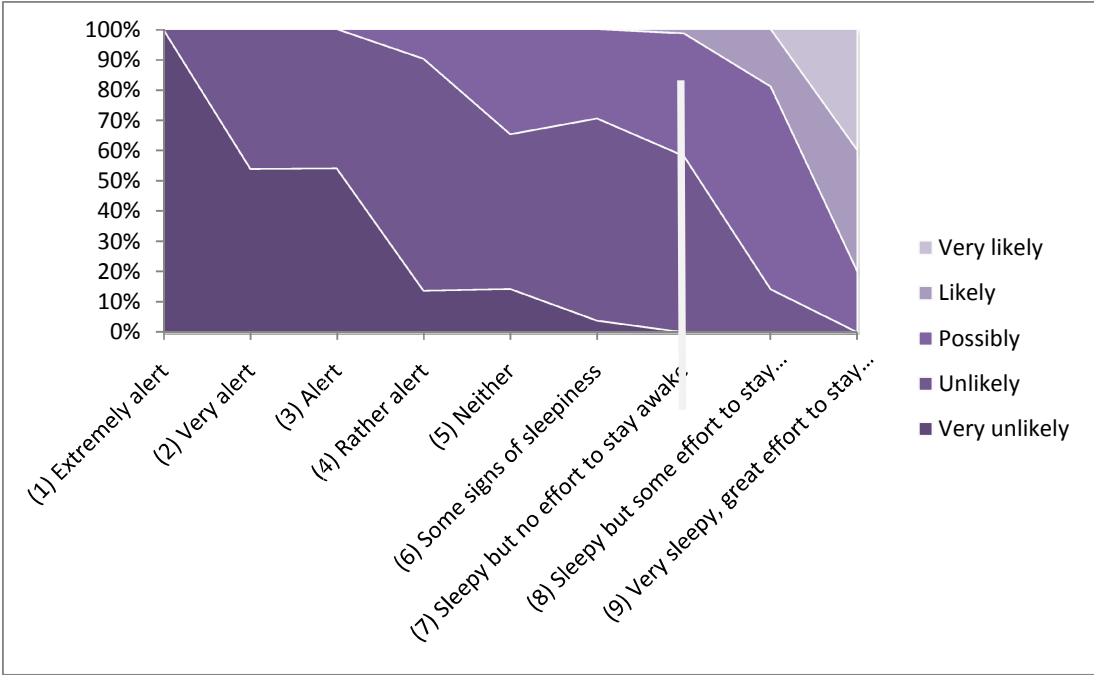


Figure 13.3-7 The percentage of each KSS spent in each LHoFA score for young participants

	Very unlikely	Unlikely	Possibly	Likely	Very likely
(1) Extremely alert	2.58	0.00	0.00	0.00	0.00
(2) Very alert	1.06	0.91	0.00	0.00	0.00
(3) Alert	3.03	2.58	0.00	0.00	0.00
(4) Rather alert	1.06	5.92	0.76	0.00	0.00
(5) Neither	1.06	3.79	2.58	0.00	0.00
(6) Some signs of sleepiness	0.46	7.89	3.49	0.00	0.00
(7) Sleepy but no effort to stay awake	0.00	12.44	8.65	0.30	0.00
(8) Sleepy but some effort to stay awake	0.00	3.64	17.15	4.86	0.00
(9) Very sleepy, great effort to stay awake	0.00	0.00	4.25	8.50	8.50

Table 13.3-1 Percentage of total time in each KSS rating, subdivided into categories of likelihood of falling asleep for young participants

Figure 13.3-7 and Table 13.3-1 show the percentage of epoch spent in each LHoFA score per KSS rating for younger participants. For comparison Figure 13.3-8 and Table 13.3-2 are repeated from chapter 8 for older healthy participants.

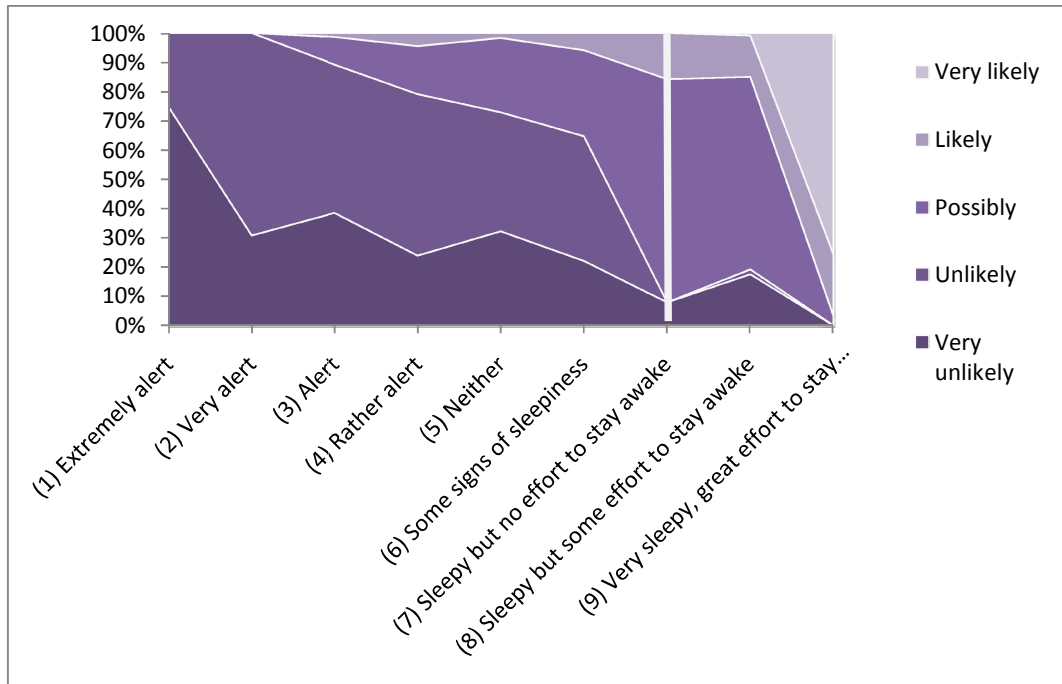


Figure 13.3-8 The percentage of each KSS spent in each LHoFA for older healthy participants

	Very unlikely	Unlikely	Possibly	Likely	Very likely
(1) Extremely alert	0.9	0.3	0.0	0.0	0.0
(2) Very alert	4.0	9.1	0.0	0.0	0.0
(3) Alert	8.2	10.8	2.0	0.3	0.0
(4) Rather alert	2.3	5.3	1.6	0.4	0.0
(5) Neither	2.7	3.5	2.2	0.1	0.0
(6) Some signs of sleepiness	2.2	4.2	2.9	0.6	0.0
(7) Sleepy but no effort to stay awake	0.4	0.0	4.2	0.9	0.0
(8) Sleepy but some effort to stay awake	3.0	0.3	11.4	2.4	0.1
(9) Very sleepy, great effort to stay awake	0.0	0.0	0.4	2.9	10.4

Table 13.3-2 Percentage of total time in each KSS rating, subdivided into categories of likelihood of falling asleep for older participants

The area of the table which is of particular interest is when participants are feeling sleepy (KSS 7 – 9) but feel unlikely to fall asleep (LHoFA 1 – 2). For young participants 11.2% of epochs were spent feeling sleepy but not likely to fall asleep compared with

3.7% of epochs for older participants. Demonstrating that young participants are more likely to think that sleepiness is not a problem to them.

13.4 Discussion

Older male participants have fewer major driving incidents while completing this 2 h driving simulator task than younger male participants, both after a normal night's sleep and sleep restriction to 5 hours. Older participants also appeared to feel less sleepy than younger participants (nsd). The greater number of incidents in younger males reflects UK RTI data where 38% of sleep-related RTIs are caused by drivers under 30 compared to approximately 14% by drivers aged 50+ (Flatley et al. 2004).

The smaller increase in driving incidents in the healthy older participants is to be expected as sleep restriction has previously been shown to have greater impact on younger participants (Adam et al. 2006). It was also anticipated that older drivers would be more aware that feeling sleepy meant they had a possibility of falling asleep, as risk perception has been shown to change with age (Finn et al. 1986).

Although comparison of this data shows older drivers to be at less risk of sleep-related incidents than young drivers it is important to remember the findings of chapter 8, which showed the older participants were not as reliable at recognising sleepiness as the younger participants had been. OSA participants have better insight into sleepiness than control participants of a similar age; however, neither are as likely to recognise that they are sleepy prior to driving incident as young participants. As older drivers represent a lower proportion of srRTIs than younger drivers (Flatley et al. 2004) it is possible that older drivers do not put themselves in situations where they may be sleepy while driving, in contrast to younger drivers.

OSA participants have a similar number of driving incidents as young healthy drivers for the second hour of the drive following normal sleep and the later 90 minutes of the drive following sleep restriction. In light of these findings it should be considered when assessing an OSA patient's fitness to drive that these patients are not only OSA sufferers but also represent a predominantly older aged group. When evaluating if an OSA patient is fit to drive assessment should be made in the context of drivers as a whole. Although OSA participants have significantly more driving incidents than

controls of the same age, these older controls have significantly fewer driving incidents than healthy young drivers. Although OSA participants have impaired driving performance compared with controls (following sleep restriction) when this is put into context with other road users, treated OSA drivers may be no worse than younger sleep restricted drivers.

This highlights the vulnerability of all road users to driver sleepiness and demonstrates the need for wide spread education in identifying driver sleepiness and effective countermeasures. As long as all drivers know how to identify when they are sleepy and what they should do about it potential risk of RTI could be lowered.

13.5 Conclusions

- Healthy older participants have fewer major driving incidents during a 2 h simulated driving task than healthy younger participants, following both a normal night's sleep and sleep restriction.
- Older participants increase in sleepiness rating across a 2 h drive in a similar pattern to younger participants; however, the younger participants start at a higher level of sleepiness and are more affected by sleep restriction.
- Young participants are more likely to rate themselves as unlikely to fall asleep when they feel sleepy than older participants.
- OSA participants appear to suffer the impact of sleep restriction to a similar level as healthy young participants.

CHAPTER FOURTEEN

General Discussion

14.1 Discussion

It has been repeatedly shown by numerous authors that untreated OSA drivers are more likely to have RTIs (George et al. 1999, Ellen et al. 2006, Vakulin et al. 2009) and that CPAP treatment reduces RTI risk (Juniper et al. 2000, Yamamoto et al. 2000, George 2001). However, a lack of research investigating long term CPAP treated OSA patients, the impact of sleep restriction and one night of CPAP withdrawal was identified. Prevalence of OSA diagnosis is increasing and now CPAP treatment is recommended on the NHS for moderate and severe cases, the number of CPAP treated OSA patients driving on UK roads will also increase from current levels. It is important for further investigations into driving ability when on treatment to be conducted, demonstrating no difference in performance between controls and OSA participants if CPAP is fully adhered to. Despite the increasing occurrence of OSA, research with commercial drivers has found participants to be reluctant to volunteer for screening (Vennelle et al. 2010). If it is widely accepted that treated OSA drivers are as safe as healthy drivers more commercial drivers may volunteer for screening, reducing the number of tragic srRTIs in undiagnosed OSA sufferers like those listed in the preface to this thesis.

In some of these cases, OSA itself has been stated as a defence that the driver was not able to identify that they were sleepy because of the disorder; however, the literature review identified no scientific research to substantiate this claim. This is particularly important when considering that approximate 10% of HGV drivers were found to have suspected undiagnosed OSA.

This thesis aimed to address the research questions posed in section 1.14, spanning 7 areas:

1. Prevalence of undiagnosed OSA in heavy goods vehicle (HGV) drivers.
2. Impact of sleep restriction on long term CPAP treated OSA participants, comparing driving to healthy controls.
3. Ability of OSA participants to identify sleepiness.
4. The impact of one night's CPAP withdrawal.

5. Individual difference in driving performance in long term CPAP treated OSA participants.
6. Ability at hazard perception.
7. Choice of countermeasures to driver sleepiness.

Research was conducted using three approaches, questionnaires, a computer based hazard perception test and a driving simulator protocol. The questionnaire was designed to be succinct and straightforward for participants to complete. Three versions of the questionnaire were used; all were based around the same core questions.

1. For HGV drivers
2. For OSA car drivers, participants of the driving simulator study
3. For control car drivers, participants of the driving simulator study

The questionnaire included anthropometric measures and questions on driving habits, attitudes to driver sleepiness, health, countermeasure preference and OSA where applicable. The questionnaire was also used for screening purposes for the simulator study.

The hazard perception test was completed by all participants in the driving simulator study; this computer based task represented that used in the UK driving test (Driving Test Success 2007).

The driving simulator protocol was completed by 19 OSA participants and 20 control participants; procedure was the same on each occasion apart from the change in test condition; (i) normal night's sleep, (ii) sleep restriction to 5 h, (iii) CPAP withdrawal for one night. The research conducted using the driving simulator focused on a realistic scenario that the majority of the general public could find themselves in at some point and something that they would not consider particularly risky to do: driving on a motorway after 5 h sleep or following one night of missed CPAP treatment.

14.1.1 Prevalence of OSA in HGV drivers

- Is undiagnosed OSA prevalent in HGV drivers on UK roads?
- Are OSA risk factors and symptoms associated with falling asleep at the wheel?

Nearly 10% of the HGV population surveyed may be suffering from undiagnosed OSA. HGV drivers as a subgroup were found to have greater prevalence of risk factors associated with OSA than the general population including: male gender, obesity, aged over 40 years, larger neck circumference and higher average ESS. This is slightly less than studies in Sweden (17%) and Australia (15.8%) using overnight PSG (Carter et al. 2003, Howard et al. 2004). This difference may in part be because the main criteria for suspected OSA in the current study were witnessed apnoeas by a bed partner and 22.3% of participants reported not having a bed partner therefore no ability to identify apnoeas. This is the first impartial study to our knowledge in the UK with HGV drivers.

Undiagnosed OSA may be a big problem in HGV drivers as those with suspected OSA were significantly more likely to have EDS. 36% of the suspected OSA cases were in participants not obliged to have regular medicals as they were under 45 years old, this demonstrates possible benefit to medical examination at a younger age. However, the remainder of suspected OSA sufferers were of an age to be receiving medicals and they had not been diagnosed.

Sleep-related RTIs involving HGV's can be devastating due to the size of the vehicle. This simple survey shows it is easy to identify people who may be at risk, therefore haulage companies have the opportunity/responsibility to monitor their drivers and recommend seeing a doctor if necessary.

14.1.2 Sleep restriction

- Do long term CPAP treated drivers have impaired driving performance at a simulator compared to control drivers following a normal night's sleep?
- Do long term CPAP treated drivers have a greater impaired ability at a simulated driving task following one night's sleep restriction compared to a control group?

At baseline, following a normal night's sleep there was no significant difference in driving performance at the simulator task between the CPAP treated OSA participants and healthy non professional control drivers. Restricting sleep to 5 hours resulted in both groups having significantly more driving incidents, shorter safe driving time and higher subjective sleepiness. The short safe driving time is of particular concern as the

UK Highway Code recommends drivers take a break every 2 hours to avoid driver fatigue. The healthy older drivers in this study were only able to safely drive for approximately 90 minutes. For this age group it is perhaps more appropriate to recommend taking a break from driving every 90 minutes.

It is also possible that older participants experience a quicker transition from alert to sleepy than younger participants as the mid range of the KSS is reported with a low frequency. The quick transition may make it harder for individuals to identify when sleepy. The KSS and LHoFA scales were found to be highly correlated, demonstrating older participants know that there is likelihood they will fall asleep when they are sleepy. The KSS and ESS were not correlated suggesting ESS may not be a suitable tool to assess fitness to drive.

The OSA participants were significantly more affected by the sleep restriction than the controls in terms of driving incidents. For the first 30 minutes performance was comparable between groups but for the remaining 90 minutes OSA participants had more major driving incidents than the control participants. However, there was no similar difference in subjective sleepiness or EEG activity between groups. As a result OSA patients may be unaware of their increased susceptibility to driving impairment, because they do not feel any sleepier than controls and for the first 30 minutes driving performance is the same as after a normal nights' sleep.

The OSA participants were also found to have greater difficulty with time on task than control participants, with a shorter time to first major incident and a greater increase in subjective sleepiness from the beginning to the end of the sleep restriction drive. Time had a significantly different effect on OSA participants than controls, with an earlier increase in EEG sleepiness and effort required to remain alert.

14.1.3 Insight into sleepiness

- Do treated OSA drivers have impaired insight into their sleepiness levels?

The majority of participants were able to identify that they were sleepy prior to having a major incident. However, not all participants could, this is in contrast to 100% of younger participants who could identify sleepiness prior to a major incident (Reyner

and Horne 1998b). A greater proportion of OSA participants had insight into sleepiness than control drivers, suggesting that despite the greater susceptibility to driving incidents following sleep restriction, the OSA participants show increased ability to recognise sleepiness, therefore they should have opportunity to stop driving. On average, OSA participants have 19 minutes warning of sleepiness prior to major incident. 15 minutes at 70 mph on a motorway equates to 17.8 miles travelled, in which time it is likely the driver would reach a safe place to stop. However, this requires the driver to take action as soon as they are aware of sleepiness. Not all participants had insight into sleepiness; in particular the poor insight in control drivers may be explained by the lack of no correlation between KSS and EEG activity.

Training in how to recognise sleepiness could be beneficial. These older participants were more likely to recognise that they might fall asleep when sleepy than younger participants (Reyner and Horne 1998b), demonstrating a willingness to accept the dangers of driver sleepiness.

14.1.4 CPAP withdrawal

- What is the effect of missing one night's CPAP treatment on simulated driving performance in the longer term treated?

CPAP withdrawal for one night results in significantly increased sleep disturbance index, suggesting the resumption of sleep disordered breathing. Despite having a normal sleep length, not using CPAP resulted in significantly more driving incidents, reduced safe driving time and feeling sleepier compared with a normal night's sleep. CPAP withdrawal resulted in impairment earlier in the drive than sleep restriction; participants started the drive feeling sleepier and had more major incidents in the first hour.

In real world terms of driving, the earlier impairment and heightened sense of sleepiness experienced without CPAP could pose a greater danger on roads than sleep restriction. Additionally insight into sleepiness was more common following sleep restriction than CPAP withdrawal. It is possible that the act of restricting sleep provided a cue to participants that heightened their awareness of sleepiness, whereas without CPAP they felt they had received their usual 8 hours they did not notice when

they became sleepy. OSA patients need to be educated to the dangers of not using CPAP.

14.1.5 Individual difference

- Is there a larger individual difference in effect of sleep restriction on simulated driving performance of long term CPAP treated OSA participants?
- If so which OSA participants are more susceptible?

A great variation in OSA driving performance following sleep restriction was reported in chapter 5, 6 and 7. The OSA group was divided into those who had been affected by sleep restriction more than the control group and those who had not. Those who had not been affected by sleep restriction show no significant difference to controls at the driving task, subjective sleepiness or EEG activity. Those who were affected had significantly worse performance at the task, felt significantly more likely to fall asleep and showed greater EEG sleepiness than those OSA participants not affected.

No predictor was found to suggest which OSA participants would be affected by sleep restriction. ESS is often used in a clinical setting to assess fitness to drive; however, there was no significant difference between groups using this scale. It may be appropriate to have a sleep restriction test in clinics to identify those OSA participants susceptible to sleep restriction. Those affected by sleep restriction were more likely to have insight into sleepiness and therefore could benefit from targeted advice in how to deal with driver sleepiness.

14.1.6 Hazard perception

- Do long term CPAP treated OSA drivers have impaired cognitive performance as measured by a hazard perception test?

There was no difference in hazard perception score or pass rate between OSA and control participants. Driving experience and age were also not correlated to test performance. ESS and hazard perception test score were significantly correlated for control participants but not for OSA participants. In practice this correlation only explains 27% of variability. Not all participants passed the test but it is possible with further practice they would.

14.1.7 Countermeasures to driver sleepiness

- What is the opinion of HGV drivers in the UK on driver sleepiness and countermeasures?
- Is there a difference in preference of countermeasures to driver sleepiness between OSA and control participants?
- Do long term CPAP treated drivers have different attitudes to driver sleepiness than control drivers of a similar age?
- Do UK drivers with prior experience of sleepiness at the wheel choose more effective countermeasures?

The UK government is providing valid advice on counteracting driver sleepiness; despite being introduced in 1999 this advice is still not being followed. The three groups investigated showed greatest preference for opening a window and stretching their legs (advice in the Highway Code before 1999) as a countermeasure to driver sleepiness. Experienced drivers did not appear to be aware of the change of advice.

OSA drivers and HGV drivers may be at increased susceptibility to driver sleepiness but are no better at choosing effective sleepiness countermeasures than controls. Also having prior experience of driver sleepiness also does not promote effective choice of countermeasure.

The majority of drivers recognised that driver sleepiness can affect their ability to drive safely, and very few reported to keep going as a preferred countermeasure. This suggests that the majority of drivers want to take some action; however, they are not making effective choices. Particularly concerning was the 25% of HGV drivers who had fallen asleep while driving but did not think that driver sleepiness affects their ability to drive safely.

14.1.8 Comparison with younger participants

Although not an original aim of this thesis, it became apparent that there were clear differences between the older participants in current work and young participant in previous publications. Thus it was appropriate to compare the current findings with previous findings using the same driving simulator protocol.

Healthy older control participants were found to have fewer driving incidents compared with the younger participants both after a normal sleep and sleep restriction. Younger participants started both drives feeling sleepier than older controls. These findings provide some suggestion as to why sleep-related RTIs are more commonly caused by younger drivers, as not only do younger drivers have more driving incidents but they are also more likely to believe that despite their sleepiness, they will not fall asleep. This provides context in which to assess OSA drivers, because although this thesis found greater impairment with sleep restriction for the patient group, realistically, driving simulator performance in the patient group is similar to young participants.

14.2 Implication of findings

14.2.1 The law

Overall, these findings suggest that current UK law, allowing OSA patients to continue driving when successfully treated, is appropriate. In all cases of comparison between the normal night's sleep condition there was no significant difference between OSA participants and healthy controls.

However, untreated OSA sufferers are known to have increased risk of RTI. Despite numerous studies on the dangers of untreated OSA and the number of miles travelled in large vehicles there is no mandatory screening of HGV drivers. Approximately 10% of those surveyed showed signs of undiagnosed OSA. Screening of all HGV drivers would be costly and unnecessary. However a simple questionnaire screening could identify those drivers most likely to be suffering from OSA, resulting in a smaller sub group which would be more efficient to complete sleep studies on. Having a legal requirement to screen drivers if certain risk factors for OSA are met would reduce the number of untreated OSA sufferers on the roads and danger to the public.

The preface to the thesis list several court cases where the defendant used OSA in their defence stating they were unable to identify they were tired due to their undiagnosed OSA. The evidence in this thesis suggests that treated OSA patients are not less likely to identify sleepiness than healthy controls either with or without CPAP treatment. Although, further work in this area is required it is probable that untreated

OSA sufferers would also not have impaired ability in recognising when they are sleepy, rendering OSA as a mitigating circumstance inappropriate.

14.2.2 Education

Although the law does appear to be appropriate this thesis has highlighted several areas requiring an improvement in education.

Currently the UK Highway Code recommends for drivers to take a break from driving every 2 hours to avoid driver fatigue. The current research found that even after a normal night's sleep the healthy older participants were only able to drive for 90 minutes without incident. Therefore it may be more appropriate to suggest taking a break every 90 minutes for older drivers to avoid driver fatigue.

Further research is needed comparing CPAP treated HGV drivers and healthy HGV driver controls; it is likely that there would be no difference between these groups. If haulage companies are aware that treated drivers are safe they may be more willing to screen those most at risk, identifying cases of undiagnosed OSA in the knowledge that with successful treatment they do not need to lose employees.

A widespread campaign to raise awareness of a caffeinated drink combined with a nap as an effective countermeasure is needed. Although this information is in the Highway Code it does not appear to be accepted by the majority of drivers surveyed. In particular, HGV employers could be key information dissemination points. Doctors with OSA patients should also be providing advice on what to do if they get sleepy while driving, as OSA patients appear to be more susceptible to sleep restriction than healthy adults.

Sleep restriction posed a problem for both groups in the simulator study; as such a general awareness campaign into the dangers of driving when sleepy would be useful. However, this would be costly so perhaps an intermediate measure such as targeting those most at risk such as OSA patients would be more valid. When a person is diagnosed with OSA time should be spent explaining the dangers of driver sleepiness. In particular the importance of not missing CPAP treatment because this causes a significant impairment in driving ability and is arguably more dangerous than sleep

restriction as the impairment happens earlier on. It has been shown that OSA patients can recognise when they are sleepy but they do not have a large time window to act on it. Information on countermeasures to driver sleepiness should be disseminated; so that OSA patients know as soon as they feel sleepy they should find somewhere safe to stop.

Medical practitioners treating OSA patients should be aware that some patients will have greater susceptibility to sleep restriction than others. When assessing fitness to drive, examining treated patients following sleep restriction would hopefully identify the susceptible sub group and aid doctors in their decision.

14.3 Limitations

The present study, as with any other, has a number of limitations to be acknowledged to allow the findings to be put into context. Firstly the main simulator studies were carried out with OSA participants who were all members of a patient association group. This specialised recruitment allowed for easy access to the patients who were most likely to be happy and compliant with CPAP treatment. It was a requirement of the study to have participants who were compliant with the treatment and, because it was not possible to check CPAP compliance with patients' CPAP machines, using this sub group of patients hopefully reduced the chance of non-compliant patients participating. However in doing so, participants were recruited from a self selecting population, meaning they cannot be representative of the general treated OSA population. Similarly for the HGV survey, by conducting it in a "truck stop" the very nature of the protocol meant all participants were from a self selected group who had decided to stop at that safe location, any drivers wishing to keep going were not represented.

The sample size of 40 for the driving simulator study could be considered small, however, within the context of driving simulator studies this is a fairly large group. Simulator studies are very costly both in time and money as such they often have small sample sizes. Again with HGV drivers a sample size of 148 for a survey may also be considered small. Due to funding and time constraints it was only possible to conduct the survey at one "truck stop" which resulted in repeat encounters with customers

over the period of data collection. Ideally additional funding would allow the survey to be completed at multiple “truck stops” across the UK therefore testing a cross section of the HGV driver community and not the regulars of one stop.

The majority of the current work was carried out in the controlled environment of a driving simulator. Although this is not a study limitation, applying findings to real world scenarios should be done with caution due to various uncontrollable factors in the real world environment. It is likely that the driving simulator represents a worst case scenario, as real roads usually offer more stimulation and as such fewer driving incidents might be expected.

Within the simulator study protocol itself, it would have been useful to have an additional subjective measure for participants to report if at any point they would take a break from driving (although the protocol would not have actually allowed them to do so). This would create an assessment of which KSS rating would need to be reached before a person would stop driving.

14.4 Directions for further research

On completion of the research within this thesis a number of potential areas for future research have been identified. These are outlined below.

14.4.1 Perception of sleepiness

The current research recognised that not all participants were able to identify that they were sleepy prior to a major driving incident. Participants with OSA were more likely to report sleepiness prior to major incident but with less warning than control participants. No factor was identified as a predictor of which participants would report sleepiness and which would not as the current research was designed to assess if perception of sleepiness occurred, not investigate why it might not. In particular it was interesting to note that for those control participants who did not report sleepiness prior to major incident EEG activity and KSS were not correlated. A more vigorous study protocol incorporating a greater number of background questions, daytime sleepiness scales and perception of sleepiness during other sustained vigilance tasks may be able to identify why some participants cannot identify they are sleepy. This

could then be followed by an intervention to educate participants on identification of sleepiness and see if it subsequently improves.

It would also be interesting to conduct a similar study with untreated OSA sufferers. Although it is widely reported that prior to treatment driving performance is impaired in OSA sufferers, there is little research examining if these participants know that they are sleepy when driving. This would have strong legal implications as undiagnosed OSA has been stated as a reason that drivers causing RTIs as they were not able to stop before falling asleep; they suggest they didn't know they had the condition and were unable to tell that they might fall asleep. As the majority of treated OSA participants did report sleepiness prior to major incident it could be hypothesised that untreated OSA participants would do the same.

14.4.2 Impact of variance of CPAP compliance

All OSA participants in the current research were compliant CPAP users. In general CPAP adherence rates are low with as many as 50% of patients rejecting the treatment outright or taking it off part way through the night (Engleman et al. 2003, Weaver et al. 2008). The current research showed that withdrawal of CPAP for one night, and reducing sleep to 5 hours with CPAP, both had significant effects on driving performance. It is reported that many OSA patients will use their CPAP for only part of a night, i.e. sleep for 8 hours but only use the CPAP for 4 (Kribbs et al. 1993b). It would be interesting to know what the impact of this partial CPAP use is on driving performance, as this may represent a more realistic scenario.

14.4.3 Individual difference in susceptibility to sleep restriction

Great individual difference between untreated OSA participants driving ability has been reported by previous studies (George et al. 1996, Findley et al. 1999, Juniper et al. 2000). The current research found this to also be true of treated OSA participants. Although various factors were investigated no predictors of which OSA participants would be affected were identified. Again a more extensive study protocol would be beneficial in measuring other possible predicting factors. This information would be very useful for doctors, who have to assess patients' fitness to drive; also if they knew which patients will suffer from sleep restriction their advice could be targeted.

14.4.4 Comparison of older and younger drivers

Although not a main topic of the current research, it became apparent that there were differences in driving performance between these older participants and findings reported in previous publications on younger participants. Now this is known a full study protocol could be designed using four groups, older and younger drivers with and without OSA. It would be interesting to see if older age contributes to fewer driving incidents in an OSA group.

14.5 Conclusions

This thesis aimed to investigate the area of obstructive sleep apnoea and daytime driver sleepiness. The objective was to provide evidence about the driving ability of treated OSA participants and consider factors which may impair ability (sleep restriction and CPAP withdrawal), whilst assessing the impact of OSA on driving. Fortunately driving ability following a normal night's sleep was found to be no different than for a healthy control group, however, OSA participants were more affected by sleep restriction than control participants. In particular missing one night's CPAP treatment is very dangerous as driving impairment occurred earlier on than following sleep restriction and sleepiness was not as well identified by participants.

Ultimately it is medical practitioners who decide if treated OSA patients are fit to drive and provide patients with advice in living with their condition. Based on this thesis the following advice would be offered:

1. ESS should not be used alone, as there was no correlation between ESS and driving simulator performance.
2. Express to patients that they are only fit to drive if they adhere to treatment.
3. Some treated patients will be particularly sensitive to sleep restriction, because of this it would be useful to assess participants following sleep restriction, regardless of their ESS.
4. Inform all patients that they may be susceptible to driver sleepiness if they do not get adequate, CPAP treated, sleep. In order to reduce the risk of RTI they should take a break from driving every 2 hours and if they feel sleepy while driving stop, have a high caffeine content drink and a 20 min nap.

The discovery of a potential 10% of HGV drivers suffering from undiagnosed OSA is particularly worrying. Although the UK system provides good treatment for OSA patients a greater awareness and understanding is needed in the haulage industry to allow screening of drivers, without the worry of job losses. It is also vital that doctors and OSA patients are aware of the dangers of sleep restriction and CPAP withdrawal and doctors pass this message on to patients along with advice on effective countermeasures.

Ultimately, untreated OSA sufferers pose a danger on the roads which would be reduced with increased diagnosis. People who suspect they have OSA are not going to come forward if they feel it may be at the expense of their driving licence. Research like the current work demonstrating the ability of treated OSA drivers will aid acceptance of the condition and hopefully increase willingness to be tested. However, it must be remembered that getting a full night's sleep and treatment compliance are vital.

CHAPTER FIFTEEN

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CHAPTER SIXTEEN

Appendices

QUESTIONNAIRE

Loughborough Sleep Research Centre

****Confidential****

Would you mind taking part in this Questionnaire, which is completed by the participant with the Investigator present.

Age (Years):

Weight (Kg or Lb):

Height (cm or inc):

Collar size (cm or inc):

Please tick the boxes which apply most to you:

- 1) How many years have you held a HGV licence?
- 2) On average how many miles do you drive a year?
- 3) On average how many hours do you drive for a week?.....
- 4) Are you a smoker?

Yes No

- 5) Have you ever been diagnosed with Sleep Apnoea?

Yes No

- 6) How many cups of coffee do you usually drink a day?

None	<input type="checkbox"/>	5-6	<input type="checkbox"/>
1-2	<input type="checkbox"/>	Over 6	<input type="checkbox"/>
3-4	<input type="checkbox"/>	Don't know	<input type="checkbox"/>

- 7) How many drinks of high caffeine content other than coffee e.g. Red Bull do you usually drink?

None	<input type="checkbox"/>	1-2 a week	<input type="checkbox"/>
1- 2 a month	<input type="checkbox"/>	3-5 a week	<input type="checkbox"/>
3-4 a month	<input type="checkbox"/>	More than 5 a week	<input type="checkbox"/>
	<input type="checkbox"/>	Don't know	<input type="checkbox"/>

- 8) Would you ever drink high caffeine content drinks or coffee with the sole purpose to remain alert during monotonous tasks?

Never Yes sometimes Yes often

- 9) How often do you nap during the day whilst working?

Never	<input type="checkbox"/>	2-3 times a week	<input type="checkbox"/>
Twice or more a day	<input type="checkbox"/>	Once per week	<input type="checkbox"/>
Every day	<input type="checkbox"/>	Sometimes, less than once a week	<input type="checkbox"/>

- 10) How long are you happy to drive for before you want to stop and take a break?

Less than 2hours 2-4 hours 4 - 5 hours

5-6 hours 6-7 hours More than 7 hours

11) How long do you actually drive for before you stop and take a break?

Less than 2 hours 2-4 hours 4 - 5 hours
 5-6 hours 6-7 hours More than 7 hours

12) Have you ever felt sleepy when driving?

Yes No

If so, please describe under what circumstances this occurred/did you have to stop driving?.....

13) Do you ever think you have fallen asleep when driving?

Yes No

14) Do you think that driving whilst drowsy affects your ability to drive safely?

Yes No

15) If you felt drowsy whilst driving which statements best describe what you are most likely to do. (You may answer more than one)

- (a) Keep going to reach your destination as soon as possible
- (b) Stop at a service station and have a nap
- (a) Turn the radio up
- (b) Stop at a service station and have a high caffeine content drink
- (c) Open a window
- (d) Stop at services and stretch your legs
- (e) Other (please give details)

16) How long does it usually take you to get to sleep?

Less than 5 min 5-10 min
 10 – 20 min Over 20min

17) On average how many hours do you sleep for a night?

On a working day On a non working day

18) Does your bed partner report anything unusual about your sleep?

Occasional loud snoring Frequent loud snoring Holding breath in your sleep N/A
 Choking None of these Other (please specify below)

Please Complete the Following:

How likely are you to fall asleep in the following situations? Please indicate, using the following scale, which is most appropriate given the situation.

0 = Would *never* doze

1 = *Slight* chance of dozing

2 = *Moderate* chance of dozing

3 = *High* chance of dozing

Situation	Chance of Dozing
Sitting and Reading
Watching TV
Sitting inactive in a public place (e.g. theatre/meeting)
As a passenger in a car for an hour without a break
Lying down in the afternoon when circumstances permit
Sitting and talking to someone
Sitting quietly after lunch without alcohol
In a car, while stopped for a few minutes in the traffic

Participant information sheet

Written Explanation of Experimental Procedure For Participants

If you are willing to take part you will be asked to attend an initial familiarisation session which will last approximately 2 hours between 10 and 12 on a week day morning. Following on from this you will visit the Driver Sleepiness Laboratory on two other occasions, on week day afternoons between 1 and 4.20pm.

Before your first visit, we will ask you to do the following:

- Drink no alcohol or caffeine containing drinks (coffee, tea, coke) from 10pm the evening prior to the study day.
- Go to bed at your normal time, and get your normal night's sleep.
- Have your normal breakfast.
- Please arrive well hydrated. I would suggest drinking about a pint of non caffeine containing liquid about an hour and a half before you arrive at the sleep centre. This is because the percent body fat measure is sensitive to dehydration.
- Please wear light weight, unrestrictive clothes

On your arrival you will have an informal talk with the investigator for approximately 30 minutes about your general health, general sleep and your driving. You will then be measured and weighed. We will also calculate your percentage body fat, this is done using scales similar to weighing scales, and you must stand on these with bare feet. A small electric pulse is then sent up your body, you are not able to feel this and the scales will instantly calculate percentage of body fat, all jewellery should be removed and you must inform the investigator if you have a pacemaker.

You will then be asked to complete a hazard perception test, similar to that currently required for the UK driving test. This is computer based test where you will see a series of 14 video clips of car journey's and be asked to press the left mouse button if you see a hazard. This takes about 20 minutes. How to complete the test will be explained fully on the day.

Finally you will be invited to drive the simulator for 30 minutes. This is a stationary car in a laboratory, a road scene is projected in front of the car. The car's steering, accelerator and brake affect its position on the simulated road. The road is a dual carriageway, you will be asked to keep in the left-hand lane at all times unless overtaking. During the drive there will be opportunities to overtake, these occur at random times. When you see another car, you must overtake as you would in a normal car and not "hang around" behind the other vehicle.

Before your second visit we will ask you to

- Put on the wrist actimeter provided, the evening before the drive one hour before going to bed, and keep wearing it until you arrive at the lab at 1pm the next day. With the exception of when showering or anytime when the actimeter may come into contact with water, and also if the actimeter is likely to get banged or knocked, e.g. when playing sport.
- Drink no alcohol or caffeine containing drinks (coffee, tea, coke) from 10pm the evening prior to the study day.
- Go to bed at 1am and get up at 6am so that you have had 5 hours sleep.
- Have your normal breakfast but please don't eat anything after 10am until you arrive in the lab and will be provided with a light lunch.
- On the morning of this visit we would like you to wash your hair. This is so that the application of the electrodes is easier.

- A pre paid taxi will be provided to get you to and from the university. Because of sleep restriction you are not allowed to drive or cycle on the morning of the experiment.

On arrival your actimeter data will be checked to confirm you were in bed for the required 5 hours. You will then be given two cheese rolls and a drink of water which must be consumed within 15 minutes. An alternative meal will be provided if you have food allergies or intolerances. Please inform the investigator of this at your first visit.

There will be eight electrodes placed on your scalp and face, these monitor your brain activity and eye movements. The substances used to attach the electrodes are not harmful to either your skin or hair. When connected to the machines, these electrodes are isolated from the main power supply (they **do not** send any input into the brain, and only monitor its activity). The electrodes are removed at the end of the visit, and any traces of adhesive removed, although we recommend that you wash your hair after the visit as sometimes small particles can be accidentally missed.

At 2pm, you will begin driving in the car simulator for 2 hours. The simulator and road layout will be exactly the same as for the previous 30minute drive.

Throughout the drive an investigator will be present in the laboratory. Your head and shoulder's will be shown on a monitor in the recording area behind the simulator, this image is videoed throughout. The data collected on video will not be used for any purpose not associated with the experiment unless you have given your written consent.

Every 200 seconds you will be asked for a "sleep check," which you must respond to using the 2 scales presented in front of you on the dashboard of the car. Before each drive you will be given time to familiarise yourself with the scales.

When the 2 hour drive is over the electrodes will be removed. The investigator will escort you to a taxi, which will take you home. You must not drive, cycle or do anything to endanger yourself or others until you have slept, and for at least 2 hours after finishing the trial.

The third day of the trial will be exactly the same as the second day except that you will have your normal night's sleep on the night preceding the study day.

You may withdraw from the experiment at any time, and are under no obligation to give reason for your withdrawal if you do not wish to do so. You must understand that you may feel sleepy throughout the experiment, and that you must undertake to obey the instructions of the investigator present whilst in the lab regarding safety.

All information you provide about yourself is treated as confidential information by the investigator(s).

You will be paid £10 for the first session, £15 for the second session and £15 for the third session.

If you have any questions please do not hesitate to contact me.

Ashleigh Filtness

Sleep Research Centre

Department of Human Sciences

Loughborough University

Loughborough

Leics, LE11 3TU

A.J.Filtness@lboro.ac.uk

01509 228225

Sleep Research Centre: Consent Form

Consent of Participant to be included in research trial:

I

- Consent to taking part in a Sleep Research Laboratory experiment. An explanation of the nature and purpose of the procedure has been given to me by Ashleigh Filtness.
- I understand that I may withdraw from the experiment at any time, and that I am under no obligation to give reasons for such withdrawal. I understand also that I may feel sleepy during some parts of the experiment and undertake to obey the instructions of the experimenter for safety purposes.
- I understand that any information about myself that I have given will be treated as confidential by the experimenter.
- I have had the opportunity to ask for further information and details.
- I understand that my percentage body fat will be measured using a set of scales which will send a very small eclectic pulse through my body and I have informed the experimenter if I have a pace maker.

Signed

.....Date.....

Signature of experimenter.....

A.J.Filtness@lboro.ac.uk

Sleep Research Centre, Department of Human Sciences

Sleep Research Centre: Use of Video Material Consent Form

Consent of Participant regarding use of videotaped material:

I

am / am not* willing to allow the use of extracts of my video recordings which have been taken whilst I participated in an experimental study for the Sleep Research Centre, Department of Human Sciences, Loughborough University, to be used for:

Scientific meetings/conferences*

Television documentary programmes and other media outlets e.g. newspaper articles *

Signed

Date

Signature of experimenter

* Please delete as appropriate

A.J.Fitness@lboro.ac.uk

Sleep Research Centre, Department of Human Sciences



SLEEP SCREENING QUESTIONNAIRE

Loughborough Sleep Research Centre

The following questionnaire to be completed in the form of a structured interview with the participant and experimenter. The experimenter will fill in the answers.

Age:
 Sex:
 Weight (Kg or Lb):
 Height (cm or inc):
 Occupation:
 Do you work shifts:
 Collar size (cm or inc):
Years held a UK driving licence

GENERAL QUESTIONS

1. How many cups of coffee do you usually drink in a day?

None	<input type="checkbox"/>
1-2	<input type="checkbox"/>
3-4	<input type="checkbox"/>
5-6	<input type="checkbox"/>
Over 6	<input type="checkbox"/>
Don't Know	<input type="checkbox"/>

2. How many drinks of high caffeine content e.g., Red Bull do you usually drink?

None	<input type="checkbox"/>
1-2 a month	<input type="checkbox"/>
3-4 a month	<input type="checkbox"/>
1-2 a week	<input type="checkbox"/>
3-5 a week	<input type="checkbox"/>
More than 5 a week	<input type="checkbox"/>
Don't Know	<input type="checkbox"/>

3. Would you ever drink high caffeine content drinks or coffee with the sole purpose to remain alert during monotonous tasks?

Never	<input type="checkbox"/>
Yes some times	<input type="checkbox"/>
Yes often	<input type="checkbox"/>

4. Do you smoke?

Yes often	<input type="checkbox"/>
Yes Sometimes	<input type="checkbox"/>
No	<input type="checkbox"/>

5. If yes often, How many cigarettes per day?

0-5	<input type="checkbox"/>
5 or more	<input type="checkbox"/>
Don't Know	<input type="checkbox"/>

HEALTH QUESTIONS

6. In general would you say your health is:

Excellent	<input type="checkbox"/>
Very Good	<input type="checkbox"/>
Good	<input type="checkbox"/>
Fair	<input type="checkbox"/>
Poor	<input type="checkbox"/>

7. Have you ever experienced any of the following medical conditions, and if so when?

No = 1 **Yes in the past = 2**
 Yes, sometimes = 3 **Yes, at present = 4**

- | | | | |
|---------------------------------|-------|-------------------------------|-------|
| (a) Obstructive sleep apnoea | | (o) Hay fever | |
| (b) Eczema | | (p) Allergies | |
| (c) Thyroid Problems | | (q) Undue anxiety | |
| (d) Sleepwalking | | (r) Loud snoring | |
| (e) Nightmares | | (s) Bruxism | |
| (f) Difficulty reading/writing | | (t) Arthritis/Rheumatism | |
| (g) Depression | | (u) Heart attack | |
| (h) Stomach problems | | (v) Waking up with a jolt | |
| (i) Waking up excessively early | | (w) Difficulty falling asleep | |
| (j) Stress/anxiety at home/work | | (x) Epilepsy | |
| (k) Migraine | | (y) Morning headaches | |
| (l) Hearing Problems | | (z) Diabetes | |
| (m) Stroke | | (aa) Hypertension | |
| (n) Irregular heart rhythms | | (bb) Asthma | |

7a) Do you currently suffer from any medical conditions not mentioned, if so please give details below? Including high cholesterol.

.....

.....

.....

.....

.....

8. Do you regularly take pills or medicines from the chemist or by prescription? Including sleeping pills and herbal remedies.

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Don't Know	<input type="checkbox"/>

If so can you tell me what they are?

.....

.....

.....

.....

.....

.....

.....

GENERAL SLEEP QUESTIONS

9. What time do you normally go to bed?

10. What time do you normally get up?

11. How long does it normally take you to fall asleep?

0-5 minutes	<input type="checkbox"/>
5-10 Minutes	<input type="checkbox"/>
10-20 Minutes	<input type="checkbox"/>
20-30 Minutes	<input type="checkbox"/>
Over 30 Minutes	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

12. Do you ever miss a night's sleep or have a shorter nights sleep than usual?

No	<input type="checkbox"/>
Yes, sometimes	<input type="checkbox"/>
Yes, regularly	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

12a) If yes, can you tell me what the reason is for this, work/social?

13. How many times on average do you wake in the night?

Never	<input type="checkbox"/>
More than twice a night	<input type="checkbox"/>
Twice a night	<input type="checkbox"/>
Once a night	<input type="checkbox"/>
Not every night but at least once a week	<input type="checkbox"/>
Not every night but at least once a month	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

13a) If you wake up:
 How long does it take you to get back to sleep again?

Less than 10 minutes	<input type="checkbox"/>
10 – 30 Minutes	<input type="checkbox"/>
30 – 60 Minutes	<input type="checkbox"/>
Over 60 Minutes	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

14. Are you a Morning Person or Evening Person?

Morning	<input type="checkbox"/>
Evening	<input type="checkbox"/>
Neither	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

15. If you currently have a bed partner, does s/he report any

unusualness about your sleep? And did they used to?

Yes
 No

15a) If yes please can you give details of what s/he reports

Loud snoring
 Moderate snoring
 Choking
 Other -please detail below

.....

16. Do you ever nap during the day?

Yes
 No
 Don't Know

16a) If yes, how often on average?

Twice or more a day
 Every Day
 2-3 Times per week
 Once per week
 Occasionally but less than once per week
 Don't know

16b) what time do you usually nap?

.....

SLEEP APNOEA QUESTIONS

17. When was your sleep apnoea first diagnosed?

18. When did you start to receive treatment for sleep apnoea?

19. Are you currently receiving treatment for sleep apnoea?

Yes
 No

19a) If yes what treatment are you currently receiving?.....

19b) How long have you been receiving this treatment?.....

20. Have you previously received any different treatment for sleep apnoea?

Yes
 No
 Don't remember

20a) If yes please can you give details below of previous treatments and why you changed to a different treatment including any surgery?

.....

21. Before knowing you had sleep apnoea do you now think you had to make any life style changes because of the condition? Since being diagnosed with sleep apnoea have you made any life style changes e.g. losing weight, increasing weekly exercise, reduced social life, restricted number or nights away from home etc.

.....

22. If you are using a CPAP machine for treating sleep apnoea:

a) How often do you sleep at night without using your CPAP

Never	<input type="checkbox"/>
Once or twice a week	<input type="checkbox"/>
Once or twice a month	<input type="checkbox"/>
Once every two to three months	<input type="checkbox"/>
Very occasionally	<input type="checkbox"/>

b) If you do sleep without your CPAP do you do so through choice or due to circumstance?

Choice	<input type="checkbox"/>
Circumstance	<input type="checkbox"/>

If you choose not to use the CPAP what is your usually reason for doing so?

.....

c) How much does the noise and vibration from the CPAP machine effect the quality of your sleep?

Very much	<input type="checkbox"/>
Moderately	<input type="checkbox"/>
Slightly	<input type="checkbox"/>
Not at All	<input type="checkbox"/>
Don't Know	<input type="checkbox"/>

23. If known, during sleep how many apnoeas do you have an hour –

23a) what is your current Apnoea/Hypopnoea Index (AHI)?

.....

23b) what was your Apnoea/Hypopnoea Index (AHI) prior to treatment?

24. How regularly are your appointments with the sleep clinic?.....

DRIVING QUESTIONS

25. On average how many hours do you drive for a week?

Less than 3 hours	<input type="checkbox"/>
3-5 hours	<input type="checkbox"/>
5 -10 hours	<input type="checkbox"/>
10–15 hours	<input type="checkbox"/>
15-20 hours	<input type="checkbox"/>
20-25hours	<input type="checkbox"/>
Over 25 hours	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

26. Do you drive as part of your job?

Yes		<input type="checkbox"/>
Yes I used to		<input type="checkbox"/>
No		<input type="checkbox"/>

27. On average how many miles do you drive a year?

Less than 1000 miles		<input type="checkbox"/>
1000 – 5000 miles		<input type="checkbox"/>
5000 – 10 000miles		<input type="checkbox"/>
10 000 – 15 000miles		<input type="checkbox"/>
15 000 – 20 000miles		<input type="checkbox"/>
20 000 – 30 000 miles		<input type="checkbox"/>
Over 30 000 miles		<input type="checkbox"/>
Don't know		<input type="checkbox"/>

28. If you are undertaking a long journey on average how long would you feel happy to drive before you take a break?

.....

29. Have you ever felt sleepy while driving?

Yes		<input type="checkbox"/>
No		<input type="checkbox"/>

29a) If yes was this before or after first receiving treatment for sleep apnoea

Before		<input type="checkbox"/>
After		<input type="checkbox"/>
Both before and after		<input type="checkbox"/>

30. Have you ever had to pull over and stop driving due to sleepiness?

Yes		<input type="checkbox"/>
No		<input type="checkbox"/>

30a) If yes was this before or after first receiving treatment for sleep apnoea

Before		<input type="checkbox"/>
After		<input type="checkbox"/>
Both before and after		<input type="checkbox"/>

31. Have you ever fallen asleep whilst driving?

Yes		<input type="checkbox"/>
No		<input type="checkbox"/>

31a) If yes was this before or after first receiving treatment for sleep apnoea

Before		<input type="checkbox"/>
After		<input type="checkbox"/>
Both before and after		<input type="checkbox"/>

32. Do you think that driving whilst sleepy affects your ability to drive safely?

Yes		<input type="checkbox"/>
No		<input type="checkbox"/>

32a) Do you think that driving whilst drowsy affects your ability to drive safely more or less than:

- Bad weather conditions	More/Less
- Legal alcohol consumption 80mg alcohol per 100ml blood (About 2 pints of beer for the average man)	More/Less

33. If you felt drowsy whilst driving which statements best describe what you are most likely to do. (You may tick more than one)

- (a) Keep going to reach your destination as soon as possible
- (b) Stop at a service station and have a nap
- (c) Turn the radio up
- (d) Stop at a service station and have a high caffeine content drink
- (e) Open a window
- (f) Stop at services and stretch your legs
- (g) If there is else you would do not covered above please give details

.....

34. Do you feel having sleep apnoea currently affects your driving?

Yes	
No	

35. Do you feel your driving was affected by sleep apnoea prior to receiving treatment?

Yes	
No	

34/35a) If yes to either question 35 or 36 in what way was/is your driving effected?

.....

36. Do you feel you have changed your driving habits as a result of your sleep apnoea diagnosis?

Yes	
No	

36a) If yes in what have you changed your driving habits?

.....

37. In the 3 years prior to receiving treatment for sleep apnoea how many car accidents resulting in greater than £250 damage or personal injury to you or another did you have?

0	
1	
2	
3	
More than 3	

38. In the last 3 years while you have been receiving treatment for sleep apnoea (or the total time you have been receiving treatment for sleep apnoea if this is less than 3 years) how many car accidents resulting in greater than £250 damage or personal injury to you or another have you had?

0	
1	
2	

39. Do you think you are greater risk while driving than some one without sleep apnoea?	3 More than 3	<input type="checkbox"/>
	Not at all Slightly Moderately Very	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>



SLEEP SCREENING QUESTIONNAIRE

Loughborough Sleep Research Centre

The following questionnaire to be completed in the form of a structured interview with the participant and experimenter. The experimenter will fill in the answers.

Age:
 Sex:
 Weight (Kg or Lb):
 Height (cm or inc):
 Occupation:
 Do you work shifts:
 Collar size (cm or inc):
 Years held a UK driving licence:

GENERAL QUESTIONS

1. How many cups of caffeinated coffee do you usually drink in a day?

None	<input type="checkbox"/>
1-2	<input type="checkbox"/>
3-4	<input type="checkbox"/>
5-6	<input type="checkbox"/>
Over 6	<input type="checkbox"/>
Don't Know	<input type="checkbox"/>

2. How many drinks of high caffeine content other than coffee e.g., Red Bull do you usually drink?

None	<input type="checkbox"/>
1-2 a month	<input type="checkbox"/>
3-4 a month	<input type="checkbox"/>
1-2 a week	<input type="checkbox"/>
3-5 a week	<input type="checkbox"/>
More than 5 a week	<input type="checkbox"/>
Don't Know	<input type="checkbox"/>

3. Would you ever drink high caffeine content drinks or coffee with the sole purpose to remain alert during monotonous tasks?

Never	<input type="checkbox"/>
Yes some times	<input type="checkbox"/>
Yes often	<input type="checkbox"/>

4. Do you smoke?

Yes often	<input type="checkbox"/>
Yes Sometimes	<input type="checkbox"/>
No	<input type="checkbox"/>

5. If yes often, How many cigarettes per day?

0-5	<input type="checkbox"/>
5 or more	<input type="checkbox"/>
Don't Know	<input type="checkbox"/>

HEALTH QUESTIONS

6. In general would you say your health is:

Excellent	<input type="checkbox"/>
Very Good	<input type="checkbox"/>
Good	<input type="checkbox"/>
Fair	<input type="checkbox"/>
Poor	<input type="checkbox"/>

7. Have you ever experienced any of the following medical conditions, and if so when?

No = 1

Yes in the past = 2

Yes, sometimes = 3

Yes, at present = 4

- | | | | |
|---------------------------------|-------|------------------------------------|-------|
| (a) Obstructive sleep apnoea | | (o) Hay fever | |
| (b) Eczema | | (p) Allergies | |
| (c) Thyroid Problems | | (q) Undue anxiety | |
| (d) Sleepwalking | | (r) Loud snoring | |
| (e) Nightmares | | (s) Bruxism | |
| (f) Difficulty reading/writing | | (t) Arthritis/Rheumatism | |
| (g) Depression | | (u) Heart attack | |
| (h) Stomach problems | | (v) Waking up with a jolt | |
| (i) Waking up excessively early | | (w) Difficulty falling asleep..... | |
| (j) Stress/anxiety at home/work | | (x) Epilepsy | |
| (k) Migraine | | (y) Morning headaches | |
| (l) Hearing Problems | | (z) Diabetes | |
| (m) Stroke | | (aa) Hypertension | |
| (n) Irregular heart rhythms | | (bb) Asthma | |

7a) Do you currently suffer from any medical conditions not mentioned, if so please give details below? Including high cholesterol.

.....

.....

.....

.....

.....

8. Do you regularly take pills or medicines from the chemist or by prescription? Including sleeping pills and herbal remedies.

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Don't Know	<input type="checkbox"/>

If so can you tell me what they are?

.....

.....

.....

.....

.....

.....

.....

9. Do you have any family history of Obstructive Sleep Apnoea?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Don't Know	<input type="checkbox"/>

GENERAL SLEEP QUESTIONS

10. What time do you normally go to bed?

11. What time do you normally get up?

12. How long does it normally take you to fall asleep?

0-5 minutes	<input type="checkbox"/>
5-10 Minutes	<input type="checkbox"/>
10-20 Minutes	<input type="checkbox"/>
20-30 Minutes	<input type="checkbox"/>
Over 30 Minutes	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

13. Do you ever miss a night's sleep or have a shorter nights sleep than usual?

No	<input type="checkbox"/>
Yes, sometimes	<input type="checkbox"/>
Yes, regularly	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

13a) If yes, can you tell me what the reason is for this, work/social?

14. How many times on average do you wake in the night?

Never	<input type="checkbox"/>
More than twice a night	<input type="checkbox"/>
Twice a night	<input type="checkbox"/>
Once a night	<input type="checkbox"/>
Not every night but at least once a week	<input type="checkbox"/>
Not every night but at least once a month	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

14a) If you wake up:
 How long does it take you to get back to sleep again?

Less than 10 minutes	<input type="checkbox"/>
10 – 30 Minutes	<input type="checkbox"/>
30 – 60 Minutes	<input type="checkbox"/>
Over 60 Minutes	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

15. Are you a Morning Person or Evening Person?

Morning	<input type="checkbox"/>
Evening	<input type="checkbox"/>
Neither	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

16. If you currently have a bed partner, does s/he report any

unusualness about your sleep?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

16a) If yes please can you give details of what s/he reports

Loud snoring	<input type="checkbox"/>
Moderate snoring	<input type="checkbox"/>
Choking	<input type="checkbox"/>
Other -please detail below	<input type="checkbox"/>

.....

.....

.....

.....

17. Do you ever nap during the day?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Don't Know	<input type="checkbox"/>

17a) If yes, how often on average?

Twice or more a day	<input type="checkbox"/>
Every Day	<input type="checkbox"/>
2-3 Times per week	<input type="checkbox"/>
Once per week	<input type="checkbox"/>
Occasionally but less than once per week	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

17b) what time do you usually nap?

.....

DRIVING QUESTIONS

18. On average how many hours do you drive for a week?

Less than 3 hours	<input type="checkbox"/>
3-5 hours	<input type="checkbox"/>
5 -10 hours	<input type="checkbox"/>
10-15 hours	<input type="checkbox"/>
15-20 hours	<input type="checkbox"/>
20-25hours	<input type="checkbox"/>
Over 25 hours	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

19. Do you drive as part of your job?

Yes	<input type="checkbox"/>
Yes I used to	<input type="checkbox"/>
No	<input type="checkbox"/>

20. On average how many miles do you drive a year?

Less than 1000 miles	<input type="checkbox"/>
1000 – 5000 miles	<input type="checkbox"/>
5000 – 10 000miles	<input type="checkbox"/>
10 000 – 15 000miles	<input type="checkbox"/>
15 000 – 20 000miles	<input type="checkbox"/>
20 000 – 30 000 miles	<input type="checkbox"/>
Over 30 000 miles	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

21. If you are undertaking a long journey on average how long would you feel happy to drive before you take a break?

.....

22. Have you ever felt sleepy while driving?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

22a) If yes what were the circumstances

.....

23. Have you ever had to pull over and stop driving due to sleepiness?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

23a) If yes what were the circumstances

.....

24. Have you ever fallen asleep whilst driving?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

24a) If yes what were the circumstances

.....

25. Do you think that driving whilst sleepy affects your ability to drive safely?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

25a) Do you think that driving whilst drowsy affects your ability to drive safely more or less than:

- Bad weather conditions More/Less

- Legal alcohol consumption 80mg alcohol per 100ml blood
 (About 2 pints of beer for the average man) More/Less

26. If you felt drowsy whilst driving which statements best describe what you are most likely to do. (You may tick more than one)

- (a) Keep going to reach your destination as soon as possible
- (b) Stop at a service station and have a nap
- (c) Turn the radio up
- (d) Stop at a service station and have a high caffeine content drink
- (e) Open a window
- (f) Stop at services and stretch your legs
- (g) If there is else you would do not covered above please give details

.....

27. In the past 3 years how many car accidents resulting in greater than £250 damage or personal injury to you or another have you had?

- 0
- 1
- 2
- 3
- More than 3

Ref No: R08-P22

LOUGHBOROUGH UNIVERSITY
ETHICAL ADVISORY COMMITTEE

RESEARCH PROPOSAL
INVOLVING HUMAN PARTICIPANTS

Title: Investigation into the effect of obstructive sleep apnoea (OSA) in subjects being treated with continuous positive airway pressure (CPAP) on driving errors in a driving simulator and subjective awareness of tiredness

Applicant: Dr L Rayner, A Filtress

Department: Human Sciences

Date of clearance: 12 February 2008

Comments of the Committee:

The Committee agreed to issue clearance to proceed subject to the following conditions: That confirmation was provided as to whether participants would need to be able to drive a manual transmission car, and if so, that this was included on the Participant Information Sheet.

That the Participant Information Sheet was checked for spelling and grammatical mistakes, that the term 'investigator' was used in place of 'experimenter' and that the term 'participants' was used in place of 'subjects.'

That an alternative meal was available to those with allergies and intolerances.

That the Participant Information Sheet stated that the drink to be consumed 1 ½ hours prior to the study should not contain caffeine.

That the Sleep Screening Questionnaire was amended so that Question 1 referred to caffeinated coffee, if appropriate.

Question 2 stated high caffeine drinks other than coffee, if appropriate.

Question 9 was removed.

Dr CD Hanning. BSc, MB, BS, MD, FRCA
Consultant in Sleep Disorders Medicine

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Dear Ashleigh,

Studies on driving ability in patients with Obstructive Sleep Apnoea

The Leicester Sleep Disorders Service has always been delighted to support the research undertaken under Professor Horne's auspices into driving ability and obstructive sleep apnoea. This has been both while I was the senior clinician and subsequently, since my retirement, when Dr Andrew Hall has been in charge. We recognise that an increased road accident rate is a major source of concern with these patients and research benefits not just the patients themselves but also the general public.

We were thus very supportive of the members of the Leicester Sleep Apnoea Patients Association who agreed to volunteer for this research. We reviewed the protocols and were happy with the procedures for ensuring that subjects did not drive while sleepy after their studies. There is no risk to the patients in discontinuing CPAP for a single night. As your own questions have confirmed, a large proportion of patients decide not to use their CPAP machines on a fairly regular basis, perhaps when they are away from home or travelling. It is probably true to say that virtually all longer standing CPAP users have slept at least one night without their machines, either voluntarily or because of machine failure. We only provide a 9-5, weekday only, replacement service, accepting that it does patients no harm to sleep without their machines for 2-3 nights over a weekend. The only consequence is sleepiness which is covered by your existing protocols.

In summary, I am happy to reassure your Ethics Committee that I have no objection to the addition to your protocol as it poses no risk to the patients. The patients are all well briefed on their condition and are able to give informed consent to the studies.

Yours sincerely,



Dr CD Hanning
Honorary Consultant in Sleep Medicine, University Hospitals of Leicester NHS Trust



BASIC SLEEP DIARY

Loughborough Sleep Research Centre

SUBJECT NUMBER:

This shortened sleep diary will enable us to gain a picture of how you slept over the three nights. This information will be linked with the actiwatch data, please put the actiwatch on one hour before you go to bed and take it off one hour after you get up.

Please fill each day as appropriate.

QUESTION	Night 1	Night 2	Night 3
Last night I went to bed at...			
This morning I woke up at....			
This morning I got out of bed at.....			
Last night, I slept for a total of hours			
Last night, I fell asleep in.... minutes			
Last night, I woke up.... times			
Last night my sleep was disturbed by....			
I did/did not sleep with my partner			

Please note below any times when you remove the actiwatch and why:

Any queries please contact:
 Ashleigh Filtness,
 Sleep Research Centre,
 Department of Human Sciences,
 Loughborough University.

a.j.filtness@lboro.ac.uk
 01509 228225