An Investigation Of The Identification Of Subjective And Objective Daytime Cognitive Failures In People With Psychophysiological Insomnia And Good Sleeper Controls.

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Clinical Research Portfolio

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for J.A.R.

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CHAPTER ONE: SYSTEMATIC REVIEW

A Comparative Meta-Analysis of Attention Bias Effects in Primary Insomnia Versus Generalised Anxiety Disorder.

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Abstract

Cognitive models of primary insomnia (PI) suggest attention bias as a maintaining factor of the disorder and within the last ten years experimental cognitive psychology methodologies have been applied to test the hypothesis that attention bias to sleep-related stimuli is exhibited by individuals with PI. This article reviews, systematically, studies of attention bias in PI, with the aim of providing conclusions relating to 1) the stability of the attention bias phenomenon in individuals with PI and 2) the most effective methodologies utilized when assessing for attention bias in PI groups. In addition, similarities in the meta-cognitive architecture, e.g. worry, rumination and negative appraisal of body sensations between PI and GAD, another psychopathological condition, is discussed and subsequently comparisons between the attention bias data of these two groups is reported. Following electronic database searching and hand searching of relevant journal titles, thirteen articles were reviewed (seven PI, six GAD). Generally, the quality of the articles is high, as denoted by the Quality Rating Score (QRS). The stability of the attention bias effect within PI populations was relatively high, with an effect size average of $d = 0.585$. Pictorial stimuli differentiated large effect sizes from moderate/small within the PI studies. Attention bias effects within the PI studies appear largely comparable to those of GAD, however effect sizes within the PI studies were larger. The stability of the phenomenon across both populations is similar, however, GAD studies had significantly more data relating to subliminal attention. Future research in PI should aim to track longitudinally, with clinical populations, supraliminal and subliminal attention bias.

INTRODUCTION

Insomnia is likely to be the most commonly reported health complaint in general practice after pain, with up to 33% of the general population reporting sleep problems at any given time (Ohayon, 2002). Primary Insomnia (PI) is defined as difficulty initiating or maintaining sleep or non-restorative sleep, associated with significant distress or daytime impairment and not due to other medical, psychiatric or sleep disorders (DSM-IV; APA, 1994), and affects approximately 3% of the population in industrialised countries (Ohayon, 2002). Insomnia can be acute or chronic, the differentiation being the period of time the individual has persistently experienced the above symptoms. The available nomenclatures purport that insomnia experienced for 6 months (ICSD2) or 1 month (DSM-IV-TR) be classified as chronic PI. More specifically, however, both recognise that there is a cognitive basis to the development and maintenance of the disorder (ICSD2; American Academy of Sleep Medicine, 2005, DSM-IV-TR; American Psychiatric Association, 2000).

Cognitive Models of Insomnia

The attention-intention-effort pathway (Espie et al., 2006) highlights this cognitive basis of PI and proposes a pathway through which the disorder develops and persists. The model has its origins in the psychobiological inhibition model (Espie, 2002), which considers what it takes to upset the course of normal good sleep, and to prevent (inhibit) it's recovery. The model attributes the disruption to the sleep-wake automaticity in PI to three distinct processes; selectively attending to sleep, explicitly intending to sleep, and an exaggerated exerted effort into the sleep engagement process. The first of these three

processes, selectively attending to sleep, which encompasses a hyper-vigilance to all things sleep-related, including the negative consequences that are appraised to be as a result of poor sleep, captures a purely cognitive element of the disorder, and has been commonly discussed within the insomnia literature. Indeed, authors have consistently reported the association between cognitive arousal and subjective sleep disruption. Harvey (2002) reported that the cognitions of people with insomnia were focused on worry about not getting to sleep, general worries, solving problems, the time, and noise in the house. Wicklow and Espie (2000) obtained voice activated audiotape recordings of spontaneous thoughts and sleep actigraph data from 21 poor sleepers over three consecutive nights. Regression models indicated that thinking about sleep and the anticipated consequences of poor sleep, along with general problem solving, were the strongest predictors of objective sleep latency. Lundh and Broman (2000) presented a theoretical model which posited that psychological vulnerability factors may predispose the person with insomnia to 1) respond with sleep-interfering processes to stressful life events i.e. with cognitive over arousal at bedtime, excessive worry etc, and 2) to engage in dysfunctional sleep-interpreting processes, such as sleep-related beliefs, attitudes, and perfectionist standards. The neuro-cognitive model (Perlis, 1997) supports the former of these two predispositions. More specifically, cortical arousal, measured through EEG activity, was found to be elevated in patients in patients with insomnia as compared to good sleepers. Perlis (1997) suggests that, as one develops chronic insomnia, there is an increase in high frequency EEG activity at or around sleep onset. In transient (acute) insomnia such activity may occur in association with stress induced worry and/or rumination, however, over time this becomes a classically conditioned response i.e.

elevated EEG is elicited in response to the visual and/or temporal cues usually associated with sleepiness and sleep, which occurs in the absence of situational stressors (Perlis et al., 1997).

The Cognitive Model of Insomnia (Harvey et al., 2002) extends the thinking about the associations between cognitive arousal and PI, into more definable contexts. Harvey highlighted the association between PI and the monitoring of sleep-related threat. In the recently reported 'real world' experiments, Harvey and colleagues manipulated attention processes in order to demonstrate the causal role in increasing and decreasing insomnia symptoms. Within one such study (Neitzert-Semler and Harvey, 2006), two groups of individuals with PI were assigned to either a focused attention group, in which they were instructed to monitor for internal reactions to their poor sleep, or the distraction group, who were distracted from internal monitoring by engaging in external activities. Both groups were subsequently compared to a healthy control group of good sleepers (GS). As predicted, the focused attention group reported higher negative thoughts and daytime sleepiness and exhibited more safety behaviours than controls. In another series of experiments, Tang et al. (2007) considered the importance of clock monitoring in insomnia as previously, in the cognitive model of insomnia, Harvey had proposed that people experiencing insomnia have a greater tendency to monitor the bedroom environment for evidence of wakefulness, and that this, in turn, results in an increase in negative thinking and worry about the consequences of poor sleep. In a preliminary experiment, Tang and colleagues instructed both GS and PI sufferers to monitor the clock and subsequently demonstrated that both groups reported higher worry ratings and

longer sleep onset latencies (SOL) than controls. In a second experiment, which controlled for the actual act of monitoring the clock, the control group were instructed to monitor a digital display which mimicked a digital clock but displayed meaningless information. Again, as predicted, the digital display group reported less worry and shorter SOL than the group monitoring the real clock, and thus supported the idea that attention bias, in the form of clock watching, aided in the sleep interfering process.

Attention and Insomnia

The 'real world' experiments have been of great value in understanding the implications of attention focus within the PI disorder. However, the most influential research to date, evidencing attention processing in PI populations, comes from the recent burst of research utilizing experimental cognitive psychology methods to demonstrate attention biases in people with PI. More specifically, recent research has used computerised experimental protocols to measure information-processing speed to salient (sleep-related) and neutral (non sleep-related) stimuli. The principle behind these 'attention paradigms' relates to the notion that reaction time (RT) responses to stimuli, that are relevant to the individual (whether positively or negatively relevant), will be different to those of stimuli that have little relevance to the individual.

To date there have been seven reported studies within the insomnia literature that have executed this experimental protocol in an attempt to evidence attention bias in people with PI. Although the methodologies between these studies differ, the fundamental principle of 'differentiation through reaction time' is consistent. This current paper aims

to systematically review these available studies and provide conclusions relating to 1) the stability of the attention bias phenomenon in individuals with PI and 2) the most effective methodologies utilized when assessing for attention bias in PI groups.

Attention and Generalised Anxiety Disorder

This current paper will also consider other available literature that evidence attention bias effects in another psychopathological disorder. Indeed, this experimental methodology, i.e. computerised attention paradigms, in detecting attention bias in psychopathological conditions has a long-standing history. Indeed attention bias toward salient, relevant, stimuli has been demonstrated in panic disorders, post traumatic stress disorder, obsessional disorders, generalized anxiety disorder (see Mogg and Bradley, 1998, Mathews and MacLeod, 1994 for reviews). Most of these identified attention bias effects have been attributed to perceived threat (Matthews et al., 1995, Matthews et al., 1998, Matthews et al., 2000, Fox et al., 2001). Indeed, in both in psychological disorders and substance abuse/dependence, attention biases have helped explain why disorders and dependencies are self-maintaining and why relapse so frequently occurs after apparently successful treatment (Jones et al., 2003). For example, if threatening stimuli are more readily noticed by those exhibiting clinical anxiety, anxiety responses will be generated more than others and the disorder maintained (Mogg et al., 1990).

In recent years cognitive models of anxiety have underpinned radical new developments in the treatment of anxiety disorders, and generalized anxiety disorder (GAD) has featured heavily within this literature. More specifically, as evidence has accumulated in support of the cognitive processes that develop and maintain the disorder, e.g. negative

automatic thoughts, inaccurate appraisal of situations, attention bias toward threatening information etc, detailed cognitive intervention strategies, aimed at reducing these cognitive distortions, have appeared within the literature. Indeed, Beck introduced his cognitive model and treatment for anxiety (Beck and Emery, 1985), the latter of which is now established to be effective for GAD (Butler et al., 1991).

Similar to GAD, it has recently been suggested that individuals with PI are characterized by higher levels of meta-cognitive beliefs and plans for processing which predispose them to appraise thoughts, experiences and body sensations negatively (Espie at al., 2006). Thus, similarly to individuals suffering GAD who frequently worry and ruminate about possible negative outcomes, this cognitive architecture in the individual with PI promotes worry, rumination and attention bias in the pre-sleep period. The consequence of which is disruption of the sleep onset and maintenance process.

When these similarities between the GAD and PI are highlighted, it seems plausible to assume that the attention processes observed within one population would exist within the other. Mores specifically, as there is an abundance of research identifying attention bias through the use of computerised methodologies in populations with GAD (see Mogg and Bradley, 2005 for review), one could hypothesize that the magnitude of effects observed within this population would be largely comparable to those observed within the PI population. If this is indeed the case, this outcome would highlight the importance of the cognitive components within the non- pharmaclogical treatment-of-choice for insomnia i.e. Cognitive Behavioural Therapy (CBT), and would support the

suggestion that such cognitive processes, that characterise insomnia, may reduce the response to largely behavioural psychological treatments. Furthermore, as recent reports have evidenced a reduction in attention bias effects in GAD following CBT intervention (fox et al., 2005), one could predict that the administration of CBT for insomnia would similarly reduce the effect within the primary insomnia population. Thus, the final aim of this current paper is to compare the attention bias effects of individuals with PI to those reported for individuals with GAD.

METHOD

Search strategy

The following databases were searched electronically using the terms *insomnia, primary insomnia, generalized anxiety disorder, anxiety*, *attention bias, information processing bias and selective attention* from the start of indexing until April 2009: PsychINFO and MEDLINE. *Behaviour research and therapy*, *British Journal of Clinical psychology*, *Cognition and Emotion* and the *Journal of Abnormal Psychology* were hand searched to identify studies that were not electronically indexed. Citation lists of relevant studies were also examined for other relevant trials.

Types of Studies

All attention bias studies assessing attention bias scores in adults (18years to 60 years) with primary insomnia (PI), secondary insomnia (SI), poor sleep or generalized anxiety disorder (GAD), relative to healthy controls, through the utilization of computerised, Emotional Stroop, Dot Probe, Inducing Change Blindness Flicker or Modified Posner

paradigms were included within this review. There were two reasons for excluding studies that utilized non-computerised tasks. First, reaction times to these tests have been shown to be significantly slower as compared to the computerised versions (Mogg et al., 1998). Second, as all the PI studies to date have utilized computerised paradigms, it was thought that fair comparison between PI and GAD studies would be optimally achieved by restricting the inclusion of GAD studies to those utilizing the same paradigm methodology.

Although the papers relating to attention bias in sleep disturbance are reviewed in full, information relating to the GAD papers is summarised in table form. This is because a full review of attention bias in the GAD population has recently been published (see Mogg and Bradley, 2005). Within this current review, relevant information from the GAD studies, that enable comparisons between PI and GAD data, will be detracted from relevant papers, reported and discussed. Exceptions to this however relate to any studies that have appeared within the literature after the publication of the Mogg and Bradley (2005) review, and these will be reviewed in full.

Types of Participants

Inclusion criteria: 18 years to 60 years (inclusive); primary diagnosis of PI, secondary diagnosis of PI, poor sleep or GAD.

Exclusion criteria: < 18 years old or > 60 years old; circadian cause of sleep difficulty i.e. Delayed/Advanced Sleep Phase Syndrome. Any anxiety disorder other than GAD.

Results of Literature Search

Electronic database searching under the search terms above initially retrieved a total of 34 studies. Limiting the search results to adults (=> 18 years and <= 65 years) reduced this to 28 studies. Further, limiting studies to those that utilized computerised paradigm methodologies (as opposed to manual paradigm methodologies) reduced the total to thirteen (seven sleep studies and six GAD studies). In order to avoid the 'splitting' of data (i.e. where RT scores reported in more than one experiment are generated from the same experimental population, but are reported in reviews as representing distinct experimental populations) all studies reporting more than one experiment, with the same population, were considered to represent one study. Despite this procedural consideration, the total number of studies being included for review remained thirteen, with seven relating to studies assessing individuals with PI, and six relating to studies assessing individuals with GAD.

Quality Rating Scores (QRS)

A limited list of criteria was established from which each paper was 'quality' rated, **Table 1**. This list was determined and agreed by the principle author of this current review and a senior colleague specialising in behavioural sleep medicine. For each individual paper, one point was assigned for every criterion met. The maximum score for any given paper was therefore six points. The criterion list related to 1) whether the study was age matched and 2) gender matched, 3) whether a clinical population was recruited, 4) whether a standardised diagnostic system was reported for group allocation, 5) whether a standardized paradigm was utilized, and finally, 6) whether means and

standard deviations were reported (thus enabling effect size calculation; small = 0.2, medium = 0.5, large = 0.8). Two independent raters evaluated each study. These independent raters yielded both identical total QRS for each individual paper, and identical ratings for each individual criterion given to each paper. The aim of this rating system was not to further eliminate papers from the current review but alternatively to validate the interpretation of comparisons later made.

Paradigm Overview

i. Emotional Stroop

The Emotional Stroop task is the most classic of all the attention bias tasks. In this task, participants are shown words written in different coloured ink and are required to ignore the meaning of the word and, instead, name the ink colour that it is written in. Participants are asked to do this as quickly as possible. Colour-naming latency has been interpreted as reflecting the extent to which processing resources are allocated to the word content. Typically, words that are emotionally salient to the individual have larger RT latencies to colour identification than non-salient words. Within the Stroop paradigm, as with the Dot-Probe and Posner paradigm, the stimulus presentation time can be manipulated to assess supraliminal (i.e. conscious) and subliminal (unconscious) attention. Typically, stimulus presentations <100 assess subliminal attention, and > 100 supraliminal attention.

ii. Inducing change Blindness Flicker Paradigm

The ICB Flicker paradigm is the most recent attention bias paradigm to be developed (Rensink, 1997; Simons, 1997). Within this paradigm, a visual scene is presented, comprising of both salient and non-salient stimuli (e.g. sleep and non-sleep objects). The scene 'flickers' back and forth between an original scene (OS) and a changed scene (CS), which are always separated by a brief mask screen (screen of X's). The CS has one of the stimuli removed or in a different position from the OS). The participant's instruction is to detect this subtle change within the scene. The cycle of OS, mask, CS, mask, OS, represents one complete cycle within the paradigm. The paradigm continues to cycle until the participant detects and signals the correct change. Typically objects that are changed within the scene that are salient to the participant are detected quickly, whereas changes made to non-salient stimuli take longer to identify. Authors have suggested that this reflects an attentional preference towards the salient stimuli within the scene.

INSERT TABLE 1 HERE

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iii. Visual Probe Paradigm

a) Dot-Probe Paradigm

The Dot Probe paradigm was adapted from experimental cognitive psychology paradigms, which indicated that the deployment of visio-spatial attention can be assessed

from manual response times (RTs) to visual probes (e.g. Posner et al., 1980). That is, individuals respond faster to a probe stimulus (e.g. a small dot), which is presented in an attended rather than unattended region of a display. In a typical version of a dot probe task assessing attentional biases from emotional stimuli, a series of word pairs or picture pairs are presented on a computer screen, with one member of the word pair above the other. On critical trials, one word of each pair is emotion-related and the other neutral. In a typical dot-probe paradigm, each pair is presented fairly briefly (e.g. 500-1000ms), and when the words disappear, a probe (e.g. a dot or arrow) appears in the location just occupied by one of the words. Participants are required to respond as quickly as possible to the probe. Typically, individuals with anxiety have been found to respond faster to probes replacing emotionally negative words than neutral words, compared with non-anxious controls, which is consistent with attention bias for threat in anxiety.

b) Modified Posner Paradigm

The Modified Posner paradigm has led the way in the differentiation of attentional bias data. More specifically, the Posner paradigm has allowed for both engagement and disengagement components of attention to be assessed. Within this computer task, participants are required to categorise a target (e.g. respond appropriately to it's orientation) that may appear on the left or the right of a fixation point. On 75% of the trials, a cue highlights the area in which the target will appear (valid). However, one 25% of the trials the cue will appear in the opposite location of the following target (invalid). The typical paradigm effects reveal that valid trials are detected quicker than invalid trials, as the exogenous cue induces a covert orienting of attention to the cued

location leading to faster RTs on valid trials and slower RTs on invalid trials. This effect is more commonly known as the cue validity effect. Analyses of valid RT's provide evidence for a speeded engagement to salient stimuli, and analyses of invalid RT's provides evidence for a delayed disengagement away from salient stimuli. Typically, anxious individuals have been shown to have a delayed disengagement away from threatening stimuli as compared to healthy controls.

iv. Mixed Modality

The Mixed Modality paradigm is a relatively new attention bias paradigm, and features rarely in the broader attention bias literature. With this paradigm the participant is required to respond differentially to two different sounds, whilst pictorial or semantic stimuli are presented as distracters. Reponses are given by the left and right index finger depending on the tone of the sound. Typically, RTs to sounds that are distracted by salient stimuli are larger than RTs to sounds that are distracted by non-salient stimuli.

ATTENTION BIAS AND PRIMARY INSOMNIA

Details of the seven PI papers that met criteria for inclusion are shown in **Table 2**. Of these papers two utilized a modified Stroop paradigm, two and Inducing Change Blindness Flicker paradigm, one a modified Posner paradigm, and one a Mixed Modality and Modified Stroop paradigm. The total number of participants was one hundred and thirteen PI, thirty-three SI, thirty-two poor sleepers and one hundred and forty-four GS. Total QRS across studies ranged from four to five out of a possible six. All studies recruited from non-clinical populations, with a further three failing to report PI

identification through the administration of a recognised diagnostic system (see Table 1). Although Taylor et al., 2003 recruited a clinical sample of cancer patients, clinical status in relation to the insomnia symptoms was not reported, thus this criterion was not met. Although four of the seven studies recruited additional groups (see table 2), comparisons of interest only relate to those depicted in the 'comparison of interest' column in table 2. The decision to focus solely on these comparisons was to aid in the subsequent comparison of PI and GAD data. Effect size (*d*) was calculated using an online effect size calculator (http://web.uccs.edu/lbecker/Psy590/escalc3.htm) and was based on the equation, M1 – M2/ S pooled. Effect sizes differentiation followed Cohen's effect size; large = 0.8, medium = 0.5, and small = 0.2.

i. Primary insomnia and the Emotional Stroop

The first study to translate the emotional Stroop task into the field of insomnia was that of Lundh et al. (1997). Lundh and colleagues reported that people with primary insomnia had prolonged response latency for sleep-related words. However this effect was also evident for the control population of good sleepers, and there was no group difference on the Stroop interference index; a result inconsistent with the attention bias hypothesis. The authors suggested that sleep-related words might have an emotional valence for people that may or may not be directly related to sleep problems. However, the extensive literature on the Stroop task would not predict experimental effects in normal control groups (Espie et al., 2006). This study, however, does not report details of the inclusion/exclusion procedure with respect to group allocation, and does not provide information regarding the diagnostic tools or standardized measures used for group

allocation and therefore it is impossible to make further predictions regarding the direction of the results with respect to group characteristics. In addition, no measure of affective state (which is known to influence Stroop findings) was reported. The authors also do not provide information about stimulus presentation timing and therefore no conclusions can be drawn with respect to whether supraliminal/subliminal attention was being assessed. However, despite these limitations and somewhat equivocal findings Lundh et al.'s pioneering work brought computerized attention paradigms into the field of insomnia research.

The second emotional Stroop experiment to appear within the insomnia literature tested the hypothesis that individuals suffering chronic insomnia (i.e. insomnia symptoms for 12–18 months) would demonstrate attention bias effects toward sleep-related words as compared to individuals suffering acute insomnia (i.e. insomnia symptoms for 0-3 months) (Taylor et al. 2003). All participants within this study had a diagnosis of cancer prior to the onset of their insomnia symptoms and thus the insomnia symptoms were viewed to be the secondary complaint. Both groups completed the computerised Stroop task comprising cancer-related, sleep-related and neutral word cues. Both groups demonstrated attention bias for cancer-related words but only the persistent insomnia group demonstrated attention bias for sleep-related words. The fact that interference effects for sleep words were absent at 0-3 months but were evident at 12-18 months, suggests that selective attention bias towards sleep may play a role in the transition from adjustment insomnia to chronic primary insomnia. Indeed, this is an important finding as it directly demonstrates that the cognitive processes of primary insomnia are not present at the onset of the sleep disruption, but rather develop over the course of the 'experience'

of insomnia. Thus, it seems appropriate to assume that cognitive therapeutic interventions would correct these errors in cognitive processing to return the individual to their original state.

INSERT TABLE 2 HERE

The authors acknowledge however, that a limitation of the study relates to the fact that it employed a cross-sectional rather than longitudinal design and did not include a control group of good sleepers without medical problems. Additionally, the paradigm employed presented the word stimuli for the standard supraliminal 500ms duration, thus it was not possible to determine to what extent the bias was pre-attentive/automatic i.e. occurred involuntary without intention or conscious control. The results, therefore, need to be interpreted with some caution.

Spiegelhalder et al. (2008) reported the most recent emotional Stroop experiment within the insomnia literature. This study recruited twenty PI identified through the DSM IV criteria for insomnia. Twenty good sleeper controls and twenty sleep experts were also recruited as controls. The inclusion of the expert group served the purpose of controlling for the effects of 'high frequency of concept usage', which relates to the notion that experts are likely to be emotionally affected by expertise-related stimuli (Williams et al., 1996), and therefore may respond in a similar way to the PI group. The results revealed

that the PI group showed significantly higher attention bias scores towards sleep-related words than the expert group, but other differences were observed for other group comparisons. The authors conclude that the significance of sleep-related attention bias at this stage should to be considered carefully as both this study and the previous work of Lundh et al. (1997) reported no group differences between people with PI and GS controls. In addition, however, the authors also acknowledge that the relatively small sample size may have been insufficient. The authors also reported a second data set generated from this population, however, this will be discussed later within the Mixed Modality task section.

ii. Primary insomnia and the ICB Flicker Paradigm

Two experiments have appeared within the insomnia literature that report attention bias effects in PI through the utilization of the ICB Flicker paradigm. The rationale behind these experiments and the use of this specific paradigm relates to the long-established interest in the control that sleep-related objects might have over sleep behaviour. Indeed, within a conditioning framework, bedroom environment objects might become more discriminative stimuli for sleep (Jones at al 2006), but when the bedroom sleep contingencies are broken, they might become discriminative stimulus for wakefulness.

In the first ICB study (Jones et al. 2006), one hundred and ninety-two participants were selected for a totally between subjects experiment. Participants first completed the computerised task and subsequently were assessed for sleep quality. Participants were allocated to either a poor, moderate or good sleep group, depending on their score on the

Pittsburgh Sleep Quality Index (>5, 4-5 inclusive, 0-2 inclusive, respectively) (PSQI, Buysee et al. 1989). Importantly, therefore, retrospective group assignment was blind to the dependent variable of the analyses, change detection latency. The stimuli included within this study were selected using a comprehensive process designed to identify objects associated with 'going to bed to sleep'. The authors note that none of the objects were intrinsically threatening or emotive.

Results revealed significant differences in change detection latencies between poor moderate and good sleepers for the sleep-related change. Only the poor sleepers, who detected the sleep-related change quicker than the neutral change, demonstrated attention bias for sleep salient stimuli. Moderate sleepers showed a trend in the same direction. By contrast, GS detected the change with the neutral objects significantly quicker. Hierarchical regression was then applied to test the relationship between change detection latency and a continuous representation of the global PSQI score. This evidenced a systematically changing effect of sleep quality upon attention bias, independent of age, gender and depressive symptom level. The authors conclude by suggesting that when in competition for attentional resources with matched neutral stimuli poor sleepers appear to prioritise sleep-related stimuli. With respect to the GS finding, the authors suggest that the direction of results may be explained by differences in physical saliencies of all the stimuli in the scene. That is the neutral half of the scene may have been more salient in general, or may have included a highly salient single item, as well as relative positional and configurational aspects. Because all the sleep quality groups were presented with the same complex scene, the authors suggest that an

attentional force that is greater than the existing physical saliencies is likely to have driven the response of poor sleepers.

The second ICB experiment aimed to replicate and extend the above work (Marchetti et al. 2006). Within the study the diagnostic methods were improved, which involved a clinical interview, based around the DSM-IV and ICSD-R nomenclatures, and actigraphy. The primary analysis was also strengthened by the inclusion of an additional control group. This comprised of individuals suffering from delayed sleep phase syndrome (DSPS). DSPS is a circadian rhythm disorder in which the alignment of the biological clock is essentially delayed with respect to the 24-hour clock. Individuals with DSPS report symptoms similar to PI, e.g. large sleep onset latencies, but the origin of their complaint is innately different. Indeed, the authors reported that due to this circadian origin, they did not expect the DSPS group to exhibit cognitive arousal as an explanatory mechanism for their continued wakefulness, thus, those with DSPS were not predicted to show a cognitive processing bias to sleep-related stimuli. Furthermore, the authors reported that often DSPS dilute PI samples, as DSPS is often not screened out of PI research. Thus, their screening and inclusion within this current study was novel to the PI literature.

This experiment used the same stimuli as the former, however a different stimuli was chosen to under-go the change in the cycle, to rule out the possibility of idiosyncratic effects to previously used stimuli. Group allocation was again not fully known to the experimenter until after the computerised task was completed. As the authors predicted,

the stimulus change/sleep quality interaction was significant with PI detecting the sleep-related change significantly quicker than the sleep-neutral change. No such differences were observed for the control groups. Post hoc testing also revealed that, for the sleep-related change, responses of PI were significantly quicker than GS and DSPS. By comparison, for the neutral change, responses of GS and DSPS were significantly quicker than PI.

The results of this experiment provide further evidence of attention bias to sleep-related stimuli in insomnia. Furthermore, the effect sizes calculated from the two ICB studies, for the PI/GS comparisons are medium to large d= -0.470 and d=-0.828 respectively, thus suggesting that this method of assessing attention bias in PI is highly sensitive to the phenomenon. The authors suggest that using pictorial stimuli may evoke more real life responses to emotionally salient stimuli than their semantic representations, and therefore future experimentation should aim to incorporate pictorial stimuli.

iii. Primary Insomnia and the Dot Probe Paradigm

MacMahon et al. (2006) reported attention bias in PI towards sleep-related words using the dot-probe paradigm. This is the only reported dot probe paradigm with the insomnia literature. Within this study sixty-three young adults across three experimental groups (PI, DSPS and GS) participated. PI and DSPS participants met ICSD-R criteria for their respective disorders following an extensive assessment comprising clinical interviews, the use of self-report scales, and sleep diary and actigraphy monitoring. As with the ICB study the DSPS was recruited as a clinical control sample for the same principle.

Following the author's predictions, and in support of the previous ICB data, the PI group showed a significantly greater processing bias toward sleep-related words (in comparison to neutral words) when compared to GS and DSPS groups. The effect size, d=0.32, for the PI versus GS comparison, denotes a medium effect size and thus provides support for utilizing this methodology with this population in the future. However, the stimulus presentation time within this experiment was 500ms, and therefore is assumed to be assessing supraliminal attention, and therefore, similar to Taylor et al's (2003) study, we cannot fully determine to what extent the bias was pre-attentive/automatic. The authors suggest that future experiment should aim to manipulate the stimulus presentation time in order to assess this further.

iv. Primary Insomnia and the Mixed Modality Task

Spiegelhalder et al. (2008) reported the only Mixed Modality Task within the insomnia literature, and reported no attention bias effect in PI towards sleep-related stimuli. This study used the same group of participant as reported for their emotional Stroop experiment previously discussed. This study again compared individuals with PI to a group of sleep experts and good sleepers. Analyses revealed no significant group differences and Pearson correlation between PSQI and attention bias scores was not significant [r = -0.14, P = 0.29]. The authors also investigated the relationship between attention bias scores and picture exposure durations, however linear regression analyses between estimated attention bias scores and picture exposure times revealed that the lack of attention bias could not be due to the varying exposure durations in any of the three groups.

v. Primary Insomnia and the Modified Posner paradigm

Woods et al. (2009) utilized the Modified Posner Paradigm in attempt to extend the interpretation of attention bias data, in PI, by revealing the components of attention, i.e. engagement/disengagement, driving attention bias effects. Previously reported studies utilizing this methodology with anxiety patients had revealed that attention bias effects were observed through a delayed disengagement away form emotionally salient stimuli, as opposed to a speeded engagement towards emotionally salient stimuli (Fox et al. 2001). The authors attempted to test this hypothesis in relation to PI. Twenty-two PI, who met DSM-IV and ICSD-R criteria for PI, and twenty-two good sleepers were recruited. The PI group was also assessed through the use of actigraphy. In line with the previous anxiety literature, PI was significantly slower to respond to targets on invalid trials (when the target was on the opposite location to the stimulus) than the controls, thus suggesting a delayed disengagement from the clock cue. The authors report that this provides further support for the existence of attention bias in PI and also provides further objective evidence for the role of clock monitoring in triggering cognitive arousal in PI, as previously discussed by Harvey (2002). The significant result generated by this paradigm and the large effect size $d = 0.8672$ for the PI/GS comparison on invalid trials, suggests that the modified Posner paradigm may be a useful tool in assessing attention bias of PI to other sleep-related stimuli in the future. Furthermore, although the presentation times within this experiment (250ms) assessed supraliminal attention, the modified Posner paradigm would enable future studies to manipulate this presentation time in attempt to assess subliminal attention profiles in PI. Indeed, this would follow in

the footsteps of the anxiety literature, within which subliminal attention biases are already reported.

Conclusions

The reviewed literature provides significant evidence in favour of attention bias towards sleep-related stimuli in PI, as five of the seven studies reviewed reported this phenomenon. Thus, attention bias within the PI population appears to be relatively stable phenomenon. This supports the prediction that due to their predisposition to appraise thoughts, experiences and body sensations negatively, the cognitive architecture in the individual with PI promotes worry, rumination and attention bias to sleep-related or sleeplessness related stimuli.

When considering the methodologies of the studies collectively and relating this to study findings and effect sizes, the biggest predictor of a significant result was stimulus type, with pictorial stimuli producing the three highest, and large, effect sizes; Woods et al. 2009, $d = 0.8672$, Marchetti et al. (2006), $d = -0.828$, Jones et al. (2005), $d = -0.470$. QRS was also largely predictive of outcome within the PI studies as two of the large effect size studies (Woods et al. 2009, Marchetti et al. 2006) had a QRS of five (the highest score achieved by of the studies). MacMahon et al's (2006) study which was also awarded a QRS of five, and also reported a significant effect, generated a moderate effect size, $d = 0.317$. Interestingly, Taylor et al's study, which reported attention bias in chronic versus acute insomnia sufferers secondary to cancer reported a moderate to large effect size despite the smaller QRS (QRS = 4). This experiment provides further support

in favour of the suggestion that insomnia, in secondary insomnia populations, exists though similar processes as in primary populations, without a co-morbid presentation, and thus should be treated with the same intervention. Indeed recently, Fleming and Espie (2008) demonstrated that CBTi, delivered to patient suffering co-morbidly from insomnia and cancer, was significantly effective in reducing SOL and total sleep time compared to the treatment as usual (TAU) control group.

ATTENTION BIAS AND GENERALIZED ANXIETY DISORDER

Details of the six papers that met criteria for inclusion are shown in **Table 3.** All of these papers were included in the review of Mogg and Bradley (2005) and therefore will not be discussed in full within this text. The purpose of extracting, and reporting, the data from these studies is to permit comparisons between the previously discussed PI data, and thus satisfy the final aim of this current review.

Overview of GAD Studies

Of the six papers that met criteria, two utilized a modified Stroop paradigm, three a Dot-Probe paradigm and one a modified Posner paradigm. The total number of participants was one hundred and nine individuals with GAD and one hundred and twenty-four healthy controls. The inconsistent ratio of GAD to healthy controls was observed within five out of the six studies. Both Stroop experiments (Mogg et al., 1993, Bradley et al., 1995) reported comparisons between people with GAD relative to healthy controls and both reported evidence in favour of attention bias in GAD in the supraliminal and subliminal experimental condition. Only one of the three Dot-probe paradigm experiments (Mogg et al., 1995) reported comparisons between people with GAD and

healthy controls at both supraliminal and subliminal experimental conditions and reported attention bias in GAD in both. Bradley et al (1999), reported attention bias in GAD in the shorter of their two subliminal conditions. The third dot-probe experiment (Matthews et al., 1996) reported a subliminal condition, in which no attention bias effects were observed in the experimental population of people with GAD and panic disorder (+/- agrophobia) relative to controls. Within the experiment utilizing the modified Posner paradigm (Mogg et al. 2000), both valid and invalid analyses were reported, however neither yielded a significant effect of group on RT data.

INSERT TABLE 3 HERE

Total QRS across studies ranged from five to six out of a possible six. Only one study, Mogg et al. (1995) failed to report mean and standard deviation values, resulting in an absence of effect size in table 3. All studies recruited clinical patients to represent the GAD group, all utilized standardised attention paradigms and all reported standardised diagnostic systems to qualify group allocation (table 1). Effect sizes from the experiments that yielded a significant difference between groups on attention bias scores were small, ranging from $d = 0.165$ to $d = 0.230$.

COMPARISONS BETWEEN PI AND GAD STUDIES

The percentage of studies that yielded a significant attention bias group effect for PI and GAD relative to their control populations was largely comparable, 71% and 66% respectively. Of these studies, effect size comparisons between PI and GAD revealed that the mean effect size of GAD studies was, on average, smaller than the effect size of PI studies, $r = 0.168$ and $r = 0.585$ respectively. In order to prevent the 'splitting' of data, effect sizes for the GAD supraliminal and subliminal data was averaged before being included into the mean effect size calculation. PI mean effect size fell within the large effect size category, and GAD mean effect size fell within the small effect size category.

Explanation for this difference in effect size between PI and GAD can be drawn form a number of sources. First, the largest effect-sizes within the PI literature relate to experiments that incorporated pictorial stimuli that represent objects that are related to sleep and sleeplessness. The GAD literature has yet to incorporate pictorial stimuli, other than happy, sad and neutral faces, into the paradigms, and thus at present it is unknown as to whether effects size would increase if this methodology was employed.

In addition, individuals suffering GAD may have differences in the extent to which they feel anxiety symptoms in relation any given stimulus. More specifically, self- reports from individuals suffering from GAD highlight that although there is meta-worry relating to many aspects of the individual's life, there is significant variation in the specific aspects of life that promote significant worry and distress for each individual. It

may be possible that the paradigms utilized within the available literature have failed to capture such specifically threatening aspects, and therefore have generated smaller differences between conditions. In comparison, the stimuli incorporated into the PI experiments represent concrete sleep/sleeplessness related stimuli (as rated by the general population) and thus would be more likely to represent emotionally salient objects.

Secondly, people with PI commonly report being highly vigilant at bedtime. More specifically, PI report that they become more awake and alert, in relation to both external and internal monitoring, as opposed to becoming increasingly tired and sleepy. One could predict that this hyper-vigilance, and environmental monitoring, may promote higher sensitivity on attention bias paradigms when responding to sleep/sleeplessness related stimuli, as opposed to neutral stimuli, thus generating larger differences with controls and subsequent effect size, within experiments.

Interestingly, all of the experimentation within the available PI studies was conducted during the day, when sleep-related bias would be less likely. However, measures of daytime sleepiness, as measured by the Stanford Sleepiness Scale (Hoddes et al., 1973), in populations of people with PI, have revealed significantly more sleepiness ratings and thus more desire to attain sleep than good sleeper controls. Thus, although the testing on the attention bias paradigms has occurred during the daytime, the consequences of poor sleep e.g. daytime sleepiness, is still largely present. Indeed, this symptom of sleepiness

may act as a primer for PI in identifying sleep-related stimuli more readily, as the desire for sleep is strong.

This suggestion alludes to the notion that 'craving' for sleep, or an intense motivation to achieve sleep, may be driving the attention bias effects in PI. Indeed, attention biases have been reported in clinical populations with drug dependence (Lusher et al., 2004), where attention bias is driven through a craving for the addictive stimulus. The A-I-E pathway suggest that the person with PI experiences sleep disruption, sleep loss and perceived sleep inadequacy and so becomes atypically motivated by sleep, which is increasingly incentivised in proportion to the preoccupation associated with it (Espie et al., 2006). Thus, the A-I-E pathway, acknowledges the possibility that attention bias in PI towards sleep relevant stimuli may be representing a motivation towards attaining sleep, and the symptom reductions associated with good sleep e.g. reduced feelings of daytime sleepiness. Indeed this thinking could be a possible explanation for the effect size difference observed between the PI and GAD studies as attention bias in GAD would follow an attention bias towards 'threat' hypothesis and not an attention bias towards 'craving' hypothesis. Furthermore, attention bias is PI may exist through both threat and craving processes, as the person with insomnia both desires the good sleep experience but also suffers from the poor sleep consequences. If both threat and craving are contributing to the maintenance of insomnia it seems plausible that the attention bias effect would be larger.

Future experimentation should consider this threat/craving hypothesis when assessing attention bias effects in PI following successful CBTi intervention. Indeed, often people successful in improving sleep quality following CBTi report that they have ongoing concerns about returning to their previous poor sleep status, although presently they are satisfied with, and refreshed by, their sleep quality. This could be taken as evidence that the craving component of attaining good sleep has been lost, as good sleep has been achieved, but the threat posed by possible poor sleep returning is still present. Assessment of the effect sizes generated within this group of PI would provide further insight into the possibility that craving plays a significant role in driving the observed attention bias effect in the PI population.

The average QRS for GAD was higher than the average QRS for PI, M = 5.6 and M = 4.5 respectively. The main criterion that differentiated the groups on QRS scores was the inclusion of a clinical sample, as all GAD studies recruited clinical samples whereas all PI studies did not. In addition, all GAD studies reported standarised diagnostic systems to qualify group status whereas three studies within the PI papers did not. Despite these methodological advantages, higher QRS was not predictive of larger effect sizes, between, or indeed, within groups. This is not surprising however, as although the QRS provided a general rating for the quality of each study, it is important to acknowledge that other factors that were not included in the limited list of criteria may have been contributing to study outcome and thus over all effects. Sample sizes within the PI studies were, on average, higher than sample sizes within the GAD studies, N= 38 (PI),

N = 22 (GS), N = 18 (GAD), N = 20 (control), respectively. **Table 4** summarises these average comparisons for PI and GAD.

INSERT TABLE 4 HERE

A further methodological advantage, for all GAD studies, in comparison to the PI studies, relates to the manipulation of stimulus presentation time within the paradigm. As previously reported within the PI section, all of the available studies only incorporated stimulus presentation times that would allow for the assessment of supraliminal attention, and therefore, all findings must be interpreted with some caution. More specifically, it is uncertain at present whether attention bias effects in PI would extend to the subliminal condition, and therefore firm conclusions regarding the specific origins, and processes, through which attention bias in PI exist are still largely unknown. However due to the comparable nature of the supraliminal attention bias effects for each disorder, one could predict that the subliminal attention bias effects would also be comparable. The testing of this hypothesis would be easily achieved, as the methodologies of the previous studies would remain largely the same, with the subtle difference being a change to the stimulus presentation time. Indeed, future research

within the PI and attention bias literature should attempt to isolate this subliminal phenomenon.

OVERALL CONCLUSIONS

At the outset of this current review three specific aims were identified 1) to provide conclusions relating to the stability of the attention bias effect in PI, 2) to highlight the most effective methodologies utilized when assessing for attention bias in PI, and 3) to identify whether attention bias effects in individuals with PI are comparable to attention bias effects in those with GAD.

This review has highlighted more information than is encapsulated by these aims, however answers relating to the specific aims will be highlighted below. First, attention bias effects in PI populations appear to be a relatively stable phenomenon, with over three quarters of studies reporting evidence in favour of the existence of the phenomenon. The stability of this finding, and the notion that it offers an objective index of sleep-related cognitive arousal, suggests that attention bias could potentially serve as a 'cognitive marker' of the PI disorder, and could potentially play a role within diagnosis (Espie et al., 2006). However, in order to clarify its' stability within clinical samples, future research should focus on recruiting large clinical samples, as, to date, only non-clinical populations have been assessed. Indeed, the lack of data relating to clinical samples within PI experimentation is a common limitation of the PI literature. It is essential that future studies should assess samples of clinical patients in order to reduce the high presence of disorder co-morbidity that is often seen within insomnia

groups. Through doing this, sleep researchers will be better placed to argue that the attention bias effects observed within the PI population are truly reflective of the sleep disorder per se rather that as a consequence of an underlying disorder.

In addition, Taylor et al. (2003) reported the absence of attention bias in acute secondary insomnia relative to chronic secondary insomnia, which suggests that the attention bias phenomenon develops over the prolonged experience of insomnia symptoms. With this in mind, future studies should aim to address the question of whether psychological treatment impact upon the cognitive profile of chronic insomnia, specifically, reducing the attention bias effect. Indeed, attention bias effects reduce following CBT therapy for generalized anxiety disorder (Mathews et al., 1995, Mogg et al. 1995). Demonstrating that established psychological treatments such as CBTi impact on attention bias in PI would add further strength to the argument that such biases play a critical role in the development and maintenance of the chronic disorder.

Secondly, although all the paradigms within this current review assessing attention bias in PI, with exception of the Mixed Modality, generated significant effects, the single criterion that differentiated large effect sizes from small and medium effect sizes was 'stimulus type'. More specifically, pictures, as opposed to words, produced the large effects sizes (Woods et al. 2009, Marchetti et al. 2006). This finding is supported by the previous suggestion that pictorial stimuli can evoke responses that are more likely to mimic those in real life situations as compared to semantic representations of the same stimuli. Townshend et al., (2001) demonstrated that pictorial and semantic versions of a

Dot-probe task, given to the same experimental population, resulted in inconsistent data. More specifically, attention bias for alcohol-related stimuli were revealed in heavy social drinkers when using a pictorial version of the dot-probe, a result that was not replicated when using the written word version. The authors suggested that this maybe due to the fact that pictures, which in this case represented concrete rather than abstract alcohol-related representations, are more salient to the individual, and thus, more sensitive in generating attention bias (Townshend et al, 2001). Thus, a common limitation of the GAD studies relates to the fact that little research has attempted to incorporate varying stimulus presentation types into the attention paradigms. If the use of pictorial stimuli can be used within GAD attention paradigm one could predict that an increase in effect sizes may be observed.

However, in addition, future experimentation should aim to differentiate people with PI from good sleepers through the use of a standardised diagnostic system, as at present three out of seven available studies failed to report such a procedure. Indeed, within the GAD literature all experimentation utilized the same two standardised diagnostic systems for group allocation. This standard approach to group allocation should be an aim of all future insomnia research.

It is important to acknowledge however that although effect size differences have been discussed in relation to QRS, a limitation of this current paper relates to the notion that other factors, which were not included in the limited list of QRS criteria, may have been contributing to the effect size generated from each study.

Finally, this review has highlighted that attention bias effects are observed within both PI and GAD populations when utilizing computerised attention paradigms. The stability of the phenomenon across both populations is similar, in that both have produced attention bias effects in 71% (PI) and 66% (GAD) of experiments. More specifically however, effect sizes from the PI studies are, on average, larger than those of GAD studies. However, GAD has significantly more data relating to both supraliminal and subliminal attention processes and thus future research within the PI literature should aim to extend the supraliminal effects into the subliminal domain.

The attention bias phenomenon within PI populations appears to represent a stable, objective, cognitive marker of the complaint. However, at present there is still much room for additional experimentation to help clarify the full nature and progression of this effect. With respect to the findings within this current review, future research concerned with attention bias in PI should aim to longitudinally track, within clinical populations, supraliminal and subliminal attention bias profiles, as well as it's response to CBTi treatment. This would serve to advance understanding about the development and maintenance of attention bias mechanisms within the PI population.

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Table 1. Individual Criterion Scores and Total Quality Rating Scores (QRS) for each individual paper**.**

Primary Insomnia	Age Matched	Gender Matched	Clinical Population	Standardised Diagnostic System	Standardised Paradigm	Mean and SD reported	Total QRS
Lundh et al., 1997	1	1	0	0 (none provided)	1	1	4
Taylor et al., 2003	1	0	0	0 (SOL)	1	1	4
Jones et al., 2005	1	1	0	0 (PSQI)	1	1	4
Marchetti et al., 2006	1	1	0	1 (DSM-1V & ICSD-R)	1	1	5
MacMahon et al., 2006	1	1	0	1 (DSM-1V & ICSD-R)	1	1	5
Spiegelhalder et al., 2008	1	1	0	1 (DSM-IV)	1	1	5
(a)	1	1	0	1 (DSM-IV)	0	1	4
(b)							
Woods et al., 2009	1	1	0	1 (DSM-IV & ICSD – R)	1	1	5
Generalized Anxiety Disorder							
Mogg et al., 1993 (Exp 1&2)	1	1	1	1 (DSM-III-R)	1	1	6
Bradley et al., 1995 (Exp 1&2)	1	1	1	1 (DSM-III-R)	1	1	6
Mogg et al., 1995 (Exp 1&2)	1	1	1	1 (DSM-III-R)	1	1	6
Mathews et al., 1996 (Exp 1&2)	1	1	1	1 (ADIS – R)	1	0	5
Bradely et al., 1999	1	1	1	1 (DSM-IV)	1	1	6
Mogg et al., 2000 (Exp 1&2)	1	1	0	1 (ADIS-R)	1	1	5

Table 2. Methodological details, QRS, attention bias reported and calculated effect size (PI vs. GS) for PI studies.

Study	QRS	Paradigm Utilized	Stimulus Type	Presentation Time	Comparison of interest	N (per group)	Other groups reported	Attention bias effect reported	Effect Size d
Lundh et al., 1997	4	Stroop	Words	Information not provided	PI vs. GS	PI=20 GS=20	N/A	No**	N/A
Taylor et al., 2003	4	Stroop	Words	500ms	Acute vs. Chronic insomnia secondary to cancer	A=18 C=15	N/A	Yes	-0.445
Jones et al., 2005	4	ICB Flicker	Pictures	OS (250ms) Mask (80ms CS (250ms)	poor vs. good sleepers	PS=32 GS=32	Moderate Sleepers	Yes	-0.470
Marchetti et al., 2006	5	ICB Flicker	Pictures	OS (250ms) Mask (80ms CS (250ms)	PI vs. GS	PI=30 GS=30	DSPS	Yes	-0.828
MacMahon et al., 2006	5	Dot Probe	Words	500ms	PI vs. GS	PI=21 GS-20	DSPS	Yes	0.3176
Spiegelhalder et al., 2008	5	Mixed Modality	Pictures	500-2500ms (M=1500)	PI vs. GS	PI=20 GS=20	Sleep-Expert Group	No	N/A
		Stroop	Words	500ms	PI vs. GS			No***	N/A
Woods et al., 2009	5	Modified Posner	Pictures	250ms	PI vs. GS	PI=22 GS=22	N/A	Yes	0.8672

* For Taylor et al., 2003 effect size reported relates to acute vs. chronic insomnia comparison.
** Although no between group effect, attention bias was reported for PI *and* GS towards sleep words.
*** Although attention bias effect was significant between PI and Sleep Expert group it was non significant in PI and GS comparison.

Table 3. Methodological details, QRS, attention bias reported and calculated effect size (GAD vs. Controls) for GAD studies.

Study	QRS	Paradigm Utilized	Stimulus Type	Presentation Time	Groups of interest	N (per group)	Other groups reported	Attention bias effect reported	Effect Size
Mogg et al., 1993	6	Stroop	Words	600ms	GAD vs. controls	gad = 19	Depression	Yes	r = -0.186
		Stroop	Words	14ms		cont = 18		Yes	r = -0.230
Bradley et al., 1995	6	Stroop	Words	600ms	GAD vs. controls	gad = 20	Co-morbid GAD and Depression	Yes	r = -0.221
		Stroop	Words	14ms		cont = 20		Yes	r = -0.169
Mogg et al., 1995	6	Dot Probe	Words	500ms	GAD vs. controls	gad =17	Depression	Yes	r = -0.1769
		Dot Probe	Words	14ms		cont = 15		Yes	r = 0.039
Mathews et al., 1996	5	Dot probe	Words	50ms	GAD, PD+-A vs. controls	gad = 25	Depression	No	N/A
						cont = 22			
Bradley et al., 1999	6	Dot Probe	Faces	500ms	GAD vs. controls	gad = 14	N/A	Yes	r = -0.165
				1250ms		cont = 33		No	N/A
Mogg et al., 2000	5	Posner	Faces	1000ms	GAD vs. controls	gad = 14 cont = 16	Depression	No (RT only)	N/A

Table 4. Comparison of mean values for PI and GAD.

	% Attention Bias Reported	Mean Effect Size (d)	Median Effect Size (d)	Effect Size range	Mean QRS	Mean N
PI	71%	0.585	0.47	0.55	3.57	PI = 38 GS = 22
GAD	66%	0.168	0.18	0.191	4.44	GAD = 18 Cont. = 20

CHAPTER TWO: MAJOR RESEARCH PROJECT

Investigating the Identification of Daytime Cognitive Deficits in People with Psychophysiological Insomnia Relative to Good Sleeper Controls, Using the Cognitive Failures Questionnaire and the Switching Attention Task.

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Abstract

Individuals suffering from psychophysiological insomnia (PI) commonly report the experience of daytime cognitive deficits, such as poor concentration and an inability to complete daily tasks. The published nomenclature is consistent and reflective of these subjective accounts. However, to date there is little, or idiosyncratic, evidence of both subjective and objective daytime deficits in people with PI. This current study aims to assess whether daytime deficits can be detected in a PI population, through the inclusion of The Cognitive Failures Questionnaire (CFQ), a novel subjective report measure assessing everyday cognitive slips in functioning, and the Switching Attention Task (SAT), an objective psychomotor assessment. This current study has demonstrated that both the CFQ and the SATcomplex differentiate a group of PI from good sleeper controls (GS). The study concludes that the CFQ is a useful inclusion to PI research and provides more detailed evidence relating to the occurrence of daytime cognitive deficits in PI, however a measure with a stable multifactor may be more beneficial in future research. In addition, the significantly poorer performance of PI on the SATcomplex is discussed in relation to high cognitive load rather than gross cognitive deficit, and results from a SATsimple task and Digit Span Task aid this discussion and support the conclusion that deficits in PI are observed in relation to tasks that require the simultaneous activation of multiple cognitive resources.

1. Introduction

1.1 Background

Individuals suffering from Psychophysiological Insomnia (PI) commonly report the experience of daytime cognitive deficits, such as poor concentration, poor memory, and decreased ability to accomplish daily tasks (Roth et al., 2003, Grunstein et al., 2002). Recent mass screening telephone surveys evidence that many people with untreated insomnia report being too tired to do things (78%), having trouble remembering things (59%), and report the experience of confused thinking and/or judgement (43%) (Ohayon et al., 2004, Carney et al., 2006). The published nomenclature (International Classification of Sleep Disorders - ICSD-2) is consistent and reflective of these subjective accounts from people suffering the PI disorder, and include these phenomenon in its description of insomnia as a disorder; *the sleep complaint must occur in association with adequate opportunity for sleep and the complaint of impaired daytime function (e.g., difficulties with attention, and memory, and/or diminished vocational functioning)*(American Academy of Sleep Medicine, 2005).

Research examining these deficits in daytime functioning, in individuals with PI, has increased significantly within the last ten to fifteen years. Indeed, both researchers and clinicians have acknowledged that people with PI commonly report that the negative impact to quality of life, associated with the daytime deficits, often out ways the night-time frustrations associated with sleep initiation and maintenance difficulties (Fichten et al., 1995, Morin, 1993, Rombaut et al., 1990). Indeed, in a recent review paper, Riedel and Lichstein (2000) reported that due to the frequency and intensity of the daytime

deficits reported by PI, insomnia treatments, that at present are evaluated at outcome through nocturnal sleep data, should also be evaluated at outcome by their effect on daytime functioning. However, this outcome measure, at present, is rarely considered in treatment efficacy studies.

Despite the consistency of patient self-report, and despite many authors utilizing both subjective and objective measures to isolate the daytime deficits in PI populations, studies have repeatedly reported inconsistent evidence for their detection. Indeed, studies have considered, various, domains of daytime functioning in attempts to capture the reported phenomenon i.e. daytime sleepiness, fatigue, physiological arousal, psychopathology, general functioning and most recently cognitive and psychomotor tasks. A brief outline of relevant literature focusing on these domains is provided below.

1.2. Daytime Sleepiness

Many studies have considered daytime sleepiness as an indicator of daytime deficit in PI populations, and within this literature the Multiple Sleep Latency Test (MSLT) has become the gold standard by which sleepiness is measured. In the MSLT, participants are given the opportunity to nap for 20minutes on four or five occasions during the daytime, and are instructed to attempt to fall asleep at each nap opportunity. The faster the participant falls asleep, the greater the sleepiness inferred. However, within the PI literature, many studies utilizing this measure have found no significant difference between PI and controls (Edinger et al., 1997, Lichstein et al., 1994, Mendelson et al., 1984, Pedrosi et al., 1995, Seidel et al., 1984, Stepanski et al., 1984, Sugerman et al.,

1985, Gass et al., 2001, Guilleminault et al., 2004), thus failing to confirm the predicted hypothesis that daytime sleepiness would reliably differentiate PI from control groups. Subjective daytime sleepiness has also been examined using the Stanford Sleepiness Scale (SSS), which measures state sleepiness on a 7-point scale, and the Epworth Sleepiness Scale (ESS), which asks respondents to rate the likelihood of falling asleep in eight situations. In over half of the studies, utilizing the SSS, PI report greater subjective sleepiness as compared to controls (Fichten et al., 1995, Hauri et al., 1997, Lichstein et al., 1992, Lichstein et al., 1996, Mendelson et al., 1984, Schneider-Helmert, 1987, Zammit et al., 1999, Danker-Hopfe et al., 2001, Alapin et al., 2000, Ohayon et al., 2002, Belenky et al., 2003,). However, these studies recruited older adult populations and college populations, and therefore researchers have argued that the direction of results may be more suggestive of differences in lifestyle factors i.e. daytime napping, which is commonly reported in these populations, than concrete evidence of daytime sleepiness. Interestingly, in a study of middle-aged working adults assessed on daytime sleepiness by the ESS, no PI/GS group difference was observed (Seidel et al., 1984), whereas in two studies of college- aged adults, assessed also by the ESS, greater subjective sleepiness within the PI population was observed (Lichstein et al., 1992, Alapin et al., 2002). Taken together, these data sets would support the prediction that lifestyle factors in populations that have greater opportunity to nap during the daytime may interfere with the reporting of daytime sleepiness, and thus cannot be used as a reliable indicator of real daytime deficit.

Furthermore, the experience and subsequent measurement of daytime sleepiness in people suffering from PI does not provide scope for identifying the specific areas of daytime functioning that PI experience deficits or the frequency of which they occur. The general concept of sleepiness is useful in interpreting the overall feeling experienced by PI throughout the day as a consequence of poor sleep, but it does not provide detailed information about areas of functioning within which PI experience cognitive failures, or the frequency with which they occur.

1.3. Fatigue

The experience of fatigue, commonly reported by individuals with PI, provides slightly more robust findings in relation to group differences between people with PI and controls. Investigators have used a variety of scales to measure fatigue in PI populations, including the Fatigue Severity Scale (FSS, Krupp et al., 1989), the Fatigue Scale of the Profile Mood States (POMS, McNair et al., 1981) and a rating scale measuring how many days per week fatigue is experienced because of a lack of sleep (Fichten et al., 1995). Over half of the studies comparing people with PI relative to controls have found that people with PI reported significantly more fatigue (Hauri et al., 1986, Lichstein et al., 1997, Means et al., 2000, Fichten et al., 1995, Dodd et al., 2004), with other studies showing trends in the same direction but without reaching significance (Bonnet et al., 1995, Seidel et al 1984, Stewart, et al., 2006). Indeed, a significant fatigue difference is a more consistent finding than subjective sleepiness scores. However, it is premature to conclude that daytime fatigue is consistently more associated with insomnia, as the only three studies that included both subjective fatigue and sleepiness measures found higher

levels of fatigue and sleepiness in people with PI (Fichten et al., 1995, Means et al., 2000) or no significant difference between PI and GS groups on both measures (Seidel et al., 1984). Therefore, when subjective fatigue and sleepiness are measured within the same sample of people with PI, similar results are found for each measure. In addition, as previously discussed in relation to measurements of sleepiness, although the measurement of fatigue is helpful in understanding the general physical and mental feelings experienced by PI during the day, no detail with regards to the physical and mental consequences of this fatigue is provided.

1.4. Measures of Psychopathology

Numerous studies have utilized measures of psychopathology in attempts to provide possible explanations for the daytime complaints reported in PI. Such studies have yielded inconsistent results. The Minnesota Multiphasic Personality Inventory (MMPI, Hathaway and McKinley, 1967) has been used most commonly to compare depression and anxiety symptoms in individuals with PI and controls. This literature includes various studies that report significantly higher depression and anxiety in populations of PI (Kales et al 1983, Levin et al., 1984, Levin et al., 1984, Coursey et al., 1975, Schneider-Helmert, 1997, Maurizio, 2004, Stewart et al., 2006, Chellappa et al., 2007). However, many other studies fail to report significant differences between the groups (Bonnet et al., 1995, Seidel et al.,1984, Bonnet, 1995., Jones et al., 2006). Taken together, however, with results from other psychopathology scales used within the PI literature, namely the Beck Depression Inventory (BDI), the Profile of Mood States (POMS), and that trait portion of the State-Trait Anxiety Inventory (STAI-T), data sets

suggest that mildly elevated depression and anxiety levels exist in people with PI relative to controls. However, as a large proportion of the literature does not reliably differentiate groups one must be cautious to conclude that elevated psychopathology is wholly responsible for the daytime deficits reported by PI populations. Furthermore, often co-morbid psychopathology is absent in PI populations, but daytime deficits are still reported. This provides further evidence that psychopathology cannot account for all daytime deficits experienced in PI populations.

1.5. Physiological Arousal

Studies considering physiological arousal as a proxy for differentiating people with PI and controls have executed, pupillometry comparisons, metabolic rate comparisons, temperature comparisons and pulse rate comparisons. Each comparison has reported largely inconsistent results. Indeed, measures used to compare physiological arousal between groups have found a mixture of increased arousal in PI (e.g. Lichstein et al., 1992, Ellen, 2007), decreased arousal in PI (e.g Bonnet et al., 1995, Cirelli, 2006), and no between group differences (e.g. Adam et al., 1986, Kraemer et al., 2001). Thus, authors conclude that physiological arousal is unlikely to account for the daytime deficits reported by individuals with PI.

1.6. Psychomotor and Neuropsychological Tasks

Several studies have utilised cognitive psychomotor and neuropsychological tasks to examine daytime functioning in people with PI (e.g. Bonnet et al., 1995, Church et al., 1979, Edinger et al., 1997, Hauri, 1997, Mendelson et al., 1984, Pedrosi et al., 1995,

Schneider-Helmert, 1987, Seidel et al., 1984, Sugerman, 1985, Vignola et al., 2000, Edinger et al., 2003, Schneider et al., 2004, Orff et al., 2007, Edingder et al., 2008). These tests extend the measurement of daytime deficits in PI to the objective domain. Typically, these studies have used a number of cognitive measures to compare groups following a night of polysomnography (PSG); i.e. digit symbol substitution, pegboard test, card sorting, addition, logical reasoning, divided attention, visual vigilance, line tracing, long term memory, short term memory, simple reaction time tasks, complex reaction time tasks, continuous performance task, and auditory vigilance. Mixed data sets have been reported for short term memory (Church et al., 1979, Mendelson et al., 1984, Hauri, 1997,), long term memory (Mendelson et al., 1984), simple reaction time (Mendelson et al., 1984, Edinger et al., 1997, Hauri, 1997, Scheider et al., 2005), complex reaction time (Pedrosi et al., 1995, Hauri, 1997, Edinger et al., 2003), continuous performance task (Mendelson et al., 1984, Edinger et al., 1997, Edinger et al., 2003, Varkevisser, et al., 2005), auditory vigilance (Schneider-Helmert, 1987, Sugerman et al., 1985, Hauri, 1997, Vignola et al., 2000). However, variations in the methodological procedures utilized within these studies, is largely variable. In addition, no significant group differences have been reported for any other measure.

In one of the most recent studies (Orff et al., 2007), Orff and colleagues investigated both subjective and neuropsychological measures of daytime impairment in people with PI and good sleepers (GS), with the aim to assess whether the groups differ on both measures, and the extent to which subjective and objective measures provide discordant information. Overall, the PI group reported worse sleep, diminished activity levels, and a

greater number and severity of daytime complaints. However, the PI group did not show deficits on neuropsychological measures (i.e. motor speed, attention, verbal fluency, verbal learning and memory), and these neuropsychological measures were not associated with severity of daytime complaints. Additionally, PSG data did not significantly differ between PI and GS and thus the authors report this lack of objective group differentiation as a clear limitation to the study. However, the authors also acknowledge that even if the experimental groups had been objectively validated, the neuropsychological tests selected may not have been sensitive enough to pick up group differences. When considering this point in further detail, it seems appropriate to hypothesis that within a PI population one would not expect gross cognitive deficits but rather mild deficits which would require employment of sensitive neuropsychological assessment measures capable of capturing subtle but significant group differences. From the neuropsychological perspective there is therefore a lack of adequate characterisation of the cognitive deficits shown by PI, due in part, arguably, to inadequate measures applied.

The most recent study assessing deficits in neuropsychological assessment performance in people with PI also highlight the limitations of previous methodologies, mainly discussing the employment of a limited range of neuropsychological tests, as well as commenting on small and poorly characterised samples (Edinger et al., 2008). Within this study, a large well-characterised PI group represented the experimental population, and predictions were made that this group would perform significantly worse than GS group on neuropsychological performance measures with group differences being most

obvious on more complex tasks. Thus, this study took into account the suggestion that sensitive neuropsychological assessment may be required to observe daytime deficit in PI populations. The neuropsychological assessment battery included a simple reaction time test, a continuous performance test (sustained attention) and two switching attention tests (SAT), with the view that these represent a hierarchy of complexity, with the latter of the two SAT being the most complex. Additionally, it was predicted that measures of daytime sleepiness, as measured by the MSLT and SSS, would also differentiate the PI group from the GS group, with PI being significantly sleepier than GS. The authors concluded that group differences were only observed on the most complex neuropsychological task (SAT). The authors suggest that because this complex SAT involved concentration, attention, response inhibition and decision-making processes, thus generating a high cognitive load, this collection of abilities may closely approximate the deficits PI sufferers present clinically when they complain of an inability to concentrate and a general lack of mental sharpness. In addition, the authors suggest that tests like the SAT, that engage a number of cognitive resources, may be required to identify performance deficits in PI sufferers (Edinger et al., 2008). This observed performance deficit in PI in response to a complex SAT assessment is a useful finding, as it highlights the possibility that PI experience daytime deficits when numerous cognitive functions are drawn upon simultaneously. Indeed, previous failure to capture deficits in PI using more global measures of cognitive functioning e.g. memory, is not surprising, because if gross cognitive failures were the consequence of poor sleep, then obvious slips in daytime functioning would be readily observed across the PI population. However, the authors also acknowledge that future experimentation

should aim to replicate this novel finding with other PI populations before firm conclusion can be drawn.

Subjective assessment of daytime sleepiness was inconsistent within this study. More specifically, PI scored as being more alert in the MSLT than the GS controls, a finding contradictive to the hypothesis. However, the PI group did report significantly greater sleepiness ratings than GS, as measured by the SSS. Edinger and colleagues suggest that the direction of the MSLT and SSS data reflects the hyper-aroused nature of the PI population, and their inability to de-arouse during the sleep initiation process despite higher levels of sleepiness. However, inconsistencies between objective and subjective measures of daytime deficits in PI are not overly surprising. Indeed, if we are to consider the nature of the objective and subjective assessment measures for daytime deficits in PI i.e. highly specific (objective) versus general concept (subjective questionnaire), it is not surprising that they fail to associate with each other. Indeed often in clinical practice objective and subjective accounts fail to correlate with one another. Furthermore, often subjective measures of complaint produce higher effect sizes between groups than objective measures, and this reflects the ability for subjective questionnaires to capture the more general concept of the complaint as opposed to it's specific features. The SSS and MSLT also have limitations with respect to the nature and specificity of the information they capture. More specifically, although both provide general measures of experienced sleepiness, neither measure produce detailed information relating to the specific daytime situations within which deficits occur, or the frequency within which PI experience cognitive deficits. Indeed, inclusion of a more detailed subjective measure,

which is sensitive to capture commonly experienced daytime failures across clinical populations, would be a useful and novel inclusion to PI research.

Thus, the inconsistency of the available literature utilizing cognitive neuropsychological tasks adds value to the administration of a standardised complex neuropsychological task in attempts to objectively evidence daytime cognitive deficits in people with PI relative to good sleeper controls (GS). Indeed, administration of computerised neuropsychological tasks that have been standardised across various populations is novel within the PI literature. As the previous literature suggests that complex neuropsychological tasks, that engage multiple cognitive resources simultaneously, are sensitive enough too differentiate PI from GS, a complex SAT will be examined within this current study. Furthermore, as previous research assessing cognitive neuropsychological performance in PI have only included indices that capture the subjective reporting of daytime sleepiness, the inclusion of a structured self-report measure that adequately captures everyday cognitive failures would be advantageous. Indeed, with respect to the previously mentioned nomenclature, which highlights the failures in vocational functioning that are experienced daily in PI populations, it seems that the inclusion of a validated and reliable subjective self-report measure, specifically assessing failures in everyday daytime functioning, would be an appropriate and novel inclusion to PI research, and would be sensitive in differentiating PI from GS.

2. AIMS AND HYPOTHESES

2.1 Aims

This current research aims to profile, evaluate and compare self-reports of everyday cognitive performance and objective psychometric neurocognitive performance in people with PI relative to GS controls.

2.2 Hypotheses

1) PI and GS will significantly differ on subjective measure of daytime deficit, with PI reporting significantly more cognitive failures relative to GS.

2) PI and GS will significantly differ on objective measure of daytime deficit, with the PI performance being significantly poorer relative to GS.

A secondary question within this current study will explore whether standardised relative effect size between PI and GS on the self-report measure will be larger than the standardised relative effect size for the objective measure. (Cohen's effect size; large = 0.8, medium = 0.5, small = 0.2).

A final question within this current study will explore the extent to which there is a relationship between the highly specialist assessment of cognitive deficit (i.e. objective assessment) and the more general concept of cognitive failures (subjective assessment).

3. METHOD

3.1 Design

This study is a cross-sectional between groups experimental research design. The initial analysis will assess between group differences on subjective and objective measures of daytime deficit, i.e. a 2x2 entirely between group comparisons with covariates entered if appropriate to control for e.g. age. The relationship between the subjective and objective measures will be examined using a correlation analysis. Scores on the subjective and objective measures will act as the dependent variable.

3.2 Inclusion and exclusion Criteria

3.2.1 Selection Criteria for All Participants

All subjects were required to be medically healthy and free from substance abuse problems, psychiatric disorders and sleep disorders (other than PI), as assessed by the screening interview.

3.2.2 Selection Criteria for Psychophysiological Insomnia

Participants were required to meet combined DSM-IV-TR and ICSD-R criteria for primary insomnia of the PI type, and were required to score > 6 on the Pittsburgh Sleep Quality Index (PSQI) with a self confessed sleep disruption of greater than 6 months. The PSQI and is a standard measure, and was recently endorsed at an NIH-sponsored Consensus Meeting to establish a 'core' assessment battery for use in insomnia research studies (Buysse et al., 2006).

3.2.3 Selection Criteria for Good Sleepers

Good sleepers were required meet Research Diagnostic Criteria (RDC) for good sleep. GS were required to score < 5 on the PSQI, and report themselves as being 'good' sleepers. In brief, they were required to have no history or symptoms of sleep disorder and report that they obtain enough restorative sleep. GS exclusion criteria also included good sleep quality as a result of active psychological or drug intervention.

3.3 Sample Size Estimation

Research to date examining subjective and objective cognitive functioning in populations with PI has varied greatly from 15 (Krupp et al. 1989) to 98 (Seidel et al. 1984). To date, the relationship between the CFQ and PI has not been specifically examined; therefore a conservative estimate of a medium effect size was adopted (d=0.5). Using the G * Power 3 (Faul *et al.*, 2007) software programme, with a medium effect size of r=0.5, β =0.80 and α= 0.05, a total sample size of N=149. Given the strict exclusion and inclusion criteria and resulting homogeneity of the participant group, as well as the adequate reliability and validity of the primary measures being utilised, it was expected that this sample size would be sufficient to detect differences if they exist.

3.4 Participants

Twenty-six PI and 26 gender and education level matched GS were included in analysis. All had English as their first language. Recruitment of the PI participants followed the University of Glasgow Sleep Centre (UGSC) core generic approach to recruitment, which included recruitment from 1) the local sleep disorder services 2) via

advertisements in local news papers, television broadcasts and radio interviews and 3) directly from 20 local primary care practices through coordinator SPPIRe (Scottish Practices and Professionals Involved in Research). The UGSC laboratory based screening of the PI participants also followed a generic protocol. One hundred and twelve interested participants were called by the primary investigator for telephone screening. Of these one hundred and twelve PI participants thirty-nine were recruited to the current study. Exclusion of participants at this stage resulted from 1) sleep disorders other than PI, 2) disinterest in entering the current study, 3) co-morbid physical or mental illness and 4) travelling costs. Of the thirty-nine recruited to the current study, nine failed to attend the subsequent testing appointment at the UGSC and four participants were excluded from analysis due to the PSQI score being <5.

The good sleeper (GS) group within this current study represented a convenience sample. This group consisted of the partners of people with PI who enrolled into the current study, as well as members of staff at the Sackler Institute of Psychobiological Sciences at the Southern General Hospital in Glasgow.

3.5 Measures and Materials

An overview of all measures, including measures used for diagnostic ascertainment of sleep quality, is presented in Table 1.

INSERT TABLE 1 HERE

3.5.1 Demographic

Demographic information include age, gender, and number of years in education.

3.5.2 Diagnostic Ascertainment of Sleep Quality.

The UGSC laboratory based screening of the PI participants follows a generic protocol. Participants interested in taking part in research at the UGSC are instructed to call the UGSC recruitment telephone number. This number diverts to a voicemail facility, which instructs participants to provide their name and telephone number in order for the primary investigator to return their call and administer a telephone-screening interview (Appendix 2.2). During the period of recruitment for this current study, over one thousand calls were made to the recruitment telephone-number. One hundred and twelve interested participants were called by the primary investigator for telephone screening. Each participant was interviewed with the telephone-screening interview to evaluate his/ her typical sleeping pattern. The telephone-screening interview consists of a comprehensive assessment of sleep quality, physical health and psychiatric health. The interview is constructed around the DSM-IV-TR and ICSD-R standardised diagnostic systems for insomnia, and asks questions in relation to the inclusion/exclusion criteria for the current study (See section *3.2* for inclusion/exclusion criteria). Completion of the interview took, on average, approximately twenty-five minutes. Upon completion of this

interview, the primary investigator either invited the participant to take part in the current experiment, or thanked the participant for their time but informed them that they did not meet criteria for the current experiment. Those who did not meet inclusion criteria were given the option of having their details stored on a generic database in order for possible enrolment in future studies at the UGSC. Additionally, the Pittsburgh Sleep Quality Index (PSQI; (Buysse et al., 1989) was used to confirm group allocation.

Participants also completed a standard sleep diary (Espie, 1991) for seven nights prior to the experiment, again to aid in confirmation of group assignment (Appendix 2.3). The sleep diary is a short questionnaire that is completed upon wakening. This questionnaire provides important information about the participant's personal subjective account of their previous nights sleep. The sleep diary provides information to the experimenter about the participants subjective Sleep Onset Latency (SOL – how long it takes participants, in minutes, to fall asleep at night), Total Sleep Time (TST – How long, in hours, did the participant sleep in total during the night) and Wake Time After Sleep Onset (WASO – How long the was the participant awake for during the night, in total).

3.5.3 Additional Sleep Measures

Each participant also completed the Stanford Sleepiness Scale (SSS). The SSS is a self-report rating of state sleepiness i.e. how sleepy the participant feels at the current time. This was recorded immediately prior to the onset of the neuropsychological assessment battery to establish the patients perceived sleepiness at time of assessment.

3.5.4 Assessment of Psychopathology

Psychopathology was evaluated using the telephone-screening interview, the Quick Inventory of Depressive Symptoms and the Spielberg State-Trait Anxiety Inventory.

The Quick Inventory of Depressive Symptoms (QIDS, Rush et al. 2003) is a 16-item questionnaire designed to assess the severity of depressive symptoms. The QIDS is available in the clinician (QIDS-C16) and self-rated versions (QIDS-SR16). The latter was employed in this current study. The QIDS assess all the criterion symptom domains designated by the American Psychiatry Association Diagnostic and Statistical Manual of Mental Disorders - 4th edition (DSM-IV) (APA 1994) to diagnose a major depressive episode. This assessment can be used to screen for depression, although they have been used predominantly as measures of symptom severity.

The Spielberg State-Trait Anxiety Inventory is a reliable and valid scale of both state and trait anxiety. This measure is not used as a diagnostic tool, but rather to aid in capturing symptom severity. Alpha coefficients (STAI-S α =. 93 & STAI-T α = .90) reflect strong internal consistency and construct, concurrent, divergent and convergent validity have also been demonstrated (Spielberger, 1983).

3.5.5 Subjective Daytime Deficit Measure

In order to assess everyday cognitive performance problems, a measure was sought that would be valid for this purpose. The Cognitive Failures Questionnaire (CFQ, Broadbent et al., 1982) was selected because it was specifically developed to measure self-reports

of real life problems of this type. The CFQ has been reported to have good discriminant validity as it has demonstrated to differentiate the frequency of cognitive failures, as compared to healthy controls, in depression (Wagle et al., 1999), the elderly (Knight et al., 2004), multiple sclerosis (Phillips et al., 2009) and individuals who are suffering from stress (Broadbent et al., 1982). It was predicted that the CFQ would be sensitive in detecting differences between PI and GS groups. The CFQ is typically used as a unitary scale, and support for this comes from Broadbent et al., (1982), who conducted a number of factor analytic studies and concluded that there was good evidence for a general factor, but that the multifactor structure was unstable. The response format uses a 5-point likert-type scale (0=never, 4=always). Scores for the CFQ can range from 0 to 100 with higher scores signifying a greater number of cognitive failures. Assessment of the CFQ with the general (healthy) population suggests that scores between 25 and 35 are typical (Wagle et al., 1999). All items on the CFQ are positively correlated with each other and the CFQ has good concurrent validity and been correlated with several other measures: Short Inventory of Memory Experiences (r=.74; Martin, 1983), Absentmindedness in Shops Questionnaire (r=.46; Reason & Lucas, 1984), and Cognitive Interference Questionnaire (r=.34; Yates et al., 1985). The CFQ has been demonstrated to have high internal consistency, $\alpha = .90$, which further supports its use as a single construct measure (Broadbent et al., 1982).

3.5.6 Objective daytime Deficit Measures

Several factors were taken into consideration in selecting measures in this domain. First it was important to select a task that would represent the complex cognitive challenge

that has proven to discriminate PI in previous studies. The switching attention task (SATcomplex) was chosen as it has recently been reported to differentiate PI from GS controls (Edinger et al., 2008). The SATcomplex was employed because it involves sensory-motor, attention, concentration and executive functioning, a range of cognitive processes that generate a high cognitive load. As it is assumed that PI experience daytime failures in tasks that rely on a high cognitive load, it is assumed that the performance of PI will be significantly poorer relative to GS. In the SATcomplex, alternating numbers and letters must be connected in chronological sequence on a touch screen (Figure 1).

INSERT FIGURE 1 HERE

Second, it was important to have a comparator task, within the same domain, to establish whether or not it was complexity as such that was responsible for any observed effect. Thus, the SATsimple was also completed. In the simple version, numbers appear on the touch-screen and the participants must connect the numbers sequentially in chronological order. The inclusion of the SATsimple task was to aid in the interpretation of the SATcomplex results. More specifically, as the SATsimple is the closest task control to the SATcomplex, however the SATsimple requires fewer cognitive functions

therefore it is not expected to differentiate PI from GS, thus supporting the argument that high cognitive load leads to observable deficits in PI populations.

Finally, having considered the importance of attentional measures, it was important to control for the possibility of any general cognitive differences being responsible for effects. A standard memory task was thought to be appropriate here. Thus, participants also completed a Digit Span Task. Within this task, participants are required to remember a list of numbers that are presented on the screen. The list of numbers is presented for a few seconds before disappearing from view. Participants are required to type on a keypad on the touch screen the list of numbers that had previously appeared. The list of numbers increases by one number on every second trial. This task has a 'forward' version within which the participant has to type the numbers in the sequence they appeared on the screen, and a 'backward' version, within which the participant is required to type the numbers in reverse sequence to how they appeared on the screen. This task is a test of working memory, which represents a gross cognitive function. Inclusion of a digit span task is again to aid in the interpretation of the SATcomplex results. More specifically, its inclusion is a further manipulation check to assess cognitive functioning across domains of measurement, and support the prediction that that daytime deficits in PI are observed when there is a high cognitive load, rather than a gross deficit in cognitive functioning. Thus it is predicted that the Digit Span Task will not differentiate PI and GS groups.

The SATcomplex, SATsimple and Digit Span Task are part of a full neuropsychological assessment system called Integ-Neuro. This system was chosen because it is automated standardised neuropsychological assessment package that is currently recognised and utilized by more than one hundred and thirty laboratories worldwide[1]. The Integ-Neuro system provides behavioural measures of the five core general cognitive domains; sensory-motor, attention, memory, language, executive function and social cognition. One advantage of the Integ-Neuro assessment battery relates to it's standard procedure for test administration. It escapes the limitation of clinician error in delivering the tests. All data generated from the Integ-Neuro is automatically uploaded to a central database. Researchers can request data sets and carry out clinical comparison. Within this current study, only the data generated from the PI and GS recruited for the study purpose were requested for analysis. The battery consists of sixteen different tasks, however this current study was concerned with only the SATcomplex, SATsimple and Digit Span Task.

Participants recruited to the study completed the objective assessment under controlled conditions in the same quiet isolated 'bedroom' laboratory with the UGSC. Testing sessions occurred between the hours of 09:00 and 16:00 at a time convenient to the participant. Research has shown that circadian phase has no effect of daytime cognitive performance in PI compared to GS and thus timing of testing was not deemed to be a necessary control (Varkevisser et al., 2005).

[1] The INTEG NEURO system follows a standard procedure. This manual for the procedure can be found in Brain Resource Cognitive Setup Guide (accessed via www.brainresource.com)

3.6 Procedure

Participants who where invited to take part in the current study following the telephone screening interview, arranged, with the principle investigator, a suitable time to attend the UGSC for testing. Additionally at this time, a participant information sheet, a participant consent form, a PSQI and a sleep diary were posted to the participant's address. Participants were requested to complete this documentation and bring it with them on the scheduled day of testing.

Upon arrival at the UGSC participants were greeted by the principle investigator and taken to a quiet 'bedroom' laboratory where the Integ-Neuro system was assembled. Before sitting at the Integ-Neuro touch-screen, participants were asked to return the documentation that had been posted to them and were given the opportunity to ask any questions. Following this, the participant was asked to complete the Stanford Sleepiness Scale. Subsequently the participants were asked to complete the Integ-Neuro assessment battery. At the end of the assessment battery, participants were offered a brief rest before being asked to complete the CFQ, QIDS, and STAI. After completion of the named questionnaires each participant was instructed that this was the end of the experiment. Each participant was then provided with an hour therapy session, within which the principle investigator discussed strategies that aim to improve sleep quality and duration. This session was based around Cognitive Behaviour Therapy for Insomnia. The whole procedure at the USGS took approximately two and a half hours.

3.7 Ethical Approval

Ethical approval for the project was granted from the Greater Glasgow and Clyde Primary Care Community & Mental Health Research Ethics Committee (See Appendix 2.4 for a copy of the approval letter).

4. RESULTS

4.1 Participant Characteristics

The mean age across all participants was 39.9 years with a total of 20 males and 32 females. Pearsons Chi-Square analysis indicated that the number of males and females was not different across groups (χ^2= .325, p = .57). Table 2 shows the demographic characteristics by group. The PI group was 12.4 years older than the GS group, a difference that was statistically significant, (t = 3.28, p < 0.01). It has previously been reported that age affects cognitive performance, thus it was predicted that within the current sample age would correlate to SATcomplex RT performance. A correlation analysis between age and RT scores on the SATcomplex was performed revealed a significant positive association between age and RT on the SATcomplex, (Pearson's r = .648, p< 0.01), with increasing age associated with a slowed RT. Thus, subsequent analyses of group difference were performed utilising an analysis of covariance (ANCOVA), with age as a covariate.

There was no difference between groups on education levels (as measured by total years in education), (t = .92, p = .36) although PI had a slightly larger mean number of years than GS. However, due to the fact that at the level of the individual there may be as

association between education level and cognitive performance, a conservative decision was made to control for education in the following ANCOVA analyses.

INSERT TABLE 2 HERE

4.2 Screening and Clinical Measures

The mean scores, standard deviations and group difference data for each screening and clinical measure are presented in Table 3. As expected, those in the PI group scored significantly higher on the PSQI than the GS group ($F(1, 50) = 64.5$, $p<0.0001$). On the sleep diary, Total Sleep Time (TST) was significantly lower in the PI group than the GS group ($F(1, 50) = 22.7$, $p<0.0001$). Wake Time After Sleep Onset (WASO) ($F(1, 50) = 14.6$, $p<0.0001$) was significantly higher in the PI group than the GS group, as was Sleep Onset Latency (SOL) ($F(1, 50) = 7.4$, $p<0.0001$). Thus, all diary data provided descriptive confirmatory support for group allocation. Scores from the sleep diary for the total number of hours slept on the night prior to testing revealed that PI slept significantly less than GS ($F(1, 50) = 21.8$, $p<0.0001$).

Scores on the QIDS, STAI-S and STAI-T were also in the expected direction with no significant differences observed between groups on either measure, ($p = .052$; $p = .415$; $p = .750$, respectively), therefore confirming good application of the exclusion criteria.

No significant differences were observed between the PI and GS groups in SSS score ($p = .232$).

INSERT TABLE 3 HERE

4.3 Experimental Data

Hypothesis;

1) PI and GS will significantly differ on the subjective measure of daytime cognitive deficit, with PI reporting significantly more cognitive failures relative to GS.

The Cognitive Failures Questionnaire was employed as a subjective account of daytime deficit. The ANCOVA produced a significant model ($F(3, 50) = 2.739$, $p = .054$). Neither covariate (age or education) contributed significantly (Appendix 2.5) As predicted the group main effect was significant, with the PI group reporting significantly more daytime cognitive failures than the GS group, ($F(1, 50) = 8.0$, $p<0.05$) (Table 3). The mean value of the GS control group is in line with previous data that report CFQ mean scores in the general, healthy, population lie between 25 and 35 (Wagle et al., 1999).

Assessment of internal consistency for the CFQ was also conducted. Cronbach's alpha of .95 indicate high internal consistency. When repeating this analysis for each item

deleted, alpha ranged between .947 and .951, this is in line with previous research (Broadbent et al., 1982)

2) PI and GS will significantly differ on the objective measure of daytime deficits with the PI performance being significantly poorer relative to GS.

i) SATcomplex

The ANCOVA produced a highly significant model ($F(3, 50) = 10.783$, $p < 0.0001$), with age contributing considerably ($p = 0.001$). However, there was still an effect of group ($F(1, 50) = 5.5$, $p<0.05$). Looking at the results descriptively, this group main effect reflects a mean difference of approximately 1 SD, with PI being significantly slower than GS as hypothesised (Table 4), (Appendix 2.5). Additionally, PI made significantly more errors than GS, ($F(1,50) = 5.8$, $p<0.05$). The calculated effect size for this comparison is $d = 1.3$.

ii) SATsimple

The prediction that PI, in comparison to GS, would be reliably impaired on the SATcomplex was based on the assumption that, when simultaneously engaging numerous cognitive functions, PI experience more deficits. To assess this prediction further an ANCOVA was also performed for a SATsimple, as the SATsimple is the most closely related control to the SATcomplex, however the SAT simple engages fewer cognitive functions. This secondary hypothesis predicted that no group differences would be observed.

The ANCOVA produced a significant model ($F(3, 50) = 3.369$, $p = .026$) with age as a significant contributory factor to explanatory variance in the equation ($p = .026$). However, in line with the hypothesis, there was no significant difference between the PI and GS groups ($p = .35$) (Appendix 2.5). Additionally, there was no significant group difference in error rates ($p = .243$) (Table 4). The calculated effect size for this comparison is $d = 0.4$.

iii) Working Memory

A final manipulation analysis of the experimental data was also carried out. This relates to the previous discussion that gross deficits in cognitive function are not predicted in the PI population, as it is postulated that deficits in PI performance will only relate to situations that simultaneously engage multiple cognitive resources. To assess this prediction, data relating to an assessment of memory, specifically working memory, was also analysed. It was hypothesised that no group differences would be observed.

The ANCOVA produced a non-significant model ($F (3, 50) = .407$, $p = .748$), ($F(3, 50) = 3.32$, $p = .802$), forwards and backwards version, respectively. Neither covariate contributed significantly for both versions (Appendix 2.5). Thus, as predicted, the results from the ANCOVA, controlling for age and years of education, revealed no significant differences between the PI and GS groups on digit span forwards, ($p = .40$), and digit span backwards, ($p = . 93$) (Table 4) (Appendix 2.5). The calculated effect size for this comparison is $d = 0.2$.

INSERT TABLE 4 HERE

3) The standardised relative effect size between PI and GS on the self-report measure will be larger than standardised relative effect size for the objective measure. (Cohen's effect size; large = 0.8, medium = 0.5, small = 0.3).

Effect sizes were calculated using the equation; d = M1 – M2/s and the online effect size calculator http://web.uccs.edu/lbecker/Psy590/escalc3.htm was used to complete the calculations. As predicted, effect on the variable for PI relative to GS was d =.48 for CFQ and d =.36 for SATcomplex. Therefore, the direction of the effect sizes between the two measures of daytime deficit is therefore in the expected direction with the CFQ producing a larger effect size than the SAT. In addition, effects on the variable for PI relative to GS was d = .28 for SATsimple and d =.21 for Digit Span Task.

Secondary Analyses

It was previously discussed that subjective measures of daytime deficits rarely associate to objective measures of daytime deficit. Thus, assessment of the relationship between subjective and objective measures of cognitive deficit was conducted.

A Pearson's correlation analysis was used to examine the relationship between the CFQ and SATcomplex, controlling for age and years of education. No significant association was observed (Pearson's r = .234, (r^2 = 5.5%), p = .271). Thus, the SATcomplex explains only about 5.5% of the variance in the CFQ. Analysis assessing the relationship

between each of the 25 items of the CFQ with the SATcomplex was also conducted. No significant correlations were observed.

5. DISCUSSION

This study aimed to assess the subjective reporting of daytime cognitive deficits and the objective performance on a standardised cognitive neuropsychological task in people with PI relative to GS controls. Three primary hypotheses were assessed, all of which were confirmed.

Firstly, in relation to the fact that previous neuropsychological research has only reported subjective accounts of daytime sleepiness, thus failing to provide any detailed information regarding the frequency of daytime deficits experienced by PI as a consequence of poor sleep, the inclusion of the CFQ to this current study was used to aid in the understanding of this daytime experience. Indeed, it was predicted that the CFQ measure would be sensitive enough to differentiating PI from GS as it enabled PI participants to individually rate twenty-five statements of everyday occurrences with respect to how commonly they make mistakes in each. The CFQ provided scope for capturing a more meaningful and detailed representation of the real life daytime consequences of insomnia. As predicted, the PI group reported significantly higher levels of daytime cognitive failures than the GS group, reporting overall a moderate level of cognitive failures.

Assessment of other clinical populations with the CFQ has previously been reported and comparisons with the findings from this current study can be made. Sullivan et al., (2007) reported scores on the CFQ for ninety-eight individuals with major depressive disorder. The mean score of fifty from this depressed clinical population is largely comparable with the mean score of forty-eight from the PI population within this current experiment, although the number of participant within this current study is significantly less than that reported in the Sullivan et al., study. The presence of depression within PI populations is high, and recent research has demonstrated that PI is often a precursor to depression (Chang et al., 1997), in that if the insomnia is left untreated depression is likely to develop. This suggestion leads to the consideration that the higher scores generated by the PI group within this current study might relate to the presence of depression within this population. However, no significant differences were observed between PI and GS on the QIDS, and neither the PI or GS groups scored within the moderate, severe, or very severe depression level, thus neither met clinical criteria for depression. In addition, screening on the telephone interview asked specific questions in relation to affective state, and inclusion to the study was dependant on both groups of individuals being free from clinical diagnosis of depression and anxiety and free from actively taking medication for associated psychopathology. Taken together, the absence of depressive symptomatology in the PI and GS groups, that would rate them above clinical threshold for diagnosis, suggests that the daytime deficits observed within the PI group are reflective of their poor sleep quality, rather than effects of underlying depressive psychopathology.

It is important to note that the depression measure employed within this current experiment incorporates questions relating to sleep symptomatology. On reflection, such a measure may skew results from PI groups as they are likely to score higher on these sleep questions that the GS control. This would result in the PI group appearing more depressed than the GS group, when in reality they are merely reporting the experience of sleep disruption, not sleep disruption as a consequence of depression.

It is also worth noting that in comparison to a clinical population with significant brain atrophy, e.g. individuals with multiple sclerosis who would unarguably have significantly more daytime cognitive failures than PI, the PI group within this current study reported significantly less daytime cognitive failures on the CFQ than this population (M=48, M=65, respectively), (Phillips at al., 2008). Thus it seems plausible that the self-reports of the PI group within this current study were reflective of their real life experience, rather than an over-reporting of symptoms, which is occasionally observed within PI populations. Taken together, the findings of Sullivan and colleagues reporting CFQ in another disorder of psychopathology and the findings of Phillips and colleagues reporting CFQ in a brain damaged population, suggest that the level of the CFQ scores from the PI sufferers in this current study are within a likely range.

The CFQ is often used as a unitary scale, as factor analytic studies have concluded good evidence for the general factor and evidence suggesting an unstable multifactor structure (Broadbent et al., 1982), thus analysis at the level of each individual factor was not recommended. However, future research may wish to devise a measure similar to the

CFQ, and suitable to PI research, which does have stable multifactor structure. Indeed, this would permit the assessment of individual responses to each scale item, which would aid in the examination of the specific situations, where deficits are reported, which are general across PI populations. If a specific item(s) is rated highly by a significant majority of PI respondents, future experimentation could consider the cognitive functions that are required for successful completion of that task or event represented by the item, and subsequent objective assessment of the same cognitive functions could be conducted. Indeed this would provide more isolated comparisons of the cognitive function deficits specifically reported by PI populations with objective assessment of the same cognitive functions. Indeed when considering the previous point that subjective and objective measurements often fail to associate due the highly specific nature of the objective measure and the generalised nature of subjective measures, assessment of subjective measures at item level could prove useful in the narrowing of it's general nature.

An interesting point within this current data set relates to the lack of group difference in SSS data. Indeed PI did not rate themselves as being more sleepy at time of testing than the GS control group. The lack of a significant difference here in comparison with the significant group difference on CFQ scores strengthens the argument for the inclusion of a more detailed self-report measure. Indeed, the disparity between the SSS and CFQ data within this current study highlights that the SSS is not an appropriate indicator of daytime cognitive deficit in PI. Furthermore, the fact that the PI did not report being

significantly more sleepy than GS suggests that a general sleepiness does not fully account for the daytime deficits that PI commonly report.

The second hypothesis within this current study predicted that people with PI would perform significantly poorer on the SATcomplex task than GS controls. This hypothesis was upheld as PI reaction time (RT) to task completion was significantly longer than the GS control group. Furthermore, PI made significantly more errors than GS. This outcome supports the findings of Edinger et al., (2008) who demonstrated that a large well defined sample of PI had longer RT latencies in the completion of a complex SAT assessment compared to GS controls. However, the Edinger et al. study did not provide information relating to the number of errors elicited by each group, so the identification of a higher error rate within the current study is novel to the PI literature. Inclusion of the assessment of error rates is important when interpreting the overall RT data. Indeed, when an error is made within the SAT tests, the participant must correct the response before being allowed to continue with the task. Thus, as the number of errors increase, RT time to completion would also increase. Therefore, without the information relating to error rate one might conclude that overall performance time is generally slowed in a PI population relative to controls, however, in reality, the overall performance time may be similar to the control but hindered by an increased number of errors. Furthermore, when considering other neuropsychological evaluation systems in relation to assessing cognitive deficits e.g. the Welschler Adult Intelligence Scale (WAIS IV) or Behavioural Assessment of the Dysexecutive Syndrome (BADS), both RT and error rate are often recorded. Indeed in both these named assessments, subtests targeting the performance of

attention, executive functioning and/or motor speed all require RT and error rate scores, as cognitive deficit is not identified by slowed performance per se but by a combination of slowed performance and increased error rate. In conclusion, the inclusion of both RT data and error rate data within this current study aid in the interpretation of the PI performance overall and highlights that error rates, which significantly impact on RT, are significantly higher in the PI population relative to controls. Indeed, this fits with the subjective accounts from PI populations who report that errors and mistakes in daytime tasks, as opposed to a general slowing of performance, is often reported as a major cause of concern and distress.

Inclusion of the SATsimple and Digit Span Task were to aid in the interpretation of the SATcomplex. More specifically, the SATsimple is the most closely related control to the SATcomplex, however the SAT simple engages fewer cognitive functions. If the prediction is correct, that PI perform significantly poorer on the SATcomplex due to the multiple cognitive resources utilized simultaneously, then it was assumed that performance on the SATsimple would not differ between groups. Put simply, the deficit in PI was not predicted to be in relation to switching attention per se, but rather in relation to the high cognitive load that only the SATcomplex requires. Results from the SATsimple test were in the expected direction, with no significant between group differences on both RT and error rate.

The Digit Span Task was included to represent the neuropsychological assessment of a more gross cognitive functioning i.e. working memory. Previous research assessing such

cognitive functioning in PI populations has failed to demonstrate differences from controls (Orff et al., 2007), indeed, it is unlikely that people with PI would develop gross deficits in one area of cognitive functioning as a result of poor sleep quality, as obvious slips in cognitive functioning would be widely observed within the population. The inclusion of the Digit Span Task within this current study was to confirm this prediction in the current PI sample, and subsequently provide further support for deficits in PI being associated with multiple cognitive resource activity. Indeed when considering the everyday situations in which PI report slips in daytime functioning e.g. taking a wrong turn when driving etc, multiple cognitive functions are required for this task, therefore it is somewhat unsurprising that objective deficit is only observed when multiple cognitive resources are drawn upon simultaneously. Results from the Digit Span Task test were also in the expected direction with no significant between group differences on both the forward and backwards subtests.

Predictions were also made in relation the effect size generated by both the subjective and objective measures of daytime deficit. As predicted, the effects size comparison was in the expected direction with the subjective comparison producing a larger effect size than the objective comparison. This is consistent with the majority of data across many clinical populations comparing subjective and objective assessment. However, the subjective effect size, $d = 4.8$ (medium), was smaller than might have been predicted. Indeed people with PI often subjectively over-report their sleep complaint, thus it could have been assumed that PI may have over-reported their daytime deficits within the CFQ. However, this smaller effect size observed between the PI group and GS group on

the CFQ, and the comparisons with other clinical populations previously discussed, suggests that the PI group may not have been significantly over reporting daytime cognitive complaints, and that the data relating to CFQ is reflective of their real life experience.

The secondary question posed by this current study related to the common finding that subjective and objective measures of daytime cognitive failures in PI often fail to correlate with one another. This is most likely due to the fact that subjective measures often tap into the general concepts of the complaint, whereas objective measures often tap into the highly specific elements of the complaint. It was hypothesised that no relationship would be observed between the objective and subjective measures within this current study. As predicted, there was no significant relationship between measures. This finding is unsurprising as the nature of the measures within this current study, are reflective of the general/specific nature of subjective and objective measures previously described. However, if future research does assess responses at the item level, within a questionnaire with multifactor stability, there may be more scope for identifying a relationship between the subjective item(s) measure and the objective measure. As a manipulation check within this current study, each individual item from the CFQ was assessed for a correlation with the SATcomplex. No significant correlations were observed.

There are a number of important limitations to the present study that must be considered. First, although this current study confirmed the predicted hypothesis it is important to

note that the number of participants included in analysis was significantly less than the number generated by the *a priori* power calculation. This has implications for both the comparisons of interest as well as subsequent comparisons. More specifically, if this study had adequately reached the recommended power significant effects may have been observed within the SATsimple and Digit span task. Future experimentation should aim to recruit a much larger sample size in order to test out this possibility and conclude that significant effects are confined to the comparison of interest i.e. SATcomplex.

Secondly, although detailed inclusion and exclusion criteria were established and PI scored significantly higher than GS on the PSQI, and group allocation was retrospectively confirmed by sleep diary data, sleep quality was not objectively validated. Future studies should aim to differentiate PI from GS controls through the use of an objective measure of sleep assessment i.e. actigraphy or polysomnography. Indeed due to the previously mentioned findings that PI occasionally over-report sleep disruption, objective sleep assessment would have served as a valuable manipulation check for accurate group allocation. In addition, another potential criticism of the present study is that telephone screening that resulted in the group allocation was not additionally assessed by an independent rater. Thus inter-rater reliability could not be provided for the group allocation within this present study.

A final limitation of this current study relates to the fact that the GS group consisted of a convenience sample. Although often sleep research struggles to recruit good sleeper into sleep related studies more attempts should have been made to recruit a randomised

control sample. Indeed, the inclusion of a random sample of GS would have strengthened the overall methodology and subsequent group comparisons.

Conclusions

This study aimed to assess whether scores on the Cognitive Failures Questionnaire (CFQ), and the SATcomplex would differentiate people with PI from GS controls. All hypotheses were confirmed. First the CFQ, which is a novel inclusion to PI research revealed that PI report significantly more cognitive failures than GS. Furthermore the reported level of cognitive failures in this PI group is largely comparable to that of another disorder of psychopathology i.e. depression, but largely incomparable to a clinical population with known brain atrophy i.e. multiple sclerosis. The SATcomplex, which requires sensory-motor, attention and executive functioning resources also effectively differentiated groups, with PI having an overall slower RT to task completion and a significantly greater number of errors than GS. This direction of results, and the absence of group differences on the SATsimple and Digit Span task, suggests that PI performance is significantly diminished when numerous cognitive resources are simultaneously required, and not due to more gross cognitive deficit. As predicted no relationship was observed between the subjective and objective measures, however future research could attempt to assess subjective accounts at item level within the indices. Nevertheless, the possibility that subjective and objective measures of daytime deficit may continue to appear unrelated remains highly possible. Indeed, if objective deficits are only observed during assessments that require multiple cognitive resources, it may prove too difficult to accurately capture multiple examples within a questionnaire

and self-report format. In conclusion, the results of this current study have important implications for future research and clinical practice. It is important that the PI patient's daytime experience is experimentally recognised and understood because, as highlighted at the beginning of this study, daytime deficits as a result of poor sleep are often reported to cause more distress and anxiety than the night-time experience of wakefulness.

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Table 1. Overview of measures included in the current study.

Demographic	*Sleep*	*Psychopathology*	*Subjective Daytime Deficit*	*Objective Daytime deficit*
Age (in years)	Screening interview: DSM-IV-TR & ICSD- R	Screening interview: current depression or anxiety, any medication for psychopathology	CFQ: daytime cognitive failures	SATcomplex: assessment of sensory-motor, attention, concentration and executive functioning
Gender	PSQI: <5 = GS, >5 = PI	QIDS: depression symptoms		SATsimple: assessment of sensory motor attention and concentration
Education level (years in education) .	Sleep diary: TST, WASO, SOL	STAI: anxiety symptoms		Digit Span: assessment of working memory
	SSS: sleepiness rating immediately prior to testing			

Table 2. Mean and Standard Deviation Demographic Data for PI and GS.

Group	Male:Female Ratio	Age		Years in Education	
	M	M	SD	M	SD
PI	9:17	46.17	12.88	16.40	3.87
GS	11.15	33.72	14.44	15.34	4.29

Table 3. Mean, Standard Deviation and Significance Screening and Clinical Measure scores for PI and GS.

Measure	PI		GS		df	F	Between group Differences
	M	SD	M	SD			
PSQI	11.96	4.28	3.56	3.18	1	64.5	p<0.0001
TST	294.3	92.6	413.8	87.8	1	22.7	p<0.0001
WASO	84.1	79.1	16.9	42.1	1	14.5	p<0.0001
SOL	37.2	38.7	13.88	20.2	1	7.4	p<0.0001
TST night prior	305.1	35.7	416.5	45.8	1	9.5	p<0.0001
SSS	2.9	1.1	2.5	0.9	1	1.5	p = .232
QUIDS	9.6	4.7	7.8	5.3	1	4.0	p = .052
STAI-S	39.6	13.1	38.4	12.9	1	0.43	p = .150
STAI-T	45.9	12.6	47.2	11.7	1	0.10	p = .124

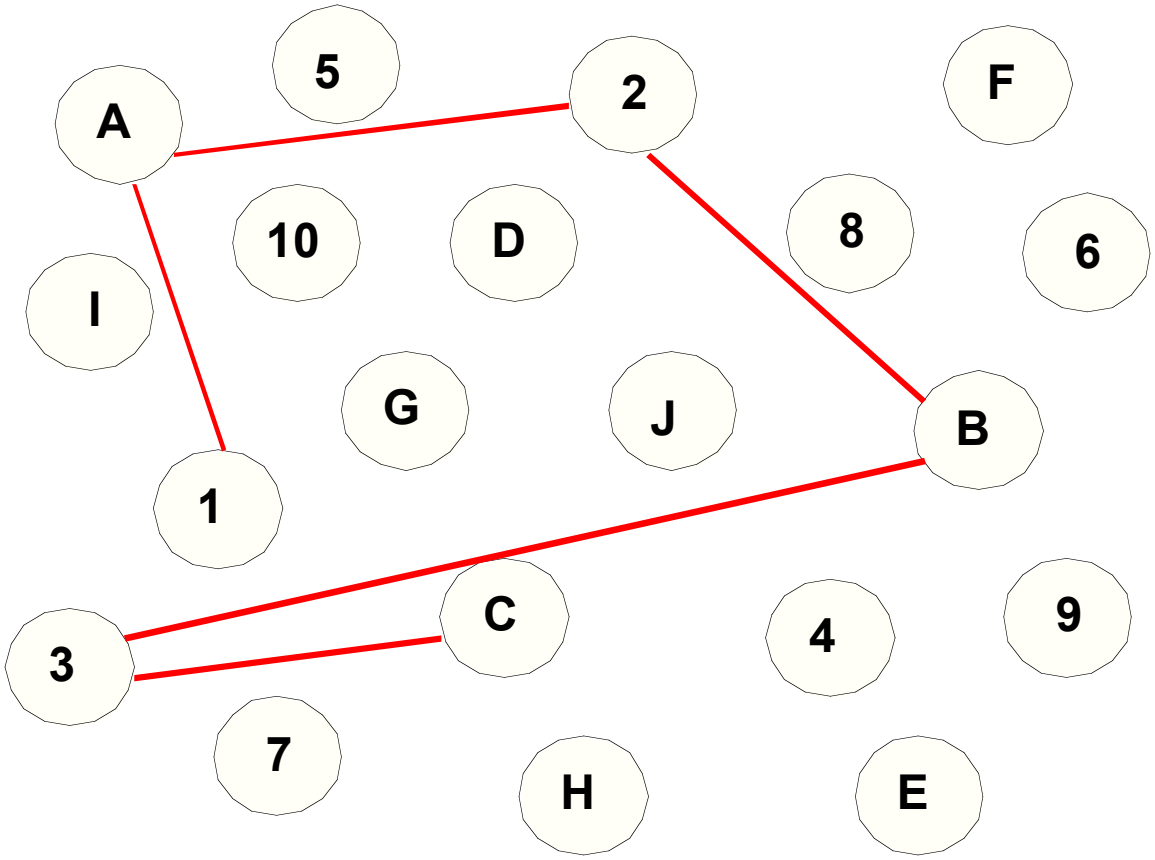
PSQI: Pittsburgh Sleep Quality Index
TST: Total Sleep Time
WASO: Wake Time After Sleep Onset
SOL: Sleep Onset Latency
SSS: Stanford Sleepiness Scale
QUIDS: Quick Inventory of Depressive symptoms – Self Report
STAI: Speilberger State Trait Anxiety Inventory

Table 4. Mean, Standard deviation and Significance Scores for Each experimental Measure.

Measure	PI		GS		d	F	Between group Differences
	M	SD	M	SD			
CFQ	47.9 19.5		34.6 15.1		1	8.0	$p<0.05$
SATcomplex RT in seconds	53.6 13.4		39.2 12.8		1	5.5	$p<0.05$
SATcomplex Errors	1.4	1.2	0.65 0.94		1	5.8	$p<0.05$
SATsimple RT in seconds	23.9	7.9	19.9	5.5	1	0.9	$p = 0.35$
SATsimple Errors	0.85	1.3	0.50 0.71		1	1.4	$p = 0.24$
Digit Span Forwards	6.6	1.4	7.0	0.4	1	0.7	$p = 0.40$
Digit Span Backwards	5.9	1.2	5.9	0.94	1	0.01	$p = 0.93$

Figure 1

SAT complex



CHAPTER FOUR:

ADVANCED CLINICAL PRACTICE II REFLECTIVE CRITICAL ACCOUNT

Reflecting on the anxieties experienced when engaging in the training of other professionals in psychological skills, knowledge and practice.

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February 2009

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Abstract

The ability to train others in the application of psychological skills, knowledge, practices and procedures is a key competence of a clinical psychologist and is highlighted with the National Occupational Standards for Psychology. This current reflective account discusses my personal experience of training other professionals within a specific area of health psychology. I attempt to reflect on this situation by following Gibbs (1988) model of reflection. I discuss the anxieties I felt in relation to the professional group to whom I was delivering the training session, and the concerns I had about ensuring I presented accurate and informative information. My evaluation and analysis of the situation has allowed me to recognise the discrepancies in my thinking in relation to the group's expertise and my belief that I was under qualified to present to such a group. I also discuss my gradual awareness about my own personal negative thinking in relation to possible negative outcomes of the situation and discuss my feelings in relation to this. I conclude by discussing my plans for action with regards to my own professional development and highlight that it is important to consistently monitor my own personal well being when taking on an additional workload.

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The ability to train others in the application of psychological skills, knowledge, practices and procedures is a key competence of a clinical psychologist and is highlighted with the National Occupational Standards for Psychology. This current reflective account discusses my personal experience of training other professionals within a specific area of health psychology. I attempt to reflect on this situation by following Gibbs (1988) model of reflection. I discuss the anxieties I felt in relation to the professional group to whom I was delivering the training session, and the concerns I had about ensuring I presented accurate and informative information. My evaluation and analysis of the situation has allowed me to recognise the discrepancies in my thinking in relation to the group's expertise and my belief that I was under qualified to present to such a group. I also discuss my gradual awareness about my own personal negative thinking in relation to possible negative outcomes of the situation and discuss my feelings in relation to this. I conclude by discussing my plans for action with regards to my own professional development and highlight that it is important to consistently monitor my own personal well being when taking on an additional workload.

APPENDICES

Guide for Authors Appendix 2.1

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University of Glasgow | Sleep Centre

Appendix 2.2

Source

How did you find out about the University of Glasgow Sleep Centre?	
Why have you contacted us?	

Personal

Full Name:	*Date of Birth:*	*Age:*
Telephone:	*Address:*	
Alternative Telephone:		
When is a good time to call?		

Sleep

Do you have difficulty sleeping at the moment? (Y/N)	
Have you always been a poor sleeper? (Y/N)	
How long have you had a sleep problem?(yr)	
Do you have difficulty falling asleep? (Y/N)	
How many nights per week do you have difficulty falling asleep? (out of 7)	

How long does it normally take you to fall asleep?(min)	
Do you have a difficulty with waking up during the night?(Y/N)	
How many nights per week do you have a difficulty with waking up during the night?(out of 7)	
How long are you normally awake during the night, in total? (min)	
What time do you normally go to bed? (time)	
What time do you normally get up?(time)	
How long do you normally sleep?(hr/min)	
Do you any other difficulties with your sleep (e.g. restless legs, breathing problems, sleep walking)?	

Health

Do you keep in good health physically? (Y/N)	
What physical health problems do you have (if applicable)?	
What medicines do you take for your physical health? (if applicable)	
Do you keep in good health mentally? (Y/N)	
What physical health problems do you have (if applicable)?	
What medicines do you take for your mental health? (if applicable)	

Notes

For Office Use			
Enquiry taken by: At (time): On (date):			
Information sent: **[study name]** **[study name]** **[study name]** On (date):	**[study name]** **[study name]** **[study name]**	**[study name]** **[study name]** **[study name]**	**[study name]** **[study name]** **[study name]**

Name_____

Week Beginning_____

MEASURING THE PATTERN OF YOUR SLEEP

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1. What time did you wake this morning?							
2. At what time did you rise from bed?							
3. At what time did you go to bed last night?							
4. Lights Out:- At what time did you put the light out to go to sleep?							
5. How long did it take you to fall asleep (minutes)? (After Lights Out)							
6. How many times did you wake up during the night?							
7. How long were you awake during the night (in total)?							
8. About how long did you sleep altogether (hours/mins)?							
9. Did you take sleeping pills to help you sleep? (please describe)							
10.Did you take alcohol before going to bed? (please describe)							
11.Did you take painkillers last evening or night? (please describe)							
12.Did you take pills for depression or anxiety? (please describe)							

MEASURING THE QUALITY OF YOUR SLEEP

1. How well do you feel this morning? 0 1 2 3 4 not at all moderately very						
2. How enjoyable was your sleep last night? 0 1 2 3 4 not at all moderately very						
3. How mentally alert were you in bed last night? 0 1 2 3 4 not at all moderately very						

Colin Esple (not for e-mail)

From: Jamieson, Liz [Liz.Jamieson@ggc.scot.nhs.uk]
Sent: 04 December 2007 10:31
To: c.espie@clinmed.gla.ac.uk
Cc: Fraser, Mary
Subject: Ethics Application - 07/S0701/136

Dear Colin

I am very pleased to advise that you have now satisfied the Committee's conditions with regard to recruitment. You are now free to go ahead and start your study. I wont confirm by letter – this email will go into your file.

Hope this is helpful. I have copied Mary to keep her up to date.

Liz

Liz Jamieson
Research Ethics Co-ordinator
R&D Directorate
Greater Glasgow Primary Care Division LREC
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Tel: 0141 211 3824
Fax: 0141 211 3814
Email: Liz.Jamieson@ggc.scot.nhs.uk

Please note my new email address. However messages will continue to reach me via my old address, i.e. Liz.Jamieson@gartnavel.glacomen.scot.nhs.uk, for the foreseeable future.

ANCOVA CFQ

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	2559.659(a)	3	853.220	2.739	.054
Intercept	4337.908	1	4337.908	13.923	.001
Education	45.594	1	45.594	.146	.704
Age	259.746	1	259.746	.834	.366
Group	2502.317	1	2502.317	8.032	.007
Error	14955.014	48	311.563		
Total	105831.000	52			
Corrected Total	17514.673	51			

a R Squared = .146 (Adjusted R Squared

ANCOVA SATcomplex

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	4553151284.099(a)	3	1517717094.700	10.783	.000
Intercept	1171298583.499	1	1171298583.499	8.322	.006
Education	7283006.861	1	7283006.861	.052	.821
Age	1804933363.666	1	1804933363.666	12.824	.001
Group	776774413.905	1	776774413.905	5.519	.023
Error	6755894483.202	48	140747801.733		
Total	123433806092.688	52			
Corrected Total	11309045767.302	51			

a R Squared = .403 (Adjusted R Squared = .365)

ANCOVA SATsimple

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	435113530.519(a)	3	145037843.506	3.369	.026
Intercept	349017709.636	1	349017709.636	8.107	.006
Education	2022653.755	1	2022653.755	.047	.829
Age	226154380.931	1	226154380.931	5.253	.026
Group	38412864.676	1	38412864.676	.892	.350
Error	2066510088.308	48	43052293.506		
Total	27369519605.000	52			
Corrected Total	2501623618.827	51			

a R Squared = .174 (Adjusted R Squared = .122)

ANCOVA Digit Span Forwards

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	2.309(a)	3	.770	.407	.748
Intercept	129.618	1	129.618	68.617	.000
AGE	1.095	1	1.095	.579	.450
EDUCATION	.675	1	.675	.357	.553
group	1.346	1	1.346	.712	.403
Error	90.672	48	1.889		
Total	2627.000	52			
Corrected Total	92.981	51			

a R Squared = .025 (Adjusted R Squared = -.036)

ANCOVA Digit Span Backwards

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	3.321(a)	3	1.107	.332	.802
Intercept	81.353	1	81.353	24.387	.000
AGE	.026	1	.026	.008	.931
EDUCATION	3.253	1	3.253	.975	.328
group	.023	1	.023	.007	.934
Error	160.122	48	3.336		
Total	1555.000	52			
Corrected Total	163.442	51			

a R Squared = .020 (Adjusted R Squared = -.041

yielded mixed results. Two recent studies have investigated daytime deficits in people with PI through the

An investigation of relationship between the Cognitive Failures Questionnaire and the Switching Attention Task in psychophysiological insomnia and good sleep

Abstract

Background: People with psychophysiologic insomnia (PI) report the experience of daytime cognitive deficits; however attempts to capture such deficits, both subjectively and objectively, have yielded mixed results. Two recent studies have investigated daytime deficits in people with PI through the use of both psychomotor tasks and subjective indices. Although one of these studies has demonstrated that a specific psychomotor test, i.e. the switching attention task (SAT), significantly differentiates people with PI from good sleeper controls (GS), both studies failed to demonstrate any significant relationship between psychomotor test performance and subjective reports of daytime deficit.
Aims: The present study aims to determine 1) whether the Cognitive Failures Questionnaire (CFQ), a standardised measure used to assess specific cognitive failures in everyday life and novel to PI literature, and the SAT can effectively differentiate PI from GS, and 2) whether there is a significant relationship between the CFQ and the SAT.
Methods: People with PI and good sleeper control volunteers will be recruited. A series of questionnaires relating to sleep pattern, the CFQ and the switching attention task will be completed.
Applications: Identification of the specific cognitive failures experienced by people with PI in everyday living, and their relationship with objective tests of cognitive function, will aid in our understanding of specific daytime consequences of poor sleep.

1. Introduction

Clinical reports from individuals with Psychophysiological Insomnia (PI) include the experience of daytime cognitive deficits such as poor concentration, poor memory, and decreased ability to accomplish daily tasks (Roth et al., 2003, Grunstein et al., 2002). The published nomenclature (International Classification of Sleep Disorders - ICSD-2) is reflective of these subjective accounts and include these phenomenon in its description of insomnia as a disorder; *the sleep complaint must occur in association with adequate opportunity for sleep and the complaint of impaired daytime function (e.g., difficulties with attention, and memory, and/or diminished vocational functioning)* (American Academy of Sleep Medicine, 2005).

In a review of the relevant literature Riedel and Lichstein (2000) found that many researchers have attempted to capture, through both subjective and objective measures, the daytime cognitive deficits reported by people with PI. Studies developed to capture such deficits have considered various ‘domains of daytime functioning’ which include;

daytime sleepiness, fatigue, physiological arousal, cognitive and psychomotor tasks, psychopathology, and general functioning. The vast majority of the data relating to these domains provide little evidence of deficits in daytime functioning in people with PI relative to individuals without PI (Edinger et al., 1997, Lichstein et al., 1994, Fichten et al., 1995, Means et al., 2000, Kales et al 1983, Levin et al., 1984, Orff et al., 2007, Edinger et al., 2008).

Recent developments in the investigation of daytime deficits in people with PI involve the use of psychomotor tests (PMT), typically incorporating a variety of tests e.g. card sorting, addition, logical reasoning, divided attention, complex reaction time tasks etc. The results of such studies comparing people with PI and controls have been mixed and inconsistent. In a recent study, Orff and colleagues investigated both subjective and neuropsychological measures of daytime impairment in people with PI and good sleepers (GS), with the aim of assessing whether people with PI differ from GS on both measures, and the extent to which subjective and objective measures provide discordant information (Orff et al., 2007). Overall, people with PI subjectively reported worse sleep, diminished activity levels, and a greater number and severity of daytime complaints, however, they did not show deficits on the objective PMT. Indeed, there was no relationship between subjective and objective outcome measures.

The most recent study comparing PMT performance in people with PI against GS controls reports a significant group difference (Edinger et al., 2008). Within this study, a large well-characterised group of people with PI represented the experimental population and predictions were made that this group would perform significantly worse than GS on performance measures, and that group differences would be most obvious on more complex tasks. The PMT assessment battery included a simple reaction time test, a sustained attention test and a switching attention test, representing a hierarchy of complexity. Group differences were only observed on the most complex task (i.e. switching attention task (SAT)) where there was a high cognitive load. These authors employed the Stanford Sleepiness Scale (SSS) to measure subjective daytime complaints and although PI reported significantly greater sleepiness ratings than GS, one arguable

weakness is that the measure did not provide any information on specific areas of cognitive failures subjectively reported.

As previously mentioned, the definition of insomnia in part includes the reporting of daytime cognitive difficulties such as attention and memory. However, in attempting to measure the subjective reporting of daytime sleepiness, all studies thus far have arguably failed to use measures that adequately capture the nature and severity of cognitive deficits subjectively reported. The inclusion of a standardised subjective measure that specifically assesses deficits in daily cognitive functioning would, by definition of insomnia, appear essential. The use of such a measure may allow for the phenotypical features of a PI population to be discerned more accurately, thus enhancing studies examining the differences between people with PI and GS, as well as those exploring the relationship between subjective and objective measures of cognitive impairment.

2. Aims and Hypotheses

2.1 Aims

This current research aims to advance our understanding of the relationship between subjective reporting of daytime cognitive deficits and objective impairment on PMT in people with PI through the inclusion of ; *i)* The Cognitive Failures Questionnaire (CFQ) and *ii)* The switching attention task (SAT) shown to differentiate PI from GS in the most recent study i.e. (Edinger et al., 2008)

This study primarily aims to determine;

1) whether the CFQ and the SAT can effectively differentiate PI from GS, and
2) whether there is any relationship between the CFQ and the SAT outcome data.

2.2 Hypotheses

1. People with PI and GS controls will significantly differ on the CFQ, with the PI group reporting significantly more cognitive failures relative to GS.

The novel use of the CFQ within the PI literature seems appropriate as it allows for the assessment of subjective reporting of cognitive failures in everyday life. The measure has the potential to tap into the everyday experience of insomnia, capturing the more phenotypical components of the disorder. Since self-report measures from people with PI consistently include reports of day-time deficits, it is predicted that the PI group will relate to significantly more everyday cognitive failures than GS.

2. People with PI and GS controls will significantly differ on the SAT, with the PI group performing significantly poorer relative to GS.

Edinger et al. (2008) report a significant difference in psychomotor performance when tested on a switching attention task. This present hypothesis aims to replicate this finding.

3. There will be no significant relationship between the CFQ and the SAT outcome data.

3. Plan of Investigation

3.1 Participants

Two groups of volunteers will be used within this study: people with psychophysiological insomnia and good sleeper controls. They will be age, gender and education level matched.

3.2 Recruitment

The University of Glasgow Sleep Centre (UGSC) has a core generic approach to recruiting participants to the lab which includes recruitment from the local sleep disorder services, via advertisements in local news papers and directly from 20 local primary care practices through the coordinator SPPIRe (Scottish Practices and Professionals Involved in Research). Participants within this current study will be recruited in this way.

3.3 Inclusion and Exclusion Criteria

The UGSC has a generic protocol for screening people with PI and GS controls to laboratory based studies. This current study will adhere to this protocol.

3.4 Procedure for Diagnostic Ascertainment

i. Assessment of Sleep

Each participant will be interviewed to evaluate his/ her typical sleeping patterns. The interview will propose questions relating to the DSM-IV and ICSD-R criteria for PI and DSPS, following the UGSC structured interview format (Espie, 2000; Morin and Espie, 2003). Additionally, the Pittsburgh Sleep Quality Index (PSQI), the Insomnia Severity Index (ISI) and the Stanford Sleepiness Scale (SSS) will be completed. Participants will also complete a standard sleep diary (Espie, 1991) for seven nights prior to the experiment.

ii. Assessment of Psychopathology

Psychopathology will be evaluated using, the Quick Inventory of Depressive Symptoms and the Spielberg State-Trait Anxiety Inventory.

All the above measures have published data on their validity and reliabilityand are referenced in *section 3.5.*

3.5 Measures/Materials

i. Demographic

Demographic information will include age, gender, ethnicity and number of years in education.

ii. Sleep Measures

i) Pittsburgh Sleep Quality Index (Buysse et al., 1989)).

iii) Sleep Diary (Espie, 1991)

iv) Stanford Sleepiness Scale (Hoddes et al., 1973)

iii. Psychopathology Measures

ii) Quick Inventory of Depressive Symptoms (Rush et al. 2003).

iii) Spielberg State-Trait Anxiety Inventory (Spielberger, 1970).

iv. Subjective Daytime Deficit Measure (See Appendix B)

i) Cognitive Failures Questionnaire (Broadbent et al., 1982)).

v. Objective daytime Deficit Measures (See Appendix B)

i)The Switching Attention Task (SAT)- taken from the NeuroBehavioural Evaluation System (NES)

ii) INTEG NEURO system – Participants will complete a standardised neuropsychological assessment battery designed to assess all cognitive domains. None of these tasks will be treated as dependant variables and will not relate to the analyses within this current study.

3.6 Design

The study design is an independent samples design, with an experimental group of participants with PI, and a control group of GS. Scores on the CFQ and SAT will act as the dependant variables.

3.7 Procedure

Recruited participants will be contacted, via email or telephone, and asked if they would like to take part in the current study. An appointment will be agreed with them to attend the UGSC. They will be emailed/posted an information pack regarding the UGSC as well as a sleep diary which they will be instructed to complete and bring with them to the appointment.

On arrival at the UGSC participants will be provided with an information sheet explaining that they will be required to complete six short questionnaires and a series of psychomotor tasks and that if they are happy to proceed to provide written consent. Participants will then be asked to complete the computerised tasks followed by the seven

questionnaires and then the clinical sleep interview. At the end of the interview participants will be thanked and thoroughly debriefed as to the purpose of the experiment and any questions they have will be answered.

3.8 Justification of Sample Size

The most recent study (Edinger et al., 2008) to have examined psychomotor task performance in people with PI relative to good sleeper controls obtained an effect size of 0.85. In agreement with Cohen's (1988) effects size conventions for means (d) such a figure correspond to a large effect. The current investigation's primary hypotheses relates to between group differences. Based on the effect sizes demonstrated in the above investigation, a suggested medium to large effect size of 0.6, related to effect size conventions appropriate for a *t*-test on means (d), would therefore seem reasonable for the proposed investigation. A series of power calculations were conducted using G * Power 3 software program (Faul et al., 1997). Such calculations revealed an estimated 28 participants per group will be required to detect significant differences at an alpha level of 0.05, with power of 0.8 (one tailed). Given that it is intended to use demographically well matched samples and strictly differentiated PI and GS groups, it is proposed that this sample size will be more than sufficient to detect differences if they exist.

3.9 Settings and Equipment

i. Settings

Participants will be tested in the UGSC at the Sacker Institute of Psychobiological Research at the Southern General Hospital, Glasgow.

ii. Equipment

The PMTs will be implemented using a standard laptop or desktop computer. Software will be required to allow the investigator to programme and run these tasks.

3.10 Data Analysis

Data analysis will be conducted using SPSS. Data on all trials with errors will be omitted. Initial descriptive statistics and visual inspections of all data will be performed to examine statistical distributions and to check for assumptions of normality. Baseline demographic and clinical characteristics of each group will be presented. If differences appear to exist between groups these will be examined using independent *t*-tests or chi-squared analyses.

Assuming data is parametric, comparison between the PI and GS group on the CFQ will be made using an independent samples t-test. The SAT is made up of four sections, each being treated as a dependent variable. As such, the comparison between groups on the SAT will require calculations using a MANOVA. The nature and strength of the relationship between scores on the CFQ and SAT, if indeed there is a relationship, will be obtained using a correlation analysis.

4. Health and Safety Issues

i. Researcher Safety Issues

No issues regarding researcher safety are envisaged. Participants will be met within NHS establishments and contact details of the principal investigator given to participants will be created solely for the purpose of the study.

ii. Participant Safety Issues

No issues regarding participant safety are envisaged.

5. Ethical Issues

Ethical approval has already been granted for the participants recruited for the on going study at the UGSC. Amendments will be made to the submitted protocol for the purpose of this current study and will be resubmitted for ethical approval to recruit new participants. Any participants identified as experiencing psychological distress or physical illness will be provided with information booklets and signposted to services.

6. Financial Issues

i. Equipment Costs

The department possesses the required equipment and materials thus no financial costs will be incurred.

ii. Travel

Participants' travel costs and travel expenses of the principle investigator incurred for the purpose the research project will be claimed from NHS Ayrshire and Arran.

7. Timetable

Ethical approval submission:	August 2008
Recruitment and data collection:	September 2008 - April 2009
Analysis and write up:	May 2009 - July 2009

8. Practical Applications

Identification of the specific cognitive failures experienced by people with PI in everyday living, and their relationship with objective tests of cognitive function, will aid in our understanding of specific daytime consequences of poor sleep.

PARTICIPANT INFORMATION SHEET

COGNITION AND MOOD FACTORS IN THE ETIOLOGY OF PRIMARY AND SECONDARY INSOMNIA

INTRODUCTION

You are invited to take part in a research study that is being carried out by the University of Glasgow. Before you decide, it is important for you to understand why the research is being carried out and what is involved. Please take some time to read the following carefully and discuss it with friends and relatives if you wish. Please ask if you would like more information or if there is anything that is not clear.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to explore the differences between primary insomnia and good sleepers The purpose is also to learn which of these types of assessments may demonstrate unique results for particular group of people. The person in charge of this study is Dr. Lauren Macphee, Trainee clinical Psychologist.

WHY HAVE I BEEN CHOSEN?

You are being asked to participate in this research study because you have:

1. no trouble sleeping at night (good sleeper)
2. persistent trouble sleeping at night (insomnia) with no current or prior symptoms of depression

.

DO I HAVE TO TAKE PART?

It is entirely up to you whether you take part or not. If you decide to take part you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part will not affect the standard of care you receive. This form describes the known possible risks and benefits of the study. You are completely free to choose whether or not to participate in this study

HOW LONG WUILL THE STUDY LAST?

This study will last about 3 hours and will involve 1 visit within that time frame. These visits will be to the University of Glasgow Sleep Centre at the Southern General Hospital.

WHAT WILL HAPPEN IF I TAKE PART?

Initial Evaluation-**VISIT 1**.

At the start we need to check with you that you are likely to meet our requirements for the study. We call this an initial 'screening'. Normally you will attend visit the Sleep centre for this, but we may also be able to make arrangements to complete some of this by telephone if that is more convenient for you. Screening will take about 45 minutes of your time.

Full Evaluation-**VISIT 2**.

At this visit you will complete some questionnaires about your attitudes, thoughts and feelings. You will also have an interview that will include questions about your psychiatric, medical and sleep history. These data will be used to establish in greater detail that you are eligible to participate in this study and as background information. If you are eligible, you will continue and have a physical examination.

This examination will include obtaining blood samples (about 15 ml. which is about 3 teaspoons) and urine samples, which are used to make sure that you are in good health and assess for toxicology (look for illegal substances or alcohol), pregnancy, and abnormal blood chemistries. You will be screened for substances of abuse including alcohol. The exam will also include heart monitoring (a cardiograph).

If you continue to qualify you will be shown some tasks to complete on a computer. These are simple to follow instructions and you will have the chance to practice with help from one of our staff. These tasks measure aspects of your attention and memory.

This whole visit will last about 3 hours. After this visit you will be asked to complete two weeks worth of sleep diaries.

3. Sleep Diaries. If you qualify for the study and wish to continue with your participation, you will be asked to undergo a two-week evaluation period during which you will fill out daily sleep diaries. The sleep diaries are paper and pencil measures that you will complete immediately prior to going to bed and immediately upon awakening each day. The diaries require no more than 10 minutes per day to complete. At the end of the two weeks you will be asked to mail in the sleep diaries to the sleep centre using the provided stamped envelopes.

4. Screening Sleep Lab Study (polysomnography) - VISIT 3**. If, following the diary assessment of your sleep, you continue to be eligible for the study, you will be scheduled for your first overnight polysomnographic study (PSG) at the sleep centre. You will be asked to arrive at the sleep lab by 7 PM. Upon arrival, to ensure accurate measurements, you will again be screened with a urine test.**

The procedure for a PSG requires that you have a set of sensors placed on your face, scalp, and body by a technician. All the sensors are attached with surgical

tape, paste and glue. The sensors on your face are attached on your left and right temple and check bone and under your nose. The sensors on the temple and check bone measure eye movements associated with falling asleep and dreaming. The sensors under your nose measure airflow through your mouth and nose. The sensors on your scalp measure brain waves during sleep. The sensors on the body are placed above the collarbones and over the calf muscles. The sensors over the collarbones measure heart muscle activity. The sensors over the calf muscles measure muscle activity from the legs.

After you are ready for bed, you will be allowed to read or watch television until "lights out." You will be expected to spend a total of 8 hours in bed (except for bathroom breaks). In the morning you will be awakened by the technician, fill out a set of brief questionnaires, be unhooked from the equipment, and then allowed to shower, dress, and eat breakfast that is provided for you before leaving to go about your day.

4. Sleep Lab Study - **VISIT 4**. After study staff have reviewed your screening PSG recordings, and it is determined that you continue to qualify for the study, you will come in for visit 4. This visit will occur the night following your screening PSG.

Questionnaires relating to seep, general health, mental health and cognitive failures.

3 computer-administered tasks. This is expected to take up to 60 minutes.

Once this is finished your participation with the study will end and you will be free to go about your day.

WHAT WILL THE RESEARCHERS DO WITH THE INFORMATION?

All of the information (data) from your assessments will help us in our research to find out more about mental factors and mood relate to sleep. We will keep most of the data in anonymised form. That is transferred to numbers and stored safely in a computer system that does not have your name on it. We do need to keep some personal information about you in written form, such as your address and contact details. This kind of information will be held in a locked cabinet in a locked room (like a medical file), and only the research team will have access to it.

WHO WILL KNOW THAT I AM TAKING PART IN THE STUDY?

We will treat your participation with strict confidence. We will however seek your permission to let your GP know that you are participating, and if you have a mental health professional working with you we would let him or her know also. This is in your best interests. For example, although it may be unlikely, it is possible that a result from one of your assessments has implications for your health or well-being. This could be to

do with your mental or physical health and we would let your GP know. Should such concerns arise, we will make every effort to talk with you first, prior to reporting.

WHAT ARE THE RISK OF PARTICIPATION?

Risks associated with the questionnaires. Answering some of the questions may make you feel uncomfortable. You don't have to answer any questions you don't want to. Well-trained staff conduct the interviews and are capable of dealing with such issues should they arise.

ARE THERE ANY BENEFITS OF PARTICIPATION?

There is no direct benefit to you expected from participating in this study; however, you will receive an extensive evaluation of your sleep/sleep disorder at no cost to you. We hope the information learned from this study will benefit patients experiencing insomnia. We also plan to provide those with insomnia who participate with a brief, non-drug treatment at the end of the study. This uses a treatment known as cognitive behaviour therapy (CBT)

ARE THERE ANY COSTS?

There is no cost to you to participate in this research study.

WHAT ARE THE CIRCUMSTANCES FOR LEAVING THE STUDY?

As we have said, you may discontinue participation from the study at any time if you decide you do not wish to take part any longer.

WHO IS FUNDING BTHIS RESEARCH?

The University of Glasgow Sleep Centre is being funded by the National Institute of Mental Health (in the USA) to conduct this study. The study is sponsored by NHS Greater Glasgow and Clyde.

WHO ARE MY BEST CONTACTS?

For more information concerning this research study or for questions regarding research-related risks or injuries as well as any side effects you might experience

from participation in this study, you may contact Professor Colin Espie, Director of the University of Glasgow Sleep Centre, or Dr Lauren Macphee (0141-232-7696).

If you wish to speak with an impartial staff member to discuss your concerns about participation, you may contact r the responsible NHS Research Manager, Mr. Brian Rae (0141-232-9523). Their role with this project is strictly to be available as impartial contacts.

The full address of the sleep centre is: University of Glasgow Sleep Centre, Sackler Institute of Psychobiological Research, Southern General Hospital, Glasgow G51 4TF