Psychophysiological Insomnia and Idiopathic Insomnia: The role of self-regulatory behaviour systems

Clinical Research Portfolio

Volume I

(Volume II bound separately)

Grant Forgan

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(Separately bound)

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CHAPTER ONE: SYSTEMATIC LITERATURE REVIEW

Have Research Diagnostic Criteria for Insomnia Impacted on Research? A Systematic Review

Prepared in accordance with the guidelines for SLEEP (Appendix A.1)

Grant Forgan*
Section of Psychological Medicine,
Division of Community Based Sciences,
Academic Centre,
University of Glasgow,
Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow, G12 0XH
Email: gforgan@blueyonder.co.uk

* Author for correspondence.

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Abstract

Background: Insomnia is a disorder of sleep characterised by difficulty initiating sleep, maintaining sleep, waking too early or sleep that is non-restorative or poor in quality. The absence of a clear consensus as to how insomnia should be conceptualised and defined has hampered diagnosis and treatment in both clinical and research settings. This has led to inconsistent research findings and limited comparability of outcomes across studies. In addition, despite phenotypic differences in the characteristics and treatment responses of different insomnia subtypes they are usually managed by clinicians in the same way. In 2004 the American Academy of Sleep Medicine (AASM) sought to address these issues with the publication of standardised Research Diagnostic Criteria (RDC) for Insomnia and recommendations for assessment procedures and information reporting. The current review aimed to identify the extent to which the RDC and associated recommendations have impacted on research into psychological treatments for insomnia since they were published in late 2004. **Methods:** Studies were identified by searching electronic databases, hand searching key journals and reviewing reference sections of relevant publications. Those studies which incorporated a randomized design and included adult participants with primary insomnia, who received a cognitive behavioural intervention for insomnia, were selected for review. These studies were rated according to: diagnostic criteria used to define their samples; methods of assessment employed; and reporting of descriptive and quantitative information relating to sample recruitment and characteristics. **Results:** Six studies were reviewed of which only one specifically employed the recommended RDC for Insomnia Disorder and Primary insomnia, although three reported criteria that corresponded to the universal RDC for Insomnia Disorder. None of the studies differentiated between primary insomnia subtypes. The results with regards to assessment procedures and information reporting were also disappointing with no study meeting the recommendations of the AASM. **Conclusions:** It was concluded that on the basis of the studies reviewed, the recommendations of the AASM have had only a minimal impact on research into psychological interventions for insomnia.

Keywords: insomnia, research diagnostic criteria, psychological intervention, cognitive behavioural therapy for insomnia.

Introduction

Insomnia is a disorder of sleep that is characterised by complaints of difficulty in initiating sleep and/or maintaining sleep, waking too early or sleep that is non-restorative or poor in quality. [1] It is one of the most prevalent health problems worldwide with around one third of the adult population experiencing insomnia symptoms and between 9% and 12% having persistent difficulties with sleeping. [2] Chronic insomnia can lead to impaired occupational performance and reduced quality of life and is seen as a major public health concern, not least because of the significant costs associated with assessing and treating the condition. [3,4] Despite our knowledge of insomnia and how it might best be managed seeing some considerable advances in recent years, it remains a poorly understood condition that is inadequately identified and treated and is often viewed by clinicians as merely a symptom of other so-called 'primary' medical or psychiatric disorders. [5] In addition, despite phenotypic differences in the characteristics and treatment responses of different insomnia subtypes they are usually managed by clinicians in the same way.

Unfortunately, lack of a clear consensus as to how insomnia should be conceptualised and defined has long hampered diagnosis and treatment in both clinical and research settings. [5-7] On the one hand, people with insomnia tend to report broadly similar experiences with regard to sleep disturbance and how it can impact on their daytime functioning and this led to the development of some relatively broad and simple definitions of insomnia. However, there can also be significant variation in terms of peoples' descriptions of the severity and duration of their insomnia and how it has developed over time. This suggests that insomnia is perhaps a more complex and heterogeneous disorder than that depicted by broad definitions and has driven the development of alternative descriptions of insomnia that acknowledge these phenotypic differences.

These different approaches to conceptualising insomnia are reflected within the current main diagnostic schedules that include criteria relating to sleep disorders, namely the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) [8] and the International Classification of Sleep Disorders, 2nd Edition (ICSD-2) (1). DSM-IV

adopts an inclusive approach with four major categories for insomnia diagnoses including Primary Insomnia (See Table 1) which includes all persons reporting difficulties associated with initiating or maintaining sleep for at least one month that are not related to other diagnosable medical or psychiatric disorders. This broad approach to diagnosing insomnia has been criticised by specialist sleep researchers and clinicians as it groups together people with widely differing insomnia complaints. [7] By contrast the ICSD-2 provides a more comprehensive classification system where insomnia complaints of a primary nature can be split into different insomnia subtypes, as presented in Table 1, and overall includes approximately 40 categories of sleep disorder that can have insomnia as a prominent complaint. There has been much debate over the years regarding the utility of insomnia subtypes, however, most sleep specialists would argue that they are crucial to the continuing development of our understanding of insomnia, and to the design of useful diagnostic tools and effective treatments protocols. [2,6,7]

(INSERT TABLE 1 HERE)

The absence of clear standard definitions for insomnia has led to the employment of widely differing inclusion and exclusion criteria across the research literature and thus has limited comparability of outcomes between studies. [5,9] This has had implications for epidemiological studies and those investigating the characteristics and pathophysiology of insomnia but has perhaps had most important relevance to treatment research and in turn helping clinicians make decisions about appropriate interventions for patients. In clinical research the criteria employed to define insomnia can vary greatly from being liberal and merely requiring the presence of a sleep disturbance, to strictly requiring participants to meet all the criteria for insomnia as laid out in one of the main diagnostic schedules. The assessment procedures that are used to ascertain whether subjects meet study criteria also vary considerably and can often be levied as a potential methodological limitation or weakness of insomnia studies. [9] It should also be noted that although the terms primary insomnia and psychophysiological insomnia in fact refer to two differing insomnia definitions, they are frequently used interchangeably in the sleep literature to describe people with a chronic insomnia complaint that is primary rather than secondary to another condition.

In order to try and address the issues around insomnia diagnosis and classification, and recognising the positive impact that the development and use of Research Diagnostic Criteria (RDC) had previously had in other areas of psychiatric research and practice, [10,11] the American Academy of Sleep Medicine (AASM) formed an Insomnia RDC Task Force to oversee the development of standard definitions for currently recognized insomnia disorders. The Task Force appointed an RDC Work Group (RWG) to carry out the tasks required to meet the three primary objectives/aims of the RDC project which were to: 1) Review the insomnia literature and determine which of the current insomnia diagnoses appear most reliable and valid regardless of the diagnostic nosology in which they originally appeared; 2) Derive standard RDC for defining each of the subset of insomnia diagnoses that have the greatest empirical and consensual support; and 3) Propose specific assessment methods/procedures for identifying the presence/absence of the RDC among the patients and study participants to which they are applied. [9]

The findings of the RWG's review were published in late 2004 [9] and included recommended *universal* RDC for insomnia, for use by all researchers regardless of the insomnia subtype in question, and RDC for a range of specific insomnia subtypes including Primary Insomnia, Psychophysiological Insomnia, Idiopathic Insomnia and Paradoxical Insomnia. These RDC incorporated elements of both DSM-IV and ICSD-2 criteria and sought to reinforce the importance of recognizing these subtypes in research and clinical practice. The RWG's report also laid out specific recommendations for methods of assessment that should be utilised by researchers to ascertain relevant RDC when recruiting study samples. These included the use of clinical interviews, polysomnography (PSG), and sleep diaries/logs. In addition, in order to assist with ongoing revisions of the RDC, the RWG also made recommendations regarding the types of descriptive information that researchers should consistently report in their published studies. Researchers were also encouraged to assign applicable ICSD insomnia subtype diagnoses to study participants who meet RDC for primary insomnia as this would help determine the utility of ICSD subtypes over the more global primary insomnia diagnosis.

The RWG hoped that their recommendations would be seen as a starting point for improving insomnia research and would discourage further studies of poorly

characterized insomnia samples that give little insight into the pathology and treatment needs of specific insomnia subtypes. It was also thought that the RDC could help standardise insomnia research and enable much needed reliability and validity studies to be carried out in future. [9] Given that a number of years have passed since the publication of the RWG's findings and recommendations, we felt that it may be timely to review the extent to which they have impacted on insomnia research, with a specific focus on research into psychological interventions for insomnia. Accordingly, the present review aimed to address the following:

Aim:
To identify the extent to which the recommendations of the RWG have impacted on research into psychological treatments for insomnia since they were published in late 2004.

The review aimed to address the following specific questions:

Primary Questions

1. Which diagnostic criteria have researchers utilised to define and describe their participant samples and do they correspond to the criteria recommended by the RWG?

2. Have researchers employed the assessment methods recommended by the RWG to ascertain whether participants meet the diagnostic criteria employed?

3. Have researchers reported the descriptive and quantitative information relating to sample recruitment and characteristics that the RWG recommended they should report?

Secondary Question

4. How do the treatment outcomes of the reviewed studies compare to those found by previous reviews and meta-analyses of research into psychological interventions for insomnia published prior to publication of the RDC for insomnia?

Methods

Search Methods, Keywords, and Databases

The following electronic databases were searched by the author:

- The Cochrane Library: 2005 to January 2010
- Ovid Medline: 2005 to January 2010
- EMBASE: 2005 to January 2010
- PsycINFO: 2005 to January 2010

Duplicates were removed and searches were limited to the English language. The electronic search was supplemented by searching the reference sections of included papers as well as those of other review papers and meta-analyses published during the period 2005 to January 2010.

The following terms were used to search the databases: ‘sleep initiation and maintenance disorders’; ‘insomnia’; ‘psychological therapy’; ‘behav* therapy’; ‘cognitive therapy’; ‘cognitive behav* therapy’; ‘pharmaco*’; ‘randomi* contro* trial’; ‘random allocation’. The results of these searches were combined where appropriate using AND.

Selection Criteria

Articles identified by the search strategies employed were screened for relevance using the following criteria:

Inclusion Criteria

- Studies incorporating a randomised design and that include a group who received a cognitive behavioural intervention for insomnia
- Participants included should have a primary insomnia disorder
- Studies of adult participants age 18 years and over

Exclusion Criteria

- Studies that do not incorporate a randomised design
- Studies including participants with secondary or comorbid insomnia
- Studies where participants were under 18 years of age

Search Results

The search of electronic databases yielded 335 potentially relevant articles after duplicates were removed. A flowchart of the study selection process is presented in Figure 1. Titles and abstracts were examined by the author and 15 studies of potential relevance were identified and retrieved in full text form. 9 of these were excluded after screening as the studies had commenced prior to the publication of the RWG's recommendations. With regard to the study by Wu and colleagues, [15] it refers to the original ICSD from 1990, [16] and not ICSD-2 and included an 8 month follow-up period. As such it appears likely that this study too was conceived and conducted prior to the publication of the RDC for insomnia. However, there is no reference within the published article as to when the data were collected or the manuscript submitted for publication and so it was thought appropriate for inclusion in the review.

(INSERT FIGURE 1 HERE)

Study Evaluation

All studies that met criteria for inclusion in the review were evaluated using an idiosyncratic tool developed by the researcher (see Appendix A.2). This was based on the various recommendations made by the RWG and was designed to assess the following:

- Which diagnostic criteria for insomnia were employed by the researchers?
- Did the criteria employed correspond to the RDC for Insomnia Disorder/Primary Insomnia?
- Were relevant insomnia subtypes identified and differentiated between?
- Were participants further categorised according to the pattern of their insomnia problem, for example, having sleep onset or waking after sleep difficulties?
- Which assessment procedures were employed to identify participants who met the criteria employed?
- Did the researchers report information about recruitment methods descriptive statistics relating to sleep measures and sample characteristics as recommended by the RWG?

The evaluation tool included eleven items relating to two subscales for *Assessment procedure* (5 items) and *Information reporting* (6 items). Each subscale had a maximum score of 12 points thus allowing each study a possible total score of 24 points. The study evaluation process was completed by the author and an independent rater whom was a qualified Clinical Psychologist who did not have an extensive knowledge of insomnia

research. Disagreements about ratings were minimal and were resolved through discussion until agreement was achieved.

With regard to evaluating the diagnostic criteria employed, it was assumed that where a study made reference to one of the existing diagnostic systems, such as DSM-IV or ICSD-2, that all of the criteria these encompass were adhered to even if they were not specifically detailed within the study text. Any additional criteria listed were also taken into account when judging whether or not the criteria employed within a study met the RDC for Insomnia, Primary Insomnia or a primary insomnia subtype.

In order to evaluate the treatment outcomes reported in the studies effect sizes were calculated to indicate the magnitude of the differences between groups on the primary outcome measures adopted in each study. Effect sizes were calculated as Cohen's *d*, [17] and were based on reported group means and pooled standard deviations for the psychological treatment groups and relevant control or placebo groups in each study. This was with the exception of the study by Zavesicka and colleagues, [24] which incorporated a clinical comparison group that received CBTi plus medication.

Results

Description of the Studies and Samples

Table 2 summarises the main features of the 6 studies selected for inclusion in this review. [15, 21, 24-27] For each study it shows; the sample size, insomnia diagnosis, diagnostic criteria employed, assessment procedures used, treatment type, treatment duration, longest follow-up period, outcome measures employed, and a summary of the main findings. The main sleep diagnoses used to describe the study samples were chronic and/or primary insomnia. A total of 548 participants took part in the studies with 284 receiving a psychological treatment intervention for insomnia either singly (n = 256) or in combination with medication (n = 28). For the purposes of comparison with the psychological intervention groups half of the studies incorporated a waiting list control group, two had placebo groups of which one was a placebo medication,[15] and the other a sham biofeedback treatment,[21] and two others compared CBTi with CBTi plus medication. [15, 24]

Five of the studies employed a form of CBTi as a treatment intervention.[15, 24-27] The remaining study claimed to employ a CBTi intervention but the treatment components listed were all behavioural and did not include cognitive therapy.[21] The most commonly employed treatment components were Stimulus Control (n = 6), Sleep Hygiene Education (n = 6), Cognitive Therapy (n = 5), Sleep Restriction (n = 5) and Relaxation (n = 3). The majority of studies (n = 5) relied on sleep diary data as a primary outcome measure and 2 also utilised PSG data. Primary dependent variables derived from these assessment methods were sleep onset latency (SOL) (n = 6), total sleep time (TST) (n = 5), sleep efficiency (SE) (n = 5), wake time after sleep onset (WASO) (n = 4), sleep quality (SQ) (n = 3) and number of nocturnal awakenings (NWAK) (n = 2). Three studies included insomnia severity ratings as a primary outcome variable.[24, 26, 27] Secondary outcomes included measures of insomnia severity, sleep quality, beliefs and attitudes about sleep and pre-sleep arousal. Half of the studies collected follow-up data with the follow-up periods ranging from 4 weeks to 8 months. [15, 26, 27]

Evaluation of the Diagnostic Criteria Employed

All of the studies reviewed provided details of the criteria that had been used to identify participants with insomnia. Table 2 shows that all but one of the studies made specific reference to one of the existing nosologies for insomnia diagnosis. Three studies made use of either DSM-IV or DSM-IV-TR criteria, [15, 24,26] with one of these also using ICSD criteria. [15] One study incorporated ICSD-2 criteria,[21] and only one of those reviewed explicitly employed the RDC for Insomnia Disorder as recommended by the RWG.[27] In addition to referring to the diagnostic systems that had guided the criteria employed, five of the studies listed additional idiosyncratic inclusion and/or exclusion criteria that had been used to assess potential participants.[15,21,24,26,27]

Three of the studies reviewed reported criteria that correspond to the RDC for Insomnia Disorder, [21, 26, 27] with one of these meeting both the RDC for Insomnia Disorder and Primary Insomnia.[27] The other three studies only partially met these criteria,[15, 24, 25] with two not making specific reference to criterion B of the RDC for Insomnia Disorder which refers to establishing that the sleep difficulties reported occur despite adequate opportunity and circumstances for sleep.[15, 24] The remaining study met only criterion A

which refers to individuals reporting difficulty initiating or maintaining sleep.[25] Indeed it could be argued that this study should not have been included in the review due to the minimal inclusion criteria it employed. However, as the study authors' had outlined the study as an examination of an intervention for insomnia and drew conclusions about the efficacy of the treatment in relation to insomnia, it was felt that a case could be made for including the study in the current review.

Evaluation of the Assessment Procedures Employed

Each of the studies reviewed outlined details of the assessment methods employed to ascertain whether potential participants met the stated inclusion criteria. Table 2 shows the type of assessment procedures used by each study. The majority of the studies included clinical interviews (n = 5) and sleep diaries (n = 4) in their assessment procedures and two recorded PSG data to validate participant inclusion.[21,24] Those two studies also made use of self-report questionnaires relating to aspects of sleep and psychological well-being in order to assess inclusion and exclusion criteria.

Table 3 shows the ratings for each of the studies on the items in the evaluation tool that relate to the assessment procedures they reported. Total assessment procedure rating scores for the studies ranged from 0 to 8 points with no study incorporating all of the assessment procedures recommended by the RWG. It can be seen from Table 3 that whilst five of the studies conducted clinical interviews with participants,[15,21,24,26,27] only one indicated that independent interviewers had been used and it did not assess inter-rater reliability.[15] Two of the studies assessed potential participants using PSG data. Of note, one study collected PSG data at baseline/pre-treatment but did not report collecting it in the initial assessment process. [15] In addition, no information was reported to indicate whether or not any potential participants were excluded as a result of the PSG data recorded at baseline.

Evaluation of the Descriptive Information Reported

Each of the studies were rated on the information they reported with regard to their recruitment methods and descriptive data relating to sleep variables and sample characteristics. Table 3 includes the rating scores for each of the studies and shows that the total information reporting scores ranged from 6 to 12 points with only one study

reporting all of the information recommended by the RWG.[26] Four of the studies provided clear information on the procedures through which participants were actually recruited,[21, 24, 26, 27] and every study indicated whether participants had been clinical or volunteer type participants. All of the studies reported appropriate descriptive data on the sleep measures they employed but the picture in relation to insomnia duration and frequency was poorer with only three studies reporting data for duration, [24-26] and just one reporting frequency data.[26] None of the studies which collected both objective and subjective measures of sleep reported data on discrepancies between subjective and objective measures of sleep variables.

Treatment Outcomes

As a secondary area of enquiry for the current review each of the studies was reviewed in relation to reported treatment outcomes. The main findings are summarised in Table 2 and shall not be repeated here. Effect sizes were calculated for each of the studies on reported sleep parameters at post-treatment and these data are presented in Table 4.

It can be seen from Table 4 that all of the studies achieved either medium or large effect sizes on SOL with the exception of one that did not find significant between group differences on any of the sleep parameters measured.[25] Two of the three studies which measured WASO as a primary outcome measure found medium effect sizes,[21,24] whilst the other study did not find any differences on this measure.[27] Only two studies reported data relating to NWAK but each found differences that equated to medium effect sizes.[26,27] The two studies which used PSG as an outcome measure achieved medium to large effect sizes on TST,[15,24] whilst two that used subjective measures reported only small effect sizes on this sleep variable.[26,27] With regard to SE, three of the studies found differences which correspond to large effect sizes,[21,24,26] and two others found small effect sizes.[15,27] Table 2 shows that all three of the studies which incorporated a follow-up period reported that the gains found in their CBTi groups at post-treatment had largely been maintained at follow-up.[15, 26, 27]

Discussion

A systematic review of six studies was conducted to assess the extent to which the recommendations of the American Academy of Sleep Medicine's Research Diagnostic Criteria Work Group [9] have impacted on research into psychological treatments for insomnia since they were published in late 2004. Specifically, the review aimed to identify whether researchers had implemented the diagnostic criteria, assessment methods and information reporting practices recommended by the RWG.

With regard to the first of these areas, the results indicate that whilst most of the studies reviewed made use of existing diagnostic schedules for insomnia diagnosis, only one made reference to and incorporated the recommended RDC for Primary Insomnia and only two other studies employed criteria that were considered to correspond to the universal RDC for Insomnia Disorder. The broadly inclusive DSM-IV criteria for primary insomnia were the most commonly employed and there was no reference in any of the studies to primary insomnia subtypes or using these to differentiate amongst participants. There was also common use of idiosyncratic additional inclusion and exclusion criteria across the studies and this when combined with the use of the different diagnostic schedules meant that no two studies employed identical criteria to define their samples even though they were largely purporting to be studying participants with the same type of sleep complaint. Overall, the findings with regard to the use of appropriate diagnostic criteria and identification of insomnia subtypes among samples of people with primary insomnia, suggest that the recommendations of the RWG have had only a minimal impact thus far.

The results in relation to the second area of enquiry were similarly varied with wide use of clinical interviews and sleep diaries to assess potential participants but no study incorporating all of the various assessment procedures recommended by the RWG. In addition, there was little indication that independent interviewers or techniques for monitoring interviewer reliability had been employed in the studies reviewed. Only two studies made use of PSG data to screen potential participants and it may be that this is due to the fact that this is a method of assessment that is time consuming, impractical in terms of available resources and organisational requirements and relatively costly to

employ. Again these findings suggest that as yet the recommendations of the RWG have not had a noticeable effect on this area of insomnia research.

The level of descriptive information relating to sample recruitment and characteristics reported within the reviewed studies might also be seen as disappointing with only one study reporting all of the information recommended by the RWG and another falling just short of this. Encouragingly all of the studies reported appropriate descriptive data on the measures they employed but the lack of data on insomnia duration and frequency reflects the lack of attention to the inclusion of participants with different insomnia subtypes. This is an important omission by the researchers as duration and frequency of insomnia is a key factor in distinguishing between Idiopathic Insomnia (IdI) and Psychophysiological Insomnia (PI) which are quite different in phenotype and thought to respond differently to psychological treatments. As such the inclusion of people with IdI in investigations of CBTi will potentially have a negative affect on outcomes. Similarly, it is not clear from the details reported whether those who may have had Paradoxical Insomnia were screened for and excluded from the studies reviewed. Generally the findings from this section of the review would also indicate that the recommendations of the RWG have yet to make the desired impact on the research literature.

Comparison of treatment outcomes

The secondary aim of the current review was to compare the reported treatment outcomes with those found by previously published reviews and meta-analyses of psychological interventions for insomnia. However, as the current review unexpectedly includes a much smaller number of studies than had been expected this limits the validity of such a comparison. Secondly, the effect sizes reported by the studies in the current review are highly variable across each of the sleep parameters measured and this too makes comparison both difficult and limited in terms of its validity. Any comparison is further complicated by the variability in the outcome measures employed and the mixture of CBTi components that were delivered across different studies and also the mode via which they were delivered i.e. by a clinician, self-help material or via the internet or television. Consequently, and in view of the fact that this was a secondary aim of the current review, it is perhaps appropriate to make only a general comparison between the main outcomes reported and previous review findings. A recently published

review of the evidence for treatments of chronic insomnia provides an appropriate and convenient comparison.[29] This paper sought to provide a comprehensive assessment of the efficacy of both benzodiazepine receptor agonists (BZRAs) and psychological interventions for insomnia and is based on all relevant meta-analyses and randomised controlled trials published up to 2006. Of note, this paper reviewed one of the studies that is also included in the current review.[15]

The results of the current review show that although there was notable variation in outcomes, several of the studies found CBTi to be effective in achieving medium to large effect sizes across the variables measured. In addition, the studies that incorporated a follow-up period all reported that these gains were largely maintained at follow-up. This is in line with the findings of Riemann and Perlis' [29] review which concluded that it was clear that patients derive benefits from psychological interventions for insomnia in both the short and long-term and that gains achieved via this mode of treatment can even appear to increase over time. They also found evidence that strongly suggested that BZRAs and psychological interventions are comparably effective during periods of active treatment but that CBTi can confer longer lasting benefits. This is reflected by the findings of studies in the current review that compared CBTi with medication. Overall, it could be said that although highly variable, the treatment outcomes reported by the studies in the current review are broadly in line with that found previously in the insomnia treatment literature.

Limitations

The main limitation of this review is the unexpectedly small number of studies it includes. This was due to a lack of appropriate studies being published since 2005 and this perhaps reflects the length of time and level of effort that it takes to get randomised studies through from conceptualization and design to completion and publication. This is evidenced by the number of studies that were published within the five years since the RWG's recommendations but had to be excluded due to their data collection having commenced before 2005. Accordingly, it may be that the timing of this review was somewhat premature and were it to be repeated in a few years time a different picture might emerge. Had the review employed broader inclusion criteria, including non-randomised study designs, this too may have resulted in different findings.

Conclusions and implications

Despite the limitations of the current review, the fact that only one of the studies reviewed made any reference to the recommended RDC and none made use of insomnia subtypes must be seen as concerning. Likewise, with regard to the overall aim of the current review, it would seem reasonable to conclude that on the basis of the studies reviewed, the recommendations of the AASM's RWG have had only a minimal impact on research into psychological interventions for insomnia. This could be seen as an indication that the RWG's hopes that their recommendations would be seen as a starting point for improving insomnia research, and would discourage further studies of poorly characterized insomnia samples, have not been met with a positive response from insomnia researchers. Indeed, the findings would suggest that research into psychological interventions for insomnia may continue to be dogged by issues of validity and comparability in the future due to the ongoing lack of the use of standardised definitions, diagnostic criteria and assessment procedures. It can clearly be seen from even the small number of studies reviewed here that the failure to make use of these is associated with significant variability in treatment outcomes and the inability to make any meaningful comparisons between different studies.

The issue of researchers not differentiating between different insomnia subtypes is also in this author's mind a particularly important one as the research evidence about the effectiveness of treatments for insomnia will continue to be questionable if researchers continue to ignore the fact that they are likely recruiting participants who suffer from variants of insomnia that are quite different in terms of their characteristics and response to psychological treatments. This of course also has implications for clinical practice as unless robust research is carried out to clearly validate these insomnia subtypes, clinicians will continue to manage many patients' insomnia complaints from a largely misinformed viewpoint and will be unable to provide them with advice and interventions that will be helpful to them.

Recommendations

In light of the above issues and given the apparent ongoing wide use of different diagnostic schedules, definitions of insomnia and methods for assessing these, it would

perhaps be useful if a standardised procedural checklist were to be devised to guide researchers in appropriate insomnia diagnosis and research protocols. This could incorporate the recommendations of the RWG and other relevant information and could be referred to easily in research articles as having guided researchers in devising and conducting their studies. If it were freely available and easily accessible via the internet this might also encourage its use. Incorporating something like this, or reference to its availability, within future revisions of the main diagnostic nosologies could also be helpful to researchers and clinicians alike. In time this would hopefully help to address many of the issues discussed and standardise how insomnia research is planned and conducted thus allowing greater validity of treatment outcomes and comparisons across studies in future.

It would seem appropriate that established researchers and research groups working in the field of insomnia research should lead the way by continuing to strive to implement the recommendations of the RWG in their research studies. This particularly applies to those researchers who contributed to the development of the RDC for Insomnia as if they do not make use of these it will be ever harder to convince others to do so. Finally, given the possibly premature timing of this review, and the importance of the subject matter to insomnia research, it is recommended that it be repeated in 3 to 5 years time to ascertain whether the RWG's recommendations have finally begun to have an impact on research practices.

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Table1: Criteria for the Diagnosis of primary Insomnia

DSM-IV Diagnostic Criteria for Insomnia

- The predominant symptom is difficulty initiating or maintaining sleep, or non-restorative sleep, for at least 1 month.
- The sleep disturbance (or associated daytime fatigue) causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- The sleep disturbance does not occur exclusively during the course of narcolepsy, breathing-related sleep disorder, circadian rhythm disorder or a parasomnia.
- The disturbance does not occur exclusively during the course of another mental disorder (e.g. major depressive disorder, generalised anxiety disorder, a delirium).
- The disturbance is not due to the direct effects of a substance (e.g. drug abuse, medication) or a general medical condition.

ICSD-2 Diagnostic Criteria for Insomnia

- A complaint of difficulty initiating sleep, difficulty maintaining sleep, or waking up too early, or sleep that is chronically non-restorative or poor in quality.
- The sleep difficulty occurs despite adequate opportunity for sleep.
- At least one of the following forms of daytime impairment related to the nighttime sleep difficulty is reported:
    - Fatigue or malaise
    - Attention, concentration, or memory impairment
    - Adverse impact on school, work or social activities
    - Mood disturbance or irritability
    - Daytime sleepiness
    - Lack of energy or motivation
    - Driving errors
    - Tension, headaches or gastrointestinal symptoms
    - Excessive worries about sleep loss

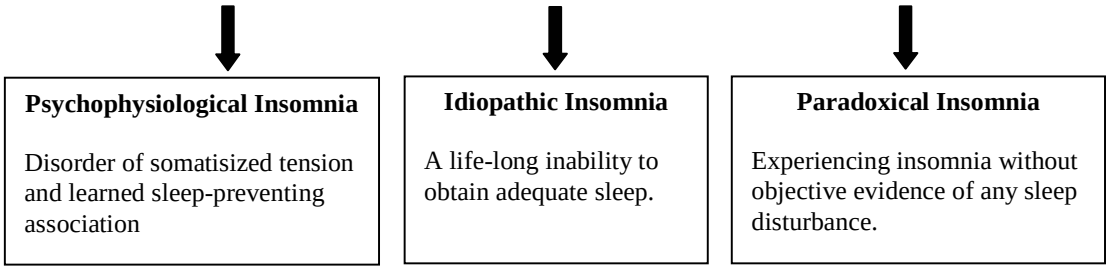

Table 2: Study characteristics and main findings

Study & Sample Size	Sleep Diagnosis & Diagnostic Criteria Employed	Assessment Procedures Used	Treatment Type, Duration & Follow-up	Outcome Measures	Summary of Main Findings
Wu et al. (2006), [15] CBTi (n =19); Meds (n = 17); CBTi + Meds Combined (n = 18); Placebo (= 17)	Chronic/Primary insomnia DSM-IV & ICSD-1	Clinical Interview x 3	CBTi (CT,SC, SR, SHE) 8 wk; 8 mo	Primary: PSG & sleep diary data of SOL, SE & TST Secondary: Pre-sleep Arousal Scale (PSAS), Dysfunctional Beliefs & Attitudes About Sleep Scale (DBAS), Pittsburgh Sleep Quality Index (PSQI)	At the end of treatment subjective SOL, SE and TST were better in the Medication only group than the CBTi only group. At 3-mth follow-up subjective and objective SOL, SE and TST were better in the CBTi group than in both the PCT and Combined group. At 8mth follow-up the CBTi group showed a steady sleep state whilst the medication only and Combined group were gradually returning to the pre-treatment condition. The CBTi group showed significantly better improvement at follow-up on the PSAS, DBAS & PSQI.
Soeffing et al. (2008), [21] CBTi (n = 20); Placebo (n = 27)	Hypnotic-dependant older adults with Chronic Insomnia ICSD-2	Clinical Interview PSG Sleep diaries Self-report questionnaires of daytime function	Behavioural Therapy (SC, SHE, Rel) 8 wk; No FU	Primary: Sleep diary measures of SOL, NWAK, WASO, TST, SE & SQ Secondary: Self-report daytime function data	The CBTi group reported significantly better self-report measures of SOL, WASO and SE at post-treatment. No significant differences found on measures of daytime function.
Zavesicka et al. (2008), [24] CBTi (n = 10); CBT + Meds (n = 10)	Chronic Insomnia DSM-IV	Clinical Interview PSG Sleep diaries Self-report questionnaires	CBTi (SR; SC, SHE CT; and Rel) 8wk; No FU	Primary: PSG data of TST, SOL, WASO & SE, Insomnia Severity Index (ISI), Epworth Sleepiness Scale (ESS)	Both groups reported significant post-treatment improvements in PSG measured SOL, SE and TST and self-reported insomnia severity and daytime sleepiness. No significant between group differences were found.

				Secondary: PSG measured sleep architecture	
Van Straten et al. (2009), [25] CBTi (n = 126); WL Control (n = 121)	Subjects with sleep problems Age 18+, Lying awake at night for >30 mins x 3 per wk for >= 1mth	Brief telephone interview to establish inclusion criteria	Self-help CBTi (Sleep Education, SHE, SR, SC, Rel and CT) 6wk; No FU	Primary: Sleep diary data of TST, SOL, SE, SQ Secondary: Use of sleep meds, Sleep Evaluation Form (SEF), DBAS	Both groups improved significantly with respect to TST, SOL & SE but there were no significant between group differences. The treatment group reported significantly better improvements on Sleep Quality, SEF and DBAS.
Ritterband et al. (2009), [26] CBTi (n = 22); WL Control (n = 23).	Primary insomnia DSM-IV-TR	Clinical Interview Sleep diaries	CBTi via Internet (SR, SC, SHE, CT & Relapse prevention) 9wk; 6mth	Primary: ISI, Sleep diary data of WASO & SOL Secondary: SE, TST, NWAK, Time in bed, Feeling restored & Soundness of Sleep.	The CBTi group showed statistically and clinically significant improvement post-treatment on ISI whereas the control group did not show change. The gains were maintained at 6mth follow-up. The CBTi group also showed significant improvements in WASO and SE at post-treatment.
Vincent & Lewycky (2009), [27] CBTi (n = 59); WL Control (n = 59)	Chronic Insomnia AASM RDC	Clinical Interview Sleep diaries	Online CBTi (SHE, SC, SR, Relaxation, CT & Sleep meds tapering. 5wk; 4wk	Primary: Sleep diary data of SQ, TST, SOL, SE, NOW & WASO; ISI, Multi-Dimensional Fatigue Inventory (MFI) Secondary: DBAS, Clinical Global Improvement Scale (CGI)	The treatment group showed significant improvements in SQ and ISI at post-treatment which were maintained at 4wk follow-up. They also showed significant improvement in General Fatigue at post-treatment. Significant changes on PSAS and DBAS were also reported.

Key:

DSM-IV: Diagnostic and Statistical Manual of Mental Disorders 4th edition; DSM-IV: Diagnostic and Statistical Manual of Mental Disorders 4th Edition - Text Revision; ICSD-1: International Classification of Sleep Disorders - 1st Edition; ICSD-2: International Classification of Sleep Disorders - 2nd Edition; PSG: Polysomnography; CBTi: Cognitive Behaviour Therapy for Insomnia; CT: Cognitive Therapy; SC: Stimulus control; SR: Sleep restriction; SHE: Sleep hygiene education; Rel: Relaxation; SOL: Sleep onset latency; NWAK: Number of wakenings; WASO: Wake time after sleep onset; TST: Total sleep time; SE: Sleep efficiency; SQ: Sleep Quality.

Table 3: Assessment procedure and information reporting ratings for each study

Study	Item 1	Item 2	Item 3	Item 4	Item 5	Assessment Procedure Score	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Information Reporting Score	Total Score
Wu et al. (2006)	2	2	0	0	0	**4/12**	2	2	2	0	0	0	**6/12**	**10/24**
Soeffing et al. (2008)	4	0	0	2	2	**8/12**	2	2	2	0	0	0	**6/12**	**14/24**
Zavesicka et al. (2008)	2	0	0	2	2	**6/12**	0	2	2	2	0	0	**6/12**	**10/24**
van Straten et al. (2009)	0	0	0	0	0	**0/12**	2	2	2	2	0	2	**10/12**	**10/24**
Ritterband et al. (2009)	4	0	0	0	2	**6/12**	2	2	2	2	2	2	**12/12**	**18/24**
Vincent & Lewycky (2009)	4	0	0	0	2	**6/12**	0	2	2	0	0	2	**6/12**	**12/24**

Key:

Item 1. Was a clinical interview used? Yes (2 points) No (0 points) Structured or Semi-structured (2pts) Unstructured or Don't Know (0pts)

Item 2. Were independent interviewers used? Yes (2 points) No (0 points)

Item 3. Was inter-rater reliability checked? Yes (2 points) No (0 points)

Item 4. Were Polysomnography data collected? Yes (2 points) No (0 points)

Item 5. Were Sleep Diary/Log data collected? Yes (2 points) No (0 points)

Item 6. Recruitment methods employed Yes (2 points) No (0 points)

Item 7. Types of individuals enrolled i.e. clinical or volunteer participants? Yes (2 points) No (0 points)

Item 8. Means, std deviations and ranges of sleep measures e.g. TST, SOL, WASO, SE? Yes (2 points) Partially (1 point) No (0 points)

Item 9. Means, std deviations and distribution of insomnia duration? Yes (2 points) Partially (1 point) No (0 points)

Item 10. Means and distribution of insomnia frequency? Yes (2 points) Partially (1 point) No (0 points)

Item 11. Means and std deviations of discrepancies between subjective estimates and objective measures of sleep measures? Yes (2 points) Partially (1 point) No (0 points)

Not Applicable (2 points)

Table 4: Standardised effect sizes of Cognitive Behaviour Therapy for Insomnia on sleep parameters at post-treatment

Outcome Variable	Wu et al. (2006)	Soeffing et al. (2008)	Zavesicka et al. (2008)	van Straten et al. (2009)	Ritterband et al. (2009)	Vincent & Lewycky (2009)
Sleep Onset Latency	1.31*	0.55	0.92*	-0.10	0.99	0.50
Wake After Sleep Onset	-	0.53	0.59*	-		0.13
Number of Awakenings	-	-	-	-	0.71	0.68
Total Sleep Time	1.01*	-	0.57*	-0.15	0.41	0.24
Sleep Efficiency	0.49*	0.89	0.91*	0.00	1.23	0.23

*As measured by PSG

Note: Effect sizes for the Zavesicka et al.(2008) study relate to within group and not between group differences as the comparison group in the study received CBTi + medication

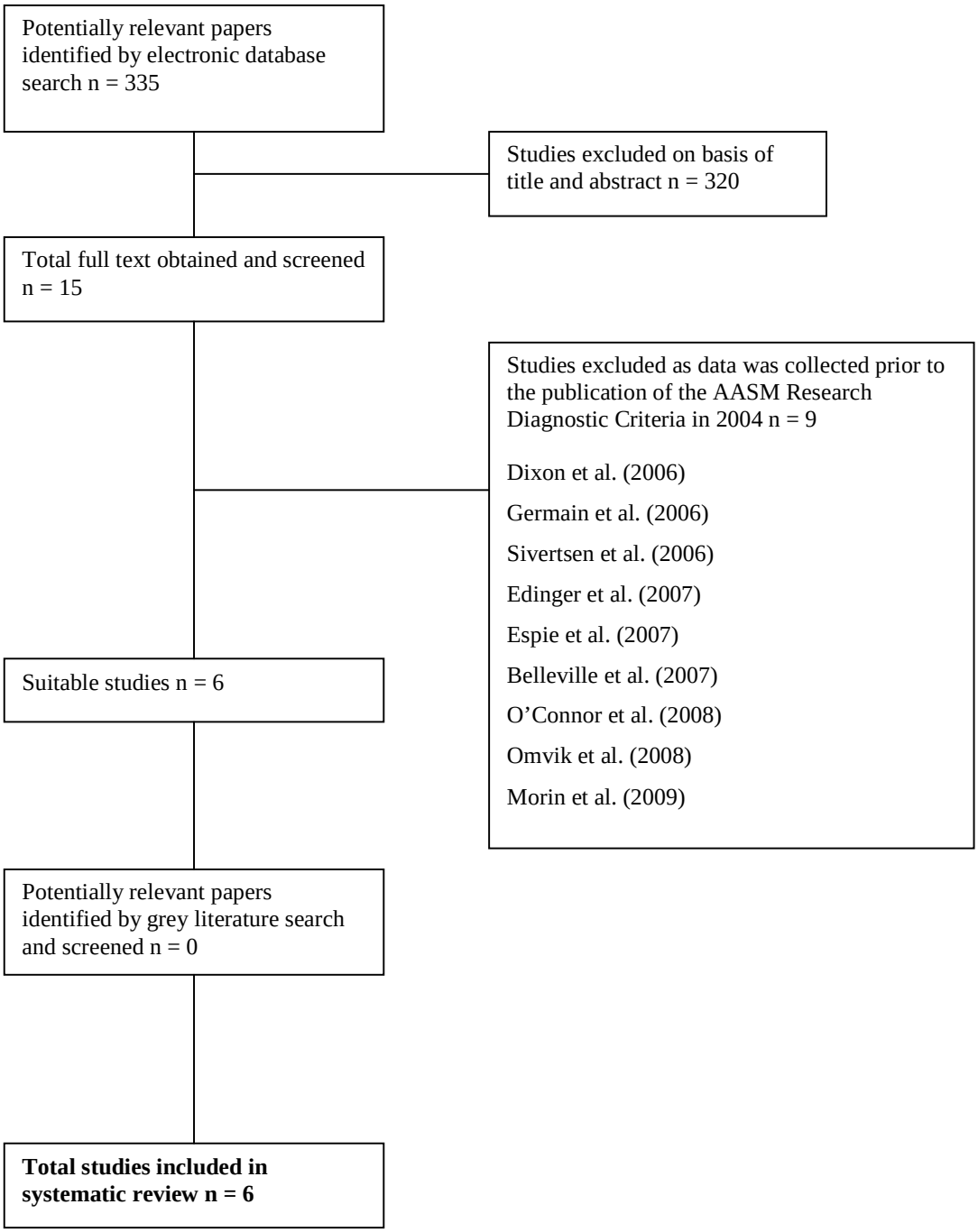

Figure 1: Summary of literature search yield and study inclusion/exclusion process

CHAPTER TWO: MAJOR RESEARCH PROJECT

Psychophysiological Insomnia and Idiopathic Insomnia: The role of self-regulatory behaviour systems*

Prepared in accordance with the guidelines for the Journal of Sleep Research (Appendix B.1)

Grant Forgan**
Section of Psychological Medicine,
Division of Community Based Sciences,
Academic Centre,
University of Glasgow,
Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow, G12 0XH
Email: gforgan@blueyonder.co.uk

***** The original protocol submitted to, and passed by the Doctorate in Clinical Psychology training course is included as Appendix B.2.

** Author for correspondence.

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology (D.Clin.Psy)

Abstract

Further research into identifying the mechanisms that underlie the development and maintenance of insomnia and its different subtypes is required. Neurobiological motivational systems are thought to mediate our experiences of negative and positive affect and are implicated in the etiology of psychiatric disorders, but their role in insomnia is unknown. The present study aimed to compare self-reported sensitivity to these systems across Psychophysiological Insomnia (PI) and Idiopathic Insomnia (IdI). Sixty one adults with PI (n = 20) and IdI (n = 20), and Good Sleepers (n = 21), completed measures of sleep characteristics, Behavioural Inhibition Sensitivity (BIS), Behavioural Activation Sensitivity (BAS), Sleep Effort, Depression and Anxiety. As predicted the PI group reported significantly greater BIS sensitivity compared with the IdI and GS groups. However, no significant differences were found between groups on BAS sensitivity. Post-hoc analysis revealed significant differences between the insomnia groups on sleep effort when age was included as a covariate. Depression and anxiety did not moderate the relationships between the other outcome variables. The findings support the notion that PI is associated with a specific tendency toward threat sensitivity, a tendency absent in IdI. This is consistent with contemporary thinking on PI that this group exhibits greater vulnerability to stress-related sleep disturbance, whereas IdI is a more stable insomnia subtype that may be less reactive to circumstances. Accordingly, this suggests that different psychological treatment approaches are indicated for these subtypes with PI requiring re-conditioning forms of CBT and IdI requiring a more acceptance based approach.

Keywords: Insomnia, Psychophysiologic Insomnia, Idiopathic insomnia, Behavioural Inhibition System, Behavioural Activation System, Sleep Effort

INTRODUCTION

Insomnia is the most prevalent disorder of sleep and is thought to affect from 6-38% of adults (Ohayon, 2002). However, it is a poorly understood condition and is frequently viewed by clinicians as merely a symptom of other so-called 'primary' health disorders rather than a clinical disorder in its own right. Consequently, insomnia symptoms can often go untreated in favour of targeting the 'primary' disorder (Harvey, 2001). In addition, despite differences in the known characteristics and apparent treatability of different insomnia subtypes, they are usually managed in the same way. The International Classification of Sleep Disorders, 2nd Edition (ICSD-2), (American Academy of Sleep Medicine, 2005) lists diagnostic criteria for 3 primary insomnia subtypes; *Psychophysiological Insomnia, Idiopathic Insomnia* and *Paradoxical Insomnia*. The present study aimed to investigate the first and second of these subtypes.

Research into the psychological mechanisms that may be implicated in the development and maintenance of insomnia has resulted in a number of explanatory models being put forward (Perlis et al., 2005). Harvey (2002) proposed a cognitive model of primary insomnia which focussed on processes that might maintain the disorder rather than be the cause of it. The model suggests that excessive worry and anxiety about sleep and the consequences of not getting enough sleep leads to cognitive arousal, emotional distress and selective attention toward both internal and external sleep-related threat stimuli. This in turn leads to the development of dysfunctional perceptions and beliefs about sleep and engagement in counterproductive safety behaviours that serve to impede sleep and thus perpetuate the sleep difficulty.

The neurocognitive model of insomnia developed by Perlis et al., (1997) is based on a behavioural concept of insomnia and suggests that chronic insomnia is primarily a central nervous system disorder relating to behavioural factors and classical conditioning. Whilst this model acknowledges that cognitive processes such as rumination and worry may prolong wakefulness, it does not see them as being responsible for the individual's inability to initiate or maintain sleep. Instead the

neurocognitive model posits that conditioned somatic, cognitive and cortical arousal underlie chronic insomnia and that cortical arousal interferes with sleep via heightened sensory and information processing and increased long-term memory (Perlis et al., 2005). Similar to Harvey's (2002) cognitive model the neurocognitive model implicates the possible role of attention bias toward salient sleep-related stimuli and threat cues in the development and maintenance of insomnia.

The cognitive and neurocognitive models of insomnia are two of several that frame insomnia as a disorder of hyperarousal of cognitive and/or physiological systems within the individual (Perlis et al, 2005). Conversely, Espie's (2002) Psychobiological Inhibition Model proposes that it is disruption to the physiological, cognitive, affective, and behavioural processes which normally inhibit wakefulness and thus allow sleep to come which underlies the development of insomnia. Within this concept the failure to inhibit wakefulness through de-arousal is attributed to an inability to sleep drawing the individual to pay attention to a usually automatic process and trying to exert control over it. This process has the unintended effect of serving only to sustain wakefulness and for some over time leading to the cognitive and behavioural patterns that characterise and maintain insomnia.

More recently the psychobiological inhibition model of insomnia was extended by Espie and colleagues to form their Attention-Intention-Effort (A-I-E) Pathway Model of Psychophysiologic Insomnia (PI) (Espie et al., 2006). Like the psychobiological inhibition model the A-I-E model posits that the sleep-wake process is primarily self-regulatory and is vulnerable to disruption by focussed attention on sleep-related cues and stimuli and by effortful attempts to control its operation. Essentially the model proposes that the sleep-wake process can be disrupted by selectively *attending* to sleep, explicitly *intending* to sleep, and by making *effortful* attempts to initiate sleep. Prolonged disruption of this normally self-regulatory process over time then leads to the development and maintenance of PI. The concept at the heart of this model mirrors that proposed for other psychiatric disorders, such as anxiety and depression, in that an attentional bias toward salient cues and stimuli is said to be involved in the etiology of the disorder (Dalgleish & Watts, 1990). In the case of those with PI, selective attention

toward sleep related cues is thought to be associated with the experience of 'craving' or 'incentive' for sleep and heightened awareness of potential 'threat' to the sleep-wake process (Espie et al., 2006).

Although there are some clear differences between the approaches of each of the above models of insomnia they all implicate the role of cognitive, behavioural and physiological processes in either the development and/or maintenance of insomnia. The inclusion of these factors within the models is supported by the results of research investigating them. For example, evidence supporting the cognitive model of insomnia can be found in studies where the pre-sleep thoughts of insomnia patients have been investigated (Harvey, 2000; Nelson & Harvey, 2003; Wicklow & Espie, 2000; and Waine et al., 2009). These studies have shown that insomnia patients often experience intrusive pre-sleep thoughts about a wide range of internal and external sleep-related stimuli and can also develop dysfunctional beliefs and misperceptions about their sleep and their ability to sleep. With regards to the neurocognitive model of insomnia, studies measuring electrical activity in the brain have found increased activity in primary insomnia patients in the sleep-onset period and during non-rem sleep thus supporting the suggestion that cortical arousal plays a role in insomnia (Bastien & Bonnet, 2001, Perlis et al., 2001). Similarly a recent study by Bastien et al., (2008) sought to explore both the neurocognitive and psychobiological inhibition models utilising measures of electrical activity in the brain to compare psychophysiological insomnia individuals with good sleepers. They found evidence of both cortical arousal and difficulties with disengaging from wake processes in the insomnia subjects thus providing empirical support for both theoretical viewpoints.

A feature of the insomnia models outlined that is of particular interest to the current study is that they all either explicitly include or allow for the inclusion of attention bias toward sleep-related stimuli as a mechanism that may play a role in insomnia. This is an area that has received much research attention of late and there is now a growing evidence base from studies, using both subjective and objective measures of attention, to support the position that patients with insomnia show attention biases toward sleep-related threat cues (Neitzert Semler & Harvey, 2004a, 2004b; Marchetti et al., 2006;

MacMahon et al., 2006; Woods et al., 2009). For example, in their recent study Woods et al. (2009) used a cognitive probe task to investigate the role of the clock as a focus of selective attention in insomnia. They utilised a modified Posner paradigm to compare reaction times between subjects with primary insomnia and good sleepers and found that the insomnia group demonstrated delayed disengagement to the clock. This finding can be seen as further support for those insomnia models which incorporate selective attention towards salient stimuli as being important to the maintenance of primary insomnia.

Insomnia subtypes

Psychophysiological Insomnia

Psychophysiological Insomnia (PI) is the most common form of persistent primary insomnia and is found in 1-2% of the general population, and 12-15% of those presenting for treatment (Espie et al., 2006). It develops in adulthood, can often be linked to identifiable precipitating events and/or stressors, and comprises both psychological and physiological features such as conditioned arousal, sleep-incompatible behaviour, sleep preoccupation, and excessive focus on and anxiety about sleep (Harvey, 2001) Clinical treatment research has demonstrated that PI can be treated effectively using psychological interventions (e.g. Cognitive Behaviour Therapy for Insomnia) (Morin et al., 2006 and Riemann & Perlis, 2009) thus suggesting that both behavioural and cognitive factors play a part in the aetiology of PI.

Idiopathic Insomnia

To date few studies have investigated the nature of Idiopathic Insomnia (IdI), also known as Childhood Onset Insomnia, and it has proved to be a conceptually difficult disorder to define and research (Greene, 2008). The ICSD-2 describes IdI as a longstanding insomnia complaint with a chronic and persistent course, few periods of sustained remission, and onset during infancy or early childhood. IdI is thought to affects around 1% of adults and is seen in less than 10% of those presenting with an insomnia complaint (Ohayon, 2002; American Academy of Sleep Medicine, 2005).

Unlike PI, there is usually an absence of identifiable precipitating and maintaining factors in relation to the sleep difficulties of those with IdI.

IdI patients typically show only minor psychological abnormalities although there is limited evidence that some may adopt denial and repression as coping strategies and of an association with neurodevelopmental disorders such as ADHD and Dyslexia (Hauri & Olmstead, 1980; Hauri, 1983). Hauri and Olmstead's (1980) findings also revealed differences in sleep architecture between participants with PI and IdI which indicated that people IdI sleep differently to those with PI. In addition, Edinger et al., (1988) found that participants who reported childhood onset insomnia displayed higher levels of arousability and were largely unresponsive to behavioural treatment methods. These findings lend weight to Hauri & Olmstead's (1980) suggestion that IdI may have less of a psychological and more of a neurophysiologcial aetiology than PI. Further to this, in the only recent and diagnostically robust study of adults with IdI, Barrie and Espie (2009) investigated how participants with IdI and PI conceptualised and accepted their sleep difficulties. The IdI group perceived their insomnia to be more permanent and rated an acceptance-based treatment approach as more acceptable than the PI group. Interestingly though, in view of Edinger et al's (1998) findings about treatment response in IdI, both groups rated behavioural therapy as more acceptable than either a pharmacological or acceptance-based approach.

Self-regulatory Behaviour Systems

Motivational theorists argue that a continual process of moving toward, and away from, mental goal representations underlies human behaviour (Carver & Scheier, 1998). Put simply, such a model proposes that human behaviour is motivated by the pursuit of desirable goals and pleasure, and the avoidance of negative outcomes and displeasure. Gray (1982, 1987, 1994) endorses this view and suggests that two main general motivational systems regulate behaviour and affect; a Behavioural Inhibition System (BIS) and a Behavioural Activation System (BAS).

The BIS is said to be involved in the experience of negative affect, and the anticipation and avoidance of threat and negative outcomes. Indeed, Gray argued that this mechanism underlies the experience of anxiety (Gray, 1987, 1994; Gray & McNaughton, 2000). Figure 1 shows a diagrammatic representation of the BIS as Gray (1982) conceived it. The BAS on the other hand is thought to control appetitive motivation and to be sensitive to signals of reward and is therefore more implicated in the experience of positive affect, and the facilitation of behaviour that may lead to positive outcomes.

(INSERT FIGURE 1 HERE)

Carver and White (1994) developed the Behavioural Inhibition/Behavioural Activation Scale (BIS/BAS Scale) to assess dispositional sensitivities to Gray's two motivational systems. Research using the BIS/BAS Scale has shown that when threat occurs individuals high in BIS sensitivity tend to experience more negative affect and be more anxious, distressed, and avoidant than persons lower in BIS sensitivity (Campbell-Sills et al., 2004; Bijttebier et al., 2009). Conversely, those high in BAS sensitivity experience greater positive affect and engage in more approach behaviour than those lower in BAS sensitivity. Low levels of BAS sensitivity have also been associated with negative affect suggesting that high levels of BAS sensitivity may be protective (Carver & White, 1994;.Gable et al., 2000, Kasch et al., 2002, O'Connor & Forgan, 2007 and Bijttebier et al., 2009).

Neurobiological Motivational Systems and Primary Insomnia

Attentional biases to threat and their relationship with behaviour and experiences of affect are implicated in models of insomnia, particularly the A.I.E. pathway model of PI (Espie et al., 2006), and also in Gray's model of neurobiological motivational systems (Gray, 1982, 1987 & 1994). In addition, variation in BIS/BAS sensitivity has previously been associated with the presence of psychopathology. Therefore, it would seem reasonable to hypothesize that BIS/BAS sensitivity may play a role in the development and maintenance of PI and that differing levels of BIS/BAS sensitivity

might be found between those with PI and normal sleepers. Figure 2 shows how many of the features of poor sleep and insomnia might map onto Gray's (1982) BIS model. Additionally, given the previously found differences in the characteristics of the PI and IdI insomnia subtypes, it would also seem appropriate to raise the question of whether they may also show differences in BIS/BAS sensitivity.

(INSERT FIGURE 2 HERE)

The present study aimed to address these areas of enquiry and extend our knowledge of the PI and IdI insomnia subtypes by measuring self-reported BIS/BAS sensitivity amongst adults who meet criteria for PI and IdI, and normal sleep. Given that sleep effort is also said to play a key part in the aetiology of PI, but its role in IdI is unknown, a measure of sleep effort was also employed. The Glasgow Sleep Effort Scale (GSES; Broomfield & Espie, 2005) allows sleep effort to be investigated as an overall construct and at the level of the core components which comprise Broomfield and Espie's proposed model of sleep effort such as anxiety about sleep, avoidance of sleep, control over sleep and dysfunctional beliefs about sleep performance. Measures of depression and anxiety were also administered in order to investigate the potential relationships between insomnia, BIS/BAS sensitivity and psychopathology.

AIMS and HYPOTHESES

Aims

The present study aimed to address the following research questions:

Primary questions:

1. Do those with PI and IdI report differing levels of BIS/BAS sensitivity compared to good sleepers?
2. Do those with PI report differing levels of BIS/BAS sensitivity compared to those with IdI?

Secondary questions:

3. Do those with PI report differing levels of Sleep Effort compared to those with IdI?
4. Do Anxiety and Depression moderate the relationships between PI, IdI, BIS/BAS sensitivity and Sleep Effort?

Hypotheses

In view of the exploratory nature of the study, the following tentative hypotheses were posited:

1. Participants with PI will report greater levels of BIS sensitivity than normal sleepers and those with IdI.
2. Participants with PI will report lower levels of BAS sensitivity than normal sleepers.
3. Participants with IdI will report greater levels of BAS sensitivity than those with PI.
4. Participants with PI will report greater levels of overall Sleep Effort than those with IdI and will differ in terms of their responses to individual GSES items relating to different core components of the sleep effort construct.
5. Participants with PI who report greater levels of psychopathology will also report greater levels of BIS sensitivity.

Methods

Participants

The study participants were aged 18 to 65 years of age and met criteria for inclusion in either a Psychophysiological Insomnia (PI) group, Idiopathic Insomnia (IdI) group, or Good Sleeper (GS) group. Participants in the PI and IdI groups were required to meet the diagnostic criteria for these insomnia subtypes, as outlined in the ICSD-2 diagnostic classification system (AASM, 2005) (See Appendix B.3) and sleep disturbance criteria as indicated by scores of >5 on the Pittsburgh Sleep Quality Index (PSQI) and > 8 (Moderate Insomnia) on the Insomnia Severity Index (ISI). The GS group was required to meet research diagnostic criteria for normal sleepers (Appendix B.3) as recommended by the American Academy of Sleep Medicine Work Group (Edinger et al., 2004). To ensure a clear distinction between the insomnia groups, the PI group was required to have developed insomnia after the age of seventeen and the IdI group by the age of twelve.

Exclusion criteria were: presence of another sleep disorder such as narcolepsy, sleep apnoea, restless legs syndrome, circadian sleep disorders or parasomnias; presence of severe psychopathological disorder; experiencing a somatic disorder directly related to the onset and course of insomnia; evidence of substance abuse; and taking medications known to influence sleep. Participants with stable medical or psychiatric disorders were included in the study provided that these conditions were not thought to be the primary cause of their insomnia difficulty.

A total of 98 potential participants expressed an interest in taking part in the study. Of these 20 were not invited to participate in the study after completing an initial telephone screening interview as they did not meet the study inclusion criteria. A further eight interested participants were excluded following a semi-structured clinical interview. Four of these had symptoms which indicated the presence of another sleep disorder (e.g. Restless Legs Syndrome, Paradoxical Insomnia) and four reported having a current diagnosis of a psychiatric disorder (e.g. Attention Deficit Hyperactivity Disorder, Borderline Personality Disorder) which may have been the

primary cause of their insomnia difficulty. Six participants were also excluded after returning their completed questionnaires as their scores on the measures of anxiety (3 participants) and depression (3 participants) were indicative of severe levels of these difficulties and as such may have been underlying their sleep problems. Three other participants who took part in the semi-structured clinical interview but did not return their completed questionnaires to the researcher were also excluded. Of the 98 potential participants who showed an interest in the study 61 were included in the final sample.

Demographic information was collected in relation to all participants' age and gender. Address and postal code data were also collected for the insomnia participants whereas this data was only collected from good sleepers who wished to be sent details of the outcome of the study once it was completed. Only five of the GS group provided their address details.

Procedure

Participant recruitment

Participants were recruited using established and ongoing University of Glasgow Sleep Centre (UGSC) recruitment methods, including emails to University of Glasgow students and staff, articles on university web pages, placement of notices in NHS staff newsletters; posters in NHS facilities including GP surgeries, newspaper advertisements etc, and contacting individuals who previously participated in sleep research and had given permission to be contacted for other studies. Publicity for the study was gained via news articles on a Scottish national television news programme and in a national newspaper. The GS group were recruited via the above methods and also from within the staff group at the researchers place of work and social connections.

Research Procedure

Volunteers were invited to contact the researcher or UGSC by e-mail or telephone. Those with a sleep problem were then screened via a brief telephone interview

(Appendix B.4) to assess their possible suitability for participation in relation to the study inclusion and exclusion criteria. A participant information sheet (Appendix B.5) and consent form (Appendix B.6) was then sent to potential participants and they were invited to participate. Upon receiving the completed consent forms the researcher then despatched the self-report measures and a 7-day sleep diary (Appendix B.7) and arranged to conduct a semi-structured clinical interview with the participants (Appendix B.8) either via telephone or in person at the UGSC. Allocation of participants to the insomnia groups took place once participants had returned the self-report measures and had completed the clinical interview. Volunteers for the GS group were sent a participant information sheet and were asked to complete and return a consent form and brief questionnaire relating to their sleep (Appendix B.9).

Study design

The study consisted of a quasi-experimental between-groups design with three groups: Adults with either PI or IdI and Good Sleepers (GS). Efforts were made to balance the groups in terms of gender and age. The primary dependent variables in relation to the stated hypotheses were participants' scores on the BIS/BAS Scales and Glasgow Sleep Effort Scale (GSES), with scores on the Beck Depression Inventory II (BDI II) and Beck Anxiety Inventory (BAI) being the secondary dependent variables. Group was the main independent variable.

Sample size/Power calculation

To our knowledge no previous studies have investigated the relationship between insomnia and BIS/BAS sensitivity. Therefore it was not possible to calculate the optimal sample size required for the proposed study by referring to previous findings in this area. In addition, previous research which has investigated psychological variables in persons with IdI is extremely limited. However, Hauri & Olmstead (1980) did compare adults with childhood and adult onset insomnia using sample sizes of n=20 and n=39 respectively, and found significant differences between the groups on sleep related characteristics.

With regards to the BIS/BAS scales, much of the previous research utilizing these has looked at within group differences. However, Kasch et al., (2002) examined BIS/BAS sensitivity in 62 depressed participants and 27 non-depressed controls. They found that the depressed participants reported significantly lower levels of BAS and higher levels of BIS. Effect sizes (calculated from reported means & standard deviations) were as follows: BIS d = 1.12, BAS Drive d = .99, BAS Reward Responsiveness d = .94 and BAS Fun Seeking d = .86. In accordance with Cohen's (1998) effect size conventions such figures correspond to large effects. Given that the present study's primary hypotheses related to between group differences it was felt that a medium to large effect size of around 0.7 would seem reasonable for the proposed investigation. A series of power calculations revealed that an estimated 24 participants per group would be required to detect significant differences between the groups. Implementing robust diagnostic criteria for group allocation and demographically matched groups would also enhance the power of the study to detect any differences.

Assessment measures

In order to ascertain that participants met the study inclusion criteria and were allocated to the correct group the following measures were administered:

1. *Pittsburgh Sleep Quality Index* (PSQI; Buysse et al., 1989) The PSQI provides a reliable, valid and standardized measure of sleep quality; to discriminate between good and poor sleepers. It consists of 19 self-rated items and 5 items rated by the bedpartner or roommate which are used for clinical information only. The 19 self-rated items are grouped into seven component scores, each weighted equally on a 0-3 scale. These component scores are summed to yield a global PSQI score with a range of 0-21. A PSQI global score >5 indicates that a subject is having severe difficulty in at least two areas, or moderate difficulty in more than three areas of sleep quality. Recent, independent study has validated this cut off and confirmed reliability (Cronbach's alpha = 0.85, test–retest r = 0.84; Backhaus et al., 2002). Cronbach's alpha for the current sample was adequate a = .67.

2. *Insomnia Severity Index* (ISI; Bastien et al., 2001) The ISI is a 7 item (Total score range 0-28) self-report measure, which asks the rater to state how severe their insomnia is, how much they feel it, the impact it has on their life and how distressed they are by it. A score of 8 or more is suggestive of insomnia. The ISI has been reported to be a reliable and valid instrument with an alpha co-efficient of internal consistency of 0.74 (Bastien et al., 2001). For the current sample Cronbach's alpha was 0.77.

3. Participants were also asked to complete a sleep diary for seven days. Data from the diary were reviewed to ensure participants met study inclusion criteria for insomnia and did not have a sleep complaint that might be better characterised by other forms of sleep disorder.

In order to test the stated hypotheses of the present study the following measures were administered:

1. BIS/BAS sensitivity was assessed using the *Behavioural Inhibition Scale (BIS) and Behavioural Activation Scales (BAS)* (Carver & White, 1994) which comprise 24 items in total (Items 1, 6, 11, & 17 are fillers which are not scored) with four subscales. Respondents rate each item on a 4-point scale ranging from 1 (very true for me) to 4 (very false for me). One scale reflects BIS sensitivity (7 items; score range 7 to 28), and three reflect aspects of BAS sensitivity: BAS Drive (4 items; score range 4 to 16); BAS Fun Seeking (4 items; score range 4 to 16); and BAS Reward Responsiveness (5 items; score range 5 to 20). The three aspects of BAS sensitivity derive from diverse theoretical statements about how BAS functioning should be reflected experientially. The three BAS-related scales were designed to reflect these somewhat distinct functions (Carver et al., 2000). Higher scores on each scale indicate greater levels of BIS/BAS sensitivity. The internal consistencies for the BIS/BAS Scales for the present sample were adequate: Cronbach's alphas = .77, .76, .78, and .70, for the BIS scale, BAS Drive, BAS Fun Seeking, and BAS Reward Responsiveness, respectively. Whilst it is feasible to merge the BAS scales to create an overall total BAS score for the purposes of analysis, this has been cautioned against by the author's of studies where factor

analysis of the BIS/BAS scales has supported a four factor structure and highlight the importance of treating the BAS subscales as independent constructs (Campbell-Sills et al., 2004 and Ross et al., 2002). Accordingly the current study has adopted this approach and analysed the BAS scales separately and not as one overall scale.

2. *Glasgow Sleep Effort Scale* (GSES; Broomfield & Espie, 2005) The GSES is designed to assess effortful preoccupation with sleep and is comprised of 7 items. Each item is rated on a 3-point scale from 0 to 2 with a totals scale score range from 0 to 14. Sleep Effort is an important construct within the ICSD-2 definition of PI; and is the 'end state' of the proposed Attention-Intention-Effort pathway. The GSES has a single factor structure but as each item relates to a different core component of Broomfield & Espie's overall model of sleep effort this also allows for comparisons at the individual item level. The internal consistency for the current sample was (α =.80). The 7 items of the GSES are presented in Table 4.

3. *Beck Depression Inventory II* (BDI-II; Beck et al., 1996) The BDI-II is a 21-item self-report form covering symptoms of depression experienced by respondents during the previous two weeks. Each item is rated on a 4-point scale from 0 to 3 with a total scale score range of 0 to 63. A cut-off score of 20 or above suggest moderate to severe depression. The BDI-II demonstrates high internal consistency, with Cronbach's alpha being .86 for the present sample. The BDI-II includes two items which relate to respondent's experiences of changes in their sleeping pattern and levels of tiredness or fatigue over the previous two weeks. These are rated on Likert scales which indicate whether or not there has been any change in these symptom areas. It would seem reasonable to hypothesize that some respondents who meet the criteria for an insomnia disorder may not indicate on these items that there has been any change over the previous two weeks as their sleep difficulties are chronic and long-term. However, they would in fact likely be experiencing ongoing difficulties with both their sleep pattern and level of tiredness or fatigue but underreporting these within the context of completing the BDI-II. Accordingly, it was felt that this could represent a confounding variable within the present study so respondent's scores on these two items were not included in the data analyses.

4. *Beck Anxiety Inventory* (BAI; Beck et al., 1988) The BAI is a 21 item questionnaire that measures the severity of anxiety in adults. Each item is rated on a 4-point scale from 0 to 3 with a total scale score range of 0 to 63. It is widely accepted that a score of '30' or above serves as a measure of severe anxiety. The psychometric properties of BAI have been widely studied, resulting in high internal consistency $\alpha = 0.92$ and excellent test-retest reliability $r(81) = 0.75$ (Beck et al.; 1988). Cronbach's alpha for the current sample was .91.

Data Analysis

Data analyses were conducted using the Statistics Package for the Social Sciences for Windows (SPSS for Windows version 15) software package. The data were checked using graphical and numerical methods with reference to skewness and kurtosis values to ensure that they were normally distributed. Due to the exploratory nature of the study and associated potential for Type II error, an alpha level of .05 (two-tailed) was initially employed in the analyses. Where appropriate this was later adjusted to correct for multiple comparisons using the Bonferroni adjustment procedure.

Descriptive statistics were calculated to describe the sample in terms of demographic, clinical and sleep related characteristics. One-way ANOVA's, Independent Samples t-tests, Chi squared tests and Correlation analyses were initially employed to compare the groups. Where appropriate ANCOVA's and MANCOVA's were utilized to further investigate the effect of potential covariates on any between-group differences.

Ethics Approval

Ethical approval was obtained from NHS Greater Glasgow and Clyde Primary Care Ethics Committee. Management approval for the protocol was granted by NHS Greater Glasgow and Clyde Research & Development Directorate (Appendix B.10).

RESULTS

Sample demographics and sleep characteristics

A total of 61 eligible participants completed the study [Mean age = 44yrs; s.d. = 12.9yrs] 44 (72.1%) of whom were female. On the basis of the diagnostic and inclusion criteria employed 21 participants were categorised as Good Sleepers (GS), 20 as having Psychophysiological Insomnia (PI) and a further 20 as having Idiopathic Insomnia (IdI). Demographic and sleep characteristics are presented in Table 1. The address and postal code data collected from the insomnia participants indicated that 78% lived in Scotland with the remaining 22% living in England. An indicator of socioeconomic status (Social Deprivation Index) was gathered for those participants who lived in Scotland. The groups did not differ significantly on this measure [t (31) = -1.89, p = .068].

(INSERT TABLE 1 HERE)

Table 1 shows that whilst there were no gender differences between groups (χ^2 = .132, p = .936) a one-way ANOVA revealed that the mean age of the GS group was significantly lower than that of the PI group by approximately 9 years; [F(2,58) = 3.518, p = .036]. Given that age may be a confounding variable, subsequent hypothesis-testing analyses were performed first without a covariate (ANOVA) and then again with age as a covariate (ANCOVA).

With regards to participants sleep characteristics Table 1 shows that there were no significant differences between the PI and IdI groups on either the PSQI [t (38) = -.231, p = .818] or the ISI [t(38) = -1.25, p = .22]. The mean scores obtained on these measures are indicative of a clinical insomnia difficulty of moderate severity and as such validated the allocation of participants to each of the insomnia groups. Group allocation was also supported by the IdI group reporting significantly lower mean age of insomnia onset and greater periods of insomnia duration and the GS group reporting significantly lower levels of sleep effort than the insomnia groups (see Table 2 and Table 3).

Testing the study hypotheses

Table 2 displays descriptive statistics for all the measures that were utilised for hypothesis testing. Notably, Table 2 shows that no significant differences were found between the insomnia groups on either the BDI-II or BAI. The mean scores reported by both groups on these measures are indicative of mild anxiety and minimal depressive symptoms and thus support the inclusion of the participants in the study as people who suffer from a *primary* insomnia disorder rather than insomnia secondary to anxiety or depression.

(INSERT TABLE 2 HERE)

Primary Hypotheses

Hypothesis 1: Participants with PI will report greater levels of BIS sensitivity than normal sleepers and those with IdI

It can be seen from Table 2 that the PI group reported greater levels of BIS sensitivity than both the GS and IdI groups with the IdI group reporting the lowest mean BIS scale score of all the groups. A one-way ANOVA and post-hoc Bonferroni procedure [$p<.05$] to correct for multiple comparisons showed this difference to be significant [$F(2,58) = 7.95$, $p = .001$] thus supporting Hypothesis 1. The ANCOVA model with age entered as a covariate showed that age did not affect these results [$F(2,58) = 7.79$, $p = .001$]. The significant difference in BIS sensitivity found between the PI and IdI groups represents a standardised effect size of $d= 1.28$ which in accordance with Cohen's (1988) conventions equates to a large effect.

Hypothesis 2: Participants with PI will report lower levels of BAS sensitivity than normal sleepers.

There were no significant differences found between the PI and GS groups on any of the BAS measures: BAS Drive ($F(2,58) = .50$, $p = .609$); Bas Fun Seeking ($F(2,58) = 1.24$, $p = .296$); BAS Reward Responsiveness ($F(2,58) = .12$, $p = .884$) therefore Hypothesis 2 was not supported.

Hypothesis 3: Participants with IdI will report greater levels of BAS sensitivity than those with PI.

This hypothesis was also not supported as no significant differences were found between the PI and IdI groups on any of the BAS measures (see analyses above). However, the difference between the insomnia groups means on the BAS Fun Seeking Scale was 1.25 (approaching half a standard deviation). Therefore, a retrospective power calculation was performed to find out what sample size would be required to detect a meaningful difference if it was present. This calculation indicated that a sample size of 79 participants in each group would be required at an alpha level of 0.05 with power of 0.8 (two- tailed).

Table 3 below presents means and standard deviations for the BIS/BAS scales collected from a large Australian community sample (Jorm et al., 1999) along with those from the current study. It can be seen that the GS group reported BIS/BAS scores that are much in line with those of the community norms, thus further supporting their inclusion in the study. The BAS scales scores reported by the PI and IdI groups are also comparable to the community norms. However, the mean BIS score of the PI group is somewhat higher than that of the community sample norms for females and males of the same age range, whereas the IdI group's mean BIS score is lower.

(INSERT TABLE 3 HERE)

Secondary hypotheses

Hypothesis 4: Participants with PI will report greater levels of overall Sleep Effort than those with IdI and will differ in terms of their responses to individual GSES items relating to different core components of the sleep effort construct.

This hypothesis was addressed first in relation to the global construct of sleep effort as measured by the GSES total scale score. Table 2 shows that whilst the PI group did appear to report greater levels of sleep effort than the IdI group (mean difference = 1.2

representing nearly half a standard deviation), this difference was not statistically significant on post hoc testing. The overall highly significant ANOVA indicated only that the GS group reported much less sleep effort than the insomnia groups (F (2,58) = 30.77, p<.001). Correlation analyses showed that age was negatively correlated with sleep effort in both the PI and IdI groups but the relationship was weak in the PI group [r (20) = -.18; R^2 = .03, p = .44] and marginally significant in the IdI group [r (20) = -.46; R^2 = .21, p = .04]. As mentioned previously the GSES comprises seven items that each relate to different components of Broomfield & Espie's (2005) sleep effort construct and Espie et al's., (2006) A.I.E. pathway model of insomnia. Accordingly, further comparisons were performed at the item level of the GSES. In light of the results of the correlation analyses age was also incorporated as a covariate within the MANCOVA model that was applied. The results of the analysis are presented in Table 4. The omnibus test was significant [F (1,38) = 3.40, p = .008] with subsequent univariate analyses revealing significant differences between the PI and IdI groups on 4 of the 7 GSES items (see Table 4).

(INSERT TABLE 4 HERE)

Hypothesis 5: Participants with PI who report greater levels of psychopathology will also report greater levels of BIS sensitivity.

Pearson correlation coefficients were calculated to investigate the relationships between reported levels of depression (BDI II) and anxiety (BAI) and BIS sensitivity among the participants in the PI group. These revealed a significant relationship between depression and BIS sensitivity [r (20) = .53; R^2 = .28, p = .016] but not between anxiety level and BIS sensitivity [r (20) = .39;R^2 = .15, p = .082]. These results partially support hypothesis 5. Given the results of the correlation analyses we retested the previously found significant difference between the PI and IdI groups on BIS sensitivity with depression and anxiety entered as covariates. The ANCOVA showed that the between group difference remained significant when variability in depression and anxiety was accounted for [F (1,38) = 14.16, p = .001].

DISCUSSION

Few previous studies have investigated Idiopathic Insomnia or compared it with Psychophysiological Insomnia using robust diagnostic criteria. In addition, the potential relationships between primary insomnia and Gray's (1987, 1994) hypothesised neurobiological motivational systems have not previously been explored. Accordingly, the present study aimed to extend our knowledge of the PI and IdI insomnia subtypes by comparing self-report measures of BIS/BAS sensitivity, sleep effort, anxiety and depression amongst adults who met diagnostic criteria for PI, IdI, and normal sleep. The main results will be discussed before the strengths, limitations and implications of the study are examined.

Insomnia and BIS/BAS Sensitivity

The findings in relation to the study's primary research questions and first three tentative hypotheses were mixed with only the hypothesis relating to BIS sensitivity receiving clear support. As predicted by hypothesis 1 the PI group reported significantly greater levels of BIS sensitivity than the GS and IdI group, with the IdI group surprisingly reporting the lowest levels of any of the groups. This suggests firstly that sensitivity to potential threat related stimuli may indeed play a role in disrupting the sleep wake process and may at least partly drive the excessive attention to and worry and anxiety about sleep that is associated with the development and maintenance of PI. Secondly, this finding also suggests that those with IdI may be less sensitive to sleep-related threat stimuli than people with PI and that despite the lifelong duration and largely unremitting pattern of their insomnia complaint they are more like those without a sleep problem in this respect.

The initial analyses did not support hypotheses 2 and 3 as no significant differences were found between any of the groups on the 3 BAS scales. However, the retrospective power analysis performed on the difference between the insomnia groups on the BAS Fun Seeking scale showed that a sample size of around only 80 participants in each group would be required to detect a meaningful difference on this measure. As the sample size in the present study was relatively small it may be that the

study was underpowered to detect any between-group differences on the BAS measures should they have been present.

Turning to how the BIS/BAS results compare with previous research using the BIS/BAS scales. Comparison with the community norms from Jorm et al, (1999) suggests that despite the current sample size being relatively small, the BAS scores reported by each of the groups are similar to those that might be found in the wider population. However, the BIS scores of the PI and IdI groups were different to those of the community norms with the PI group's being greater and the IdI group's lower. The pattern of BIS/BAS results observed in the PI group is similar to that found by previous research relating to anxiety and BIS/BAS sensitivity as described in a recent review by Bijttebier et al., (2009). They outline consistent evidence that participants with anxiety symptoms often show associations with high BIS sensitivity and report levels of BAS sensitivity that show no or only weak relationships with their anxiety symptoms and tend not to differ much from those of normal controls. This of course lends weight to Gray's (1987, 1994) belief that the BIS underlies our experiences of anxiety. Similarly, as both anxiety and PI are thought to be driven by arousal of physiological systems and attention biases toward threatening stimuli, the pattern found in the present study could be seen as supporting the hypothesis that increased BIS sensitivity may also underlie PI. In addition, the fact that the PI group in this study reported only mild levels of anxiety, and no relationship was found between anxiety and BIS levels, suggests that the measures employed are tapping into distinct constructs and also that participants' insomnia symptoms could not easily be accounted for by anxiety alone.

Sleep Effort

The findings in relation to sleep effort were consistent with that of Broomfield and Espie (2005) with higher levels being reported by those with insomnia compared with normal sleepers. This lends support to those models of insomnia, and particularly the A.I.E. pathway model (Espie et al., 2006), which site sleep effort as being involved in the development and/or maintenance of PI.

With regards to the differences in sleep effort observed between the insomnia groups. Although the PI group reported higher levels than the IdI group the primary analysis of this difference indicated that it was not statistically significant, thus it initially appeared that hypothesis 4 was not supported. However, further testing at both the overall scale and item levels of the GSES revealed significant differences between the insomnia groups when age was included as a covariate. Given that the PI and IdI groups did not significantly differ in age this result might at first seem somewhat incongruent. However, perhaps less so when viewed within the context of IdI being a lifelong sleep difficulty and age therefore largely equating to insomnia duration in IdI. It may be that as a person with IdI becomes older they expend less effort on trying to find sleep when a lifetime of experience has shown them that these efforts will largely go unrewarded. This supposition is supported by the findings that age and sleep effort were negatively correlated in the IdI group and that the only item of the GSES on which the IdI reported greater scores on than the PI group was item 5 - "I am no good at sleeping". For people with IdI this item may reflect a statement of fact rather than a concern relating to a current sleep difficulty as it perhaps is for those with the type of insomnia complaint that is often described by those with PI.

Interestingly, the PI group also reported a mean duration of insomnia (16yrs) that would indicate that this was a sample of people of whom many would also have had a lengthy history of seeing their efforts to sleep going unrewarded. Despite this, they reported greater mean scores than the IdI group on all items of the GSES, apart from item 5, with the difference reaching statistical significance in the case of 3 of the items. These findings are consistent with those of Barrie and Espie (2009) which indicated that those with IdI perceive their insomnia to be more permanent and unchangeable in nature than those with PI who may tend to view it as a problem that they have some influence over and can be solved. This also lends support to Barrie and Espie's suggestion that an acceptance based treatment approach may be more appropriate for IdI patients than CBT for insomnia which aims to actively treat and reduce sleep problems rather than foster acceptance of them as a chronic condition that the sufferer cannot positively influence to any great extent.

BIS Sensitivity and Psychopathology

Hypothesis 5 was partially supported by the finding of a significant positive correlation between depression level and BIS sensitivity in the PI group and this reflects previous research in which depression has been positively associated with higher BIS levels (e.g., Beevers & Meyer, 2002; Campbell-Sills et al., 2004; Jorm et al.,1999; Kasch et al., 2002). However, after reviewing the literature Bijttebier et al., (2009) concluded that whilst high BIS sensitivity should be considered as a common factor to emotional problems like depression and anxiety through its link with negative affectivity, the association between high BIS and depression is not consistently found and it is weak BAS sensitivity that appears to represent the trait vulnerability factor to this disorder through its association with low levels of positive affectivity. The levels of depressive symptoms found in the present study were minimal and not indicative of the presence of a depressive disorder. In addition, the BAS levels reported were similar to that of community norms and thus greater than those usually associated with depression. Also, post-hoc analyses showed that variance in reported depression or anxiety did not account for the difference found between the PI and IdI groups on BIS sensitivity. When viewed together this pattern of results could be interpreted as lending support to the suggestion that BIS sensitivity may an important underlying construct in the development and maintenance of PI.

Strengths and Limitations

The principal strength of this study was that the participants were recruited to each group using well defined and strict diagnostic criteria and appropriate assessment methods to discern these criteria and in particular taking a detailed history of when each participant's insomnia complaint had emerged and how it had developed over time. This was supported by findings which showed clear differentiation of the groups on several of the measures employed. This adds to Barrie and Espie's (2009) recent findings in providing empirical support for distinguishing between the PI and IdI subtypes in both research and clinical practice and is consistent with the practices recommended by the AASM (Edinger, J.D., Bonnet, M.H., Bootzin, R.R., Doghramji, K., Dorsey, C.M., Espie, C.A. et al., 2004). It is worth noting that the identification of

participants as meeting the criteria for IdI was not as problematic as previous literature would suggest thus raising the question of why this subtype of primary insomnia has not received more attention in the past.

The study does have some limitations which might limit the generalisation of the findings beyond the current sample. Firstly, although the study was comprised of a well defined sample, due to the relatively small sample size recruited the study may have been vulnerable to Type II error. As this was an exploratory study there was limited information for determining a sample size which would ensure that any significant differences between the groups would be detected. In addition, the retrospective power calculation performed suggested that a significant result may have been found in relation to the BAS Fun Seeking scale had the obtained sample been larger. Accordingly, this study provides some guidance for future research in relation to desirable sample size.

Secondly, as the study exclusively employed self-report measures within a cross-sectional design we cannot make any clear inferences about possible cause and effect relationships between any of the variables measured. Future research could employ objective measures of sleep and arousal in both the assessment of potential participants and measurement of outcome variables. For example, it might be advantageous to be able to compare BIS/BAS sensitivity with objective measures of physiological arousal and attention bias across well defined groups of participants with PI and IdI. In addition, future research could employ prospective study designs to explore the relationships between BIS/BAS sensitivity and insomnia over time and thus be able to perhaps shed more light on potential causal relationships and how BIS/BAS sensitivity relates to peoples' experience of changes in their insomnia such as periods of remission and relapse.

Thirdly, it was decided not to have the GS participants complete the anxiety and depression measures in order to encourage willingness to participate in the study by minimising the amount of effort and time their participation would involve. In hindsight this may have been an error and it would perhaps have been advantageous to

have had the GS participants also complete these measures for the purposes of comparison and to further validate their inclusion in the study. This may have been particularly relevant to comparisons between the GS and IdI groups given that those with IdI are thought to typically show only minor psychological abnormalities and in this particular study the IdI group's BIS scores indicated that they may be similar to those without a sleep problem in terms of sensitivity to threat related stimuli. Accordingly, had the GS group been found to report similar levels of anxiety and depression symptoms as the IdI group, this could have provided further evidence in support of the supposition that the basis of IdI is more physiological than psychological.

Implications

The findings obtained in this study have potentially important implications for both the treatment of primary insomnia and its subtypes and the study of these in research. The study was able to identify and clearly differentiate between people with PI and IdI and the differences found on the measures of BIS/BAS sensitivity and sleep effort suggest that there may be differences in treatment suitability for these insomnia subtypes. These findings could be interpreted as suggesting that those with PI may be best suited to a treatment approach such as CBTi which seeks to target and moderate psychological factors relating to poor sleep and insomnia. This is in line with the available treatment research evidence which shows that cognitive-behavioural approaches can offer significant benefits to insomnia sufferers (see Morin et al., 2006 and Riemann & Perlis, 2009).

By contrast the pattern of results found in the IdI group might be seen as suggesting that people with this condition may be more suited to an acceptance based approach that aims to foster acceptance and appropriate management of what appears to be a lifelong and generally unremitting chronic sleep difficulty. This echoes the findings and suggestions of Barrie and Espie (2009). Future research could explore whether acceptance based interventions and/or mindfulness based techniques could be of benefit to people with IdI and help to reduce the impact of their chronic sleep problem on their daily lives.

With regard to the implications for researchers, the present study provides additional evidence for the need to differentiate between different insomnia subtypes and utilize appropriate diagnostic criteria and assessment procedures, particularly in clinical trials where the efficacy of psychological interventions are being investigated. This is particularly important to the validity and comparability of research findings across studies and also has implications for epidemiological research. The findings of the study might also be seen to have implications for the further development of cognitive, neurocognitive and psychobiological models and how these could be incorporated into transdiagnostic conceptualisations of psychopathology.

Conclusions

Despite some limitations the present study met its primary aim of extending our knowledge of PI and IdI by investigating the potential role of Gray's neurobiological motivational systems in primary insomnia via self-report measures relating to sleep and BIS/BAS sensitivity. The findings showed that those with PI reported greater levels of BIS sensitivity than both good sleepers and those with IdI thus suggesting that sensitivity to threat may play a role in PI but not necessarily in IdI. This taken with the findings relating to sleep effort could be interpreted as offering support to models of insomnia which implicate arousal of physiological systems, attention bias toward threat stimuli and effortful attempts to control the sleep-wake process in the development and/or maintenance of PI. Future research could employ objective measures of sleep, physiological arousal and attention bias to explore the potential relationships between these objective measures and BIS/BAS sensitivity in primary insomnia and its subtypes.

Overall, and perhaps most importantly, the results support the need to differentiate between the PI and IdI subtypes in research and clinical practice whilst also lending some further support to the view that IdI is more physiological in origin than PI which seems to be more clearly associated with both physiological and psychological processes.

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Table 1: Sample Demographics and Sleep Measures

	GS (n=21) M (SD)	PI (n=20) M (SD)	IdI (n=20) M (SD)	F (2,58) / t (38) / x^2 (2)	p value	post-hoc
Age (years)	40.24 (8.1)	49.95 (12.7)	42.15 (15.4)	3.518	.036	GS<PI=IdI
	N (%)	**N (%)**	**N (%)**			
Gender:				.132	.936	
Female	15 (71.4)	15 (75)	14 (70)			
Male	6 (28.6)	5 (25)	6 (30)			
	M (SD)	**M (SD)**	**M (SD)**			
Age of Onset	n/a	34.33 (13.8)	4.7 (4.1)	-9.18	<.001	
Insomnia Duration	n/a	16.33 (11.0)	37.15 (14.2)	5.01	<.001	
ISI	n/a	17.39 (4.67)	15.25 (5.77)	-1.25	.22	
PSQI	n/a	13.11 (2.95)	12.85 (3.88)	-.231	.818	

Key: GS = Good Sleepers; PI = Psychophysiological Insomnia; IdI = Idiopathic Insomnia

Table 2: Hypotheses Testing Measures

	GS (n=21) M (SD)	PI (n=20) M (SD)	IdI (n=20) M (SD)	F (2,58) / t (df38)	p value	post-hoc
BIS	20.71 (3.41)	22.85 (2.71)	18.65 (3.77)	7.95	.001	PI>IdI=GS
BAS DRIVE	9.57 (2.39)	10.25 (2.93)	9.5 (2.52)	.500	.609	
BAS FUN	11.28 (1.87)	10.60 (2.74)	11.85 (2.83)	1.243	.296	
BAS REWARD	15.67 (1.77)	15.95 (2.01)	16.0 (3.03)	.123	.884	
GSES	2.0 (1.58)	7.5 (3.0)	6.3 (2.34)	30.77	<.001	GS<PI=IdI
BDI II	n/a	9.6 (6.64)	5.65 (7.24)	-1.8	.08	
BAI	n/a	12.75 (11.12)	8.2 (7.46)	-1.52	.137	

Key: GS = Good Sleepers; PI = Psychophysiological Insomnia; IdI = Idiopathic Insomnia

Table 3: Means & Standard Deviations for the BIS/BAS Scales from a large community sample and the current sample

Sample Type & Source	**BIS**	**BAS DRIVE**	**BAS FUN**	**BAS REWARD**
Community Sample Female - Age 40 to 49yrs (n = 393) From *Jorm et al.* (1999)	21.4 (3.4)	9.8 (2.7)	10.8 (2.3)	16.8 (2.0)
Community Sample Male - Age 40 to 49yrs (n = 336) From *Jorm et al.* (1999)	20.0 (3.7)	10.3 (2.4)	10.6 (2.2)	16.1 (2.1)
Current Sample - GS Group (Mean Age = 40.24, SD = 8.1)	20.71 (3.41)	9.57 (2.39)	11.28 (1.87)	15.67 (1.77)
Current Sample - PI Group (Mean Age = 49.95.24, SD = 12.7)	22.85 (2.71)	10.25 (2.93)	10.60 (2.74)	15.95 (2.01)
Current Sample - IdI Group (Mean Age = 42.15, SD = 15.4)	18.65 (3.77)	9.5 (2.52)	11.85 (2.83)	16.0 (3.03)

Table 4 Glasgow Sleep Effort Scale Item Analyses

Item/Statement	M (SD)	F (1, 38)	p value	post-hoc
1. I put too much effort into sleeping when it should come naturally	GS = .14 PI = 1.10 IdI = .70	16.78	<.001	PI>IdI>GS
2. I feel I should be able to control my sleep	GS = .67 PI = 1.15 IdI = .90	3.754	.029	GS<PI=IdI
3. I put off going to bed at night for fear of not being able to sleep	GS = .00 PI = .50 IdI = .75	10.711	<.001	GS<PI=IdI
4. I worry about not sleeping if I cannot sleep	GS = .67 PI = 1.35 IdI = 1.05	6.738	.002	GS<PI=IdI
5. I am no good at sleeping	GS = .00 PI = 1.20 IdI = 1.70	57.252	<.001	IdI>PI>GS
6. I get anxious about sleeping before I go to bed	GS = .00 PI = .80 IdI = .30	13.682	<.001	PI>IdI=GS
7. I worry about the consequences of not sleeping	GS = .52 PI = 1.40 IdI = .90	10.737	<.001	PI>IdI>GS

Key: GS = Good Sleepers; PI = Psychophysiological Insomnia; IdI = Idiopathic Insomnia

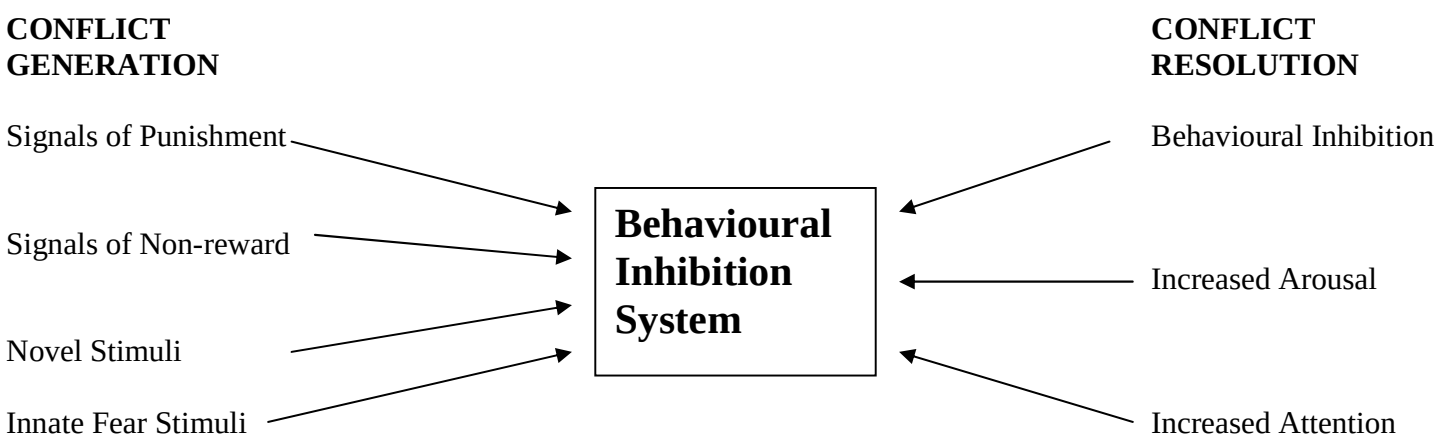

Figure 1. The Behavioural Inhibition System postulated by Gray (1982)

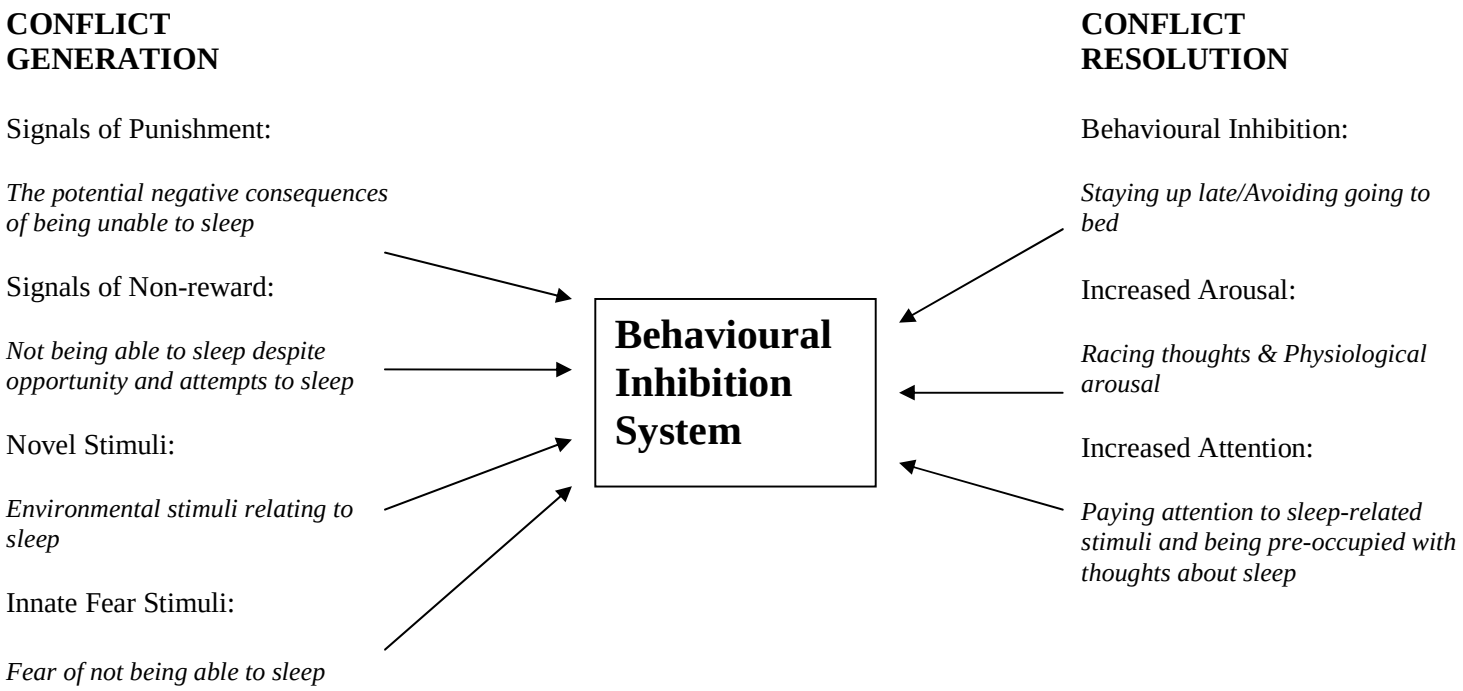

Figure 2. The Behavioural Inhibition System postulated by Gray (1982) and how it might relate to the experience of poor sleep and insomnia

CHAPTER THREE

ADVANCED CLINICAL PRACTICE I REFLECTIVE CRITICAL ACCOUNT

Risk assessment within a Child & Adolescent Mental Health Service: Reflections on its relevance to professional development

Grant Forgan*
Section of Psychological Medicine,
Division of Community Based Sciences,
Academic Centre,
University of Glasgow,
Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow, G12 0XH
Email: gforgan@blueyonder.co.uk

* Author for correspondence.

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology (D.Clin.Psy)

Abstract

This reflective account focuses on my experience of a risk assessment appointment within a multi-disciplinary Child and Adolescent Mental Health Service that I found to be extremely demanding and emotionally challenging. It makes use of models of reflective practice from Gibbs (1988) and Johns & Graham (1996) to structure my understanding of the experience as a key event in my development as a reflective practitioner. The account starts with the professional and personal context in which the learning experience took place before going on to describe the experience and the feelings I encountered during it and afterward. It then outlines how I went on to process and evaluate the experience within the context of my personal and clinical development and further training needs.

CHAPTER FOUR

ADVANCED CLINICAL PRACTICE II REFLECTIVE CRITICAL ACCOUNT

Reflections on Resource Management and Service Provision within an Early Intervention Service for Clients with First Episode Psychosis

Grant Forgan*
Section of Psychological Medicine,
Division of Community Based Sciences,
Academic Centre,
University of Glasgow,
Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow, G12 0XH
Email: gforgan@blueyonder.co.uk

* Author for correspondence.

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology (D.Clin.Psy)

Abstract

This account focuses on my experiences within a service for people experiencing First Episode Psychosis and uses elements of Gibbs' (1988) model of reflective practice to reflect upon these as a learning experience in my development as a Clinical Psychologist. The account begins by introducing the service based and personal context of the learning experience which included joining a service that was about to see a significant reduction in the number of psychologists it had available to it. It then goes on to explore how I felt about the situation and how I came to came to process and manage it through reflective practice. Finally, it outlines the positive outcomes of the experience in terms of my clinical and professional development.

Appendix A.1: Guidelines for submissions to SLEEP

SLEEP - Author Information

MANUSCRIPT SUBMISSION GUIDELINES

SLEEP is a publication of the Associated Professional Sleep Societies, LLC (APSS), a joint venture of the American Academy of Sleep Medicine and the Sleep Research Society. It is distributed to more than 10,000 readers.

The text of the manuscript should be in the following form:

a. Title page: This page should include the title and subtitle; full first and last names, highest academic degrees, and institutional affiliations for all authors; the institution at which the work was performed; disclosure of the presence OR absence of financial support and off-label or investigational use; the presence OR absence of any conflicts of interest for each author; corresponding author's full address, phone and fax numbers and e-mail address. No submission will be considered for review without complete disclosure included on the title page. This page should be separate from the other pages.

b. Abstract: Each article must be preceded by a structured abstract. For clinical or original investigations, the abstract is limited to 250 words. The components of this format are (start each on a new line): Study Objectives; Design; Setting; Patients or Participants; Interventions; Measurements and Results; Conclusions. (For any of the previously mentioned components of the abstract not supplied, whether the information is unavailable or not supplied, it will be published as N/A (Not Available) for continuity purposes.) For smaller departmental articles, abstracts should not exceed 100 words. Please provide no fewer than three but no more than ten key words that reflect the content of your manuscript. For guidance consult the Medical Subject Headings - Annotated Alphabetic List, published each year by the National Library of Medicine and available in most hospital or institution libraries.

c. Introduction: State the object of research with reference to previous work.

d. Methods: Describe methods in sufficient detail so that the work can be duplicated, or cite previous descriptions if they are readily available. Manuscripts that require extensive details about methods and procedures may place some of this information in an electronic Supplement that will accompany the manuscript through production and electronic publication on the *SLEEP* website (not in printed version). The supplement should be referred to in the appropriate locations in the published paper.

e. Results: Describe results clearly, concisely, and in logical order. When possible give the range, standard deviation, or mean error, and significance of differences between numerical values. Results (including tables and figures) that go beyond the key findings reported in the paper may be placed in an electronic Supplement that will accompany the manuscript through production and publication on the *SLEEP* website (not in the printed version). The supplement should be referred to in the appropriate locations in the published paper.

f. Discussion: Interpret the results and relate them to previous work in the field.

g. Acknowledgments: The minimum compatible with the requirements of courtesy should be provided.

h. Legends: Figure legends, numbered sequentially. Give the meaning of all symbols and abbreviations used in the figure.

i. Tables: ALL tables must be created using the table function in a word processor program and also should conform to a one- (3.25") or two-column (6.5") format. Prepare each table with a title above and any description below the table. Tables should be self-explanatory and should not duplicate textual material. They must be numbered and cited in consecutive order in the text, and must have a short title. **Tables consisting of more than 10 columns are NOT acceptable.** Previously published tables must have a signed permission from the publisher and complete reference data so that appropriate credit can be given.

j. References: References should be limited to no more than 60 citations for original articles. *SLEEP* complies with the reference style given in "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (see Ann Intern Med 1997;126:36-47 or online at http://www.acponline.org). Each reference should be cited in the text, tables, or figures in consecutive numerical order by means of Arabic numerals outside periods and commas and inside colons and semicolons. When 3 or more references are cited at one place in the manuscript, a hyphen should be used to join the first and last numbers of a series; commas should be used without spaces to separate other parts of a multiple-reference citation. The reference section should be included starting on a separate page at the end of the text, following the style of the sample formats given below. It is highly recommended that a standard bibliography program such as EndNote or ProCite be used. For EndNote users, the formatting style for *SLEEP* should be used. For abbreviations of journal names, refer to "List of Journals Indexed in Index Medicus" (available from the Superintendent of Documents, US Government Printing Office, Washington, DC 20402, USA, DHEW Publication No. (NIH) 80-267; ISSN 0093-3821). Provide all authors' names when fewer than seven; when seven or more, list the first three and add et al. Provide article titles and inclusive pages. Accuracy of reference data is the responsibility of the author. Include the journal name, year published, volume number, and page numbers. The *SLEEP* journal style does not include issue numbers. We cannot guarantee that citation/reference software will match all *SLEEP* author guidelines.

Sample citations

According to our previous work,[1,3-8,19]
The patients were studied as follows[3,4]:

Sample references

Article:
1. Kapur VK, Baldwin CM, Resnick HE, Gottlieb DJ, Nieto FJ. Sleepiness in patients with moderate to severe sleep-disordered breathing. Sleep 2005;28:472-7.

2. Quan SF, Howard BV, Iber C, et al. The Sleep Heart Health Study: design, rationale, and methods. Sleep 1997;20:1077-85.

Book:
3. Guilleminault C, Lugaresi E, eds. Sleep/wake disorders: natural history, epidemiology, and long-term evolution. New York: Raven Press, 1983.

Chapter of a book:
4. Coleman RM, Bliwise DL, Sajben N, et al. Epidemiology of periodic movements during sleep. In: Guilleminault C, Lugaresi E, eds. Sleep/wake disorders: natural history, epidemiology, and long-term evolution. New York: Raven Press, 1983:217-30.

DETAILS OF STYLE

Drug names: Use generic names in referring to drugs; trade names may be given in parentheses after the first mention, but the generic name should be used thereafter. Abbreviations: Follow the list of abbreviations given in "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (see section on References). For additional abbreviations, consult the Council of Biology Editors Style Manual (available from the Council of Biology Editors, Inc., 9650 Rockville Pike, Bethesda, MD 20814) or other standard sources.

Please provide on a separate sheet all abbreviations used with their full definition. Each should be expanded at first mention in the text and listed parenthetically after expansion.

FIGURES AND ILLUSTRATIONS

1. Figures should be black-and-white line drawings, professionally drawn and lettered. Avoid the use of screens and grayscale elements within a figure.
2. Figures and illustrations should be submitted in their final size, either 3.25 inches wide or 6.5 inches wide (see #4 below), and must be clear and easily readable.
3. Photographs, either black-and-white or color, are permitted, provided they fit the size requirements and are of high quality.
4. Most figures and illustrations should have a maximum width of 3.25 inches so they can fit into the confines of a single column. Only illustrations of particular importance and relevance, or figures that incorporate several smaller elements, should appear in two-column size, which is 6.5 inches wide.
5. Figures should be of a uniform style within the manuscript; the same typeface should be used for each figure (the font and size is Arial 9 point) you submit, and figures of the same type-such as bar graphs-should appear similar and be proportioned ' to the same scale.
6. Figures will be evaluated both for scientific relevance and for design integrity, and authors may be asked to modify figures based on either of these concerns.
7. All figures and illustrations will be reproduced in “portrait” format; *SLEEP* cannot accommodate “landscape” presentation (i.e., no table or figure will be included that requires the reader to turn the journal sideways).
8. Each figure and illustration should be numbered and cited in consecutive numerical order within the text of the manuscript. A legend should be provided for each figure and illustration.
9. Reproduction in color must be approved by the Editor. Authors are required to pay a color fee for each color reproduction. The cost to the author will be $100.00 per figure/photo/illustration, and payment will be required before publication.

Appendix A.2: Systematic Review - Study Evaluation Tool

Study No.	
Study title:	
Journal title:	
Year of publication:	
First author:	
Study Design:	
Participant characteristics:	
Types of groups included in the study. For example, Primary Insomnia, Normal Sleepers etc.	
Intervention/treatment mode:	
Does the paper specifically refer to which diagnostic criteria were employed in the study?	DSM IV ICSD AASM RDC Other (Specify):

What inclusion and exclusion criteria are actually listed in the paper?	
Do the criteria employed correspond to the RDC for Insomnia Disorder?	YES PARTIALLY NO
Where specific insomnia subtypes were being studied were appropriate RDC for these subtypes utilised? If yes which ones? For example Idiopathic Insomnia.	YES PARTIALLY Not Applicable Subtypes utilised:
Were participants further categorised according to the pattern of their insomnia problem i.e. Sleep Onset difficulty or Waking After Sleep difficulty? If yes which categories were used?	YES NO Sleep Onset Waking After Sleep Mixed

Which methods of assessment were reportedly employed to identify participants who met the criteria employed?:

Item 12.	Clinical Interview	Yes (2 points)	No (0 points)	Structured or Semi-structured (2pts) Unstructured (1pt) DK (0)
Item 13.	Were independent interviewers used?		Yes (2 points)	No (0 points)
Item 14.	Was inter-rater reliability checked?	Yes (2 points)	No (0 points)	
Item 15.	Were Polysomnography data collected?	Yes (2 points)	No (0 points)	
Item 16.	Were Sleep Diary/Log data collected?	Yes (2 points)	No (0 points)	

Other assessment procedures utilised? (specify):

Section Total Score:

Was the following information reported by the researchers?

Item 17. Recruitment methods employed Yes (2 points) No (0 points)

Item 18. Types of individuals enrolled i.e. clinical or volunteer participants? Yes (2 points) No (0 points)

Item 19. Means, std deviations and ranges of sleep measures e.g. TST, SOL, WASO, SE? Yes (2 points) Partially (1 point) No (0 points)

Item 20. Means, std deviations and distribution of insomnia duration? Yes (2 points) Partially (1 point) No (0 points)

Item 21. Means and distribution of insomnia frequency? Yes (2 points) Partially (1 point) No (0 points)

Item 22. Means and std deviations of discrepancies between subjective estimates and objective measures of sleep measures?

Yes (2 points) Partially (1 point) No (0 points) Not Applicable (2 points)

Section Total Score:

What were the main findings of the study in relation to the psychological interventions employed?

Notes

Appendix B.1: Guidelines for submissions to the Journal of Sleep Research

Journal of Sleep Research

Official Journal of the European Sleep Research Society

Edited by:
Derk-Jan Dijk

Print ISSN: 0962-1105
Online ISSN: 1365-2869
Frequency: Quarterly
Current Volume: 19 / 2010
ISI Journal Citation Reports® Ranking: 2008: 35/156 Clinical Neurology; 73/219 Neurosciences
Impact Factor: 3.255

Author Guidelines

Title Page
This should contain a concise title of the article, a shortened version (no more than 50 characters including spaces) for the running head, names of the authors, their affiliations, and the full postal and e-mail address, fax and telephone number of an author to whom correspondence can be addressed.

Conflicts of interests - Disclosure of any personal of financial support and author involvement with organization(s) with financial interest in the subject matter of the paper, or any actual or potential conflict of interest, and if no conflict exist, a statement must be included for each author.

Summary
This should be on a separate page, and less than 250 words. It should be followed by up to six key words. It should not be structured.

Main Text
This should start on a separate page, and include an introduction, methods, results and discussion. The suggested points of insertion of figures and tables, etc., should be indicated. Authors should avoid abbreviations (except for those commonly understood), long sentences, and many juxtaposed numbers in sentences.

References
References cited in the text should include the author's name and year of publication. Where there are more than two authors, list the first author only, followed by *et al.*

Reference list entries should be alphabetized by the last name of the first author of each publication. For publications with six or less authors, list the last name and initials for all authors. For publications with more than six authors, list the first three authors and then use *et al.* after the third author's name to indicate the rest of the authors. Provide article title, source, year of publication, volume, and inclusive pages. Note that periods should be included as part of authors' initials and journal abbreviations as required, and at the end of a reference entry. A list of abbreviations of journal names is offered by the US National Library of Medicine (NLM) (ftp://nlmpubs.nlm.nih.gov/online/journals/ljiweb.pdf) and in the Journal Database of PubMed (http://www.ncbi.nlm.nih.gov/sites/entrez?db=journals).

References to abstracts or letters may be included but these must be stated as such. Unpublished work should only be cited in the text. Only references that have already been published or that are genuinely in press should be included in the reference list.

We recommend the use of a tool such as EndNote or Reference Manager for reference management and formatting.
EndNote reference styles can be searched for here:
http://www.endnote.com/support/enstyles.asp
Reference Manager reference styles can be searched for here:
http://www.refman.com/support/rmstyles.asp

Examples of basic references format:
Loomis, A. L., Harvey, E. N. and Hobart, G. Cerebral states during sleep as studied by human brain potentials. *J. Exp. Psychol.*, 1937, 21: 127-144.

Kleitman, N. *Sleep and Wakefulness.* University of Chicago Press, Chicago, 1963 (second edition).

Webb, W. B. Theories about sleep and some clinical implications. In: R. Drucker Colin, M. Shkurovich and M. B. Sterman (eds) *The Functions of Sleep.* Academic Press, New York, 1979: 1936.

Supporting Information
Quantitative or qualitative data too extensive for inclusion in the print edition of the Journal may be presented in the online edition, as supporting information. It must be included as part of the original submission and will be reviewed as an integral part of the paper. The availability of supporting information should be indicated in the main manuscript, to appear after the references at the end of the paper, providing titles of figures, tables, etc. formatted as if the material was to appear in the print edition. We welcome audio and video material, if relevant to your paper. Full details on how to submit supporting information, including videos, can be found at **http://authorservices.wiley.com/bauthor/suppmat.asp**.

Illustrations
These should be referred to in the text as figures using Arabic numbers, e.g. Fig. 1, Fig. 2, etc., in order of appearance. Each figure should be labelled with its appropriate number.

In the full-text online edition of the journal, figure legends may be truncated in abbreviated links to the full screen version. Therefore, the first 100 characters of any legend should inform the reader of key aspects of the figure.

Tables
These should include only essential data. Each table must be typewritten on a separate sheet and should be numbered consecutively in Arabic numerals, e.g. Table 1, and given a short caption.

Appendix B.2: Original Major Research Project Proposal submitted to and passed by the Doctorate in Clinical Psychology training course

MAJOR RESEARCH PROJECT PROPOSAL

Psychophysiological Insomnia and Idiopathic Insomnia: The role of self-regulatory behaviour systems.

Trainee Clinical Psychologist: Grant Forgan

Research Supervisor: Professor Colin Espie, University ofGlasgow Sleep Centre

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology (D.Clin.Psy)

Abstract

Background: Insomnia is the most widely prevalent disorder of sleep, affecting 6 to 38% of adults. There has long been debate around how insomnia should be conceptualised, diagnosed and treated. Further research into identifying the mechanisms that underlie the development and maintenance of insomnia and its different subtypes is required. Neurophysiological self-regulatory behaviour systems have been implicated in the etiology of a variety of other psychiatric disorders, however, it is not known what role they might play in the development and maintenance of insomnia.

Aims: The proposed study aims to investigate the potential role of self-regulatory behaviour systems in the development and maintenance of Psychophysiological Insomnia (PI) and Idiopathic Insomnia (IdI) among a sample of adults.

Methods: Groups of participants with PI and IdI, and Good Sleepers, will complete self-report measures of Behavioural Inhibition Sensitivity, Behavioural Activation Sensitivity, Sleep Effort, Depression and Anxiety. Analyses of variance (ANOVA) and covariance (ANCOVA) will determine any between group differences and moderating effects of psychopathology.

Applications: Despite differences in clinical presentation and response to standard treatment, patients with PI and IdI are managed by clinicians in the same way. The proposed study will further consider how the PI and IdI subtypes differ. The findings may have implications for how treatment protocols could be further developed for use with persons presenting with different insomnia subtypes.

1. Introduction

1.1 Insomnia

Insomnia is a common problem which is thought to affect from 6-38% of adults [1]. However, it is poorly understood and frequently viewed by clinicians as merely a symptom of so-called 'primary' disorders rather than a clinical disorder in its own right. Consequently, insomnia symptoms can go untreated in favour of targeting the 'primary' disorder [2]. In addition, despite differences in the characteristics and treatability of different insomnia subtypes, they are usually managed in the same way. The International Classification of Sleep Disorders, 2nd Edition (ICSD-2), [3] lists diagnostic criteria for 3 primary insomnia subtypes; *Psychophysiological Insomnia, Idiopathic Insomnia* and *Paradoxical Insomnia*. The proposed study aims to investigate the first and second of these subtypes.

1.1.2 Psychophysiological Insomnia

Psychophysiological Insomnia (PI), is found in 1-2% of the general population, and 12-15% of those presenting for treatment [4]. It develops in adulthood, can often be linked to identifiable precipitating events and/or stressors, and comprises both psychological and physiological features such as conditioned arousal, sleep-incompatible behaviour, sleep preoccupation, and excessive focus on and anxiety about sleep [2]. Research literature has demonstrated that PI can be treated effectively using psychological interventions (e.g. Cognitive Behaviour Therapy for Insomnia) thus suggesting that behavioural and cognitive factors play a part in PI.

Research into the psychological mechanisms implicated in the development and maintenance of PI has resulted in a number of explanatory models being put forward [5]. The proposed study will focus on the Attention-Intention-Effort (A-I-E) pathway model of PI development proposed by Espie et al. [5]. They posit that the primarily self-regulatory sleep-wake process is disrupted by selectively *attending* to sleep, explicitly *intending* to sleep, and by making *effortful* attempts to initiate sleep, leading to the development of PI. This model mirrors that of other psychological disorders, (i.e. Depression & Anxiety) that also cite attention biases as being involved in etiology.

1.1.3 Idiopathic Insomnia

Few studies have investigated the nature of Idiopathic Insomnia (IdI), also known as Childhood Onset Insomnia, and it has proved to be a conceptually difficult disorder to define and research. The ICSD-2 describes IdI as a longstanding insomnia complaint with a chronic and persistent course, few periods of sustained remission, and onset during infancy or early childhood. IdI affects around 1% of adults and is seen in less than 10% of those presenting with an insomnia complaint [1, 2] Unlike PI, there is usually an absence of identifiable precipitating and maintaining factors in the history of those with IdI.

IdI patients typically show only minor psychological abnormalities although there is limited evidence that some of them adopt denial and repression as coping strategies and of an association with neurodevelopmental disorders such as ADHD and Dyslexia [6, 7]. Edinger et al. [8] found that participants who reported childhood onset insomnia had higher levels of arousability and were largely unresponsive to behavioural treatment. These findings lend weight to Hauri & Olmstead's [6] supposition that IdI may have a less psychological and more neurophysiologcial etiology than PI.

1.2 Self-regulatory Behaviour Systems

Motivational theorists argue that a continual process of moving toward, and away from, mental goal representations underlies human behaviour [9]. Put simply, the model proposes that human behaviour is motivated by the pursuit of desirable goals and pleasure, and the avoidance of negative outcomes and displeasure. Gray [10, 11] endorses this view and suggests that two general motivational systems regulate behaviour and affect; a Behavioural Inhibition System (BIS) and a Behavioural Activation System (BAS).

The BIS is said to be involved in the experience of negative affect, and the anticipation and avoidance of threat and negative outcomes. Indeed, Gray has argued that this mechanism underlies the experience of anxiety [10, 11]. The BAS, is thought to control appetitive motivation and to be sensitive to signals of reward. It is therefore implicated in the experience of positive affect, and the facilitation of behaviour that might lead to positive outcomes.

Research has shown that when threat occurs individuals high in BIS sensitivity become more anxious, distressed, and avoidant than persons lower in BIS sensitivity. Conversely, when potential reward arises, those high in BAS sensitivity tend to experience more positive affect and engage in more approach behaviour than those lower in BAS sensitivity. Low levels of BAS sensitivity have also been associated with negative affect suggesting that high levels of BAS sensitivity may be protective [12-15].

1.3 The role of Self-regulatory Behaviour Systems in Insomnia

Attentional biases and there relationship with affect and behaviour are central to the A.I.E. pathway model of PI and self-regulatory behaviour system models. Both insomnia and differing levels of BIS/BAS sensitivity have also been associated with psychopathology. Therefore, it would seem reasonable to hypothesize that differing levels of BIS/BAS sensitivity might be found between those with PI and healthy normal sleepers. For example, would greater levels of BIS sensitivity be found among those with PI and greater levels of BAS sensitivity in normal sleepers?

It is also possible that BIS/BAS sensitivity may be related to the difference in some characteristics of PI and IdI. For example, as higher levels of BAS sensitivity are thought to be protective of psychological wellbeing, might people with IdI, report greater levels of BAS sensitivity than those with PI who often present with psychological distress.

2. Aims and Hypotheses

2.1 Aims

The proposed study aims to extend our knowledge of insomnia subtypes by measuring self-reported BIS/BAS sensitivity amongst adults who meet criteria for PI and IdI, and normal sleep. Given that sleep effort is said to play a key part in PI, but its role in IdI is unknown, it will also measure levels of sleep effort. Additionally, it is proposed to take measures of depression and anxiety to investigate the relationship between insomnia and psychopathology and BIS/BAS sensitivity. The inclusion of participants with PI and IdI will compliment other research into these subtypes that is being carried out within the University of Glasgow Sleep Centre (UGSC).

Specifically, it aims to address the following research questions:

Primary questions:

5. Do those with PI and IdI report differing levels of BIS/BAS sensitivity compared to good sleepers?
6. Do those with PI report differing levels of BIS/BAS sensitivity compared to those with IdI?

Secondary questions:

7. Do those with PI report differing levels of Sleep Effort compared to those with IdI?
8. What are the relationships between BIS/BAS sensitivity and Sleep Effort in those with PI and IdI?
9. Do Anxiety and Depression moderate the relationships between PI, IdI, BIS/BAS sensitivity and Sleep Effort?

2.2 Hypotheses

Given the exploratory nature of the proposed study, the following tentative hypotheses are proposed:

6. Participants with PI will report greater levels of BIS sensitivity than normal sleepers.

7. Participants with PI will report lower levels of BAS sensitivity than normal sleepers.
8. Participants with IdI will report greater levels of BAS sensitivity than those with PI.
9. Participants with PI will report greater levels of Sleep Effort than those with IdI
10. Participants with PI who report greater levels of psychopathology will also report greater levels of BIS sensitivity.

3. Plan of Investigation

3.1 Participants

Participants will be 18 years of age or over. There will be a PI group, IdI group, and Good Sleeper (GS) group.

3.1.1 Inclusion and Exclusion Criteria

Participants in the PI and IdI groups will meet sleep disturbance criteria as indicated by scores of >5 on the Pittsburgh Sleep Quality Index (PSQI) and > 14 (Moderate Insomnia) on the Insomnia Severity Index (ISI). They will also meet general criteria for insomnia and specific criteria for PI and IdI as outlined in the ICSD-2 [2]. The GS group will meet research diagnostic criteria for Normal Sleepers (Controls) [16].

Exclusion criteria will include:

a. The presence of another sleep disorder such as narcolepsy, sleep apnoea, restless legs syndrome, circadian sleep disorders or parasomnias
b. The presence of severe psychopathological disorder
c. The presence of a physical/medical disorder which may be influencing sleep patterns
d. Where sleep disturbance is suspected as being the result of substance misuse
e. Being in receipt of concurrent psychological or pharmacological treatment for sleep problems.

To ensure a clear distinction between the insomnia groups, the IdI group will be required to have developed insomnia by age twelve and the PI group after the age of seventeen.

Group allocation shall be verified by individual case reviews with Professor Colin Espie, whom is a highly experienced researcher of sleep disorders. Data obtained from sleep diaries will assist with confirming group allocation

3.2 Recruitment Procedures

Participants will be recruited using standard UGSC methods, including emails to University of Glasgow students and staff, placement of notices in NHS staff newsletters; posters in NHS facilities including GP surgeries, newspaper advertisements etc, and contacting individuals who have previously participated in sleep research and given permission to be contacted for other studies.

3.3 Measures

Participants will complete the following standard self-report questionnaires*, which have been found to be reliable and possess appropriate levels of internal consistency:

1) Pittsburgh Sleep Quality Index (PSQI) [17]
2) Insomnia Severity Index (ISI) [18].
3) Beck Depression Inventory (BDI) [19]
4) Beck Anxiety Inventory (BAI) [20]
5) Behavioural Inhibition Scale (BIS) and Behavioural Activation Scales (BAS) [12] The BIS/BAS questionnaire is comprised of 24 items with four subscales: One reflects BIS sensitivity (7 items), and three reflect aspects of BAS sensitivity: BAS Drive (4 items); BAS Fun Seeking (4 items); and BAS Reward Responsiveness (5 items)
6) Glasgow Sleep Effort Scale (GSES) [21] The GSES is a 7-item scale designed to assess effortful preoccupation with sleep.

*Further details of these can be found in Appendix 1

3.4 Design

The study will comprise a quasi-experimental between-groups design with the following three groups:

1) Psychophysiological Insomnia (PI) 2) Idiopathic Insomnia (IdI)

3) Good Sleeper (GS)

Efforts will be made to balance the groups in terms of gender and age.

Group will be the main independent variable and participant scores on the PQSI, ISI. BIS/BAS sensitivity and Sleep Effort will be the main dependent variables. Psychopathology, as measured by the BDI and BAI will be the main secondary dependent variables.

3.5 Research Procedures

Potential participants will be invited to contact the researcher/Glasgow Sleep Centre by e-mail or telephone. They will be provided with further information regarding the study and invited to participate. They will then complete a brief telephone screening instrument which is routinely used at the UGSC. Participants meeting criteria for an appropriate group will be invited to meet with the researcher at the UGSC to complete the self-report measures, a consent form and patient information sheet. They will then participate in a clinical interview and assessment which will last about 1 hour.

Participants will be asked to complete a 7-day sleep diary after meeting the researcher, and to return it in the freepost envelope provided. Individuals not meeting the criteria for an appropriate group will be debriefed regarding the aims and objectives of the study and thanked for their interest. They will also be offered a copy of ‘The Good Sleep Guide’, a leaflet providing advice on effective self-help, prepared by Professor Colin Espie and recommended by the British Sleep Society.

3.6 Justification of sample size

To our knowledge no previous studies have investigated the relationship between insomnia and BIS/BAS sensitivity. Therefore it was not possible to calculate the optimal sample size required for the proposed study by referring to previous findings in this area. In addition, previous research which has investigated psychological variables in persons with IdI is extremely limited. However, Hauri & Olmstead's [6] did compare adults with childhood and adult onset insomnia using sample sizes of n=20 and n=39 respectively, and found significant differences between the groups on sleep related characteristics. More recently, an as yet unpublished study which investigated the role of acceptance and coping style in IdI and PI was completed within the UGSC. In accordance with the relevant power calculations this study included PI, IdI and GS groups with 30 participants in each.

Unfortunately, the majority of previous research utilizing the BIS/BAS scales has looked at within group differences in large clinical and non-clinical community samples. However, Kasch et al., [15] examined BIS/BAS sensitivity in 62 depressed participants and 27 non-depressed controls. They found that the depressed participants reported significantly lower levels of BAS and higher levels of BIS. Effect sizes (calculated from reported means & standard deviations) were as follows: BIS d = 1.12, BAS Drive d = .99, BAS Reward Responsiveness d = .94 and BAS Fun Seeking d = .86. In accordance with Cohen's (1998) effect size conventions such figures correspond to large effects.

The proposed study's primary hypotheses relate to between group differences. Based on the effect sizes found by Kasch et al., [15], and the sample sizes employed in previous studies of IdI, a large effect size of 0.7 would seem reasonable for the proposed investigation. A series of power calculations was conducted using the G*Power 3 software program. These revealed that an estimated 24 participants per group would 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 matched samples and clearly differentiated experimental groups, it is proposed that a sample size of 30 participants per group will be sufficient to detect any differences.

3.7 Settings and Equipment

Access to e-mail and telephone facilities will be required for recruitment purposes. The UGSC laboratory at the Sackler Institute will provide suitable rooms for conducting interviews with participants.

3.8 Data Analysis

Analysis will be conducted using the Statistics Package for the Social Sciences for Windows (SPSS for Windows) software package. The data will be checked visually, and with reference to skewness and kurtosis values to ensure that they are normally distributed. If necessary, the data will be transformed to meet criteria for the use of parametric tests. Initial descriptive statistics will then be produced for the purposes of sample description. Demographic and sleep related data will be analysed to determine any differences between the groups and which variables should be included as covariates in further analyses. A series of ANOVAs will be performed to identify any between group differences on the main dependent variables. Post-hoc testing will be utilized to further analyse these. Within group correlation analyses shall also be computed to investigate the relationship between BIS/BAS sensitivity, Sleep Effort, Anxiety and Depression in participants with PI and IdI. Should the groups differ on measures of anxiety and depression, ANCOVAs will be performed to investigate the potential moderating effects of psychopathology. Where necessary, corrections will be made for the effects of multiple comparisons.

4. Health and Safety Issues

This study will conform to the standard operating procedures of the UGSC which include a comprehensive risk assessment analysis.

4.1 Researcher Safety Issues

The study will adhere to the following procedures to ensure that there are no risks to the researcher in conducting this study. Firstly, an email account will be set up for the sole purpose of recruitment, thus ensuring that participants do not have access to personal information about the researcher. The researcher will meet participants in a secure building, and at a time when colleagues are present.

4.2 Participant Safety Issues

Participants will be fully briefed on study procedures prior to consent being obtained and will be advised that interviews will take place during the day in a secure and occupied building.

5. Ethical Issues

Participation will be voluntary and participants will be informed that they are free to withdraw from the study at any stage. The proposed research method does not require the deception of participants and there are no invasive procedures involved. Therefore, it does not appear to pose any foreseeable threat to participants' psychological well-being, health values or dignity.

Methods will be employed to ensure confidentiality during data input and storage of data. Following completion of the study participants will be offered the opportunity to be provided with a summary of the outcome of the research.

6. Financial Issues

It is anticipated that the cost of questionnaires and administration related costs will be covered by the University Section of Psychological Medicine. No equipment requires to be purchased for the purposes of the proposed study. The researcher will have access to appropriate computer based data analysis software via the Section of Psychological Medicine and UGSC. It is envisaged that Greater Glasgow & Clyde Research and Development Department will reimburse participant travel costs.

7. Timetable

Ethical approval submission:	September/October 2008
Participant recruitment & data collection:	December 2008 to May 2009
Analysis & write up:	May 2009 to August 2009

8. Practical Applications

Despite the differences in presentation, diagnostic criteria and variability in responses to standard treatment, patients with different subtypes of insomnia are usually managed by clinicians in the same way. The proposed study will further consider how the PI and IdI subtypes of insomnia differ, and may provide some suggestions as to how psychological treatments for insomnia could be further developed and utilized more appropriately.

9. Ethical and Management Approval Submissions

Ethical approval will be sought from Greater Glasgow Primary Care Trust Ethics Committee and management approval from Greater Glasgow & Clyde Research and Development Department. Approval will also be sought from the relevant University faculties to contact potential participants within the staff and student body.

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APPENDIX 1

Participants will complete the following self-report questionnaires:

1) Pittsburgh Sleep Quality Index: The Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989) provides a reliable, valid and standardized measure of sleep quality; to discriminate between good and poor sleepers. A PSQI global score >5 indicates that a subject is having severe difficulty in at least two areas, or moderate difficulty in more than three areas of sleep quality. Recent, independent study has validated this cut off and confirmed reliability (Cronbach's alpha = 0.85, test–retest r = 0.84; Backhaus et al., 2002).

2) Insomnia Severity Index (ISI; Bastien, Vallieres & Morin, 2001) The ISI has been reported to be a reliable and valid instrument for reporting perceived insomnia severity with an alpha co-efficient of internal consistency of 0.74 (Bastien, Vallieres & Morin, 2001). The ISI is a self-report measure, which asks the rater to state how severe their insomnia is, how much they feel it, the impact it has on their life and how distressed they are by it. Adequate internal consistency of this measure has been reported

3) Beck Depression Inventory (BDI; Beck, Steer & Brown, 1996) The BDI is a 21-item self-report form covering symptoms of depression. It is widely accepted that a score of '23' or above serves as a measure of severe depression. The BDI demonstrates high internal consistency, with alpha coefficients of 0.86 and 0.81 for psychiatric and non-psychiatric populations, respectively.

4) Beck Anxiety Inventory (BAI; Beck, Epstein, Brown & Steer, 1988) The BAI is a 21=item questionnaire that measures the severity of anxiety in adults. This measure will therefore be able to identify and exclude participants with high levels of anxiety. It is widely accepted that a score of '30' or above serves as a measure of severe anxiety. The psychometric properties of BAI have been widely studied, resulting in high internal consistency $\alpha = 0.92$ and excellent test-retest reliability $r(81) = 0.75$ (Beck, Epstein. Brown & Steer; 1998).

5) Behavioural Inhibition Scale (BIS) and Behavioural Activation Scales (BAS) (Carver & White, 1994) Behavioural Inhibition System (BIS) and Behavioural Activation System (BAS) Sensitivity. BIS/BAS sensitivity will be assessed using the BIS/BAS Scale (Carver & White, 1994) which is comprised of 24 items with four subscales: One reflects BIS sensitivity (7 items), and three reflect aspects of BAS sensitivity: BAS Drive (4 items); BAS Fun Seeking (4 items); and BAS Reward Responsiveness (5 items). The three aspects of BAS sensitivity derive from diverse theoretical statements about how BAS functioning should be reflected experientially. The three BAS-related scales were designed to reflect these somewhat distinct functions (Carver, Meyer, & Antoni, 2000). Respondents rate each item on a 4-point scale ranging from 1 (very true for me) to 4 (very false for me). Higher scores on each scale indicate greater levels of BIS/BAS sensitivity. Internal consistencies for the BIS/BAS Scales have been found to be adequate: Cronbach's alphas = .79, .72, .69, and .69, for the BIS scale, BAS Drive, BAS Fun Seeking, and BAS Reward Responsiveness, respectively (O'Connor & Forgan,.2007). In an 8-month follow-up study of both depressed and non-depressed individuals, Kasch et al. (2002) found that the BIS and BAS scales showed stability over time and changes in participants' clinical state.

6) Glasgow Sleep Effort Scale (GSES; Broomfield & Espie, 2005) The GSES is a short (7-item) scale designed to assess effortful preoccupation with sleep. This is an important construct within the ICSD-2 definition of PI; and is the 'end state' of the proposed Attention-Intention-Effort pathway. The GSES has a single factor structure with acceptable internal consistency (α =.77).

Appendix B.3: Diagnostic Criteria for Insomnia Groups and Good Sleepers

Participants in the PI and IdI groups will meet the following general criteria for insomnia as outlined in the ICSD-2 diagnostic classification system:

A. A complaint of difficulty initiating sleep, difficulty maintaining sleep, or waking up too early or sleep that is chronically non-restorative or poor in quality.
B. The above sleep difficulty occurs despite adequate opportunity and circumstances for sleep.
C. At least one of the following forms of daytime impairment related to the night time sleep difficulty is reported by the patient:
    i. Fatigue or malaise
    ii. Attention, concentration, or ,memory impairment
    iii. Social or vocational dysfunction
    iv. Mood disturbance or irritability
    v. Daytime sleepiness
    vi. Motivation, energy, or initiative reduction
    vii. Proneness for errors or accidents at work or while driving
    viii. Tension, headaches, or gastrointestinal symptoms in response to sleep loss
    ix. Concerns or worries about sleep

Participants eligible for inclusion in the PI group will also meet the following diagnostic criteria for Psychophysiological Insomnia:

A. The patient's symptoms meet the criteria for insomnia
B. The insomnia is present for at least one month
C. The patient has evidence of conditioned sleep difficulty and/or heightened arousal in bed as indicated by one or more of the following:
    i. Excessive focus on and heightened anxiety about sleep
    ii. Difficulty falling asleep in bed at the desired bedtime or during planned naps, but no difficulty falling asleep during other monotonous activities when not intending to sleep
    iii. Ability to sleep better away from home than at home

iv. Mental arousal in bed characterized either by intrusive thoughts or perceived inability to volitionally cease sleep-preventing mental activity

v. Heightened somatic tension in bed reflected by a perceived inability to relax the body sufficiently to allow sleep onset

D. The sleep disturbance is not better explained by another sleep disorder, medical or neurological disorder, medication use, or substance use disorder.

Participants eligible for inclusion in the IdI group will meet the following diagnostic criteria for Idiopathic Insomnia:

A. The patient's symptoms meet the criteria for insomnia
B. The course of the disorder is chronic, as indicated by each of the following:
    i. Onset during infancy or childhood
    ii. No identifiable precipitant or cause
    iii. Persistent course with no periods of sustained remission
C. The sleep disturbance is not better explained by another sleep disorder, medical or neurological disorder, medication use, or substance use disorder.

The GS group will meet the following research diagnostic criteria for Normal Sleepers (Controls):

A. The individual has no complaints of sleep disturbance or daytime symptoms attributable to unsatisfactory sleep
B. The individual has a routine standard sleep/wake schedule characterized by regular bedtimes and rising times
C. There is no evidence of a sleep-disruptive medical or mental disorder
D. There is no evidence of sleep disruption due to a substance exposure, use, abuse, or withdrawal
E. There is no evidence of a primary sleep disorder

Appendix B.4: Participant enquiry screening form

Source

How did you find out about the University of Glasgow Sleep Centre?	
Why have you contacted us?	
Method of initial contact (mobile, email, office phone)?	

Personal

Full Name:	*Date of Birth:*	*Age:*
Telephone:	*Address:*	
Alternative Telephone:		
When is a good time to call?		
What GP practice do you attend, and who is the GP you normally see?		

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)?	
Do you work shifts, night shifts?	
Roughly, how many units of alcohol do you drink per week? *(Remember: One standard (175ml) glass of wine = 2 unit* *One pint of standard lager = 2.3 units* *Spirit & Mixer = 1 unit)*	
Does your sleep disturbance affect how you feel and function during the day (e.g. fatigue, sleepiness, concentration, memory, mood, motivation, irritable, work/social functioning etc.). If yes, specify most salient.	

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 mental health problems do you have (if applicable)?	
What medicines do you take for your mental health? (if applicable)	

Notes

Appendix B.5: Participant Information Sheet

PARTICIPANT INFORMATION SHEET

The role of behaviour motivation in Adult Onset and Childhood Onset Insomnia

Principal Researcher: Grant Forgan, Trainee Clinical Psychologist, University of Glasgow, Department of Psychological Medicine.

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 information carefully and discuss it with others if you wish. Please contact the researcher if you would like more information or if there is anything that is not clear.

What is the purpose of the study?

Sleep difficulties such as insomnia are common with about one in ten adults experiencing a problem getting to sleep or staying asleep. People can develop insomnia in childhood or adulthood. The purpose of this study is to explore the differences between childhood and adult onset insomnia and some psychological factors which may be involved in the development and maintenance of these types of insomnia. It is hoped that the findings from this study will add to our understanding of these types of insomnia and contribute to the development of more effective ways of treating them.

Why have I been chosen?

You are being asked to participate in this research study because you have indicated that you are either a good sleeper, who has no trouble sleeping at night, or have been experiencing problems with your sleep. It is hoped that altogether, around 90 people will be studied in this project.

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 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 or not to take part will not affect the standard of care you receive and any data collected from you will be destroyed.

What will happen to me if I take part?

If you do not have a sleep problem and decide to take part as a ‘good sleeper’ you will only be asked complete a consent form, and some questionnaires which will be posted to you.

If you have a sleep problem and decide to take part you will be asked to meet with the researcher to complete a consent form, a set of questionnaires and to take part in an interview. The interview will take place at the University of Glasgow Sleep Centre at the Sackler Institute of Psychobiological Research, Southern General Hospital. It should last no longer than one hour.

(The interview could be conducted by telephone instead at a pre-arranged time if this would be more convenient for you. You would then be sent the set of questionnaires to complete and return in a postage paid envelope). After the interview you will be asked to complete a sleep diary over the following week and then return it to the researcher. You will be asked questions relating to sleep quality, the effort you put into getting to sleep and behaviour motivation. There will also be some questions about your physical health, mental health and drug/alcohol use.

Will my taking part in this study be kept confidential?

Your participation will be treated with strict confidence. All personal information, such as your address and contact details, which is collected about you during the course of the research will be kept in a locked cabinet in a locked room (like a medical file) and only the researcher and their research supervisor, Professor Colin Espie, Director of the University of Glasgow Sleep Centre will have access to it. Most of the information (data) from your assessments will be kept in anonymised form and transferred to a password protected computer system that will not have your name on it.

It is possible that a result from one of the questionnaires you complete has implications for your health or well-being. This could be to do with your mental or physical health and in such an event 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 risks of participation?

Answering some of the questions in the questionnaires and interview may make some people feel uncomfortable. You do not have to answer any questions you don't want to.

Are there any benefits of participation?

There is no direct benefit to you 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 people experiencing insomnia in the future.

What will happen to the results of the research study?

It is intended that they will be used as part of the researcher's Doctorate in Clinical Psychology, and will also be submitted for publication in a scientific journal. You will not be identified in any publication. You will be asked if you wish to receive a summary of the research findings once the study has been completed.

Is there someone I can contact to seek independent advice about participating in this study?

You may contact NHS Greater Glasgow and Clyde Research and Development Office on 0141-211-6313.

Should you wish to participate or require some more information:

Please contact the researcher Grant Forgan on **07989 405 359** or by email at **g.forgan.1@research.gla.ac.uk**

Appendix B.6: Participant Consent Form

Consent form

Title of research study: Psychophysiological (Adult Onset) Insomnia and Idiopathic (Childhood Onset) Insomnia: The role of self-regulatory behaviour systems.

Principal Researcher: Grant Forgan, Trainee Clinical Psychologist, University of Glasgow, Department of Psychological Medicine.

Please initial each of the boxes

I confirm that I have read and understood the Participant Information Sheet for the above study and have had the opportunity to ask questions about the study. ☐

I understand that participation in the study is voluntary and that I am free to withdraw at any time without giving a reason and that all data relating to my participation will be destroyed. ☐

I understand that all personal information and data relating to my participation in the study will be kept confidential. ☐

I agree to take part in the study. ☐

I consent/do not consent (please delete as appropriate) to being contacted in the future regarding other sleep research studies and to my personal contact details being retained for this purpose. ☐

Participant Name: _____

Signature: _____

Date: _____

Appendix B.7: Sleep Diary

Daily Sleep Diary

Complete the diary each morning ("Day 1" will be your first morning). Don't worry too much about giving exact answers, an estimate will do.

Your Name_____ The date of Day 1_____

		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
	Enter the Weekday (Mon, Tues, Wed, etc.)							
1	At what time did you go to bed last night?							
2	After settling down, how long did it take you to fall asleep?							
3	After falling asleep, about how many times did you wake up in the night?							
4	After falling asleep, for how long were you awake during the night in total?							
5	At what time did you finally wake up?							
6	At what time did you get up?							
7	How long did you spend in bed last night (from first getting in, to finally getting up)							
8	How would you rate the quality of your sleep last night? 1 2 3 4 5 V. Poor V. Good							

Appendix B.8: Sleep Disorder Assessment Interview

University of Glasgow Sleep Centre Assessment Proforma

1. ORIENTATION

Although we a have some information regarding your current sleep problem, it is very limited and lacks important detail. Could you explain in your own words the nature of your sleeping problem and why you are here today?

2. PERSONAL SLEEP HISTORY

Presentation of Sleep Problem
a)Pattern

Key Q. **What is the pattern of your sleep on a typical night?**	
How long does it take you to fall asleep?	
How often do you wake up?	
How long are you awake during the night?	
How much sleep do you get?	
How many nights a week were like this?	

b) Quality

Key Q. **How do you feel about the quality of your sleep?**	
Is it refreshing?	
Is it enjoyable?	
Is it restless?	
How would you describe it in your own words?	

c) Daytime effects

Key Q. **How does your nights sleep affect your day?**	
Do you feel tired?	
Do you feel sleepy?	
Do you have problems concentrating?	
Do you feel irritable?	
What do you think insomnia does to your day?	
When are your worst times in the day?	

d) Impact on your life

Key Q. **How does your insomnia affect your quality of life?**	
What consequences does insomnia have for you?	
What are you not able to do because of your insomnia?	
How would things be different in your life if you overcame insomnia?	

Development of the Sleep Problem

Key Q. **Do you remember how and when your poor sleep started?**	
What were the events and circumstances then?	
What were the important dates and times?	

How has your sleep changed over time?	
Anything that has happened that has made it worse?	
Anything that has happened that has made it easier?	

Lifetime History of the Sleep Problem

Key Q. **Did you used to be a good sleeper?**	
How did you sleep as a child?	
How did you sleep as a teenager?	
How did you sleep as a younger adult?	
Were there previous episodes of poor sleep?	
Dates and times?	
Did these past episodes resolve? If so how?	

Family History of Sleep Problems

Key Q. **Do other people in your family have problems sleeping?**	
Do either of your parents have sleep difficulties (now or in the past)	
What about brothers and sisters?	
What about the extended family including grandparents?	
Does anyone have problems that are similar to your problems sleeping?	

General Health and Medical History

Key Q. **Have you generally kept in good health?**	

Have you had any major illness?	
Have any health problems been persistent ones?	
Dates and times?	
Have there been any recent changes in your health?	

History of Psychological Well-being

Key Q. **Are you the kind of person who usually copes well?**	
Have you had any psychological problems?	
Any problems with anxiety or depression or with stress?	
Dates and times	

Current and Previous Treatments for Insomnia

Key Q. **Are you taking anything to help you sleep?**	
What (if any) medications are you taking now to help you sleep?	
What have you taken in the past?	
Dates and times?	
Are you taking anything you have bought over the counter?	
What sorts of things have you tried to do	

yourself to help you sleep?	
What have you found has worked and not worked?	

3. OTHER SLEEP DISORDERS

Sleep Related Breathing Disorder (SBD)

Key Q. **Are you a heavy snorer?**	
Do you have interrupted breathing during the night?	
Does your partner say that you sometimes stop breathing?	
Do you waken up gasping for breath?	
Are you excessively sleepy during the day?	
Do you fall asleep in the day without wanting to?	

Periodic Limb Movements in Sleep (PLMS) and Restless Leg Syndrome (RLS)

Key Q. **Do your legs sometimes twitch or jerk or can't keep still?**	
Is it difficult to sleep because of muscle jerks?	
Do you waken out of sleep with sudden jerky movements or feeling the need to move your legs?	
Do you have to get out of bed and pace around to get rid of these feelings?	
Are you excessively sleepy in the day?	

Circadian Rhythm Sleep Disorders

a) Delayed Sleep Phase Syndrome (DSPS)

Key Q. **Do you tend to sleep alright but at the 'wrong time'?**	

Can you sleep well enough but only if you stay up really late?	
Are you alert and not sleep until a long while after normal bedtime?	
Are you sound asleep at the normal waking time and can sleep on for hours more?	

b) Advanced Sleep Phase Syndrome (ASPS)

Key Q. **Do you tend to sleep alright but at the 'wrong time'?**	
Can you sleep well enough but only if you go to bed very early?	
Are you very sleepy if you try to stay up until normal bedtime?	
Do you waken up very early, bright and alert and no longer sleepy?	

Parasomnias

Key Q. **Do you have unusual behaviours associated with your sleep?**	
Do you sleepwalk?	
Do you sleep talk?	
Do you have confused behavioural episodes during the night?	
Do you have night terrors when you are very distressed but not properly awake?	
Do you grind your teeth in the night?	
Do you sometimes act out your dreams?	
Do you have nightmares?	

Narcolepsy

Key Q. **Do you sometimes just fall asleep without warning?**	
Do you have sudden sleep attacks?	
Is it impossible to resist falling asleep during the day?	
Do you have collapses or extreme muscle weakness triggered by emotion?	
Do you have hallucinations or odd sensations when you fall asleep or when you waken in the morning?	
Do you sometimes feel paralyzed and unable to move when you waken from your sleep?	

Appendix B.9: Good Sleeper Questionnaire

The sections marked with **** need to be completed for the purposes of completing the study. Your name and address is required if you would like to be sent a summary of the study's findings once it is completed.

Name:_____

Address:

_____

_____

_____

****Date of Birth**:_____

****Age:** _____

****Sex:** **Male** **Female**

__Sleep Details__**

Do you currently have difficulties with your sleep? Yes No

Have you ever had serious or noticeable problems with your sleep in the past? Yes No

If yes; a) How long do you estimate this problem lasted for? _____

b) Did the problem resolve itself or did you seek assistance with it from your GP or another source of help? Yes No

Many thanks for providing the above information and for taking part in this study.

Appendix B.10: Ethics approval letter

Primary Care Division

NHS
Greater Glasgow and Clyde

Research Ethics
Primary Care, Community & Mental Health REC
R&D Directorate
1st Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT
www.nhsggc.org.uk

Mr Grant S Forgan
Trainee Clinical Psychologist
NHS Greater Glasgow and Clyde
Dept of Psychological Medicine
Academic Centre, Gartnavel Royal Hospital,
055 Great Western Road
Glasgow G12 0XH

Date 09 December 2008
Your Ref
Our Ref
Direct line 0141 211 2123
Fax 0141 211 2811
E-mail Liz.Jamieson@ggc.scot.nhs.uk

Dear Mr Forgan

Full title of study: **Psychopyhysiological Insomnia and Idiopathic Insomnia: The Role of self-regulatory behaviour systems**

REC reference number: **08/S0701/158**

The Research Ethics Committee reviewed the above application at the meeting held on 04 December 2008.

Ethical opinion

Members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. However this favourable opinion is subject to the following issues being clarified through the Committee Co-ordinator as soon as possible. The favourable opinion is **not** valid until these issues have been answered.

1) The poster states 'Over 65s with Insomnia' whereas the Inclusion/Exclusion Criteria states 'Participants will be 18 to 65 years of age'. Please clarify.

2) Consent to be contacted in the future regarding other sleep research studies taking place should be included in the Consent Form. A revised Consent Form is required.

3) There should also be a line in the Consent Form indicating that participants know that all their information will be kept confidential. Again a revised Consent Form is required.

4) Question A36 has not been fully answered, i.e. whether a computer will be used. Please clarify.

Conditions of the favourable opinion

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

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

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
CV - Professor C Espie		
Participant Consent Form – **to be revised**	Version 1	17 November 2008
Participant Information Sheet	Version 1	17 November 2008
Advertisement		
Questionnaire: Non-Validated		
Questionnaire: Validated		
Protocol	Version 1	17 November 2008
Investigator CV		
Application		17 November 2008
Covering Letter		17 November 2008

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

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

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

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

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

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

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

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

08/S0701/158	**Please quote this number on all correspondence**

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

Yours sincerely

Liz Jamieson

Liz Jamieson
Committee Co-ordinator
On behalf of Martin Hattie, Acting Chair

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments "After ethical review – guidance for researchers
Copy to:	Mr Brian Rae, R&D office for NHS care organisation at lead site

Primary Care Division

NHS
Greater Glasgow and Clyde

Research Ethics
Primary Care, Community & Mental Health REC
R&D Directorate
1st Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT
www.nhsggc.org.uk

Mr Grant S Forgan
Trainee Clinical Psychologist
Dept of Psychological Medicine
Academic Centre,
Gartnavel Royal Hospital,
1055 Great Western Road
Glasgow G12 0XH

Date 23 December 2008
Your Ref
Our Ref
Direct line 0141 211 2123
Fax 0141 211 2811
E-mail Liz.Jamieson@ggc.scot.nhs.uk

Dear Mr Forgan

Full title of study: **Psychophysiological Insomnia and Idiopathic Insomnia: The Role of self-regulatory behaviour systems**

REC reference number: **08/S0701/158**

I refer to your letter dated 18th December 2008 in response to my letter dated 9th December 2008.

I can now confirm that you have met the conditions of the approval letter and that the favourable opinion is now valid.

I have copied all correspondence to R&D to keep them up to date.

08/S0701/158	**Please quote this number on all correspondence**

Yours sincerely

Liz Jamieson

Liz Jamieson
Committee Co-ordinator

Copy to: Mr Brian Rae, R&D