

VOLUME I: RESEARCH

Insomnia Predisposing, Precipitating and Perpetuating Factors

By

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A thesis submitted to
the University of Birmingham
for the partial fulfilment for the Doctorate in Clinical Psychology

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OVERVIEW OF DOCTORATE IN CLINICAL PSYCHOLOGY THESIS

As partial fulfilment for the degree of Doctorate of Clinical Psychology (Clin.Psy.D) at the University of Birmingham, a research and clinical volume are submitted.

Throughout the thesis, all identifying information has been anonymised to ensure confidentiality is maintained.

Volume I represents the research component. This is comprised of three papers that explore possible precipitating and perpetuating factors involved in the development and/or maintenance of insomnia. The first paper systematically reviews the findings of research implementing non-pharmacological sleep hygiene interventions within a hospital setting. The second paper presents research designed to identify whether the same underlying cognitive mechanisms that have been found to contribute to the maintenance of depression, are present in people who report poor sleep. Both papers will be edited for submission to the Journal of Behavioural Sleep Medicine. The third paper provides a brief executive summary of the literature review and the empirical paper.

Volume II represents the clinical volume. This is comprised of five Clinical Practice Reports (CPRs). The first presents a psychodynamic and systemic formulation of an 11-year-old boy presenting with conduct disorder. A service evaluation is presented in the second paper. This evaluates the cygnet parenting program; an autistic spectrum condition parenting support program. The third report presents the case study of Annie who had been admitted to the hospital due to cardiac palpitations. She had presented to staff with low mood and suicidal ideation. A psychodynamic formulation was based on Malan's 'two triangles model' and its development and exploration was integral in intervention. A single-case experimental design report details a six-week Cognitive Behavioural Therapy for Insomnia (CBT-I) intervention. Julie presented with a multitude of physical symptoms, particularly related to her multiple sclerosis, but reported her overwhelming fatigue and inability to sleep to be the most difficult. Finally, the fifth report is an abstract for the presentation of a 19-year-old female who was referred to the renal clinical psychology team. Exploring Eleri's depression and anxiety informed a psychodynamic and attachment formulation and intervention.

For Leo

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Sincere thanks go to all my participants. This thesis would be incomplete without you, so thank you for helping make it happen.

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A review of non-pharmacological sleep
hygiene interventions in hospital settings.

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Abstract

Background: Sleep is a fundamental component of good health and yet hospital patients report sleep disturbance as one of the most stressful components of their hospital care experience. Hospitalisation is also a risk factor for insomnia that remains for months or years after discharge.

Aim: The aim of this review was to systematically evaluate the findings of research implementing non-pharmacological sleep hygiene interventions within a hospital setting and inform recommendations for future research.

Method: Fifteen papers met specified inclusion criteria. Downs and Black's (1998) quality checklist was used to assess the methodological quality and the main components of each paper were collated. Together this structured a consideration of the overall quality and findings from the papers reviewed.

Results: Main outcome data show elements of improvement in hospital patients' sleep quality, as well as other related measures such as pain, delirium and 'as needed sedative' medication. Improvements were statistically reported in thirteen of the fifteen papers reviewed, however compromised internal validity and moderate sample sizes weakened the reliability of these data.

Recommendations: Pragmatic 'intention-to-treat' research, recruiting large sample sizes with appropriate randomisation and allocation concealment during analysis is needed. Subjective sleep measures and relevant measurements consistent with the requirement of a pragmatic trial, such as 'as needed' sedatives or pain should be included, and cost utility of sleep hygiene practices in routine hospital care should inform a fully costed service delivery model.

Key words: Sleep quality; hospitalised patients; sleep hygiene; non-pharmacological intervention

A review of non-pharmacological sleep hygiene interventions in hospital settings.

The aim of this review is to systematically review and synthesise the findings of research implementing non-pharmacological sleep hygiene interventions within a hospital setting.

Aim

Sleep is a fundamental component of health and recovery and yet patients report sleep disturbance as one of the most stressful components of their critical care experience (Novaes et al., 1999). Historically, literature looking at sleep within a hospital setting has focused on observing critical care patient's sleep quality and investigating causes of disturbance. Fewer studies designed and measured interventions for promoting sleep quality, however with research data now available this review aimed to evaluate its quality and inform recommendations for future research.

Jones and Dawson (2012) report a divergence within the literature regarding the sleep of patients in critical care settings. They reflect on data showing reduced total sleep time (Hilton, 1976; Gabor et al, 2003; Kudchadker et al, 2009), as well as data showing no quantitative sleep deprivation among patients (Friese et al., 2007; Patel et al., 2008), but recognise data showing 50% of total sleep time for critical care patients is likely to occur during the day (Freedman et al., 2001; Gabor et al., 2003; Parthasarathy and Tobin, 2004).

Sleep quality has been found to be compromised in critical care environments. When patients are asked to compare their sleep in critical care with their typical sleep at home, they report significantly poorer sleep quality (Freedman et al., 1999; Nicolas et al., 2008). This includes greater fragmentation and frequent arousals, circadian rhythm irregularity, decreased total sleep time and decreased sleep efficiency (Freedman et al., 1999, 2001, Cooper et al., 2000). Polysomnography data support this, showing inferior sleep architecture among patients who are admitted to hospital compared to normal sleep.

Patients spend greater periods of time in stages 1 and 2 of Non-REM (Rapid Eye Movement) sleep and significantly less time in stages 3 and 4 and REM (Hilton, 1976; Freedman et al., 2001; Gabor et al., 2003; Parthasarathy and Tobin, 2003; Friese et al., 2007; Cabello et al., 2008; Nicolas et al., 2008).

The detrimental effects of sleep deprivation on patient recovery has important implications not only for the patient but also for the health care system. Sleep disturbances in critically ill patients can have adverse effects on cognition and immune function, both of which can prolong hospitalisation (Heiser et al., 2000; Kato et al., 2000; Connor et al., 2002; Salas & Gamaldo 2008). It can further deteriorate patients' health and prolong their hospital stay; tissue repair is slowed down; the ability to fight infection is compromised (Snyder-Halpern, 1985) and stress levels increase. A stark conclusion from Dracup's (1988) review suggested that critical care units endanger psychological health and delay recovery. Such a statement becomes more salient when considering more recent evidence that hospitalisation is also a risk factor for insomnia that remains for months or years after discharge (Griffiths & Peerson, 2005; Smith et al., 2008).

Disturbers of sleep in Critical Care Environments

Individual patient factors that may impact on sleep quality include physical and psychological health. These can include physical health status (Reishstein, 2005), morbidity, trauma, medications (Cooper et al., 2000; Bourne & Mills, 2004), pain and discomfort from surgical procedures, tubes and lines and 24-hour treatment activities (Epstein & Breslow, 1999, Nadolski, 2005). Isolation, an inability to get comfortable or lay comfortably, inability to perform the usual routine prior to going to bed, muscular and joint discomfort from prolonged bed rest, as well as acute anxiety and stress have all been identified as factors that can impair sleep quality (Simpson et al., 1996). Environmental factors can include noise (Freedman et al., 2001; Freedman et al, 1999; Meyer et al., 1994; Kahn et al., 1998; Gabor et al., 2003), light (Freedman et al, 1999; Meyer et al., 1994), patient care interaction (Tamburri et al., 2004) and overall unfamiliarity.

Hospital ward noise has been shown to increase blood pressure, heart rate, respiratory rate and body temperature, and in turn has been associated with failure to thrive, impaired immune function, delayed wound healing and increased stress levels (Topf and Thompson, 2001). Abnormal lighting can cause disturbance of circadian rhythms and low light intensity can suppress nocturnal melatonin secretion (Boivin et al., 1996; Drouot et al., 2008; Patel et al., 2008). Frequent and repeat interruptions minimise the opportunity for patients to achieve the deeper levels of sleep (Hilton, 1976; Meyer et al., 1994; Freedman et al., 1999; Celik et al., 2005) and lead to lighter, less restorative sleep and many medications commonly found in critical care units disrupt normal sleep architecture (Honkus, 2003; Pandharipande and Ely, 2006; Weinhouse et al., 2009; Tembo and Parker, 2009; Weinhouse and Watson, 2009).

Literature has long suggested interventions should be developed to improve the hospital environment by addressing and minimising those modifiable factors identified as disruptive to sleep quality among patients. These included recommending wards maintain a quiet and dim environment where possible and decrease interruptions from care activities at night if viable.

Interventions to assist patients' sleep quality that have been reported in outcome studies include

- *Environmental control of stimuli*: dimmed light, temperature, lowered machine alarms.
- *Environmental control of procedures*: reducing unnecessary patient care interventions; clustering patient care activities; scheduled quiet times.
- *Individual sensory control*: using earplugs or eye masks; audiotapes, white noise.
- *Relaxation* – massage, footbaths, relaxation scripts.

The following review aims to systematically evaluate and synthesise the characteristics and findings of research implementing sleep hygiene interventions within a hospital setting.

Method

This review aimed to seek and collate all evidence that fit a pre-specified eligibility criterion to address the specific research question.

The keyword 'sleep' in combination, with 'quality', 'hygiene', 'disruption', 'pattern', 'poor' and 'deprivation', were searched and then combined with the keyword combination of 'hospital', 'ward' or 'unit' and 'noise', 'light' or 'temperature'.

These terms were entered into three search engines. PsychINFO (39 articles), Medline (183 articles) and EMBASE (335 articles). The search was between 1987 to 2014. Further inclusion and exclusion criteria are described in Table 1.

Table 1: Inclusion and Exclusion criteria.

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • Empirical papers • Intervention design • Sleep quality included as a main outcome • Data collected from patients within a hospital setting. 	<ul style="list-style-type: none"> • Articles focusing on identifying the factors within a hospital setting that disrupt sleep • Articles focused on the consequences of sleep disruption within a hospital setting • Medicinal Interventions • Sleep research data completed within nursing homes/psychiatric wards • Articles only measuring environmental factors in hospital i.e. light, noise • Articles without data collection and analysis • Research design involving stimulated / artificial hospital environment (i.e. recording ICU noise) • Conference papers, magazines, dissertations and books • Articles focusing on medical staff sleep.

A review of titles and abstracts indicated an initial fifty-nine potential studies to consider for review. Papers were excluded if they focused on: sleep mechanisms, hypnotic medications, factors affecting sleep hygiene, sleep deprivation and health/recovery implications, consequences of disturbed sleep hygiene, artificial research environments as well as medical staff shift work, circadian rhythms, sleep quality or deprivation. Using the inclusion and exclusion criteria (Table 1) irrelevant or inappropriate full articles were identified. Secondary sources were also obtained from reference lists, and fifteen papers were finally accepted (Figure 1). A summary of the main characteristics and findings of the qualitative and quantitative studies are presented in the following table (Table 2).

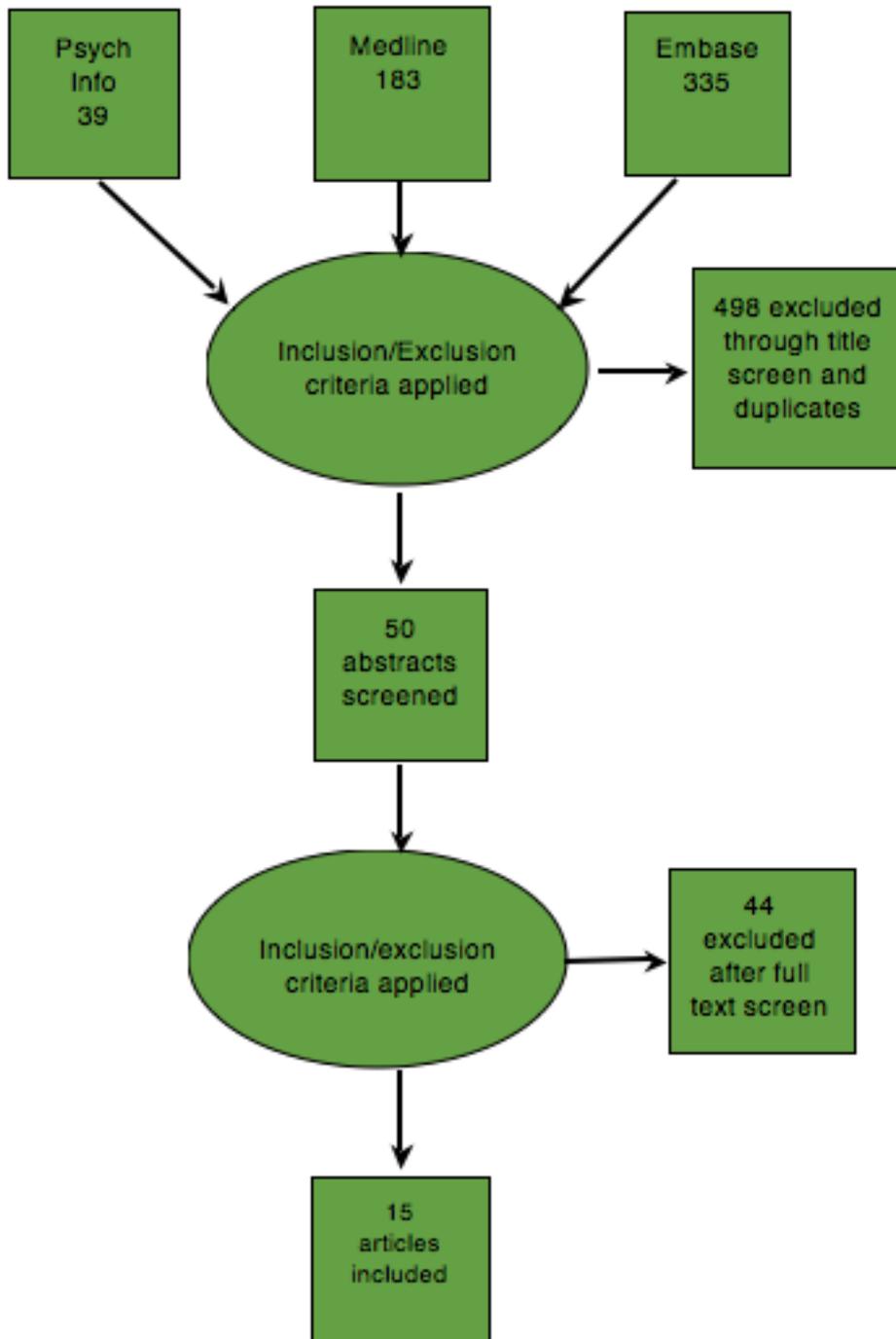


Figure 1: PRISMA Diagram of literature search

Table 2: Summary of main characteristics and findings reviewed papers.

	Study	Sample Size	Patient Group	Intervention	Design	Measure	Limitations	Key results	Direction of result
Environmental control of stimuli + scheduled procedures	[1] Bartick et al., (2010) USA	N =161 pre-intervention N=106 intervention. Intention to treat analysis.	Community teaching hospital. Excl: patients requiring intensive care or actively dying; known sleep disorders; alcohol/drug withdrawal; sig hearing loss; blindness.	An 8-hour quiet time 10pm-6am. Automated lights out & lullaby; staff-monitored noise and avoidance of waking patients for routine medical checks.	Pre-post study. Patients and medical staff blinded to measurement of as needed sedative.	Sedative use. Verran Snyder-Halpern (VSH) sleep scale. Sleep Quality. Adherence (door closing)	Lack of randomised concurrent controls. Moderate sample size. Lack of measures of disease severity.	Sig reduction in night time as-needed sedatives The noise from staff 'voices' Sig. decreased. No improvement in any measure of the VSH. Closing doors did not change. Timings for medication orders were Sig. more flexible.	+ + - -
	[2] Chong et al., (2013) Singapore	N = 228 patients	Delirious patients admitted to the GMU Singapore. Classified into 1) hyperactive 2) hypoactive 3) mixed delirium subtype. Inclusion >65 years Exclusion: requiring special monitoring; dangerously ill; terminal illness; contraindication for bright light.	Bright lights installed in the ceiling were turned on from 6-10pm daily. Sleep hygiene principles were practiced during patient's GMU stay.	Quasi experiment.	Confusion Assessment Method (CAM) Charlson Co morbidity Index; Chinese Mini Mental State Examination; Modified Barthel Index. GMU nurses completed hourly patient sleep logs (TST, number of awakenings; number and duration of sleep bouts (SB).	No control group. Sleep measures collected by nurses. Unable to delineate benefits from multi component.	Sig improvement in sleep wake disturbance sub-score. Increased length of first SB; decreased number of SB; fewer awakenings. Hyperactive subgroup showed Sig increase in TST, decreased number of SB + increased first length of SB. Hypoactive subgroup showed Sig increase in TST. Following adjustment only length of SB in hypoactive delirium remained Sig. Sig improvement in functional status at discharge.	+ + + + + +
	[3] Dennis et al (2010) USA	N = 50 N = 35 observed during day N = 15 observed during night	Neuro-ICU patients. Excl. GCS < 10 < 18 yrs old sedated or mechanically ventilated.	Quiet time twice a day 2-4pm & 2-4am: reduced noise & light levels.	Observational prior and during implemented 'quiet time'	Noise – digital sound meter. Light meter. Sleep Observation Tool (SOT)	Did not present stats for sleep. Nurses reported patient sleep status.	Noise + light levels were Sig. lower during day shift quiet time. Patients were Sig more like to be 'observed' sleeping during day shift quiet time. No Sig change in noise or light during night shift quiet time.	+ + -

Table 2: Summary of main characteristics and findings reviewed papers.

	Study	Sample Size	Patient Group	Intervention	Design	Measure	Limitations	Key results	Direction of result
Environmental control of stimuli + scheduled procedures	[4] Faraklas et al., (2013) USA	N = 130: 81 PRE 49 Post Male (Pre 69%, post 76%) Mean age (Pre 41; post 49 yrs)	Adult patients admitted to a single burn-trauma care unit. Not delirious, able to respond verbally; no anaesthesia prior 24hr	A unit wide nursing-driven sleep hygiene protocol. Minimise environmental stimuli: noise, lights, schedule-nursing care, anticipate medical alarms.	Non (Randomised Pre-post design 2 separate cohorts	Subjective: RCSQ Pain score 0-10	Results were self-reported by patients. Post group data fell to n = 49. Pre and post participants separate cohorts.	Sig. decreased SOL latency & pain in post patients who had pre-existing sleep difficulties. Sleep disruption was unchanged. Post patients complained Sig. less about clinician disruptions	+ - +
	[5] LaReau et al., (2008) USA	Total N = 59 patients (57% female, mean age 79.6. N = 29 intervention N = 30 TAU	Adult medical patients. 35 bed cardiology unit and a 20 bed adult unit later expanded to 34 beds.	Experimental group received nursing sleep protocol intervention including a sign on door reminding people to speak quietly, sleep hygiene measures, room temperature adjustment, noise + light control measures, relaxation techniques, clustering nursing activities, minimised unnecessary interruptions.	RCT. Experimental versus control group.	Sleep hours and number of awakenings recorded in electronic hospital documentation system. RCSQ. Staff checklist for project. Patient medication record. The Benson-LeReau Ranking of Sleep Interventions.	Different wards. Insufficient power, inconsistent protocol application.	Sig improvement in patient's ability to remain asleep and sleep quality were improved. Experimental group used significantly less sleep medication. Patients rated interventions personal hygiene; bedtime awareness.	+ +
	[6] Olson et al., (2001) USA	Total = 239 Control n = 118 (1446 observations). Intervention n= 121 (1529 observations).	Inclusion >10 on Glasgow Coma Scale	Environmental sounds + lights were decreased from 2am to 4am and from 2pm to 4pm.	Pretest-posttest design. Data collection divided into 2 phases each lasting 2 months with 1-month run-in period separating phases. Phase 1 – control Phase 2 – initiation of quiet time policy	Light measured using a light meter. Nurses observed participants & indicated whether they were asleep, awake or in an indeterminate sleep-wake state. Patients were observed for a min of 5 sec and entered onto a modified nurse observation checklist.	No blinded observations. Compliance with protocol varied. Sleep judged by nurses.	Percentage of patients observed asleep was Sig. higher during the protocol months. Increase in sleep behaviour was associated with decreased sound + light levels achieved during quiet times. 1.6 times more likely to be asleep compared to controls	+ +

Table 2: Summary of main characteristics and findings reviewed papers.

	Study	Sample Size	Patient Group	Intervention	Design	Measure	Limitations	Key results	Direction of result
Environmental control of stimuli + scheduled procedures	[7] Li et al., (2011). Taiwan	N= 60 recruited; N= 55 completed: N = 28 experiment group N = 27 control group Male 67.3% Mean age 50	Convenience sample Adult patients undergone chest, abdominal/other major surgeries. Exclusion: head injuries, convulsions, mental diseases or hearing problems; alcoholism, use of sedative/narcotics, having sleeping problems/taking sleeping pills on a regular basis.	Changing night-time nursing care routine between 11pm-5am: Closing all doors and dimming lights to 40 lux; < telephone noise to 40dB, <monitors to 50dB; check volume of IV fluid and tube feeding and replace at 11pm; respond to an alarm within 1 min. rearrange medical treatments, lower volume of staff conversation.	Non Randomised 2 phase quasi-experimental design.	Objective noise level Subjective Sleep Quality: Sleep in the Intensive Care Unit & RCSQ	Due to selection criterion results may not be generalisable to post-surgery ICU patients. Non-equivalent post test only.	Peak and average noise level Sig. reduced at patients' bedside and nurses station. Experimental group reported: Sig better sleep quality and sleep efficiency. Sig. less daytime sleepiness & less sleep interruptions from night time care & environmental noise. No Sig. difference in perceived sleep interruptions from light, taking vital signs or taking a blood sample.	+ + + -
	[8] Thomas et al., (2012). USA	All patients were screened daily for eligibility. > 16 years old; medically stable.	Patients admitted to a neurological tertiary care teaching hospital ward.	Phase 2: nurses conducted sleep rounds at bedtime (approx. 23:00hr) sleep promoting practices were implemented – lights out, television off, temperature adjusted, final restroom usage. Phase 4: undergraduate students assisted with checklist; offering warm blankets, milk, white noise, lotion, room spritzer. Noise traffic lights placed at nurse stations.	Prospective, observational study: Four phases 1 baseline noise recordings 2 basic intervention 3 washout 4 deluxe intervention	Authors designed a survey to evaluate sleep quality, identify sleep disruptors and assess patient satisfaction. Noise meters were placed in each room. A hospital survey assessed patient experience.	The delivery of an education in-service to the nursing team prior to intervention may have arisen awareness of the importance of sleep & been responsible for the unintended decrease in ward noise levels prior to the intervention phase.	Patient perception of sleep experience improved during the sleep round phases, however no Sig. was found. Noise levels returned to normal levels during the wash out period prior to advanced intervention.	+/-

Table 2: Summary of main characteristics and findings reviewed papers.

	Study	Sample Size	Patient Group	Intervention	Design	Measure	Limitations	Key results	Direction of result
Sensory control	[9] Jones & Dawson (2012) UK	N =100: 50 received standard care (mean age 58; male n= 27).	Convenience sample One large critical care unit. Exclusion: >24 post intravenous; > 24h since general anaesthetic; length of stay >24 h; level; patient lucid and capacious to understand question and provide verbal consent. Exclusion: Insufficient ability to communicate English, eye/ear contra-indications.	Control group received TAU. Intervention group were offered earplugs and eye masks. 50 were given eye masks and earplugs (mean age 56; male n= 30).	Prospective pre/post service evaluation.	Hospital charts and medical notes. 5-point likert scale. 4-item sheet with 1 closed and 3 open-ended questions designed to investigate factors helping/preventing sleep. Qualitative analysis. Content analysis.	Small sample size. Differed in the time of year studied. Autumn-Winter Spring-Summer. Possible investigator variations. Different patient locations. Self-selection. Those who declined the earplugs and eye masks were not included in the study. No measure of who in the intervention group used the earplugs or eye masks. No numerators or transparent statistical analysis.	Graphical (percentage) data showed: Patient's subjectively reported sleeping longer using the eye masks + ear plugs; no evidence that eye masks + ear plugs had enhanced sleep. Noise was identified as a Sig. factor preventing sleep in the pre-intervention & intervention group.	+ -
	[10] Richardson et al., (2007) UK	Convenience sample: Patients self selected into either group N = 64 consented N = 34 intervention N = 28 control	Critical care environment patients. Inclusion: >24h following intravenous and/or anaesthetic; > 24h length of stay; lucid; high dependency level of care' able to apply/remove earplug & eye masks.	Eye masks & ear plugs	Pilot study: 2 group pre post test quasi-experiment.	Sleep assessment tool; comfort rating scale.	Small sample. 1 night. Self selected into treatment/ non-treatment group. Participant numbers prevented valid statistics.	Participant numbers prevented valid statistics. However, participants in the intervention group perceived they slept longer & reported the intervention promoted sleep. Controls reported 'tiredness' promoted sleep. Both groups subjectively reported noise to prevent sleep.	+

Table 2: Summary of main characteristics and findings reviewed papers.

	Study	Sample Size	Patient Group	Intervention	Design	Measure	Limitations	Key results	Direction of result
Sensory Control	[11] Scotto et al., (2009). USA	N =100 recruited. N = 88 completed N = 49 intervention N = 39 control. Mean age 63 56% males; 93% Caucasian.	Adults admitted to one of two critical care units in teaching hospital. Midwestern US. Inclusion: alert, orientated patients who were able to understand the study. Exclusion: diagnosed sleep disorder, hearing loss, sedation or anesthesia in last 12 h, those requiring mechanical ventilation.	Intervention group received instructions on the use of earplugs from the nurse. These were used during regular night-time sleeping hours for one night. Participants were allowed to remove the earplugs briefly (10 minute or less at a time) for communication purposes and then replace them.	Quasi-experimental intervention study with Random assignment of participants. T-tests determined differences between groups.	The VSH Sleep Scale 8 item visual log.	Small sample. Used non-validated Halpern Sleep Scale.	Total sleep satisfaction scored Sig. better for intervention group. Only variable with no significant improvement was Sleep Onset Latency.	+ -
	[12] Williamson (1992). USA	Consecutive sample of n = 60 first time CABG patients systematically assigned to control or experimental group.	Large public hospital with primary, secondary & tertiary care facilities. Excl: documented sleep disorder; repeat surgery; tricyclic anti-depressant within last month; hearing difficulties.	Ocean sounds (white noise) were played for three consecutive nights posttransfer from the ICU. Control group - no control of environment, except for the elimination of white noise.	Pre-post. Intervention trial. Experimental and a control group.	RCSQ provided self-reported sleep scores on six variables.		There were significant differences in sleep depth, awakening, return to sleep, quality of sleep, and total sleep scores; the group receiving ocean sounds reported higher scores, indicating better sleep. There were no difference in sleep onset latency scores.	+ -
Relaxation	[13] Namba et al., (2012) Japan	N = 6 ICU patients. 3 females; 3 males. Mean age 65 years.	Patients admitted to a high care unit or ICU. Exclusion: Head injury/ neurotrauma, burn and comatose patients.	Foot baths. 40 deg.c for 10 min before sleep onset on one of two nights.	Single group cross over design. Randomly assigned order.	Objective sleep measures using PSG for 2 nights.	Sample size	No Sig. difference was found in TST for each sleep stage. Participants who received footbath subjectively reported sleeping better.	- +

Table 2: Summary of main characteristics and findings reviewed papers.

	Study	Sample Size	Patient Group	Intervention	Design	Measure	Limitations	Key results	Direction of result
Relaxation + sensory control	[14] Richards (1998). USA	N = 69 Massage N = 24 Relaxation N = 28 Control N = 17	Convenience sample of older men (55-79 yrs) with cardiovascular illness admitted to hospital critical care unit. Alert and oriented. Able to speak and understand English. Stable blood pressure; absence of life threatening symptoms. Hospitalised for no more than 48 hours before study selection. No prior diagnosis or indication of OSA.	Holistic non-pharmacological techniques. 1) Massage 2) Combined muscle relaxation mental imagery, and music audiotape.	Post test with participants randomly assigned to 6 min. back massage or: a teaching session on relaxation with 7.5 minute relaxation audiotape at bedtime; Or the TAU. Staff we unaware of patients' group assignment.	PSG measured 1 night of sleep for each participant. SE was variable of interest.	Variance in data meant losing participants. A greater sample size would be beneficial.	Descriptive data showed improved sleep quality among the back-massage group. Back rub participants slept more than 1 hour longer than controls, however no significance was found. Variance between groups was significantly different and reanalysis of data with n = 17 in each group showed no significance difference.	+ +/-
Environmental control + Event scheduling + sensory control + pharmacology	[15] Kamdar et al., (2013) USA	Baseline N =122 Intervention =178	All patients spending ≥1 full night in the MICU were eligible. Excl. ≥ 1 night in another ICU during hospitalization. Pre-existing cognitive impairment (dementia/stroke/ brain injury/drug abuse). Visual/hearing impairment, cardiac arrest during admission.	Quality Improvement Intervention. Implemented in 3 additive stages. 1) night-time and daytime environmental interventions –lighting, noise, care activities. 2) In addition earplugs, eye mask and soothing music offered. 3) A Pharmacological guide was implemented to those unable to sleep despite stages 1+2.	Observational Pre-post design Baseline Stage 1 Stage 2 Stage 3 Post ICU Home sleep quality	Subjective: RCSQ Patient cognition Noise Delirium/coma free days (Confusion Assessment Method-ICU). Hospital length of stay and mortality. PSQI.	Pre-post design introduces possible confounds e.g. seasonal, temporal differences. Subjective measures of sleep and noise.	No Sig change in sleep quality ratings. No Sig reduction in ICU/hospital stay/mortality. Sig. improvements in daily noise rating, incidence of delirium/coma and daily delirium/common free status.	- - +

Quality Review

The methodological quality of the studies was systematically assessed using a checklist based on Downs and Black (1998). This quality framework was chosen as it can assess the quality of both RCT and non-randomised studies.

Down and Black's (1998) checklist consists of 26 items distributed between five subscales (Appendix 1):

- 1) Reporting: 9-items assessed whether the information provided in the paper was sufficient to allow a reader to make an unbiased assessment of the findings of the study.
- 2) External validity: 3-items addressed the extent to which the findings from the study could be generalised to the population from which the study subjects were derived.
- 3) Bias: 7-items addressed biases in the measurement of the intervention and the outcome.
- 4) Confounding: 6-items addressed bias in the selection of study subjects.
- 5) Power: 1-item which attempted to assess whether the negative finding from a study could be due to chance. For the purpose of this review, sample size was used to determine the power of results.

The framework items were considered for each article and coded as green (yes), orange (unable to determine) or red (no). The matrix aimed to provide a simple visual aid summarising the quality within and between the reviewed literature (Table 3).

Table 3: Quality review matrix

		Environmental control of stimuli + scheduled procedures							Sensory control				Relaxation		+ + +	
Quality Criteria Downs & Black (1998)		[1] Bartick 2010	[2] Chong et al 2013	[3] Dennis et al	[4] Faraklas et al 2013	[5] LaReau et al 2008	[6] Olson 2001	[7] Li 2011	[8] Thomas et al 2012	[9] Jones & Dawson 2012	[10] Richards et al 1998	[11] Scotto et al 2009	[12] Williamson 1992	[13] Namba et al 2012	[14] Richardson 2007	[15] Kamdar 2013
Reporting	Is the hypothesis/aim/objective of the study clearly described?	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Are the main outcomes to be measured clearly described in the introduction or methods section?	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Are the characteristics of the patients included in the study clearly described?	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Are the interventions of interest clearly described?	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Are the distributions of principal confounders in each group of subjects to be compared clearly described?	Green	Green	Red	Green	Orange	Orange	Green	Red	Orange	Green	Orange	Green	Green	Orange	Green
	Are the main findings of the study clearly described?	Green	Green	Green	Green	Green	Orange	Green	Green	Red	Green	Green	Green	Green	Green	Green
	Does the study provide estimates of the random variability in the data for the main outcomes?	Green	Green	Green	Green	Green	Red	Green	Red	Red	Green	Green	Red	Green	Green	Green
	Have all important adverse events that may be a consequence of the intervention been reported?	Red	Red	Red	Orange	Red	Red	Red	Orange	Red	Red	Red	Red	Red	Orange	Red
	Have the characteristics of patients lost to follow up been described?	Red	Red	Red	Red	Red	Red	Red	Red	Orange	Red	Orange	Orange	Red	Orange	Red
	Have actual probability values been reported for the main outcomes except?	Green	Green	Green	Green	Green	Green	Green	Red	Red	Green	Green	Green	Green	Green	Green
External Validity - generalisation	Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Green	Orange	Orange	Orange
	Were the subjects who were prepared to participate representative of the entire population from which they were recruited?	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Orange	Orange
	Were the staff, places and facilities where the patients were treated, representative of the treatment the majority of patients receive?	Green	Green	Green	Green	Green	Green	Green	Green	Orange	Orange	Green	Green	Green	Red	Orange

Table 3: Quality review matrix

Quality Criteria Downs & Black (1998)	Environmental control of stimuli + scheduled procedures								Sensory control				Relaxation		+++
	[1] Bartick 2010	[2] Chong et al 2013	[3] Dennis et al	[4] Faraklas et al 2013	[5] LaReau et al 2008	[6] Olson 2001	[7] Li 2011	[8] Thomas et al 2012	[9] Jones & Dawson 2012	[10] Richards et al 1998	[11] Scotto et al 2009	[12] Williamson 1992	[13] Namba et al 2012	[14] Richardson 2007	[15] Kamdar 2013
Internal validity - bias															
Was an attempt made to blind those measuring the main outcomes of the intervention?															
If any of the results of the study were based on "data dredging", was that made clear?															
In trials and cohort studies, do the analyses adjust for different lengths of follow up of patients, or in case-control studies, is the time period between the intervention + outcome the same for cases?															
Were the statistical tests used to assess the main outcomes appropriate?															
Was compliance with the intervention/s reliable?															
Were the main outcome measures used accurate (valid and reliable)?															
Internal validity - Confounding															
Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?															
Were study subjects in different intervention groups (trials and cohort studies) or were the cases + controls (case-control studies) recruited over the same period of time?															
Were study subjects randomised to intervention groups?															
Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?															
Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?															
Were losses of patients to follow up taken into account?															
Sample Size															

Reporting

All papers clearly informed the reader of their hypotheses, aims and objectives. Main outcomes of interest were clearly described in the introduction or methods section before addressing these within results. Characteristics of the patients included in the study were provided, including inclusion and/or exclusion criteria. Interventions were described, however papers varied in thoroughness, and this seemed related to the level of patient involvement and autonomy in the intervention. Richardson et al., (2007) for example, provided the intervention group with earplugs and eye masks and details of the intervention included only this (Richardson et al., 2007).

Few of the studies showed evidence of equal distribution of confounding variables. The majority reported demographic data within groups, however factors such as health status, medication and pain level differed markedly between the studies. Olson et al., (2001) for example, used a combined population of neurosurgical and neurological patients, but provided no details of within group distribution and reported only on patient Glasgow Comma Score (GCS). Dennis et al., (1998) reported only gender, age and GCS for the participant groups, with Thomas (2012) similarly providing only percentages for 'female', 'age', 'neurology' and 'white' participants involved in the study. A more thorough description included expanded details of admission, such as diagnosis, burn injury, previous sleep problems, medication, mechanical ventilation, history of psychological issues, pain, anxiolytic or antipsychotic medications (Faraklas et al., 2013; Kamdar et al., 2013, Li et al, 2011, Richards et al, 1998, Chong et al., 2013). Li et al., (2011) acknowledged, however that even when between-group confounds appear equally distributed in terms of demographics, disease severity, types of surgery, pain, use of medicine and perceived sleep quality at home, only randomised assignment can ensure groups are truly equivalent and that observed differences in sleep quality are not pre-existing differences or the consequence of extraneous causes.

Study outcomes should be presented in a way amenable to third party scrutiny and re-analysis. While the majority did provide these data, Jones & Dawson (2012) presented findings using only bar charts and percentages and provided no numerators or actual probability values; Olson et al., (2001) similarly presented only percentages.

Both papers also failed to provide estimates of the variability in the main outcome data, weakening the utility of results and reducing the relevance of these papers for meta-analysis (Faraklas et al., 2013; Kamdar et al., 2013; Li et al., 2011; Bartick, 2010, Dennis et al, 2010; Richards 1998; Scotto et al., 2008; Richardson et al., 2007; Chong et al., 2013).

Adverse effects of the intervention

Richardson et al., (2007) addressed possible adverse effects relating to the implemented intervention when a majority of twenty-eight from an initial thirty-four consenting participants reported not using the eye masks and earplugs provided. Issues for each were identified. Eye mask issues included participants reporting them to be hot and sweaty, too tight, or claustrophobic. For earplugs, patients reported that they could still hear, found it difficult keeping them in place or developed sore ears when using them. Scotto et al., (2009) reported similar difficulties, attributing several participant losses to earplug discomfort or difficulty keeping them in place. Jones and Dawson (2012) also reported limits in their data due to a high number of participants declining to use eye masks (18%) or ear plugs (22%), however with no explanation or sub group analysis reported, the attribution of adverse outcomes here must remain speculative. Williamson (1992) reported four patients withdrew from the study after refusing to continue listening to ocean sounds after the first night. All four patients reported to have been in pain and three were nauseated and were reported to have indicated that sound, or stimulation of any sort was annoying and increased their discomfort.

Other papers, while not explicitly reporting adverse effects of interventions, acknowledged some unplanned consequences. For example, 'by improving the environmental factors influencing sleep, individual patient factors that are less easily modified – such as pain – became the focus of patient concern' (Faraklas et al., 2013 p. 253). Similarly, Thomas et al., (2012) discussed the possibility that an increased awareness of noise created by virtue of informing and recruiting patients, and placing noise meters in their rooms, may have influenced their perception and appraisal of the level of noise disruption.

Losses to follow up

It was difficult to establish whether the studies provided sufficient detail of participant attrition, as the majority did not report these data. LaReau et al., (2008) paper however afforded greater transparency by reporting on declining and withdrawing patients after enrolment. Reasons for patient attrition included change in medical condition/status, nursing interruptions within the intervention period (Scotto et al., 2009), discharge before surveys were complete, unreported sleep disorders and as previously noted, adverse effects of the intervention. Unfortunately sub group analysis was not reported to substantiate any significant differences among these groups.

External Validity

Downs and Black (1997) suggest participants are representative if they are randomly sampled from the entire source population or are an unselected sample of consecutive patients. Additionally the staff, places, and facilities where patients are treated should be representative of the treatment that the majority of patients receive.

A commonly imposed eligibility criteria excluded patients whose illness was deemed too severe, had received anaesthetic within the last 24 hours (Faraklas et al., 2013), had a previous diagnosis of a sleep complaint (Bartick et al., 2010; Li et al., 2011; Williamson 1992) and varying degrees of delirium. Li et al., (2011) acknowledged that such criteria can impose limitations in the generalisability of these studies. In particular, selection criteria that recruited only patients who stayed in the ICU for more than two nights and who were not under sedation (e.g., Li et al., 2011), using narcotics or had sleeping problems, make it difficult to ensure data represent those non-eligible and possibly more typical patients on the ward.

Indeed, the exclusion of patients with an existing diagnosis of a sleep complaint is questionable, given research has shown people with insomnia have more than twice as many doctor visits (12.9 v's 5.2) and almost double the hospitalisation rates (21.9% v'x 12.2%) over a 1-year period than good sleepers (Weyerer and Dilling, 1991; Chilcott and Shapiro, 1996). Kamdar et al., (2013) addition of a sleep quality survey was an exception. The survey enquired about the presence of pre-existing sleep problems, home sleep quality and frequency of sleep medication use, and while data showed no significant group differences in sleep quality, the inclusion of participants with and without sleep difficulties strengthened external validity.

The diversity of patients admitted to hospital can be challenging when ensuring fair distribution of principal confounders are representative of the source population in all experimental groups. Only three studies resolved this by allocating participants randomly (LaReau et al., 2008; Scotto et al., 2009; Williamson 1992), however even with RCT's inherent advantages in terms of internal validity, strict participant eligibility criteria often result in a non-representative sample. These strict selection criteria are often intended to maximize treatment efficacy and homogeneity of patient groups, but can impair external validity by making the sample unrepresentative of the clinical population.

With regards to the representativeness of the clinical setting and treatment, all of the literature reviewed was carried out in working hospitals and appeared representative of the environment and standard of care typical in such a setting.

Internal validity - bias

Due to the nature of the research setting, population and intervention protocol, blinding participants and nursing staff to the intervention or protocol phase could be challenging, if not impossible. Environmental interventions, such as manipulating light wave length (Chong et al., 2013) or noise levels could be more easily concealed from participants, especially compared to those interventions involving the introduction of eye masks, earplugs (Richardson et al., 2007) massage, relaxation scripts (Richards et al., 1998) or foot baths (Namba et al., 2012). Williamson (1992) sought to minimise possible participant reporting bias by informing them only that the study was looking at sleep patterns after surgery, and did not elaborate further. To control for the Hawthorne effect, Williamson (1992) also included the same number of research visits to the control participant's room, however discussion suggest the placement of the white noise machine in experimental patient's rooms may have confounded this.

Difficulties of allocation concealment occur when implementing changes in scheduled medical checks, quiet times, and available treatment or aids, involves the nursing team altering, augmenting and implementing different 'than usual' practices. Nursing staff may inadvertently become more cautious about their behaviour knowing that patients are being studied, which could falsely augment the intervention effect.

The more obvious disadvantage to internal validity was noted when the same nurses were also collecting pre and post data from participating patients. Indeed, Jones and Dawson (2012) discussed this limitation by reflecting on the possibility that data may have been biased if patients felt unable to evaluate accurately for 'fear of compromising their care' (Jones and Dawson, 2012, p. 252). This implies the presence of possible patient self-report inaccuracies, as well as research/rater biases where ward nurses were enlisted to collect outcome data having also provided the intervention (Dennis et al., 2010 and Olson et al., 2001).

Notably, Barlick et al., (2010) study was strengthened by concealing nurses, physicians and patients to the measurement of as-needed sedatives, as was Richardson et al., (1998) who masked all information regarding the identity of group allocation of participants prior to polysomnography analysis.

Concealing the identity of participating patients and protocol phase to staff/researchers who are in contact with them can also influence the fidelity of the intervention design. Indeed, Thomas et al., (2012), unexpectedly found participant's evaluation of noise levels significantly improved prior to the implementation of the intervention. The authors suggest this could have been due to the educational sessions delivered to the nursing team regarding the purpose and overall aims of the project. This raised awareness of sleep and its importance to patients may have had the unintended effect of an increased focus on sleep prior to commencing the intervention phase. Interestingly, Thomas et al., (2012) went on to observe a return to baseline of noise levels during the wash out period following the basic 'sleep round' intervention and prior to the 'deluxe sleep round'. These data highlight the challenges involved in pragmatic trials showing that even during an experimental trial period, with raised awareness of the importance of sleep, 'treatment as usual' practices can resume very quickly.

Intervention fidelity can also be compromised by compliance to the specifics of its design and delivery. Bartick et al., (2010) adherence measure showed complete adherence with the new vital signs schedule and avoidance of routine evening diuretics, however closing of patients' doors did not change. Similarly Olson et al., (2001) reported variance in compliance with their quiet time policy intervention.

They reported the quiet time to be the most challenging element of the intervention, stating that while there was a general consensus from nursing staff that sleep was an important issue, many found the logistics of organising their tasks and assessments to accommodate the 2-hour quiet time impracticable and difficult. Nurses expressed a reluctance to request consulting physicians change their times to accommodate the quiet hours and described the shutting down of the neurocritical care unit as impossible and impractical. The introduction of any deviations to an intervention protocol can threaten the internal validity of the study.

Internal validity - confounding

The quality review matrix indicated an overall weakness in internal validity for the reviewed papers. While participants were recruited from the same population, limiting external confounds appeared challenging, with the majority of papers imposing a cross sectional pre-post design. Most authors acknowledged the weakness this design imposed and recognised that non-equivalent pre-post test (quasi-experimental) design cannot rule out initial differences between groups (Li et al., 2011) or possible confounds such as seasonal or temporal differences (Kamdar et al., 2013). That said, while concurrent cross sectional data collection could eliminate some of these confounding variables this design also has limitations. No papers included a prospective evaluation of patient sleep prior to or during an intervention during the entire duration of their hospital stay. This snap shot of patients' sleep could weaken the representativeness of sleep quality data across days spent in hospital. It is well evidenced that there is sleep quality variability both in good and poor sleepers when measured at home (Valleries et al., 2005; Perlis et al., 2014) but this variability, which was predicted by both the Spielman model (sleep extension (Spielman et al., 1987) and the Two Process model (curtailed time awake (Borbely, 1982), has not been explored in the papers reviewed.

Power

Half of the papers reviewed made reference to the lack of statistical power available during analysis and attributed this to small/moderate sample sizes (Bartlick et al., 2010; Dennis et al., 2010; LaReau et al., 2008; Scotto et al., 2009; Jones and Dawson et 2012; Richardson et al., 2007; Richards et al., 1998). The number of participants prevented two papers from presenting any valid statistical analysis (Dennis et al., 2010; Richardson et al., 2007).

Richards et al., (1998) suggested that the failure to show significance in the observed improvement of descriptive data was due to the significant difference in variance between groups. In an attempt to control this Richards et al., (1998) reanalysed the data on equal groups, however data remained non significant

Summary conclusions regarding evidential quality

The majority of papers provided sufficient detail of the intervention and protocol, hypotheses being tested and main outcomes being measured. Characteristics of patients were described, however data on distribution of principle confounders between groups varied in thoroughness. The majority of authors omitted data on patients lost to follow up and few detailed any possible adverse events related to the interventions.

External validity was weakened by the strict eligibility criterion imposed when selecting participants. The majority of discussions therefore inherited a common note of caution when interpreting data. The clinical staff, setting and facilities appeared representative of that typical in such a setting.

The main bias in the measurement of the intervention and outcome came from the lack of group allocation concealment and compliance with the intervention protocols. Research protocols relying on observers rating sleep quality imposed further limitations with regards to the reliability of outcome data.

Sampling was considered compromised due to the majority of protocols imposing a non-randomised, non-equivalent pre-post design. In addition, at least half of the reviewed papers reported a lack of statistical power, which undermines the veracity of negative results.

Main findings

Main outcome measures for the studies reviewed were predominately based on patient self-report. Measures of sleep quality and quantity included self-report, observer report (Chong et al., 2013), self report of daytime sleepiness (Li et al., 2011) and polysomnography (Namba et al., 2013 Richards et al., 1998). Other outcome measures included comfort rating scales (Richardson et al., 2007, Dennis et al., 2010), a pain scale (Faraklas et al., 2013), satisfaction surveys, measures of delirium, medication or sedative use (LaReau et al., 2008; Bartick et al., 2010; Olson et al., 2001) and length of hospital stay data (Kamdar et al., 2013). A measure of adherence to intervention were also included (Bartick et al., 2010; LaReau et al., (2008). Four papers also included an objective measure of noise and light (Dennis et al., 2010; Li et al., 2011; Thomas et al., 2012; Olson et al., 2001).

Interventions included in the reviewed literature fell under the subheading clusters outlined in the introduction. Main findings will be presented under these.

Environmental control of stimuli and procedure

Eight studies amalgamated elements of both environmental control of stimuli and control of procedures (Bartick, 2010; Chong et al., 2013; Dennis et al., 2010; Faraklas et al., 2013; LaReau et al., 2008; Olson et al., 2001; Li et al., 2011 and Thomas et al., 2012). All incorporated an element of light and noise control, with several also clustering or scheduling nursing activities to minimise multiple medical checks and/or machine alert disruptions (Bartick, 2010; Faraklas et al., 2013; LaReau et al., 2008; Li et al., 2011 and Thomas et al., 2012). Faraklas et al., (2013) and Thomas et al., (2012) adjusted room temperature, and Chong et al., (2013) installed bright lights.

Sleep outcome measures for these papers were subjective. The majority were completed by the patients, however three were completed by nurse observers (Chong et al., 2013, Dennis et al., 2010, and Olson et al., 2001). The Richards-Cambell Sleep Questionnaire was used in three papers (Faraklas et al., 2013; LaReau et al., 2008 and Li et al., 2011) with the remaining authors drawing on the Verran Snyder Halpern sleep scale (Bartick et al., 2010) and a survey designed to evaluate sleep quality (Thomas et al., 2012).

Four of these papers also included an objective measure of noise and light (Dennis et al., 2010; Olson et al., 2001; Li et al., 2011 and Thomas et al., 2012) and for the majority significant improvements were observed during the intervention phase. The exception was reported by Dennis et al., (2010) who found that while noise and light levels were significantly lower during their day shift quiet period (2-4pm), no such change was observed during their night shift quiet period (2-4am).

Results for the majority of environmental control of stimuli and control of procedures showed improvement in patients' perception of sleep quality. Dennis et al., (2010) and Olson et al., (2001) both reported a significant increase in observed sleep during the daytime quiet period, however Dennis et al., (2010) reported these differences were lost during the night time period. This is likely due to the failure in significantly lowering noise volume during this time. It is worth mentioning again here that both papers relied on nurses observing sleep-wake status. Interestingly, Bartick et al., (2010) longer 8-hour quiet period between 10pm and 6am resulted in no subjective change in sleep quality measured by the Verran Snyder-Halpern sleep scale (VSH) despite the significant decrease in conversation volume, but did show a significant reduction in 'as needed night-time sedatives'.

Clustering and timetabling activities aimed to decrease multiple disturbances and minimise audible monitors, significantly improved elements of sleep quality. Li et al., (2011) reported significant improvements in sleep efficiency and decreased daytime sleepiness, while Faraklas et al., (2013) noted significant improvement in sleep onset latency as well a significant decrease in pain levels for the intervention group. Both also reported an improvement in patients' perception of clinician interruptions.

Interventions implementing a 'bedtime round' involving a schedule where lights were turned off or dimmed, televisions were turned off or down and room temperatures were adjusted, also improved patient perception of their sleep experience (Thomas et al., 2012) and decreased sleep medication (LaReau et al., 2008).

The introduction of bright lights daily from 6am-10pm showed positive results for patients with varied levels of delirium (Chong et al., 2013), however following post hoc statistics only the duration of first sleep bout for the hypoactive delirium subset remained significantly improved.

In summary, the main findings for environmental control of stimuli and procedures showed elements of improvement in patients' sleep quality, while other variables were reported unchanged within the same data. For example Bartick et al., (2010) reported significant reduction in 'as needed sedatives' but showed no improvement in any subjective measure of the Verran Snyder-Halpern (VSH). Objective data of environmental control, such as noise, light or closing doors, showed similar mixed results within and between papers. As was noted in the quality review two of these papers relied upon nurses reporting sleep status, which may have introduced bias. Sample sizes weakened the power in three of these papers, and was thought to contribute to the lack of significance or statistical analysis.

Sensory control: using earplugs or eye masks; audiotapes, white noise.

Four studies were grouped into sensory control interventions (Jones and Dawson 2012; Richardson et al., 2007; Scotto et al., 2009 and Williamson 1992). Richardson et al., (2007) and Jones and Dawson et al., (2012) provided patients with eye masks and earplugs, while Scotto et al., (2009) provided only earplugs. Descriptive data from these sensory control interventions indicate an improvement in sleep quality variables, however these varied between and within papers and small sample sizes prevented statistical analysis for Jones and Dawson (2012) and Richardson et al., (2007). In addition, and as noted in the quality review, both articles were also found to have compromised external validity with the inclusion of self-selected participating patients and the impact of observed adverse effects from the intervention on completion.

Williamson's (1992) intervention provided patients with three consecutive nights of ocean sounds and reported similar significant improvements in sleep quality and efficiency but not sleep onset latency, seen also in Scotto et al., (2009) study. Together these data suggest that while the efficacy of sensory intervention is variable, patients perceive improved sleep quality. Authors highlighted the minimum cost involved in providing patients with the option of using eye masks or earplugs and suggest that this is a small price to pay to improve the experience of sleep among patients admitted to a hospital ward.

Relaxation – massage, footbaths, mental imagery.

Three studies included a relaxation intervention element (Namba et al., 2012; Richards et al., 1998; LaReau et al. 2008). Patients who received a footbath prior to settling down to sleep subjectively reported sleeping better compared to a control group, however no significant difference was found in total sleep time (Namba et al., 2012). Richards et al., (1998) explored sleep changes following either a massage or a combined muscle relaxation mental imagery and music audiotape, and compared this to a control group. Descriptive data showed improved sleep quality among the back massage group, however these differences failed to reach significance.

Kamdar et al., (2013) quality improvement intervention presented an amalgamation of environmental and procedural control, sensory and relaxation elements, as well as a pharmacological component. No significant changes in sleep quality or duration of hospital stay was observed, however significant improvement in daily incidence of delirium was reported.

Summary of main findings

Main outcome data for the reviewed non-pharmacological sleep hygiene interventions to improve the sleep of hospitalised patients, show elements of improvement in patients' sleep quality, as well as other related measures such as pain, delirium and 'as needed sedative' medication. Improvements were statistically reported in thirteen of the fifteen papers reviewed, with the three remaining reporting descriptive improvements in patients' perception of sleep, but lacking a significant statistical finding.

Objective measures of manipulation in the environment or schedules imposed by the interventions, also showed positive change, however these data varied within and between papers in the degree of modification. Indeed within the same paper data could show improvements in one aspect of the intervention protocol and no change in another (Bartick et al., 2010).

Discussion

The causes of sleep disruptions are multifactorial and complicated by the physiological, psychological, environmental factors and individual differences of patients. The aim of this review was to systematically present and synthesise the characteristics and findings of research implementing non-pharmacological sleep hygiene interventions within a hospital setting. Downs and Black's (1998) quality checklist was used to assess the methodological quality and the main components of each paper were collated. Together this structured a consideration of the overall quality and findings from the papers reviewed.

Main outcome data from the reviewed non-pharmacological sleep hygiene interventions, showed improvement in patients' sleep quality, however compromised internal validity and moderate sample sizes weakened the reliability of these data. Identified intervention infidelities included rigidity of timetables and priorities of the hospital ward.

Review limitations

Downs and Black's (1998) quality checklist assesses the methodological quality both of randomised and non-randomised studies of health care interventions, however this tool may be more suitable for explanatory rather than pragmatic research, which may require different criteria or altered weighting of factors related to quality.

Indeed the quality criteria highlighted weaknesses in the internal validity of the majority of the reviewed papers. The dominance of pre and post, unequivocal, non-randomised design meant authors could not control for intrinsic or extrinsic group differences. However, measuring the efficacy of an intervention under ideal or selected conditions can create an artificial environment or population, and augment the validity and reliability of the data retrieved. Notably research involving simulated ICU noise within sleep laboratories were excluded from the literature search with an aim to assimilate the more pragmatic research evidence for sleep hygiene interventions in hospital wards. Perhaps then the weaknesses in internal validity provide insight into the actual validity of an intervention.

Weaknesses in external validity were related to the strict participant eligibility criteria imposed by the majority of papers. Indeed, patient selection for a pragmatic study should reflect routine practice and all patients who might receive the intervention should be studied. Selection criteria should be broad, with exclusions limited to patient groups for whom either the intervention or control are contraindicated. These data will show whether the intervention works for patients in general.

Limitations in reporting included the lack of data provided on participant attrition and only one study included intention-to-treat analysis. Future research should include data analysis on the initial treatment assignment to minimise misleading artefacts that can arise in intervention research such as non-random attrition of participants from the study.

According to the quality framework, the lack of concealment of group allocation for the majority of the reviewed studies was considered a bias risk. Indeed research guidelines recommend measurement of outcomes should, if possible be performed by someone who is blind to group allocations. However, blinding of patients and carers may be inappropriate for a pragmatic trial. While it is true that patients may derive benefit from mechanisms other than the direct effect of the treatment, a pragmatic study should be concerned with whether patients derive benefit, not how or why.

Convergence with other systematic reviews

Tamrat et al., (2014) reported thirteen interventions studies (including relaxation techniques, interventions to improve sleep hygiene or reduce sleep interruptions improved, and daytime bright light exposure) and concluded that there was insufficient to low strength of evidence that any non-pharmacologic intervention improved sleep quality or quantity of general inpatients. Tamrat et al., (2014) recommended that future research studies use appropriate randomisation, allocation concealment, and objective measures of sleep quality and quantity. Studies should blind those assessing outcomes and report participant attrition. These conclusions are consistent with that of the current review.

Currently in press Hoey et al., (2014) examined the literature on sleep measurement to identify subjective sleep assessment tools that may be suitable for routine use with hospitalised patients. Three subjective sleep measurement scales were reviewed: the Richards-Campbell Sleep Questionnaire; the St Mary's Hospital Sleep Questionnaire; and the Verran Snyder-Halpern Sleep Scale. The authors concluded that the Richards-Campbell Sleep Questionnaire held greatest potential due to its ease of use. However having not yet been validated for use with general hospital inpatients, further research in this area was recommended.

These recent publications illustrate the current relevance of this literature to an agenda of improving the sleep of patients admitted to hospital.

Conclusion

Sleep is a fundamental component of health and recovery and this literature review has shown that improving sleep hygiene in hospital environments can improve sleep quality for patients. However pragmatic intention-to-treat research, recruiting large sample sizes with appropriate randomisation and allocation concealment during analysis is needed. Subjective sleep measures and relevant measurements consistent with the requirement of a pragmatic trial, such as 'as needed' sedatives or pain should be included, and cost utility of sleep hygiene practices in routine hospital care should inform a fully costed service delivery model.

This literature review presents protocols that are worthy of further exploration within the context of minimising disruption to patients' sleep during their admission to a hospital ward. Educating health providers and commissioners about the importance of sleep would provide the necessary foundations to develop a more sleep conducive infrastructure. This review showed that ward staff education alone resulted in a positive change in the level of noise on the ward, illustrating the importance of informed practises. From here, research should involve ward staff and expert patients, to develop clear inpatient sleep protocols aimed at minimising patient sleep disruption without compromising patient care.

Decreasing ward noise should also be a priority. The World Health Organization (WHO) guidelines state that on hospital wards, noise levels should not exceed 30 dB L_{Eq} (day and night) and that peak noise levels at night should not exceed 40 dB. Interventions to reduce noise to these recommended levels should be designed and executed with standardised sleep measures used to monitor any changes in subjective sleep quality.

Circadian rhythms and homeostatic sleep drive are important regulators of sleep. Future research looking at how daytime bright light therapy may improve patients' sleep should therefore be added to the agenda. While the research reviewed here incorporated lowering ward lights during scheduled 'quiet time,' bright light therapy has been shown to influence circadian rhythms (Czeisler et al., 1981). A better understanding of the role bright light therapy may play within a hospital environment, would further our understanding of possibilities to design more sleep conducive hospital wards.

Hospitals should be a place of treatment and recovery, and sleep disturbance should no longer be one of the most stressful components of the hospital care experience, or indeed a precipitating risk factor for chronic insomnia.

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EMPIRICAL PAPER

Do people with insomnia show deficits in
inhibition and in set switching cognitive tasks?

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Abstract

Context: The aim of this research was to identify whether the underlying cognitive mechanisms suggested to contribute to the maintenance of depression are present in a community sample of people who report insomnia.

Design: In a cross section study, rumination, inhibition and set switching cognitive processes were compared in a community sample of 79 participants aged 18-59 years. The Insomnia Severity Index (ISI) was used to identify subjective 'good' and 'poor sleepers'. Using Morin et al., (2011) recommendations, a cutoff score of 10 was used to differentiate between this community sample of good (n = 43) and poor (n = 36) sleepers.

Measures: Assessments included: the ISI; Pittsburgh Sleep Quality Index; Epworth Sleepiness Scale; The Ruminative Response Styles questionnaire; Pre Sleep Arousal Scale; Spielberger's State/Trait Anxiety Inventory and the Beck Depression Inventory. The task-switching paradigm described by Mayr and Keele (2000), was used to design a computer-based program to obtain an index of *set shifting* and an index of *inhibition* of previously relevant information.

Main findings: Between group comparisons were made using a one-way ANOVA. Data replicated previous findings showing people with poor sleep differ significantly in their psychological makeup compared to good sleepers. Data show a distinct psychological profile that has been found in previous research when comparing a community sample of people with and without poor sleep.

Data indicate a ruminative profile is also present in people reporting poor sleep. However no differences in cognitive performance regarding inhibition or set switching was found between good and poor sleepers, or high and low ruminators. Sleep moderators showed high inter correlation with each other as well as the Rumination Scale, however no correlation between set switching and rumination was found.

Future research could utilise Joorman's (2010) model to inform an additional element of CBT-I for people with insomnia.

Key words: Insomnia; ISI; rumination; cognitive performance.

Introduction

Sleep problems are the most frequently reported psychological symptom in Britain, with 24% of men and 34% of women reporting problems getting to sleep or staying asleep in the past month (Singleton et al., 2003). Insomnia is a prevalent disorder, with between 4% and 22% of people reporting chronic insomnia (Ancoli-Israel and Roth, 1999; Ohayon, 2002; Roth et al., 2011). Commonly reported consequences of insomnia include complaints of impaired concentration and memory, elevated risk of accidents, more frequent use of medical services and augmented work absenteeism (Ohayon et al., 1997; Roth and Ancoli-Israel, 1999).

With an emphasis on the need to reduce hypnotic drug prescribing, and provide effective non-pharmacological approaches to sleep management (DoH, 2001; Morin, et al., 2005; NICE, 2004;), understanding better the mechanisms involved in the development and maintenance of insomnia will help inform treatment. This research aims to explore the role of cognitive control of working memory in the aetiology of insomnia. Specifically, this research will assess the role of two potential mechanisms by which information processing is controlled in working memory. These mechanisms, set switching and inhibition, are hypothesised to work together to control the contents of working memory. Set switching refers to the ability to redirect attentional focus from one aspect of the information being processed toward a different aspect. Accordingly, set switching involves the *potentiation* of some specific aspect of the information being processed (Mayr and Keele, 2000). In contrast, inhibition refers to the *depotentiation* of those aspects of the information being processed which are not required of the current cognitive set (Mayr and Keele, 2000). It is evident that the processes of switching and inhibition work cooperatively in order to maintain attentional focus. Deficits in switching and inhibition may result in either the inability to redirect attention away from the currently processed theme (i.e., a failure of set switching) or, having successfully switched to another theme, finding oneself returning to ruminate on previous themes (i.e., a failure on inhibition). Anecdotal report of people with sleeping difficulties often includes failures of both switching and inhibition and Jansson-Fröjmark et al., (2012) demonstrated that attention bias in individuals with insomnia is due to an inability to disengage from sleep-related stimuli, rather than increased vigilance towards such stimuli.

The cognitive perspective of insomnia

Behavioural and cognitive approaches have led to significant advances in the understanding and treatment of insomnia (Harvey et al., 2005; Bootzin and Epstein, 2011). Cognitive accounts have suggested hyperarousal (Harvey, 2002) or problems with de-arousal (Espie, 2002) play an important role in acute and chronic forms of insomnia. Inadequate emotional processing during the day, as well as selective attention to sleep related cues is also thought to maintain excessive negatively toned pre-sleep cognitive activity and perpetuate a vicious cycle of cognitive rumination and physiological arousal (Barclay & Ellis 2013; Espie et al., 2006; Harvey, 2002).

Schmidt et al., (2011) suggest dysfunctional forms of cognitive control, such as thought suppression, worry, rumination, and imagery control, are associated with sleep disturbance, as they are with other forms of psychopathology. Research suggests that cognitive processes, such as the phenomena of not being able to shut-off or control thoughts (Lichstein & Rosenthal, 1980) and sleep-related attention bias (Lundh et al., 1997) are an important maintaining factor in insomnia (Espie, 2002; Harvey, 2002; Lundh et al., 1997; Lundh & Broman, 2000). This emphasis upon processes of cognitive control has obvious overlap with the processes of set switching and inhibition and indeed, Jansson-Fröjmark et al., (2012) found individuals with insomnia were not more vigilant than normal sleepers, but instead had greater difficulties in shifting away from insomnia specific stimuli. Carney et al., (2010) notes that repetitive thought and difficulties with disengagement has been identified as a transdiagnostic risk factor for depression, anxiety and poor physical health, and that the effect of rumination within insomnia warrants further discussion.

A Transdiagnostic Model

Historically the dominant schemes driving mental health classification have tended to rely on a 'disorder-focused approach', in which a specific disorder is conceived to have specific pathological processes and specific etiological factors. However, the 'disorder-focused approach' is less well suited to accommodate comorbidity and common etiological or risk factors (Kessler et al., 2005). Indeed, Espie's (2007) review described insomnia as both a disorder in its own right as well as a symptom of other disorders where physiological, cognitive and behavioural elements are involved. As a group, psychiatric disorders represent the most common comorbidities in insomnia. A psychiatric diagnosis is present in 40% of people with insomnia (Ford and Kamerow, 1989). Common psychiatric comorbidities include anxiety and depressive disorders.

A transdiagnostic model offers an understanding of a process, such as cognitive control, that may act as predisposing factors for many varied disorders, including insomnia. Gruber et al., (2008) examined three candidate transdiagnostic processes involved in emotion regulation – rumination, worry and automatic negative thoughts and sought to explore this in euthymic, bipolar, insomnia and control participants. Results indicated rumination and worry, but not negative automatic thoughts, might be common across people with bipolar disorder and insomnia.

Rumination and insomnia

Carney et al., (2010) examined whether people who show extremes of rumination and worry differ on subjective sleep measures. Rumination has been defined as a mode of responding to distress that involves repetitively and passively focussing on symptoms of distress and on the possible causes and consequences of these symptoms (Nolen-Hoeksema et al., 2008). Worry and rumination are generally distinguished on the basis of their temporal orientation: worry refers to distress regarding future events, whereas rumination concerns thoughts of past events and current symptoms (Kaplan et al., 2009). No main effect of worry was found, but rumination and worry were found to be separate constructs, with high and low ruminators differing on several sleep indices, including sleep efficiency, wakefulness after sleep onset and sleep quality. Carney et al., (2010) wrote that rumination has received much less attention than the role of worry within the insomnia literature (Borkovec et al., 1998; Hall et al., 1996; Gross & Borkovec, 1982; Kales et al., 1983) and that this literature has often further clouded functional distinctions by grouping the two processes together, even labelling them “ruminative worry” (Espie & Lindsay, 1987).

There is considerable theoretical and empirical support for the central role of cognitive arousal (intrusive, uncontrollable cognitive activity, negative and worrying thoughts) in insomnia (Borkovec et al., 1981; Coyle & Watts, 1991; Fichten & Libman, 1991; Harvey 2000; Morin, 1993). Cognitive arousal can be a negative, neutral, or even a positive experience (Morin, 1993), however ‘having an overactive mind’ (Wicklow & Espie, 2000) has been a commonly reported reason for preventing sleep onset. Indeed, most people with insomnia complain of being unable to fall asleep because they cannot switch off their ‘racing’ mind (Espie et al., 1989; Geer & Katkin, 1966; Harvey 2002; Broman & Hetta, 1994; Lichstein & Rosenthal, 1980).

Accordingly, the research to date has focused on two elements of the 'overactive mind'; the arousal element and the control element. The element of control will now be considered in more detail.

Cognitive Processing

Joorman (2010) proposes that cognitive inhibition is key in the regulation of emotion and that increased risk of depression is related to deficits in inhibition of negative material. Negative mood activates mood congruent cognition (both cognitive content and processes) in working memory (WM). Impairment of inhibition has been shown to be crucial in differentiating people who recover from negative affect from those who get caught in a vicious cycle of escalating negative thinking and low mood. Negative material is thought to remain for longer in the WM of depressed people, who find it more difficult to repel or reappraise it (Joorman, 2010). Deficits in inhibition may lead to a failure to reappraise low mood congruent material, and consequently increase in mood congruent cognitive content and processes.

Cognitive inhibition is part of the executive control processes that select and update the content of working memory. Working memory (WM) has limited capacity and reflects the focus of attention, acting as a temporary store for active representations that form the content of awareness. Hasher et al., (1999) suggests the efficiency of WM depends on the inhibitory process that limits information entering WM and revises the content of WM by filtering information that is no longer relevant. Those with an inhibitory deficit are more susceptible to thoughts which may disrupt the fluid and rational stream of thought. Such experiences are frequently reported in people with depression (Joorman, 2010).

Cognitive control and insomnia

Joorman (2010) suggests two candidate cognitive processes that may underlie the experience of rumination. Firstly, the cognitive processes which underlie 'set switching' are required to allow the individual to disengage, redirect and re-engage attentional resources from one stimulus stream to another. Secondly, in order to maintain attentional resources on the current stimulus stream the individual is required to 'inhibit' other potentially interfering information, inclusive of previously attended stimulus streams.

The phenomenological experience of deficits in the set-switching would relate to a perceived inability to think of anything other than the ruminative content.

Alternatively, deficits in inhibition would be associated with the experience of the ruminative content frequently returning to consciousness, especially when attentional resources are not being directed toward another source via deliberative cognitive control.

Using this model, psychological interventions should target one or more of the following modalities: □

- Reduce the mood valence and activation of negative cognitions (segment A of the model in Figure 1).
- Remediate the deficits in cognitive inhibition and improve control of working memory (segment B of the model in Figure 1).
- Address the failure of reappraisal and its consequences for the subjective acceptability of the depressiogenic interpretation of ongoing experience (segment C of the model in Figure 1).

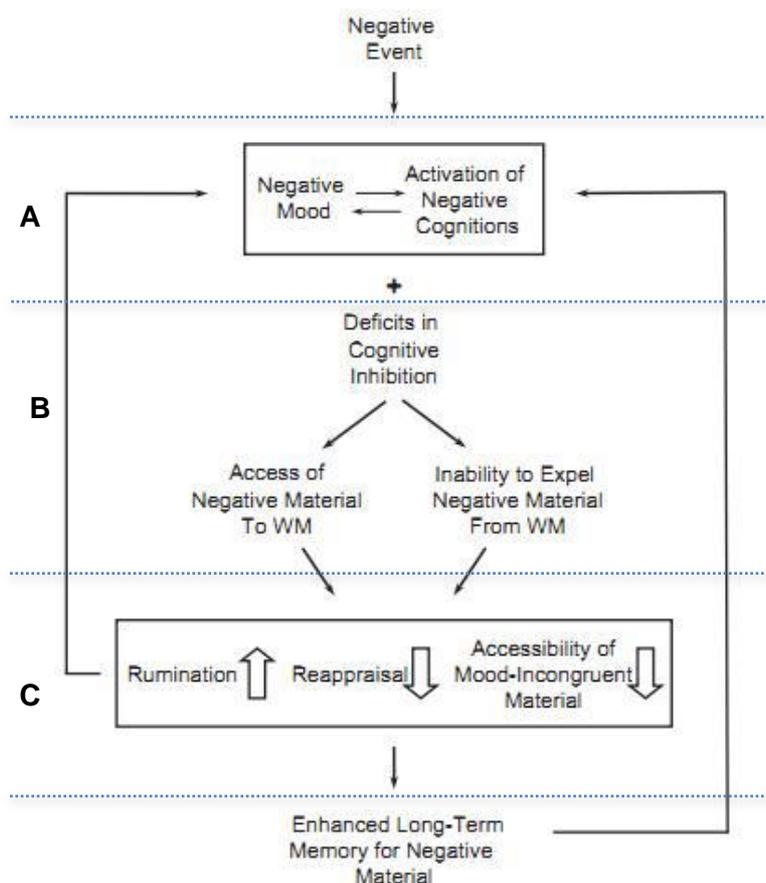


Figure 1: Schematic representation of the Joorman (2010) model linking cognitive inhibition with emotion regulation in depression. Segments A, B and C highlight separate therapeutic objectives of psychological interventions.

Aims

The aim of this research was to identify whether the underlying cognitive mechanisms (Joorman, 2010) suggested to contribute to the maintenance of depression are present in people who report poor sleep. Specifically, it is hypothesised that:

- i) 'Poor sleepers' will show a greater ruminative tendency than 'good sleepers'.
- ii) Differences between 'poor sleepers' and 'good sleepers' in set switching and inhibition will be found.
- iii) Set inhibition will positively correlate with the scores on the Ruminative Response Styles.
- iv) Set switching will positively correlate with the scores on the Ruminative Response Styles.

Full research ethics approval was granted by the University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee (ERN_13-1041). See Appendix 1.

Method

A cross sectional design compared two groups of participants. The Insomnia Severity Index (ISI) was used to identify 'good' and 'poor sleepers'. Using Morin et al., (2011) recommendations, a cutoff score of 10 was used to differentiate between this community sample of good and poor sleepers. Morin et al., (2011) suggested this cutoff to be the best compromise to achieve optimal balance between sensitivity and specificity in a population-based sample.

Participants were recruited via public advertisement and the research participation schemes at the University of Birmingham and Loughborough University.

All participants were fluent in English.

Power

In a similar study of cognitive control of working memory in normal participants (Depue et al., 2006) an effect size of $\eta^2 = 0.12$ was reported. This would suggest a sample size of approximately 30 participants per group would afford a power of greater than 0.8 (mixed between and within subjects ANOVA).

Procedure

All eligible participants were invited to attend a specified thirty-minute testing time slot between 10am and 12pm. Testing was facilitated by the researcher and took place in a well lit, air-conditioned room. Eight pre-programmed computers were evenly spaced around the room. Privacy screens were used to ensure responses could not be observed by anyone other than the person sitting directly at the computer. While much experimental research is conducted in isolation, a group setting was chosen, as this is more consistent with daily requirements to maintain attention in non-sterile environments. Conditions were 1) consistent for all participants 2) ecologically valid, and 3) minimised peripheral distractors.

All participants were encouraged to make themselves comfortable using chair adjustments and by alternating the angle and brightness of the computer screen. Participants were presented with written and verbal instructions (appendix 2) and asked to complete an informed consent form (appendix 3) should they wished to participate. Once ready to begin, all participants completed a standard practice trial immediately prior to starting the true trial. The practice lasted no more than one minute and the full task lasted on average 5 minutes.

The task-switching paradigm described by Mayr and Keele (2000) was used to obtain an index of *set shifting* and an index of *inhibition* of previously relevant information. During testing the computer screen display contained four rectangles arranged with one in each corner (2x2 matrix). These rectangles could vary from each other on one of three dimensions: 1) shape; 2) colour or; 3) orientation. A central cue indicated the dimension participants needed to respond to just prior to the rectangle appearing (Figure 2) and participants were asked to identify the spatial location of the deviant element.

Participants used corresponding compatible keys on a computer keyboard 'Q' (top left) 'A' (bottom left) 'W' (top right) 'S' (bottom right) to respond to the cue. Reaction times (RTs) were used to obtain separate measures of set switching and inhibition. Trials with RT's in excess of 5 seconds were discounted. At the end of the task-switching task the computer screen returned to the front menu which prompted participants to begin the questionnaires. When all components were complete, data were saved using an anonymous ID before participants left.

By way of thanking those who participated, all were invited to a workshop on 'Sleep Management' delivered by the researcher. The three-hour workshop was well attended and received positive feedback.

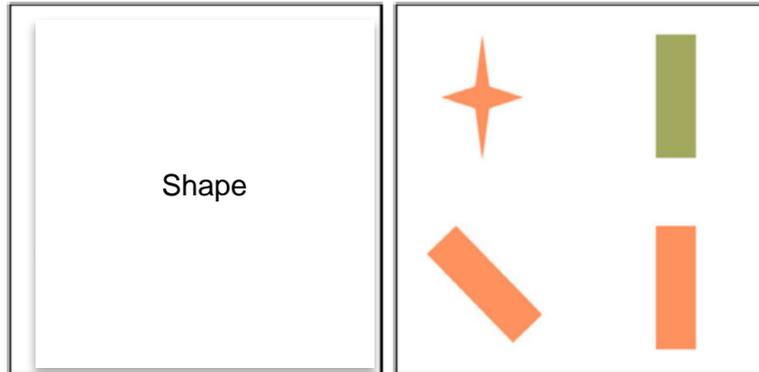


Figure 2 Example screen shot of the cue screen and the subsequent stimuli

Each trial was analysed in terms of the previous three trials. *Inhibitory trials* were those where the cue is different from the cue on the immediately preceding trial (n-1) but the same as the cue two trials back (n-2; e.g. orientation-shape-orientation). *Control trials* are those where the cue is different from the cue on the preceding two trials, which also have different cues from each other (e.g. orientation-size-motion).

Both control and inhibitory trials are preceded by at least two task switches. When switching from one task to another, the first task set is thought to be inhibited to allow faster and smoother transition to the second. If the participant returns to the inhibited task immediately afterwards it takes more time than switching to a less recently abandoned task because of the extra time needed to overcome inhibition of the prior task set's representation (Mayr & Keele, 2000).

The extra time involved in switching back to a recently abandoned task (e.g. orientation at the end of an orientation-size-orientation sequence) relative to that of a less recently abandoned task set (e.g. orientation in a motion-size-orientation sequence) is considered a measure of *set inhibition* not confounded by switching abilities (Mayr, 2002). If participants display set inhibition difficulties they should show faster RT to set inhibition trials (reflecting the lower level of residual n-back inhibition).

Set switching was measured by the additional time it takes to respond to non-inhibitory trials that require the use of a different task set than used in the previous trial (e.g. orientation – motion) as compared with repeat trials, in which the same task set is used (e.g. orientation – orientation). *Set switching* RT is thought to reflect time needed to reconfigure the cognitive processes involved in the representation of the to-be-used task set (Monsell, 2003). If participants display set switching difficulties they should show increased set-switching RT (reflecting the increased difficulty of switching task set).

Table 1: Task types and measures of executive function.

Measure of Executive Function	Calculation and interpretation
Set Inhibition Cost	Inhibitory RT(e.g., A-B-A) – Control RT (e.g., A-B-C) Larger difference = better executive ability
Set Switching Cost	Control RT (e.g., A-B-C) – Repeat RT (e.g., A-A-A) Smaller difference = better executive ability

Questionnaire Measures

1) The Insomnia Severity Index (ISI; Bastien et al., 2001) is a valid and reliable 5-point likert scale (0 = no problem; 4 = v. severe problem) comprising seven items evaluating: 1) sleep latency; 2) sleep maintenance; 3) early awakening problems; 4) satisfaction with current sleep pattern; 5) interference with daily functioning 6); noticeability of impairment attributed to the sleep problem; and 7) level of distress caused by the sleep problem (appendix 4). ISI internal consistency was excellent (Cronbach α of 0.90 and 0.91) for community and clinical samples with and without insomnia. Convergent validity was supported by significant correlations with measures of fatigue, quality of life, anxiety and depression. A cut off score of 10 is optimal (86.1% sensitivity and 87.7% specificity) for detecting insomnia cases in the community sample (Morin et al., 2011), and was used to allocate participants to either a good or poor sleeper group in this research.

2) The eleven-item Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989) assessed sleep quality in relation to a range of subjective estimations. The PSQI generates both a global (total) score and seven component scores (appendix 5). These component scores include 1) sleep quality, 2) sleep latency, 3) the use of medication, 4) daytime dysfunction, 5) sleep duration, 6) sleep efficiency and 7) sleep disturbances. PSQI global scores are in the range 0 – 21 with higher scores indicating an increased dissatisfaction with sleep and a greater severity of sleep disturbance. Scores ≥ 5 on the PSQI represent a clinically significant level of sleep disruption.

3) The Epworth Sleepiness Scale (ESS; Johns, 1991) is an eight item, self-administered questionnaire that is designed to quantify an adult's sleep propensity; measuring daytime sleepiness (appendix 6). Respondents rate the likelihood of dozing, 0 = would never doze through to 3 = high chance of dozing in eight specific situations that are commonly met in daily life e.g. sitting and reading, watching TV, etc.). The ESS score is the sum of the eight item scores and can range from 0-24 (Johns, 1991).

4) The Pre Sleep Arousal Scale (Nicassio et al., 1985) is comprised of sixteen 5-point likert scale assessing the phenomenology of nocturnal awake time, which are rated on a scale ranging from a score of 1 for 'not at all' through to 5 for 'extremely'. Individuals are asked to indicate the degree to which they experience listed feelings during the pre-sleep period, e.g. can't shut off thoughts (appendix 7).

Two scores are derived; *Somatic Scale* (a tight tense feeling in muscles), and *Cognitive Scale* (thoughts running through one's head). Higher scores indicate greater arousal. The PSAS total score is the sum of the sixteen scores with a range of 16-80. Somatic and cognitive subscales have a range of 8–40.

5) The Ruminative Response Styles questionnaire (RRS; Nolen-Hoeksema and Morrow, 1991) is a twenty-two item, 4-point likert scale with anchors of 1 = never to 4 = always (appendix 8). The self-report questionnaire assesses how frequently participants ruminate on their feelings of sadness or depression. The RRS has good internal consistency (Cronbach α 0.82), moderate to high test-retest reliability over one year ($r = 0.47$, $p < 0.001$). Treynor et al., (2003) report the RRS is comprised of three subscales; reflection, brooding and depression-related. 'Reflection' questions are related with problem-solving and coping, in contrast with 'brooding' questions that focus around self criticism and the 'depression' related questions that describe general symptoms of depression.

6) The Spielberger State/Trait Anxiety Inventory (Spielberger et al., 1970) consists of two separate twenty item self-report scales for measuring trait and state anxiety (appendix 9). It asks individuals to describe how they 'generally feel' on a 4-point likert scale (1 = almost never; 4 = almost always). Scores range from 20-80. Higher scores indicate greater anxiety. Psychometric properties of this scale, including reliability and validity have been shown to be excellent.

7) The Beck Depression Inventory-II (BDI-II; Beck et al., 1996) is a twenty-one item self-report instrument for measuring the severity of depression (appendix 10). The BDI-II requires participants to read each statement and select the one that best describes the way they have felt during the past two weeks. Items are scored on a 4-point scale (0-3); scores are summed and produce a range from 0 to 63. Higher scores indicate greater depression. The British adult norm values for BDI are 5.40 ± 5.80 . A score >20 is usually considered indicative of clinical depression, while a score of ≤ 10 is generally considered non-depressed. The boundary for mild depression is 10; scores at this level are counted as evidence of daytime functioning complaint.

Results

Of eighty-five people who replied to the recruitment advertisement, seventy-nine met the inclusion criteria and agreed to participate. The participant demographic characteristics are presented in Table 2.

Defining ‘good’ and ‘poor’ sleepers

The Insomnia Severity Index (ISI) was used to identify ‘good’ and ‘poor sleepers’. Using Morin et al., (2011) recommendations, a cutoff score of 10 was used to differentiate between this community sample of ‘good’ and ‘poor sleepers’. Morin et al., (2011) suggested this cutoff to be the best compromise to achieve optimal balance between sensitivity and specificity in a population-based sample.

Seventy-nine participants aged 18-59 years completed the study (table 2): 36 participants (26 female, 10 male) met Morin et al., (2011) community sample criteria for insomnia; 43 participants (23 female, 20 male) fell below threshold and were allocated to the ‘good sleeper’ group. No significant differences were found in demographics between these groups (Table 3).

Table 2: Participants demographic characteristics

	Total	Mean	SD	Range
Total N	79			
Age		38.17	11.55	41
Gender				
Female	49	-	-	-
Male	30	-	-	-
BMI	28.52	25.48	5.40	28.52
Relationship status				
Married	39			
Cohabiting	11			
Single	16			
Boy/girlfriend	12			
Widowed	1			
Occupation				
Full time	56			
Part Time	6			
Manager	26			
Engineer	7			
Accountant	3			
Technician	5			
Administration	4			
Analyst/ Scientist	6			
Marketing	3			
Student/Trainee	18			

Table 3: Good and Poor Sleep group demographics.

Sleep Group	N	Demographics					
		Gender		Age		BMI	
Good	43	Female 23	Male 20	36.58	\pm 12.02	26.44	\pm 6.11
Poor	36	Female 26	Male 10	40.08	\pm 10.82	24.57	\pm 4.55
	79	ns		t = 1.35 p=ns		t=-1.40 p=ns	

The relationship between sleep quality, rumination and sleep moderators

Comparison of 'good' and 'poor sleepers' scores on rumination (GS = 24.91 ± 9.75 < PS = 32.83 ± 11.61 ; $t=-3.20$, $p=0.001$), depression (GS = 10.86 ± 5.95 < PS = 15.50 ± 8.08 ; $t = -2.86$ $p = 0.006$), were significantly greater in the 'poor sleep' group (Table 3). Brooding (GS = 8.93 ± 3.05 < PS = 9.69 ± 2.78 ; $t=-1.16$ $p = 0.252$) and reflection (GS = 9.50 ± 3.0 < PS = 9.26 ± 3.10 ; $t=-0.35$ $p = 0.73$) showed no significant differences.

Table 4: Good and Poor Sleep group rumination scores.

Sleep Group	N	RUMINATION SCALE							
		Total Score \pm		Depression \pm		Brooding \pm		Reflection \pm	
Good	43	24.91	\pm 9.75	10.86	\pm 5.95	8.93	\pm 3.05	9.50	\pm 3.0
Poor	36	32.83	\pm 11.61	15.50	\pm 8.08	9.69	\pm 2.78	9.26	\pm 3.10
		$t=-3.20$, $p=0.001$		$t=-2.86$ $p=0.006$		$t=-1.16$ $p=ns$		$t=-0.35$ $p=ns$	

BDI-II scores (GS = 4.58 ± 4.16 < PS = 15.50 ± 10.31 ; $t = -5.96$, $p = 0.000$) and state (GS = 33.91 ± 8.22 < PS = 47.19 ± 11.96 ; $t = -5.65$ $p = 0.000$) and trait anxiety (GS = 33.21 ± 9.06 < PS = 47.42 ± 13.10 ; $t = -5.50$ $p = 0.000$) were significantly elevated within the 'poor sleep' group (Table 5).

Table 5: Good and Poor Sleep group mood scales

Sleep Group	N	MOOD SCALES					
		BDI \pm		State Anxiety \pm		Trait Anxiety \pm	
Good	43	4.58	\pm 4.16	33.91	\pm 8.22	33.21	\pm 9.06
Poor	36	15.50	\pm 10.31	47.19	\pm 11.96	47.42	\pm 13.10
		$t=-5.96$, $p=0.000$		$t=-5.65$ $p=0.000$		$t=-5.50$ $p=0.000$	

'Poor sleepers' reported significantly higher pre-sleep arousal (GS = 22.33 ± 5.27 < PS = 30.94 ± 9.24 ; $t = -4.96$ $p = 0.000$), with both somatic (GS = 9.47 ± 2.07 < PS = 11.61 ± 3.77 ; $t = -3.05$ $p = 0.004$) and cognitive pre-sleep arousal (GS = 12.86 ± 3.92 < PS = 19.33 ± 7.06 ; $t = -4.91$ $p = 0.000$) significantly elevated compared to 'good sleepers' (Table 6).

Table 6: Good and Poor Sleep group sleep measures

Sleep Group	N	Pre sleep arousal scale					
		Pre sleep arousal \pm		Somatic Pre sleep arousal \pm		Cognitive Pre sleep arousal \pm	
Good	43	22.33	± 5.27	9.47	± 2.07	12.86	± 3.92
Poor	36	30.94	± 9.24	11.61	± 3.77	19.33	± 7.06
		$t=-4.96$ $p=0.000$		$t=-3.05$ $p=0.000$		$t=-4.91$ $p=0.000$	

The Ruminator's Profile

'High' and 'low ruminators' were defined using a mean split of 28.5. All below the mean were allocated to the 'low rumination group' and all those scoring above this were allocated to the 'high rumination' group, this resulted in $n = 34$ and $n = 45$ respectively.

Participants in the 'high rumination' group showed significantly elevated PSQI (LR = 4.6 ± 3.17 < HR = 7.5 ± 3.86 ; $t = -2.4$, $p < 0.05$) and ISI (LR = 7.73 ± 5.46 < HR = 11.03 ± 6.88 ; $t = -2.28$, $p < 0.05$) scores. Between group analysis also showed significantly greater scores for depression (LR = 6.20 ± 5.48 < HR = 14.0 ± 11.30 ; $t = -3.68$, $p = 0.001$) state (LR = 35.93 ± 8.9 < HR = 45.29 ± 13.61 ; $t = -3.49$, $p = 0.001$) and trait anxiety (LR = 34.22 ± 9.06 < HR = 46.91 ± 14.21 ; $t = -4.55$, $p < 0.001$) and somatic (LR = 9.69 ± 2.77 < HR = 11.44 ± 3.36 ; $t = 2.47$, $p = 0.02$) and cognitive pre-sleep arousal (LR = 13.42 ± 4.38 < HR = 18.97 ± 7.32 ; $t = -3.92$, $p = 0.000$). No between group difference was found between the cost for set switching or inhibition (Table 7).

Table 7: Differences between high and low ruminators.

	Low n = 45		High n = 34		Independent samples T - Test		
	Mean	SD	Mean	SD	N	T	p value
PSQI	4.6	± 3.17	7.5	± 3.86	78	-2.4	0.02
ISI	7.73	± 5.46	11.03	± 6.88	60	-2.28	0.026
ESS	6.4	± 4.11	8.0	± 4.75	78	-1.58	0.12
State Anxiety	35.93	± 8.9	45.29	± 13.61	55	-3.49	0.001
Trait Anxiety	34.22	± 9.06	46.91	± 14.21	54	-4.55	0.000
BDI-II	6.20	± 5.48	14.00	± 11.40	45	-3.68	0.001
PSAS Total	23.11	± 6.30	30.41	± 9.26	56	-3.96	0.000
PSAS-Somatic	9.69	± 2.77	11.44	± 3.36	64	-2.47	0.02
PSAS-Cognitive	13.42	± 4.38	18.97	± 7.32	52	-3.92	0.000
Set switching cost	32.14	± 12.99	31.11	± 13.99	78	0.34	0.74
Inhibition cost	0.13	± 6.84	1.97	± 8.53	78	-1.06	0.29

Sleep moderators showed high inter correlation with each other as well as the Rumination Scale. No correlation between set switching and rumination was found in Table 8.

Table 8: Pearson correlation. Intercorrelations between self-report of measures

	PSAS Som	PSAS cog	Total PSAS	BDI-II	State	Trait	Glpsq	ESS	ISS	Set Switch	Inhib	RS Total	RS Dep	RS Brood
PSAS cog	.52 **													
Total PSAS	.76 **	.95 **												
BDI-II	.44 **	.63 **	.64 **											
State	.41 **	.63 **	.626 **	.75 **										
Trait	.45 **	.64 **	.65 **	.83 **	.905 **									
Glpsq	.33 **	.46 **	.47 **	.53 **	.55 **	.575 **								
ESS	-0.1 ns	-0.09 ns	-0.12 ns	0.19 ns	0.08 ns	0.08 ns	0.08 ns							
ISS	.31 **	.58 **	.56 **	.60 **	.57 **	.57 **	.75 **	0.14 ns						
Set Switch	-0.02 ns	-0.11 ns	-0.09 ns	0.01 ns	-0.15 ns	-0.10 ns	0.05 ns	.22 *	0.11 ns					
Inhibition	0.12 ns	0.18 ns	0.17 ns	0.17 ns	0.08 ns	0.11 ns	-0.13 ns	-.23 *	-0.06 ns	-.40 **				
RS Total	.41 **	.53 **	.55 **	.45 **	.38 **	.46 **	.34 **	.30 **	.40 **	-0.08 ns	0.09 ns			
RS Dep	.31 **	.47 **	.47 **	.37 **	.34 **	.37 **	.285 *	.268 *	.40 **	0.01 ns	0.05 ns	.90 **		
RS Brood	.29 **	.39 **	.40 **	.33 **	.46 **	.47 **	0.21 ns	-0.00 ns	0.17 ns	-0.19 ns	0.12 ns	.38 **	.28 *	
RS Reflect	.31 **	.29 **	.34 **	.297 **	.39 **	.42 **	0.13 ns	0.04 ns	0.07 ns	-0.13 ns	0.08 ns	.41 **	.29 **	.84 **

** Correlation significant at the 0.01 level (2-tailed) * Correlation is significant at the 0.05 level (2-tailed)

The role of set-switching and backward-inhibition in rumination and poor sleepers

As can be seen in Figure 3, control and inhibition trials evidenced similar mean response times, and both of these trial types had lengthier response times when compared to the less cognitive demand 'repeat' task.

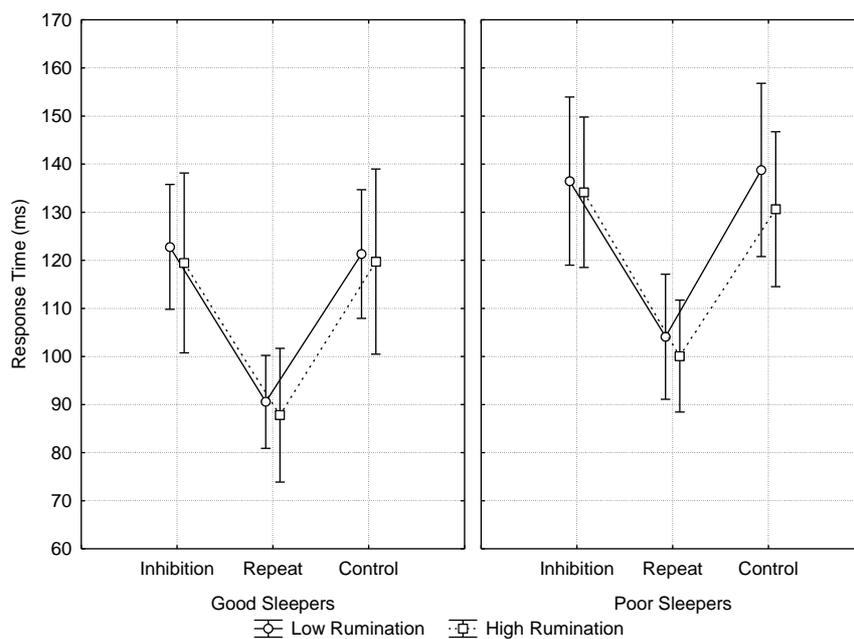


Figure 3: Mean response time by trial and type and sleep and rumination

The effect of quality of sleep and rumination upon control of working memory was explored using a mixed between and within measures Analysis of Variance, in which WM Control Mechanism was the within-subjects factor (Set Switching Costs Versus Backward Inhibition Costs) and the between-subjects factors where Sleep Group (good sleepers Versus poor sleepers) and Rumination Group (high rumination versus low rumination). The results of this analysis are shown in Table 9.

Table 9: Repeated Measures Analysis of Variance with Effect Sizes and Powers

	Sum of Squares	d.f	Mean Squares	F	p	Partial eta-squared
Intercept	38874.141	1.0	38874.141	487.810	0.000	0.867
Sleep Group	15.215	1.0	15.215	0.191	0.663	0.003
Rumination Group	3.004	1.0	3.004	0.038	0.847	0.001
Sleep Group by Rumination Group	11.743	1.0	11.743	0.147	0.702	0.002
Error	5976.838	75.0	79.691			
WM Control Mechanism	36037.372	1.0	36037.372	226.792	0.000	0.751
WM Control Mechanism by Sleep Group	14.540	1.0	14.540	0.092	0.763	0.001
WM Control Mechanism by Rumination Group	113.850	1.0	113.850	0.716	0.400	0.009
WM Control Mechanism by Sleep Group by Rumination Group	383.811	1.0	383.811	2.415	0.124	0.031
Error	11917.532	75.0	158.900			

Figure 4 illustrates the 3-way model (Sleep group (good/poor) – Rumination group (high/low) - Executive task (set switching/inhibition)). No interaction or difference between groups for these executive processes was found ($F = 2.42$, $p = 0.12$).

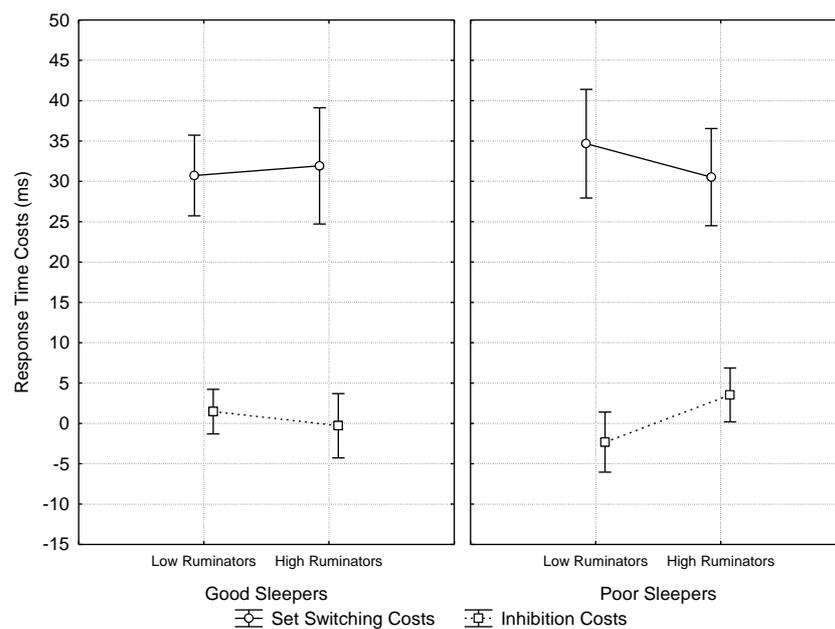


Figure 4: Mean response time for Set-Switching and Inhibition costs by ruminator and sleep groups.

All analysis included in these results were also completed using the PSQI (Buysee et al., 1989) classification of 'good' (< 5 PSQI score) and 'poor' sleep group (≥ 5 PSQI score; Backhaus et al., 2002). No difference in outcome was found.

Discussion

The aim of this research was to identify whether the underlying cognitive mechanisms thought to contribute to the maintenance of depression are also present in people who report poor sleep. Four hypotheses were addressed.

‘Poor sleepers’ will show a greater ruminative tendency than ‘good sleepers’.

In support of the hypothesis, ‘poor sleepers’ scored significantly higher on the total rumination scale, as well as its ‘depression’ subscale. This supports previous findings showing a significantly distinctive mood profile for people reporting ‘poor sleep’ compared to those who do not report poor sleep (David & Morgan 2008). Relative to ‘good sleepers’, ‘poor sleepers’ subjectively reported greater sleep disturbance, elevated cognitive and somatic pre-sleep arousal, and sub-clinical elevations of depression and anxiety symptoms (trait and state).

High ruminators shared this distinctive mood and sleep profile, showing significantly greater state and trait anxiety, depression and somatic and cognitive pre-sleep arousal.

Differences between ‘poor sleepers’ and ‘good sleepers’ in set switching and inhibition will be found.

This study failed to support the hypothesis that ‘good’ and ‘poor sleepers’ and ‘high’ or ‘low’ ruminators would differ in set switching and inhibition laden executive tasks. Previous research has shown a significant difference between the RT cost when required to draw on an inhibitory cognitive process compared to that of set switching. (Mayr & Keele, 2000). Using the same tasks as the present study Whitmer and Banich, (2007) showed that depressive rumination was associated with a deficit in inhibiting prior mental sets. While our data failed to support this difference, the expected significant decrease in RT was observed for the RT of ‘repeat trials’ i.e. where no inhibition or switching was required. The decrease in RT for repeat trial supports the assumption of attentional cognitive demand on the other trials. However, the attention cognitive demand did not differ in either the ‘good’ or ‘poor’ sleepers or the high or low ruminators.

Set inhibition (hypothesis iii) and switching (hypothesis iv) will positively correlate with Ruminative Response Style data.

Data did not support the hypothesis that set inhibition and switching would correlate with ruminative response scores. In addition, no significant difference in RT for set inhibition or set switching was found between the high and low rumination groups.

Summary

This study replicated previous findings showing people with poor sleep differ significantly in their psychological makeup compared to good sleepers (Borkovec, 1982). Data show significant differences in subjectively reported sleep moderators and confirm a distinct psychological profile that has been found in previous research when comparing people with poor sleep with control participants. Our findings indicate a ruminative profile is also present in people reporting poor sleep, however no significant differences in set inhibition or set switching was found between good and poor sleepers, or high and low ruminators.

General discussion

In keeping with the literature, rumination was found to be associated with poor sleep (Carney et al., 2006; Guastella and Moulds, 2007). Carney et al., (2010) suggested rumination may contribute to clinical insomnia independently of worry and depressed mood states, and Schmidt et al., (2011) suggested problems with cognitive control may contribute to sleep problems independently of negative mood states. However, these data failed to replicate the deficits observed in executive control of working memory that have been found in depressed ruminators (Whitmer & Banich 2007).

This suggests the rumination found in depressed ruminators may be different to that observed in depressed patients. Whitmer & Banich (2007) suggest different forms of rumination are associated with different cognitive mechanisms and that different deficits may contribute to the maintenance that is associated with ruminative tendencies. Interestingly, poor sleepers have been found to respond to disruptions in their mood by thinking repetitively about the cause of their fatigue, achiness and concentration difficulties (Carney et al., 2006; Nolen-Hoeksema & Morrow 1991).

Objective tests and people with insomnia

It is well recognised that people with insomnia report impairment in everyday life and indeed a complaint of impaired functioning during the waking hours is necessary for DSM IV TR (Riedel & Lichstein, 2000). Riedel & Lichstein (2000) however, challenged assumptions that daytime functioning deficits are associated with insomnia, suggesting most cognitive/psychomotor tasks do not find significant deficits within this population. Compared to normal sleepers, poor sleepers have shown no significant impairment in reaction time (Adam et al., 1986), card sorting (Seidel, 1984) or vigilance (Sugerman et al., 1985). Research has detected no deficits among people with insomnia on types of psychomotor tasks (Broman et al., 1992, Mendelson, et al., 1984) and various measures of attention, vigilance, learning and memory. Schneider-Helmert (1987), examined performance on a variety of tasks, including logical reasoning, addition, digit symbol substitution, word detection, visual search, line judgment auditory vigilance and line tracing. Of thirty-eight tests, only six showed significant differences between groups, with three favouring the insomniacs and three favouring the control group. Furthermore, across different psychological functions, reduced performance was found in only one-fifth (22.9%) of all comparisons for people with insomnia (Fulda and Schulz 2001). More recently Orff et al., (2007) suggested that this discordance may suggest that daytime impairment corresponds less to “output” and more to attentional bias or to the realistic appraisal that “effort” is required to maintain normal performance.

A recent meta-analysis, comparing people with insomnia and healthy sleepers' daytime cognitive performance (Fortier-Brochu et al., 2012) showed no significant differences between people with insomnia and good sleepers for tasks assessing general cognitive function, perceptual and psychomotor processes, procedural learning, verbal functions, different dimensions of attention (alertness, complex reaction time, speed of information processing, selective attention, sustained attention/vigilance) and some aspects of executive functioning (verbal fluency, cognitive flexibility). Significant impairments of small to moderate magnitude were suggested to be found in individuals with insomnia for tasks assessing episodic memory, problem solving, manipulation in working memory, and retention in working memory. Tests measuring working memory (e.g., Digit Span, Letter-Number Sequencing) and executive function (e.g., Wisconsin Card Sorting Test, verbal fluency, maze tasks) were said to yield contradictory findings (Fortier-Brochu, et al, 2012).

An explanation for these contradictions included the extensive night-to-night variability in the sleep of individuals with insomnia (Vallieres et al., 2005; Perlis et al., 2014), and how their cognitive performance may be modulated by the quality of sleep on the night prior to testing. Individual variation regarding vulnerability to sleep loss, fatigue and mood was also considered as a possible confound to cognitive functioning and authors recognised that performance may vary across days depending on the quality and duration of recent sleep (Fortier-Brochu et al, 2012).

Type of insomnia may also contribute to contradictory findings; notably, insomnia with objective short sleep duration is associated with deficits in set-switching attentional abilities (Fernandez-Mendoza et al., 2010). These points highlight the necessity for prospective studies when exploring differences between good and poor sleepers and suggest caution is needed when interpreting single point cross sectional data.

Limitations

No significant differences in set stitching and inhibition were found between good or poor sleepers, high or low ruminators or combined groups (sleep group by rumination group). Failure to find support for the hypothesis that set switching and inhibition would differ for those in the 'poor sleep' group with those in the 'good sleep' group may be due to the test design, the timing of the performance testing, or perhaps to the participant population.

Riedel & Lichstein (2000), argue that the tests used to examine daytime functioning of people reporting poor sleep compared to controls may not be sensitive enough to detect the problems reported. Indeed, it is certainly true that the lack of any significant differences in set switching and inhibition data between our groups do not conclusively rule out the presence of all possible deficits. After all, on this occasion, neither group showed typical differences between the two cognitive processes/demands i.e. set switching versus inhibition. That said, further development of this test and the calculation of set switching and set inhibition costs may increase its sensitivity to detect any cognitive deficits among participants. While conventional performance tests may not identify the magnitude of daytime impairment reported by people with poor sleep, the identification of measures sensitive to the effect of insomnia remains a high research priority.

Espie (2007), recommended the further development of computerised testing of information processing bias, to offer an objective means of appraising mental processes in insomnia; already advances have been made. Using the dot-probe task, Jansson-Fröjmark et al., (2012) demonstrated that attention bias in insomnia is due to an inability to disengage from sleep-related stimuli, rather than increased vigilance towards such stimuli. This supports the hypothesis that set switching and set inhibition may have a role to play in either or both precipitating or perpetuating insomnia. Tasks offering an objective, non-threatening (Barclay & Ellis, 2013) means of appraising cognitive processes, such as the task-switching paradigm (Mayr and Keele, 2000), therefore warrant further exploration and development.

Timing for performance tasks should also be carefully considered, as alertness and human performance show clear fluctuations across the 24-hour day due to wake- and sleep-promoting input from the biological clock (Cajochen et al., 1999). Our test period coincided with a wake-promoting region in the circadian timing system and may have been unable to elucidate subtle differences in alertness and performance at this time. Examination of performance during the daytime circadian nadir for alertness (~1-4pm) may have unmasked vulnerabilities in alertness and performance in these groups.

Participants were recruited from a community sample, which may have introduced heterogeneity in the sample and compromised the representativeness of people with poor sleep who seek help. That said, we can assume that the present findings extend at least to those with untreated poor sleep who appear to be in the majority (see Ohayon, 2002), and that understanding variability at the subclinical poles has the potential to inform nosology (Barclay & Ellis, 2013).

Assignment of our community sample to 'good' and 'poor sleeper' groups was based upon Morin et al., (2011) cut off score of ten. This index proved successful in significantly differentiating 'good' and 'poor sleepers' in areas including anxiety and depression (Borkovec, (1982). Indeed commonly found inter-correlations were present between subjective poor sleep, anxiety, depression and rumination suggesting substantial amount of shared variance. Part of the difficulty in understanding the mechanisms involved in insomnia is the co-morbidity of depression, anxiety and worry. Studies have shown substantial overlap between depression and the symptoms of insomnia, most notably, nocturnal sleep disturbance, irritability, decreased concentration, and fatigue (Carney et al., 2008).

Possible underlying processes that may explain these overlaps could fit a transdiagnostic model. Indeed, repetitive thought has been identified as a transdiagnostic risk factor for depression, anxiety and poor physical health. The intention of this research was to continue this discussion in relation to insomnia. Future research could explore how rumination, anxiety and depression may differ in construct. They may be similar processes but vary in valence content, and different treatment strategies might be needed for each (Carney et al., 2010). Indeed, Carney et al., (2010) considered whether rumination plays a significant and independent role in the maintenance of insomnia and suggested that rumination and worry may be distinct and have independent or dynamic effects on individuals with insomnia.

Treatment implications

Cognitive Behavioural Therapy for insomnia (CBI-I) continues to be an effective strategy, however Carney et al., (2010) proposes there is room for improvement and punctuates this point by asking whether or not poor sleepers who receive or practice CBT-I ever actually become a good sleeper.

The results from this study show rumination is present in individuals reporting poor sleep. Carney et al., (2010) suggest that CBT-I contains worry adjuncts (Carney & Waters, 2006; Harvey, Tang & Browning, 2005) but contains no rumination-specific strategies.

Future research could utilise Joorman's (2010) model to inform the development and evaluation of an additional element of intervention for people with insomnia aimed at 1) reducing the mood valence and activation of negative cognitions 2) remediating possible deficits in cognitive inhibition and improve control of working memory, and 3) addressing the failure of reappraisal and its consequences for the subjective acceptability of the depressiogenic interpretation of ongoing experience.

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Public Dissemination Document

Insomnia Predisposing, Precipitating and Perpetuating Factors

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A thesis submitted to
the University of Birmingham
for the partial fulfilment for the Doctorate in Clinical Psychology

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Public Dissemination Document

This research was submitted as partial fulfilment for the degree of Doctorate in Clinical Psychology at the University of Birmingham. The research is comprised of two parts. Paper one reviews the literature exploring non-pharmacological sleep hygiene interventions in hospital settings. The second paper explores the cognitive processes in people with poor sleep.

A review of non-pharmacological sleep hygiene interventions in hospital settings.

The aim of this review was to methodically review and combine the findings of research implementing non-pharmacological sleep hygiene interventions within a hospital setting.

Sleep is a fundamental to health and recovery and yet patients report sleep disturbance as one of the most stressful components of their hospital care experience (Novaes et al., 1997). Historically, literature focussed on the causes of disturbances for hospital care patients, such as health status, medications, noise, pain, light and discomfort from surgical procedures, tubes and lines and 24-hour treatment activities. Isolation, an inability to get comfortable or lay comfortably, inability to perform the usual routine prior to going to bed, and discomfort from prolonged bed rest, as well as worry and stress have all been identified as factors that can impair sleep quality.

Fewer studies looked at ways to promote sleep quality, however with research data now available this review aimed to evaluate its quality and make recommendation for future research. Sleep hygiene interventions can include recommending wards maintain a quiet and dim environment where possible and decrease interruptions from care activities at night where possible.

Main findings showed sleep hygiene interventions improve sleep as well as other related measures, such as pain, delirium and medication in hospitalised patients. Improvements in the design of future research were however recommended. Patient selection should reflect routine practice and all patients who might receive the intervention should be included. Research should also take place in the environment for which it is designed, and together with greater patient numbers, this will show whether an intervention works for patients in general. Research should aim to calculate the cost of sleep hygiene practices in routine hospital care so that a full service delivery model can be considered by health care commissioners.

Hospitals should be a place of recovery and sleep disturbance should no longer be one of the most stressful components of the hospital care experience, or indeed a precipitating risk factor for chronic insomnia. Research identifying ways of ensuring this happens is paramount.

Do people with insomnia show deficits in inhibition and in set switching cognitive tasks?

Sleep problems are the most frequently reported psychological symptom in Britain, with 24% of men and 34% of women reporting problems getting to sleep or staying asleep in the past month (Singleton et al., 2003). Insomnia has been associated with daytime fatigue, greater medical service utilisation, self medication with alcohol or over the counter medication, greater functional impairment, greater work absenteeism, impaired concentration and memory, decreased enjoyment of interpersonal relationships. With an emphasis on the need to reduce hypnotic drug prescribing, and provide effective non-pharmacological approaches to sleep management this research aimed to explore the role of cognitive control (switching and inhibition) of working memory in insomnia so that we may better understand the mechanisms involved and inform treatment development.

Difficulties in switching, involve the inability to redirect attention to a new theme. Successfully switching attention to a new theme but finding oneself returning to ruminate on previous themes indicate a failure in inhibition. Anecdotal report of people with sleeping difficulties often includes failures of both switching and inhibition. This study sought to identify any differences between these two processes in good and poor sleepers.

Seventy-nine participants completed the study. Participants were allocated to two groups; a 'poor sleeper' and a 'good sleeper'; group. Scores were then compared using statistical methods to see if the two groups differed.

Four statements were tested. 1) 'Poor sleepers' will show a greater ruminative tendency than 'good sleepers'; 2) Differences between 'poor sleepers' and 'good sleepers' in two cognitive tasks (switching and inhibition) will be found; 3+4) Set inhibition and set switching will relate to scores on the ruminative response Scales.

Sleep quality and personality constructs were measured using participant questionnaires. The two cognitive processes (set switching and inhibition) were assessed using a computer-based task that, without the participant knowing, measured their reaction time when needing to use this kind of process.

This study replicated previous findings showing people with poor sleep differ significantly in their psychological makeup compared to good sleepers. Findings supported a distinct psychological profile that has been found in previous research when comparing people with poor sleep with good sleepers. Our findings indicate a ruminative profile is also present in people reporting poor sleep, however no differences in cognitive performance was found between good and poor sleepers, or high and low ruminators.

LITERATURE REVIEW APPENDICES

Appendices

Appendix 1:

Quality Framework Questions (Downs & Black, 1998):

1. Is the hypothesis/aim/objective of the study clearly described?
2. Are the main outcomes to be measured clearly described in the introduction or methods section?
3. Are the characteristics of the patients included in the study clearly described?
4. Are the interventions of interest clearly described?
5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?
6. Are the main findings of the study clearly described?
7. Does the study provide estimates of the random variability in the data for the main outcomes?
8. Have all important adverse events that may be a consequence of the intervention been reported?
9. Have the characteristics of patients lost to follow up been described?
10. Have actual probability values been reported for the main outcomes except where the probability value is less than 0.001?

External validity

11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?
12. Were the subjects who were prepared to participate representative of the entire population from which they were recruited?
13. Were the staff, places and facilities where the patients were treated, representative of the treatment the majority of patients receive?

Internal validity - bias

14. Was an attempt made to blind study subjects to the intervention they have received?
15. Was an attempt made to blind those measuring the main outcomes of the intervention?
16. If any of the results of the study were based on "data dredging", was that made clear?
17. In trials and cohort studies, do the analyses adjust for different lengths of follow up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?

18. Were the statistical tests used to assess the main outcomes appropriate?
19. Was compliance with the intervention/s reliable?
20. Were the main outcome measures used accurate (valid and reliable)?

Internal validity - confounding

21. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?
22. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?
23. Were study subjects randomised to intervention groups?
24. Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?
25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?
26. Were losses of patients to follow up taken into account?
27. Did the study have sufficient power?

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Behavioral Sleep Medicine (BSM) addresses behavioral dimensions of normal and abnormal sleep mechanisms and the prevention, assessment, and treatment of sleep disorders and associated behavioral and emotional problems. Standards for interventions acceptable to this journal are guided by established principles of behavior change. Intending to serve as the intellectual home for the application of behavioral/cognitive science to the study of normal and disordered sleep, the journal paints a broad stroke across the behavioral sleep medicine landscape. Its content includes scholarly investigation of such areas as normal sleep experience, insomnia, the relation of daytime functioning to sleep, parasomnias, circadian rhythm disorders, treatment adherence, pediatrics, and geriatrics. Multidisciplinary approaches are particularly welcome. The journal's domain encompasses human basic, applied, and clinical outcome research. BSM also embraces methodological diversity, spanning innovative case studies, quasi-experimentation, randomized trials, epidemiology, and critical reviews.

Please note that ***Behavioral Sleep Medicine*** uses CrossCheck™ software to screen papers for unoriginal material. By submitting your paper to ***Behavioral Sleep Medicine*** you are agreeing to any necessary originality checks your paper may have to undergo during the peer review and production processes.

Audience:

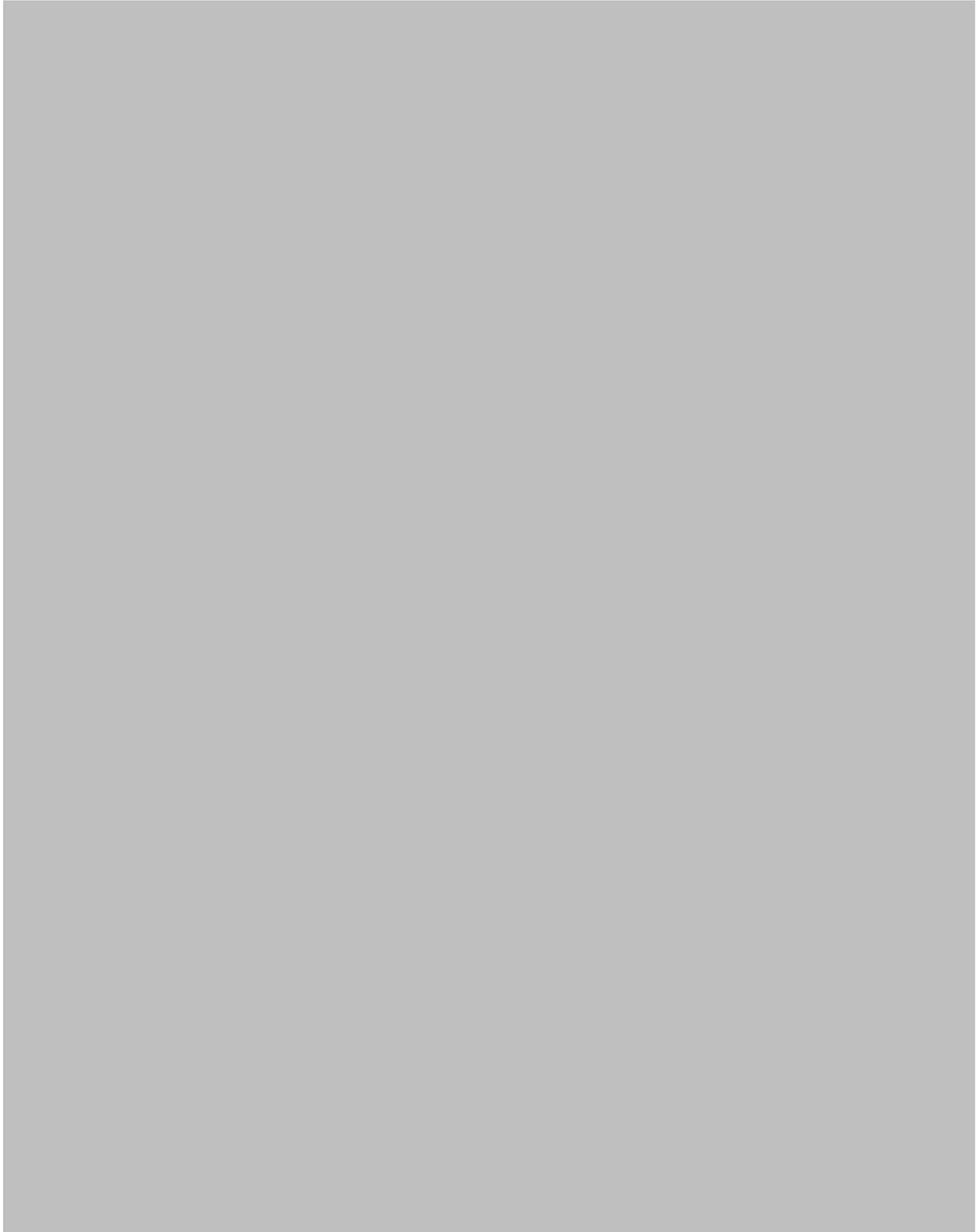
Psychologists, physicians, nurses, and other health care researchers and clinicians who prize knowledge of normal and disordered sleep from the perspective of behavioral/cognitive science.

Manuscript Preparation:

All manuscripts submitted must contain material that has not been published and is not being considered for publication elsewhere. Manuscripts should be prepared in accordance with the *Publication Manual of the American Psychological Association* (APA; 5th ed.). The manual sets forth guidelines for referencing, preparation of abstracts (maximum 120 words), bias-free language, margins (1 in., 2.54 cm, on four sides), formatting tables and figures, etc. Double space all text and number all pages consecutively. On the first page, indicate the title of the article; a short form of the title (less than 50 characters); and the author(s) name(s), affiliation(s), and complete mailing address(es). Define acronyms and abbreviations used in the manuscript when first mentioned. Print each figure and table on a separate page. To briefly summarize APA format for references, sources are cited in the text by author and year (e.g., Loomis, Harvey, & Hobart, 1937), and the reference list is arranged alphabetically.

RESEARCH APPENDICES

Appendix 1: Ethics Approval Letter



Appendix 2: Information Sheet

Our invitation to you

We are currently running a study investigating possible mechanisms that may be involved in the development and the maintenance of poor sleep / insomnia. By learning more about mechanisms involved in insomnia we are better placed to inform and improve sleep medicine.

We would like to invite you to take part in this research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish, or email the research team on the address at the bottom of this sheet.

What is this study all about?

The aim of this study is to find out more about the mechanisms driving and maintaining poor sleep. In the course of this study, two groups will be compared, 1) people with insomnia and 2) people without. Both groups will complete the same computer base task and at the end of the study results from both groups will be compared to see if there are any significant differences.

This trial is supported by The University of Birmingham and Loughborough University, and is being managed by Birmingham University's Psychology Department and Loughborough's Clinical Sleep Research Unit.

What will happen to me if I take part?

If you consent to take part we will contact you to arrange a convenient time for you to complete a computer-based task. The computer task will involve you responding (using the keyboard) to certain shapes presented to you (e.g. indicating their size, position or orientation). And that's it; all together the task will last approximately half an hour but you can take a break if you wish to.

What do the questionnaires ask? In order to assess your sleep profile and thinking style we need to ask you for information on your sleeping patterns and your thinking style. These questionnaires have been uploaded on the computer so that you can complete them before or after the computer-task.

What happens to this information? All the questionnaires are anonymous (we will place a number on the form). The information will also be stored anonymously and securely, and only people with correct authority will have access. If you decide to withdraw from the study we will destroy your personal (contact) information, but we will need to use the questionnaire data collected up to your withdrawal. At all times we will follow strict codes of ethical and legal practice.

What if I want to complain?

If you have concerns about any aspect of this study, you can bring this to the attention of the researchers (office number) who will do their best to address the issues. For the University call 0121 414 7124 (ask for the Research Manager).

If you remain unhappy and wish to complain formally, you can do this through the University authorities.

Do I have to take part? Participation, is of course, entirely voluntary. If, after reading this information, you decide to participate, we will ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. If you wish to withdraw your data, you must request this in writing before January 23rd 2014. Whether or not you agree to participate now, or whether you agree but withdraw in the future, your routine medical care will not be affected.

We recommend you speak with your GP if you have any concerns about your sleep.

If you would like to participate, have any queries, or would just like to discuss the project further, please email the lead researcher on Bmd916@bham.ac.uk

Appendix 3: Participant consent form

Title of Project: Rumination and Insomnia

Name of Researcher: Dr Beverley David

Please initial box

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw my data prior to 23.3.13 without giving any reason, without my medical care or legal rights being affected.

3. I agree to take part in the above study

Name of Participant

Date

Signature

Name of Person
taking consent

Date

Signature

Appendix 4: ISI

Please **shade in** the most appropriate response to the questions below. Please answer all questions. If a question does not apply to you, please shade in **NA**.

- Please rate the current (i.e. last 2 weeks) SEVERITY of your sleep problem
- How satisfied / dissatisfied are you with your current sleep pattern?

	NA	Mild	Moderate	Very	Severe
Difficulty falling asleep	<input type="radio"/>				
Difficulty staying asleep	<input type="radio"/>				
Problem waking up too early	<input type="radio"/>				

1 = Very Satisfied

5 = Very Dissatisfied

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

- To what extent do you think your sleep interferes with your daily functioning (e.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, mood)?

Not at all interfering	A little	Somewhat	Much	Very much interfering
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

- How NOTICEABLE to others do you think your sleep problem is, in terms of impairing the quality of your life?

NA	Not at all noticeable	A little	Somewhat	Much	Very much noticeable
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

- How WORRIED/distressed are you about your sleep?

Not at all	A little	Somewhat	Much	Very much
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Thank you, this questionnaire is now complete.
Please move on to the next questionnaire

Appendix 5: PSQI

The following questions relate to your usual sleep habits during the past month. Your answers should indicate the most accurate reply for the *majority* of days and nights in the past month.

1. During the past month, when have you usually gone to bed at night?
usual bed time _____
2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?
number of minutes _____
3. During the past month, when have you usually got up in the morning?
usual getting up time _____
4. During the past month, how many hours of *actual* sleep did you get at night? (This may be different than the number of hours you spend in bed).
hours of sleep per night _____

For each of the following questions, please **shade in** the most appropriate response:

5. During the past month, how often have you had trouble sleeping because you:
 - (a) Cannot get to sleep within 30 minutes

Not During the Past Month	Less than Once a Week	Once or Twice a Week	Three or More Times a Week
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
 - (b) Wake up in the middle of the night or early morning

Not During the Past Month	Less than Once a Week	Once or Twice a Week	Three or More Times a Week
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
 - (c) Have to get up to use the bathroom

Not During the Past Month	Less than Once a Week	Once or Twice a Week	Three or More Times a Week
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

(d) Cannot breathe comfortably

Not During the Past Month	Less than Once a Week	Once or Twice a Week	Three or More Times a Week
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

(e) Cough or snore loudly

Not During the Past Month	Less than Once a Week	Once or Twice a Week	Three or More Times a Week
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

(f) Feel too cold

Not During the Past Month	Less than Once a Week	Once or Twice a Week	Three or More Times a Week
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

(g) Feel too hot

Not During the Past Month	Less than Once a Week	Once or Twice a Week	Three or More Times a Week
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

(h) Had bad dreams

Not During the Past Month	Less than Once a Week	Once or Twice a Week	Three or More Times a Week
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

(i) Have pain

Not During the Past Month	Less than Once a Week	Once or Twice a Week	Three or More Times a Week
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

(j) Other reason(s), please describe

How often during the past month have you had trouble sleeping because of this?

Not During the Past Month	Less than Once a Week	Once or Twice a Week	Three or More Times a Week
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

6. During the past month, how would you rate your sleep quality overall?

Very good	Fairly good	Fairly bad	Very bad
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

7. During the past month, how often have you taken medicine (prescribed or “over the counter”) to help you sleep?

Not During the Past Month	Less than Once a Week	Once or Twice a Week	Three or More Times a Week
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not During the Past Month	Less than Once a Week	Once or Twice a Week	Three or More Times a Week
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. Do you have a bed partner or roommate?

No bed partner or roommate	Partner/roommate in other room	Partner in same room, but not same bed	Partner in same bed
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

11. How often do you feel **tired** during the following times during the day? Please circle the one best response.

Morning:

most days

often

occasionally

never

Afternoon:

most days

often

occasionally

never

Evening:

most days

often

occasionally

never

12. Do you nap?

most days

often

occasionally

never

Appendix 6: Epworth Sleepiness Scale

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

- 0 = Would *never* doze
- 1 = *Slight* chance of dozing
- 2 = *Moderate* chance of dozing
- 3 = *High* chance of dozing

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

**Thank you, this questionnaire is now complete.
Please move on to the next questionnaire.**

Appendix 7: Pre Sleep Arousal Scale

During the pre-sleep period last night (in bed with the lights out before falling asleep for the first time), did you have any of the following feelings?

		Not at all	A little	Moderately	A lot	Extremely
1	Heart racing, pounding, or beating irregularly	1	2	3	4	5
2	A jittery, nervous feeling in your body	1	2	3	4	5
3	Worry about falling asleep	1	2	3	4	5
4	Review or ponder events of the day	1	2	3	4	5
5	Shortness of breath or laboured breathing	1	2	3	4	5
6	Depressing or anxious thoughts	1	2	3	4	5
7	A tight, tense feeling in your muscles	1	2	3	4	5
8	Worry about problems other than sleep	1	2	3	4	5
9	Being mentally alert, active	1	2	3	4	5
10	Cold feeling in your hands, feet or your body in general	1	2	3	4	5
11	Can't shut off your thoughts	1	2	3	4	5
12	Have stomach upset (knot or nervous feeling in stomach, heartburn, nausea, gas, etc.)	1	2	3	4	5
13	Perspiration in palms of your hands or other parts of your body	1	2	3	4	5
14	Thoughts keep running through your head	1	2	3	4	5
15	Dry feeling in mouth or throat	1	2	3	4	5
16	Distracted by sounds, noise in the environment (e.g., ticking clock, house noises, traffic)	1	2	3	4	5

Appendix 8: Rumination Scale

People think and do many different things when they feel depressed. Please read each of the items bellow and indicate whether you almost never, sometimes, often, or almost always think or do each one when your feel down, sad or depressed. Please indicate what you generally do, not what you think you should do.

1 almost never 2 sometimes 3 often 4 almost always

1. Think about how alone you feel.
2. Think "I won't be able to do my job if I don't snap out of this".
3. Think about your feelings of fatigue and achiness.
4. Think about how hard it is to concentrate.
5. Think "What am I doing to deserve this?"
6. Think about how passive and unmotivated you feel.
7. Analyse recent events to try to understand why you are depressed.
8. Think about how you don't seem to feel anything any more.
9. Think "Why can't I get going?".
10. Think "Why do I always react this way?"
11. Go away by yourself and think about why you feel like this.
12. Write down what you are thinking about and analyse it.
13. Think about a recent situation, wishing it had gone better.
14. Think "I won't be able to concentrate if I keep feeling this way".
15. Think "Why do I have problems other people do not have?"
16. Think "Why can't I handle things better?"
17. Think about how sad you feel.
18. Think about all your shortcomings, failings, faults and mistakes.
19. Think about how you don't feel up to doing anything.
20. Analyse your personality to try to understand why you are depressed.
21. Go someplace alone to think about your feelings.
22. Think about how angry you are with yourself.

Appendix 9: STAI

Q1) Please **shade** the circle that best indicates how you feel *right now*, that is, *at this moment*. There are no right or wrong answers.

		Not at all	Somewhat	Moderately	Very much so
1.	I feel calm	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.	I feel secure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3.	I am tense	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4.	I feel strained	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5.	I feel at ease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6.	I feel upset	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7.	I am presently worrying over possible misfortunes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8.	I feel satisfied	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9.	I feel frightened	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10.	I feel comfortable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11.	I feel self-confident	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12.	I feel nervous	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13.	I am jittery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14.	I feel indecisive	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15.	I am relaxed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16.	I feel content	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17.	I am worried	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18.	I feel confused	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19.	I feel steady	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20.	I feel pleasant	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please continue over page...

Q2) Now please **shade** the circle that best indicates how you *generally feel*.

		Almost never	Sometimes	Often	Almost always
1.	I feel pleasant	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.	I feel nervous and restless	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3.	I feel satisfied with myself	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4.	I wish I could be as happy as others seem to be	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5.	I feel like a failure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6.	I feel rested	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7.	I am "cool, calm and collected"	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8.	I feel that difficulties are piling up so that I cannot overcome them	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9.	I worry too much over something that really doesn't matter	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10.	I am happy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11.	I have disturbing thoughts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12.	I lack self confidence	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13.	I feel secure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14.	I make decisions easily	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15.	I feel inadequate	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16.	I am content	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17.	Some unimportant thought runs through my mind and bothers me	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18.	I take disappointments so keenly that I can't put them out of mind	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19.	I am a steady person	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20.	I get in a state of tension or turmoil as I think over my recent concerns	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Thank you, this questionnaire is now complete.
Please move on to the next questionnaire.**

Appendix 10: BDI-II

Please **shade in** the most appropriate response to the questions below. Please answer all questions.

1. Sadness

I do not feel sad

I feel sad much of the time

I am sad all of the time

I am so sad or unhappy that I can't stand it

2. Pessimism

I am not discouraged about my future

I feel more discouraged about my future than I used to be

I do not expect things to work out for me

I feel my future is hopeless and will only get worse

3. Past Failure

I do not feel like a failure

I have failed more than I should have

As I look back, I see a lot of failures

I feel I am a total failure as a person

4. Loss of Pleasure

I get as much pleasure as I ever did from things I enjoy

I don't enjoy things as much as I used to

I get very little pleasure from the things I used to enjoy

I can't get any pleasure from the things I used to enjoy

5. Guilty Feelings

I don't feel particularly guilty

I feel guilty over many things I have done or should have done

I feel quite guilty most of the time

I feel guilty all of the time

6. Punishment Feelings

I don't feel I am being punished

I feel I may be punished

I expect to be punished

I feel I am being punished

7. Self-Dislike

I feel the same about myself as ever

I have lost confidence in myself

I am disappointed in myself

I dislike myself

8. Self-Criticalness

I don't criticise or blame myself more than usual

I am more critical of myself than I used to be

I criticise myself for all of my faults

I blame myself for everything bad that happens

9. Suicidal Thoughts or Wishes

I don't have any thoughts of killing myself

I have thoughts of killing myself, but I would never carry them out

I would like to kill myself

I would kill myself if I had the chance

10. Crying

I don't cry anymore than I used to

I cry more than I used to

I cry over every little thing

I feel like crying, but I can't

11. Agitation

I am no more restless or wound up than usual

I feel more restless or wound up than usual

I am so restless or agitated that it's hard to stay still

I am so restless or agitated that I have to keep moving or doing something

12. Loss of interest

I have not lost interest in other people or activities

I am less interested in other people or things than before

I have lost most of my interest in other people or things

It's hard to get interested in anything

13. Indecisiveness

I make decisions about as well as ever

I find it more difficult to make decisions than usual

I have much greater difficulty in making decisions than I used to

I have trouble making any decisions

14. Worthlessness

I do not feel I am worthless

I don't consider myself as worthwhile and useful as I used to

I feel more worthless as compared to other people

I feel utterly worthless

15. Loss of Energy

I have as much energy as ever

I have less energy than I used to have

I don't have enough energy to do very much

I don't have enough energy to do anything

16. Irritability

I am no more irritable than usual

I am more irritable than usual

I am much more irritable than usual

I am irritable all of the time

17. Concentration Difficulty

I can concentrate as well as ever

I can't concentrate as well as usual

It's hard to keep my mind on anything for very long

I find I can't concentrate on anything

18. Tiredness or Fatigue

I am not more tired or fatigued than usual

I get more tired or fatigued more easily than usual

I am too tired or fatigued to do a lot of the things I used to do

I am too tired or fatigued to do most of the things I used to do

19. Loss of Interest in Sex

I have not noticed any recent change in my interest in sex

I am less interested in sex than I used to be

I am much less interested in sex now

I have lost interest in sex completely

20. Changes in Sleeping Pattern

I have not experienced any change in my sleeping pattern

I sleep somewhat more than usual

I sleep somewhat less than usual

I sleep a lot more than usual

I sleep a lot less than usual

I sleep most of the day

I wake up 1-2 hours early and can't get back to sleep

21. Changes in Appetite

I have not experienced any change in my appetite

My appetite is somewhat less than usual

My appetite is somewhat greater than usual

My appetite is much less than before

My appetite is much greater than usual

I have no appetite at all

I crave food all the time

