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The Relationship between Disturbed Sleep and Cognitive

Functioning during Pregnancy: An Exploratory Study

& Clinical Research Portfolio

PART ONE

(Part Two bound separately)

Mrs Kirsty Horne,

BSc (Hons), MSc.

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

Faculty of Medicine Graduate School

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I would like to thank everyone who has helped me achieve my goals. Thank you firstly to my parents for all their support and encouragement throughout the years. I'm sorry you're not here to see me become a doctor Dad, but believe me, it's you that has kept me going through some very difficult times. I always admired your strength and determination and because you instilled in me the belief that anything was possible, failure was never an option.

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Chapter One

Systematic Review

Should I Leave My Baby to 'Cry It Out'? A Systematic Review of Extinction for Infant Sleep Disturbance

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Background: Infant sleep disturbance (ISD) is a common problem, with 20-30% of families reporting problems with night settling and waking in their infants. Research has linked ISD with infant insecurity, difficult temperament and longer-term sleep and behavioural problems. Although extinction or 'planned ignoring' is widely endorsed in the treatment of ISD, many parents find it difficult to ignore their infant's distress and have difficulty following through with the procedure. As a result, various modifications to the procedure have been developed. Although there is a growing evidence base for extinction and its variants in the treatment of ISD, research to date has failed to separate younger from older infants, therefore, failing to take account of important developmental differences. The current review examined the existing evidence for the use of extinction techniques for treating ISD in infants aged 6-24 months and aimed to determine whether any adverse effects or associated difficulties with implementing the procedures had been documented.

Methods: Multiple databases from Ovid and EBSCOhost were searched from the earliest entries until April 2010. Key journals were hand searched. Eligible studies were reviewed systematically and evaluated using a purpose-designed quality protocol.

Results: Eleven studies were eligible for inclusion in the review; the majority were rated as high quality. Extinction techniques were found to be effective in the treatment of 6-24 monthold infants with disturbed sleep and although occasionally resulted in a post extinction response burst (PERB), no other adverse effects of using the procedures were documented. The majority of parents were satisfied with the interventions provided and reported finding the techniques helpful, despite some difficulties with implementation and adherence being reported.

Conclusions: The current review provides support for the use of extinction techniques in the treatment of ISD in 6-24 month-old infants. Methodological considerations and limitations

are discussed, as are implications of the findings for clinical practice and suggestions for future research.

Keywords: Infant sleep disturbance, extinction, efficacy, adverse effects, difficulties.

Abbreviations: ISD: Infant sleep disturbance; SBS: Sleep Behaviour Scale; PERB: post extinction response burst; RCT: randomised controlled trial; VAR: voice-activated relay.

Infant sleep disturbance (ISD) is a term used to describe various sleep difficulties occurring in infancy, including long delays in initial sleep onset, crying and oppositional behaviour during settling to sleep (sleep-onset delay) and chronic repeated wakening with difficulty returning to sleep alone (night waking). ISD is a common complaint, with 20-30% of families reporting problems with sleep-onset delay and night waking (Burnham, Goodlin-Jones, Gaylor & Anders, 2002; Mindell, 1999). Although the majority of healthy normally developing infants sleep through the night by approximately six months of age (Stores, 2009), many families continue to experience problems beyond this age.

Infant sleep disturbance has been found to impact on the family as a whole. For example, it has been correlated with infant insecurity (Elizabeth, 1988), difficult infant temperament (Halpern, Anders, Garcia-Coll & Hua, 1994; Minde, et al., 1993), poor maternal mental health (Armstrong, Van Haeringen, Dadds & Cash, 1998; Hiscock & Wake, 2001; Mindell & Durand, 1993), marital discord (Richman, 1981) and family stress (Ferber, 1987). Infant sleep disturbance has also been correlated with long-term infant sleep and behavioural problems (Pollock, 1992; Thunström, 2002; Zuckerman, Stevenson & Bailey, 1987).

Behavioural techniques such as scheduled awakenings, stimulus control and extinction have been developed to help improve sleep in infants and children. Extinction, otherwise known as planned ignoring or letting the infant "cry it out", is based on operant conditioning and refers to the decline of an operant response when it is no longer reinforced in the presence of its discriminative stimulus. Extinction is observed after the withholding of reinforcement for a previously reinforced behaviour, which decreases the future probability of that behaviour. As some researchers have suggested that parental attention may shape and inadvertently reinforce infants' waking and crying (Owens, Palermo & Rosen, 2002), extinction is currently the most widely endorsed technique. In the context of ISD, extinction involves putting the infant to bed at a designated time and ignoring them until a set time the following morning. The aim is to modify parental responses to infant crying at bedtime and through the night, therefore withdrawing positive reinforcement of this behaviour and teaching the infant to return to sleep without parental attention.

The majority of research examining the use of extinction for infant sleep disturbance has found it to be highly effective in comparison to other methods (e.g. France, 1992; France, Blampied & Wilkinson, 1991; Hiscock & Wake, 2002). It has been found to work quickly (Reid, Walter & O'Leary, 1999) and although the technique is sometimes condemned by popular literature due to the distress observed in infants during implementation (Sears, 1985; Hogg, 2001; Pantley, 2002), the majority of empirical studies report no adverse consequences of the procedure. In fact, some studies examining other aspects of infants' behaviour following the use of extinction techniques, have reported positive effects, including improved infant daytime behaviour, improved family well-being and decreased stress in parenting (France, 1992; Reid et al., 1999).

One drawback, however, is that the procedure often results in an increase in the variability, frequency and intensity of responding, known as the post extinction response burst (PERB) prior to a decrease in the target behaviour, which can result in implementation difficulties (Lerman & Iwata, 1995; Skuse, 1994). The PERB occurs because the infant's cries, which are normally reinforced by parental attention, are no longer being reinforced, resulting in the infant initially crying more intensely, for longer, in an attempt to gain attention before eventually giving up. Parents often report finding it difficult to ignore their child's distress

and often do not follow-through with the technique (France, 1994; Rickert & Johnson, 1988; Johnson, 1991; Tse & Hall, 2007).

As a result of these difficulties, graduated extinction, involving various modifications of extinction, has been developed. The most common form of graduated extinction is known as 'controlled crying' and involves instructing parents or carers to put their infant to bed and then to ignore their distress for progressively longer time periods, whilst periodically checking on them. The parents are instructed not to pick up the child or have any physical contact with them. As in unmodified extinction, the aim is for the infant to develop self-soothing abilities and learn to settle themselves to sleep without assistance, which although may take longer due to the more gradual nature of the de-conditioning process, has been found to be more acceptable to parents and carers as it allows them to gradually withdraw reinforcement of the behaviour without abandoning the infant (Eckerberg, 2002). Standard instructions for extinction and its variants in the treatment of ISD are presented in Table 1.

Table 1 Standard instructions for extinction techniques

- Unmodified extinction: Put your child to bed at a set bedtime and do not enter their bedroom until morning unless they are ill or in danger.
- **Graduated extinction**:
- **Controlled crying/controlled comforting/minimal parental check**: Enter bedroom for a brief period when infant cries, provide reassurance (in neutral tone of voice), check for signs of illness or danger then leave the room. Wait progressively longer periods of time between checks (e.g. 5, 10, 15 minutes).
- **Systematic ignoring**: Check the infant briefly during crying on settling or awakening at fixed pre-set intervals (e.g. every 5 minutes) in order to reassure/ restore sleeping position.
- **Parental presence/co-sleeping**: Lie down in a separate bed in the infant's room during crying on settling and awakening. Feign sleep and do not attend to the infant directly.
- **Camping out**: Sit with the infant until he/she falls asleep and gradually remove your presence (over a pre-determined period of time).

Although there is a growing evidence base for the use of extinction and its variants for ISD, the majority of research has failed to separate infants under the age of two years from older children and has focused on behavioural interventions for sleep problems in infants *and* young children, often up to the age of five (e.g. Mindell, Kuhn, Lewin, Meltzer & Sadeh, 2006; Ramchandani, Wiggs, Webb & Stores, 2000), despite clear developmental differences in the organisation of sleep stages within this age range (Durmer & Chervin, 2007).

The present review will examine the existing evidence for the use of extinction techniques in treating ISD (including sleep-onset delay and night waking) in infants aged between 6 and 24 months. This age range was selected as firstly, infants under the age of 6 months normally require to be fed through the night and developmentally are not expected to sleep through the night prior to this age (Stores, 2009) and secondly, from the age of two years, children's developing cognitive and language abilities make them more able to benefit from other operant conditioning programmes, involving the provision of positive reinforcement (e.g. praise, 'star charts', etc.) for desirable behaviour, making these more appropriate treatments for older infants and children (France & Hudson, 1993).

The systematic review will firstly examine the effectiveness of extinction and its variants for treating ISD in 6-24 month-old infants. Secondly, the review will ascertain whether any associated adverse effects of using the procedure or implementation difficulties have been reported.

Methods

Search Strategy and Sensitivity Analysis

The following databases were searched:

OVID

- Medline (1950-April 2010)
- Embase (1947- April 2010)
- All EBM Reviews (Cochrane DSR, ACP Journal Club, DARE, CCTR) (until April 2010)
- British Nursing Index and Archive (1985- April 2010)
- ERIC (1965- April 2010)
- Maternity and Infant Care (1971- April 2010)

EBSCOhost

- CINAHL (1981- April 2010)
- Health Source Nursing/Academic Edition (1960- April 2010)
- International Bibliography of the Social Sciences (1951- April 2010)
- Professional Development Collection (1965- April 2010)
- PsycARTICLES (1894- April 2010)
- Psychology & Behavioral Sciences Collection (1965- April 2010)
- PsycINFO (1806-April 2010)
- SocINDEX (1908- April 2010)

Criteria for including and excluding studies

The following inclusion and exclusion criteria were applied:

- Include healthy, normally developing infants between 6 and 24 months of age, who have disturbed sleep (sleep-onset delay and/or night waking)
- Examine the use of extinction techniques (modified or unmodified) for ISD
- Primary outcome related to ISD (e.g. time to settle, frequency and duration of night waking)
- Published in a peer-reviewed journal

Research examining infants with health problems, parasomnias, sleep apnoea, developmental delay or disabilities was excluded, as was research presented in languages other than English. Reviews and discussions papers were excluded; however, no limitations were placed on study design or date of publication.

Search Terms

The following search terms were used:

[Extinction] or [controlled crying] or [controlled comforting] or [graduated extinction] or [cry* it out] or [ignoring] or [ignore] or [stop*] or [treat*] or [improv*] or [behavio?r* management] or [behavio?r* treatment] or [behavio?r* intervention] or [behavio?r* program*] or [behavio?r* technique*] or [behavio?r* method*] or [behavio?r* modification*] or [behavio?r* strateg*]

And

[Infan*] or [child] or [children] or [childhood] or [toddler*] or [pre-school] or [neonate*] or [newborn*] or [p?ediatric*]

And

[Sleep*] or [settling] or [bedtime] or [night* wak*] or [night awak*] or [night* crying] or [nocturnal crying] or [nocturnal awakening*] or [nocturnal wak*] or [disturbed sleep] or [insomnia*]

Not

[autis*] or [disab*] or [down*] or [intell*] or [impairment*] or [special needs] or [neurodev*] or [preterm] or [illness] or [disease] or [death] or [epilep*] or [lesion*] or [asthma] or [pain] or [cold*] or [reflux] or [terror*] or [adenot*] or [apn?ea] or [breathing] or [obstruct*] or [hypoventilation] or [dysplasia] or [rhinitis] or [hyperactiv*] or [ADHD] or [bipolar] or [obsessive] or [OCD] or [melatonin] or [adolescent*]

An independent rater assessed the search strategy and assessed a selected sample of studies for eligibility. A diagram of the search strategy is presented in Appendix 2.1.

Data Extraction Form

A data extraction form (see Table 2) was devised in order to facilitate comparisons across study design, methodology, outcomes and other aspects deemed to be important and relevant for the current review. This process also aided with development of the quality assessment protocol. Given the heterogeneity of the study designs, interventions and outcome measures used, as is apparent from the data extraction form, it was not possible to perform a meta-analysis.

Study and quality rating (%)	Sample N, gender, age range	Recruitment strategy	Design	Intervention	Outcomes	Assessment method	Follow -up	Stats	Results	Adverse effects/ Implementation difficulties	Limitations
Chadez & Nurius 1987 (60%)	$N=1, \mathcal{Q},$ 7 months	Not reported	Single subject ABAB (quasi- experimental)	Extinction implemented by parents and cognitive restructuring	Sleeping alone in crib through the night 90% of the time	Diary	6, 12 months	Proportion frequency and Shewart chart procedure	In own cot p<.001. Sleeping through night 90% time. Crying reduced. Combined treatment better	Worry, fear, uncertainty, difficulty	Single subject
Durand & Mindell 1990 (76%)	N=1, ♀, 14 months	Advert placed in local newspaper	Single subject multiple baseline across sleep problems	Graduated extinction implemented by parents	Bedtime, frequency & duration night waking, parental depression, marital satisfaction	Video recording, diary, BDI	1, 2, 9 months	Visual analysis, means, range	Earlier bedtime, frequency & duration night waking, maternal depression decreased, increased marital satisfaction	None reported	Single subject
France & Blampied 2005 (76%)	N=14, 5 ♀, 9 ♂, 6-15 months	Referred to infant sleep clinic for help with ISD	Single subject multiple baseline	Extinction or graduated extinction with parental checking or parental presence	Frequency & duration night waking/crying, parental attention	Video recording, diary	none	Visual analysis, means, range	Frequency wakening decreased in all groups. Group with parental checking resulted in most crying and waking	Not assessed/ reported upon	Small n in each group, variability in individual results
France & Hudson 1990 (80%)	N=7, 2 ♀, 5 ♂, 8-20 months	Referred by nurse due to ISD	Single subject non-concurrent multiple baseline	Extinction and stimulus control implemented by parents	Frequency and duration of night waking	Recording devices (n=3), diary, SBS	3, 24 months	Visual analysis, means, range	Frequency and duration of night waking decreased for all participants	One parent had difficulty when child was ill. Some initially resistant	Not enough detail on stimulus control. Not evaluated separately

Table 2 Data extraction form

Study and quality rating (%)	Sample N, gender, age range	Recruitment strategy	Design	Intervention	Outcomes	Assessment method	Follow -up	Stats	Results	Adverse effects/ Implementation difficulties	Limitations
Healey, France, & Blampied 2009 (88%)	$ \begin{array}{c} N=7, \\ 3 \bigcirc , 4 \swarrow , \\ 6-20 \\ months \end{array} $	Not reported	Single subject multiple baseline across settings & subjects	Graduated extinction (at bedtime alone then through night also) and stimulus control by parents	Frequency and duration of night waking, sleep onset latency, 'ISD' score	Video recording, diary, parent evaluation questionnaire	3 months	Visual analysis, means, range	Decrease in sleep problems for 5/7 infants (only consistent when intervention was also used throughout night)	Parents found intervention helpful, non- stressful and were satisfied with it	Recruitment process not described. Didn't evaluate stimulus control separately
Hiscock & Wake 2002 (88%)	N=156, 79 ♀, 89 ♂, 6-12 months	Attended routine screening assessment and reported ISD	RCT	Graduated extinction or camping out, or information alone (and stimulus control)	Sleep problem (presence and severity), infant temperament, maternal depression, marital satisfaction	Sleep problem- yes/no, diary, EPDS	4 months	χ ² , independent t-tests, Mann- Whitney U tests, multiple regression	Fewer sleep problems in intervention group at 2 but not 4 months. Maternal depression decreased in treatment group	The majority of parents found intervention helpful. It did not increase stress.	No objective measures.
Hiscock et al. 2007 (84%)	N=328, 150 ♀, 178 ♂, 6-12 months	Nurses invited mothers of 4 month- olds attending health visit to take part	RCT (cluster randomised trial)	Graduated extinction or camping out, with information, or 'treatment as usual'	Sleep problem (presence and severity), infant temperament, maternal depression, health and sleep quality, costs	Sleep problem- yes/no, diary, Global Infant Temperament scale, EPDS, SF-12	4 months	Mean difference, odds ratios, random effects linear regression, logistic regression	Prevalence sleep problems lower and maternal depression decreased in treatment group. Treatment group cost less	Mothers were satisfied with intervention and found it helpful	No objective measures. No details of 'treatment as usual'
Lawton, France & Blampied 1991 (80%)	N=6, $4 \bigcirc, 2 \circlearrowleft,$ 6-14 months	Approached sleep programme for help	Single subject non-concurrent multiple baseline across subjects	Graduated extinction and stimulus control	Frequency and duration of night waking, sleep onset latency	Recording device, evaluation questionnaire, diary, SBS	2 months	Visual analysis, means, range	3 participants had significant decrease in frequency & duration night waking, 1 decreased duration night waking only	Parents found treatment somewhat- moderately stressful, evidence of non-adherence & response burst	

Study and quality rating (%)	Sample N, gender, age range	Recruitment strategy	Design	Intervention	Outcomes	Assessment method	Follow -up	Stats	Results	Adverse effects/ Implementation difficulties	Limitations
Leeson et al. 1994 (60%)	N=23, 10 ♀, 13 ♂, 8-12 months	All parents of 8-12 month-olds requesting help for ISD in 6 month period	Uncontrolled trial	Graduated extinction and stimulus control, swaddling and decrease night feeds	Frequency and duration of night waking, number feeds, parental depression, infant behaviour	Diary, CES-D, questionnaire about stress and changes	1, 3 months	Paired t- tests	Frequency & duration night waking, no. night feeds decreased (p<.001), maternal depression decreased	3 mothers did not persist with treatment in long- term. Qualitative information on parental satisfaction	No control group
Sadeh 1994 (72%)	N=50, 22 ♀, 28 ♂, 9-24 months	Referred to sleep disorders centre for night waking problems	Randomised uncontrolled trial	Graduated extinction or parental co- sleeping	Frequency of night waking, sleep onset time, sleep duration, sleep %	Recording device, diary	none	ANOVA	Reduced frequency night waking and increased sleep % in both groups. No significant difference between groups	6 parents reported treatment was ineffective or very limited positive effect	No control group
Thunström 2000 (80%)	N=27, 11 ♀, 16 ♂, 6-11 months	Parental questionnair e population study	Non- randomised controlled trial	Graduated extinction and family work and stimulus control	Frequency and duration of night waking, total sleep time	Diary and questionnaire	1 year, 2.5 years	χ², ANOVA	Decreased night waking at 1 month, increase in total sleep. Maintained at f/u	3 parents did not agree with treatment and declined to take part. 92% were satisfied with the advice and support	Other family problems were addressed but doesn't detail how. No control with ISD

Key for abbreviations: BDI: Beck Depression Inventory; CES-D: Center for Epidemiologic Studies Depression Scale; EPDS: Edinburgh Postnatal Depression Scale; SBS: Sleep Behaviour Scale; SF-12: Short Form Health Survey (12-item).

Quality Assessment Protocol

Quality of studies included in the review was assessed using a purpose-designed rating protocol (see Appendix 2.5). The protocol was adapted from existing guidelines, such as the revised version of the Scottish Intercollegiate Network 'SIGN 50: A guideline developer's handbook' (SIGN, 2004) and the Single-Case Experimental Design Scale (SCED, Tate et al., 2008) and assessed study objectives, recruitment, sample, design, intervention, outcomes, analyses and results, which were all areas deemed to be important in assessing the quality of studies included in the current review.

Responses for the majority of the 22 questions were rated 0 (no) or 1 (yes). Three items were scored 0, 1 or 2; further guidance was provided on the protocol for scoring these items. The protocol resulted in a possible score of 25 and was then converted into a percentage score for ease of comparison. An independent rater assessed the quality of 6 studies; disagreements were resolved by discussion. Using an arbitrary rating system, studies were classified as high quality if they scored \geq 70%, moderate if they scored 40-69% and low if they scored \leq 39%.

Results

Following removal of duplicates, the search identified 168 studies. On the basis of the titles, 129 studies were excluded due to including infants less than 6 months, or more than 24 months of age, not examining behavioural treatment of ISD, the primary outcome not being related to ISD, being presented in a language other than English or being a review/discussion paper. Of the 39 studies in which full text was reviewed, a further 29 were excluded for similar reasons and for not examining extinction techniques. Reference lists of all reviewed studies were examined for relevant papers, resulting in an additional 11 studies subsequently being reviewed and 10 of these being excluded. Key journals were hand-searched and key

authors were contacted. No further studies were identified. Eleven studies therefore fitted inclusion criteria for the current review. Studies included in the current review are listed in Appendix 2.2 and are identified by an asterisk in the reference list. Excluded studies are listed in Appendix 2.4.

Quality ratings for the 11 studies ranged from 60% to 88%. The mean rating for the 11 papers was 77.8% (SD=8.1), with an inter-rater agreement of 83.3% (perfect agreement on 5 out of 6 studies). Ten studies were rated as high quality and one was rated as moderate quality. These data are presented in Appendix 2.2 and Table 2. Included studies will now be reviewed according to each area assessed by the quality rating protocol. A discussion and conclusion will then be presented.

Study Objectives

The majority of studies used appropriate and clearly defined objectives, which were predominantly to evaluate the use of behavioural interventions in treating ISD. Some studies included secondary aims, such as evaluating the effects of ISD and its treatment on parents and evaluating costs of treatment to the healthcare system (e.g. Durand & Mindell, 1990; Hiscock & Wake, 2002; Hiscock et al., 2007). Other studies also examined factors such as the presence of a PERB and intermittent reinforcement by way of parental attention (e.g. France & Blampied, 2005). Healey, France and Blampied (2009) attempted to ascertain whether 'bedtime changes' would generalise to later night waking when the intervention was firstly only implemented at bedtime, whereas Chadez and Nurius (1987) explored the effects of extinction for bedtime crying, whilst also addressing potential intervening covert variables, related to parents' beliefs associated with using extinction techniques.

Sample and Recruitment

In line with the inclusion criteria, all studies included infants between the ages of 6 and 24 months. Only two studies, using relatively large sample sizes (N=156, N=328, respectively), reported power calculations to justify their sample size (Hiscock & Wake, 2002; Hiscock et al., 2007). The remaining studies were limited by relatively small sample sizes ranging from 1-50 (mean, N=15). One study acknowledged that their small sample size (N=14) limited the generalisability of results (France & Blampied, 2005).

Eight of the 11 studies used slightly more male than female infants. One study failed to provide demographic information (Chadez & Nurius, 1987). All remaining studies provided sufficient participant and demographic characteristics. The majority reported birth order of the infant, parental relationship status and employment type, or estimated socioeconomic status (SES). Others also reported details of previous management strategies employed, sleeping arrangements and feeding method.

The majority of studies provided sufficient detail on the type of sleep disturbance under investigation and also reported upon any periods of illness during intervention periods. Six studies examined infants with sleep-onset delay and night waking (Chadez & Nurius, 1987; Durand & Mindell, 1990; Healey, France & Blampied, 2009; Hiscock & Wake, 2002; Lawton, France & Blampied, 1991; Thunström, 2000). One of these also reported upon an infant who refused to sleep alone in their crib (Chadez & Nurius, 1987). Four studies used infants who had problems with night waking only (France & Blampied, 2005; France & Hudson, 1990; Leeson, Barbour, Romaniuk & Warr, 1994; Sadeh, 1994).

Only four studies explicitly stated both the inclusion and exclusion criteria (France & Hudson, 1990; Healey, France & Blampied, 2009; Hiscock & Wake, 2002; Thunström, 2000). Two studies stated exclusion criteria only (France & Blampied, 2005; Hiscock et al., 2007) and two stated inclusion criteria only (Lawton, France & Blampied, 1991; Sadeh, 1994). Three studies scoring at the lower range using the quality protocol, failed to explicitly state either the inclusion or exclusion criteria (Chadez & Nurius, 1987; Durand & Mindell, 1990; Leeson et al., 1994). It is important to report this information to facilitate comparison with other studies, to aid with study replication and to help determine generalisability of study results.

As can be seen in Table 2, two studies failed to describe the recruitment process clearly (Chadez & Nurius, 1987; Healey et al., 2009). The remaining studies varied in their recruitment method, although all utilised convenience sampling. Five studies recruited infants from a sleep clinic (France & Blampied, 2005; France & Hudson, 1990; Lawton, France & Blampied, 1991; Leeson et al., 1994; Sadeh, 1994), two recruited infants attending routine health/screening appointments (Hiscock & Wake, 2002; Hiscock et al., 2007), one recruited by placing an advert in a local paper (Durand & Mindell. 1990) and one used a population survey (Thunström, 2000). Selection or sampling bias may be introduced when using convenience samples, therefore reducing the external validity of findings.

Only four studies reported response rates (Hiscock & Wake, 2002; Hiscock et al., 2007; Leeson et al., 1994; Thunström, 2000), which were generally high, ranging from 67% (Hiscock & Wake, 2002) to 95% (Leeson et al., 1994). However, due to the remainder of studies not reporting response rates, the number of potential participants declining to take part and possible reasons for doing so are unknown.

Study Design

Two studies used randomised controlled trials (RCTs) (one of which was a clusterrandomised trial) (Hiscock & Wake, 2002; Hiscock et al., 2007), one used a non-randomised controlled trial (Thunström, 2000), one used a single subject quasi-reversal design (Chadez & Nurius, 1987), five used multiple baseline designs (Durand & Mindell, 1990; France & Blampied, 2005; France & Hudson, 1990; Healey, France & Blampied, 2009; Lawton, France & Blampied, 1991) and two used uncontrolled trials (Leeson et al., 1994; Sadeh, 1994).

Studies using RCT designs scored at the upper end using the quality assessment protocol, as these designs are considered the 'gold standard' and increase the credibility as a basis from which to draw conclusions (Armstrong, Waters & Doyle, 2008). In the context of infant sleep, it is important that interventions are evaluated against a control group, due to the impact of basic developmental changes affecting infant sleeping patterns over time. This ensures that any maturational changes are controlled for, and not misinterpreted as treatment effects (Wolfson, Futternman & Lacks, 1992). Well-designed single-subject designs (in which, each participant serves as his or her own control, with performance prior to an intervention being compared to performance during and/or after intervention) and non-randomised controlled trials, although not as sophisticated as RCTs, were also rated as high quality designs, whereas uncontrolled trials (Leeson et al., 1994; Sadeh, 1994) were deemed to be of poorer quality and therefore scored in the lower range using the assessment protocol. Leeson and colleagues (1994) provided justification for not using a control group, mainly due to ethical reasons.

All studies obtained adequate baseline data, either in the form of a questionnaire or sleep diary, prior to interventions being implemented. However, some studies demonstrated considerable variability of the dependent variables during baselines (e.g., France & Blampied, 2005; Healey et al., 2009), which limited the ability to document an effect following intervention. Measurement of the dependent variable during baseline should occur until the pattern of responding observed is stable enough to allow prediction of future responding (Horner et al., 2005).

Two studies failed to obtain follow-up data and therefore did not examine the longer term impact of the interventions implemented (France & Blampied, 2005; Sadeh, 1994). The remaining studies varied in the number and time of follow-up periods used, ranging from one month to 30 months (see Table 2).

Intervention

The majority of studies provided a clear description and rationale for the interventions used, detailed the amount of support and training provided and the timing of different treatment components; all were deemed appropriate to the study objectives. Interventions were predominantly implemented by parents, with varying amounts of advice and support from other professionals being provided. The majority of studies provided initial face-to-face consultations, three included additional consultations (Hiscock & Wake, 2002; Hiscock et al., 2007; Sadeh, 2004) and five also provided regular ongoing telephone contact with participants (France & Blampied, 2005; France & Hudson, 1990; Healey, France & Blampied, 2009; Lawton, France & Blampied, 1991; Thunström, 2000). Only two studies reported providing warnings to parents about the possibility of experiencing a PERB (France & Blampied, 2005; France & Hudson, 1990).

One study investigated the success of an intervention provided in a short-stay residential unit (although 40% of participants were not admitted to the unit, as they were able to implement the programme at home) (Leeson et al., 1994). The remaining studies all involved interventions being carried out at home.

As can be seen in Table 2, three studies examined the use of unmodified extinction in comparison to, or in conjunction with other methods (Chadez & Nurius, 1987; France & Blampied, 2005; France & Hudson, 1990). The study by Chadez and Nurius (1987) was unique in that it examined the effectiveness of extinction techniques in conjunction with cognitive re-structuring. Extinction was initially implemented alone; however, due to adherence difficulties, training in cognitive restructuring was then provided; the amount of time allocated to this element was not detailed. The next phase of the intervention involved the use of extinction techniques in conjunction with cognitive techniques. In this phase, the mother was permitted to check if the infant was wet or hungry if crying persisted for longer than 15 minutes. It is unclear whether this was permitted during this first phase; if so, it could be argued that the intervention would be more appropriately described as graduated extinction or systematic ignoring, as it involved systematically checking the infant. It is also unclear whether both parents were permitted to periodically check the infant, or only the mother. No details of further support or monitoring by the researchers were reported for the second phase. This study would have scored higher if it had provided sufficient details of the intervention used and the amount of time/ support provided to parents.

France and Blampied (2005) compared the effects of using unmodified extinction with two forms of graduated extinction, whereas France and Hudson (1990) evaluated the effects of using unmodified extinction and stimulus control on ISD. Parents in the latter study were instructed to use their 'usual bedtime routine', as opposed to being given a standard routine to follow, hence it is possible that considerable variation may have existed in the stimulus control element of the intervention.

Eight studies examined graduated extinction, either in the form of controlled crying, parental presence or 'camping out' (techniques are described in Table 1). Variation in controlled crying procedures existed across studies, with studies differing in their definition of 'neutral' or 'minimal' interactions, in the time spent checking the infant and in the time intervals between checks. In the study by France and Blampied (2005) the researchers described minimal interaction during parental checking, as "speaking gently, stroking the infant's head and lying him/her down." It is questionable whether stroking an infant's head would be considered 'minimal' interaction; this interaction could in fact be providing intermittent reinforcement of the infant's night waking.

Some studies recommended checking the infant every five or ten minutes (e.g., France & Blampied, 2005; Hiscock & Wake, 2002; Sadeh, 1994), whereas others recommended waiting for progressively longer time periods between checks, some also increasing this time period on subsequent nights (e.g., Durand & Mindell, 1990; Healey et al., 2009; Hiscock et al., 2007; Leeson et al., 1994; Thunström, 2000). Lawton, France and Blampieds' study (1991) aimed to gradually reduce the average amount of time the parent spent attending to the infant on each awakening (recorded from baseline data) throughout the course of the study. Of these studies, time spent reassuring the infant varied from 15-30 seconds in one study to up to two minutes in another. Others failed to specify exactly how long the parent was permitted to spend reassuring the infant.

Extinction techniques were often implemented along with other components such as positive bedtime and daytime routines, implementing set bed and rising times, disallowing the infant to sleep anywhere other than their bed (Healey et al., 2009; Hiscock & Wake, 2002; Lawton et al., 1991; Leeson et al., 1994; Thunström, 2000), swaddling (Leeson et al., 1994), family work (Thunström, 2000), providing information on reducing night feeds and managing problems with soothers (Hiscock & Wake, 2002; Hiscock et al., 2007; Leeson et al., 1994). These additional components or the support provided by the researchers were rarely examined or evaluated separately from the extinction components.

In two high quality studies, extinction techniques were compared with controls, which consisted of receiving information on normal sleep patterns, without specific advice on managing ISD (Hiscock & Wake, 2002) or 'usual care' (Hiscock et al., 2007), although no detail was provided regarding what this entailed. Another randomised study compared graduated extinction with parental co-sleeping, however, failed to include an untreated control group (Sadeh, 1994).

Outcomes

All studies reported outcomes measures that were precise, repeatable and operationally defined (summarised in Table 2). Eight studies reported frequency and duration of night waking as the main outcomes. Other outcomes included time of going to bed, sleep onset time, sleep onset latency, total sleep time, sleep efficiency, sleeping alone in the crib through the night, parental attention, presence or not of a 'sleep problem', severity of 'sleep problem' and number of night feeds. As can be seen in Table 2, some studies examined additional outcomes unrelated to ISD, including parental depression, maternal stress and coping, maternal health, maternal sleep quality, marital satisfaction and treatment costs.

Assessment Methods

Five studies used subjective measures only (diary and/or questionnaire) to assess sleeprelated outcomes (Chadez & Nurius, 1987; Hiscock & Wake, 2002; Hiscock et al., 2007; Leeson et al., 1994; Thunström, 2000). Three of these studies used subjective reports from the mother only; the other two studies did not clearly state whether one or both parents completed measures. Although sleep diaries have been demonstrated to be a reliable measure of night waking and crying (e.g. France et al., 1991), they are vulnerable to response bias and reporting inaccuracies, particularly so when required to be completed during respondents' usual sleep period (Sadeh, 1994).

Six studies used recording devices such as video recording, actigraphic devices or voiceactivated relays (VARs) connected to event recorders, with a microphone close to the infant's head and a floor switch-mat placed on the floor next to the infant's bed (designed to detect movement of the infant or parent) to assess the reliability of subjective measures (Durand & Mindell, 1990; France & Blampied, 2005; France & Hudson, 1990; Healey et al., 2009; Lawton et al., 1991; Sadeh, 1994). However, these devices can also be problematic, in that actigraphic devices and VARs can result in false positives or false negatives depending on their settings, and switch-mats designed to detect movement of the child or parent around the bed are easy to avoid.

Adverse effects

Due to reports in popular media regarding the potential adverse effects of using extinction techniques and the consequent fears many parents have of using these approaches, it was deemed important that studies attempted to assess other aspects of infant's behaviour that might be affected by the use of extinction procedures. However, many studies failed to do so.

Two studies recorded duration of crying as a measure of infant distress (France & Blampied, 2005; Healey et al., 2009) and one assessed infant behaviour (by rating whether infants were 'asleep', 'awake and happy', 'crying' or 'screaming') (Leeson et al., 1994).

Maternal ratings of infant temperament were assessed in two high quality studies using a validated 5-point infant temperament scale (Hiscock & Wake, 2002; Hiscock et al., 2007). However, subjective maternal ratings of infant temperament can be problematic, in that mothers, who may be depressed and fatigued (e.g. Leeson et al., 1994) can overestimate difficulties in their infant's temperament. Alternatively, a positive response bias can occur due to mothers being aware of their group allocation and wishing to please the researchers.

Implementation difficulties

One study used videotapes to assess difficulties with treatment implementation (Durand & Mindell, 1990). Although the remainder of studies did not directly assess implementation difficulties, many assessed related aspects, such as acceptability, satisfaction, usefulness, stressfulness and ease of use of the techniques (France & Blampied, 2005; Healey et al., 2009; Hiscock et al., 2002, 2007). Other studies asked parents to provide general comments and opinions about the programme following completion of the intervention (Leeson et al., 1994; Thunström, 2000). Gathering data on implementation difficulties and satisfaction is important as it can help highlight potential adherence difficulties with the various procedures.

Statistical Analyses

Statistical analyses utilised varied according to study designs and type of data collected; all were appropriate for purpose. Studies using single-subject designs reported the means, range and used visual analyses, which are appropriate for single-subject designs (Logan, Hickman,

Harris & Heriza, 2008). Hiscock et al. (2007) reported odds ratios in their study; however, effect sizes were not reported in any of the other studies.

Results

Attrition. Four studies failed to report attrition rates (Chadez & Nurius, 1987; Durand & Mindell, 1990; France & Hudson, 1990; Sadeh, 1994); however, three of these were single subject designs and had no attrition.

Reliability of subjective data. Levels of agreement between subjective data and recording devices ranged from 40% to 100%, depending on the method used. Sadeh (1994) reported a growing discrepancy between actigraphically detected night awakenings and parental reports, which they suggested was possibly due to parents becoming exhausted by the procedure or being less motivated following positive changes and consequently failing to report occurrences of night awakenings. In a study using video recording to assess the reliability of diary data, it was found that parents consistently reported their infant's bedtime to be, on average, 93 minutes later than the recordings indicated and the time of falling asleep to be 24.5 minutes later than observed (Durand & Mindell, 1990). These discrepancies highlight the importance of using both objective and subjective measures to measure infant's sleep patterns.

Treatment efficacy and adverse effects. Treatment efficacy and adverse effects of the procedures are presented in Table 2 and will now be reported upon, with studies rated as higher quality using the assessment protocol, being presented first. For the purpose of the current review, effect sizes (Cohen's d) were calculated where possible using means and

standard deviations, in order to facilitate comparisons across studies. These data are presented in Appendix 2.3.

Using subjective maternal reports, Hiscock and colleagues (2002, 2007) found significantly more sleep problems had resolved at 2 months in a group receiving either controlled crying or 'camping out', than in a control group. Maternal depression was also significantly better in the intervention groups at two months. These differences remained significant at four-month follow-up in the 2007 study, but not in the 2002 study. In their 2007 study, additional gains included improved maternal health and lower overall treatment costs, in comparison with controls. Maternal rating of infant temperament did not differ significantly between groups following intervention. Similar to other studies, parents in the intervention group were encouraged to use other strategies, such as developing consistent daytime and bedtime routines, reducing night feeds and managing problems with soothers. The efficacy of controlled crying versus camping out was not compared and numbers receiving each of these interventions were not clearly reported. The variability in treatments used by parents in the intervention group limits the reproducibility of the study and precludes interpretation of results. Despite these studies being rated as high quality and using RCT designs, treatment gains were not maintained at four months in the 2002 study and effect sizes, reported as odds ratios, were moderate (OR=0.5) in the 2007 study.

Healey et al. (2009) found clinically significant reductions in sleep problems (defined as a reduction in 'ISD' scores of 50% or greater) for five out of seven infants treated with graduated extinction (controlled crying), initially implemented at bedtime only. However, these reductions were not consistently observed until parents started using the extinction procedure throughout the night also. Observed improvements occurred more slowly than

improvements observed in other studies, which again, implied that implementing treatment at bedtime alone was not as effective as doing so throughout the night also. In addition to using graduated extinction, parents were instructed to set a regular bedtime and positive half-hour bedtime routine. These components of the intervention were not evaluated separately from the extinction procedures. Furthermore, five parents are reported to have modified the procedures to suit their individual circumstances (e.g., by using a set waiting time between checks rather than increasing time intervals), which may also have affected outcomes and complicated interpretation of study findings. As means and standard deviations were not reported, it was not possible to calculate the effect size. Despite these limitations, significant improvements in ISD were evident following treatment and were maintained at follow-up.

Using graduated extinction and positive bedtime routines, Lawton et al. (1991) demonstrated reduced mean scores on the Sleep Behaviour Scale (SBS; Richman, 1981) following intervention and clinically significant reductions in the frequency and duration of night waking in 3 out of 6 infants (defined as improvements in 'ISD' scores exceeding 80% of baseline levels following treatment). A fourth infant substantially reduced duration but not frequency of awakenings. Improvements in 'bedtime delay' were also evident for the five infants for whom this was a problem. Gains were maintained at two-month follow-up. Despite some success following treatment, several infants exhibited PERBs and considerable variability in treatment response was evident.

In a controlled trial, Thunström (2000) found that graduated extinction, stimulus control techniques (day and night routines, separating feeding and sleep times) and 'family work' resulted in decreased frequency of night waking (d=1.7), decreased duration of night waking (d=1.68) and increased total sleep time (d=0.83) in 27 infants. At follow-up periods of one

and 2.5 years, infants' sleep characteristics were not significantly different from healthy, good sleeper controls, implying that changes were stable over time. None of the infants in the treatment group showed signs of anxiety in bedtime settling one year following treatment. However, considerable variability in interventions received was evident. For example, five infants were prescribed sedatives for the first two weeks of the intervention in addition to behavioural techniques. Furthermore, details of the 'family work' provided, or number of participants receiving this, were not reported. The study's internal validity was compromised due to this variability and to the lack of control group of problem sleepers. The author acknowledged that including such a control group could have helped determine whether resolution of ISD would have occurred naturally over time, although highlighted the ethical dilemma this would have posed.

Using unmodified extinction and stimulus control, France and Hudson (1990) demonstrated decreased mean scores on the SBS and decreases in frequency (d=2.36) and duration (d=1.34) of night waking in seven infants following intervention. Gains were maintained at 3 and 24-month follow-up. Given that both extinction and stimulus control were used as interventions, and were not evaluated separately, the precise nature of and basis for the effectiveness of the interventions is unclear.

France and Blampied (2005) found that unmodified extinction, and two forms of graduated extinction (minimal check or parental presence) all led to decreases in night waking. Effect sizes were large for all interventions, however, were higher in the parental presence group (d=2.28) than the minimal check group (d=1.66) or the unmodified group (d=1.56). Infants treated with minimal parental checking exhibited greater variability of response and woke and cried more than the other groups over the intervention period. In addition to infants in the

parental presence group achieving superior results to the unmodified group, they were less likely to experience a PERB, suggesting that parental presence is preferable to parental checking or unmodified extinction in the treatment of ISD. The authors highlighted potential limitations of relying on a small sample size (N=14) and of the variability in individual results.

Durand and Mindell (1990) found that graduated extinction resulted in an earlier bedtime and rapid reductions in the frequency and duration of night waking in a 14-month old infant. Improvements were maintained at 1, 2 and 9-month follow-up periods, although it is possible ISD would have improved over this time period without intervention, as the infant matured. Parental depression and marital satisfaction also improved as a function of the infant's improved sleep pattern.

As part of a residential programme, Leeson et al. (1994) evaluated graduated extinction in conjunction with stimulus control techniques (day and night routines, separating feed and sleep times), swaddling and cessation of night feeds. The intervention resulted in significant decreases in frequency (d=1.87) and duration (d=1.29) of night waking and reductions in night feeding. In addition, parental depression scores significantly decreased and parental perception of infant's behaviour improved. Eighty-six percent of infants continued to sleep well at 3-month follow-up. This study would have been rated as higher quality if a control group had been included for comparison. Due to individual elements of the programme not being evaluated separately and to no control group being used, interpretation of the precise mechanisms of change is not possible.

Sadeh (1994) compared graduated extinction and parental co-sleeping in 50 infants and found that both interventions resulted in reduced frequency of night awakenings (d=1.37) and increased sleep efficiency. No significant differences in outcomes or length of treatment were found between the two interventions. Subjective data indicated that the interventions had completely solved night waking in 68% of infants and had made significant improvements in 20% of infants. Due to the similarity in outcomes between the two interventions and to the absence of a control group, interpretation of specific factors leading to improvements was not possible. As no follow-up data were gathered, longer-term efficacy of the interventions is unknown.

Finally, the use of unmodified extinction alone was unsuccessful in the study by Chadez and Nurius (1987) as the mother had difficulty not overtly responding to the cries of her daughter, due to believing this would make her a bad parent. However, when supplemented with cognitive re-structuring, the techniques proved successful, in that the infant quickly began sleeping through the night 90% of the time, in her own cot. During a treatment withdrawal period, the infant began waking and crying again. However, upon reinstatement of the intervention, returned immediately to a successful sleeping pattern, indicating that the intervention, rather than maturation, was responsible for the change in her sleep pattern. Improvements were maintained at 6 and 12-month follow-up periods. This study would have scored higher if it had provided more detail on the recruitment process, demographics, inclusion and exclusion criteria and used objective methods of assessment in addition to subjective reports.

Implementation Difficulties. When assessing variables related to implementation difficulties, such as acceptability, compliance, satisfaction and usefulness, the majority of studies reported
high satisfaction and compliance with the interventions used. For example, in the study by Leeson et al. (1994), parents reported "drastic changes" and "fantastic improvements". Three mothers stated they had not persisted using the techniques in the long term, and although reasons for not doing so were not reported, the authors stated these families had identified a lot of stresses and changes in their lives.

Healey et al. (2009) found the average ratings of helpfulness and satisfaction on a parent evaluation questionnaire to be high and average ratings for stress to be low. However, as many of the parents modified the techniques, this would suggest the procedures, in their original form, were possibly difficult to implement and not as helpful to parents as the evaluation questionnaires suggest.

Using an evaluation questionnaire, Lawton et al. (1991) also reported a high level of satisfaction. However, five participants found the procedure somewhat stressful and one found it moderately stressful, which possibly negates the principal rationale for the use of graduated extinction. Parents in this study often failed to adhere to the bedtimes they had set for their infants. In addition, one parent never ceased to attend to night waking and another displayed a subtle form of non-adherence by prematurely commencing the maintenance phase of the programme, in which parents were permitted to resume attending to their infants, therefore providing intermittent reinforcement of the waking. Again, these adherence difficulties could be related to difficulty implementing the procedures, which are known to be at least somewhat stressful to some parents.

Hiscock and colleagues (2002, 2007) found that mothers were generally satisfied with strategies used and rated them as useful in treating and coping with their infant's sleep

problem. Over 93% reported finding it helpful to talk to someone; controlled crying was found to be more helpful than camping out.

Despite some studies reporting high satisfaction, difficulties with adherence and dissatisfaction were reported in other studies. For example, in the study by Chadez and Nurius (1987), the mother had difficulty adhering to using extinction techniques due to negative beliefs associated with the techniques. Sadeh (1994) reported that six parents considered the treatment either totally ineffective or as having very limited positive effect. Also, in the study by Thunström (2000), 3 sets of parents disagreed with the premise on which the programme was based, and therefore decided not to take part. However, 25 of the 27 parents undertaking the intervention reported their infants having good sleep after the intervention and were satisfied with the advice and support received.

Finally, France and Hudson (1990) found that some parents were initially resistant to implementing the recommended procedures, although repeated explanations of the procedures and their potential benefits helped. One parent had difficulty distinguishing illness behaviour from cries that did not require attention. However, overall, adherence was found to be high; following their programme, some parents commented that an 'intensive approach' was easier than a more gradual one.

Discussion

The current review aimed to examine the evidence for using extinction techniques in the treatment of sleep disturbance in 6-24 month-old infants. By systematically reviewing the evidence from 11 eligible studies, the review attempted to determine whether extinction techniques were effective, whether there were any documented adverse effects of using the

procedures and whether there were any associated implementation difficulties, which might affect parental compliance with procedures.

Studies in the review varied in their methodological quality, although the majority were deemed to be of high quality using a quality assessment protocol developed specifically for this purpose. Many used small sample sizes, were subject to sampling bias, failed to report response rates, or to include a control group. Others exhibited unstable baseline data or failed to collect follow-up data. Studies varied in the design employed, the outcome variables assessed and in the method of assessment, with many using only subjective measures. Considerable variation also existed in the interventions provided and in the details included. For these reasons, a meta-analysis would not have been feasible.

Despite these methodological considerations, the current review provided support for the use of extinction techniques in the treatment of ISD in 6-24 month-old infants. The majority of studies examined graduated extinction techniques in combination with other techniques, such as stimulus control and family work, and found improvements in ISD both in the short and longer term. In addition to improving infant sleep, graduated extinction was reported to decrease parental depression, increase marital satisfaction, improve maternal health and result in lower overall healthcare costs. The studies examining unmodified extinction, either in conjunction with stimulus control or cognitive re-structuring also resulted in improved sleep, which was maintained longer term. Large effect sizes were evident for the majority of trials in which they were able to be calculated.

Due to the variability in extinction techniques and combinations of techniques examined, it was not possible to determine which type of technique or combinations were more effective in treating ISD in this age group. However, the review found some evidence that graduated extinction in the form of controlled crying, resulted in PERBs (and caused more overall crying than unmodified extinction or parental presence), took longer to work than unmodified extinction and was perceived as stressful by some parents. In addition, difficulties in implementation were reported upon in some studies. Due to unmodified extinction working more quickly and being easier to implement, this might be a more effective treatment for parents not opposed to its use. In one study, some parents who had initially been resistant to using unmodified extinction commented that it was easier to implement than a more gradual approach would have been, suggesting that if the rationale is clearly presented and support and guidance provided, the chances of success may be increased.

A larger effect size was found for parental presence than unmodified extinction or controlled crying in one study. Furthermore, this procedure did not result in a PERB, implying that it was possibly less stressful for infants and parents. These findings suggest that this version of graduated extinction might be a viable alternative to those not willing to use unmodified extinction; however, further research is necessary to validate these findings.

Due to the majority of studies in the current review failing to compare longer term outcomes with untreated controls, it was not possible to conclude whether infants with sleep disturbance treated with extinction techniques were more likely to have better sleep in the long term than those not receiving such treatment, or whether untreated infants would outgrow their poor sleep naturally as part of normal maturation. Despite the review being unable to shed light on this important issue, several authors using longitudinal research, have found associations between earlier and later sleep problems (e.g. Pollock, 1992, 1994; Thome & Skuladottir, 2005) and others have demonstrated that although ISD improves over time in some infants, left untreated, between 25% and 45% continue to exhibit night waking at three years of age (e.g. Zuckerman et al., 1987).

Many studies failed to examine potential adverse effects or changes in infant behaviour following the use of extinction techniques. Although two studies reported the presence of a PERB, which could be evidence of increased infant distress in the short term, this usually passed quickly, resulting in improved sleep and less overall crying and distress in the long term. Parental perception of infant behaviour had improved following extinction in one study, which described infants as being less "grizzly" following treatment. No long-term detrimental effects on infant temperament or bedtime anxiety were found in infants treated with extinction.

One study stated that a small number of parents disagreed with the premise on which treatment was based and therefore refused to take part. However, as response rates were not often reported, the overall number of parents declining to take part due to disagreeing with the use of the techniques is unknown. Of those who agreed to take part, many reported high rates of satisfaction with the interventions provided. However, although the majority of parents seemed to find many of the interventions helpful, others reported them to be 'somewhat' to 'moderately' stressful to implement. Reported resistance and non-compliance with the techniques in some studies perhaps reflects parents' concerns and difficulties with using the procedures. Other indications that parents had difficulty implementing strategies are the modifications made to techniques by some parents and the failure to persist with using techniques in the long term.

Clinical Implications

Due to the negative views of extinction techniques expressed by some popular literature (Sears, 1985; Hogg, 2001; Pantley, 2002) and to the fears and uncertainties expressed by some parents, it is essential that parents considering using the techniques are provided with clear explanations for the treatment rationale, the importance of consistency, assurances that the techniques are not harmful and ongoing support from health care professionals. Preparing parents for the possibility of a PERB and also providing information about the potential benefits for the infant and family as a whole would also be important for treatment success and parental compliance. Parents with particularly negative beliefs associated with using the procedure might benefit from a cognitive intervention in conjunction with extinction techniques.

Without support from a health professional, parents might be more likely to experience the procedures as stressful and have difficulty with implementation, therefore resulting in inconsistency and intermittent reinforcement of infants' crying and worsening of the sleep problem. Parents might then abandon the procedure, being left physically and emotionally exhausted, unsupported and feeling a sense of failure for being unable to implement a procedure, which is often reported to work quickly and be easy to implement.

All studies in the current review involved a degree of support from members of the research team, some even providing 24-hour telephone support if required. In routine clinical practice, it is unlikely that this degree of support would be available. Instead, parents may rely on advice from family members, friends, or from other sources of parenting advice, which are often contradictory and not always evidence-based. None of the studies in the current review assessed the impact of the support provided, independently of the interventions. It is possible,

however, that the support and ongoing contact with health care professionals may have been therapeutic in itself. A growing body of evidence has found that if a strong alliance is established between a patient and therapist, the patient will experience the relationship as therapeutic, regardless of other psychological interventions (e.g. Martin, Garske & Davis, 2000). This being the case, ongoing support is vital for successful outcomes.

Implications for future research

The majority of studies supplemented extinction techniques with other components, such as stimulus control, cognitive restructuring and family work, which were not evaluated independently of the extinction techniques. Further research examining the effects of these techniques separately would help determine their efficacy as stand-alone treatments. Additionally, research comparing extinction techniques with or without additional components would also add value to the growing evidence base. Although multifaceted interventions create difficulties in analysing the efficacy of individual components, Mindell et al. (2006) argue they have high ecological validity and are more reflective of clinical practice than interventions using only one component. Other researchers (e.g. Owens et al., 2002) have also recommended ISD be treated using combined behavioural strategies, taking account of parents' preferences where possible, due to the high success rates observed in clinical research.

Many variations of extinction were examined in the current review. More research using larger sample sizes, comparing the various techniques, alongside untreated control groups, using longer follow-up periods would be of value. Adopting standardised subjective and objective outcome measures in order to enable comparisons across studies would also be beneficial. Research examining different delivery methods, comparing treatments

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incorporating varying amounts of support would help determine the 'ideal' method of delivery and amount of support required for successful outcomes. Perhaps particular variations would be more suited to particular family and infant circumstances.

Future research taking into account individual treatment responses of infants of different ages, cognitive abilities, types of sleep disturbance, temperament, sleeping arrangements, parental affective and cognitive components, social support and living conditions needs to be undertaken. Despite the current review limiting the age range from 6-24 months, it is possible that important developmental changes occur during this time. Once more is known and understood about individual responses to various treatments, tailored treatment plans can be implemented, incorporating the evidence base where possible.

Although the current review did not report any adverse effects of using extinction techniques, other than a couple of studies reporting the presence of a PERB, adverse effects such as changes in temperament, behaviour and security were not thoroughly investigated in any study. The studies attempting to assess infant temperament or behaviour following intervention relied on subjective maternal reports, which can be problematic and biased. Systematic investigation using objective measures of the potential adverse effects of using extinction techniques is therefore warranted, including longitudinal studies to assess the longer term impact on infant characteristics such as temperament, security and attachment.

Conclusion

The current review systematically examined the evidence for the use of extinction techniques in the treatment of sleep disturbance in 6-24 month-old infants. The majority of the 11 studies included were deemed to be of high quality, when rated using a quality assessment protocol developed specifically for this purpose. Although various methodological considerations and limitations were discussed, overall, extinction techniques were found to be effective in treating ISD. Extinction techniques occasionally resulted in a PERB; however, no other adverse effects of using the procedure were documented. The majority of parents were satisfied with the interventions provided and reported finding the techniques helpful; however, some difficulties with implementation and compliance were reported upon. Implications of the findings for clinical practice and suggestions for future research are discussed.

Summary

- Extinction techniques were found to be effective in the treatment of ISD in 6-24 month-old infants
- Extinction techniques occasionally resulted in a PERB; however, no other adverse effects of using the procedure were documented
- The majority of parents were satisfied with the interventions provided and reported finding the techniques helpful (although some difficulties with implementation were reported upon)
- Future research would benefit from using larger samples, untreated control groups, longer follow-up periods, comparing different techniques alone and in combination with other components, using varying amounts of support and examining potential adverse consequences of using the procedures.

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*Studies included in the current review



Chapter Two

Major Research Project

The Relationship between Disturbed Sleep and Cognitive Functioning during Pregnancy: An Exploratory Study

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Abstract

Women commonly complain of cognitive impairment during pregnancy; although some research has confirmed impairments using objective tests, the aetiology of this is uncertain. The relationship between disturbed sleep during pregnancy and cognitive functioning has not been specifically investigated. Using a correlational design, the present study aimed to examine the relationship between disturbed sleep and cognitive functioning during pregnancy. Method: Sixty-four women in the third trimester of pregnancy completed the Pittsburgh Sleep Quality Index and the Insomnia Severity Index. A sub-sample also undertook actigraphic monitoring to obtain objective estimates of sleep quality. Cognitive functioning was measured subjectively using the Cognitive Failures Questionnaire and objectively using the IntegNeuro computer package. Results: Women reported significant sleep disturbance, which was confirmed by actigraphic monitoring in a sub-sample. Poorer subjective and objective sleep quality was related to more self-reported cognitive failures. Subjective sleep quality was also significantly correlated with objective measures of delayed verbal recall, but not to other domains of cognitive functioning. Poorer objectively measured sleep was related to decreased vigilance. Women reporting significant sleep disturbance reported significantly more cognitive failures than good sleepers, although this difference was not reflected by performance on objective cognitive tests. Conclusion: Sleep disturbance during pregnancy is related to subjective cognitive impairment and to some domains of cognitive performance using objective cognitive tests.

Keywords: pregnancy, sleep disturbance, cognitive functioning, memory

Introduction

Existing literature has consistently demonstrated that sleep is disturbed during pregnancy (Gaylor & Manber, 2005), particularly so in the third trimester (Beebe & Lee, 2007). Reasons for sleep disruption during pregnancy include, but are not limited to, hormonal changes, changes in respiration, foetal movements, physical discomfort, nausea or vomiting, restless leg syndrome (RLS), reflux, nightmares and an increase in the frequency of urination (Hedman, Pohjasvaara, Tolonen, Suhonen-Malm, & Myllyla, 2002; Lee, 1998).

Disturbed sleep during pregnancy has been linked with longer and more painful labour, birth complications (Beebe & Lee, 2007; Lee & Gay, 2004) and increased risk of postnatal mood disturbance in mothers (Karacan, Williams, Hursch, McCaulley, & Heine, 1969; Parry et al., 2006). Sleep disturbance in general has been associated with depression (Tsuno, Besset, & Ritchie, 2005) and impaired cognitive functioning (Pilcher & Huffcut, 1996). For example, sleep deprivation has been found to decrease reaction times and vigilance, and to increase perceptual and cognitive distortions (Krueger, 1989). Sleep disruptions have also been associated with significant decrements on memory tasks (Bonnet, 1985). In a recent review, Walker (2008) emphasised the need for sleep prior to and following learning, in order to firstly commit new experiences to memory and then to consolidate them.

Pregnancy has also been associated with fluctuations in mood (Johanson, Chapman, Murray, Johnson, & Cox, 2000) and perceived impairments in various aspects of cognition including memory, attention, concentration, coordination and general cognitive slowing, with 50 to 80% of women reporting some degree of disturbance in cognitive ability (Brett & Baxendale, 2001). The concept of "baby brain" has also been reinforced in popular media and parenting books (e.g. Mitchison, 1997; Regan, 2005). However, while pregnant women appear to consistently report experiencing impaired cognitive functioning, research examining this using objective tests has produced mixed results.

Silber and colleagues found that pregnant women performed more poorly than nonpregnant women on a reaction time task and a paired associate learning task (Silber, Almkvist, Larsson, & Uvnas-Moberg, 1990). Crawley, Grant and Hinshaw (2008) found that pregnant women rated their cognitive abilities as poorer than before they were pregnant and performed more poorly than non-pregnant controls on tasks of speed of language processing and switching of attention. Attention deficits have also been found by de Groot, Adam and Hornstra (2003) using the finger precuing technique, which selectively prepares two of four finger responses, but were not found to be impaired in other studies (Christensen, Poyser, Pollitt, & Cubis, 1999; Crawley, Dennison, & Carter, 2003). Speed of information processing was found to be impaired in late pregnancy by Buckwalter et al. (1999) and Christensen, Leach, and Mackinnon (2010), but was not found to differ between pregnant and nonpregnant women in other studies (Condon, Derham, & Kneebone, 1991; De Groot, Hornstra, Roozendaal, & Jolles, 2003; De Groot, Vuurman, Hornstra, & Jolles, 2006; Vanston & Watson, 2005).

Shetty and Pathak (2002) reported poorer overall performance on the Wechsler Memory Scale (WMS) from a group of pregnant, compared with non-pregnant women. Deficits in verbal recall (using word or story recall) and working memory have also been found in pregnant women, when compared with non-pregnant women (Condon et al., 1991; De Groot, Hornstra, et al., 2003; De Groot et al., 2006; Janes, Casey, Huntsdale, & Angus, 1999; Keenan, Yaldoo, Stress, Fuerst, & Ginsburg, 1998). Other studies have, however, failed to find such differences (Casey, 2000; Casey, Huntsdale, Angus, & Janes, 1999; Christensen et al., 1999; Christensen et al., 2010; Crawley et al., 2003; McDowall & Moriarty, 2000; Vanston & Watson, 2005). When examining the role of foetal sex, Vanston and Watson (2005) found no differences between pregnant women and controls, but found that women who were pregnant with boys performed more poorly on tasks measuring working memory and spatial ability than those expecting girls.

Although there is some evidence for deficits in implicit memory in pregnant women (Brindle, Brown, Brown, Griffith, & Turner, 1991; Sharp, Brindle, Brown, & Turner, 1993), the majority of research examining this aspect of memory has not supported such differences (Casey et al., 1999; Christensen et al., 1999; Janes et al., 1999; Keenan et al., 1998; McDowall & Moriarty, 2000). The difference found by Brindle et al. (1991) was found in primiparous, but not multiparous women, although other studies examining the effects of parity or gravidae status on memory performance have not found such differences (Casey et al. 1999; McDowall & Moriarty, 2000; Sharp et al., 1993). One study found that pregnant women performed better than controls on verbal recognition memory when information was pregnancy-related (Christensen et al., 1999).

Mixed findings have also emerged when trimester of pregnancy has been examined as a possible mediating factor. For example, while Brindle et al. (1991) found memory deficits were most marked in the second trimester, Keenan et al. (1998) suggested women in the third trimester experienced most noticeable memory deficits and Christensen et al. (2010) found that late pregnancy was associated with deterioration in working memory. However, Sharp et al. (1993) and De Groot et al. (2006) found that pregnant women presented with poorer memory performance across all three trimesters and that differences persisted at 32 weeks postpartum.

Henry and Rendell (2007), in a meta-analytic review of memory function in pregnancy, concluded that some but not all measures of memory were affected during pregnancy, and that memory measures that placed high demands on executive functioning might be selectively disrupted. In particular, they suggested that prospective memory might be affected, given the demands it imposes on executive functioning and self-initiated retrieval. Recent studies examining prospective memory in pregnancy (Crawley et al., 2008; Rendell &

Henry, 2008) have found no differences in performance between pregnant women and nonpregnant controls when assessed using laboratory measures; however, significant impairments were found in pregnant women in comparison to controls in the latter study when using a naturalistic time-logging prospective-memory task conducted over a period of seven days. Finally, a study assessing prospective memory by asking participants to telephone the researcher the following week, found no significant differences between pregnant women and controls in the numbers remembering to phone (Casey et al., 1999). With regards to executive functioning, a recent study by Crawley et al. (2008) failed to find deficits in performance during pregnancy when compared with a non-pregnant matched control group.

Where deficits in cognitive performance have been found in pregnant women, the effects have been relatively small, with performance remaining within normal limits (Crawley et al., 2008). The aetiology of any cognitive impairment during pregnancy is uncertain. Explanations have included mood alterations, cultural stereotypes, lifestyle factors, changes in hormones and neurotransmitters, and chronological age of circulating erythrocytes (Henry & Rendell, 2007).

Although some studies examining cognitive functioning in pregnancy have found positive correlations between self-reported sleep disturbance and subjective memory deficits (Casey, 2000; Casey et al., 1999; Janes et al., 1999), self-reported sleep has not been found to correlate with objective measures of memory (Casey, 2000; Casey et al., 1999; Janes et al., 1999; Keenan et al., 1998). One study examining postpartum women found that memory and psychomotor functioning of new mothers was related to subjective reports of mood and self-reported sleep loss (Swain, O'Hara, Starr, & Gorman, 1997). Given that sleep loss and mood fluctuations are also common during pregnancy, these relationships were deemed worthy of further investigation. Until now, the effects of disturbed sleep during pregnancy on cognitive functioning have not been specifically investigated.

The present study therefore aimed to examine the relationship between disturbed sleep during pregnancy and subjective and objective cognitive functioning, controlling for the effects of mood. Specifically, self-perception of cognitive failures, reaction time, speed of information processing, visual and verbal memory, working memory, attention, prospective memory and executive functioning were examined.

Hypotheses

- 1. Sleep disturbance will be related to poorer subjective cognitive functioning, independent of mood.
- Sleep disturbance will be related to poorer objectively measured cognitive functioning, independent of mood.
- 3. Women scoring above the threshold for significant sleep disturbance, as measured by the PSQI, will perceive their cognitive functioning to be poorer than those without significant sleep disturbance.
- 4. Women scoring above the threshold for significant sleep disturbance will exhibit poorer objectively measured cognitive functioning than those without significant sleep disturbance.

Methods

Design

A correlational design was used for the primary analyses. Relationships between sleep disturbance and cognitive functioning were examined. Secondary analyses were conducted to compare the cognitive functioning of those with significant sleep disturbance and those without. Objective cognitive functioning was also compared with that of a non-pregnant control group matched on gender, age and years of education using multivariate analyses.

Participants

Women were recruited opportunistically using posters (See Appendix 3.1), which were placed in antenatal departments of all the maternity hospitals in Glasgow. In addition, women attending Parentcraft classes (excluding the teenage mothers' class) were given brief details of the research at the start of their class. Women attending pregnancy yoga classes, aqua-natal classes and childbirth preparation classes run by the National Childbirth Trust (NCT) were also informed of the study. Finally, adverts were posted to relevant Internet websites (e.g., babycentre.co.uk, babyandbump.co.uk) giving brief details of the study.

Women who expressed an interest in taking part in the study were sent information about the purpose of the study (See Appendix 3.2). Women aged 20 to 39 inclusive, in their third trimester of pregnancy and expecting their first child were included. This age group was selected due to the significantly higher risk of adverse outcomes in adolescent pregnancies (Chen et al., 2007) and the increase in risk of pregnancy complications in women aged over 40 (Gilbert, Nesbitt, & Danielsen, 1999; Luke & Brown, 2007). Third trimester of pregnancy was chosen due to the decreased risk of miscarriage in later pregnancy, the increased sleep disturbance evident in this trimester (Beebe & Lee, 2007), previous research showing that women in the third trimester experience the most noticeable memory deficits (Keenan et al., 1998) and also due to convenience of obtaining the sample at the parenting classes, which take place in the third trimester. Women expecting their first child were chosen due to previous research finding that primiparous, but not multiparous women experienced deficits in implicit memory (Brindle et al., 1991) and also as it was thought that women with existing childcare responsibilities may have less available time and therefore find it more difficult to participate in a research study. Women expecting their first child are also more likely to attend parenting classes than women experiencing subsequent pregnancies (Delvaux, Buekens, Godin, & Boutsen, 2001), making them easier to recruit.

Participants were excluded if they were experiencing a complicated pregnancy or other significant health problem, as these factors are likely to increase stress and worry, affect sleep, possibly interfere with cognitive functioning and therefore add additional confounding variables. Those with a specific diagnosis of a sleep disorder (such as narcolepsy), known psychiatric disorders, depressive disorders or illicit drug or alcohol abuse were also excluded from participating, as these factors are also likely to affect cognitive functioning and sleep and therefore confound the results. Applying these inclusion/exclusion criteria increased the homogeneity of the group under examination, therefore increasing the power of the study.

Using the G * Power 3 (Faul, Erdfelder, Lang, & Buchner, 2007) software programme, with a medium effect size of r=0.3, $\beta =0.80$ and $\alpha = 0.05$, a total sample size of N=64 was calculated, based on hypotheses one and two, which are one-tailed as directional relationships are specified. Given the strict exclusion and inclusion criteria and resulting homogeneity of the participant group, as well as the adequate reliability and validity of the primary measures being utilised, it was expected that this sample size would be sufficient to detect differences if they existed.

Measures

Demographic information.

A demographic questionnaire was used to obtain information related to participants' age, number of years in formal education, marital status, employment status, income and ethnicity (see Appendix 3.3).

Measures of sleep

Pittsburgh Sleep Quality Index. Subjective sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). The PSQI is

a self-report questionnaire, which assesses sleep quality and disturbances over a month. Nineteen individual items generate seven 'component' scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction. The sum of scores for these seven components yields one global score. The PSQI is a widely used, internally consistent (Cronbach's alpha = .83) screening instrument for the detection of significant sleep disturbance, using a threshold score of 6. A recent study by Backhaus and colleagues validated this cut-off and confirmed reliability (Cronbach's alpha = .85, test-retest r = .84) (Backhaus, Junghanns, Broocks, Riemann, & Hohagen, 2002). Additional questions enquired about daytime naps, which are common amongst pregnant women, previous sleep problems, the effects of pregnancy on the participants' current sleep and quality of sleep the night prior to testing (See Appendix 3.4).

Insomnia Severity Index. Although the PSQI was the primary measure, the Insomnia Severity Index (ISI; Morin, 1993) was used to examine the proportion of participants reaching the threshold for insomnia. The ISI is a brief self-report instrument, measuring an individual's perception of their sleep disturbance. It comprises seven items assessing the severity of sleep-onset and sleep maintenance difficulties (both nocturnal and early morning awakenings), satisfaction with current sleep pattern, interference with daily functioning, how noticeable the impairment attributed to the sleep problem is, and degree of distress or concern caused by the sleep problem. Each item is rated on a 0-4 scale, with total scores ranging from 0 to 28. Higher scores indicate more severe insomnia. Scores of between 8 and 14 indicate 'sub threshold insomnia'; 15-21 indicates 'moderate insomnia' and 21-28 indicates 'severe insomnia'. Acceptable validity and reliability has been reported by Bastien, Vallières and Morin (2001).

Actigraphy. Objective estimates of sleep quality were recorded in a sub-sample (n=26) of participants using actigraphy (Ambulatory Monitoring, Inc.) and sleep diaries over a period of five nights. Although previous studies have recommended seven-day monitoring periods, the present study monitored for five weekdays in order to decrease systematic error caused by changing weekday and weekend sleep patterns and to minimise missing data. The wrist actigraph provides continuous motion data by using a battery-operated wristwatch-size microprocessor that senses motion (see Appendices 3.5 and 3.6 for illustrations of an actigraph and output). Various sleep-related outcome variables can be calculated including sleep quantity as total sleep time (TST) at night, sleep onset latency (SOL) (time taken to fall asleep), wake after sleep onset (WASO) and sleep efficiency (see Appendix 3.7 for an illustration of Sleep Analysis and Sleep Summary). For the purposes of the present study, all variables calculated from actigraphy and sleep diaries were used to describe sleep quality in the sample; however, only actigraphically measured WASO and sleep efficiency were included in the analyses as measures of objective sleep disruption.

The mean reported TST for young adults during weekdays is 7.5 hours (Carskadon & Dement, 2005). The average SOL in 'normal' adults, aged 20-55 years is approximately 13 minutes (Johns, 1977). As an estimate of sleep disruption, WASO is reported as the percentage of minutes awake divided by minutes in bed after falling asleep. During a typical 7 to 8-hour sleep period, WASO of 15% represents more than an hour of wake time after falling asleep. WASO between 5% and 10% is typical in healthy, non-pregnant women (Lee, Zaffke, & McEnany, 2000) and greater than 15% is considered severe sleep deprivation. Sleep efficiency is the percentage of time spent in bed that a person sleeps; 90% is considered to be normal for good sleepers (Salin-Pascual, Roehrs, Merlotti, Zorick, & Roth, 1992). Congruence between polysomnographic measures and actigraphy measures indicates adequate validity and reliability when sleep is assessed in healthy young adults, including women of childbearing age

(Ancoli-Israel et al., 2003), with 88% agreement between the two methodologies (Cole, Kripke, Gruen, Mullaney, & Gillin, 1992).

Measures of cognitive functioning

Cognitive Failures Questionnaire. Subjective cognitive functioning was assessed using the Cognitive Failures Questionnaire (CFQ; Broadbent, Cooper, FitzGerald, & Parkes, 1982). The CFQ is a 25-item questionnaire (see Appendix 3.8), which measures everyday task failures that individuals are normally capable of completing (e.g., Do you bump into people? Do you find you forget appointments?). The definition of the construct of cognitive failure implies that the ability is present but something interferes with the successful completion of the task (Broadbent et al., 1982). The scale measures the perceived frequency of lapses in three broad areas: perception, memory and psychomotor function in the past 6 months (for the purposes of the current study, the past month was enquired about), using a 5-point scale, ranging from never (0) to very often (4), resulting in a total score from 0-100. Although most commonly used to assess the single factor of general cognitive failure, Wallace and colleagues (Wallace, Kass, & Stanny, 2002; Wallace, 2004) have provided support for a fourfactor solution measuring memory, distractibility (inattention), blunders and memory for names.

The CFQ has been applied in a large variety of settings and it has been found to predict cognitive deficits related to stress (Mahoney, Dalby, & King, 1998), anxiety (Mathews & Wells, 1982), depression (Wagle, Berrios, & Ho, 1999), psychophysiological insomnia (Macphee, 2009) and pregnancy (Crawley, 2002). When used within pregnancy, it has been found to significantly correlate with mood (using a mood adjective checklist) (Morris, Toms, Easthope, & Biddulph, 1998).

Mean scores have ranged from 43.2 to 48 when used with students (Wallace et al., 2002; Matthews, Coyle, & Craig, 1990; Mecacci, Righi, & Rocchetti, 2004), navy recruits (Wallace et al., 2002), women of child-bearing age (Crawley, 2002; Morris et al., 1998) and a group with psychophysiological insomnia (Macphee, 2009). Mean scores for pregnant women have varied, with one study reporting means of 42.2 (mean gestation 23.66 weeks) (Morris et al., 1998) and another reporting a mean of 53.7 (33-36 weeks gestation) (Crawley, 2002). A higher mean score of 56.8 has been reported in a depressed group (Wagle et al., 1999) and a lower mean score of 33.4 has been reported for a community sample of 1603 Dutch women (mean age= 45.7 years) (Boomsma, 1998). Wallace (2004) reported a high internal consistency of the scale (Cronbach's $\alpha = 0.96$) when used with 709 university students.

Neurocognitive assessment: 'IntegNeuro'. Cognitive functioning was measured objectively using tests from the standardised computer package 'IntegNeuro' (The Brain Resource Company, 2004). IntegNeuro uses touch screen technology and consists of 12 subtests, which measure various domains of cognitive functioning (see Appendix 3.9). The test is used as a screening tool for possible dysfunction and compares people with a large, normative database. For the purpose of the present study, motor tapping, choice reaction time, span of visual memory, digit span, memory recall and recognition, sustained attention, switching of attention, spot the real word and executive maze tests were used. These tests measure aspects of cognitive functioning previously found to be affected during pregnancy. A non-pregnant control dataset, matched on gender, age and years of education and in good physical and mental health, was provided upon completion of the study.

Prospective Memory. To assess prospective memory, participants were asked for a personal belonging at the start of the testing session (e.g. a watch, purse or mobile phone) and instructed

to request it back when they were told the appointment was finished. This is similar to a test of prospective memory used in the Rivermead Behavioural Memory Test (RBMT; Wilson, Cockburn, & Baddeley, 1985). Participants were also asked to telephone the researcher at a pre-specified time the following week to provide feedback on their experience of taking part in the study.

Measure of Mood.

Hospital Anxiety and Depression Scale. Mood was assessed using the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). The HADS is a brief (14-item) self-report measure, which was designed to assess anxiety and depression in non-psychiatric hospital populations (Herrmann, 1997) and is now widely used in a variety of settings, including use for screening in non-clinical populations (Crawford, Henry, Crombie, & Taylor, 2001) and screening of psychological distress in pregnant women (Cederholm, Sjoden, & Axelsson, 2001). The scale is quick and easy to administer and consists of two sub-scales of seven items designed to measure levels of both anxiety and depression, each of which has cut-off points to identify caseness. Many studies have reported on the construct validity in various clinical populations. Abiodum (1994) validated the scale for use with pregnant women, reporting a sensitivity and specificity of 93% and 90%, respectively, for the anxiety subscale and 90% and 91%, respectively, for the depression subscale.

Ethical Issues.

Participants provided informed consent to take part in the study and were made aware that they were free to withdraw without penalty at any time. Participants were provided with information on strategies to help improve sleep and were invited to attend an event at the University of Glasgow Sleep Centre, focusing on guided self-help to improve sleep, following participation in the study (See Appendix 3.10). Those with more significant sleep or affective problems were advised to visit their GP for advice. Ethical approval was granted from the Greater Glasgow and Clyde NHS ethics committee (see Appendix 3.11).

Data Analysis.

Data were analysed using the Statistical Package for Social Sciences (SPSS), Version 18 computer package. Descriptive statistics were used to examine demographic data, mood, prospective memory and subjective and objective sleep quality data.

Distribution of the data was examined to determine whether parametric or non-parametric analyses were appropriate. One participant was identified from descriptive statistics as being an outlier, whose scores were not representative of the data as a whole and was therefore excluded from data analyses. All other data were normally distributed, other than components of the IntegNeuro data, which were subsequently transformed using square root (Sqrt) or logarithmic transformations (Lg10), which was sufficient to normalise the data in most cases. Variables unable to be transformed were analysed using non-parametric analyses. In order to maintain a significance level of α = 0.05, Bonferroni corrections were made for multiple comparisons where appropriate.

As the PSQI is a continuous scale, which measures sleep disturbance as a dimension of sleep quality and similarly, the CFQ is a continuous measure of subjective cognitive functioning, which is not diagnostic in nature, correlational analyses were deemed appropriate for primary analyses. Relationships between subjective sleep (PSQI), objectively measured sleep (actigraphically measured WASO and sleep efficiency), perceived cognitive functioning (CFQ) and objectively measured cognitive functioning (IntegNeuro) were examined. Partial correlations were carried out to control for the effects of mood (using the HADS) on the above relationships where possible.

Secondary analyses used t-tests and multivariate analyses to examine differences in cognitive functioning (subjective and objective) between those with significant sleep disturbance, differentiated by the recognised cut-off score of 6 on the PSQI, and those without.

Results

Demographic information.

Sixty-four primigravid women took part in the study. Another 32 women enquired about the study, although either failed to meet the inclusion criteria or were unable to attend for various reasons. The mean age of participants was 31 years (range: 24 to 39, *SD* 3.7). Mean gestation was 34 weeks (range: 27-39). The majority were British (n=55) and spoke English as their first language (n=58); data from the remaining six participants whose first language was not English were included, apart from those IntegNeuro analyses involving language subtests. Most were married (n=44) or co-habiting (n=19). The majority were university-educated (n=53) and in employment (n=59); three were unemployed and two were students. Mean household income was £57,898, which is considerably higher than the reported UK average household income of £34,382 in 2008 (Finance & Performance Environment Directorate, 2009). All were in good health and had uncomplicated pregnancies. Prior to pregnancy, 44 were classed as being in the normal range for body mass index (BMI), six were underweight, 11 were overweight and three were obese. Three participants were classified as having moderate depression using the HADS and six were classified as having moderate anxiety. Further participant details are presented in Table 1.

Subjective sleep.

The majority of women (n=44) reported having had daytime naps, ranging from ten minutes to two and a half hours, in the past month. Details of the frequency and duration of daytime naps (for those who reported napping) are presented in Appendix 3.12.

When asked about their sleep prior to pregnancy, approximately a third (29.7%) of women reported having had sleep problems in the past. The most common complaints were of transient insomnia during times of stress; two reported having had RLS. Fifty-nine of the 64 women believed pregnancy had made their sleep worse. Typical reasons for current sleep disturbance included discomfort/pain, increased frequency of urination, foetal movements, RLS, heartburn, snoring, vivid dreams, anxiety and worry about the baby and impending birth.

Using the PSQI, 45 women (70%) exhibited significant self-reported sleep disturbance, using the global cut-off score of 6. Based on ISI scores, 23 women (36%) were classified as having 'sub threshold insomnia', 15 (23%) had 'moderate insomnia' and 3 (5%) had 'severe insomnia'. When comparing good with poor sleepers, differentiated by the PSQI threshold score of 6, no significant differences in age, number of years education or estimated premorbid IQ (using 'spot the real word' subtest) were found. Further subjective sleep quality data are presented in Table 1.

	Mean	Range	SD
Age (years)	31.4	24-39	3.7
Gestation (weeks)	33.6	27-39	3.4
Education (years)	17.6	12-25	2.4
Household income	£57,898	£16,000-£150,000	21,836.18
BMI (prior to pregnancy)	23.3	17.5-34.3	3.4
HADS: A	5.7	0-14	3.6
HADS: D	4.1	0-14	3.1
PSQI	7.5	1-17	3.8
ISI	10.6	0-24	6.2

Table 1. *Demographic information and subjective sleep data for the study sample (N=64)*

Objective sleep.

A sub-sample of 26 women (mean age= 31.6, mean gestation= 34.6 weeks, mean education= 18 years, mean BMI= 22.8) completed sleep diaries and undertook actigraphic monitoring for a period of five nights. TST, SOL, WASO and sleep efficiency were calculated. Women undertaking actigraphic monitoring did not differ significantly from the remaining participants on age, education, estimated pre-morbid IQ or self-reported sleep. However, women undertaking actigraphy had significantly higher number of weeks gestation (M= 34.6 weeks) than those not undertaking actigraphy (M= 32.7 weeks) (t= 2.2; df= 61; p= .035). Despite this difference, participants were from a relatively homogeneous group and were all in their third trimester of pregnancy. Descriptive statistics for objective sleep quality data are presented in Table 2.

		Mean	Range	SD
SOL	Diary:	36	5-175	42.5
(minutes)	Actigraphy:	18.5	0-58	17.6
TST (hours)	Diary:	7.2	4.5-10.3	1.5
	Actigraphy:	6.0	4.3-7.5	0.9
WASO	Diary:	69.9	1-336	69.1
(minutes)	Actigraphy:	66.5	14-114	26.3
Sleep efficiency (%)	Diary:	75.8	43-98.9	14.9
	Actigraphy:	80.1	64.3-94.4	8.6

Table 2. *Objectively estimated sleep (using wrist actigraphy) and subjective sleep diary data in a sub-sample of the study population (n=26)*

As can be seen in Table 2, the majority of women exhibited significant sleep disturbance. SOL was longer than the mean of 13 minutes previously reported for 'normal' sleepers; TST ranged from six hours (measured objectively) to 7.2 hours (measured subjectively), which is slightly less than the average of 7.5 hours for young adults. The mean duration of WASO, measured using the diary and actigraphic device, was over an hour, indicating severe sleep disruption.

Sleep efficiency was between 75.8 and 80%, which is lower than the 'normal' of 90% for good sleepers. Significant correlations, ranging from r= .453 to r= .659, were found between subjective and objective sleep measures (See Appendix 3.13). Both subjective and objective sleep measures were significantly correlated with the mood subscale of the HADS. Subjective sleep was also significantly correlated with the anxiety subscale (See Appendix 3.14).

Subjective and objective cognitive functioning.

Total scores on the CFQ ranged from 11 to 80 (M= 44.5) (see Figure 1). Mean CFQ scores for good and poor sleepers are presented in Figure 2. CFQ scores were significantly related to the anxiety (r= .527, p <.001) and depression (r= .530, p <.001) subscales of the HADS.



The CFQ factor scores proposed by Wallace and colleagues (Wallace et al., 2002; Wallace, 2004) were examined for good and poor sleepers (determined by PSQI threshold score of 6) and are presented in Table 3.



Figure 2. Mean CFQ scores for good and poor sleepers (using PSQI threshold score of 6)

Table 3. Mean and SD for CFQ factor scores in good and poor sleepers

	Good sleepers (PSQI<6) (<i>n</i> =19)		Poor sleepers (PSQI≥6)		
			(<i>n</i> =44)		
	Mean	SD	Mean	SD	
Distractibility	15.4	5.38	20.16	5.61	
Memory	7.68	4.75	11.23	4.92	
Blunders	7.89	4.4	11.9	3.98	
Names	4.16	1.64	4.4	1.80	

Note: higher scores indicate more reported cognitive failures

With regards to prospective memory, 53 women remembered to request their belonging back at the end of the appointment; however, only 23 (36%) remembered to phone the following week. Slightly more good than poor sleepers remembered to request their belonging
back (89.5% versus 83.7%) and slightly more good sleepers than poor sleepers remembered to phone the following week (42.1% versus 34.1%). Mean scores for good and poor sleepers on IntegNeuro variables are presented in Table 4.

Function measured	IntegNeuro variable	Good	Poor
		sleepers	sleepers
Verbal & visual Memory	Immediate verbal recall	35.79	35.05
	Verbal learning rate	1.35	1.27
	Short delay verbal recall	9.14	8.55
	Long delay verbal recall	8.79	8.5
	Verbal recognition memory	10.64	10.7
	Span of visual memory	7.5	7.68
Working memory	Digit span score (forward)	8.28	8.9
	Digit span score (backwards)	5.5	5.57
Attention	Sustained attention- reaction time	561.18	627.78
	Sustained attention- total errors	1.44	1.52
	Switching of attention completion time	19,173.72	20,225.88
	Switching of attention total errors	0.33	0.49
	Switching of attention 2 completion time	44,170.79	40,970.68
	Switching of attention 2 total errors	1.06	0.85
Processing speed	Number of taps (dominant hand)	162.44	165.86
	Number of taps (non-dominant hand)	149.94	151.86
	Choice reaction time	643.61	690.92
Executive functioning	Executive maze, trials completed	10.11	8.9
	Executive maze, completion time	252,139.50	231,421.44
	Executive maze, path learning time	220,287.94	197,928.17
	Executive maze, errors	36.78	33.50
	Executive maze, overruns	13.5	11.29
Pre-morbid functioning	Spot the real word	49.71	50.4

Table 4. *IntegNeuro mean scores for good and poor sleepers (determined by PSQI threshold score of 6)*

Note: Timed tests are measured in milliseconds

When examining relationships between subjective and objective cognitive functioning, significant correlations were found between CFQ total scores and short delay verbal recall (rho=-.316, p=.020), number of errors on the switching of attention task (rho=.355, p=.006) and completion time for switching of attention (rho=.317, p=.014). These differences were no longer significant when correcting for multiple comparisons (n=22) between CFQ total score and the Integneuro variables listed in Table 4; however, when adjusting for multiple comparisons within sets of variables (as presented in Table 4), the relationship between CFQ scores and short delay verbal recall remained significant.

Objective cognitive functioning of participants was compared with a non-pregnant control group (accessed from the IntegNeuro normative database), matched on gender, age and years of education. Mean IntegNeuro scores for pregnant women and controls are presented in Appendix 3.15.

Multivariate analyses (MANOVA) were performed, with IntegNeuro variables grouped into each of the six domains of function measured (as in Table 4). These analyses indicated that pregnant women's performance on memory tasks was significantly poorer than controls [F(6, 107) = 3.7, p= .002]; with the difference being accounted for by verbal recognition memory (p <.001). As recognition memory was a skewed variable, which was unable to be normalised, a Mann-Whitney U test was conducted, which again confirmed a significant difference between pregnant women and controls on this variable (p <.001). Pregnant women also performed more poorly on attention tasks [F (3, 101) = 6, p= .009], with the difference being accounted for by reaction time on the sustained attention task (p <.001). Deficits in executive functioning were also identified in the pregnant sample compared with controls [F (5, 115) = 8.1, p <.001], with the difference being accounted for by completion time (p= .022) and path learning time (p= .029). However, pregnant women had significantly fewer overruns than controls (p= .002). No significant differences were found on the three remaining variables (working memory, processing speed, pre-morbid functioning) between pregnant women and controls.

When examining relationships between objective cognitive functioning and HADS subscales, significant relationships were found between mood and delayed verbal recall (short delay: rho = -.352; p = .009; long delay: rho = -.302, p = .027) and between mood and accuracy (number of errors on switching of attention) (rho = -.275, p = .035). Relationships between the anxiety subscale and performance of objective tests were not significant.

Relationship between sleep and subjective cognitive functioning.

Subjective sleep quality, as measured by the PSQI was significantly correlated with subjective cognitive functioning, as measured by the CFQ (r= .488, p <.001) (see Figure 3). This relationship reduced in strength but remained significant when controlling for the effects of mood (pr= .271, p= .033).

Significant relationships were also found between PSQI scores and CFQ factor scores for distractibility, memory and blunders. These results are presented in Table 5. The relationship between subjective sleep and memory reduced in strength but remained significant when controlling for the effects of mood (pr=.277, p=.03), as did the relationship between subjective sleep and blunders (pr=.27, p=.036). However, the relationship between subjective sleep and distractibility was no longer significant when controlling for the effects of mood (pr=.277, p=.036). However, the relationship between subjective sleep and distractibility was no longer significant when controlling for the effects of mood (pr=.074, p=.570). These findings provide partial support for the first hypothesis.



Table 5. Correlation coefficients between PSQI scores and CFQ factor scores

	PSQI
Distractibility	r= .404, R ² = 0.16, p = .001 ^{**}
Memory	r= .470, R ² = 0.22, p < .001 ^{**}
Blunders	r= .486, R ² = 0.24, p < .001 ^{**}
Names	r= .198, R ² = 0.19, p = .119

Note: * Correlation is significant at the 0.05 level (two-tailed)

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

When examining relationships between objective sleep and subjective cognitive functioning, a significant positive correlation between actigraphically measured WASO and scores on the CFQ was found (r= .478, p= .016), indicating that increased sleep disruption was moderately related to increased perceived cognitive failures. Furthermore, a significant

negative correlation between sleep efficiency and scores on the CFQ was found (r= -.465, p= .019), indicating that decreased sleep efficiency was related to more perceived cognitive failures. However, when controlling for the effects of mood, these relationships were no longer statistically significant and therefore provide only partial support for the first hypothesis.

Relationship between sleep and objective cognitive functioning.

As many of the IntegNeuro variables were skewed, nonparametric (Spearman's) correlations were conducted to assess the relationships between sleep and objective cognitive functioning. Significant negative correlations were found between the PSQI total score and immediate verbal recall (rho= -.315, p= .020), short delay verbal recall (rho= -.436, p= .001) and long delay verbal recall (rho= -.328, p= .015), indicating that poorer subjective sleep was related to poorer verbal recall. Following corrections being made for multiple comparisons (involving the six IntegNeuro memory variables), the relationship between short delay verbal recall and subjective sleep was the only one to remain significant. These results are presented in Table 6. Subjective sleep was not significantly correlated with the remaining IntegNeuro variables (working memory, attention, processing speed or executive functioning).

When objective sleep variables were examined in the sub-sample who undertook actigraphic monitoring, a significant negative correlation was found between actigraphically measured WASO and verbal recognition memory (rho= -.487, p= .019), meaning that longer duration of wakefulness after sleep onset was related to poorer recognition memory. A significant positive correlation was found between WASO and number of errors on the sustained attention task (rho= .585, p= .003), meaning that longer duration of wakefulness after sleep onset was related to decreased by errors on the sustained attention task) was also significantly negatively correlated with sleep efficiency (rho= -.614, p= .002), implying that poorer sleep efficiency was related to decreased vigilance.

The relationships between objective sleep and vigilance remained significant when conservative corrections were made for multiple comparisons (within sets of IntegNeuro variables presented in Table 4); however, the relationship between WASO and verbal recognition memory was no longer significant. These results are presented in Table 6. Objective sleep was not significantly correlated with working memory, processing speed or executive functioning. These findings provide partial support for the second hypothesis. However, as non-parametric correlations were conducted, it was not possible to control for the effects of mood on the above relationships.

	PSQI	WASO	Sleep efficiency
Immediate verbal recall	<i>rho</i> =315 [*] ; <i>p</i> = .020	<i>rho</i> =145; <i>p</i> = .509	<i>rho</i> = .013; <i>p</i> = .954
Short delay verbal recall	<i>rho</i> =436 ^{**} ; <i>p</i> = .001	<i>rho</i> =266; <i>p</i> = .220	<i>rho</i> = .043; <i>p</i> = .847
Long delay Verbal recall	<i>rho</i> = .328 [*] ; <i>p</i> = .015	<i>rho</i> =379; <i>p</i> = .075	<i>rho</i> = .164; <i>p</i> = .456
Recognition Memory	<i>rho</i> =134; <i>p</i> = .336	<i>rho</i> =487 [*] ; <i>p</i> = .019	<i>rho</i> = .379; <i>p</i> = .074
Vigilance	<i>rho</i> = .122; <i>p</i> = .405	<i>rho</i> = .585 ^{**} ; <i>p</i> = .003	<i>rho</i> =614 ^{**} ; <i>p</i> = .002

 Table 6. Correlations between sleep and objective cognitive functioning

Note: ^{*}Correlation is significant at the 0.05 level (two-tailed) ^{**}Correlation is significant at the 0.01 level (two-tailed)

Differences in cognitive functioning between those with/without significant sleep disturbance.

Women scoring above the threshold for significant sleep disturbance on the PSQI reported significantly more cognitive failures on the CFQ than those scoring below the threshold (t= - 3.3; df= 61; p= .001, one tailed), providing support for the third hypothesis.

Multivariate analyses were performed comparing poor sleepers with good sleepers on the four factors of the CFQ proposed by Wallace and colleagues (2002; 2004). Results indicated a significant overall effect [F (4, 57) = 3.51, p= .013], with differences being accounted for by distractibility (p= .003), blunders (p= .001) and memory (p= .009).

Chi-square analyses were conducted to determine whether differences in prospective memory between good and poor sleepers were significant. These confirmed there were no significant differences between good and poor sleepers in the number of women remembering to request their belonging at the end of the appointment (X^2 (1, N=62) = .351, p= .553), or in the number remembering to telephone the researcher the following week (X^2 (1, N=63) = .368, p= .544).

Multivariate and non-parametric analyses were conducted to examine differences in objective cognitive functioning between those scoring above the threshold for significant sleep disturbance on the PSQI and those scoring below. No significant differences were found on any of the IntegNeuro variables. These results are presented in Appendix 3.16. The fourth hypothesis was therefore not supported.

Discussion

In an attempt to determine the possible aetiology of subjective and objective cognitive impairments during pregnancy, the present study examined the relationship between disturbed sleep and cognitive functioning during the third trimester.

Subjective cognitive functioning

When examining subjective cognitive functioning, pregnant women in the present study reported more cognitive failures than was found in a large community sample of Dutch women, and fewer cognitive failures than found in a group of depressed patients, or a sample of women in late pregnancy by Crawley (2002). Mean scores on the CFQ were similar to those found in studies using students, navy recruits, women in the second trimester of pregnancy and to a group suffering from psychophysiological insomnia. These findings suggest that pregnancy is associated with higher subjective cognitive failures than normal community samples, which is consistent with previous research, which has found that a high proportion of women report cognitive impairments during pregnancy (Brett & Baxendale, 2001), but lower perceived deficits in functioning than in a depressed group. The similarity in findings between the present sample and other groups could be explained by the fact that students and navy recruits are also undergoing periods of stress, transition and sleep disturbance (Lund, Reider, Whiting, & Prichard, 2010; Miller, Shattuck, Matsangas, & Dyche, 2008), resulting in higher perceived cognitive failures.

As the inclusion and exclusion criteria were not reported in the study by Crawley (2002), it is not possible to explain the difference in reported cognitive failures between women in that study and women in the present study, who were of similar age, education level and gestation. One difference between Crawley's (2002) study and the present study is that women in the present study were expecting their first child, whereas women in the study by Crawley (2002) already had one child of approximately two years of age. However, it is unlikely that this factor alone accounts for the difference in reported cognitive failures, as a study by Morris et al. (1998) found comparable mean scores to the present study and examined pregnant women of similar age and education level, some of whom also had existing children. Further research using the CFQ in different stages of pregnancy with women of different parity and different levels of sleep disturbance might help clarify the differences in findings between groups.

When dividing the sample into good and poor sleepers, the mean score for good sleepers was similar to that found in a large community sample of Dutch women and the mean score of poor sleepers was similar to the pregnant group studied by Crawley (2002) and to the psychophysiological insomnia group examined by Macphee (2009). The finding that poor sleepers in the present study scored more comparably with the group examined by Crawley (2002) might suggest that the sample under investigation in Crawley's study included a sample of pregnant women with poorer sleep, which is possible due to them having existing childcare responsibilities and therefore being less likely to nap during the day. Finally, the finding that CFQ scores of poor sleepers were comparable to a group with insomnia, suggests that sleep disturbance during pregnancy results in similar perceived cognitive deficits to those with insomnia.

The finding that CFQ scores were related to verbal recall and aspects of attention (although failed to reach significance when correcting for multiple comparisons) is concordant with previous research, which has found CFQ scores to correlate with objective cognitive performance in attention (Manly, Robertson, Galloway, & Hawkins, 1999; Tipper & Baylis, 1987) and everyday memory tasks (Martin, 1983; 1986). However, the finding that CFQ scores were not correlated with other domains of objective cognitive performance and were correlated more strongly with anxiety and depression, suggests that the CFQ more closely reflects psychological factors than actual cognitive deficits.

Objective cognitive functioning

When examining prospective memory data, findings from the present study are similar to those found by Rendell and Henry (2008), in that the majority of women remembered to request their

belonging back in the laboratory setting. However, nearly two-thirds forgot to telephone the researcher at a pre-specified time the following week, suggesting that prospective memory (assessed in naturalistic settings) may indeed be an area in which pregnant women are impaired. These findings are also similar to those found by Casey et al. (1999), who found that two-thirds of pregnant women forgot to telephone the researcher the week following their assessment, which although was a higher percentage than in the control group, was not found to be significantly different. It is possible that telephoning the researcher was not deemed to be a priority for the women in either study, some of whom were due to give birth in the very near future. Lack of a non-pregnant control group for comparison in the present study, limits the ability to draw conclusions. Future research would benefit from using more rigorous prospective memory tasks, involving both laboratory-based assessments and more ecologically valid assessments, with tasks more closely resembling everyday activities and demands, in naturalistic settings.

With regards to measures of objective cognitive functioning obtained from the IntegNeuro assessments, the present study was able to compare functioning with a matched non-pregnant control group, accessed from the IntegNeuro normative database. Compared with controls, pregnant women were impaired in verbal recognition memory, the reaction time aspect of the sustained attention task and aspects of executive functioning involving learning and completion time. These results imply that other than being poorer at recognising verbal information, pregnant women take longer to perform complex tasks. This finding, although not related to the study aims or hypotheses, is interesting, as many previous studies have attempted to determine whether pregnancy is associated with objective cognitive decline, with some studies supporting the notion and others refuting it.

The present findings are in agreement with those of previous studies, which have demonstrated that pregnant women perform more poorly than controls in tasks of reaction

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time, attention, learning and memory (Condon et al., 1991; de Groot et al., 2003; De Groot, Hornstra, et al., 2003; De Groot et al., 2006; Keenan et al., 1998; Silber et al., 1990), but at odds with other studies, which have failed to find such differences (Casey, 2000; Christensen et al., 1999; Christensen et al., 2010; Crawley et al., 2003; McDowall & Moriarty, 2000; Vanston & Watson, 2005). No differences in speed of information processing were found in the current study, which is concordant with findings from some previous studies (Condon et al., 1991; De Groot, Hornstra, et al., 2003; De Groot et al., 2006; Vanston & Watson, 2005), but at odds with others which have found pregnant women to be impaired in processing speed (Buckwalter et al., 1999; Christensen et al., 2010; Crawley et al., 2008). Due to studies using differing designs, varying sample sizes and assessment methods, examining women at different stages of pregnancy, of different parity and often failing to report inclusion or exclusion criteria, differences in findings are difficult to interpret. However, given the adequate power of the current sample, the use of standardised objective tests, the fact that pregnant women and controls were matched on educational status and did not differ in their estimated pre-morbid functioning, physical or mental health status, it is likely that the differences in cognitive functioning found in the present study between pregnant women and matched controls do exist. It is possible that as the 'deficits' remained within normal limits, they are not always identified during objective testing sessions, perhaps due to pregnant women applying increased effort in order to compensate for perceived cognitive deficits.

The suggestion by Henry and Rendell (2007) that executive functioning might be affected during pregnancy was supported by the results of the current study. However, despite taking longer to learn and complete the executive functioning task, pregnant women made fewer errors and made significantly less overruns than controls, suggesting they were less impulsive and possibly being more cautious than the control group, perhaps compensating in some way for a perceived decline in cognitive functioning. As few studies have examined executive functioning during pregnancy, this is an area warranting further investigation.

In the present study, measures of verbal recall and accuracy were related to the depression subscale of the HADS, suggesting that those with lower mood performed more poorly on these domains. These results are consistent with those of Harris (1996), who found that objective cognitive functioning was related to the depression subscale of the HADS and that when this was controlled for, differences in cognitive functioning between pregnant women and controls were no longer significant. However, other studies have found no relationship between mood and objective cognitive functioning (e.g., Vanston & Watson, 2005; Keenan et al., 1998; Condon et al., 1991; Casey et al., 2000). As mood data were not available for the matched control group (accessed from the IntegNeuro normative database) in the present study, it was not possible to control for its effects.

Sleep quality

Consistent with previous research (e.g., Gaylor & Manber, 2005), analyses of both subjective and objective sleep quality data confirmed significant sleep disturbance in the majority (64-70%) of women. Although approximately a third of women reported having had sleep difficulties in the past, these were mainly transient difficulties during times of stress; 92% believed pregnancy had made their sleep quality worse. Reported reasons for sleep disruption were similar to those found in previous studies (e.g., Hedman et al., 2002; Lee, 1998), typically including discomfort/pain, increased frequency of urination, foetal movements, RLS, heartburn, snoring, vivid dreams, anxiety and worry about the baby and impending birth.

Women took longer to get to sleep, had a longer period of wakefulness following sleep onset and had poorer sleep efficiency than normal sleepers. Although total sleep time at night was slightly less than the mean reported for young adults in other studies (e.g., Carskadon & Dement, 2005), the majority of women reported having had daytime naps in the past month, ranging from ten minutes to two and a half hours, which would suggest that they might actually be sleeping slightly longer than 'normal' sleepers over a 24-hour period. Self-reported sleep disturbance was related to self-reported anxiety and depression using the HADS, whereas objectively measured sleep was related to the depression subscale only. It is unknown whether sleep disturbance was exacerbated by anxiety and/or low mood, or whether sleep disturbance resulted in anxiety and/or low mood. It is likely, however, that the interaction between sleep and psychological factors is a complex one, with psychological factors impacting upon sleep and vice versa.

Relationship between sleep and subjective cognitive functioning

The hypothesis that sleep disturbance would be related to subjective cognitive functioning was supported. Poorer subjective sleep was related to higher total cognitive failures and specifically, to blunders (e.g., bumping into people, leaving important letters unanswered for days), poorer memory (e.g., forgetting appointments, forgetting where put something like a newspaper or a book) and distractibility (e.g., failing to notice signposts on the road, daydreaming when ought to be listening to something). These relationships remained significant when controlling for mood, other than the relationship between distractibility and self-reported sleep, which failed to reach significance when mood was controlled for, suggesting that a significant proportion of variance in perceived distractibility (or inattention) can be accounted for by low mood. These findings are similar to those of previous researchers who have found self-reported sleep disturbance to be related to subjective memory (Casey, 2000; Casey et al., 1999; Janes et al., 1999).

The present study was unique, in that it was the first to examine the relationship between objectively measured sleep quality during pregnancy and cognitive functioning. Although

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objective measures of sleep quality were found to be related to subjective cognitive functioning, in that increased WASO and poorer sleep efficiency were related to more reported cognitive failures, these relationships were no longer statistically significant when controlling for the effects of mood, indicating that mood accounts for a significant proportion of the variance in self-reported cognitive failures. These findings, suggest that sleep disruption and mood fluctuations during pregnancy interact and have an influence on perceived cognitive performance.

The third hypothesis, that those classified as having significant sleep disturbance on the PSQI would report poorer subjective cognitive functioning, was upheld. Further exploration of this data revealed that those with poorer subjective sleep quality reported being significantly more distractible, having a poorer memory and experiencing more blunders. These findings again suggest that poorer subjective cognitive functioning during pregnancy is partly attributable to poorer sleep.

Relationship between sleep and objective cognitive functioning

The finding that poorer self-reported sleep was related to poorer verbal recall provides partial support for the second hypothesis, as does the finding that poorer objectively measured sleep was related to poorer verbal recognition memory and decreased vigilance. These findings are contrary to findings from previous studies, which have found no relationship between self-reported sleep disturbance and objective cognitive performance (e.g. Casey, 2000; Casey et al., 1999; Janes et al., 1999; Keenan et al., 1998). The disparity in findings might be due to the methods used to assess sleep quality in previous studies. For example, some used only a single item to assess sleep quality (Casey, 2000; Janes et al., 1999), others used an unvalidated sleep questionnaire (Casey et al., 1999) or failed to report how sleep was assessed (Keenan et al., 1998); as previously mentioned, none used objective measures of sleep quality. As non-

parametric correlations were used for these analyses, it was not possible to control for the effects of mood on the above relationships. However, given that mood was significantly correlated with poorer subjective and objective sleep quality, it is likely that its effects will have accounted for some of the variance in these relationships.

When correcting for multiple comparisons, the relationship between objective sleep and verbal recognition memory failed to reach statistical significance; possibly due to the smaller number of participants (n=26) involved in this analysis, decreasing the power to detect a significant relationship. A total of 37 participants would have been required to maintain significance, following corrections for multiple comparisons. However, relationships between poorer objective sleep and decreased vigilance remained significant, despite the small sample size involved, implying that women in the third trimester of pregnancy do experience deficits related to vigilance, and these are at least partly attributable to their poor sleep quality. As this is the first study to examine the relationship between objective sleep quality and objectively measured cognitive functioning during pregnancy, this finding should be interpreted with caution and requires to be replicated in larger studies before any conclusions can be reached.

The fourth hypothesis, that women scoring above the threshold for significant sleep disturbance would exhibit poorer objectively measured cognitive functioning than those scoring below the threshold, was not supported. It is possible therefore, that women overestimate reported cognitive deficits during pregnancy, perhaps due to cultural stereotypes and popular beliefs that cognitive functioning is impaired during pregnancy, or as previously suggested, reported deficits may be more related to psychological factors than reported sleep disturbance. Similar findings have been found in research examining subjective and objective cognitive functioning in patients with temporal lobe epilepsy, in that subjective complaints have not been confirmed by objective assessments and have been more closely associated with psychological factors such as anxiety and depression (Vermeulen, Aldenkamp, & Alpherts, 1993). This may be the case during pregnancy also, when fluctuations in mood are common.

Other researchers have questioned the validity of self-reported memory abilities (e.g., Morris, 1984) and have suggested that self-reported memory failures might be more a reflection of people's beliefs about their performance (i.e. meta-memory), rather than reflecting their actual performance (e.g., Herrmann, 1984). This could help explain the finding in the current study that women reporting more disturbed sleep rated their cognitive functioning as poorer, but did not perform significantly differently than those reporting less disturbed sleep. Despite this possibility, it is likely that sleep disturbance and mood do interact and contribute to some deficits in subjective and objective cognitive functioning during late pregnancy.

Limitations

The present study was limited in that no subjective data for mood or cognitive functioning were available for the matched control group (accessed from the IntegNeuro database) in order for comparisons to be made between pregnant woman and controls. Similarly, prospective memory data from the pregnant sample was not compared with a non-pregnant control group, therefore limiting the ability to reach conclusions regarding this aspect of functioning during pregnancy. Furthermore, methods used to assess prospective memory were fairly crude and perhaps not rigorous enough to detect meaningful changes or relationships with sleep, in real-life settings.

With regards to sleep measures, only a small sample of participants undertook actigraphic monitoring, which therefore increased the chances of a type two error when examining relationships between objective sleep measures and cognitive functioning. Also, the HADS was chosen to assess symptoms of anxiety and depression in the present study, due to its focus on affective symptoms and inclusion of fewer somatic complaints (e.g., dizziness,

insomnia, fatigue), which are common in pregnancy and could therefore potentially inflate the rates of anxiety and depression if included in a screening instrument for psychological disturbance. However, recent findings have suggested the HADS lacks the internal reliability requirements of a clinical screening tool for anxiety and depression during pregnancy (Karimova & Martin, 2003). As the HADS was not being used for clinical purposes in the present study, this is not particularly significant. However, future studies examining mood during pregnancy, could perhaps more appropriately utilise the Edinburgh Postnatal Depression Scale (EPDS; Cox, Holden, & Sagovsky, 1987), which has been shown to be valid during pregnancy and the postnatal period (Evans, Heron, Francomb, Oke, & Golding, 2001).

Finally, due to time constraints, the present study was unable to include a follow-up assessment during the postpartum period, in order to determine whether reported changes in sleep and cognitive functioning changed following the birth. This would be useful and interesting to assess in future research examining sleep disturbance and cognitive functioning during pregnancy, as would the inclusion of women prior to becoming pregnant.

Despite these limitations, the present study adds to the existing literature on sleep disturbance and cognitive functioning during pregnancy. It is the first study to specifically investigate the potential role of sleep disturbance in the aetiology of pregnancy-related cognitive impairment. It is also the first study to utilise objective measures of sleep quality in the exploration of relationships between sleep quality and cognitive functioning during pregnancy, and the first to use the standardised IntegNeuro computerised cognitive tests, both for the pregnant group and to access a non-pregnant, matched control group for comparison.

Clinical implications.

The study findings indicate that sleep may be an important factor affecting the perceived and objective cognitive functioning of women in late pregnancy, as well as impacting upon mood. These findings are concordant with a growing body of evidence, suggesting that sleep is important for memory processing and emotion regulation (Walker, 2008; Walker & van der Helm, 2009). The current findings have implications for antenatal care, in that information regarding cognitive difficulties commonly experienced during pregnancy, the potential role of sleep disturbance in the aetiology of these difficulties, and strategies to help overcome them could be incorporated into existing care. Strategies might include simply advising women in late pregnancy to take their time when learning new tasks, to carry a notebook for taking messages, to set reminders in a mobile phone, or to use a diary or calendar to help overcome any difficulties with memory.

Given the importance of sleep in memory processing and emotion regulation, and the finding that sleep is often disturbed during pregnancy, it is important that sleep quality during pregnancy is routinely enquired about during antenatal appointments, so that those at risk of developing problems with mood and cognitive processing are identified early. A screening questionnaire with recognised cut-off scores for significant sleep disturbance, such as the PSQI, might be useful in this regard. The fact that sleep disruption during pregnancy has been associated with an increased risk of adverse birth outcomes and post-natal mood disturbance (Karacan et al., 1969), and post-natal mood disturbance is known to impact negatively upon mother-infant interactions (Stein et al., 1991), further exemplifies the importance of sleep disturbance being a priority in antenatal health care, with interventions being offered where appropriate.

Interventions targeting the causes of sleep disturbance previously highlighted might include teaching strategies for coping with stress and anxiety, reducing worry about the birth by increasing knowledge of pregnancy and birthing options, offering advice about sleeping positions, dietary factors known to affect sleep during pregnancy, and ways of reducing uncomfortable sensations associated with leg cramps and RLS.

The present study findings also have implications for employers, in that they highlight the importance of workload adjustments being considered during late pregnancy, especially when sleep is particularly disturbed. Finally, perhaps women with significantly disturbed sleep during late pregnancy should be advised to consider starting maternity leave earlier, in order to allow themselves to rest prior to the arrival of their newborn, especially as the postnatal period is also a time associated with significant sleep disturbance and fluctuations in mood.

Future research.

Future research examining the relationship between sleep disturbance and cognitive functioning during pregnancy would benefit from using controlled, prospective, longitudinal designs, examining both the antenatal and postnatal period in addition to comparing sleep and cognitive functioning across all trimesters of pregnancy, and including women of differing parity. Longitudinal studies would be useful in comparing changes in sleep pattern, mood and cognitive functioning prior to, during and after pregnancy and also to help determine which stage or stages of pregnancy, if any, are associated with cognitive decline.

Due to the suggestion that prospective memory tasks are more valid and sensitive to detecting actual change when assessed outside the laboratory, future research would benefit from employing more rigorous measures of prospective memory, perhaps requiring participants to undertake a range of tasks in naturalistic settings. As some deficits in aspects of executive functioning were identified in pregnant women, compared with the control sample, this is an area that merits further exploration, as is the possibility that pregnant

women may compensate in some way for perceived cognitive deficits, by being more cautious and less impulsive when completing complex tasks. Furthermore, in addition to assessing sleep and cognitive functioning objectively (using a minimum of 37 participants), future research could ask women about their attributions of any perceived cognitive changes, perhaps including more qualitative, detailed information and also enquiring about strategies already utilised by women to cope with any reported cognitive changes.

Further exploration of the aetiology of cognitive changes during pregnancy, including more detailed investigations of the causes of sleep disturbance, the relationship between sleep disturbance and psychological factors (using appropriate measures) and further examination of the functional consequences of sleep loss and decreased cognitive functioning during pregnancy would be beneficial.

Conclusion

The present study examined the relationship between disturbed sleep and cognitive functioning in late pregnancy. Findings indicated that sleep was often disturbed during this time and impairments in cognitive functioning were commonly reported, although not always detected using objective assessments. It is possible that in the context of laboratory-based assessments, women were able to focus all their attention on the task at hand, and therefore overcome any mild cognitive deficits experienced in their everyday lives. The pregnant women may also have been compensating by applying increased effort, due to perceived cognitive deficits. Women may also exaggerate subjective cognitive impairments during pregnancy due to cultural stereotypes and expectations.

When deficits in perceived and objective cognitive functioning do exist, it is likely that they are influenced by a complex interaction between sleep disturbance and psychological factors, as well as other biological factors, which have been reported in previous studies. Women may also become more focused on their pregnancy and therefore have less available cognitive resources for other everyday demands.

The present study adds to the literature on sleep disturbance and cognitive functioning during late pregnancy and helps increase understanding of the aetiology of both subjective and objective cognitive impairment during this time.

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Chapter Three

Advanced Clinical Practice I

Reflective Critical Account

(Abstract only)

A Reflection on the Role of Therapist Self-Disclosure in Clinical

Practice

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

¹Author for correspondence

Abstract

The following reflective account is based upon a situation that arose in the context of a clinical session with a patient. It is structured using the Gibbs' (1988) model and relates to my reactions, thoughts, feelings, evaluations and resulting professional learning and development, following a comment made by the patient. The process of deeper thought and reflection that occurred regarding my communication style with patients in general, and specifically in relation to the issue of therapist self-disclosure (TSD) and its place in the therapeutic alliance is then discussed. Relevant professional practice guidelines and empirical evidence are reviewed, as is my relevant background and development as a practitioner prior to commencing Clinical Psychology training. Finally, my experience of completing the reflective account is discussed and the relevance of my learning experience to my professional development and more widely, to the profession of Clinical Psychology is reflected upon.



Chapter Four

Advanced Clinical Practice II

Reflective Critical Account

(Abstract only)

A Reflection on the Roles of Teaching and Training within the

Profession of Clinical Psychology

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

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Abstract

The following reflective account is based upon my indirect experience of teaching and training of Clinical Psychologists and other professionals within my second advanced clinical practice placement. It is structured using the Boud et al. (1985) model and relates to my thoughts, feelings, evaluations, behaviour and resulting professional learning and development, regarding the role of teaching within my placement and within the profession of Clinical Psychology as a whole. In order to put the reflection into context, the background and context of teaching and training within Clinical Psychology is discussed. Relevant professional practice guidelines and national occupational standards are reviewed. Finally, my experience of completing the reflective account is discussed and the relevance of my learning experience to my professional development and more widely, to the profession of Clinical Psychology is reflected upon.

Appendix 1.1 Guidelines for authors: The Journal of Child Psychology and Psychiatry

The Journal of Child Psychology and Psychiatry

Published on behalf of the Association for Child and Adolescent Mental Health

Edited by: Edmund Sonuga-Barke

Print ISSN: 0021-9630 Online ISSN: 1469-7610 Frequency: Monthly Current Volume: 51 / 2010 ISI Journal Citation Reports® Ranking: 2008: 9/101 Psychiatry; 6/85 Psychiatry (Social Science); 2/55 Psychology, Developmental Impact Factor: 4.854

TopAuthor Guidelines

Notes for Contributors

Why submit your article to The Journal of Child Psychology and Psychiatry?

- Ranked 2nd in Developmental Psychology category, Thomson ISI;
- Impact Factor 4.432 (2007);
- Publishes an <u>Annual Research Review</u> bringing you the very best papers on current critical topics of the field;
- Over 6,000 institutions with access to current content;
- Massive international readership; over 450,000 articles downloaded every year with strong online usage in the US, Australasia and Asia as well as the UK and Europe;
- Genuinely international authorship 1/3 in the US, 1/3 in the UK and 1/5 in Europe;
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- Acceptance to Early View publication approx. 2 months; Acceptance to print publication approx. 6 months;
- Authors receive free online access to their article once published as well as 20% discount on all Wiley-Blackwell publications.

General

Contributions from any discipline that further knowledge of the mental health and behaviour of children and adolescents are welcomed. Papers are published in English, but submissions are welcomed from any country. Contributions should be of a standard that merits presentation before an international readership.

Papers may assume either of the following forms:

• Original articles

These should make an original contribution to empirical knowledge, to the theoretical understanding of the subject, or to the development of clinical research and practice. Adult data are not usually accepted for publication unless they bear directly on developmental issues in childhood and adolescence. Original articles should not exceed 6000 words, including title page, abstract, references, tables, and figures; the total word count should be given on the title page of the manuscript. Limit tables and figures to 5 or fewer double-spaced manuscript pages. It is possible to submit additional tables or figures as an Appendix for an online-only version. Manuscripts exceeding the word limit will not be accepted without permission from the Editor.

• Review articles

These should survey an important area of interest within the general field. These include papers in the Annual Research Review, Research Review and Practitioner Review sections, which are usually commissioned. Word limits for review papers are stated at the time of commissioning.

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Submission of a paper to JCPP will be held to imply that it represents an original contribution not previously published (except in the form of an abstract or preliminary report); that it is not being considered for publication elsewhere; and that, if accepted by the Journal, it will not be published elsewhere in the same form, in any language, without the consent of the Editors. When submitting a manuscript, authors should state in a covering letter whether they have currently in press, submitted or in preparation any other papers that are based on the same data set, and, if so, provide details for the Editors.

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Authorship

Authorship credit should be given only if substantial contribution has been made to the following:

· Conception and design, or collection, analysis and interpretation of data

 \cdot Drafting the article or revising it critically for important intellectual content, and final approval of the version to be published

The corresponding author must ensure that there is no one else who fulfils the criteria who is not included as an author. Each author is required to have participated sufficiently in the work to take public responsibility for the content.

Conflict of interest

All submissions to JCPP require a declaration of interest. This should list fees and grants from, employment by, consultancy for, shared ownership in, or any close relationship with, an organisation whose interests, financial or otherwise, may be affected by the publication of the paper. This pertains to all authors, and all conflict of interest should be noted on page 1 of the submitted manuscript. Where there is no conflict of interest, this should also be stated.

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http://www.controlled-trials.com/isrctn/ Australian Clinical Trials Registry http://actr.ctc.usyd.edu.au Clinical Trials http://www.clinicaltrials.gov ISRCTN Register http://isrctn.org Nederlands Trial Register http://www.trialregister.nl/trialreg/index.asp UMIN Clinical Trials Registry http://www.umin.ac.jp/ctr

Access to data

If the study includes original data, at least one author must confirm that he or she had full access to all the data in the study, and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Manuscript preparation and submission

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1. The manuscript should be double spaced throughout, including references and tables. Pages should be numbered consecutively. The preferred file formats are MS Word or WordPerfect, and should be PC compatible. If using other packages the file should be saved as Rich Text Format or Text only.

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Headings: Articles and research reports should be set out in the conventional format: Methods, Results, Discussion and Conclusion. Descriptions of techniques and methods should only be given in detail when they are unfamiliar. There should be no more than three (clearly marked) levels of subheadings used in the text.

Acknowledgements: These should appear at the end of the main text, before the References.

Correspondence to. Full name, address, phone, fax and email details of the corresponding author should appear at the end of the main text, before the References.

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For up to five authors, all surnames should be cited in the first instance, with subsequent occurrences cited as et al., e.g. Smith et al. (1981) or (Smith et al., 1981). For six or more authors, cite only the surname of the first author followed by et al. However, all authors should be listed in the Reference List. Join the names in a multiple author citation in running text by the word 'and'. In parenthetical material, in tables, and in the References List, join the names by an ampersand (&). References to unpublished material should be avoided.

Reference list: Full references should be given at the end of the article in alphabetical order, and not in footnotes. **Double spacing must be used**.

References to journals should include the authors' surnames and initials, the year of publication, the full title of the paper, the full name of the journal, the volume number, and inclusive page numbers. Titles of journals must not be abbreviated and should be italicised.

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Kiernan, C. (1981). Sign language in autistic children. *Journal of Child Psychology and Psychiatry*, 22, 215-220.

Thompson, A. (1981). Early experience: The new evidence. Oxford: Pergamon Press.

Jones, C.C., & Brown, A. (1981). Disorders of perception. In K. Thompson (Ed.), *Problems in early childhood* (pp. 23-84). Oxford: Pergamon Press.

Use Ed.(s) for Editor(s); edn. for edition; p.(pp.) for page(s); Vol. 2 for Volume 2.

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Appendix 1.2 Guidelines for Authors: Journal of Reproductive and Infant Psychology

Journal of Reproductive and Infant Psychology welcomes reports of original research and creative or critical review articles which make an original contribution. Articles should not currently be submitted for publication elsewhere.

topics of interest to the journal include psychological, behavioural, cognitive, affective, dynamic, medical, societal and social aspects of: fertility and infertility; menstruation and menopause; pregnancy and childbirth; antenatal preparation; motherhood and fatherhood; early infancy; infant feeding; early parent-child relationships; postnatal psychological disturbance and psychiatric illness; obstetrics and gynaecology including preparation for medical procedures; psychology of women; nursing, midwifery, neonatal care, health visiting, health promotion and health psychology.

The journal also publishes brief reports, comment articles and special issues dealing with innovative and controversial topics. A review section reports on new books and training material.

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Description of the Journal's reference style, Quick guide

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Diagrams, graphs, drawings and half-tone illustrations should be on a separate sheet labelled 'Figure. 1' and so forth. Where possible they should be submitted as artwork ready for photographic reproduction, larger than the intended size. Where more than one figure is submitted, they should as far as possible be to the same scale.

SI units should be used for all measurements. Imperial measurements may be quoted in brackets. Where studies involve small numbers of subjects, both numbers and percentages of groups should be given.

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Appendix 2.1 Results of Search Strategy



Author	Year	Title	Quality	Category
			rating	
Chadez, L.H.	1987	Stopping bedtime crying: Treating the child and	60%	Moderate
& Nurius, P.S.		the parents.		
Durand, V.M.	1990	Behavioral treatment of multiple childhood sleep	76%	High
& Mindell,		disorders. Effects on child and family.		
J.A.				
France, K.G.	2005	Modifications of Systematic Ignoring in the	76%	High
& Blampied,		Management of Infant Sleep Disturbance:		
N.M		Efficacy and Infant Distress.		
France, K.G.&	1990	Behavior management of infant sleep disturbance.	80%	High
Hudson, S.M.				
Healey, D.,	2009	Treating sleep disturbance in infants: What	88%	High
France, K.G.		generalizes?		
& Blampied,				
N.M.				
Hiscock, H. &	2002	Randomised controlled trial of behavioural infant	88%	High
Wake, M		sleep intervention to improve infant sleep and		
		maternal mood.		
Hiscock, H. et	2007	Improving infant sleep and maternal mental	84%	High
al.		health: a cluster randomised trial.		
Lawton, C.,	1991	Treatment of infant sleep disturbance by	80%	High
France, K. G.,		graduated extinction.		
& Blampied,				
N. M				
Leeson et al.	1994	Management of infant sleep problems in a	72%	High
		residential unit.		
Sadeh, A.	1994	Assessment of intervention for infant night	72%	High
		waking: parental reports and activity-based home		
		monitoring.		
Thunström,	2000	A 2.5-year follow-up of infants treated for severe	80%	High
M.		sleep problems.		

Appendix 2.2 Studies selected for inclusion and quality ratings

Appendix 2.3 Effect sizes (Cohen's d), calculated from Mean and SD where possible

Study	Intervention(s)	Outcome measures	Effect size
France, K.G. &	Parental presence,	Frequency of night	<i>d</i> =2.28
Blampied, N.M (2005)	minimal check,	waking	<i>d</i> =1.66
	unmodified		<i>d</i> =1.56
France, K.G.& Hudson,	Unmodified	Frequency &	<i>d</i> =2.36
S.M. (1990)		duration of night waking	<i>d</i> =1.34
Hiscock, H. et al. (2007)	Controlled crying,	Presence of sleep	OR= 0.5
	camping out,	problem	
	usual care		
Leeson et al. (1994)	Graduated extinction	Frequency &	<i>d</i> =1.87
	and stimulus control	duration of night waking	<i>d</i> =1.29
Sadeh, A. (1994)	Graduated extinction,	Frequency of night	<i>d</i> =1.37
	parental co-sleeping	waking	
Thunström, M. (2000)	Graduated extinction,	Frequency &	<i>d</i> =1.7
	stimulus control &	duration of night waking	<i>d</i> =1.68
	family work	total sleep time	<i>d</i> =0.83

Author	Year	Title	Reason
Adair, R. et al.	1992	Reducing night waking in infancy: A primary care	Not extinction.
,		intervention.	Includes infants
			<6m
Adams, L.A. &	1989	Reducing bedtime tantrums: Comparison between positive	Includes infants
Rickert, V.I.		routines and graduated extinction.	>24m
Anders	1979	Night waking in infants during the first year of life.	Not behavioural
			intervention.
Armstrong, K.L. et	1998	Sleep deprivation or postnatal depression in later infancy:	Includes infants
al.	2002	Separating the chicken from the egg	>24m
Burnham, M.M. et	2002	Nighttime sleep-wake patterns and self soothing from birth	Not extinction.
al.		to one year of age: a longitudinal intervention study.	Includes infants
Ealzanhang D	2002	Tractment of clean problems in families with small	<0III Includes infonts
Eckerberg, D.	2002	childrent of sleep problems in families with small	includes infants
Eckerberg B	2004	Treatment of sleep problems in families with young	 Uncludes infants
Lekerberg, D.	2004	children effects of treatment on family well-being	>24m
France K G	1992	Behavior characteristics and security in sleep-disturbed	Main outcome not
Trance, Res	1772	infants treated with extinction.	ISD
France, K.G.,	1991	Treatment of infant sleep disturbance by trimeprazine in	Includes infants
Blampied, N.M. &		combination with extinction.	>24m
Wilkinson, P.			
Friman, P.C. et al.	1999	The bedtime pass: An approach to bedtime crying and	Includes infants
		leaving the room.	>24m
Hall, W.A. et al.	2006	Effects on parents of an intervention to resolve infant	Main outcome not
		behavioral sleep problems.	ISD
Hall, W.A. et al.	2006	Effects of an intervention aimed at reducing night waking	Includes infants
	• • • • •	and signalling in 6- to 12-month-old infants.	<6m
Hiscock, H. et al.	2008	Long-term mother and child mental health effects of a	Main outcome not
		population-based infant sleep intervention: cluster-	ISD
Jonas DDU &	1092	Pahavioural management of clean problems	Includes infents
Verduyn C M	1965	behavioural management of steep problems.	>24m
Kerr S M Iowett	1996	Preventing sleep problems in infants: A randomised	Not extinction
S.A. & Smith. L.N.	1770	controlled trial.	Includes infants
~,,			<6m
Minde, K., Faucon,	1994	Sleep problems in toddlers: effects of treatment on their	Not extinction.
A. & Falkner, S.		daytime behavior.	Includes infants
			>24m
Minde, K., Popiel,	1993	The evaluation and treatment of sleep disturbances in young	Not extinction
K., Leos, N.,		children.	
Falkner, S. et al.	1002		
Mindell, J.A. &	1993	I reatment of childhood sleep disorders: generalisation	Includes infants
Durand, V.IVI.	2007	Priof report: Evaluating the badtime page program for shild	>24111 Includes infents
MOOIE, D.E. et al.	2007	resistance to bedtime, a randomised controlled trial	>24m
Pinilla P & Birch	1993	Help me make it through the night. Behavioral entrainment	Not extinction
L.L.	1770	of breast-fed infants' sleep patterns.	Includes infants
		I I I	<6m
Pritchard, A. &	1988	Management of sleep problems in preschool children:	Includes infants
Appleton, P.		Effects of a behavioural programme on sleep routines,	>24m
		maternal depression and perceived control.	
Rapoff, M.A. et al.	1982	The management of common childhood bedtime problems	Includes infants
		by pediatric nurse practitioners.	>24m
Reid, M.J., Walter,	1999	Treatment of young children's bedtime refusal and	Includes infants
A.L. & O'Leary,		nighttime wakings: A comparison of "standard" and	>24m
S.G.		graduated ignoring procedures.	1

Appendix 2.4 Studies in which full text was reviewed and excluded

Richman, N. et al.	1985	Behavioural methods in the treatment of sleep disorders- a pilot study.	Includes >24m	infants
Rickert, V.I. & Johnson, C.M.	1988	Reducing nocturnal awakening and crying episodes in infants and young children: a comparison between scheduled awakenings and systematic ignoring.	Includes >24m	infants
Robinson, K.E. & Sheridan, S.M.	2000	Using the Mystery Motivator to Improve Child Bedtime Compliance	Includes >24m	infants
Rolider , A.& Van Houten, R.	1984	Training parents to use extinction to eliminate nighttime crying by gradually increasing the criteria for ignoring crying.	Includes >24m	infants
Sanders, R., Bor, B. & Dadds, M.	1984	Modifying bedtime disruptions in children using stimulus control and contingency management techniques.	Includes >24m	infants
Selim, C.A. et al.	2006	Treating treatment-resistant infant sleep disturbance with combination pharmacotherapy and behavioural family interventions.	Includes >24m	infants
Seymour, F.W.	1987	Parent management of sleep difficulties in young children.	Includes >24m	infants
Seymour, F.W. et al.	1983	Management of night-waking in young children.	Includes >24m	infants
Seymour, F.W. et al.	1989	Reducing sleep disruptions in young children: Evaluation of therapist-guided and written information approaches: A brief report.	Includes >24m	infants
Smart, J. & Hiscock, H.	2007	Early infant crying and sleeping problems: a pilot study of impact on parental well-being and parent-endorsed strategies for management.	Main outc ISD	ome not
St James-Roberts, I.	2008	Infant crying and sleeping: helping parents to prevent and manage problems.	Not extinc	ction
Stremler, R. et al.	2006	A behavioral-educational intervention to promote maternal and infant sleep: A pilot randomized, controlled trial.	Not extinc	ction
Symon, B.G., Marley, J.E., Martin A.J. & Norman, E.R.	2005	Effect of a consultation teaching behaviour modification on sleep performance in infants: a randomised controlled trial.	Not extinc Includes <6m	ction. infants
Weir, I.K. & Dinnick, S.	1988	Behaviour modification in the treatment of sleep problems occurring in young children: a controlled trial using health visitors as therapists.	Includes >24m	infants
Williams, C.D.	1958	The elimination of tantrum behaviour by extinction procedures.	Poor healt	h
Wolfson, A., Futterman, A. & Lacks, P.	1992	Effects of parent training on infant sleeping patterns, parents' stress, and perceived parental competence.	Not extinc Includes <6m	ction. infants

Appendix 2.5 Quality rating tool

Study identificat	tion (au	thor, year of publication, title, journal title, pages):	
Rated by:			
Paper	Item	Descriptor	Score
Section/Topic		F	~
Objectives	1	The study addresses an appropriate and clearly focused	0,1
		question.	
Recruitment	2	The recruitment process is clearly described.	0,1
Sample	3	The sample characteristics are sufficiently described.	0,1
		(age, gender, demographics etc)	
	4	The sleep problem is sufficiently described.	0,1
	5	The inclusion criteria are stated.	0,1
	6	The exclusion criteria are stated.	0,1
Design	7	The study design is appropriate to answer the study question.	0,1,2
		(RCT=2, well designed single subject design or non-	
		randomised controlled trial =1, uncontrolled trial=0)	
	8	Baseline data has been obtained.	0,1
	9	A follow-up assessment is undertaken.	0,1
Intervention	10	The intervention is clearly described	0,1,2
		(clearly described including amount of therapist support	
		involved, who implemented intervention, timing of treatment	
		components= 2, clearly described with some detail of therapist	
		support, timing etc=1, not clear=0)	0.1
	11	The planned intervention is appropriate to answer study	0,1
	10	question.	0.1
Outcomes	12	larget behaviour is precise, repeatable and operationally	0,1
		defined. (e.g. time to settle, number and duration of night	
	12	awakenings)	012
	15	rarget behaviour is measured remaining and conjected in a	0,1,2
		(objective and subjective measures-2) subjective measures by	
		(objective and subjective measures=2, subjective measures by more than one rater=1 subjective measures by one rater= 0)	
	14	Other aspects of the infant's behaviour are assessed (adverse	0.1
	14	effects)	0,1
	15	Implementation difficulty/treatment acceptability is assessed.	0.1
Analyses	16	The analyses used are clearly described.	0.1
	17	The analyses used are appropriate to answer the study	0.1
		question.	
	18	Effects of individual treatment components are analysed.	0,1
Results	19	Results are clearly presented.	0,1
	20	Attrition rates and reasons are recorded (if n/a, rate as 1)	0,1
	21	The results are accurately interpreted	0,1
	22	The discussion and conclusions are in keeping with the results	0,1
		obtained	
			/25

Appendix 3.1 Poster







Expecting your first child?

In your third trimester?

We would like to hear from you.

We are currently carrying out research into the effects of disturbed sleep during pregnancy on memory and absentmindedness. We are looking for women in the third trimester of pregnancy, aged 20-39 and expecting their first child to take part in our research.

Interested? Contact Kirsty Horne on 07833 095249 or

sleepinpregnancy@yahoo.co.uk for more information.





SLEEP AND MEMORY PROBLEMS IN PREGNANCY

PARTICIPANT INFORMATION SHEET

My name is Kirsty Horne. I am a trainee clinical psychologist from the University of Glasgow. I would like to invite you to take part in a study looking at disturbed sleep during pregnancy and memory. The information gathered is for research purposes only and is a requirement of my training. You will not be identifiable in the results.

Before you decide whether or not to take part, it is important for you to understand why the research is being carried out and what it will involve. Please take your time to read the following information carefully. If there is anything that is unclear or if you would like more information, please let me know. Take your time to decide whether or not you wish to take part.

• What is the title of this project?

The Relationship between Disturbed Sleep during Pregnancy and Cognitive Functioning.

• Why is this study important?

Although previous studies have shown that women report memory loss and absentmindedness ('baby brain') during pregnancy, there has been very little research looking at the possible reasons for this. Many women also report having disturbed sleep during pregnancy. The current research will look for a relationship between poor sleep in pregnancy and memory difficulties.

• What are the aims of this study?

The current study aims to measure women's sleep quality in pregnancy and look for a link between sleep quality and memory difficulties.

• Who can take part in this study?

Women in good health, aged between 20 and 39 and expecting their first child can take part. Women must also be in their last 3 months of pregnancy.

Women will not be able to take part if they have had pregnancy complications. Those with a diagnosis of sleep disorder, known psychiatric or depressive disorder or drug or alcohol problems will not be able to take part.

• Do I have to take part?

You do not have to take part in this study. Participation is entirely voluntary. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to come out of the study at any time without giving a reason.

• What does participation in this study involve?

If you decide to take part, you will be asked to meet with me at the University of Glasgow Sleep Centre, based in the Southern General Hospital at a time that is convenient to you. This is about a three-minute walk from the maternity unit. You will be given the chance to ask questions and will sign the consent form. You will then be asked to complete 5 short questionnaires about

your background, your sleep, your memory and your mood. I will then ask you to complete some memory tasks. This should take approximately 1 hour in total.

I may ask you to take home a special wristwatch to be worn during the night for a period of 5 nights in order to measure your sleep quality. I will ask you to return this to me the following week.

You will be given some self-help information and offered the opportunity to attend an event about ways of improving sleep at the end of the study.

• What will happen to all of the information?

All of the information collected about you during the research study will be kept *strictly confidential*. Personal details (such as your name and address) will not be stored on computer, so that you cannot be recognised from it.

Written feedback will be provided to those who request it following completion of the study.

• Who is supervising this study?

My research supervisor, Professor Colin Espie, who works for the University of Glasgow, will supervise me.

• Who is paying for this study?

This study is being funded through the University of Glasgow and has been reviewed by a Research Ethics Committee. The committee has approved the research as appropriate.

• What if something goes wrong?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact my supervisor, Professor Colin Espie at the University of Glasgow (Tel: 0141 232 7696), who will be able to advise you on the appropriate complaints procedure, should you wish to use this.

• What should I do if I have any questions about this study?

If you would like further details about the study, you can either contact me by phone or email. Alternatively you can write down any questions you have and we can discuss them at our first meeting together.

• What do I do now if I want to take part in this study?

If you decide that you would like to take part in the study you can either contact me on 07833 095249 or sleepinpregnancy@yahoo.co.uk and we will arrange an appointment. If you decide you don't want to, there is no need to reply. *

You are under **no obligation** to take part; participation in this study is **completely voluntary**. You **do not** have to give a reason for not wanting to take part in this study.

I would like to take this opportunity to thank you for your time and consideration.

Appendix 3.3 Demographic questionnaire

Fit the inclusion criteria? Yes No

Allocated participant number

Name:	
Post Code: Phone number:	
GP name and address:	
• Age:	
Marital Status: (please circle) Single Co-habiting Married Divorced Ot (please specify)	ther
How would you describe your ethnic origin?	
Number of weeks pregnant:	
Are you expecting your first child? Yes [] No []	
Have you had complications with this pregnancy? Yes [] No [] If yes, please describe:	
Are you currently suffering from any physical health problems? Yes [] No [If yes, please describe:	
Are you currently taking any medication? Yes [] No [] If yes, please describe:	_
Pre-pregnancy weight? and height?	
Are you currently suffering from a diagnosed sleep disorder? Yes [] No [] If yes, please describe:	_
Are you suffering from a psychiatric or depressive disorder? Yes [] No [] If yes, please describe:	_
Do you have any problems with drug or alcohol misuse? Yes [] No [] If yes, please describe:	_
Employment status: Employed [] Unemployed [] Other [] If other, please state:	
Occupation (if unemployed, usual occupation):	
What is your household annual income?	
 How many years have you been in formal education (including primary and second school, college, university)? 	dary

Appendix 3.4 Additional questions on the PSQI

1. During the past month, have you gone for naps during the day? Yes/No

If Yes, how many and for how long?

2. Have you suffered from poor sleep in the past? Yes/ No If Yes....

• Please describe (eg. insomnia, restless leg syndrome, snoring/difficulty breathing)

If no....

• What do you think is the cause of your sleep problems at present? (if applicable)

3. Has your sleep changed since becoming pregnant? Yes/ No If Yes....

- Please describe
- Has pregnancy made it better/worse?

4. Was your sleep <u>last night</u> a typical night's sleep for you? Yes/ No If no, was it better or worse than usual?_____

5. From the list below please circle the number that best describes your level of alertness or sleepiness <u>right now</u>.

LEVEL OF ALERTNESS/SLEEPINESS

- 1. Feeling active, vital, alert, wide awake.
- 2. Functioning at a high level but not at peak, able to concentrate
- 3. Relaxed, awake but not fully alert, responsive
- 4. A little foggy, let down
- 5. Foggy, beginning to lose track, difficulty in staying awake
- 6. Sleepy, prefer to lie down, woozy
- 7. Almost in reverie, cannot stay awake, sleep onset appears imminent.

Appendix 3.5 Example of a wrist actigraph



Appendix 3.6 Actogram output





Appendix 3.7 Sleep analysis and sleep summary

Sleep Summary								
File Copy								
	- Analysis Period	Start Day	22-Apr-1997	÷	End Day	28-Apr-1997	÷	
Date	22-Apr-1997	23-Apr-1997	24-Apr-1997	25-Apr-1997	26-Apr-1997	27-Apr-1997	28-Apr-1997	Mean Values
Day	Tue	Wed	Thu	Fri	Sat	Sun	Mon	
Bed time	23:20	23:20	23:20	23:20	23:20	23:20	23:20	0
Get up time	07:40	07:40	07:40	07:40	07:40	07:40	07:40	
Time in bed	08:20	08:20	08:20	08:20	08:20	08:20	08:20	08:20:00
Sleep start	23:38	23:37	23:30	23:21	23:20	23:34	00:01	1
Sleep end	07:22	07:22	07:17	07:40	07:38	07:08	07:08	
Assumed sleep	07:44	07:45	07:47	08:19	08:18	07:34	07:07	07:47:43
Actual sleep time	06:25	06:35	06:37	07:09	06:43	06:43	06:11	06:37:34
Actual sleep (%)	83.0	84.9	85.0	86.0	80.9	88.8	86.9	85.07
Actual wake time	01:19	01:10	01:10	01:10	01:35	00:51	00:56	01:10:09
Actual wake (%)	17.0	15.1	15.0	14.0	19.1	11.2	13.1	14.93
Sleep efficiency	77.0	79.0	79.4	85.8	80.6	80.6	74.2	79.51
Sleep latency	00:18	00:17	00:10	00:01	00:00	00:14	00:41	00:14:26
Sleep bouts	30	28	30	28	40	26	24	29.43
Wake bouts	31	29	30	28	40	26	23	29.57
Mean sleep bout time	00:12:50	00:14:06	00:13:14	00:15:19	00:10:04	00:15:30	00:15:27	00:13:47
Mean wake bout time	00:02:33	00:02:25	00:02:20	00:02:30	00:02:22	00:01:58	00:02:26	00:02:22
Immobile mins	388.0	395.0	392.0	429.0	413.0	392.0	357.0	395.14
Immobile time (%)	83.6	84.9	83.9	86.0	82.9	86.3	83.6	84.46
Moving mins	76.0	70.0	75.0	70.0	85.0	62.0	70.0	72.57
Moving time (%)	16.4	15.1	16.1	14.0	17.1	13.7	16.4	15.54
No of immobile phases	46	41	49	44	55	38	44	45.29
Mean length immobility	8.4	9.6	8.0	9.8	7.5	10.3	8.1	8.81
One Minute immobility	10	9	10	4	12	5	5	7.86
One Min immobility (%)	21.7	22.0	20.4	9.1	21.8	13.2	11.4	17.09
Total activity score	10181	9069	9128	8617	11809	5109	6660	8653.29
Mean activity score	21.94	19.50	19.55	17.27	23.71	11.25	15.60	18.40
Mean score in active periods	133.96	129.56	121.71	123.10	138.93	82.40	95.14	117.83
Fragmentation index	38.1	37.1	36.5	23.1	38.9	26.9	27.8	32.63
Avg wake movement	241.5	316.7	312.2	328.8	391.0	279.1	330.1	314.20

Appendix 3.8 The Cognitive Failures Questionnaire

THE COGNITIVE FAILURES QUESTIONNAIRE

The following questions are about minor mistakes, which everyone makes from time to time, but some of which happen more often than others. We want to know how often these things have happened to your <u>in the past month</u>. Please circle the appropriate number.

		Very often	Quite often	Occasionally	Very rarely	Never
1.	Do you read something and find you haven't been thinking about it and must read it again?	4	3	2	1	0
2.	Do you find you forget why you went from one part of the house to the other?	4	3	2	1	0
3.	Do you fail to notice signposts on the road?	4	3	2	1	0
4.	Do you find you confuse right and left when giving directions?	4	3	2	1	0
5.	Do you bump into people?	4	3	2	1	0
6.	Do you find you forget whether you've turned off a light or a fire or locked the door?	4	3	2	1	0
7.	Do you fail to listen to people's names when you are meeting them?	4	3	2	1	0
8.	Do you say something and realize afterwards that it might be taken as insulting?	4	3	2	1	0
9.	Do you fail to hear people speaking to you when you are doing something else?	4	3	2	1	0
10.	Do you lose your temper and regret it?	4	3	2	1	0
11.	Do you leave important letters unanswered for days?	4	3	2	1	0
12.	Do you find you forget which way to turn on a road you know well but rarely use?	4	3	2	1	0
13.	Do you fail to see what you want in a supermarket (although it's there)?	4	3	2	1	0
14.	Do you find yourself suddenly wondering whether you've used a word correctly?	4	3	2	1	0

		Very often	Quite often	Occasionally	Very rarely	Never
15.	Do you have trouble making up your mind?	4	3	2	1	0
16.	Do you find you forget appointments?	4	3	2	1	0
17.	Do you forget where you put something like a newspaper or a book?	4	3	2	1	0
18.	Do you find you accidentally throw away the thing you want and keep what you meant to throw away- as in the example of throwing away the matchbox and putting the used match in your pocket?	4	3	2	1	0
19.	Do you daydream when you ought to be listening to something?	4	3	2	1	0
20.	Do you find you forget people's names?	4	3	2	1	0
21.	Do you start doing one thing at home and get distracted into doing something else (unintentionally)?	4	3	2	1	0
22.	Do you find you can't quite remember something although it's "on the tip of your tongue"?	4	3	2	1	0
23.	Do you find you forget what you came to the shops to buy?	4	3	2	1	0
24.	Do you drop things?	4	3	2	1	0
25.	Do you find you can't think of anything to say?	4	3	2	1	0

[Broadbent, Cooper, FitzGerald & Parkes, 1982]

Appendix 3.9 IntegNeuro illustration





Appendix 3.10 Self-help for sleep difficulties during pregnancy







Self-help for Sleep Difficulties during Pregnancy

Causes of Sleep Difficulties during Pregnancy

Almost all pregnant women have sleep problems at some point. These problems may include:

- Trouble falling asleep
- Trouble returning to sleep
- Waking up often during the night
- Sleep that isn't restful

A number of problems can contribute to your sleeplessness during pregnancy. During early pregnancy, the same hormone that causes <u>fatigue</u> during the day can also disrupt your sleep cycle at night. In later pregnancy, as the size of your abdomen increases, you may have trouble finding a comfortable position. Anxiety and stress can also contribute to sleeplessness, particularly as your due date approaches.

Other problems contributing to discomfort and insomnia include:

- Frequent urination, as the growing baby puts pressure on your bladder
- Backache and leg cramps as a result of the extra weight you are carrying
- Restless leg syndrome (crawling or moving feelings in the foot, calf, or upper leg)
- Shortness of breath or snoring, as the growing baby increases the pressure against your diaphragm
- Heartburn or indigestion
- Vivid dreams or nightmares

Sleep Tips for Pregnant Women

- To cut down on the number of trips to the toilet through the night, drink lots of fluids during the day, but less in the evening.
- Put a nightlight in the bathroom instead of turning on the light— this will be less arousing and help you return to sleep more quickly.
- To prevent indigestion or heartburn, eat small, frequent meals rather than three large ones. Eat two to three hours before bedtime, and sit up after eating. Do not eat large amounts of spicy, acidic, citrus, or fried foods. If heartburn is a problem, sleep with your head elevated on pillows. If none of these measures help, it's fine to eat an antacid tablet after meals.

- In later pregnancy, sleep on your left side. This position helps blood and nutrients flow to your baby and uterus, and helps your kidneys to eliminate waste and fluids. Avoid lying flat on your back for long periods of time.
- Try to exercise for at least 30 minutes per day (unless your health care provider has advised against it), but do so at least three hours before bedtime. Even moderate exercise, like walking, can help you get a better night's sleep. Always be sure to find out from your health care provider what exercises are safe for you and how long you can maintain your exercise programme.
- Regular exercise can also help reduce leg cramps. If you are prone to leg cramps, straighten your leg and flex your foot upwards several times before going to bed, gently massage your leg, try placing a hot water bottle on the cramped area, or getting up and walking around. Eating more calcium-rich foods and avoiding carbonated drinks may also help.
- If you develop Restless Legs Syndrome, you may want to ask your health care physician to check you for an iron deficiency.
- Try frequent bland snacks (like crackers) throughout the day. This helps avoid nausea by keeping your stomach full.
- Special "pregnancy" pillows and mattresses may help you sleep better. You can also use regular pillows to support your back and abdomen and tuck one pillow between your legs.
- Take short (30-60 minute) naps if possible to avoid getting too fatigued. Keep in mind, though, that napping too late in the day (or for too long) could disrupt a good night's sleep.
- Learn to relax with relaxation and breathing techniques, such as those you've learned in your childbirth classes. Many women find meditation and yoga helpful for relieving stress during pregnancy. A warm bath or shower before bed can be helpful. Remember that your sense of balance is off during your pregnancy, however, and be careful not to slip in a wet bath! Never take a bath if you think your waters may have broken.
- Try not to get too stressed over your lack of sleep anxiety will only make it worse. If you find
 yourself worrying about your baby's well-being or the many unknowns involved in having a
 baby, it may help to arm yourself with information. To ease your anxieties, read up and take a
 childbirth preparation class. Confide in your partner, or a friend. Try to reduce stress and avoid
 placing yourself in stressful situations.

- If you start snoring, have your blood pressure and urine protein checked by your health care
 provider—especially if you have swollen ankles and headaches. If you suffer from shortness of
 breath, use pillows to elevate your upper body.
- Talk to your GP if your sleeplessness lasts a long time or continues to increase. Do not take sleeping medications unless prescribed by your GP.

Following the Birth

Once your baby is born, your sleep may be frequently interrupted, particularly if you are breastfeeding. If you are woken by your baby frequently during the night, you should try to nap when your baby does. Sharing baby care if possible, especially during the night, is important for your health, safety, performance and vitality.

Guidelines during Pregnancy and Beyond

Leave your worries at the bedroom door.

 If you feel anxious or find yourself running through your 'to do list' before bed, take some time to write down your worries before going to sleep. This will help you get your thoughts out on paper so you don't have to dwell on them after your head hits the pillow. Try to finish making your list at least an hour before bedtime, and don't start tackling it until morning.

Watch what you eat and drink

- Avoid smoking and drinking alcohol. Not only can nicotine and alcohol harm your baby, but both can make it difficult to get a good night's sleep.
- Cut down on caffeinated substances such as coffee, tea, soda, and chocolate (too much of which aren't safe, anyway), and avoid them entirely in the afternoon and evening.

Practice good sleep "hygiene"

- Try to regulate your sleep/wake schedule by going to bed and getting up at the same time every day. You may need to go to bed earlier than usual, however, especially if you find yourself waking up several times during the night. Go to bed when you feel tired. Don't push yourself to stay awake until your usual bedtime.
- Establish a regular, relaxing bedtime routine for the 20 to 30 minutes before you go to bed, such as reading or taking a warm bath.

- Make your bedroom a sleep sanctuary. Since you may feel warmer than usual when you're pregnant, keep your room on the cool side. Block out light and noise, too they can wake you from a light sleep.
- Avoid looking at the clock (knowing the time won't make you feel better), close your eyes, and concentrate on your breathing. Some research suggests that willing yourself to stay awake will slide you into the land of nod in no time.
- Use your bed only for sleep.
- If you're still awake after about 20 minutes, don't lie in bed forcing yourself to sleep. Get up and go into another room. Listen to soothing music, take a warm bath or read a magazine. When you feel drowsy, go back to bed.

Appendix 3.11 Ethical approval letter

WoSRES West of Scotland Research Ethics Service

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

Mrs Kirsty Horne Trainee Clinical Psychologist University of Glasgow Academic Centre Department of Psychological Medicine 1055 Great Western Road Glasgow G12 0XH Date Your Ref Our Ref Direct line Fax E-mail

0141 211 2123 0141 211 1847 Liz.Jamieson@ggc.scot.nhs.uk

10th November 2008

Dear Mrs Horne

Study Title:

REC reference number:

The Relationship between Disturbed Sleep during Pregnancy and Cognitive Functioning 08/S0701/103

The Research Ethics Committee reviewed the above application at the meeting held on 06 November 2008.

Ethical opinion

The members of the Committee present gave a favourable ethic opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions below.

Ethical review of research sites

The favourable ethical opinion applies to the research sites listed on the attached form.

Conditions of the favourable opinion

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

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

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

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Approval Letter – University of Glasgow		22 July 2008
Supervisor's CV – Professor Colin Espie		
Advertisement	Version 1	18 August 2008
Questionnaire: Validated HADS, ISI, CFQ, PSQI		
Questionnaire: Non Validated – follow up	Version 1	18 August 2008
Interview Schedules/Topic Guides	Version 1	18 August 2008
Letter from Sponsor		12 August 2008
Summary/Synopsis	Version 1	18 August 2008
Covering Letter		18 August 2008
Protocol	Version 1	18 August 2008
Investigator CV		18 August 2008
Application		18 August 2008
Response to the request for further information		10 September 2008
Response to the request for further information		16 October 2008
Participant Consent Form: Additional Consent Form	Version 1	16 October 2008
Participant Consent Form	Version 3	16 October 2008
Participant Information Sheet	Version 3	16 October 2008
Questionnaire – Demographics	Version 2	16 October 2008

Membership of the Committee

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

Statement of compliance

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

After ethical review

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

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

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

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

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

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

08/S0701/103 Please quote this number on all correspondence

Yours sincerely

Liz Jamieson Committee Co-ordinator on behalf of Dr Paul Fleming, Chair

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



Frequency of daytime naps

Duration of daytime naps



Appendix 3.13 Correlations between subjective and objective sleep data

	Diary WASO	Diary TST	Diary SOL	Diary sleep eff.
Act. WASO	r= .453, p=.023*			
Act. TST		r=.277, p=.181		
Act. SOL			r= .659, p=.000**	
Act. sleep eff.				r= .336, p=.100

Note: *Correlation is significant at the 0.05 level (two-tailed)

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

Appendix 3.14 Correlations between sleep and HADS subscales

		HADSA	HADSD	PSQItotal		
HADSA	Pearson Correlation	1	.605**	.494**		
	Sig. (2-tailed)		.000	.000		
	Ν	63	63	63		
HADSD	Pearson Correlation	.605**	1	.561**		
	Sig. (2-tailed)	.000		.000		
	N	63	63	63		
PSQItotal	Pearson Correlation	.494**	.561**	1		
	Sig. (2-tailed)	.000	.000			
	Ν	63	63	63		

Correlations between PSQI scores and HADS scores

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

		awaso	asleepefficiency	HADSA	HADSD
awaso	Pearson Correlation	1	883**	.290	.546**
	Sig. (2-tailed)		.000	.159	.005
	Ν	25	25	25	25
asleepefficiency	Pearson Correlation	883**	1	165	408 [*]
	Sig. (2-tailed)	.000		.430	.043
	Ν	25	25	25	25
HADSA	Pearson Correlation	.290	165	1	.605**
	Sig. (2-tailed)	.159	.430		.000
	Ν	25	25	63	63
HADSD	Pearson Correlation	.546**	408 [*]	.605**	1
	Sig. (2-tailed)	.005	.043	.000	l.
	Ν	25	25	63	63

Correlations between objective sleep and HADS scores

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

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

Appendix 3.15

Function measured	IntegNeuro variable	Pregnant	Controls
Verbal & visual Memory	Immediate verbal recall	35.24	35.95
	Verbal learning rate	1.29	1.30
	Short delay verbal recall	8.70	9.17
	Long delay verbal recall	8.57	8.84
	Verbal recognition memory	10.69	11.39
	Span of visual memory	7.62	7.75
Working memory	Digit span score (forward)	8.72	7.97
	Digit span score (backwards)	5.55	5.30
Attention	Sustained attention- reaction time	595.99	506.10
	Sustained attention- total errors	1.49	1.18
	Switching of attention completion time	19,904.88	20,270.19
	Switching of attention total errors	0.44	0.67
	Switching of attention 2 completion time	41,946.98	41,790.50
	Switching of attention 2 total errors	0.92	0.86
Processing speed	Number of taps (dominant hand)	164.85	163.02
	Number of taps (non-dominant hand)	151.30	144.20
	Choice reaction time	677.870	676.12
Executive functioning	Executive maze, trials completed	9.27	8.87
	Executive maze, completion time	237,636.86	192,644.18
	Executive maze, path learning time	204,636.10	163,014.57
	Executive maze, errors	34.48	39.89
	Executive maze, overruns	11.95	16.97
Pre-morbid functioning	Spot the real word	50.22	50.81

Mean IntegNeuro scores for pregnant women and non-pregnant matched controls

Note: Timed tests are measured in milliseconds

Appendix 3.16 IntegNeuro comparisons for those with and without significant sleep

disturbance

<u>Nonparametric Tests comparing IntegNeuro variables for those with and without</u> <u>significant sleep disturbance</u>

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of memrecco is the same across categories of insomniapsqi.	Independent- Samples Mann- Whitney U Test	.944	Retain the null hypothesis.
2	The distribution of wmerr is the same across categories of insomniapsqi.	Independent- Samples Mann- Whitney U Test	.604	Retain the null hypothesis.
3	The distribution of tapdomn is the same across categories of insomniapsqi.	Independent- Samples Mann- Whitney U Test	.367	Retain the null hypothesis.
4	The distribution of tapndmn is the same across categories of insomniapsqi.	Independent- Samples Mann- Whitney U Test	.646	Retain the null hypothesis.
5	The distribution of ch_avrt is the same across categories of insomniapsqi.	Independent- Samples Mann- Whitney U Test	.702	Retain the null hypothesis.

Hypothesis Test Summary

Asymptotic significances are displayed. The significance level is .05.

Appendix 3.16 Continued

<u>Multivariate analyses comparing IntegNeuro variables for those with and without</u> <u>significant sleep disturbance</u>

Between-Subjects Factors

		Ν
insomniapsqi	.00	14
	1.00	37

Effect		Value	F	Hypothesis df	Error df	Sig.
Intercept	Pillai's Trace	.988	499.404 ^a	7.000	43.000	.000
	Wilks' Lambda	.012	499.404 ^a	7.000	43.000	.000
	Hotelling's Trace	81.298	499.404 ^a	7.000	43.000	.000
	Roy's Largest Root	81.298	499.404 ^a	7.000	43.000	.000
insomniapsqi	Pillai's Trace	.053	.341 ^a	7.000	43.000	.931
	Wilks' Lambda	.947	.341 ^a	7.000	43.000	.931
	Hotelling's Trace	.055	.341 ^a	7.000	43.000	.931
	Roy's Largest Root	.055	.341 ^a	7.000	43.000	.931

Multivariate Tests^b (memory variables)

a. Exact statistic

b. Design: Intercept + insomniapsqi

Between-Subjects Factors				
Ν				
insomniapsqi	.00	16		
	1.00	33		

Multivariate Tests ^b (Attention variables)

Effect		Value	F	Hypothesis df	Error df	Sig.
Intercept	Pillai's Trace	.965	238.049 ^a	5.000	43.000	.000
	Wilks' Lambda	.035	238.049 ^a	5.000	43.000	.000
	Hotelling's Trace	27.680	238.049 ^a	5.000	43.000	.000
	Roy's Largest Root	27.680	238.049 ^a	5.000	43.000	.000
insomniapsqi	Pillai's Trace	.103	.987 ^a	5.000	43.000	.437
	Wilks' Lambda	.897	.987 ^a	5.000	43.000	.437
	Hotelling's Trace	.115	.987 ^a	5.000	43.000	.437
	Roy's Largest Root	.115	.987 ^a	5.000	43.000	.437

a. Exact statistic

b. Design: Intercept + insomniapsqi

Appendix 3.16 Continued

Between-Subjects Factors

		N
insomniapsqi	.00	18
	1.00	42

Effect		Value	F	Hypothesis df	Error df	Sig.
Intercept	Pillai's Trace	.999	18129.600 ^a	5.000	54.000	.000
	Wilks' Lambda	.001	18129.600 ^a	5.000	54.000	.000
	Hotelling's Trace	1678.667	18129.600 ^a	5.000	54.000	.000
	Roy's Largest Root	1678.667	18129.600 ^a	5.000	54.000	.000
insomniapsqi	Pillai's Trace	.038	.431 ^a	5.000	54.000	.825
	Wilks' Lambda	.962	.431 ^a	5.000	54.000	.825
	Hotelling's Trace	.040	.431 ^a	5.000	54.000	.825
	Roy's Largest Root	.040	.431 ^a	5.000	54.000	.825

Multivariate Tests^b (Executive functioning variables)

a. Exact statistic

b. Design: Intercept + insomniapsqi



Appendix 4

Major Research Project Proposal

The Relationship between Disturbed Sleep and Cognitive

Functioning During Pregnancy

Kirsty Horne

1. Abstract

1.1 Background: Existing literature has consistently demonstrated that sleep is disturbed during pregnancy and postpartum. Disturbed sleep during pregnancy has been linked with longer labour, birth complications and increased risk of postnatal mood disturbance in mothers. Sleep disturbance in general has been associated with depression and impaired cognitive functioning. It has also been reported that cognitive function is impaired during pregnancy, although the aetiology of this impairment is uncertain. The relationship between disturbed sleep during pregnancy and cognitive functioning has not been specifically investigated.

1.2 Aims: The present study aims to examine the relationship between disturbed sleep during pregnancy and subjective and objective cognitive functioning, controlling for the effects of mood.

1.3 Methods: 82 women in their 3rd trimester of pregnancy will be recruited from the Southern General Hospital in Glasgow. The Pittsburgh Sleep Quality Index and the Insomnia Severity Index will be used to measure subjective sleep quality. Actigraphy will be used to obtain an objective estimate of participants' sleep quality. Cognitive functioning will be measured subjectively using the Cognitive Failures Questionnaire and objectively using the Hospital Anxiety and Depression Scale.

1.4 Applications: The study will add to the literature on sleep disturbance and cognitive functioning during pregnancy. It will be useful for obstetricians, employers and other professionals working with women in late pregnancy. Findings will highlight the importance of enquiring about sleep quality in pregnancy and educating pregnant women about the possible cognitive changes they may experience. The need to develop interventions to improve sleep and cognitive functioning in this group will be highlighted.

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2. Introduction

Existing literature has consistently demonstrated that sleep is disturbed during pregnancy and postpartum (Gaylor & Manber, 2005). Reasons for sleep disruption during pregnancy include, but are not limited to hormonal changes, changes in respiration, foetal movements, physical discomfort, nausea or vomiting, restless leg syndrome, reflux, nightmares and an increase in the frequency of urination (Hedman *et al.*, 2002; Lee, 1998). Sleep disruption during the postpartum period may be related to physical discomfort following the birth, medications used during delivery, endocrine changes, infant temperament and sleep pattern, parenting style, method of feeding, family size, paternal involvement and social support (Gaylor & Manber, 2005).

Disturbed sleep during pregnancy has been linked with longer labour, birth complications (Lee & Gay, 2004) and increased risk of postnatal mood disturbance in mothers (Karacan *et al.*, 1969; Parry *et al.*, 2006). Sleep disturbance in general has been associated with depression (de Gennaro *et al.*, 2004) and impaired cognitive functioning (Pilcher & Huffcut, 1996). For example, sleep deprivation has been found to decrease reaction times and vigilance, and to increase perceptual and cognitive distortions (Krueger, 1989). Sleep disruptions have also been associated with significant decrements on memory tasks (Bonnet, 1985).

Pregnancy has also been associated with perceived impairments in various aspects of cognition including memory, attention, concentration, coordination and general cognitive slowing, with 50 to 80% of women reporting some degree of disturbance in cognitive ability (Brett & Baxendale, 2001). While pregnant women appear to consistently report experiencing

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impaired cognitive functioning, research examining this using objective tests has produced mixed results.

Silber *et al.* (1990) found that pregnant women performed more poorly than non-pregnant women on a reaction time task and a paired associate learning task. Crawley, Grant & Hinshaw (2008) found that pregnant women rated their cognitive abilities as poorer than before they were pregnant and performed more poorly than non-pregnant controls on tasks of speed of language processing and switching of attention. Speed of information processing was also found to be impaired in late pregnancy by Buckwalter *et al.* (1999) but was not found to differ between pregnant and non-pregnant women in the study by De Groot *et al.* (2006).

Shetty & Pathak (2002) reported poorer overall performance on the Wechsler Memory Scale (WMS) from a group of pregnant compared with non-pregnant women. Deficits in verbal recall (using word or story recall) have also been found in pregnant women, when compared with non-pregnant women (e.g. de Groot *et al.*, 2003, 2006; Keenan *et al.*, 1998). Other studies have, however, failed to find such differences (e.g. Crawley *et al.*, 2003; McDowall & Moriarty, 2000).

Although there is some evidence for deficits in implicit memory in pregnant women (e.g. Brindle *et al.*, 1991; Sharp *et al.*, 1993), the majority of research examining this aspect of memory has not supported such differences (Casey *et al.*, 1999; Christensen *et al.*, 1999; Janes *et al.*, 1999; Keenan *et al.*, 1998; McDowall & Moriarty, 2000). The difference found by Brindle *et al.* (1991) was found in primiparous, but not multiparous women, although
other studies examining the effects of gravidae status on memory performance have not found such differences (Casey *et al.*, 1999; McDowall & Moriarty, 2000; Sharp *et al.*, 1993).

Mixed findings have also emerged when trimester of pregnancy has been examined as a possible mediating factor. For example, while Brindle *et al.* (1991) found memory deficits were most marked in the second trimester, Keenan *et al.* (1998) suggested women in the third trimester experienced most noticeable memory deficits. However, Sharp *et al.* (1993) and De Groot *et al.* (2006) found that pregnant women presented with poorer memory performance across all three trimesters and that differences persisted at 32 weeks postpartum.

Differences in reaction time and paired associate learning found by Silber *et al.* (1990) persisted at 3 days and 3 months postpartum, although improvements had been made by 6 and 12 months. Keenan et al. (1998), Buckwalter *et al.* (1999) and Lurie *et al.* (2005) found that women's performance improved from 3^{rd} trimester to postpartum.

Henry & Rendell (2007), in a meta-analytic review of memory function in pregnancy, concluded that some but not all measures of memory are affected in pregnancy and the postpartum period, and that memory measures that place high demands on executive functioning may be selectively disrupted. They pointed out that only limited research to date had examined deficits in prospective memory during pregnancy, which, they suggested might be particularly prominent, given that this type of memory is considered to impose particular demands on executive cognitive control, and in particular self-initiated retrieval.

Where deficits in cognitive performance have been found in pregnant women, the aetiology of this impairment is uncertain. Explanations have included mood alterations, cultural stereotypes, lifestyle factors and changes in hormones, plasma neurotransmitters and chronological age of circulating erythrocytes (Henry & Rendell, 2007).

Although two studies examining memory functioning in pregnancy have found positive correlations between self-reported memory deficits in pregnancy and self-reported sleep disturbance, objective measures of memory have not been found to correlate with self-reported sleep (Casey *et al.*, 1999; Janes *et al.*, 1999). Until now, the effects of disturbed sleep during pregnancy on cognitive functioning have not been specifically investigated.

The present study therefore aims to examine the relationship between disturbed sleep during pregnancy and subjective and objective cognitive functioning, controlling for the effects of mood. Specifically, perception, psychomotor functioning, attention, concentration, speed of processing, visual and verbal memory, working memory, prospective memory and executive functioning will be examined. Due to sleep disturbance being common in the postpartum period and previous research finding that cognitive deficits may persist following the birth, relationships between sleep disturbance and cognitive functioning will also be examined 2 months postpartum.

3. Aims and Hypotheses

3.1 Primary Aims

- To examine the subjective sleep quality of women during the third trimester of pregnancy.
- To examine the relationship between subjective sleep quality during the third trimester of pregnancy and perceived cognitive functioning, controlling for the effects of mood.

• To examine the relationship between subjective sleep quality during the third trimester of pregnancy and objectively measured cognitive functioning, controlling for the effects of mood.

3.2 Secondary Aims

- To examine the objective sleep quality of women during the third trimester of pregnancy.
- To examine the relationship between objective sleep quality during pregnancy and cognitive functioning (subjective and objective), controlling for the effects mood.
- To compare the cognitive functioning (subjective and objective) of women in the third trimester of pregnancy who report a significant sleep disturbance with those who do not.
- To examine new mothers' subjective sleep quality and perceived cognitive functioning two months following the birth.

3.3 Hypotheses/Research Questions

- Women will report disturbed sleep, as measured by the Pittsburgh Sleep Quality Index (PSQI) and the Insomnia Severity Index (ISI), during the third trimester of pregnancy.
- There will be a positive correlation between sleep quality, as measured by the PSQI, ISI and actigraphy, and subjective cognitive functioning, as measured by the Cognitive Failures Questionnaire (CFQ), independent of the effects of mood.
- There will be a negative correlation between sleep quality, as measured by the PSQI, ISI and actigraphy, and objectively measured cognitive functioning (as measured by the IntegNeuro package), independent of the effects of mood.

- Women who score above the threshold for a significant sleep disturbance, as measured by the PSQI, the ISI and actigraphy, will score higher on the CFQ, than those without a significant sleep disturbance.
- Women who score above the threshold for a significant sleep disturbance, as measured by the PSQI, the ISI and actigraphy, will exhibit poorer objectively measured cognitive functioning, as measured by the IntegNeuro package, than those without a significant sleep disturbance.
- Relationships between subjective sleep quality and subjective cognitive functioning will persist two months following giving birth.

4. Plan of Investigation

4.1 Participants

Participants will be 64 women in their 3rd trimester of pregnancy.

4.2 Inclusion/Exclusion Criteria

Women aged 20 to 34 inclusive, in their 3rd trimester of pregnancy, expecting their first child will be included. This age group was selected due to the significantly higher risk of adverse outcomes in adolescent pregnancies (Chen *et al.*, 2007) and the increase in risk of pregnancy complications in women aged over 35 (Luke & Brown, 2007). Third trimester of pregnancy was chosen due to the decreased risk of miscarriage in later pregnancy, the increased sleep disturbance evident in this trimester (Brunner et al., 1994), previous research showing that women in the third trimester experience the most noticeable memory deficits (Keenan *et al.*, 1998) and also due to convenience of obtaining the sample at the parenting classes, which take place in the third trimester. Women expecting their first child were chosen as it was thought that women with existing childcare responsibilities may have less available time and

therefore find it more difficult to participate in a research study. Women expecting their first child are also more likely to attend parenting classes than women experiencing subsequent pregnancies, meaning they will be easier to recruit.

Participants will be excluded if they are experiencing a complicated pregnancy or other significant health problem, as these factors may increase stress and worry levels, affect sleep, possibly interfere with cognitive functioning and therefore add additional confounding variables. Those with a specific diagnosis of a sleep disorder (such as narcolepsy), known psychiatric disorders, depressive disorders or illicit drug or alcohol abuse will also be excluded from participating, as these factors are also likely to affect cognitive functioning and sleep and therefore confound the results. These inclusion/exclusion criteria being applied will help increase the homogeneity of the group under examination, therefore increasing the power of the study.

4.3 Recruitment Procedures

The study will aim to recruit 64 women in their 3rd trimester of pregnancy by placing posters in the antenatal department of the Southern General Hospital in Glasgow. In addition, all women attending Parentcraft classes at the hospital (excluding the teenage mothers' class) and antenatal exercise classes will be given brief details of the research at the start of their class.

Women who express an interest in taking part in the study will be sent information about the purpose of the study with details of the inclusion and exclusion criteria. Subsequently, the researcher will meet with participants at an office, based in the University of Glasgow Sleep Centre in the Southern General Hospital in Glasgow (about a three-minute walk from the maternity unit), at a mutually convenient time, to fully explain the study and answer any questions they may have. Written informed consent for participation will then be obtained.

Two months following the birth, women will be contacted by post and asked to complete follow-up questionnaires.

4.4 Measures

4.4.1 Demographic information

Demographic information including age, number of years in formal education, marital status, employment status, income and ethnicity will be collected.

4.4.2 Pittsburgh Sleep Quality Index

Subjective sleep quality will be assessed using the Pittsburgh Sleep Quality Index (PSQI; Buysse, *et al.*, 1989). The PSQI is a self-report questionnaire, which assesses sleep quality and disturbances over a month. Nineteen individual items generate seven 'component' scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction. The sum of scores for these seven components yields one global score. The PSQI is a widely used, internally consistent (Cronbach's alpha = .83) screening instrument for the detection of significant sleep disturbance (using a threshold score of 6). A recent study by Backhaus *et al.* (2002) has validated this cut-off and confirmed reliability (Cronbach's alpha = .85, test-retest r = .84).

4.4.3 Actigraphy

Objective estimates of sleep quality will be recorded using actigraphy (Ambulatory Monitoring, Inc, Ardsley, NY). The wrist actigraph provides continuous motion data by using

a battery-operated wristwatch-size microprocessor that senses motion. An autoscoring algorithm yields 2 sleep-related outcome variables: (1) sleep quantity as total sleep time (TST) at night and (2) sleep quality, as wake after sleep onset (WASO). As an estimate of sleep disruption, WASO is reported as the percentage of minutes awake divided by minutes in bed after falling asleep. During a typical 7 to 8-hour sleep period, WASO of 15% represents more than an hour of wake time after falling asleep. WASO between 5% and 10% is typical in healthy, non-pregnant women (Lee, Zaffke & McEnany, 2000) and greater than 15% is considered severe sleep deprivation. Congruence between polysomnographic measures and actigraphy measures indicates adequate validity and reliability when sleep is assessed in healthy young adults, including women of childbearing age (Ancoli-Israel *et al.*, 2003), with 88% agreement between the two methodologies (Cole *et al.*, 1992).

4.4.4 Insomnia Severity Index

Although the PSQI will be the primary measure, the Insomnia Severity Index (ISI; Morin, 1993) will be used to examine the proportion of participants that reach threshold for insomnia. The ISI is a brief self-report instrument (takes less than 5 minutes to complete), measuring an individual's perception of their sleep disturbance. The ISI comprises seven items assessing the severity of sleep-onset and sleep maintenance difficulties (both nocturnal and early morning awakenings), satisfaction with current sleep pattern, interference with daily functioning, how noticeable the impairment attributed to the sleep problem is, and degree of distress or concern caused by the sleep problem. Each item is rated on a 0-4 scale, with total scores ranging from 0 to 28. Higher scores suggest more severe insomnia.

4.4.5 Cognitive Failures Questionnaire

Subjective cognitive functioning will be measured using the Cognitive Failures Questionnaire (CFQ; Broadbent *et al.*, 1982). The CFQ is a 25-item questionnaire, which measures everyday task failures that individuals are normally capable of completing. It measures the perceived frequency of lapses in three areas: perception, memory and psychomotor function in the past 6 months, using a 5-point scale, ranging from never (0) to very often (4), resulting in a score from 0-100. Wallace (2004) reports a high internal consistency of the scale (Cronbach's $\alpha = 0.96$) when used with 709 university students. For the purposes of the current study, participants will be asked about the perceived frequency of cognitive failures in the past month.

4.4.6 IntegNeuro

Cognitive functioning will be measured objectively using tests from a standardised computer package called IntegNeuro (The Brain Resource Company, 2004). IntegNeuro uses touch screen technology and consists of 12 subtests, which measure various domains of cognitive functioning. The test is used as a screening tool for possible dysfunction and compares people with a large international normative database. A report is generated following completion of the test. For the purpose of the present study, choice reaction time, span of visual memory, digit span, memory recall and recognition, sustained attention, switching of attention and executive maze tests will be used. These tests measure aspects of cognitive functioning previously found to be affected during pregnancy.

4.4.7 Prospective Memory

Prospective memory will be assessed by asking participants to give the researcher a belonging of theirs at the start of the cognitive testing session (e.g. a watch, purse or mobile

phone) and instructing them to ask for it back when they are told "this is the end of the appointment". This is similar to a test of prospective memory used in the Rivermead Behavioural Memory Test (RBMT; Wilson, Cockburn, & Baddeley, 1985). Participants will also be asked to telephone the researcher at a pre-specified time to provide feedback on their experience of taking part in the research study.

4.4.7 Hospital Anxiety and Depression Scale

Mood will be measured using the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). The HADS is a brief (14-item) self-report measure, which was designed to assess anxiety and depression in non-psychiatric hospital populations (Herrmann, 1997) and is now widely used across a variety of settings, including use for screening in non-clinical populations (Crawford *et al.*, 2001) and screening of psychological distress in pregnant women (Cederholm *et al.*, 2001). The scale is quick and easy to administer and consists of two sub-scales of seven items designed to measure levels of both anxiety and depression, each of which has cut-off points to identify caseness. Many studies have reported on the construct validity in various clinical populations.

4.4.8 Follow-up questionnaires

Follow-up questionnaires will enquire about the birth and associated complications.

4.5 Design

A correlational design will be used for the primary analyses. Relationships between sleep quality and cognitive functioning will be examined. Secondary analysis will be conducted to compare cognitive functioning of those with a sleep problem and those without. A group of 64 women in their third trimester of pregnancy will be utilised.

4.6 Research Procedures

Following recruitment, participants will be asked to complete the PSQI, the ISI, the CFQ and the HADS. In addition, participants will undertake standardised cognitive testing using the IntegNeuro computer package. A third of participants will be asked to wear a wrist actigraph at home for a period of 5 nights. Although previous studies have recommended 7-day monitoring periods, the present study will only monitor for 5 weekdays in order to decrease systematic error caused by changing weekday and weekend sleep patterns and to minimise missing data. Participants will be given full instructions on the use of their actigraph watches and asked to return these to the researcher when attending their next Parentcraft or exercise class.

Participants will be contacted again by post two months postpartum and asked to complete the PSQI, the ISI and the CFQ for a second time, along with a short questionnaire about the birth experience and any associated complications.

Actigraph and IntegNeuro data will be analysed by the primary researcher, who will be trained in the procedures. Results will be analysed and a report will be compiled. Participants will be sent a written summary of the results should they request it.

4.7 Justification of Sample Size

In order to conduct an a-priori sample size calculation, a number of variables must be known, including effect size (*f*), statistical significance level (α) and power (β). For the purposes of this study α = 0.05 and β = 0.8.

Research to date examining subjective cognitive functioning in pregnancy has varied greatly, with sample sizes ranging from 35 (Crawley, Dennison & Carter, 1993) to 236 participants (Parsons & Redman, 1991). To date, the relationship between disturbed sleep during pregnancy and cognitive functioning has not been specifically examined, therefore a conservative estimate of a medium effect size will be adopted (r=0.3).

Using the G * Power 3 (Faul *et al.*, 2007) software programme, with a medium effect size of r=0.3, $\beta =0.80$ and $\alpha = 0.05$, a total sample size of N=64 was calculated for one-tailed hypotheses or N=82, two-tailed. The aim will therefore be to obtain 64 participants. Given the strict exclusion and inclusion criteria and resulting homogeneity of the participant group, as well as the adequate reliability and validity of the primary measures being utilised, it is expected that this sample size will be sufficient to detect differences if they exist.

4.8 Settings and Equipment

Recruitment will take place at the Southern General Hospital in Glasgow. Questionnaires and objective measures of cognitive functioning (using the IntegNeuro computer package) will be completed at an office, based in the University of Glasgow Sleep Centre in the Hospital, with follow-up questionnaires being posted to participants' homes for completion. Actigraph watches will be given to participants with instructions on their use during their attendance at the office. Participants will be asked to return these to the researcher at their next Parentcraft or exercise class following the 5-day monitoring period.

4.9 Data Analysis

Data will be analysed using the Statistical Package for Social Sciences (SPSS) computer package. Descriptive statistics will be used to examine demographic data, mood, prospective

memory, subjective and objective sleep quality data and details of participants' birth experience. Any potential underlying sleep problems identifiable from the PSQI and the ISI will be reported upon.

Distribution of the data will be examined to determine whether parametric or non-parametric analyses are appropriate. Assuming data will be relatively normally distributed, parametric analyses will be used. If an unequal distribution is found, transformations will be carried out to normalise the data, otherwise non-parametric analyses will be used. In order to maintain a significance level of α = 0.05, conservative corrections will be made for multiple comparisons.

As the PSQI is a continuous measure, which views sleep disturbance on a continuum, rather than defining participants according to diagnostic groupings, and similarly, the CFQ is a continuous measure of behaviour, which is not diagnostic in nature, correlational analyses are appropriate to use. Correlational analyses will therefore examine relationships between subjective sleep (PSQI, ISI), objectively measured sleep (actigraphy), perceived cognitive functioning (CFQ) and objectively measured cognitive functioning (IntegNeuro). Partial correlations will be carried out in order to control for the effects of mood (HADS) on the above relationships. Further correlations will examine relationships between subjective sleep quality and perceived cognitive functioning two months postpartum.

Secondary analyses will use independent t-tests to examine differences in cognitive functioning (subjective and objective) between those with a significant sleep disturbance (as measured by the PSQI, the ISI and actigraphy) and those without. This will help determine

whether future research should primarily examine subgroups (i.e. those with/without a significant sleep disturbance), and what the appropriate cut-off points would be.

5. Health and Safety Issues

Informed consent will be sought prior to participants taking part and appointments will be prearranged for mutual convenience. All participants will be seen in the Southern General Hospital, where staff members will always be present. The university supervisor will be informed of the date, time, and location of appointments. The researcher will wear an identification badge and carry a personal alarm and mobile telephone during appointments. Valuables will not be taken to appointments.

6. Ethical Issues

Participants will provide informed consent to take part in the study. They will be made aware that their data will remain anonymous and strictly confidential and they will be free to withdraw from the study without penalty at any time, without giving a reason. All information obtained throughout the duration of the study will be saved on a passwordprotected computer, or in a locked filing cabinet, to which only the researcher and supervisor will have access. Participants will be sent a written summary of the results should they request it.

The researcher will advise participants on the appropriate support structures available to them should they become distressed by their participation in the study; if necessary, supervision will be provided by the university supervisor. Participants experiencing sleep disturbance will be sent some information on ways to help improve sleep at the end of the study. Those with more significant sleep problems will be advised to visit their GP for advice and may be offered the opportunity to attend a one-off event at the University of Glasgow Sleep Centre, focusing on guided self-help to improve sleep.

Ethical approval will be sought from the local ethics committees in Greater Glasgow and Clyde NHS Trust and Ayrshire & Arran NHS Trust (should the clinical governance team in Ayrshire deem this to be necessary).

7. Financial Issues

Costs will include photocopying, stationary and postage. Costs associated with the actigraph watches and IntegNeuro computer packages will be absorbed by the University of Glasgow Sleep Centre.

8. Timetable

The researcher will aim to have ethical approval by October 2008. Recruitment is expected to take place between August 2009 and February 2010. Data analysis and write up are expected to take place between March 2010 and July 2010. Submission will be in August 2010.

9. Practical Applications

The current research will add to the existing literature on sleep disturbance and cognitive functioning during pregnancy. It will help increase awareness of these issues in obstetricians, employers and other professionals working with women in late pregnancy.

Increased awareness may lead to improved antenatal care, with women's sleep quality in pregnancy being routinely enquired about and interventions being developed to help improve sleep in this group. Improvements in antenatal care may also include educating women about cognitive difficulties commonly experienced during pregnancy and possible strategies they may use to help overcome these difficulties.

Greater knowledge in employers of the difficulties faced by many women in late pregnancy may lead to more understanding, empathy, and acceptance of workload adjustments during this time in pregnancy.

The present research may lead to further exploration of the aetiology of cognitive changes during pregnancy and to additional research examining the functional consequences of sleep loss and decreased cognitive functioning during pregnancy.

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