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Sleep Difficulties and Sustained Attention Following Traumatic Brain Injury

& Research Portfolio

Part One
(Part two bound separately)

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University of Glasgow
Section of Psychological Medicine

August 2007

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology
ACKNOWLEDGEMENTS

I am beholden to my supervisors- Professor Jon Evans for his inspiring enthusiasm and knowledge, and his patient consideration of all my thoughts and questions, and Professor Colin Espie for his expertise, encouragement and grounding. Thank you also to Doctor Andrew Gumley for his supervision of my Small Scale Service Related Project and to all the other course and clinical supervisors who have taught me a lot.

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On a personal note I could not have done this without all my classmates, friends and family. Very special mention is due to my mum (for the food parcels and the elephant analogies), to my dad (the grammatical grandmaster – I aspire to be as good as you) and last but never ever least Mike who always made me smile and who deserves an accolade for his motivational abilities! Thank you all for caring so much.
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CHAPTER ONE: SMALL SCALE SERVICE RELATED PROJECT

General Practice Referrals to the Riverside Locality Direct Access Clinical Psychology Department - West of Glasgow

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Running Title: General Practice referrals to Riverside Clinical Psychology Department

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology.
EXECUTIVE SUMMARY

Objectives: The audit sought to investigate and characterise general practitioner referrals to the Riverside locality Direct Access Clinical Psychology Service, in the West of Scotland. The audit aimed to describe any variations in general practice referral rates, and to consider why such variation might be occurring in terms of practice characteristics (primary care CPN support and single-handed practices) and referral characteristics (demographic and referral problem of patients).

Design: A retrospective analysis of general practice referrals to the Riverside Direct Access Clinical Psychology Service was conducted.

Setting: An out-patient Direct Access Clinical Psychology Department in the West Sector of Glasgow, which covers three localities. One of these localities, Riverside, was the focus of this audit.


Results: Four hundred and eighty referrals were received by the psychology department from 51 general practices. Of these practices, 23 were members of the two locality LHCCs and accounted for 79.3% (n=381) of referrals. There was a high degree of variation in the number and rate of referrals by individual practices. There were no significant differences between practice characteristics in groups of practices that referred more or less frequently.
Fifty five percent (n=266) of all general practice referrals were female, and forty five percent (n=214) were male. The median age of referrals was 35 years (the mean age was 36.1). According to Carstairs deprivation categories clients most frequently fell into category four (n= 126, 29.4%) which is an area of no deprivation and band six (n=119, 27.7%) which is an area of medium deprivation (McLoone, 2001). The referral reasons most frequently used in GPs letters were the general categories of anxiety (n=143, 29.8%), and depression / low mood (n=143, 29.8%). Where more specific categories were described, the most frequent primary problems were stress/coping difficulties (n=23, 4.8%) and panic (n= 20, 4.2%). There were no obvious differences in these referral characteristics between groups of practices that referred higher and lower than the median referral rate.

**Conclusions:** The majority of referrals came from practices within the Riverside locality. There was a wide variation of referral rates. This variation in referral rates was not explained by the presence of the practice characteristics examined in this audit. In line with the results of other audits the broad referral categories of anxiety and depression/low mood were utilised most frequently by referring GPs. However, looking at more specific problems that were frequently referred may be more useful in terms of future service provision. Implications for future service delivery, allocation of resources and staff training, which take account of and meet the needs of general practice referrals, were discussed. Limitations of this study and ideas for further investigation were also discussed along with a dissemination strategy for these data.
INTRODUCTION

In the United Kingdom mental health problems are common; with an overall prevalence of 23%. However, this figure is three times higher in those individuals that visit a General Practitioner (GP) each year (Lucas et al., 2005). Therefore, the management and treatment of mental health problems is now a national priority. Mental health clinical practice guidelines frequently cite psychological interventions as effective interventions that should be available to presenting patients (e.g. Roth & Fonagy, 2005).

GPs play a vital role in the detection, management and treatment of psychological problems (Lucas et al., 2005; Ross & Hardy, 1999). They are often referred to as the 'gatekeepers' of health services because they form an integral link between primary and secondary care (Royal College of General Practitioners Information sheet No. 4, 2002). GPs comprise the most frequent referral pathway to adult psychology services (Telford et al., 1996). Therefore, an imperative service-related issue for the NHS is the quality of communication between GPs and clinical specialists (Ross & Hardy, 1999), a principal aspect of which is referral practice (O’Donnell, 2000).

GPs’ responses to psychological problems have an impact that extends beyond the individual; their referral behaviour has a consequential effect shaping psychological treatment services (Ross & Hardy, 1999). Variation in referral rates between general practices and individual GPs has long been the focus of policy makers (Coulter, 1998; Wilkin & Smith, 1987).
A number of practice, GP and patient factors have been proposed to influence referral rates. For example, the availability of specialist services (O'Donnell, 2000) and the effect of practice composition in terms of single-handed versus multi-practitioner practices (Hippisley-Cox et al., 1997; Madeley et al., 1990). Sigel and Leiper (2004), found that referral decisions were made by GPs when they felt they had reached the limits of their capabilities for treating a particular problem, taking into account the patient's suitability for psychological therapy and access to psychology services. GPs were found to perceive clinical psychology favourably in relation to other mental health disciplines. However, clinical psychology was rated poorly in relation to accessibility (Chadd & Svanberg, 1994). Long waiting lists along with other factors have also been noted as obstacles to therapy for clients (Kaltenthaler et al., 2002). In terms of patient factors a higher prevalence of psychiatric problems were found in individuals living in less affluent areas (Jenkins et al., 1998). These individuals have been found to be less likely to engage in services, thus socio-economic status has been proposed to affect referral rates.

Unfortunately the current situation in adult clinical psychology services is epitomised by long waiting lists, and compromised equity of access (The Health Plan for Scotland, 2000). The implications of this are that GPs may be referring to other, perhaps less suitable, professions (Clinical Psychology Workforce Planning Group, 2002) Therefore, although the clinical effectiveness of psychological therapy is accepted, demand outstrips resources (Department of Health, 2001). Waiting list initiatives and equity of access are imperative service issues recognised nationally and locally (Greater Glasgow Primary Care NHS trust 2001; Scottish Office, 1999).
The setting for the current audit is a clinical psychology department covering the West sector of Glasgow. The direct access clinical psychology service at the Lansdowne Clinic has a catchment area divided into three localities. One of these localities, the Riverside area was the focus of this audit. Riverside has a population of 73,310 adults between the ages 15-64, and covers an area with a mixture of affluent and economically underprivileged districts; deprivation categories 2-6 (McLoone, 2001). Twenty-five general practices comprise the two locality Local Healthcare Cooperatives (LHCCs) (Riverside and West one), and 62 GPs are registered to these practices.

The department accepts referrals from several different sources; GPs are the principal referral source. Referrals are accepted based on clients’ postcodes; therefore, some referrals are also received from general practices out with this area. All patients referred are seen within the clinical psychology department which is based centrally within the locality. The average time to wait to be seen in the West of Glasgow was reported to be 6 months (Boyle, 2001).

It is estimated that there is much variability in the frequency of referrals. Discussions between the auditor and service provider highlighted that a priority for the service was increasing understanding of GP referrals. This had implications for equity of access to services. Also, as there are tentative plans to change the psychology services in the area and develop a separate Primary Care Mental Health Team with psychology input, there was a need to map current service demand and access by GPs. Thus, the following questions were developed:
1. a) How many referrals from general practitioners were received by the Riverside locality Direct Access Clinical Psychology Department in 2004, and were these referrals from locality LHCC practices?
   b) How many practices accounted for 50% and 75% of referrals, and what were the associated practice characteristics (single-handed or multi-practitioner, and primary care CPN support available or not)?
2. How did referral rates vary across individual locality practices compared with the median referral rate of these general practices?
3. What were the overall referral characteristics (age, gender, deprivation category and presenting problems)?
4. What differences were there in referral characteristics between locality based practices referring above and below the median referral rate?

METHODOLOGY

Design
The present audit was designed to identify the type and rate of referrals received from general practices to the clinical psychology department. Characteristics of the referring practices were also considered. Therefore all referral data from general practices, accepted by the Riverside locality clinical psychology direct access service, over a one-year period (1\textsuperscript{st} of January to the 31\textsuperscript{st} of December 2004) (N= 480) were retrospectively included in this study.

Procedure
At the time of this audit details of all new referrals to the direct access service were placed on a database. Data that were routinely collected comprised; name, address,
date of birth, referral source, general practice code, and referral problem, as described in the referral letter. Data collection consisted of two sections; referral data and general practice data.

Referral data

Prior to any formal data analysis, data stored on the departmental database were anonymised by removing all personal identifiers including, name, date of birth and postal address. Data regarding gender, age and Carstairs deprivation category (McLoone, 2001) were extracted and retained. In order to allow consistent categorisation of referral problems these were coded according to Effective Purchasing and Providing in the Community (EPPIC) ‘reason for care’ categories (Wight & Macphail, 1995). Several additional categories were also assumed as additions to the coding system in line with descriptions in the referral letters: abuse/trauma, psychiatric illness, panic, fluctuating mood/bipolar, stress/coping difficulties, self harm, self esteem issues, phobias, bereavement and health anxiety. When more than one presenting problem was described the first problem mentioned was categorised as primary. Additional data were gathered on secondary problems.

In order to ensure reliability of coding, the system of allocation to categories was subjected to a test of inter-rater reliability. A random sample of 25% (n=120 observations) of all problems referred were allocated to the same set of categories utilised by the auditor. To avoid bias due to disparity of experience a Trainee Clinical Psychologist completed this procedure. Obtained data indicated a high degree of inter-rater agreement overall (92.5%).
General Practice Data

Missing data on practice codes had to be gathered from a list of Greater Glasgow Health Board general practices and GP names and entered into the database for each client. Once all the codes were compiled, a separate database of practice characteristics was developed which comprised data on the frequency and percentage of referrals from each general practice. Data on practice population sizes were gathered via contact with Greater Glasgow Health Board at Dalian House. The referral rate was then calculated by dividing the population served by the practice with the number of referrals, this allowed frequency data to be quantified. Data on practices who were members of the two locality LHCCs were also gathered as were data on those practices that had CPN support available.

RESULTS

How many referrals from general practitioners were received by the Riverside locality Direct Access Clinical Psychology Department in 2004, and were these referrals from locality LHCC practices?

Between the 1st of January 2004 and the 31st of December 2004, 480 referrals were received by the psychology department from 51 general practices. Of these practices 23 were members of the two locality LHCCs. The other 29 practices were based out with the locality area. The 22 locality practices accounted for 381 (79.3%) referrals and the 29 other practices accounted for 92 (19%) referrals. Data was unavailable for seven referrals.
How many practices accounted for 50% and 75% of referrals, and what were the associated practice characteristics?

There was a high degree of variation in the number of referrals by individual practices. Seven practices accounted for 51.4% (n=247) of referrals. Of these, six were locality practices. One (14.2%) of the practices was a single-handed practice, and one (14.2%) had CPN support. Of the 44 practices accounting for the other 48.6% of referrals; 8 (18.2%) were single-handed practices and 8 (18.2%) had CPN support.

Fourteen practices accounted for 75.3% (n=362) of referrals; of these 12 were locality Practices. Two (14.2%) of the practices were single-handed practices, and 3 (21.4%) had CPN support. Of the remaining 37 practices 6 (16.3%) were single-handed practices and 6 (16.3%) had CPN support.

In order to investigate whether there were differences in the practice characteristics (single-handed and CPN support data) of the groups of practices accounting for >50% or 75% of referrals and the groups of practices accounting for <50% or 25% of referrals, Pearsons Chi-squared tests were utilised. There were no significant differences between either of these two sets of groups.

How did referral rates vary across individual locality practices compared with the median referral rate of these general practices?

The referral rate for the locality practices was calculated by dividing the total population served by the general practice by the number of referrals accepted by the
clinical psychology service for this practice. This results in the calculation of a ratio; one referral per ‘x’ people registered to the practice.

The overall referral rate for each practice is depicted in Figure 1.1. The median referral rate was 1:285 (range: 1:86 – 1:2558). Twelve practices with 37 GPs referring had a referral rate equal to or higher than the median referral rate. Two of these were single-handed practices and three had CPN support. Eleven practices had a referral rate lower than the median referral rate, with 28 GPs referring. One of these practices was single-handed and five had CPN support.

Insert Figure 1.1

*What were the overall referral characteristics (age, gender, deprivation category and presenting problems)?*

*Socio-demographic characteristics*

A total of 480 referrals were included in the analysis; 266 (55.4%) were female and 214 (44.6%) were male. The median age of referrals was 35 years (the mean age was 36.1). The youngest clients referred were 18 years old and the oldest client was 67 years old (the range was 49 years). According to Carstairs deprivation categories clients most frequently fell into category four (n= 126, 29.4%) which is an area of no deprivation and category six (n=119, 27.7%) which is an area of medium deprivation (McLoone, 2001). Least referrals were from category three areas (n=30, 7%). No referrals were received for individuals living in category one or seven areas (Figure 1.2).
Prevalence of presenting problems

Of the 480 referrals accepted the primary referral reasons most frequently used in GPs letters were the general categories of; anxiety (n=143, 29.8%) and depression / low mood (n=143, 29.8%). Where more specific categories were described the most frequent primary problems were; stress / coping difficulties (n=23, 4.8%) and panic (n=20, 4.2%). The unspecified/ other category was used in 20 (4.2%) referral letters. The category least frequently used was personality disorder (n=1, 0.2%).

Only 134 (27.9%) referrals detailed a secondary referral problem. Where secondary referral problems were used; depression / Low mood (n= 45, 9.4%) was the most common. The categories of; health anxiety (n=1, 0.2%), Self Harm (n=1, 0.2%), Panic (n=1, 0.2%), Sexual Dysfunction (n=1, 0.2%), Cognitive /developmental/ speech (n=1, 0.2%) were used relatively infrequently and PTSD, relationship /social, behavioural problems, personality disorder, psychiatric illness and sleep disorder were not used at all (Table 1.1).

What differences were there in referral characteristics between locality based practices referring above and below the median referral rate?

Table 1.2 illustrates the socio-demographic and clinical characteristics of patients referred by practices referring higher and lower than the median referral rate. There were no obvious differences in these characteristics between these groups of practices.
Genera) Practice referrals to Riverside Clinical Psychology Department

DISCUSSION

Referrals from general practices to the Riverside direct access clinical psychology department were investigated in this audit. It aimed to investigate any variations in general practice referral rates, and to consider why such variation might be occurring in terms of practice characteristics (primary care CPN support and single-handed practices) and referral characteristics (demographic and referral problem of patients). Specifically the study investigated four questions.

Firstly the audit investigated variation in general practice referrals. The majority of referrals came from practices within the catchment area, (79.3%). There was a wide variation of referral rates. This variation in referral rates was not explained by the presence of primary care CPN support nor by the practice being single-handed. This was in line with research by Madeley et al., (1990), who found no difference in referral rates between single-handed GPs and those in partnerships in Lincolnshire. O'Donnell (2000), found that other structural factors including waiting lists and proximity to the hospital influenced GPs' decisions to refer. However, these factors were not investigated in this audit.

Another aim was to describe the demographic and clinical characteristics of referrals. More referrals were received for females than males; 55.4% and 44.6% respectively.
The Riverside catchment area comprised deprivation categories two to six. Overall referrals were distributed across these categories.

The most frequently used referral categories were anxiety 29.8% and depression / low mood 29.8%. This is in line with other audit findings (Broomfield et al., 2001). More specifically stress / coping difficulties 4.8% and panic 4.2% were commonly referred problems.

The audit also investigated whether there were significant differences between referral characteristics of referrals coming from the group of general practices referring higher than and lower than, the median referral rate. No differences in terms of socio-demographic and primary referral problems were observed between these two groups of practices.

These data had several implications. Referral data may help to ensure that future service delivery, allocation of resources and staff training takes account of and meets the needs of general practice referrals. This will be imperative if a primary care mental health team with psychological input is set up. More immediately these data could have implications for setting up waiting list initiatives. A relatively small number of locality practices account for the majority of referrals. Thus, services could be directed at the primary referral problems of these practices, for example, ensuring that self-help materials, and/ or groups were available in these practices. The aim of these would be to reduce the time from referral until initial contact. Past literature has highlighted problems with broad referral categories in that these cases are often subsequently treated for different problems. There is a suggestion that this possibly
occurs due to labelling effects; depression/low mood detailed rather than the cause (e.g. relationship problems), or due to patients reporting secondary symptoms caused by an underlying primary problem (Broomfield et al., 2001). Therefore, the targeting of more specific referral problems may be more useful.

Although this study has identified some useful information, certain limitations do exist. The audit was retrospective and data on primary problems came from judgements made by the department secretaries on the basis of the content of referral letters. Although they describe the letters as being generally clear, on some occasions the letters are vague or complicated. It might be better for a trained psychologist to enter this data. Furthermore, it was time consuming and difficult to attain data on general practice codes retrospectively without the practice name. The auditor has composed a list of practice names and their corresponding codes for all practices included in this audit to make this data more easily obtainable.

Also the number of referrals looked at in this study were relatively small and data was only collected for a one year period, as such it is possible that these data were susceptible to the effects of random variation in the number of referrals due to chance. Also in her critical review O’Donnell (2000) questioned whether variation in referral rates is a problem. She emphasised that referral rates themselves tell us nothing about the appropriateness of referrals. What is required, is to reduce inappropriate referrals where there is no benefit to the client, and increase appropriate referrals where there is benefit (Ross & Hardy, 1999). Therefore, until studies on the appropriateness of referrals have been carried out, great care must be taken in passing judgement on practices which are high or low referrers compared with the numerical norm.

Looking
at the appropriateness of referrals is an area for future audit. Although the composition of an ‘appropriate’ referral is complex Coulter (1998), one aspect that could feasibly be considered in this service is the concordance between the GPs primary referral reason and the problem worked on by the clinical psychologist. This data is already recorded on paper on discharge of a client, and although this data was not available for 2004 due to waiting lists, it could be utilised in a future audit. Also data could be recorded on the number of referrals that were not accepted, that were re-referred to other services or that would have been re-referred if services were available.

Completion of the present study demonstrated a benefit to expanding the current database to incorporate more data that are already being gathered in the department. It also highlighted difficulties in term of gathering data on locality areas as these seemed to be defined differently in different places also it seemed difficult to contact other services within these localities perhaps highlighting some of the barriers to effective communication and continuity between services.

The data found have implications in terms of facilitating a dialogue between General Practitioners and clinical psychology services. In terms of dissemination strategies O’Donnell (2000), highlights that although locally developed guidelines are often suggested as the way to alter referral patterns, there is no clear evidence to suggest that guidelines are effective in modifying referral behaviour. Indeed, she suggests that pressure on GPs to review their referral behaviour through the use of guidelines may reduce their willingness to tolerate uncertainty and manage problems in primary care, resulting in an increase in referrals to secondary care. Therefore, the use of data to
stimulate dialogue and joint working between GPs and other specialists (e.g. CPNs) may be more appropriate. As the majority of referrals come from locality practices LHCC meetings may be a good forum for dissemination of information and service discussions with other professionals.

In terms of dissemination the findings of this audit will be presented to and discussed with the head of the Riverside clinical psychology service in a planned meeting at the end of July (see appendix 1.1). The findings will also be presented at a clinical governance meeting either in August or September.
REFERENCES


Greater Glasgow Primary Care NHS Trust. Primary Care Strategy. 2001.
(http://www.nes.scot.nhs.uk.)


Figure 1.1 Referral Rates
Figure 1.2. Range of Carstairs deprivation categories

Graph with frequency values notated, missing data (n=51) is not included.
Table 1.1 Primary and Secondary referral problems

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<th>Primary Referral Reason</th>
<th>Secondary Referral Reason</th>
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<td>n (%)</td>
<td>n (%)</td>
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<td>Anxiety</td>
<td>218 (43.4)</td>
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<td>Obsessive Compulsive Disorder</td>
<td>143 (29.8)</td>
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Table 1.2 Comparison of referral characteristics for practices with referral rates higher and lower than the median

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<tr>
<td></td>
<td>Referral rate higher than median n (%)</td>
</tr>
<tr>
<td>Demographics</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>131 (43.1)</td>
</tr>
<tr>
<td>Female</td>
<td>173 (56.9)</td>
</tr>
<tr>
<td>Age</td>
<td>Median 35</td>
</tr>
<tr>
<td></td>
<td>Mean 36.75</td>
</tr>
<tr>
<td></td>
<td>Min-Max 18-66</td>
</tr>
<tr>
<td>Carstairs Deprivation Categories</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>57 (21)</td>
</tr>
<tr>
<td>3</td>
<td>17 (6.3)</td>
</tr>
<tr>
<td>4</td>
<td>81 (29.8)</td>
</tr>
<tr>
<td>5</td>
<td>13 (19.1)</td>
</tr>
<tr>
<td>6</td>
<td>18 (26.5)</td>
</tr>
</tbody>
</table>

Table 1.2 Continued on next page: Primary referral problems
Table 1.2 Continued: Primary Referral Problems

<table>
<thead>
<tr>
<th>Primary Referral Problem</th>
<th>Referral rate higher than median n (%)</th>
<th>Referral rate lower than median n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anxiety Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>98 (32.2)</td>
<td>22 (28.6)</td>
</tr>
<tr>
<td>Obsessive Compulsive Disorder</td>
<td>7 (2.3)</td>
<td>3 (3.9)</td>
</tr>
<tr>
<td>Post-traumatic stress disorder</td>
<td>15 (4.9)</td>
<td>2 (2.6)</td>
</tr>
<tr>
<td>Panic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specific / social phobia</td>
<td>14 (4.6)</td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>Health anxiety</td>
<td>7 (2.3)</td>
<td>2 (2.6)</td>
</tr>
<tr>
<td><strong>Affective Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression / low mood</td>
<td>90 (29.6)</td>
<td>24 (31.2)</td>
</tr>
<tr>
<td>Fluctuating mood / bipolar</td>
<td>1 (0.3)</td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>Bereavement</td>
<td>5 (1.6)</td>
<td>-</td>
</tr>
<tr>
<td>Self esteem</td>
<td>5 (1.6)</td>
<td>2 (2.6)</td>
</tr>
<tr>
<td>Relationship / social</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Stress / coping difficulty</td>
<td>18 (5.9)</td>
<td>2 (2.6)</td>
</tr>
<tr>
<td>Cognitive / development / speech</td>
<td>3 (1)</td>
<td>-</td>
</tr>
<tr>
<td>Anger</td>
<td>8 (2.6)</td>
<td>6 (7.8)</td>
</tr>
<tr>
<td>Eating Disorders</td>
<td>8 (2.6)</td>
<td>4 (5.2)</td>
</tr>
<tr>
<td>Behaviour</td>
<td>1 (0.3)</td>
<td>-</td>
</tr>
<tr>
<td>Abuse / Trauma</td>
<td>6 (2)</td>
<td>2 (2.6)</td>
</tr>
<tr>
<td>Self Harm</td>
<td>-</td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>Physical Health</td>
<td>1 (0.3)</td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>Sleep disorder</td>
<td>1 (0.3)</td>
<td>-</td>
</tr>
<tr>
<td>Personality Disorder</td>
<td></td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>Psychiatric Illness</td>
<td>3 (1)</td>
<td>-</td>
</tr>
<tr>
<td>Addictions</td>
<td>1 (0.3)</td>
<td>-</td>
</tr>
<tr>
<td>Sexual Dysfunction</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Unstated / Other</td>
<td>9 (3)</td>
<td>3 (3.9)</td>
</tr>
</tbody>
</table>
CHAPTER TWO: SYSTEMATIC LITERATURE REVIEW

Prevalence of Insomnia Following Traumatic Brain Injury: A Systematic Review of the Literature

Imogen L. M. Bloomfield*, Jonathan J. Evans and Colin Espie

Prepared in accordance with instructions for contributors to the Journal of the International Neuropsychological Society (Appendix 2.1)

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Running Title: Prevalence of Insomnia Following Traumatic Brain Injury.

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology.
ABSTRACT

Insomnia is a common complaint after traumatic brain injury (TBI) which can exacerbate other clinical sequelae, and have negative implications for quality of life and rehabilitation progress. Therefore, accurate information about the prevalence of insomnia post-TBI is important to inform service planning and provision. Past reviews have been conducted but they did not take a systematic approach and were limited in the conclusions they could draw by a scarcity of literature. The aim of the current systematic review was: to update the current state of knowledge in this area; to answer key questions about the prevalence of insomnia after TBI and the factors influencing prevalence rates; and through the consideration of methodological strengths and weaknesses to make recommendations for future researchers conducting studies in this area. Eleven studies were identified from the systematic literature search that met specified inclusion exclusion criteria. These were rated according to quality criteria. Two studies received a high quality rating. Prevalence rates for insomnia complaints reported in reviewed studies ranged from 4% to 92.6%; median 37%. The rate of people who had sustained a TBI meeting diagnostic criteria for insomnia was consistently reported to be between 25 to 30%. Despite heterogeneity between studies, the consistent conclusion was that rates of insomnia in TBI samples were significantly higher than rates of insomnia in the non-injured population. Several methodological recommendations were made.
INTRODUCTION

Traumatic Brain Injury (TBI) is reported to affect 279 people per 100,000 in the United Kingdom (Tennant, 1995). It is the leading cause of disability in people under 40 years of age and the ratio of males to females is 3-4:1 (Khan et al., 2003; Seeley & Hutchinson, 2006). Survivors are often left with a range of biopsychosocial sequaeae (Sbordone et al., 1995).

Although patients commonly report sleep changes, these have only started to receive research attention in the last thirty years. There is now growing evidence for the manifestation and persistence of a range of diagnosable sleep disorders after TBI (Vela-Bueno et al., 2006). The focus of this review will be on insomnia.

Insomnia and TBI

There has been considerable variability in how insomnia is defined in the general sleep literature (Edinger et al., 2004). Broad definitions have focused solely on insomnia symptoms, for example, difficulties initiating or maintaining sleep (Buysse et al., 2006). These have tended to capture heterogeneous groups and offer little indication of morbidity. Narrower definitions have emphasised the importance of additional facets such as sleep quality reflecting the impact of sleep disturbance on daytime functioning. However, they have not been standardised. Several validated nosological classifications of insomnia are available and have improved standardisation (e.g. DSM-IV-TR: American Psychiatric Association, 2000; ICSD-2: American Academy of Sleep Medicine, 2005). However, they have received some criticism because they are not entirely concordant (Edinger et al., 2004). In an attempt
to improve consensus between studies, a working group was commissioned to
develop standard definitions of all insomnia disorders (Edinger et al., 2004).

The relationship between insomnia and TBI is complex and there has been some
debate about the time of onset of the sleep disturbance, and whether definitions of
'primary insomnia disorder' (PID) or 'insomnia secondary to a medical condition'
(ISMC) apply (see table one below).

Table 1: RDC for PI and ISMC

<table>
<thead>
<tr>
<th>Insomnia Disorder</th>
<th>Insomnia due to Medical Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. The individual reports one or more of the following sleep related complaints:</td>
<td>A. The individual meets criteria for insomnia disorder.</td>
</tr>
<tr>
<td>1. difficulty initiating sleep,</td>
<td>B. The insomnia is present for at least one month.</td>
</tr>
<tr>
<td>2. difficulty maintaining sleep,</td>
<td>C. There is an association between the insomnia and a co-existing medical disorder as reflected by both of the following:</td>
</tr>
<tr>
<td>3. waking up too early, or</td>
<td>1. The onset of the insomnia coincides with the onset of the associated medical disorder.</td>
</tr>
<tr>
<td>4. sleep that is chronically non-restorative or poor in quality.</td>
<td>2. The temporal course of the insomnia coincides with the temporal course of the medical disorder.</td>
</tr>
<tr>
<td>B. The above sleep difficulty occurs despite adequate opportunity and circumstances for sleep.</td>
<td>D. The insomnia is either the sole complaint or is sufficiently severe to warrant separate clinical attention.</td>
</tr>
<tr>
<td>C. At least one of the following forms of daytime impairment related to the nighttime sleep difficulty is reported by the individual:</td>
<td>E. One of the following two conditions applies:</td>
</tr>
<tr>
<td>1. fatigue/malaise;</td>
<td>1. There is no current or past sleep-disruptive mental condition.</td>
</tr>
<tr>
<td>2. attention, concentration, or memory impairment;</td>
<td>2. There is a current or past sleep-disruptive mental condition but the temporal course of the insomnia shows some independence from the temporal course of this mental condition.</td>
</tr>
<tr>
<td>3. social/vocational dysfunction or poor school performance;</td>
<td></td>
</tr>
<tr>
<td>4. mood disturbance/irritability;</td>
<td></td>
</tr>
<tr>
<td>5. daytime sleepiness;</td>
<td></td>
</tr>
<tr>
<td>6. motivation/energy/initiative reduction;</td>
<td></td>
</tr>
<tr>
<td>7. proneness for errors/accidents at work or while driving;</td>
<td></td>
</tr>
<tr>
<td>8. tension headaches, and/or GI symptoms in response to sleep loss; and</td>
<td></td>
</tr>
<tr>
<td>9. concerns or worries about sleep.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F. The insomnia cannot be attributed exclusively to another primary sleep disorder (e.g., sleep apnea, narcolepsy, or parasomnia) or to an unusual sleep/wake schedule or circadian rhythm disorder.</td>
</tr>
<tr>
<td></td>
<td>G. The insomnia cannot be attributed to substance abuse or to use or withdrawal of psychoactive medications.</td>
</tr>
</tbody>
</table>
Current literature
Two recent reviews have considered sleep disturbances and insomnia after TBI (Ouellet et al., 2004; Rao & Rollings, 2002).

Rao and Rollings (2002) reviewed the literature on insomnia, hypersomnia and sleep-wake schedule disturbance after TBI and considered their evaluation and treatment. They considered four studies relevant to insomnia post-TBI and reported prevalence rates ranging from 30-81% (Beetar, 1996; Cohen et al., 1992; Fichtenberg et al., 2000; Mann, 1997).

More recently, Ouellet et al., (2004), conducted a more comprehensive critical review of empirical findings on insomnia in the context of TBI. They investigated its diagnostic features and prevalence, potential etiological factors, consequences, and possible pharmacological and psychological interventions.

The ten studies they reviewed were heterogeneous and ranged from studies that had measured sleep difficulties as a general construct on a symptom checklist (and may also have captured other sleep disturbances) to studies that had used diagnostic criteria to define insomnia (Beetar et al., 1996; Clinchot et al., 1998; Cohen et al. 1992; Dikmen et al., 1986; Fichtenberg et al., 2002; Hibbard et al., 1998; Keshavan & DeHaan, 1981; Ouellet et al., 2006; Perlis et al., 1997; Segalowitz & Lawson, 1995). Thus, they emphasised the importance of using sleep specific measures and distinguishing insomnia syndrome (i.e. meeting diagnostic criteria) from insomnia symptoms (e.g. difficulty falling asleep without any serious consequences). Prevalence rates ranged from 30-70%; which they reported were greater than those
reported in the general population. They also found evidence of insomnia reported several years after TBI which suggested that for a proportion of patients insomnia was chronic and persisting. Only one of the studies had considered pre-morbid sleep history so they were unable to draw conclusions about whether it was a pre-existing disorder or not. Insomnia was more frequent in patients with mild rather than moderate or severe injuries. However, none of the studies corroborated subjective reports with objective data, leaving the possibility that patients with severe injuries are not able to accurately report their problems. Furthermore, many of the studies had small samples sizes and were heterogeneous in terms of TBI severity and time since injury. Thus, discrepancies in the research methodologies meant that only cautious conclusions could be drawn.

**Justification for the current review**

Insomnia may have wider implications for quality of life and rehabilitation progress post-TBI. For example, there is evidence that insomnia may cause memory impairments (Kales & Kales, 1984), exacerbate other difficulties post-TBI and complicate rehabilitation progress (Worthington & Melia, 2006). Accurate information about the prevalence of insomnia is therefore important to inform service planning and provision for this group.

Due to the limited literature available key questions concerning the prevalence of insomnia after TBI remain unanswered. Since the publication of these reviews several other relevant studies have been completed using sleep-specific measures. To date a systematic review of this literature has not been completed. The aim of the current systematic review was to update the current state of knowledge in this area. More
precisely, it is hoped that by reviewing the influence of methodological strengths and weaknesses on findings it will be possible to account for some of the heterogeneity in findings and answer the questions listed below.

Key question

1. What is the prevalence of insomnia after TBI, and is it higher than the prevalence in the non-TBI population?

Additional questions

2. Is the prevalence of sleep disturbance higher for people with mild versus severe TBI, and are these results reflective of the sleep assessment methods used (subjective versus objective)?
3. What is the relationship between pre-morbid and post-TBI prevalence rates of insomnia and do sleep complaints diminish over time?
4. What is the relationship between demographic factors and prevalence rates?

METHODOLOGY

Search strategy

Relevant articles were initially identified by a search of the following electronic databases from January 1980 to May 2007:

- Ovid Medline R 1980-1995
- Ovid Medline R 1996-2007
- Journals @ Ovid full text May 18th 2007
- Your Journals@ Ovid and Psyc Articles
• All EBM Reviews - Cochrane, DSR, ACP, Journal Club, DARE and CCTR
• EMBASE 1980-2007 wk 19
• PsychInfo 1967 – May wk 3 2007

Some electronic resources did not go back to 1980 so necessary years were hand searched. Reference sections of relevant papers were examined to identify further articles of relevance and researchers who had conducted previous reviews were contacted and consulted in case they were aware of any relevant unpublished studies.

Search terms

The following terms were entered into a keyword search:

• Sleep$
• Insomnia$
• Head injur$ or TBI or brain injur$

$ denotes truncation.

Article selection

The citations and abstracts of all the papers identified by the search strategies were read. This allowed the exclusion of irrelevant studies and the more detailed consideration of studies that potentially met the following inclusion and exclusion criteria. When examination of the abstract suggested relevant content, the full publication was obtained and examined before a final decision was made about its inclusion or exclusion.
Inclusion criteria

Participants were adults who had sustained a minor, mild, moderate or severe TBI. Studies had to include a specific sleep measure (e.g. self-report sleep questionnaire, sleep diary, sleep monitoring or objective sleep measure).

Exclusion criteria

Review articles, case studies or dissertation abstracts were excluded, as were studies that were not available in the English language. Articles that focused on other sleep disorders e.g. narcolepsy, sleep apnoea, excessive daytime sleepiness or circadian rhythm disorder but that did not have information on sleep initiation, maintenance, or insomnia were also excluded. Articles pre 1980 were excluded, and studies that were based on responses to global statements about sleep or that only assessed sleep as one aspect of a broader symptom checklist were also excluded. Articles that considered changes to sleep architecture but did not contain information about subjective complaints or key sleep variables were also excluded.

Assessment of methodological quality

Published guidelines for conducting systematic reviews were considered when constructing the quality rating criteria for this systematic review (NHS CRD, 2001; SIGN, 2004; Verhagen et al., 1998). However, their main emphasis was on randomised control trials, so guidelines for evaluating prevalence studies (Boyle, 1998) and methodological issues raised in relevant reviews were also considered (Buysse et al., 2006; Edinger et al., 2004; Ouellet et al., 2004; Rao & Rollings, 2002).
A large number of factors influence the overall quality of a research paper. In the present review the following topics were considered:

- Sampling and whether the sample was representative of the target population
- Sleep variables and the reliability and validity of assessment methods
- Head injury variables and classification methods

Sixteen items comprised the quality checklist (see appendix 2.2). Each was rated on a 0-2 scale, giving a maximum score of 32 (see appendix 2.3). Total scores were expressed as a percentage and study quality was classified as high (75% and above), moderate (60-74%), low (50-59%) and poor (under 49%). Although, these were arbitrary categories they enabled the classification and comparison of studies.

The quality of each study was also calculated by a second independent rater. Rating differed on 12 out of 176 items; there was a 95% inter-rater agreement. Differences in ratings were resolved via discussion.

RESULTS

Literature search

Initially 407 articles were identified from the electronic database search. Following the article selection process (detailed above) 11 relevant articles remained that met inclusion criteria (see article selection flow chart appendix 2.4). The majority of articles that were excluded were not relevant to this systematic review and pertained to other neurological, psychiatric or medical conditions, or were drug or treatment studies (n=229).
PART A

What is the prevalence of insomnia after TBI, and is it higher than the prevalence in the non-TBI population?

Eleven studies provided data concerning the prevalence of insomnia after TBI (see table two below). According to the quality rating criteria two of these were ‘high quality’ (Ouellet et al., 2006; Parcell et al., 2006), four were ‘moderate quality’ (Fichtenberg et al., 2002; Mahmood et al., 2004; Verma et al., 2007; Worthington & Melia., 2006), three were ‘low quality’ (Beetar et al., 1996; Clinchot et al., 1998; Perlis et al., 1997) and two were ‘poor quality’ (Burke et al., 2004; Cohen et al., 1992). Methodological considerations will be discussed in further detail below.

Study findings

Prevalence rates will be considered according to the sleep definitions and classifications used. For example, studies where diagnostic criteria have been used, studies where sleep and day time complaints have been considered, studies that have used broader definitions based only on sleep variables, and studies that have included individual sleep complaints.

Diagnostic criteria

Three studies used diagnostic criteria to define the prevalence of insomnia. Verma et al., (2007) retrospectively analysed data obtained through diagnostic interviews and standard sleep-wake questionnaires administered by a sleep specialist at a nationally accredited sleep clinic. They reported that insomnia was a presenting symptom in 33% of patients and the presenting complaint in 25%. Unfortunately, this paper did not explicitly state either the diagnostic criteria used or the content of the sleep-wake
questionnaires. In addition to subjective data, Polysomnography (PSG) was used to look at four key parameters relevant to insomnia (see table two). The frequency with which these criteria were met ranged from 22% (delayed SOL) to 93.5% (excessive number of awakenings). The discrepancy between these findings will be discussed in more detail in part B.

Ouellet et al., (2006) amalgamated DSM-IV (1994) and ICSD (1990) criteria; 29.4% of their TBI population met diagnostic criteria for insomnia and 50.2% reported insomnia symptoms. Using a similar study sample and DSM-IV criteria Fichtenberg et al., (2002), found that 30% of TBI participants met diagnostic criteria for insomnia. Both Ouellet et al., (2006) and Fichtenberg et al., (2002) concluded that rates of insomnia symptoms and insomnia syndrome were significantly higher in the TBI populations compared to rates in the general population.

_Pittsburgh Sleep Quality Index (PSQI)_

Fichtenberg et al., (2002), utilised the Pittsburgh Sleep Quality Index (PSQI), a sleep questionnaire widely used and validated in the general sleep literature. Items consider sleep quality and quantity but also the impact of these on daytime functioning. They found that global scores greater than eight had high sensitivity and specificity for insomnia syndrome in TBI participants when compared to diagnostic criteria; 28% of participants met this criterion. A score greater than five reflected more general poor sleep quality and applied to 42% of participants. Mahmood et al., (2004), also used the PSQI to define insomnia. They utilised a cut off score of six
<table>
<thead>
<tr>
<th>Results</th>
<th>Definition and assessment of sleep</th>
<th>Prevalence of insomnia following traumatic brain injury</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Table 2. Characteristics of Included Studies</td>
</tr>
</tbody>
</table>

Prevalence of insomnia following traumatic brain injury
<table>
<thead>
<tr>
<th>Prevalence of Insomnia Following Traumatic Brain Injury</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before TBI:</strong></td>
</tr>
<tr>
<td>Only 6.4% total sample had a sleep complaint.</td>
</tr>
<tr>
<td>- 3.5% and 2.4% had a sleep complaint.</td>
</tr>
<tr>
<td>- Higher in moderate or severe TBI compared to mild TBI</td>
</tr>
<tr>
<td>- Average WASO: min 86.7 vs 22.49</td>
</tr>
<tr>
<td>- Average NWAQ: 3.2 vs 1.42</td>
</tr>
<tr>
<td>- Average SDQ: 6.8 vs 2.4</td>
</tr>
<tr>
<td>- Average SOI: 57.88 vs 27.87</td>
</tr>
<tr>
<td>- Sleep was significantly different compared to TBI.</td>
</tr>
<tr>
<td>- 29.4% met criteria for insomnia syndrome.</td>
</tr>
<tr>
<td>- 50.2% met criteria for insomnia symptoms.</td>
</tr>
</tbody>
</table>

| **Post-TBI:**                                         |
| - Mean AHI 7.85                                       |
| - Mean 4.02                                          |
| - 17 patients                                        |
| - Group: TBI Support of chronic and residual insomnia |
| - Longer follow-up                                   |
| - TBI and sleep associations                         |
| - Support for community rehabilitation               |
| - Rehabilitation services                            |
| - Severance                                          |
| - Post-traumatic                                   |
| - Moderate                                          |
| - Mild                                              |
| - Severe                                            |
| - Significant difference                            |
| - Following LOC                                      |
| - Symptoms                                          |
| - Professional report                                |
| - Measures                                           |

| **Sleep Quality:**                                   |
| - Early morning waking                             |
| - Daytime napping                                   |
| - Nighttime napping                                 |
| - Restless nights                                   |
| - Excessive daytime sleep                           |

| **Post-traumatic:**                                  |
| - 13.3%                                              |
| - 11.9%                                              |
| - 18.5%                                              |
| - 21.5%                                              |
| - 27.4%                                              |
| - 31.5%                                              |
| - 38.3%                                              |
| - 45.2%                                              |
| - 78.1%                                              |
| - 106.2%                                             |
Prevalence of Insomnia Following Traumatic Brain Injury

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants (n)</th>
<th>Follow-up</th>
<th>Insomnia Post-TBI</th>
<th>Disability Post-TBI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial (1998)</td>
<td>114 patients</td>
<td>1 year post concussive injury</td>
<td>Moderate</td>
<td>31 patients</td>
</tr>
<tr>
<td>Methuen et al. (2002)</td>
<td>25 MSK</td>
<td>7 months</td>
<td>Severe</td>
<td>50% (65/127)</td>
</tr>
<tr>
<td>Methuen et al. (2004)</td>
<td>49 TBI</td>
<td>1 year post TBI</td>
<td>Moderate</td>
<td>7% (3/42)</td>
</tr>
</tbody>
</table>

- SE below 85% in approximation 25%
- Average SD fell below 6.5 hours in 18%
- Average SOL exceeded 30 min in 34%

Patients with moderate TBI reported significantly more sleep disturbance than did patients with severe TBI. Patients with mild TBI reported significantly less sleep disturbance. 37% met clinical criteria for sleep disturbance.
Prevalence of Insomnia Following Traumatic Brain Injury

<table>
<thead>
<tr>
<th>Post Injury</th>
<th>Prevalence of Insomnia Following Traumatic Brain Injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>24.9 months</td>
<td>*</td>
</tr>
<tr>
<td>Pain Problems</td>
<td>Moderate/Severe</td>
</tr>
<tr>
<td>No Specificity</td>
<td>2 months</td>
</tr>
<tr>
<td>Consequence of</td>
<td>Insomnia</td>
</tr>
<tr>
<td>General Neurological</td>
<td>CAT/MAT scan</td>
</tr>
<tr>
<td>Neuropsychological</td>
<td>36.1</td>
</tr>
<tr>
<td>Extent of</td>
<td>TBI</td>
</tr>
<tr>
<td>Insomnia</td>
<td>TBI</td>
</tr>
<tr>
<td>27%</td>
<td>Patients in Each Group</td>
</tr>
<tr>
<td>Orthopaedic Surgery</td>
<td>9%</td>
</tr>
<tr>
<td>Injury Group</td>
<td>39</td>
</tr>
</tbody>
</table>

*Note: All percentages are calculated based on the respective dataset provided.*

<table>
<thead>
<tr>
<th>Insomnia</th>
<th>post-traumatic brain injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantitative and qualitative measures of sleep disturbance and quality</td>
<td></td>
</tr>
<tr>
<td>Estimation that sleep took longer to fall asleep</td>
<td></td>
</tr>
<tr>
<td>Estimated average duration 5.9 hours</td>
<td></td>
</tr>
<tr>
<td>Estimated average duration 3.6 hours</td>
<td></td>
</tr>
</tbody>
</table>

**Table Legends:**
- TBI: Traumatic Brain Injury
- CAT/MAT: Comprehensive Assessment of Health and Recovery
- TBI: Traumatic Brain Injury
- Orthopaedic Surgery
- Injury Group

**Additional Notes:**
- 90% of patients with a mild brain injury reported problems with a full night's sleep.
- 50% of patients with a moderate/serious brain injury reported problems with a full night's sleep.
<table>
<thead>
<tr>
<th>Key to Abbreviations</th>
<th>DOES: disorder of excessive sleepiness</th>
<th>PSDI: Pittsburgh Sleep Quality Index</th>
<th>TBI: Traumatic Brain Injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>GCS: Glasgow Coma Scale</td>
<td>LOC: loss of consciousness</td>
<td>ABI: Acquired Brain Injury</td>
<td>PSQI: Pittsburgh Sleep Quality Index</td>
</tr>
<tr>
<td>WASO: wake after sleep onset</td>
<td>SD: Sleep duration</td>
<td>ISI: Insomnia Severity Index</td>
<td></td>
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<tr>
<td>FIM: Functional Independence Measure</td>
<td>NWAK: number of awakenings</td>
<td></td>
<td></td>
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<tr>
<td>M: Moderate quality rating</td>
<td>P: Poor quality rating</td>
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<tr>
<td>L: Sleep onset latency</td>
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</tbody>
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Prevalence of insomnia following Traumatic Brain Injury:

<table>
<thead>
<tr>
<th>Duration of coma was not related to sleep</th>
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<tbody>
<tr>
<td>Group 1: 29.5 months post injury</td>
</tr>
</tbody>
</table>

- 38-item questionnaire
- DBS: dopamine receptor stimulation
- 62% of those reported using DBS, 52% of those not using DBS
- TBI sample

- Mild to moderate
- Severe

- Group 1: 26 patients seen at rehabilitation department
- Group 2: 26 patients seen at rehabilitation department
- Group 1: 29 patients with TBI = 77
- Group 2: 29 patients with TBI = 99

- Group 1: 99 (43.8%)
- Group 2: 77 (42.8%)

- Then et al.
which they purported to reflect "clinically significant sleep disturbance"; 37% of participants met these criteria for sleep disturbance.

**Non-standardised definitions**

Two studies used non-standardised definitions of insomnia that focused on difficulties initiating and maintaining sleep but did not consider additional facets of the disorder (Beetar et al., 1996; Cohen et al., 1992). Beetar et al., (1996) reported that 56.4% of TBI participants satisfied their criteria for insomnia. In line with these results Cohen et al., (1992) found that 59.5% of their hospitalised TBI participants endorsed the questionnaire items relevant to disorders initiating and maintaining sleep (DIMS). However, in contrast only 4% of their discharged participants endorsed these symptoms. Both studies concluded that rates of sleep complaints in TBI participants were far higher than those in the general population.

**Individual sleep complaints and comparisons**

Other studies reported individual sleep complaints making it difficult to identify the clinical significance of the complaints or the number of participants reporting more than one symptom. However, several of these studies included comparison groups.

Only one study used a control group of healthy adults matched for age and gender (Parcell et al., 2006). However, they looked at sleep change rather than sleep complaints. Again this is a broader concept and may not reflect problems that have a clinical impact for participants. They found that 80% of the TBI group reported that their sleep had changed (both insomnia and hypersomnia) post-TBI. Relevant to insomnia complaints post-injury TBI participants reported: longer SOL
5%); more NWAK (46% versus 5%) and lighter sleep (25% versus 3%). On the sleep diary parameters the TBI group reported significantly longer SOL and poorer SE than the control group. Thus, these results provide evidence that TBI participants experience more sleep disturbances than matched controls.

Other studies used clinical control groups. Perlis et al., (1997), compared TBI and orthopaedic controls. They found that patients with post-concussion syndrome (PCS) reported significantly more problems with sleep initiation (52.6% compared to 16% of controls) and sleep duration (53.8% compared to 20% of controls). These results were discordant with Fichtenberg et al., (2002; described above) who found higher prevalence rates (based on PSQI scores>5) in their unmatched spinal cord injury (72%) and musculoskeletal (80%) comparison groups than in their TBI participants (42%).

Hospital staff in Burke et al’s (2004) study rated sleep/ wakefulness every hour and found that 56% of TBI patients experienced interrupted sleep versus 92% of patients with anoxic injuries and concluded that rates of sleep disturbance are higher in TBI patients than the general population, but not as high as those patients with anoxic injuries. These results contrast with the results from Beetar et al., (1996) (described above), who reported that TBI participants had significantly more pain and insomnia complaints than a control group of general neurologic, non-TBI subjects. Furthermore both these results are inconsistent with Worthington and Melia (2006), who did not report the results of the ABI and TBI participants separately because they conducted statistical analyses which showed that there was no difference in terms of reports for ABI and TBI patients. They found that 21.5% of the sample experienced frequent
wakenings at night, 18.5% experienced delayed sleep onset, and 11.9% had early morning wakening. It is important to note that all of their participants had sustained severe injuries.

Clinchot et al., (1998) also looked at individual sleep complaints but did not include a control group. They found that 50% of TBI participants had difficulty with sleep, 32% described waking too early and 22.5% described problems falling asleep.

Methodological quality of the studies

Studies reviewed varied considerably on many methodological variables including sampling considerations, the classification of groups, assessment methods used and the impact of injury and of demographic factors. These last three factors are addressed in the subsidiary sections and so will not be replicated in this section.

Sampling

The power of the sample and how representative it is of the target population are of significant importance in prevalence studies as they provide readers with information about how verifiable it is to generalise the results of the study (Boyle et al., 1998). Unfortunately, there were no population-based studies. Thus, all the studies reported prevalence in restricted populations. The samples used varied considerably between studies and may have influenced the prevalence rates reported. Four studies utilised community-based TBI samples (outpatients recruited after rehabilitation or from support groups; Clinchot et al., 1998; Cohen et al, 1992; Ouellet et al., 2006; Parcell et al., 2006) four studies recruited current outpatients (Beeter et al., 1996; Fichtenburg et al., 2002; Mahmood et al., 2004; Verma et al., 2007) and two studies recruited...
inpatient or institutionalised participants (Burke et al., 2004; Worthington & Melia, 2006). Using discharged outpatient samples has been reported to be better methodologically than using inpatient or institutionalised samples who tend to have daily routines and environmental factors imposed on them which can influence sleep patterns (Parcell et al., 2006). It has also been reported to be more representative than using current outpatients who may be more symptomatic than the general TBI population (Parcell et al., 2006).

The sample sizes of the studies reviewed ranged from 17 (Burke et al., 2004) to 452 (Ouellet et al., 2006), with a mean of 110. Although many of the studies appeared to have reasonable sample sizes, only one study reported that a power calculation had been completed Fichtenberg et al., (2002). This may reflect the nature of the studies and the fact that only a minority of the studies included comparison groups.

Only one study utilised a matched control group from the general population (Parcell et al., 2006) and afforded true comparisons to be made between TBI participants and non-injured adults. It received a high quality rating. Four studies included control groups from other clinical populations (Beetar et al., 1996; Burke et al., 2004; Fichtenberg et al., 2002; Perlis et al., 1997). However, the comparison groups were heterogeneous and were not matched with TBI participants limiting the validity of the comparisons. Other studies compared their results to rates previously reported in the general population. The difficulty with this is that there have been many different prevalence rates reported in the general population (Edinger et al., 2004). Furthermore, TBI populations tend to include more men than women and more people
in the 19-25 age group compared to the general population (Ouellet et al., 2006). Thus, comparisons may not be valid.

**Classification**

Four studies used diagnostic criteria, or the PSQI – these were all rated as high or moderate quality (Fichtenberg et al., 2002; Mahmood et al., 2004; Ouellet et al., 2006; Verma et al., 2007). With the exception of Verma et al., (2007), the strength of these studies was that their methodologies were transparent and operational allowing easy replication in clinical and research settings. However, there were inconsistencies in the definitions and cut-off scores used, suggesting that classifications may not have been concordant across studies and necessitating further standardisation across studies in the future. Two studies used non-standardised definitions which were less clinically useful because although they afforded an indication of the severity of sleep disruption, they did not provide information on morbidity (Beetar et al., 1996; Cohen et al., 1992). Also the methodologies were less standardised, reducing the reliability and replicability of the results. The remaining studies focused on the frequency of individual sleep complaints. The quality of these ranged from poor to high quality. The difficulty with these studies is that, although they provide information on the frequency of sleep complaints, they do not provide information of the clinical severity of participants’ difficulties so again the information is less useful for clinicians working in the area or service planning.

**Discussion**

In summary, the studies reviewed differed greatly in terms of quality and methodology; heterogeneous classification and sampling methods limited
comparisons between studies and the wider extrapolation of findings. These factors are likely to have contributed to the wide variation of reported prevalence rates; 4% to 92.6%; median 37% (Cohen et al., 1992; Verma et al., 2007; Mahmood et al., 2004, respectively).

Despite these constraints, there were some conclusions that could be drawn from consistencies within the studies. Sleep definition had a significant impact on the prevalence rates reported. Even though they used different assessment methodologies and samples from different populations, the studies that used operational definitions based on validated criteria found roughly equivalent prevalence rates for clinically significant insomnia syndrome (25 to 30%). Again, studies that considered the frequency of insomnia symptoms or used broader non-standardised definitions found generally found higher prevalence rates of (37% to 59.5%). The finding of Cohen et al., (1992) of a 4% prevalence of DIMS in their post-acute TBI sample, was the exception to this. When individual sleep complaints or parameters were reported, these accounted for the highest and most wide-ranging prevalence rates: 11.9%, early morning wakening to NWAK >6 on PSG: 92.6% (Worthington & Melia, 2006 and Verma et al., 2007). Thus, the definition of insomnia is imperative to the results of studies and has a strong bearing on outcome even in spite of methodological differences between studies.

Despite variability in comparisons used, studies consistently reported that prevalence rates were higher for TBI participants than in the general population. It was less clear whether the rates seen were higher for TBI participants than other clinical groups.
PART B: SUBSIDIARY QUESTIONS

The following section examines selected factors that may influence the reported prevalence of insomnia symptoms in people who have sustained a TBI. Methodological considerations already discussed in Part A will not be re-iterated.

Is the prevalence of sleep disturbance higher for people with mild versus severe TBIs, and are these results reflective of the sleep assessment methods used (subjective versus objective)?

Study findings

Seven studies addressed this issue and six reported a significant association between the severity of TBI sustained and the prevalence of insomnia (see table two). Sleep assessment methods are relevant here because of suggestions that people with severe head injuries may find it difficult to report subjective sleep difficulties accurately.

Two studies looked at the relationship between objective sleep disturbances and severity of TBI and both reported that higher rates of sleep disturbance were found in individuals with more severe injuries (Burke et al., 2004; Verma et al., 2007). However, they also both used functional outcome measures to assess head injury severity.

Four studies reported that higher rates of sleep disturbance were found in participants with mild head injuries. All of these studies used subjective sleep assessment methods. Three of these studies used the initial Glasgow Coma Scale (GCS) score as a measure of head injury severity (Clinchot et al., 1998; Mahmood et al., 2004; Parcell et al., 2006). Ouellet et al., (2006), categorised head injury severity based on
initial GCS, duration of Post traumatic Amnesia (PTA), duration of loss of consciousness (LOC) and sequelae and again reported that the frequency of an insomnia syndrome was slightly higher in minor and mild TBI than in moderate or severe TBI. A strength of the study by Mahmood et al., (2004) was that they conducted exploratory analyses to investigate the possibility that patients in the mild injury group simply over reported their post injury complaints in general compared to the moderate and severe groups but did not find evidence that this was the case.

One study found no relationship between head injury severity and sleep complaints (Cohen et al., 1992). They used coma duration as a measure of head injury severity. However, all their participants had been in a coma for at least a day, suggesting they had all suffered from severe injuries. It is likely that the use of this restricted population contributed to their lack of findings.

Methodological considerations

Again, the papers that considered the impact of head injury severity on prevalence varied in quality ratings from ‘poor’ to ‘high’. Methodological variability, notably in terms of assessment methods and definitions of head injury severity, limited the conclusions that could be drawn.

Assessment methods

The studies reviewed differed substantially in their sleep assessment methods. Buysse et al., (2006) recommend the use of multimodal assessment methods (i.e. subjective and objective) in the diagnosis of insomnia in the general population, where study design made this practical. While they also acknowledged that the use of objective
measurers was not always practical in larger prevalence studies, multimodal assessment seems particularly important where there is any doubt about the ability of participants to accurately report their difficulties (i.e. people who have significant cognitive deficits following TBI). Only one study in this review (Verma et al., 2007) corroborated sleep complaints with an objective sleep measure; PSG. One other study used objective observational ratings but unfortunately did not measure subjective complaints (Burke et al., 2004).

Ouellet et al., (2006) corroborated participants’ subjective reports with reports from significant others and these were shown to correlate. Corroboration of complaints is a technique commonly used in clinical settings and this is a useful addition in larger community-based studies where it would be impractical to assess everybody with objective sleep measures. However, care should be taken to ensure that the significant other has not also helped the individual complete their other questionnaires as this may contaminate results.

No other studies reported collateral support for subjective measures but three studies used published sleep-wake questionnaires with validated cut-off scores. The PSQI (Fichtenberg et al., 2002; Mahmood et al., 2004) has been specifically validated for use with TBI patients and the Insomnia severity index (ISI) (Ouellet et al., 2006) has also been used effectively in this population. Thus, both of these measures provide quick and effective screening methods for research and clinical purposes. Parcell et al., (2006) used the General Sleep Habits Questionnaire (Monroe, 1967) that had been used previously in healthy adults and in TBI patients (Parsons & Ver Beek, 1982). However, as its name suggests this questionnaire is not specific to insomnia. The
difficulty with all of these methods is that they are retrospective. Two studies (Fichtenberg et al., 2002; Parcell et al., 2006) used sleep diaries; the strength of these is the prospective information they provide. Five studies utilised unpublished questionnaires, non-standardised rating methods or chart reviews making it difficult to replicate results or to fully consider the basis on which sleep complaints were defined (Beetar et al., 1996; Clinchot et al., 1998; Cohen et al., 1992; Perlis et al., 1997; Worthington & Melia, 2006).

Definition of head injury severity
There is not a universally accepted method for classifying head injury severity. Definitions of minor, mild, moderate and severe head injuries, especially in studies given poorer quality ratings, were often unclear. There was a lack of consensus both in terms of measures used and in how the groups were defined on the measures used. While some studies provided data for all four categories, others considered broader categories or simply used overall correlations. Even studies that used the same measures e.g. (GCS score) often used different cut off scores, making comparisons difficult.

Discussion
The majority of studies reviewed did provide evidence for a significant relationship between injury severity and the prevalence of sleep complaints. The direction of the relationship differed between studies that used objective and subjective sleep measures. However, these studies also differed in terms of measures of head injury severity used making it difficult to distinguish which of these factors may have accounted for the results seen. The tautology associated with using functional
outcome measures to assess TBI severity, and then comparing the results with an area of functioning (e.g. sleep) was a weakness of two of these studies (Burke et al., 2004; Verma et al., 2007). Thus, limited evidence and methodological difficulties meant that conclusions could not be drawn for this question. Future research is needed using subjective and objective sleep measures and using both initial and outcome measures of head injury severity.

What is the relationship between pre and post-TBI prevalence rates of insomnia, and do sleep complaints diminish over time?

Study findings

Three studies included in this review explicitly considered the relationship between pre and post-TBI prevalence rates and they all reported a significant increase in sleep difficulties post-TBI (Ouellet et al., 2006; Parcell et al., 2006; Verma et al., 2007; see table two).

The average time post injury of participants in the reviewed studies ranged from 2 months to 9 years (Burke et al., 2004; Worthington & Melia, 2006). All of these studies found rates of insomnia which they reported were higher than the rates in the general population. Furthermore, when the results were placed in ascending order of time since injury there was no obvious pattern of prevalence rates over time, suggesting that sleep difficulties are prevalent in the acute stages post TBI but also that they persist over time.

Five studies considered the time since injury in their statistical analyses (Beetar et al., 1996; Cohen et al., 1992; Fichtenberg et al., 2002; Ouellet et al., 2006; Parcell et al.,
Prevalence of Insomnia Following Traumatic Brain Injury

2006). Only one of these supported the traditional view that sleep difficulties improve over time (Cohen et al., 1992). In contrast, Parcell et al., (2006), reported that increased time since injury was associated with an increase in night time awakenings (other sleep parameters were not significantly related). The three remaining studies did not find any statistical significant relationships (Beetar et al., 1996; Fichtenberg et al., 2002; Ouellet et al., 2006).

Methodological quality

Consideration of whether the sleep disorder was primary or secondary was only included by studies rated as of high or moderate quality. The consideration of a wider range of confounding factors and the use of more stringent methodologies is reflected by their quality ratings. Since pre-morbid sleep can only be assessed retrospectively, a particular strength of Ouellet et al’s (2006), study is that they included a significant other’s questionnaire. Thus, they have corroboratory confirmation that sleep has changed compared to pre-TBI.

In contrast, all of the reviewed studies reported average time since injury. However, there was considerable variance both within and between the studies. Therefore, it would have been useful if studies had reported the median time since injury as well as the mean.

Five of the studies reviewed went on to consider the time post-injury in their statistical analyses. Although there was variability between whether group-wise comparisons or correlations were used, the results were fairly consistent.
Discussion

Three good quality studies provided consistent evidence that insomnia occurred secondary to TBI; suggesting TBI was the critical incident precipitating, perpetuating or exacerbating insomnia.

Methodological limitations and differences make it impossible to draw decisive conclusions about any relationship between time since injury and prevalence rates. It may be that if sleep complaints or parameters were looked at individually a pattern would emerge to suggest that there is some qualitative change in the insomnia complaint over time. This is something that should be considered in future studies.

What is the relationship between demographic and psychosocial factors and prevalence rates?

The relationships between a broad range of psychosocial factors and insomnia were investigated in the 11 reviewed studies. Demographic factors, psychiatric and medical symptoms, and neuropsychological variables will be considered here.

Study findings

Women had significantly more sleep complaints than men in three studies (Burke et al., 2004, Clinchot et al., 1998, Cohen et al., 1992). However, in contrast Mahmood et al., (2004) found that male gender was positively related to PSQI score. Furthermore, Fichtenberg et al., (2002) did not find any relationship between gender and sleep disturbance. Older age was associated with higher rates of insomnia in two studies (Burke et al., 2004; Clinchot et al., 1998) but no relationship was found between age
and sleep disturbance in two further studies (Fichtenberg et al., 2002; Mahmood et al., 2004).

Four studies found that insomnia was associated with higher anxiety scores (Cohen et al., 1992; Ouellet et al., 2006; Parcell et al., 2006; Verma et al., 2007) and five studies found that insomnia was associated with higher depression scores (Cohen et al., 1992; Mahmood et al., 2004; Ouellet et al., 2006; Parcell et al., 2006; Verma et al., 2007). In contrast, Wothington and Melia, (2006) did not find any relationship between depression and sleep complaints. However, only eight participants in their sample met criteria for depressive disorder. Other psychological variables and psychiatric disorders (e.g. anger irritability, schizophrenia, apathy) were also associated with higher rates of insomnia (Cohen et al., 1992; Ouellet et al., 2006; Wothington & Melia., 2006) as were physical factors such as fatigue (Clinchot et al., 1998; Ouellet et al., 2006) and pain and headaches (Beetar et al., 1996; Clinchot et al., 1998; Ouellet et al., 2006).

Two studies found that higher rates of cognitive disturbance were related to increased insomnia complaints (Cohen et al., 1992; Ouellet et al., 2006). However, other studies that looked at specific cognitive domains found that better functioning on some measures such as memory, attention and executive functioning was associated with increased insomnia complaints (Clinchot et al., 1998; Mahmood et al., 2004).

Three studies completed regressions to identify factors that best predicted sleep difficulties post TBI (Clinchot et al., 1998; Mahmood et al., 2004; Ouellet et al., 2006). However, again the results were varied. Ouellet et al., (2006), found that four
factors significantly contributed to the production of insomnia; milder severity of injury, higher severity of depressive symptoms, a higher intensity of pain, and a higher level of fatigue. Mahmood et al., (2004) found that injury severity and gender accounted for 17% and that neuropsychological variables accounted for an extra 14% of the variance. Clinchot et al., (1998) completed a univariate logistic regression and only average or above average memory and attention were predictive of sleep problems (P=0.027). When a multiple logistic regression of demographic factors was completed, female gender, older age and alcohol abuse history formed the best predictive equation (P=0.0034). When all the variables were considered, older age and better immediate memory formed the best descriptive model (P=0.002).

Methodological considerations

Again heterogeneous methodologies and variation in the factors considered made comparisons difficult. The studies that were rated as of high or moderate quality tended to have considered a broader range of demographic influences. Also many different techniques were used to assess variables. Only three studies conducted regressions to consider the predictive utility of these factors which have wider clinical and research implications. This was a strength of these studies.

Discussion

A range of factors were shown to correlate with increased sleep complaints. However, again results were not unequivocal between studies. There was considerable variation in the results found for demographic and neuropsychological factors. However, there was more consistent evidence for a positive relationship between psychological and medical variables and sleep complaints; particularly depression and anxiety. These
factors must at least be measured in future studies looking at sleep complaints after TBI. Methods of assessment that have been validated for use with TBI participants should be utilised where possible. Only three studies looked at which factors predicted sleep complaints and unfortunately different predictive factors were found in each study. Thus, due to limited evidence and lack of agreement, it is not possible to identify the most important predictive factors in this review.

DISCUSSION

Overall prevalence rates for insomnia complaints reported in reviewed studies ranged from 4% to 92.6%; median 37% (Cohen et al., 1992; Verma et al., 2007; Mahmood et al., 2004, respectively). Systematically reviewing the literature revealed that the sleep definition used had a significant impact on prevalence rates. The rate of people who had sustained a TBI meeting diagnostic criteria for insomnia was consistently reported to be between 25-30%. The studies supporting this finding were all rated as of high or moderate quality, adding credence to this conclusion (Fichtenberg et al., 2002; Ouellet et al., 2006; Verma et al., 2007). Furthermore, despite heterogeneity between studies, the consistent conclusion was that rates of insomnia in TBI samples were significantly higher than rates of insomnia in the non-injured population. This conclusion is in line with the results from previous reviews (Ouellet et al., 2004; Rao & Rolling, 2002).

Further research is still needed to consolidate these findings. Of note, there have still not been any epidemiological studies conducted. Further studies utilising matched control groups and operationalised RDC criteria to define the prevalence of participants who meet criteria for: primary insomnia; insomnia secondary to a medical
Inconsistent findings meant that it was impossible to draw conclusions about whether prevalence rates were higher for those individuals with mild versus severe TBIs. The data opened up the possibility that the use of subjective versus objective sleep assessment methods may influence whether higher rates are seen in individuals with mild or severe TBIs. This discussion point is interesting when considered in the context of previously-stated debates about the ability of patients with severe TBIs to utilise subjective sleep assessment methods accurately (see Mahmood et al., 2004). However, the lack of correspondence between subjective and objective assessment methods is a common finding in the general sleep literature, where increased credence is given to subjective complaints and perceived resultant deficits when diagnosing insomnia on account of individual differences in basal sleep requirements and awareness of the commonality of sleep misperceptions (Erman et al., 2001). A recent study by Ouellet and Morin (2006) compared subjective (sleep diary) and objective (PSG) measures of sleep in 14 TBI patients suffering from insomnia and 14 healthy good sleeping controls. They found that while all subjective measures revealed significant sleep disturbance in TBI participants, they tended to overestimate their sleep disturbance compared to PSG measures, where only 70% of participants met criteria for objective insomnia. In contrast to these results, the study by Verma et al., (2007) suggested that more of their TBI participants met objective versus subjective
criteria for insomnia. Again methodological differences are likely to account for these inconsistencies. This is an area that requires further research.

With regard to the evidence that insomnia increases post TBI, although only limited data was available, the studies reviewed were all given moderate to high quality ratings and reported convergent evidence that insomnia and sleep disruption developed following TBI. Furthermore, in line with results from Ouellet et al’s. (2004) review, insomnia was shown to affect both acute (e.g. Verma et al., 2007) and post-acute TBI patients (e.g. Fichtenberg, 2002), in some cases persisting and developing a chronic course post-TBI (Worthington & Melia., 2006).

Several mechanisms have been suggested to account for these findings. It has commonly been proposed that insomnia following TBI is the result of organic changes. However, Ouellet and Morin (2006) debated this probability, given that studies of sleep architecture post-TBI have consistently failed to find evidence of organic changes. Instead, they proposed that psychological factors such as anxiety, depression, and disrupted sleep habits probably play an important role in precipitating, exacerbating or perpetuating sleep disturbances after TBI.

Interestingly, when the relationship between demographic factors and prevalence rates was reviewed, the results were ambiguous for demographic and neuropsychological variables. However, there was strong evidence for a positive relationship between psychological and medical symptoms, and increased rates of sleep disturbance. High rates of psychiatric co-morbidity have commonly been reported with insomnia in the general sleep literature (e.g. Kessler et al., 1994). The relationship between sleep and
psychiatric complaints is complex and multifaceted - they may occur concurrently but independently, or they may interact, either one precipitating or perpetuating the other. Furthermore, the course may differ between individuals and/or fluctuate over time within individuals (Buysse et al., 2006).

The findings of this systematic literature review have important clinical and research applications. Clinicians working with patients post-TBI should be aware of the increased risk of sleep disturbance and routinely screen patients using one of the brief validated questionnaires mentioned in this review (PSQI, ISI). It seems likely that, similarly to primary insomnia in the general population, a range of multifaceted intertwined and interacting variables lead to the increased rates of insomnia commonly reported post-TBI. Psychological variables seem to be strongly related to these increased prevalence rates and there is also recent support that psychological interventions can be effectively used to treat insomnia post-TBI. Thus, although further research is needed to assess the day-to-day impact of insomnia post-TBI on functioning and also to investigate further the best treatments, these findings suggest that it is important for patients in rehabilitation settings post-TBI to have access to psychological support so that individualised formulations and bespoke interventions can be developed and sleep disruptions can be minimised before they develop a chronic course.

**Methodological implications**

The studies in the present review proved difficult to compare. Different definitions of sleep and TBI, measurement tools, ways of describing the outcome variables, sample
A number of key considerations should be made in future studies:

- Operational RDC criteria should be used to classify participants with insomnia syndrome to increase standardisation across studies. In epidemiological studies where this might not be practical, screening measures with validated cut-off scores such as the PSQI or ISI should be used. It would also be useful for studies to report the proportion of participants with insomnia symptoms and also individual sleep parameters.

- Appropriate matched control groups should be included where feasible and power calculations should be used to determine necessary sample size.

- Subjective sleep assessment methods should be corroborated by objective methods where practical, or in larger studies, collateral information should be gathered from significant others. (Attempts should also be made to minimise contamination of results that may occur from significant others helping participants provide information). It would also be advisable to use sleep diaries as a prospective subjective method.

- Head injury severity should be defined using validated criteria (for example those described by Ouellet et al., 2006). Where this range of data is not available, initial measures such as GCS or duration of PTA should be used in preference to outcome measures. All injury characteristics should be clearly reported and also considered in statistical analyses.

- A minimum of gender, age, anxiety and depression should be assessed routinely in studies looking at sleep disturbance post-TBI. Assessment methods used to assess
anxiety and depression should have been validated for use in the TBI population and should minimise the impact of co-morbid physical difficulties e.g. the hospital anxiety and depression scale (Zigmond & Snaith, 1983).

Limitations of this review
This review considered only a restricted proportion of all the studies that have commented on sleep post-TBI. Studies that did not use specific sleep behavioural sleep measures were excluded, for example those that used a general checklist of symptoms or studies from child populations. It is likely that these studies reported findings relevant to this review. However, the variability that made comparisons difficult in this review of restricted studies would have been further increased if these studies had been included.

Potential Conflict of Interests
No conflicts of interest were identified. No commercial party has financial interests in the results of the review or will confer a benefit to the author or organisation.
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CHAPTER THREE: MAJOR RESEARCH PROJECT PROPOSAL

Do Sleep Difficulties Exacerbate Deficits on a Sustained Attention Task Following Traumatic Brain Injury?

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Project Summary

Attention difficulties are the most common neuropsychological symptoms reported following traumatic brain injury (TBI). In particular sustained attention has been shown to be vulnerable to both direct and diffuse damage after TBI. The Sustained Attention to Response Test (SART), is a relatively new test of sustained attention that has been shown to have increased discriminative power compared to traditional vigilance and continuous performance tests. It has been shown to be sensitive to severity of TBI and to self-reports of everyday cognitive failures. Attention deficits after TBI have clinical implications because they impact on general cognitive and day-to-day functioning, as well as rehabilitative progress.

Sustained attention has also been shown to be sensitive to sleep deprivation, restriction, and circadian modulation. Research has looked at the effects of restricting sleep in "normal" populations, and the cognitive functioning of people who have diagnosable sleep disorders. The SART has also been shown to be sensitive to circadian modulation in people without a TBI. Sleep disturbances and disorders are common but under-diagnosed after TBI. It seems possible that cotermious sleep disturbances may exacerbate cognitive deficits for a proportion of individuals who have sustained a TBI.

The primary aim of this study is to examine whether cotermious sleep disturbances have an additive negative impact, on top of the negative impact of the brain injury itself, on performance on the SART and a further set of neuropsychological tests that are sensitive to attentional functioning. This has practical implications for the support of the treatment of sleep disorders, to maximise rehabilitative opportunities in people with TBI.
Introduction

Attention difficulties following traumatic brain injury (TBI)

Traumatic brain injury (TBI) affects approximately 279 people per 100,000, with a much higher prevalence for young adults of 1202 per 100,000 (Tennant, 1995). Along with fatigue and decreased arousal, changes in attention are the most commonly observed and reported neuropsychological symptoms associated with brain damage (Lezak, 2004).

Posner & Petersen (1990), have proposed the existence of three main functionally and anatomically distinct attentional control systems: an orienting system that relies upon the posterior brain areas and is involved in the selection of sensory information; an executive system involving the anterior cingulate, lateral prefrontal cortex and the basal ganglia responsible for exercising control over lower-level cognitive functions and resolving conflicts; and an alerting or sustained attention system centred on fronto-parietal regions responsible for achieving and maintaining sensitivity to incoming stimuli (Dockree et al., 2004).

The sequential processing and capacity characteristics of attention can be resistant to brain damage. However, other aspects such as selective, sustained, and divided attention have been found to be sensitive to disruption (Lezak, 2004). Common complaints include increased levels of, absentmindedness, distractibility, mental fatigue, benefits from breaks in activity and overt somnolence (Whyte et al., 1995; Whyte & Rosenthal, 1993; Robertson et al., 1997). The functions of the prefrontal cortex have been found to be particularly vulnerable after TBI as a result of both direct and diffuse damage, and thus
this damage is, in part, responsible for the reported deficits (Garnett et al., 2000; Stuss et al., 1992; Mattson & Levin, 1990).

**Sustained attention after TBI**

The right fronto-parietal cortices are thought to be responsible for the internally generated ‘wake up and pay attention’ functions required to remain vigilant and ‘on-task’ in the context of routine tasks (Whyte et al., 1995). An inability to remain vigilant has serious implications for day-to-day performance. However, despite frequent reports of poor concentration and sustained attention following TBI, studies using traditional vigilance tests generally fail to find disproportionate deficits (see Manly et al., 2003). Traditional vigilance tests require participants to monitor a stream of information for the occurrence of a target item, performance being measured in terms of total error scores or time-on-task proportionate decrements in performance.

Continuous performance tests (CPT) have considered errors of omission (failure to respond to a target when it is presented) and commission (responding when a target is not present), as well as a measure of variability in performance. There is some evidence to suggest that these are sensitive to TBI. For example on the Integrated visual and auditory CPT there is evidence that both auditory and visual sustained attention are impaired after mild TBI (see Tinius, 2003). TBI groups tend to have slower RT, more variability in RT over the course of assessment, and make more errors of impulsivity (Arcia & Gualtieri, 1994). Western & Long (1996), suggested that RT data may provide an additional measure of cognitive function and increase the accuracy of decisions regarding the
presence and extent of brain damage. Studies substantiated RT to be correlated with the severity of injury (Collins & Long, 1996).

Robertson et al (1997), developed a brief computerised measure of sustained attention; The Sustained Attention to response Test (SART). The SART was developed to be more sensitive to transient lapses in attention than traditional vigilance and continuous performance tests. It is designed to measure a person's ability to withhold responses to infrequent and unpredictable stimuli during a period of rapid and rhythmic responding to frequent stimuli. Thus participants have to respond to all stimuli except the target, when they have to withhold their response. The SART was designed to encourage participants to lapse into an automatic 'task-driven' response set which participants had to continuously combat to maintain accuracy. Our ability to maintain a goal directed focus without support from the environment requires the endogenous control of behaviour (Dockree et al., 2004). The error score on no-go trials on the SART is a measure of endogenously maintained attention. Again data on RT, errors of omission and errors of commission are available from this measure.

There is a growing body of evidence to support the SART as a useful and sensitive measure of sustained attention. It has been show to accurately distinguish between TBI patients and controls (Manly et al., 2003; Chan, 2001; Robertson et al., 1997). It is also sensitive to injury severity as measured by the Glasgow Coma Scale (Robertson et al., 1997), and predictive of everyday attention failures and action slips in participants with brain injury and control participants (Manly et al., 1999).
Wilkins et al., (1987), showed that patients with right frontal lesions found it difficult to sustain attention on vigilance tests if intervals between stimuli were increased. They suggested that this was indicative of a deficit in the system that was necessary to "impose attention voluntarily on an uninteresting task". Manly et al., (2003), explored whether manipulating the temporal demands of the standard SART to reduce its continual challenge, placing greater demands on the endogenous system necessary to mediate sustained attention, would enhance its sensitivity to distinguish between TBI patients and controls. They compared the standard random sequence version of the SART with a modified version in which the no-go trials occurred at an entirely predictable point; the SART fixed. Evidence from patient studies has confirmed that the effect size discriminating patients and controls is enhanced for the SART fixed compared to the SART standard (Dockree et al., 2004; Manly et al., 2003). Patient studies have confirmed that lesions of the frontal and parietal lobe, particularly in the right hemisphere, have strong effects on performance on the SART (Sturm & Willmes, 2001; Robertson et al., 1995). The involvement of these anatomical areas has recently been substantiated by PET and fMRI studies and more recent studies have shown that left fronto-parietal areas are also involved (Coull et al., 2001).

Deficits in attentional functioning are of clinical interest because, in combination with reduced processing speed, they can have far-reaching effects on a person's overall cognitive, and day-to-day functioning (Lezak, 2004). The inability to remain vigilant has serious implications for day-to-day performance. This is supported by a growing literature on the role that attentional deficits may play in cognitive rehabilitation (Gummow et al., 1983).
Attention deficits associated with sleep deprivation, restriction, or circadian modulation in participants with 'normal' functioning

Good sleep is an imperative component of a physically and mentally healthy lifestyle. Research has suggested that a primary function of sleep is resultant good quality daytime alertness. It is now widely accepted that the impact of sleep deprivation is broad-ranging. Reduced sleep and increased sleep propensity has been shown to have a negative impact on mood, cognitive performance, and motor function (Pilcher & Huffcutt, 1996).

Early studies focused on total sleep deprivation. However, more recent studies have looked at the effects of partial sleep deprivation. Experiments on healthy adults have demonstrated that limiting daily sleep duration to less than seven hours leads to cumulative deficits in neurocognitive performance and alertness; within one-to-two weeks of sleep restriction, performance deficits on tasks requiring sustained attention, working memory and processing speed reached levels equivalent to those found after one-to-two nights of total sleep loss (Dinges, in press). Interestingly, mood and cognition have been found to be more affected by partial sleep deprivation than total sleep deprivation (Dinges & Weaver, 2003).

Sleep deprivation and circadian effects are not uniformly distributed within the brain (Cajochen et al., 1999). There are indications that the frontal lobes are disproportionately impaired by sleep deprivation (May & Hasher, 1998), and that restricted sleep negatively affects the neurocognitive functions related to these areas. This has been supported by research showing that sleep loss produces a range of fundamental neurocognitive deficits such as reductions in vigilance, working memory and executive function (Harrison &
Horne, 1998, Durmer et al., 2005). Sleep deprivation does not eliminate the ability to perform neurocognitive tasks, rather it makes it difficult to maintain stable performance for more than a few minutes (Dinges & Kribbs, 1991). In general, regardless of the task, cognitive performance becomes progressively worse when time on task is extended; this is the 'classical fatigue effect' that is exacerbated by sleep loss (Wilkinson, 1963).

Measures of attention, vigilance, and declarative memory are often used to assess the impact of sleep deprivation (Durmer et al., 2005). Studies using Continuous Performance Tests (CPT), and Psychomotor Vigilance Tests (PVT) to study vigilance have shown that reaction time variability and errors of both omission (i.e. lapses) and commission (i.e. responding when a stimuli is not present) are typical of sleep deprivation (Dinges & Kribbs, 1991). Supportive evidence for the sensitivity of sustained attention to sleep-wake patterns comes from a study by Kamdar et al., (2004) who showed that extended sleep led to substantial improvements on a sustained attention task.

A recent study by Manly et al., (2002), examined the effects of circadian modulation on the SART in people without a brain injury. In line with self-report data they found significantly higher error rates at 1am and 7am compared to 1pm and 7pm. No circadian modulation of the more routine aspects of the task was observed. This again highlights that sustained attention is particularly sensitive to changes in sleep-wake patterns. It also highlights that the SART is able to pick up fairly subtle changes in functioning within a normal population. Thus, sustained attention has been shown to be sensitive to sleep disturbance as well as to TBI.
The impact of sleep disorders on cognitive functioning

Further evidence that sleep affects cognitive functioning has come from studies looking at the impact of particular sleep disorders. Kamdar et al., (2004), have suggested that sleep disorders represent the largest number of cases of reversible cerebral dysfunction in the population.

Most research exists for the impact of Obstructive Sleep Apnea (OSA) on cognitive functioning. A meta-analysis of cognitive dysfunction in sleep-disordered breathing patients was recently performed (Fulda & Schulz, 2001). Twenty-eight studies met criteria for evaluation and revealed several relevant neurocognitive deficits. Moderate to large effect sizes were noted for performance on sustained attention tasks, delayed visual memory retrieval, and working memory tasks requiring mental flexibility. Although no definitive pattern could be identified due to the broad range of smaller effect sizes over a number of neurocognitive domains, it seems that OSA and sleep-related disordered breathing may cause significant deficits in working memory and executive functions. It is difficult to determine the relative contribution of disturbed sleep versus disordered breathing to these deficits.

Individuals with disorders initiating and maintaining sleep commonly complain of increased difficulty with attention, memory and concentration (Hauri, 1997). In a community based study of participants over sixty years of age short sleep duration (<7 hours per night) or poor sleep quality were found to be significantly associated with lower cognitive function, particularly for tests of attention/concentration and orientation (Ohayon & Vecchierini, 2002). More recently Tworoger et al., (2006), found that women who reported short duration of sleeping (<=5 hours/night) and women who reported
having frequent difficulties sleeping were at increased risk for cognitive impairment. Circadian disruption is often reported to result in a varying sense of sleepiness of which distractibility, attention difficulties, and difficulty mobilising 'mental effort' are common components (Daan, et al., 1984).

Insomnia is the most prevalent sleep problem (Partinen, 1994). Patients with insomnia typically complain of disturbed mood, increased irritability and cognitive problems such as poor concentration, attention and memory. While these complaints are typical, evidence corroborating cognitive deficits in this group has been mixed. For example Bastien et al., (2003), found that self-reported insomnia was associated with concentration and memory problems. However, memory for newly learned information was not found to be impaired in three studies reported by Roth et al., (2001). In the studies reviewed by Roth et al., (2001), there was evidence of poorer digit span and semantic memory but not of divided attention or vigilance. However, in a study by Schneiger et al., (2004), cognitive tests showed decrements in alertness and selective attention in untreated patients with insomnia. Mahmood et al., (2004), report that the literature shows that insomniacs demonstrate neurological deficits on measures of information processing speed, working memory and attention when compared to matched controls who report no sleep complaints. However, Spiegel et al., (1999), objectively measured sleep disturbance using polysomnography (the gold standard) and reported few associations with cognitive function. The mixed use of subjective and objective measures could go some way to explaining some of the inconsistencies in the data. Although self-reported sleep quality is a subjective measure, an individual's perception of their sleep quality is a motivating factor for seeking treatment, and may also be related to other brain functions so the importance of this data should not be discounted.
In conclusion although there are some inconsistencies, there is additional evidence from research into sleep disorders to suggest that sleep quality, quantity, and sleep-wake patterns have an imperative role to play in day-to-day functioning. The inconsistent data also highlights the importance of including both subjective and objective measures of sleep disturbance in research studies.

*Coterminous sleep difficulties following TBI*

Traditionally, post-head injury sleep disturbance has received minimal attention or tended to be attributed to a depressive symptom profile (Kemp et al., 2004). The relationship between sleep, sleepiness and TBI is complex; sleepiness after brain injury may result from a pre-existing sleep disorder or from the effects of the brain injury itself. However, there is no doubt that sleep problems are a common complaint following brain injury (Kemp et al., 2004; Fichtenberg et al., 2000; Clinchot et al., 1998; Richter et al., 1995; Parsons & Ver Beek, 1981).

Research has shown that there is a high prevalence of diagnosable sleep disorders, such as disorders instigating or maintaining sleep and circadian dysfunction after TBI (Castriotta & Lai, 2001; Clinchot et al., 1998). Acquired brain injury is associated with a range of disturbances in arousal and sleep patterns occurring in 30-70% of patients (Ouellet et al., 2004). A prospective study of 50 consecutive post-acute TBI cases, utilizing established self-report sleep assessment methods as well as DSM-IV diagnostic criteria, found that 30% of the patients suffered from insomnia, with sleep initiation being a particular problem. An additional 12% did not meet DSM-IV criteria for insomnia but, nevertheless, experienced reduced sleep quality, as measured by the PSQI (Fichtenberg et al., 2002).
A recent study by Worthington & Melia, (2006), investigated the impact of disorders of arousal and sleep disturbance on everyday living and participation in rehabilitation via naturalistic survey of rehabilitation centres. They found that disturbance of arousal or sleeping was reported in 47% of the sample, with significant adverse effects on the activity evident in two thirds of such cases. Contrary to the generally accepted view they also found evidence that sleep and arousal problems were evident for many years after injury and there was little evidence of diminution over time. The occurrence of sleep disorders appears to be of a magnitude that merits attention from TBI healthcare providers. Currently, sleep disorders are largely under diagnosed and untreated in TBI patients despite findings that abnormal sleep patterns can exacerbate behavioural deficits and increase difficulties with new learning (Zafonte et al., 1996), and that the treatment of sleep disorders usually leads to substantial improvement in daytime functioning in this population (Castriotta & Lai, 2001).

*Impact of sleep disturbances following TBI*

Sleep disturbance can produce substantial cognitive deficits even in people without brain injury, and although there is a dearth of research in this area, evidence suggests that sleep disturbance could significantly exacerbate neuropsychological deficits and be particularly disruptive in individuals following TBI (Mahmood et al., 2004). This idea is supported by evidence of differential deficits as a function of severity of TBI. Cohen et al., (1992) found that the time since injury was inversely related to the severity of cognitive deficits and was also an important factor influencing the nature and severity of sleep complaints. Ron et al (1980) found the time since injury was related to the restoration of normal REM sleep and concomitant improvements in cognitive functioning. However, in contrast to
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this, some studies report that patients with severe brain injuries are less likely than those with mild injuries to report sleep disturbance (Mahmood et al., 2004; Clinchot et al., 1998). These studies used subjective self-report measures of sleep disturbance, so functional deficits may have been an obstacle to accurate self-reporting in subjects with moderate and severe TBI. It has been found that patients with severe TBI have reduced insight into their difficulties and thus, they would be expected to underreport their symptoms compared to patients with less severe injuries (Trudel et al., 1998). This may be an important flaw of these studies, and highlights the importance of the use of objective data to collaborate self-report information.

The present study

Brain injury significantly increases the probability of deficits in specific attentional functions such as sustained attention. There is also evidence that sleep disturbances may impact on attentional functions, particularly sustained attention. Although data on the prevalence of sleep disorders after TBI vary, there is evidence that TBI carries considerable risk for a range of sleep and arousal disturbances (Worthington & Melia, 2006; Fichtenberg et al., 2001). Thus, it seems possible that a percentage of individuals who experience coterminous sleep difficulties following TBI may experience an exacerbated deficit in attentional functioning, on top of that caused by the TBI. To date there are relatively few studies that have investigated this. Studies that have been completed to look at neurocognitive functioning after TBI have often used only subjective measures of sleep disturbance, and may not have utilised the most sensitive neurocognitive measures (e.g. Mahmood et al., 2004; Clinchot et al., 1998). Subjective measures are related to an individual’s perceptions and complaints, and so are useful.
However, their utility with patients after moderate and severe TBI who may struggle to recall this information, or who lack the insight to be aware of their difficulties may be less useful. In these cases objective measures are also necessary to corroborate self-reports.

This study aims to examine whether, after sustaining a TBI, poor sleepers have poorer sustained attention and general attentional functioning, than good sleepers. Poor and good sleep groups will be clearly defined using subjective and objective measures. This study will use the SART which has been shown to be sensitive to severity of TBI and to circadian modulation, and a further set of neuropsychological measures picked for their sensitivity to attentional functioning.

This is of clinical importance because, if attentional functioning was poorer in the PS group it would support the importance of investigating sleep disturbances after TBI and also support investment in strategies to manage sleep disturbances after TBI.

Aims and hypotheses

(i) Aims

This study aims to assess whether, after TBI, poor sleepers have poorer attentional functioning than good sleepers. This will involve using standardised measures of attention and of related cognitive functions including processing speed, and working memory. A measure of everyday cognitive failures will also be used to investigate whether there is evidence for poorer performance in everyday life as well as on formal cognitive tests.
(ii) Hypotheses

The following hypotheses will therefore be tested:

1) The poor sleep group (PS) will have poorer performance on the SART (standard and fixed versions) than the good sleep group (GS); the PS group will make significantly more errors of commission than the GS group; they will make significantly more errors of omission; and they will have a significantly poorer performance measured by their reaction time (RT) data.

2) The PS group will also show impaired cognitive abilities, in the form of poorer attentional functioning, slower information processing speed, and poorer working memory capacity, relative to the GS group.

3) The PS group will obtain higher scores (indicating poorer functioning) on a questionnaire about daily cognitive failures than the GS group.

Plan of Investigation

(i) Participants

Participants will be aged 18 years of age or over and have sustained a TBI (minimum time since injury will be 3 months).

To ensure that the two groups in this study are clearly defined, sleep research diagnostic criteria (Edinger et al., 2004), and screening methods used by researchers at the Sleep Research Laboratory at the Sackler Institute in Glasgow, have been considered when deciding upon criteria for allocation of the PS and GS groups. The screening protocol for allocation to these groups will following three stages: firstly, completion of a brief semi
structured-interview; secondly, completion of a subjective sleep quality questionnaire (the Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989); and thirdly, the collation of sleep diary and Actigraphy data.

The PS group will score >6 on the (PSQI; Buysse et al., 1989). The individual will report the presence of a sleep complaint (i.e. problems with sleep initiation, or maintenance difficulty, and/or poor sleep quality, and/or non-restorative sleep), and daytime impairment that is perceived to be the result of nocturnal sleep symptoms. Actigraphy data will be looked at to support that they are a poor sleeper.

The GS group will be defined as ‘good sleepers’ and not simply ‘without sleep difficulties’. The GS will be defined as scoring five or less on the PSQI. The individual will perceive themselves as a good sleeper and will not have a history of sleep problems. Actigraphy data will be looked at to support that they are a good sleeper.

Exclusion criteria for both groups will include impairments of language, perception or general intellect which are, in the judgement of the clinical team or researcher, likely to make it impossible for the participant to understand the task instructions, or the lack of the motor ability to perform computer tasks. Individuals with active psychiatric symptoms or those who fit the criteria for a primary sleep disorder (e.g. sleep apnea, narcolepsy, restless legs syndrome etc.) will also be excluded. Where the sleep disorder is suspected to be the result of ongoing substance misuse, or if individuals are undergoing active psychological or pharmacological interventions for sleep problems, or if they have
a neurological history (excluding a previous TBI) then they will be excluded from the study.

(i) Recruitment

Participants will be recruited from: the Community Treatment Centre for Brain Injury, with the permission of the Clinical Director, Dr Denyse Kersel; through Momentum, a vocational rehabilitation centre for people with brain injury, with the permission of Kimberley Beckett, Brain Injury Services Manager; through Headway Scotland a voluntary organisation for rehabilitation of people with brain injury, with permission of Pauline Linn, Manager of Headway Scotland; and through the Physically Disabled Rehabilitation Unit (PDRU), at the Southern General Hospital, with permission of Dr Julia Clark and the ward Consultants (letters of agreement to support recruitment are attached). The researcher will provide each of the organisations with sealed research information packs. These will contain a letter of invitation, an information sheet and a reply form. Only participants judged to be able to give informed consent will be invited to participate; the clinical managers/consultants will be asked to identify these potential participants. These research packs will be sent out by the administration staff of each of the organisations with both their consent and the consent of the Clinical Managers.

Participants will be invited to return a form back to the researcher to indicate whether they are interested in participating (in the free post envelop provided). The researcher will contact participants who indicated that they are interested, and arrange a meeting. At the meeting any questions can be addressed; informed consent will be obtained, if participants met inclusion/exclusion criteria, and still want to participate. Participants will
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be informed that they can withdraw from the study at any point. This method has been used successfully in previous studies.

Measures

Initial interview

In order to gather information about participants' sleep, psychological and cognitive profiles the following measures will be utilised:

1) The Morningness-Eveningness Questionnaire-Reduced Form (MEQ; Adan et al, 1991) assesses preference for ‘morningness’ or ‘eveningness’. This measure was chosen as an aid to the classification of any circadian rhythm disorders.

2) The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was chosen to assess current depression and anxiety symptomatology because this measure is less susceptible to somatic complaints than other measures.

3) The Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989) is a self-report questionnaire pertaining to sleep quality and disturbances. It is brief measure that has been shown to discriminate between good and poor sleepers in clinical research (Buyssee et al, 1989). It has also been shown to be a valid and useful screening measure for sleep disturbance in patients with TBI (Fitchenberg et al., 2001).

4) The Insomnia Severity Index (ISI; Morin, 1993), is a brief self-report instrument measuring the patient's perception of his or her insomnia. The ISI targets the subjective symptoms and consequences of insomnia as well as the degree of concerns or distress caused by those difficulties. Its content corresponds in part to the DSM diagnostic criteria of insomnia.
5) The Weschler Test of Adult Reading (WTAR; Wechsler, 2001) is an assessment of pre-morbid intellectual functioning, previous research emphasised the importance of characterising groups for pre-morbid IQ (e.g. Robertson et al., 1997).

6) The Wechsler Abbreviated Scale of Intelligence (WASI; Wechsler, 1999) is a brief reliable measure of verbal, performance and full Scale IQ scores, and will be used to characterise groups in terms of current intellectual functioning.

Sleep diaries and actigraphy
Participants will also be asked to complete daily sleep diaries for a period of one week to give a subjective record of sleep parameters. An objective measure of sleep will also be taken through the use of Actigraphy. Participants will be asked to wear an Actiwatch (Cambridge Neurotechnology) day and night for one week. An Actiwatch is slightly smaller than a wristwatch and records the wearer’s movements. Actigraphy estimates discriminating between sleep and wake states have been found to agree with polysomnigraphically scored sleep, the ‘gold standard’, in approximately 88% of normal subjects (Bender et al., 2003). Actigraphy has the advantage of obtaining data from participants in their natural settings and following their normal routines.

Second interview
At the end of the week participants will return to complete a set of measures to assess their attentional functioning. The measures that will be used are as follows:

1) The SART (standard and fixed versions; Robertson et al., 1997 and Manly et al., 2003) have been chosen to assess sustained attention because research supports
their use with TBI populations (e.g. Robertson et al., 1997 and Manly et al., 2003), and the SART has also been shown to be sensitive to sleep variables (Manly et al., 2002). It has been shown to have better discriminative power and sensitivity than other vigilance and continuous performance tests, and has been used with people with mixed severities of brain injury without causing anxiety or frustration. Thus, it is felt to be sensitive enough to detect differences, if they exist in this study.

2) The Paced auditory serial addition test (PASAT; Gronwall & Wrightson, 1974) is one of the best established measures of attentional deficit following TBI. It has been reported to be sensitive to injury severity and also, to the sometimes subtle processing impairments that can result from TBI (Robertson et al., 1997). Thus, it will be included here as a sensitive measure of general attentional functioning.

3) The Digit symbol substitution and letter-number sequencing tasks from WAIS-III (Wechsler, 1997) will be used to assess processing speed, working memory, and co-ordination. Previous researchers suggest that it is the combination of working memory and speed of information processing which best indicates an individual’s ability to learn new information (Bartlett et al., 2004). The ability to learn new information has been show to be effected by sleep deprivation (Durmer et al., 2005). As is mentioned in the introduction there is mixed evidence to suggest that these measures are sensitive to sleep disturbance (Mahmood et al., 2004; Hauri, 1997)

4) The Cognitive Failures Questionnaire: Self-report (CFQ; Broadbent et al., 1982) is a 25 item checklist that asks people to rate the frequency with which they make everyday cognitive errors. It will be used in this study as a measure of day-to-day
attentional failures; as an indicator of the generalisability of the results to participants real life functioning.

5) Sleepiness before and after testing will also be measured on a visual analogue scale the Stanford Sleepiness Scale.

6) A visual analogue scale may also be used to measure subjective effort before and after testing.

Some of the standard neuropsychological tests may have been administered already as part of routine clinical assessment and in this case data will be obtained from case records. The tests will be administered by the researcher who will be trained to administer the tests.

Design and Procedure

A quasi-experimental between-group design is envisaged with the following groups:

1. Good sleepers, who have sustained a TBI 2. Poor sleepers, who have sustained a TBI

Groups will be examined to determine whether there are significant differences in terms of age, gender, injury severity, time since injury and pre-morbid IQ.

Following recruitment, potential participants will be met at the Community Treatment Centre for Brain Injury in Glasgow, by the researcher. They will be given a brief, written summary of the purpose of the study which would outline what would be required of them if they agreed to participate. Any questions they have regarding the study will be answered. If they consent to take part they will be asked to complete a consent form.
In the initial interview demographic data and sleep data will be gathered. Four standardised questionnaires pertaining to DSM-IV and ICSD-10 criteria for various sleep disorders (previously utilised by sleep researchers from the Sleep Research Laboratory at the Sleep Research Laboratory at the Sackler Institute) will be used to help assess whether participants meet inclusion/exclusion criteria and to facilitate the allocation of participants to groups (MEQ-R, ISI, HADS, PSQI). They will also complete two neuropsychological measures to help characterise participants in the GS and PS groups (WTAR, WASI). Combined, these measures should take no longer than an hour to complete. Participants who do not meet the inclusion criteria or who meet the exclusion criteria will be excluded. If the sleep data obtained from participants suggested that they had poor sleep as the result of a primary sleep disorder then these participants will be offered the opportunity to be referred for further investigations.

Remaining participants will then be allocated an Actiwatch. They will be asked to return in one week, completing a sleep diary following each night of sleep, and wearing the Actiwatch day and night. They will be instructed to wear the Actiwatch continuously on their non-dominant wrist.

At the end of this week participants will be asked to return the Actiwatch and to complete a set of measures designed to pick up subtle differences that may exist between the groups. Two measures of sustained attention (the SART standard and SART fixed) and a set of standard neuropsychological tests, that are sensitive to attentional functioning (PASAT, LNS, DSS) will be completed. A questionnaire of day-to-day
attentional functioning will also be completed (CFQ). Neuropsychological tests will be administered by the researcher according to the standard instructions for administration. This process will take no longer than an hour and a half to complete.

At this point, participants will be fully debriefed as to the purpose of the study and the hypotheses behind it. Participants will then be thanked for their participation and asked to tick a box signalling whether they would like feedback on the results of the study. Allocation of participants will not occur until the all data have been collected and analysed.

At the end of the study a brief summary of the results will be written and sent to each of the participants who signalled that they wanted feedback. Participants will also be asked whether they would like the results of their clinical test data to be passed on to the service from which they were recruited (Community Treatment Centre, Headway or Momentum).

Settings and Equipment
Suitable rooms in the community treatment centre will be used for conducting interviews and testing with participants. A computer will be required for administration and analysis of the SART. The SART software is available from the researchers at the Sleep Research Laboratory at the Sackler Institute. A copy of the other neuropsychological tests and questionnaires will also be required these are available from the department of Psychological Medicine. Actiwatches and software for analysis will be borrowed from the Sleep Research Laboratory at the Sackler Institute.
Power Calculation

A prior study that had looked at the effects of good and poor sleep on the SART after TBI was not identified. However, previous literature has shown that both the ‘SART standard’ and the ‘SART fixed’ can reliably differentiate between the performance of controls and those individuals with TBI. For the ‘SART standard’, effect sizes were around 1.03 for errors of commission, and 0.923 for variability within performance as measured by within subject reaction time data (Robertson et al., 1997). For the ‘SART fixed’, standard effect sizes were around 1.3 for errors of commission (Manly et al., 2003). Although these studies were differentiating between more clearly defined groups, the fact that the effect sizes are so large is encouraging.

More relevantly a previous study showed that the SART is sensitive to circadian modulation in non-brain injured participants (Manly et al., 2002). Using a within subject design, and ten undergraduate participants, medium effect sizes were found for the difference between the proportion of commission errors at 1pm and 1am (+ 0.66) and at 7am and 7pm (+ 0.5).

For this study, with an effect size of 0.7, it is estimated that 21 participants per group will be required to detect significant differences between groups at an alpha level of .05, with a power of 0.8 (one tailed). Given that it is intended to use demographically well-matched samples, differentiated on sleep parameters through both subjective and objective measures, it is expected that this sample size will be sufficient to detect differences if they exist.
Data Analysis

Groups will be examined to determine whether there are significant differences in terms of age, gender, injury severity, time since injury and pre-morbid IQ. In the event that there are between group differences the relationship between the variable and the outcome measures will then be examined. If this relationship is found to be significant then it will be considered as a covariate in analysis.

Analysis will be conducted using the Statistics Package for the Social Sciences for Windows (SPSS for Windows). Initial, descriptive statistics will be produced for the purposes of sample description and group differentiation.

ANOVA will be used to compare whether there is a significant difference between the results of the SART (standard and fixed versions) for the two groups in terms of errors of commission, omission and variability in RT data. ANOVA will also be used to examine whether there is a significant difference between participants scores on the set of neuropsychological tests and on the questionnaires.

Practical Implications

This study has practical implications because, if attentional functioning was poorer in the PS group it would support the importance of investigating sleep disturbances after TBI, and also support investment in strategies to manage sleep disturbances after TBI. Sleep difficulties and their resultant deficits have been shown to be effectively reduced with psychological treatments in both the normal population and in individuals following TBI.
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(see Ouellet & Morin., 2004). Richter et al., (1995), propose that assessment and treatment of sleep disorders among people with TBI improves clinical outcomes and reduces the persistence of cognitive, somatic, and emotional complaints among persons with brain injury. This is substantiated by Castriotta & Lai, (2001), who reported that the treatment of sleep disorders usually leads to substantial improvement in daytime functioning in the TBI population. Thus, sleep interventions could have implications for improving general day-to-day functioning, as well as responsiveness to rehabilitation programmes.

**Timescale**

The proposed start date for this project in June 2006. It is anticipated that data collection will take nine months. Analysis and write up is expected to take two months.

**Ethical Approval**

Ethical approval will be sought from Greater Glasgow Primary Care Trust Ethics Committee.
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CHAPTER FOUR: MAJOR RESEARCH PROJECT PAPER

Sleep Difficulties and Sustained Attention Following Traumatic Brain Injury.

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Prepared in accordance with instructions for contributors to the Journal of the International Neuropsychological Society (appendix 2.1)

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Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology.
ABSTRACT

Difficulties with attention and concentration are commonly reported following traumatic brain injury (TBI). In particular sustained attention has been shown to be vulnerable. Sleep restriction and disturbances have also been shown to affect sustained attention negatively. Sleep disorders are common but under-diagnosed after TBI. Thus, it seems possible that sleep disturbances may exacerbate neuropsychological deficits for a proportion of individuals who have sustained a TBI. The primary aim of this prospective study was to examine whether poor sleepers post-TBI had poorer sustained attention ability than good sleepers post-TBI. Additionally, differences in general attentional functioning were investigated. Retrospective subjective, prospective subjective and objective measures were used to assess participants’ sleep. When general good and poor sleep groups were created based on participants’ global scores on the PSQI there were no differences on either sustained or general attention measures. When sleep groups were conservatively defined with reference to research diagnostic criteria, the poor sleep group performed more poorly than the good sleep group on the SART random; a specific measure of sustained attention. The differences between the conservative groups on the general measures of attention were not significant, although there was a trend for the poor sleepers to perform more poorly. This study suggests that it is important to differentiate between general sleep complaints and clinically significant sleep difficulties, and also supports the need to use sensitive measures that capture specific components of attention.
INTRODUCTION

Traumatic brain injury (TBI) has been reported to affect 279 people per 100,000 in the United Kingdom, with a much higher prevalence for young adults of 1202 per 100,000 (Tennant, 1995). Changes in concentration and attention are commonly reported neuropsychological symptoms associated with brain damage (Lezak, 2004).

Posner & Petersen (1990), proposed the existence of an attention network with three inter-related sub-systems: an orienting system that relies upon the posterior brain areas and is involved in the selection of sensory information; an executive system involving the anterior cingulate, lateral prefrontal cortex and the basal ganglia responsible for detecting signals for focal (conscious) processing; and an alerting or sustained attention system centred on right fronto-parietal regions, responsible for the internally-generated functions required to remain vigilant in order to select high priority visual information for further processing.

Sustained attention after TBI

The prefrontal cortex associated with sustained attention is particularly vulnerable post-TBI. However, studies using traditional vigilance tests have often failed to find disproportionate deficits (see Manly et al., 2003).

Robertson et al (1997), developed a new computerised measure designed to be more sensitive to transient lapses in attention than traditional vigilance and continuous performance tests; the Sustained Attention to Response Test (SART) - random version. It measures a person's ability to withhold responses to infrequent and unpredictable stimuli.
(targets), during a period of rapid and rhythmic responding to frequent stimuli (non-targets). The task encourages participants to lapse into automatic, attentionally undemanding, ‘task-driven’ responding to non-target trials. However, effective sustained attention is required to counter these effects so that the response to infrequent target trials can be withheld. The error of commission score (responding to targets) was found to be a sensitive measure of endogenously-maintained sustained attention. Participants with decreased sustained attention ability also responded more quickly to correct non-target items prior to errors of commission because their response was triggered by the anticipation of the stimuli rather than as a result of an evaluation of its relevance (Robertson et al., 1997).

More recently, Manly et al., (2003), developed a revised version of the SART that placed greater demands on sustained attention by reducing the explicit challenge of the task. In the SART-fixed version the target trials occur at an entirely predictable point. Results showed that this modification further enhanced its sensitivity to distinguish between TBI patients and controls (Dockree et al., 2004; Manly et al., 2003).

There is a growing body of evidence to suggest that both versions of the SART are useful and sensitive measures of sustained attention (Dockree et al., 2004; Manly et al., 1999, Manly et al., 2003; Robertson et al., 1997). However, the results have not been unequivocal (see Whyte et al., 2006).
Attention deficits associated with sleep in healthy adults

Sleep deprivation has been cited as a cause of impaired cognitive performance in otherwise healthy adults (Pilcher & Huffcutt, 1996). There are indications that functioning of the frontal lobes is also disproportionately affected by sleep deprivation and circadian modulation (May & Hasher, 1998).

Studies using Continuous Performance (CPT), and Psychomotor Vigilance Tests (PVT) under sleep-deprived conditions have shown increased reaction time variability, errors of omission (i.e. lapses) and errors of commission (i.e. responding when a stimuli is not present) (Dinges & Kribbs, 1991). In healthy adults, ten consecutive days of sleep restriction (less than eight hours) were shown to produce progressive performance deficits in sustained attention, working memory and processing speed that were equivalent to those found after one-to-two nights of total sleep loss (Van Dongen et al., 2003). Inversely, Kamdar et al., (2004) showed that extended sleep led to substantial improvements on a sustained attention task. A progressive ‘state instability hypothesis’ has been advanced to explain the relationship between sleep deprivation and deficits; when sleep propensity is high enough, subtle and frequent shifts between sleep and wake occur that interrupt cognitive functioning but that are outside of conscious awareness (Durmer & Dinges, 2005).

A recent study by Manly et al., (2002), examined the effects of circadian modulation on the SART in students. They found significantly higher errors of commission at 1am and 7am compared to 1pm and 7pm. No circadian modulation of the more routine aspects of the task were observed. This again highlights that sustained attention is particularly
Sleep disorders, attention and vigilance

Kamdar et al., (2004), reported that sleep disorders represent the largest number of cases of reversible cerebral dysfunction. People with insomnia commonly report cognitive problems such as poor concentration, attention and memory which they perceive as significantly impacting on their daytime functioning and quality of life (Hauri, 1997). However, objective evidence corroborating deficits in this group has been mixed (Bastien et al., 2003; Roth et al., 2001; Schneiger et al., 2004; Spiegel et al., 1999). Methodological variations and different definitions of insomnia are likely to have contributed to inconsistencies. Furthermore, studies have tended to use global measures of cognitive domains rather than measures sensitive to the components of domains most affected by sleep disruption (Versace et al., 2006).

Coterminous sleep difficulties following TBI

There is now growing evidence for the manifestation and persistence of a range of sleep disorders after brain trauma (Castriotta & Lai, 2001). A recent systematic literature review provided evidence of increased prevalence rates of insomnia post-TBI compared to the general population (Bloomfield, chapter 2).

Again there has been inconsistent evidence on the relationship between sleep disturbance and cognitive functioning post-TBI (see Bloomfield, chapter 2). In their review, Ouellet et al., (2004), commented on the indirect evidence to suggest that insomnia may exacerbate cognitive difficulties post-TBI, and on the lack of studies that have assessed
the impact of insomnia on daytime cognitive functioning in TBI patients. In the studies that have assessed the impact of sleep disturbance on cognitive functioning post-TBI, specific tests of sustained attention have not been used (e.g. Mahmood et al., 2004). Furthermore, studies have often only used subjective measures of sleep disturbance; these are related to an individual’s perceptions and so are important. However, patients after moderate and severe TBIs may find it difficult to give accurate retrospective reports. In these cases objective measures could be used to corroborate self-reports.

**The present study**

Frontal lobe functions such as sustained attention are known to be particularly vulnerable post-TBI. There is also evidence that sleep disturbance can increase the probability of deficits in sustained attention. Thus, it seems possible that increased levels of sleep disturbance post-TBI could further exacerbate neuropsychological deficits. The primary aim of this study was to examine whether, poor sleepers (PS) post-TBI had poorer sustained attention ability than good sleepers (GS) post-TBI. The SART random and fixed versions were chosen as the primary measures of sustained attention. Additionally, differences in general attentional functioning between good and poor sleepers who had all sustained a TBI were investigated. The Paced Auditory Serial Attention Test (PASAT), the letter number sequencing (LNS) and digit symbol substitution (DSS) tasks provided additional standardised measures of attention. A self-report measure of everyday cognitive failures was also used (CFQ). Retrospective subjective, prospective subjective and objective measures were used to assess participants’ sleep.
HYPOTHESES

Primary hypothesis:

1) The PS group would make more errors of commission and have faster average reaction times (RT) than the GS group on both versions of the SART (random and fixed versions).

Secondary hypotheses:

2) The PS would have poorer performance than the GS group on additional attentional measures (PASAT, LNS, DSS).

3) The PS group would report more attentional lapses on the CFQ than the GS group.

METHODOLOGY

Ethics and consent

Ethical and Research and Development approval were granted by Greater Glasgow Community and Primary Care Trust, and South Glasgow University Hospitals, NHS Committees (see appendices 4.1 and 4.2 for approval letters). Written informed consent was obtained from all participants (see appendix 4.3).

Participants

Potential participants were identified from a community brain injury service, a vocational rehabilitation centre and via Headway, a charitable organisation for people with head injuries. Letters of invitation to participate and participant information sheets (see appendix 4.4 and 4.5) emphasised that both good and poor sleepers were needed.
To meet inclusion criteria participants had to be 18 years or older, and had to have sustained a TBI at least three months previously. Exclusion criteria included any impairment of language, perception or general intellect which were, in the judgement of the clinical team or researcher, likely to make it impossible to participate. Individuals with active psychiatric symptoms or those who were identified in the interview to fit criteria for a primary sleep disorder such as sleep apnea or narcolepsy were also excluded. If the sleep disorder was suspected to be the result of ongoing substance misuse, if individuals were undergoing active psychological or pharmacological interventions for sleep problems, or if they had a neurological history (excluding a previous TBI) then they were also excluded.

Sample size estimation was conducted prior to commencement of the study to determine how many participants would be required in each of the groups to detect statistically significant differences at a power of 0.8 (one-tailed) with an alpha level set at 0.5.

No prior study that looked at the effects of good and poor sleep on the SART after TBI was identified. However, previous studies showed both versions of the SART could reliably differentiate between control and TBI participants and large effect sizes were reported for differences in errors of commission; $d=1.03$ (Robertson et al., 1997) and $d=1.3$ (Manly et al., 2003). Furthermore, a recent study showed that the SART was sensitive to circadian modulation in non-brain injured participants. Medium effect sizes were found for the difference between the proportion of commission errors at 1pm and 1am (0.66) and at 7am and 7pm (0.5) (Manly et al., 2002). For the present study, with
an effect size $d$ of 0.7, it was estimated that 21 participants per group would be required to detect significant differences between groups if they existed.

**Materials and apparatus**

*Background measures of mood and cognition*

1) The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was used to assess depression and anxiety symptomatology.

2) The Weschler Test of Adult Reading (WTAR; Wechsler, 2001) was used to assess pre-morbid intellectual functioning.

3) The Wechsler Abbreviated Scale of Intelligence (WASI; Wechsler, 1999) was used as a brief measure of verbal, performance and full Scale IQ.

*Sleep measures*

4) The Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989) was used as a self-report measure of global sleep quality. It is brief and has been shown to be a valid screening measure post-TBI (Fitchenberg et al., 2002). Although, it is a continuous measure, a cut off score of 6 has been validated to differentiate between those with and without sleep disturbances (Mahmood et al., 2004).

5) The Insomnia Severity Index (ISI; Morin, 1993) provided a self-report measure of subjective symptoms of insomnia and also quantified scores into four categories to reflect insomnia severity.

6) Sleep diaries were utilised (see appendix 4.6). The strength of these was that they provided a prospective measure of subjective sleep parameters.
7) Actigraphy was used as an objective measure of sleep. The Cambridge Neurotechnology ‘Actiwatch’ system 2000, wrist Actiwatches (Model AW-2) and sleep analysis software (Actiwatch Sleep Analysis v 1.06) were used. Actigraphy has been shown to be a satisfactory objective estimate of sleep particularly in terms of global sleep parameters such as total sleep time (TST) and sleep efficiency (SE; Sadeh & Acebo, 2002).

Measures of attention

8) The Sustained Attention to Response Test- random version (Robertson et al., 1997) was used as a measure of sustained attention. It was programmed in E-prime software for the PC and run on a Toshiba laptop computer.

9) The Sustained Attention to Response Test- fixed sequence version (Manly et al., 2003) was used as a second measure of sustained attention. This version was similar to the version described above. However, the digits were presented in a fixed, repeating ascending order (1,2,3,...9, 1,2,...9). Both versions of the SART were set up and administered as detailed by (Manly et al., 2003).

10) The Paced Auditory Serial Attention Test (Gronwall & Wrightson, 1974) was included as one of the best established, most sensitive measures of attentional deficit following TBI. A CD was played on the Toshiba laptop of the two second inter stimulus interval version of the test.

11) The Digit Symbol Substitution and Letter Number Sequencing tasks from WAIS-III (Wechsler, 1997) were used to assess processing speed, working memory, and co-ordination.
12) The Cognitive Failures Questionnaire (Broadbent et al., 1982) is a 25 item checklist of self-reported attentional failures that was used to assess participants’ perceptions of their sustained attention ability.

**Design and procedure**

A quasi-experimental between-group design was used with participants allocated to GS or PS groups.

Following recruitment and screening by telephone, an initial meeting was held. Demographic and sleep data were gathered via standardised questionnaires (PSQI, MEQ-R, ISI, HADS) and a brief clinical interview that included questions relevant to research diagnostic criteria for insomnia (RDC; Edinger et al., 2004). Participants also completed the WTAR and WASI to help characterise the GS and PS groups.

Participants were allocated an Actiwatch to wear continuously on their non-dominant wrist, for one week. They were also asked to complete a sleep diary following each night of sleep. Written instructions were provided to support the retention of this information (see appendix 4.7).

One week later participants returned their Actiwatch and completed the cognitive measures (SART random, SART fixed, PASAT, LNS, DSST and CFQ). All tests were
administered according to standard instructions. The order of administration of the SART fixed, SART random and PASAT were balanced such that a third of those initially reporting that they were good sleepers and a third of those initially reporting they were poor sleepers were given the SART fixed first, a third were given the SART random first and a third were given the PASAT first.

Allocation of participants to PS or GS groups did not occur until all the data had been collected:

1. Initially general GS and PS groups were categorised on the basis of global reports of sleep quality. The PS group had a current sleep complaint and a global score of 6 or greater on the PSQI (Buysse et al., 1989; Mahmood et al., 2004). The GS group scored five and below on the PSQI and perceived themselves as good sleepers.

2. In order to improve the classification of the independent variable by creating more clearly discriminated groups, participants were subsequently categorised as; GS, PS or neither on the basis of the following criteria developed with reference to RDC criteria (Edinger et al., 2004). PS participants were required to have a global score of six or above on the PSQI, in addition to a score of greater than 14 (clinical range insomnia) on the ISI and to have reported that their sleep complaint had been present for longer than a month, even although they had had adequate opportunity to sleep. They were also required to meet one or more of the following Actigraphy parameters; TST of less than 6.5 hours at least three times a week, a SE score of less than 85% at least three times a week, or a SOL of greater
than 30 minutes at least three times a week. The GS group were required to have a score of less than six on the PSQI, in addition to a score of less than seven (sub-clinical range) on the ISI and not to meet any of the Actigraphy criteria outlined above. A proportion of participants who did not meet either of these groups of criteria were classified as neither good nor poor sleepers.

Participants were then fully debriefed as to the purpose of the study and thanked for their participation. All participants were offered a copy of the Good Sleep Guide (National Medical Advisory Press Committee, 1994), and those who complained of poor sleep were given some general advice based on this guide.

RESULTS

Data analysis

Analysis was conducted using the Statistics Package for the Social Sciences for Windows (SPSS for Windows version 14.0; 2005). Normal distribution was assessed for key parameters using graphical and numerical methods; Shapiro-Wilk tests were applied to statistically test normality. Some of the variables were not normally distributed so Mann-Whitney U and Chi squared tests were used to compare the groups. Spearman’s rho was used to look at correlations. Effect sizes were represented by $r$ for key measures to illustrate the magnitude of differences between groups; .1 representing low effect, .3 representing medium effect, and .5 representing strong effect (Field & Hole, 2003).
The results were examined in three stages: firstly, data for the general GS and PS groups were examined; secondly, objective data were looked at for all participants; and thirdly the data for the conservatively-discriminated GS and PS groups were analysed.

Preliminary analysis: comparison of general GS and PS groups categorised by global sleep quality ratings

Participant Characteristics

Fifty five participants indicated that they would be willing to participate. Of these, five were excluded because they did not meet the inclusion/exclusion criteria (two had neurological histories, one was on sleeping tablets, one had dysarthria and severe motor difficulties, and one had co-morbid psychiatric difficulties) six did not attend. Thus 44 participants were included in total. On the basis of PSQI scores 21 were categorised as good sleepers and 23 as poor sleepers. The demographic characteristics of participants are detailed in table 1. The median age of all the participants was 46 years old (range: 55 years), with a total of 38 males and 6 females. The majority of participants in the sample (n=30, 68%) had sustained a severe TBI. The median time since injury was 71.5 months (range: 482 months). Road traffic accidents (RTA) were the most common mechanism of injury. There were no significant differences between the groups on any of these demographic factors.

Self report measures of sleep and mood

Scores on the PSQI and ISI were compared between groups to provide collateral support for the use of two groups (see table 2). Scores on the HADS were compared to investigate any emotional disorders (see table 2). As expected, the PS group had significantly higher
<table>
<thead>
<tr>
<th>Severe = 13</th>
<th>Moderate = 6</th>
<th>Severe = 17</th>
<th>Moderate = 3</th>
<th>Severe = 30</th>
<th>Moderate = 9</th>
</tr>
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<tbody>
<tr>
<td>MILD = 4</td>
<td></td>
<td>MILD = 1</td>
<td></td>
<td>MILD = 5</td>
<td></td>
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<tr>
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<td>Other = 3</td>
<td>Assault = 0</td>
<td>Other = 1</td>
<td>Assault = 5</td>
<td>Other = 4</td>
</tr>
<tr>
<td>Fall = 4</td>
<td>R.T.A. = 11</td>
<td>Fall = 6</td>
<td>R.T.A. = 14</td>
<td>Fall = 10</td>
<td>R.T.A. = 27</td>
</tr>
<tr>
<td>76 (351)</td>
<td></td>
<td>56 (482)</td>
<td></td>
<td>71.5 (482)</td>
<td></td>
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<tr>
<td>96 (62)</td>
<td></td>
<td>107 (40)</td>
<td></td>
<td>98 (62)</td>
<td></td>
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<tr>
<td>(68)</td>
<td></td>
<td>(57)</td>
<td></td>
<td>(72)</td>
<td></td>
</tr>
<tr>
<td>21 males, 2 females</td>
<td>17 males, 6 females</td>
<td>38 males, 6 females</td>
<td>C3 females</td>
<td>Gender</td>
<td>Age</td>
</tr>
<tr>
<td>44 (51)</td>
<td></td>
<td>48 (55)</td>
<td></td>
<td>46 (55)</td>
<td></td>
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<tr>
<td>Poor Sleep Group (n=21)</td>
<td>Good Sleep Group (n=44)</td>
<td>Whole Sample (N=44)</td>
<td>Variable</td>
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</tr>
</tbody>
</table>

Table 1. Characteristics of whole sample, and general GS and PS groups (median and range are reported where appropriate).
scores on the PSQI and ISI than the GS group (U=0.000, N1=21, N2=23, p<0.0001, two-tailed and U=6.6, N1=21, N2=23, p<0.0001, two-tailed, respectively). The effect sizes, were very large (r=0.86 and r=0.83, respectively). These results supported the differentiation of the two groups. The median score of the PS group on the ISI was 16 which reflected ‘clinical insomnia (moderate severity)’. In line with previous findings of a significant relationship between depression, anxiety and insomnia ratings (Ouellet et al., 2004), the PS group presented with significantly more symptoms of depression and anxiety than the GS group (P =0.001 and p= 0.015, respectively).

Table 2. Scores for self-report mood and sleep measures for the whole sample, and general GS and PS groups (median and range reported where appropriate)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Whole sample (N=44)</th>
<th>Good sleep group (N=21)</th>
<th>Poor sleep group (n=23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSQI</td>
<td>6.5 (20)</td>
<td>3 (5)</td>
<td>11 (14)</td>
</tr>
<tr>
<td>ISI</td>
<td>8.5 (28)</td>
<td>1 (10)</td>
<td>16 (21)</td>
</tr>
<tr>
<td>ISI categories*</td>
<td>1=20 2=9 3=12 4=3</td>
<td>1=20 2=1 3=0 4=0</td>
<td>1=0 2=8 3=12 4=3</td>
</tr>
<tr>
<td>HADS anxiety</td>
<td>6 (17)</td>
<td>4 (13)</td>
<td>7 (16)</td>
</tr>
<tr>
<td>HADS depression</td>
<td>4 (14)</td>
<td>3 (12)</td>
<td>5 (14)</td>
</tr>
</tbody>
</table>

*ISI categories: 1=No clinically significant insomnia (0-7); 2=Sub-threshold insomnia (8-14); 3=Clinical insomnia (moderate; 15-21); 4=Clinical insomnia (severe; 22-28).
Sleep Difficulties and Sustained Attention Following Traumatic Brain Injury

Sleep Diary and Actigraphy data

Sleep diary and Actigraphy data were examined to see whether the general sleep groups split on the basis of PSQI scores were also differentiated by prospective self-report (sleep diary) and objective data (tables 3 and 4 show the data).

On the sleep diary measures the GS group reported a significantly longer average TST than the PS group (U=46, P=0.006 two-tailed) and also had significantly higher SE ratings (U=41, P=0.003, two-tailed). The American Academy of Sleep Medicine suggests that SE is usually lower than 85% in those experiencing insomnia (Chesson et al., 1999). The median in the PS group was lower than this. The GS group had significantly better sleep quality ratings in terms of how enjoyable their sleep was and how well they felt that morning (U=39.5, p=0.005 two-tailed and U=50.5, p=0.019 two-tailed, respectively). The effect sizes for all these variables were either medium or large (Field & Hole, 2003). There were no significant differences seen between the GS and the PS groups on any of the other sleep diary parameters, and the effect sizes for all of these variables were small.

There were no significant differences between the GS and PS groups on any of the Actigraphy sleep parameters (p>0.05) and the effect sizes were all small. Actigraphy data were also utilised to complete non-parametric circadian rhythm analyses (NPCRA). Analyses of L5 (time of onset of lowest five hours of activity) and M10 (time of onset of highest ten hours of activity) confirmed that the phases of lowest and highest activity were similar between the two groups, although there was more variability in the PS group (GS group: median= 00:30am; range 22:00-5:00; PS group: median: 1am; range 14:00-4:00).
Abbreviations: SOL=sleep onset latency; WASO=wake after sleep onset; TST=total sleep time; SE=sleep efficiency; NWASO=number of awakenings after sleep onset.

<table>
<thead>
<tr>
<th>Variable</th>
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<th>Good Sleep Group (N=16)</th>
<th>Poor Sleep Group (N=14)</th>
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</thead>
<tbody>
<tr>
<td>SOL (min)</td>
<td>0.28 (1.97)</td>
<td>0.25 (1.41)</td>
<td>0.35 (2.64)</td>
</tr>
<tr>
<td>TST (min)</td>
<td>4.29 (4.73)</td>
<td>4.42 (4.23)</td>
<td>4.07 (3.71)</td>
</tr>
<tr>
<td>SE (%)</td>
<td>88.15 (4.41)</td>
<td>87.76 (4.74)</td>
<td>88.54 (4.19)</td>
</tr>
<tr>
<td>WASO (min)</td>
<td>10.59 (18.86)</td>
<td>11.45 (17.96)</td>
<td>10.13 (16.73)</td>
</tr>
<tr>
<td>NWASO (no.)</td>
<td>1.39 (3.46)</td>
<td>1.34 (3.40)</td>
<td>1.45 (3.52)</td>
</tr>
</tbody>
</table>

**Table 3.** Sleep diary data for whole sample, and general, CS and PS groups (median and range). Mann-Whitney U value, two-tailed (p) and effect size (r) are reported.

**How physically tense**

<table>
<thead>
<tr>
<th>1</th>
<th>1.5</th>
<th>1.5</th>
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<tbody>
<tr>
<td>0.5</td>
<td>1.3</td>
<td>1.3</td>
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</table>

**How alert felt in the morning**

<table>
<thead>
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<th>1</th>
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<th>2.5</th>
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<tbody>
<tr>
<td>0.5</td>
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**How enjoyable sleep was**

<table>
<thead>
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<th>1</th>
<th>2.5</th>
<th>2.5</th>
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<tbody>
<tr>
<td>0.5</td>
<td>1.3</td>
<td>1.3</td>
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</table>

**How well felt in the morning**

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<tr>
<th>1</th>
<th>2.5</th>
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<tr>
<td>0.5</td>
<td>1.3</td>
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Difficulties and Sustained Attention Following Traumatic Brain Injury

<table>
<thead>
<tr>
<th>Variable</th>
<th>Poor Sleep Group</th>
<th>Good Sleep Group</th>
<th>Whole Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>TST</td>
<td>0.17</td>
<td>0.36</td>
<td>0.12</td>
</tr>
<tr>
<td>SOL</td>
<td>0.05</td>
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<tr>
<td>WASO</td>
<td>0.97</td>
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<td>NWBASO</td>
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<tr>
<td>WSB</td>
<td>2.23</td>
<td>2.23</td>
<td>2.23</td>
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</table>

**Note:** Cohen's d (d) effect size (t) are reported.

**Table 4.** Actiwatch data for whole sample, and general GS and P5 Groups (median and range, Mann-Whitney U value, two-tailed (p)
These results suggested that the sleep groups categorised on the basis of global sleep quality reports were not clearly discriminated as good and poor sleepers. The poor correspondence between the PSQI and Actigraphy sleep measures verified the need to look at the results relevant to the hypotheses separately for these measures. Subsidiary analysis on the basis of more conservatively defined sleep groups (pertaining to diagnostic criteria) was also supported in order to test fully the stated hypotheses.

_results of cognitive assessments_

Initially the research hypotheses were considered in terms of any differences seen between the PS and GS groups defined by global reports of sleep quality (PSQI) (see table 5).

 primary hypothesis

It was predicted, _a priori_, that PS group would have poorer sustained attention than the GS group reflected by more errors of commission and faster reaction times. However, no significant differences were found between the groups on any of the SART variables (p>0.05) and the majority of effect sizes calculated were small or very small (0.021 to 0.213). The mean errors of commission on the SART, random and fixed versions, seen for the whole group in this study (11.7 and 5.95 respectively), were very similar to those reported for the TBI group in the study by Manly et al. (2003; 11.11 and 6.95 respectively).

 secondary hypotheses

It was also predicted that the PS group would have poorer performance on the other attentional measures (PASAT, LNS, DSS) than the GS group. However, no significant
<table>
<thead>
<tr>
<th>Variable</th>
<th>Poor Sleep Group</th>
<th>Mean (SD)</th>
<th>Median (R)</th>
<th>Good Sleep Group</th>
<th>Mean (SD)</th>
<th>Median (R)</th>
<th>Whole Sample</th>
<th>Mean (SD)</th>
<th>Median (R)</th>
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<td>p</td>
<td>w</td>
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<th>Secondary Hypotheses</th>
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<tr>
<td>SART Fixed MRT</td>
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<td>SART Fixed commission</td>
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<tr>
<td>SART Random MRT</td>
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<td>SART Random commission</td>
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**Primary Hypotheses**

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<td>SART Fixed MRT</td>
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<td>SART Random MRT</td>
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<td>SART Random commission</td>
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</table>

Table 5 Scores on attention measures for the whole sample, and General Cognitive and Psychosocial Groups (median and range, mean, and standard deviation (SD)). Mean-Whitney P value, two-tailed (p) and effect size (r) are reported.
differences were seen on any of these measures (p>0.05), and the effect sizes were all small (r=0.0057 to 0.163). The final prediction was that the PS group would report more difficulties on the CFQ than the GS group. Although this prediction was not supported, a medium effect size was seen indicating a trend for the PS group to have higher scores on the CFQ; indicative of more attentional lapses (p>0.05; r=0.313).

**Actiwatches**

*Results of cognitive assessments*

Correlations (Spearman’s rho) between parameters from the Actigraphy data and scores on the attention measures were examined (See appendix 4.8 for the data table).

**Primary hypothesis**

There were no significant correlations between any of the Actiwatch parameters and either, SART errors of commission or MRT, on either the fixed or standard versions. Thus, these results did not support the *a priori* predictions.

**Secondary hypotheses**

There were no significant correlations between Actigraphy parameters and the PASAT. In line with predictions a significant negative correlation was seen between DSS task and Actiwatch SE (rs=-0.383, N=39, p=0.02). However, contrary to the prediction, there was a significant negative correlation between Actiwatch average sleep efficiency and LNS (rs=-0.389, N=41, p=.012. two-tailed). No significant correlations were seen between Actigraphy parameters and scores on the CFQ.
Comparison of conservative GS or PS groups

Finally, participants were classified on the basis of combined subjective and objective data, pertaining to RDC. It was hoped that the creation of two specifically defined groups (better discrimination of the independent variable) would allow for more stringent analyses of the hypotheses.

Participant data

Fifteen participants met criteria for the conservative good sleep (CGS) group and eleven participants met the criteria for the conservative poor sleep (CPS) group. There were no significant differences between these groups on any of the characteristic variables (data are detailed in appendix 4.9). However, the CPS group had significantly higher scores on the HADS- depression scale than the CGS group (U=26, N1=15, N2=11, P=0.003, two-tailed; data for self report measures of sleep and mood are detailed in appendix 4.10). Sleep diary data confirmed that the groups were more clearly discriminated (data are detailed in appendix 4.11). In terms of the average Actigraphy data the observed trends for all parameters supported the differentiation of the groups. However, statistically significant differences were only seen on one of the five parameters; CPS had significantly lower SE than the CGS (U=55.5, N1=15, N2=11, P=0.036). This suggests that the technique adopted in the classification of the conservative groups (i.e. classifying those meeting criteria on 3 or more nights) may be more sensitive to the variability often observed in poor sleepers than averaging data (Actigraphy data are detailed in appendix 4.12).
Results of cognitive assessments

Primary hypothesis

The results of the assessments of attention are detailed in table 6 (below). Consistent with predictions, the CPS group made significantly more errors of commission on the SART random than the CGS group ($U=41.5$, $N_1=15$, $N_2=11$, $P=0.032$, two tailed). The effect size ($r=0.42$) was approaching the large range. Furthermore, the CPS group had significantly faster mean RTs (median: 315.2, 164.60), than the CGS group (median: 416.2). A large effect size was seen for this difference ($r=0.5204$). No significant differences were seen between the CGS and CPS groups on any of the SART fixed variables. However, when effect sizes were examined, similar trends were seen for errors of commission and RT data on the SART-fixed ($r=0.211$and $r=0.3644$, respectively) as on the SART random.

As well as the significant difference between CPS and CGS groups on HADS-depression scores, a significant positive relationship existed between HADS-depression score and SART-random errors of commission ($rs=0.0518$, $N=26$, $p=0.007$, two-tailed). Thus, the possibility that differences between groups could be accounted for by depression was considered. However, further examination of the data revealed there was a correlation between HADS-depression and SART-random errors of commission for the GS group but not for the PS group ($rs=0.589$, $N=15$, $p=0.021$, two-tailed and $rs=0.035$, $N=11$, $P=0.919$, two-tailed). Small and uneven sample sizes, the nature of the relationship between the HADS-depression scores and SART random errors of commission and the
<table>
<thead>
<tr>
<th>Variable</th>
<th>Median (R)</th>
<th>Mean (SD)</th>
<th>p</th>
<th>t</th>
<th>Variable</th>
<th>Median (R)</th>
<th>Mean (SD)</th>
<th>p</th>
<th>t</th>
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</thead>
<tbody>
<tr>
<td>Good sleep Group</td>
<td>7.0 (7)</td>
<td>30.92 (15.4)</td>
<td></td>
<td></td>
<td>Poor sleep Group</td>
<td>7.0 (7)</td>
<td>30.92 (15.4)</td>
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</table>

*Table 6. Scores on cognitive measures for the conservative GS and PS groups (median and range (R), mean, standard deviation (SD)). Mean - Whitney p value, two-tailed (p) and effect size (r) are reported.*

Sleep Difficulties and Sustained Attention Following Traumatic Brain Injury
violation of the assumption of homogeneity of regression meant that Analysis of covariance would not be appropriate.

Secondary hypotheses

No significant differences were seen on any of the additional attention measures. The results for the PASAT were in the predicted direction; the effect size was small ($r=0.06$). The PS group reported making more everyday slips of attention on the CFQ than the GS group, this difference was not significant but a medium effect size was seen ($r=0.406$).

DISCUSSION

The present study was the first prospective study to examine the consequences of sleep disturbance on attentional functioning following TBI using specific measures of sustained attention.

The data were looked at in three stages: firstly, general PS and GS groups were categorised via global reports of sleep quality (PSQI); secondly, the relationships between objective sleep (Actiwatch) parameters and outcome measures were considered; and, thirdly, conservative PS and GS group were discriminated according to those who met criteria for insomnia syndrome or good sleepers.

Whichever criteria were used to split GS and PS, the groups did not differ significantly on any of the characteristic variables.
Sustained attention

It was predicted, *a priori*, that participants who had sustained a TBI and were poor sleepers would make more errors of commission and have faster average correct reaction times than the good sleepers on both versions of the SART, reflecting poorer sustained attention. When the analysis of the general sleep groups was conducted the results did not support this prediction. Similarly, the correlations seen between objective sleep parameters and both versions of the SART did not approach statistical significance. However, when subjective and objective sleep assessment methods were combined, and specific, conservative sleep groups were created, the results from the SART-random did support this prediction. Despite reduced sample sizes, the effect sizes suggested a medium to large difference between the groups. A post-hoc power analysis suggested that the power was 0.6 (two-tailed) with an alpha level of 0.05. Additionally, the results for the SART fixed, though not significant, also suggested a trend towards the predictions - the effect sizes seen here were smaller and a post-hoc power calculation suggested that 70 participants would have been required in each group for a significant effect to have been seen if there was one.

However, the CPS group also had more depression symptoms (HADS) than the CGS group. So the relationship between depression and SART errors of commission was examined. The results suggested that there was a positive relationship between SART errors of commission and depression for the CGS group but not for the CPS. This suggests that it was sleep rather than depression that accounted for the differences between the groups in terms of SART errors of commission. Furthermore, it was noted that while separating the contribution of depression and sleep disturbance was meaningful
from a research perspective, high rates of psychiatric co-morbidity have commonly been reported with insomnia (Kessler et al., 1994) so this differentiation might not reflect the common complex clinical interaction of these conditions. The disorders may occur concurrently but independently, or they may interact, either one precipitating or perpetuating the other. Furthermore, the course may differ between individuals and/or fluctuate over time within individuals (Buysse et al., 2006).

_The value of making conservative sleep classifications based on subjective and objective measures_

There are several reasons why the prediction of poorer sustained attention might not have been upheld until more conservative groups were created. Buysse et al., (2006) emphasised the importance of differentiating between insomnia as a disorder with various sleep/wake symptoms and insomnia as a syndrome, where symptoms meet specific diagnostic criteria. Equally, Edinger et al., (2004) emphasised the importance of using good sleepers rather than just sleepers who were not poor as a control group. It may be that sleep problems have to be of a clinically significant magnitude before they have a significant impact on sustained attention. Thus, better discrimination of the independent variable allowed the impact on the dependant variable to be tested.

Moreover, a lack of correspondence was seen between subjective and objective sleep measures for a proportion of participants in this study. This finding has been reported previously in studies conducted with both non-injured adults and TBI participants (Erman, 2001; Ouellet & Morin, 2006). However, Buysse et al., (2006) emphasised that, despite inevitable discrepancies among subjective and quantitative assessment modalities,
they should be seen as complementary since insomnia symptoms are heterogeneous. A multi-measurement system may be necessary to adequately capture the different components of insomnia.

The use of multi-modal sleep assessment methods post-TBI may be particularly important because there are several methodological issues that must be minimised. For example, there has been debate in the TBI sleep literature about the utility of self report measures in participants who have sustained severe TBIs due to the increased prevalence of awareness and memory difficulties which might make it difficult for them to accurately report any sleep difficulties. Despite broad inclusion criteria, 68% of participants included in this study had sustained a severe TBI. Additionally, although Actiwatches provide useful collateral measures of sleep patterns especially when the patient’s report is in question (Ancoli-Israel et al., 2003), they have been criticised for being less reliable when distinguishing between still wakefulness and sleep (Sadeh & Acebo, 2002). Thus, it may be that GS and PS groups were only adequately differentiated in this study when both subjective and objective methods were combined and methodological limitations were minimised.

The lack of correspondence between sleep complaints and Actigraphy parameters may also have been influenced by inter-individual differences in the propensity to be affected by sleep reduction and disturbance. The ability of people to cope with sleep deprivation and to compensate for deficits is thought to reflect inter-individual differences in their basal sleep needs (Durmer & Dinges, 2005).
General attentional functioning

The second prediction made was that the PS would show poorer performance on other attentional measures (PASAT, LNS, DSS) than the GS group. Whether GS and PS groups were split according general or conservative sleep definitions, these predictions were not supported. Similarly, when the relationships between objective parameters and attention measures were investigated, the predictions not supported. This supports the use of measures sensitive to the sub-systems of attention that are vulnerable to sleep.

Everyday slips of attention

The third prediction was that the PS group would report more everyday lapses of attention on the CFQ than the GS group. When general sleep groups were investigated, higher scores (indicative of increased attention lapses) were seen in the PS compared with the GS group. Although the difference between the groups was not significant, medium effect sizes supported the trend. This effect was strengthened when groups were stringently differentiated but still did not reach statistical significance. Robertson et al., (1997) found that significant others’ reports on the CFQ correlated with SART errors but that individuals’ own reports did not- relevant to this study reduced insight and memory difficulties in severe TBI participants may have reduced the utility of this retrospective self-report measure. It would have been better to also include the rating of a significant other.

Limitations

Around 300 invitations to participate were sent out of these 55 potential participants replied but only 44 attended and were suitable for inclusion in the study. Thus, the
relatively low response rate may limit the ability to generalise from the findings of this study. Responders may have been more likely to have either sleep or attention difficulties or both.

Additionally, although the sample size was consistent with that required for statistical power when general sleep groups were categorised, a sample size estimation was not calculated for the more conservative classification. Thus, a larger sample size may have been necessary to detect a significant effect on all attention measures in this condition.

The use of sleep diaries as a prospective record of sleep over the assessment week was a strength of this study. However, low return rates of diaries and the fact that the version used did not include a validity check (to ascertain that data had been filled in on the correct day) were limitations of this tool. It might be better to phone participants for daily ratings or ask them to text or e-mail rating to increase the validity of data. In the present study participants whose diary data did not confirm them to be a GS or PS could have been excluded from the analysis to further increase the strength of the independent variable. This could be considered in future studies with larger sample sizes. Future studies might also consider including PSG as an alternative/ additional objective sleep measure post-TBI. Including the report of a significant other would also provide good collateral information on both sleep measures and the CFQ.

A further limitation of this study was that time of testing was not controlled for between groups. Sustained attention performance has been shown to be affected by circadian modulation. Thus, it may have been useful to test all participants at a similar stage in their
circadian cycle. Further research is needed to investigate the differential impact of circadian factors on cognitive functioning.

Further research

Prior to this study, no studies had used the SART to measure the impact of insomnia on cognition in uninjured participants. Results from studies using traditional vigilance, continuous performance, attention and memory measures have been inconsistent. The results of this study have suggested that the SART may be a new sensitive measure able to substantiate subjective complaints in uninjured individuals with primary insomnia. The identification of performance measures sensitive to the effects of insomnia has been emphasised as a high research priority (Buysse et al., 2006).

Further research comparing the sensitivity of different versions of the SART to these types of subtle differences would also be useful. Further research considering the utility and correspondence of subjective measures with participants with severe TBIs is also necessary, as is research differentiating between different types of insomnia disorders seen after TBI (specifically primary or comorbid insomnia and circadian rhythm disorders) as these may have different impacts on neuropsychological performance.

Conclusions and clinical implications

There was some evidence from this study that clinically significant levels of sleep disturbance post-TBI negatively impacted on sustained attention functioning. The findings supported the use of the SART random as a sensitive measure of endogenously maintained sustained attention. A medium strength trend was seen for PS group to report
more daytime lapses of attention than GS group on the CFQ, although, gathering collateral information from significant others may have improved the strength of information for this measure. Future research is needed to replicate these results with a larger sample size and to confirm whether or not these results can be generalised to the wider TBI population. In association with evidence of increased prevalence rates of insomnia post-TBI (Bloomfield, Ch 2) and evidence that insomnia can be successfully treated post-TBI (Zafonte et al., 1996), these findings suggest that clinicians working with TBI survivors should be vigilant to the occurrence, assessment and treatment of sleep difficulties.
REFERENCES


CHAPTER FIVE: SINGLE CASE RESEARCH DESIGN PROPOSAL

(Abstract only)

Visual Rehearsal and Motor Imagery - Adjunctive Interventions Used With an Older Adult after Trans-tibial Amputation: A Single Case Study

Imogen L. M. Bloomfield*, Jonathan J. Evans and Colin Espie

Prepared in accordance with course guidelines

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Running Title: VMRI in an older adult post trans-tibial amputation

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology.
ABSTRACT

**Background:** After amputation patients have to learn several new motor skills in order to be able to mobilise successfully with a prosthetic limb. While many people make good progress, it is reported that older adults, especially those with vascular risk factors, make slower progress and have poorer functional outcomes. However, despite this common finding, there is limited evidence for the types of strategies that might improve learning and retention of new motor tasks in these patients. Motor imagery has been used successfully in athletes, healthy older adults and with stroke and dementia patients. The benefit of motor imagery is that it is less tiring than repeated physical practice and it can be used when physical practice is not possible. It is also time effective and financially viable.

**Design and hypotheses:** This proposal outlines the use of a multiple baseline single-case experimental design to examine the effectiveness of an intervention, referred to here as visual rehearsal coupled with motor imagery (VRMI), in improving the performance of an older adult on two novel motor tasks post trans-tibial amputation. The VRMI intervention will involve supplementing routine physiotherapy training of two novel motor tasks with visual rehearsal (watching a video sequence of steps involved in the motor task) and motor imagery; the participant will be instructed to imagine the kinaesthetic experience of performing the task whilst watching the video. It is hypothesised that performance will significantly improve when VRMI is used as an adjunct to physiotherapy versus physiotherapy as usual.
Data Analysis: It is proposed that the effectiveness of VMRI will be evaluated via visual inspection and inferential statistics using short time series analysis: C statistic. The C statistic postulates the randomisation of data and has two advantages over other interrupted time-series analysis and randomisation test techniques. Firstly it is suitable for analysing smaller numbers of observations per phase, and secondly it can account for the occurrence or non-occurrence of a baseline trend.
APPENDICES
Appendix 1.1: Power point presentation

An Investigation into General Practice Referrals To The Riverside Locality Direct Access Clinical Psychology Department, in the West of Glasgow.

**BACKGROUND**

Lucas, Scammeil & Hagelskamp (2005)
- Overall prevalence of mental health problems in the UK: 23%.
- Prevalence in the population that visit a GP each year: 75%.
- GPs play a vital role in the detection, management and treatment of psychological problems (Ross & Hardy, 1999).
- They comprise the most frequent referral pathway to adult psychology services (Telford Murphy & Wright, 1996).
- Their referral behaviour has a consequential effect shaping psychological treatment services (Rass & Hardy, 1999).
- Therefore, an imperative service-related issue is GPs referral practice (O'Donnell, 2000).

Variation in referral rates between general practices and individual GPs has long been the focus of policy makers (Wilkin & Smith, 1989; Coulter, 1998).
- A number of practice, GP and patient factors have been proposed to influence referral rates:
  - Availability of specialist services (O'Donnell, 2000).
  - Single handed versus multi-practitioner practices (Rogers & Curtis, 2004).
  - GP's perceptions of their capacity to treat psychological problems, the benefits of clinical psychology services and the availability and accessibility of specialist services (Siegel & Leiper, 2005; Chadd & Svanberg, 1994).
  - Higher prevalence of psychological in individuals living in more deprived areas (Jenkins et al., 1998).

Audit Setting: Riverside locality of a direct access clinical psychology department in the West of Glasgow.
- GPs are the principal referral source.
- 25 general practices comprise the two locality LHCCs.
- Referrals accepted based on clients' postcodes not GP postcodes.
- It is estimated that there is much variability in the frequency of referrals.
- Priority for the service was to map current service demand and access by GPs and to help increase understanding of GP referrals.
- This had implications for equity of access to services and service development.

**AUDIT QUESTIONS**

1. a) How many referrals from general practitioners were received by the Riverside locality direct access clinical psychology department in 2004, and were these referrals from locality LHCC Practices?
   - b) How many Practices accounted for 50% and 75% of referrals, and what were the associated Practice characteristics (single handed or multi-practitioner and primary care CPN support available or not)?
2. How did referral rates across general practices in the Riverside locality vary compared with the overall median referral rate?
3. What were the overall referral characteristics (age, gender, deprivation scores and presenting problem)?
4. What differences are there in referral characteristics between locality based practices referring above and below the median referral rate?

**METHODOLOGY**

All referral data from general practices, accepted by the Riverside locality clinical psychology direct access service, over a one-year period (1st of January to the 31st of December 2004) (N= 480) were retrospectively included in this study.
- Data collection consisted of two sections; referral data and general practice data.
- Referral characteristics: gender, age, Carstairs deprivation category, primary and secondary referral problems.
- Practice characteristics: members of the locality LHCCs, single handed or multi-practitioner, primary care CPN support available or not.
RESULTS

- 480 referrals received from 51 general practices
- 23 practices were members of the two locality LHCs
- Locality practices accounted for 397 referrals (83.5%)
- There was a high degree of variation in the number of referrals by individual practices.
  - Seven practices accounted for 51.4% (n=247) of referrals, of these six were locality practices.
  - Fourteen practices accounted for 75.3% (n=362) of referrals, of these 12 were locality practices.

Neither primary care CPN support nor single handed practice data accounted for the variation.

• The referral rates for locality practices were also calculated.
  - The median referral rate was 1.285 (range: 1.86 - 3.205).
  - Twelve practices with 37 GPs referring had a referral rate equal to or higher than the median.
  - Eleven practices with 28 GPs referring had a referral rate lower than the median.

RESULTS

- 55.4% of all GP referrals were female and 44.6% were male.
- The median age of referrals was 35 years (mean age was 36.1).
- Carstairs deprivation categories 1 = most affluent - 7 = most deprived.

The referral reasons most frequently used in GP referrals were the general categories of anxiety (n=143, 29.8%) and depression/lowl mood (n=143, 29.8%).
- When more specific categories were described the most frequent primary problems were stress/coping difficulties (n=23, 4.8%) and panic (n=20, 4.2%).
- There were no obvious differences in these referral characteristics between groups of practices that referred higher and lower than the median referral rate.

DISCUSSION

- The majority of referrals came from practices within the Riverside locality.
- There is a wide variation of referral rates.
- Not explained by the presence of primary care CPN support nor by the practice being single handed.
- More referrals were received for female than males.
- The age profile was also skewed for the outward remit of the service (18-65) with a median age of 35 years.
- Overall referrals were distributed across deprivation categories 2-6.
- Broad referral categories of anxiety and depression/lowl mood were utilized most frequently by referring GPs.
- No differences in terms of sociodemographic and primary referral problems were observed between the two groups of practices accounting for <50% and >50% of referrals.

IMPLICATIONS

- Referral data may help to ensure that future service delivery, allocation of resources and staff training takes account of and meets the needs of general practice referrals.
- Data has implications if an ostensibly planned a separate primary care mental health team with psychological input is set up.
- More immediately these data could have implications for setting up waiting list initiatives.
- Directing services at common referral problems in frequently referring locality practices.
  - E.g. ensuring that self-help materials, and/or groups were available.
  - Aim is reduce the time from referral until initial contact.
LIMITATIONS

- The audit was retrospective and data on primary problems came from judgements made by the department secretaries on the basis of the content of referral letters.
- Number of referrals looked at in this study were relatively small and data was only collected for a one year period.
- What can referral rates tell us about the appropriateness of referrals?
- Difficulties in terms of gathering data on locality areas and services.

FUTURE DIRECTIONS

- Looking at the appropriateness of referrals in an area for future audit.
- Possible changes in the data gathered on the departmental database.
- Dissemination of information.
- The use of data to stimulate dialogue and joint working between clinical psychology services, GPs and other specialists (e.g. CPNs).

REFERENCES


The Journal of the International Neuropsychological Society welcomes original contributions in all areas of neuropsychology, including but not limited to: development of cognitive processes, brain-behavior relationships, adult and pediatric neurodevelopmental and neurodegenerative disorders, and the use of functional brain imaging techniques. Authors are encouraged to review the Instructions for Contributors (see http://www.ncbi.nlm.nih.gov/ijns/about.html) for further details.

Prevalence of Insomnia Following Traumatic Brain Injury

Appendix 2.1 Instructions for contributors – Journal of the International Neuropsychological Society

Aims and Scope:
The Journal of the International Neuropsychological Society (JINS) is the official journal of the International Neuropsychological Society. It publishes original contributions in all areas of neuropsychology, including but not limited to: development of cognitive processes, brain-behavior relationships, adult and pediatric neurodevelopmental and neurodegenerative disorders, and the use of functional brain imaging techniques. Authors are encouraged to review the Instructions for Contributors (see http://www.ncbi.nlm.nih.gov/ijns/about.html) for further details.

Instructions for Contributors

1) Manuscript Preparation and Style

The entire manuscript should be typed double-spaced throughout using word processing software. Manuscripts should be formatted in CMYK and not in RGB, because 4-color separation cannot be done in RGB. However, the extra cost of printing these figures must be paid by the author, and the cost typically ranges from $750 to $1500 per figure. Figures and tables should be numbered in Arabic numerals. The approximate position of each table and figure should be provided in the manuscript (S1, S2, etc.). Figures and tables should be on separate pages. Figure captions and table legends should be self-contained and appear below the figure or table.

References

References should be in the style of the American Psychological Association, 5th edition. For example: Cohen et al. (1997) demonstrated... "References cited in the text should not include authors' names. References should be twice the intended final size and should be submitted in a single column of a two-column format. Color figures can be accepted. All color graphics must be formatted in CMYK and not in RGB, because 4-color separation cannot be done in RGB. However, the extra cost of printing these figures must be paid by the author, and the cost typically ranges from $750 to $1500 per figure. Figures and tables should be in a single column format. The approximate position of each table and figure should be provided in the manuscript (S1, S2, etc.). Figures and tables should be on separate pages. Figure captions and table legends should be self-contained and appear below the figure or table.
## Appendix 2.2: Quality Rating Criteria

<table>
<thead>
<tr>
<th>Study quality criteria</th>
<th>0=inadequate</th>
<th>1=adequate</th>
<th>2=well</th>
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<tbody>
<tr>
<td><strong>Sampling</strong></td>
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</tr>
<tr>
<td>1. Source of TBI participants?</td>
<td>Not stated</td>
<td>Inpatient or outpatient population</td>
<td>Population based e.g everyone who presented to A and E</td>
</tr>
<tr>
<td>2. Method of recruitment?</td>
<td>Not stated, convenience</td>
<td>Mixture of consecutive and convenience</td>
<td>Consecutive referrals or probability sampling</td>
</tr>
<tr>
<td>3. Sample size adequate?</td>
<td>Power not conducted/ reported</td>
<td>Power stated but not achieved or large sample size would have met power</td>
<td>Power stated and achieved</td>
</tr>
<tr>
<td>4. Inclusion and exclusion criteria clearly stated?</td>
<td>No/ not reported</td>
<td>Partly</td>
<td>Yes – both inclusion and exclusion</td>
</tr>
<tr>
<td>5. Control group included?</td>
<td>Not reported</td>
<td>Yes but not matched</td>
<td>Matched control group</td>
</tr>
<tr>
<td>6. Demographic factors considered?</td>
<td>No/ not reported</td>
<td>Yes – two out of three</td>
<td>Yes- minimum of 3 of gender, age, education</td>
</tr>
<tr>
<td>7. Psychiatric screen completed?</td>
<td>No/ not reported</td>
<td>Yes - assessed</td>
<td>Yes- minimum of depression and anxiety assessed and reported</td>
</tr>
<tr>
<td>8. Other possible confounding factors considered?</td>
<td>Not considered/ reported</td>
<td>Considered/reported</td>
<td>Excluded or considered in statistical analysis at least one of: current use of medication that can affect sleep, substance use, pre-morbid neurological conditions.</td>
</tr>
<tr>
<td>9. Data on non-responders reported?</td>
<td>Not reported</td>
<td>Number/ % reported but comparability with responders or target population not reported.</td>
<td>Assessed for any differences between responders and non-responders.</td>
</tr>
<tr>
<td><strong>Assessment – sleep difficulty</strong></td>
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<tr>
<td>10. Definition of poor sleep?</td>
<td>Report only individual sleep complaints or general sleep complaints (insomnia and hypersomnia).</td>
<td>Partly e.g. definition of insomnia partly fulfilling criteria or cut off from a questionnaire validated against criteria.</td>
<td>Used validated criteria e.g. RDC/DSM/ICSD/ICD</td>
</tr>
<tr>
<td>11. Method of assessing sleep</td>
<td>Not reported/ unpublished questionnaire/ retrospective file review</td>
<td>Validated subjective methods (e.g. standardised sleep questionnaire/ clinical interview) or objective method (e.g. PSG, actiwatch, standardised observer rating).</td>
<td>Subjective and objective methods</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>12. History of sleep disturbance prior to TBI considered?</td>
<td>Not considered</td>
<td>Considered</td>
<td>Assessed and reported</td>
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</table>

### Assessment - Head Injury

<table>
<thead>
<tr>
<th>13. Severity of injury characteristics of the sample?</th>
<th>Not stated</th>
<th>Partly e.g. mixed categories</th>
<th>Clearly reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>14. Head Injury severity measurement?</td>
<td>Not stated or other method</td>
<td>One or two of PTA, GCS, LOC or validated outcome measures GAF, FIM, RLA etc.</td>
<td>All three of; PTA initial GCS score, duration of LOC.</td>
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<tr>
<td>15. Impact of injury severity on sleep complaint considered?</td>
<td>Not considered</td>
<td>Reported</td>
<td>Homogeneous sample or considered in statistical analysis.</td>
</tr>
<tr>
<td>16. Impact of time since injury considered?</td>
<td>Not reported</td>
<td>Reported time since injury</td>
<td>Yes considered in statistical analysis or time frame specified in inclusion criteria.</td>
</tr>
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</table>

Total out of 32

Total (%) 100%

Quality Rating 157
## Appendix 2.3: Quality Rating Table

<table>
<thead>
<tr>
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<td>3. Sample size</td>
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<td>12. Hx sleep</td>
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<td>14. HIS measure</td>
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<td>16. Impact time</td>
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<td>25/32</td>
<td>25/32</td>
<td>21/32</td>
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<td>22/32</td>
<td>16/32</td>
<td>16/32</td>
<td>14/32</td>
<td>16/32</td>
</tr>
<tr>
<td>%</td>
<td>62.5%</td>
<td>78.1%</td>
<td>78.1%</td>
<td>65.6%</td>
<td>31.3%</td>
<td>62.5%</td>
<td>68.7%</td>
<td>50%</td>
<td>50%</td>
<td>43.8%</td>
<td>50%</td>
</tr>
</tbody>
</table>

* specified in earlier paper (Finchtenberg et al., 2001)
Appendix 2.4: Article selection flow chart

407 Titles and abstracts obtained using search strategy

366 = not relevant at all.
Excluded by title and abstract

41 = appeared relevant and full text obtained

Further 35 papers excluded
6 papers that met the inclusion criteria

Reference list search highlighted another 41 potential papers for which abstracts were obtained.

- 229 pertained to other neurological, psychiatric or medical conditions, or were drug or treatment studies.
- 76 case studies or animal studies, book reviews or abstracts.
- 40 focused on other sleep disorders or were relevant had TBI samples but no consideration of sleep
- 21 used paediatric populations

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Appendix 4.1: Ethics Approval Letters

Greater Glasgow Primary Care NHS Trust

Greater Glasgow

Ms Imogen Bloomfield
Trainee Clinical Psychologist
University of Glasgow
Academic Centre
Gartnavel Royal Hospital
1055, Great Western Road, Glasgow
G12 0XH

Date 09 June 2006
Your Ref
Our Ref
Direct line 0141 211 3824
Fax 0141 211 3814
E-mail anne.mcmahon@gartnavel.
        glacom en.scot.nhs.uk

Dear Ms Bloomfield

Full title of study: Do sleep difficulties exacerbate deficits on a sustained attention task following traumatic brain injury?

REC reference number: 06/S0701/66

The Research Ethics Committee reviewed the above application at the meeting held on 08 June 2006.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation. **However, data to be kept for 5 years.**

Ethical review of research sites

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

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application</td>
<td></td>
<td>19 May 2006</td>
</tr>
<tr>
<td>Investigator CV</td>
<td></td>
<td>19 May 2006</td>
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</tbody>
</table>
Protocol | 19 May 2006
---|---
Covering Letter | 19 May 2006
Letter from Sponsor | 19 May 2006
Questionnaire | 19 May 2006
Letter of invitation to participant | 19 May 2006
GP/Consultant Information Sheets | 19 May 2006
Participant Information Sheet | 19 May 2006
Participant Consent Form | 19 May 2006
Letter from Physically Disabled Rehab Unit | 19 May 2006
Letter from Headway | 19 May 2006
Letter Centre for Brain Injury | 19 May 2006
Supervisor CV | 19 May 2006

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

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.

06/S0701/66 Please quote this number on all correspondence

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

Yours sincerely

A W McMahon
Research Ethics Co-ordinator (Manager) on behalf of Dr Paul Fleming, Chair

Email: Anne.McMahon@gartnavel.glaomen.scot.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

Standard approval conditions

Site approval form (SF1)

Copy to: NHS Greater Glasgow Primary Care Division R&D Directorate
Gartnavel Royal Hospital
1055 Great Western Road, Glasgow
G12 0YA
NHS Greater Glasgow Primary Care Division (Community & Mental Health)

LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For Issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

<table>
<thead>
<tr>
<th>REC reference number:</th>
<th>06/S0701/65</th>
<th>Issue number:</th>
<th>1</th>
<th>Date of issue:</th>
<th>09 June 2006</th>
</tr>
</thead>
</table>

Chief Investigator:  
Ms Imogen Bloomfield

Full title of study:  
Do sleep difficulties exacerbate deficits on a sustained attention task following traumatic brain injury?

This study was given a favourable ethical opinion by NHS Greater Glasgow Primary Care Division (Community & Mental Health) on 08 June 2006. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Post</th>
<th>Research site</th>
<th>Site assessor</th>
<th>Date of favourable opinion for this site</th>
<th>Notes (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Imogen Bloomfield</td>
<td>Trainee Clinical Psychologist</td>
<td>NHS Greater Glasgow/Primary Care Division In-patient mental health, ward 4 (Leverndal Hospital), and community mental health team, Stewart Centre</td>
<td>NHS Greater Glasgow Primary Care Division (Community &amp; Mental Health)</td>
<td>09/06/2006</td>
<td></td>
</tr>
</tbody>
</table>

Approved by the Chair on behalf of the REC:

13/10/2006 Telephone conversation with Liz Jamieson re: Research Site not exposed site assessor Secan is not incorrect also said that outcome from N C.T.C for brain injury was unknown/unknown in the community was fine. No further action/medical letter etc is necessary.

Jane Bloomfield

(Signature of Chair/Administrator)
Dear Ms Bloomfield

Full title of study: Do sleep difficulties exacerbate deficits on a sustained attention task following traumatic brain injury

REC reference number 06/S0701/66

Reference your application for Site Specific Approval at the Southern General Hospital for the above noted study, this letter will formally confirm that this has been give. I had previously given you a verbal confirmation.

Yours faithfully

Winifred McCartney
Research Ethics Administrative Assistant
Appendix 4.2: Research and Development Approval Letters

Primary Care Division

Ms Imogen Bloomfield
Trainee Clinical Psychologist
University of Glasgow
Academic Centre
Gartnavel Royal Hospital
1055 Great Western Road, Glasgow
G12 0XH

Date 28 September 2006
Your Ref
Our Ref BR/AW/approve
Direct Line 0141 211 3661
Fax 0141 211 3814
Email annottc.walt@garnavcl.glaclin.scot.nhs.uk

Dear Ms Bloomfield

Project Reference Number: PN06CP012
Project Title: Do Sleep Difficulties Exacerbate Deficits on a Sustained Attention Task Following Traumatic Brain Injury?

Thank you for completing the Research & Development (R&D) Management Approval Application for the above study. I am pleased to inform you that R&D management approval has been granted by Greater Glasgow Primary Care Division subject to the following requirements:

• You should notify me of any changes to the original submission and send regular, brief, interim reports including recruitment numbers where applicable. You must also notify me of any changes to the original research staff and send CVs of any new researchers.

• Your research must be conducted in accordance with the National Research Governance standards. (see CSO website: www.show.scot.nhs.uk/csog)

Local Research Governance monitoring requirements are presently being developed. This may involve audit of your research at some time in the future.

• You must comply with any regulations regarding data handling (Data Protection Act).

• Brief details of your study will be entered on the National Research Register (NRR). You will be notified prior to the next submission date and asked to check the details being submitted.

• A final report, with an abstract which can be disseminated widely within the NHS, should be submitted when the project has been completed.

Do not hesitate to contact the R & D office if you need any assistance.

Thank you again for your co-operation.

Yours sincerely

Brian Rae
Research Manager

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Dear Ms Bloomfield,

Title: Do sleep difficulties exacerbate deficits on a sustained attention task following traumatic brain injury?

The above postgraduate project has undergone registration with the R&D Office and I am satisfied that all necessary arrangements have been set in place. Therefore on behalf of South Glasgow University Hospital, Division of Greater Glasgow and Clyde Health Board I am writing to confirm approval is given, to allow the project to commence.

Please advise R&D office of any changes i.e. to the protocol, recruitment numbers, and staff. I wish you every success with your study.

Yours sincerely,

[Signature]

Mrs. Sonia Whyte
Research & Development Co-ordinator

CC: Brian Rae R&D Manager PC GGHB
Appendix 4.3: Consent Form

CONSENT FORM

Project Title: ‘After sustaining a brain injury, do people with sleep difficulties have poorer attention that people without sleep difficulties?’

Name of Researcher: Ms Imogen Bloomfield

Please initial box

- I confirm that I have read and understand the Participant Information Sheet Dated ________(version____) for the above study, and have had sufficient opportunity to ask questions.

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

- I agree to take part in the above study.

- I agree to the researchers informing my GP of my participation

- I agree to my records being accessed by the research team only for the purpose of collecting information on my head injury and for any results of neuropsychological tests that have been done previously.

- I agree to the results from this study being passed on to the relevant healthcare professionals currently treating me in relation to my brain injury

Participant Name..............................................................................

Signature...........................................................................................

Date ...................................................................................................

Researcher .......................................................................................
Appendix 4.4: Participant Invitation

NHS
Greater Glasgow and Clyde

Participant Invitation

"After sustaining a brain injury, do people with sleep difficulties have poorer attention and concentration than people without sleep difficulties?"

We are conducting a study looking at the impact of sleep on attention and concentration after head injury. We are inviting both good and poor sleepers who have sustained a head injury to take part in this study. So whether you are someone who finds it hard to get a good nights sleep or someone who finds it easy to sleep, if you would like to find out more about the study please read the information sheet included. If you think you might like to take part please complete the returns form and send it in the freepost envelope provided.

Thank you for your time.

Yours sincerely

Imogen Bloomfield
Trainee Clinical Psychologist, Principle Researcher.
University of Glasgow

Professor Jonathan Evans
Professor of Applied Neuropsychology
University of Glasgow

Professor Colin Espie
Professor of Clinical Psychology
University of Glasgow.
Appendix 4.5: Participant Information Sheet

Participant Information Sheet

Study: ‘After sustaining a brain injury, do people with sleep difficulties have poorer attention and concentration that people without sleep difficulties?’

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask the research investigator if there is anything that is not clear, or if you would like further information. Take time to decide whether or not you wish to take part.

Some background information
Problems with attention and concentration are a common difficulty after brain injury. Not getting enough sleep might make attention difficulties worse; between 30-70% of people report that they have problems sleeping after their brain injury. Sleeplessness can be upsetting during the night but can also make people tired during the day and can make it more difficult for people to go about their day-to-day activities. This research study aims to understand more about how good and poor sleep affects the attention of people who have had a brain injury. It is hoped that the findings of this study will help to develop ways of identifying people who have sleep difficulties after they have had a brain injury. It is also hoped that the findings can be used to encourage resources to be put in place to effectively treat sleep problems after brain injury in the future.

Why have I been chosen?
You have been given this information sheet because you have had a brain injury. We need good and poor sleepers to take part in this study. So if you feel you have problems with your sleep or if you feel you don’t have any problems, your taking part would be valuable. All together, around 40 people from Scotland will be studied in this project.
Do I have to take part?
Taking part in the research is completely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. This is simply to indicate that you have read this information sheet, and have had the chance to discuss the study with the investigator. If you do decide to take part you are still free to withdraw at any time, without giving a reason, and any data collected from you will be destroyed.

What is involved in taking part?
If you decide to take part, there will be a number of stages to your involvement. First of all you will be asked to meet with the researcher. This involves filling in some questionnaires about the quality and quantity of your sleep. This will take about an hour.

You will be asked to wear an ‘actiwatch’ on your wrist for seven days so that we can measure your sleep and wake patterns. The actiwatch is just like a small wristwatch, but instead of telling the time, it measures body movements and stores information in a tiny microprocessor inside. A computer is then used to ‘read’ the information once we have the actiwatch back from you. You will also be asked to complete a simple sleep diary for each of these nights. We can summarise the information on your sleep for you if you would like.

When you return the actiwatch you would be asked to complete two tasks on a computer these takes about five minutes each. You would be asked to complete a number of other tasks and answer some questions to do with attention. All in all this meeting should take no more than an hour and a half.

So, your involvement in the study would be for around two and a half hours, over a ten day period. The study itself will be running for around six months.

Would my results be kept confidential?
Any information collected about you during the course of this research will be kept in a locked filling cabinet and will be strictly confidential. All questionnaires and other data
relating to you will be identified by a number only, so you could not be recognised from it. If you are currently being seen by a brain injury service, and if you give us permission, we will pass the results of your tests back to the team.

What will happen to the results of the research study?
It is intended that they will be used as part of the main researcher’s Doctorate in Clinical Psychology, and will also be submitted for publication in a scientific journal. You would not be identified in any report or publication. If you would like a copy of the final results, the researcher will send you one when they are complete.

What are the benefits to taking part?
We will be able to provide a detailed assessment of your sleep at the present time. Whether you have indicated that you are a good sleeper or a poor sleeper we will be able to provide some general advice about sleep to help you now, or if you have any problems in the future. The information we receive from this study may also help to identify the impact of sleep problems after brain injury, and to encourage work to help people who have sleep problems be identified and treated in the future.

If I do decide to take part what happens next?
If you would like to take part, please could you return the completed form in the freepost envelope provided.

Imogen, will then contact you to arrange a time for you to discuss the study further. If you still want to participate you will also complete the interview part of the study. You will also be issued with an actiwatch and asked some questions at this time.

You will be given a copy of this information sheet and, if you decide to participate, a signed consent form to keep. Thank you for reading this information. If there is anything you are not clear about, or if you have any questions, please feel free to call the researcher, Ms Imogen Bloomfield (Trainee Clinical Psychologist) on 07974 393 282 or Professor Jonathan Evans on 0141 211 3978.
Return Form

Project Title: ‘After sustaining a brain injury, do people with sleep difficulties have poorer attention than people without sleep difficulties?’

Name of Researcher: Ms Imogen Bloomfield

Please initial the box
I have read the Participant Information Sheet that you sent out and I would be interested in participating in the study/ finding out more about the study.

Please tick the box that describes you best:

I am a good sleeper

I am a poor sleeper

Participants name: .................................................................

Signature: .............................................................................

Date: .....................................................................................

Contact telephone number: .......................................................
Appendix 4.6: Sleep diary

SLEEP DIARY

ID No:

Week Beginning:

MEASURING THE PATTERN OF YOUR SLEEP

<table>
<thead>
<tr>
<th></th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
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</thead>
<tbody>
<tr>
<td>1. What time did you rise from bed this morning?</td>
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<tr>
<td>2. At what time did you go to bed last night?</td>
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<tr>
<td>3. How long did it take you to fall asleep (minutes)?</td>
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<tr>
<td>4. How many times did you wake up during the night?</td>
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<tr>
<td>5. How long were you awake during the night (in total)?</td>
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<tr>
<td>6. About how long did you sleep altogether (hours / mins)?</td>
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<tr>
<td>7. How much alcohol did you drink last night?</td>
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<td></td>
</tr>
<tr>
<td>8. How many sleeping pills did you take to help you sleep?</td>
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</table>

MEASURING THE QUALITY OF YOUR SLEEP

<table>
<thead>
<tr>
<th></th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
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<th>Day 5</th>
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<td>3. How mentally alert were you in bed last night?</td>
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<td>4. How physically tense were you in bed last night?</td>
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<td>not at all</td>
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</table>
Appendix 4.7: Actiwatch and Sleep Diary Instructions

**USING YOUR ACTIWATCH**

Your Actiwatch is set-up and is ready for you to wear.

Please wear it at all times, night and day, on your non-dominant hand. The only time you should take it off is when you are doing wet activities, such as taking a shower, a bath or going swimming. The Actiwatch will not be damaged if you get it a bit wet in the rain, so don’t worry about this.

You should press the button on the front of the Actiwatch once you put the lights out at night when you go to bed, and once when you finally get up in the morning. Don’t worry if you forget to press the button, or if you think you have pressed it twice: the button does not switch the Actiwatch ‘on’ or ‘off’, it just lets us know when you went to bed and got out of the bed in the morning.

**COMPLETING YOUR SLEEP DIARY**

I would also like you to fill-out the enclosed sleep diary. Tomorrow morning, fill out the questionnaires for day one. Then, the next morning, answer the questions for day two, and so on for the next week.

Although, I would like you to be as accurate as possible when filling out your sleep diary you do not need to be too exact; e.g. it’s okay to write that you were awake for 10 minutes during the night rather than writing that you were awake for 7 minutes 30 seconds! You might find it difficult to estimate how long it takes you to fall asleep each night, but just try and make your best guess.

Finally, don’t try and ‘clock watch’ during the night, just be as precise as possible with your sleep diary. Just sleep in the way you usually would, and make your best estimate the following morning for your sleep diary.

If you have any questions at all, please don’t hesitate to contact me on 07974 393 282, or e-mail me on i.bloomfield.1@research.gla.ac.uk

Thank you very much for taking part in this study. Imogen Bloomfield
### Appendix 4.8: Actiwatch correlational data for full data set

(Spearman’s rho: correlation co-efficient and significance, two-tailed)

<table>
<thead>
<tr>
<th></th>
<th>SOL</th>
<th>WASO</th>
<th>NWBASO</th>
<th>TST</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SART-random commission</td>
<td>-.008</td>
<td>.143</td>
<td>.142</td>
<td>-.163</td>
<td>-.113</td>
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<td>.443</td>
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Appendix 4.9: Characteristics of CGS and CPS groups
(Median and range are reported where appropriate)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Good sleep group (n=15)</th>
<th>Poor sleep group (n=11)</th>
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<tbody>
<tr>
<td>Age</td>
<td>51 (51)</td>
<td>44 (41)</td>
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<tr>
<td>Gender</td>
<td>13 males, 2 females</td>
<td>10 males, 1 females</td>
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<tr>
<td>WTAR</td>
<td>97 (57)</td>
<td>96 (51)</td>
</tr>
<tr>
<td>WASI</td>
<td>107 (38)</td>
<td>90 (53)</td>
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<tr>
<td>Time since TBI</td>
<td>48 (482)</td>
<td>124.5 (269)</td>
</tr>
<tr>
<td>TBI – Mechanism</td>
<td>Fall = 6, RTA = 9</td>
<td>Fall = 1, RTA = 5</td>
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<tr>
<td></td>
<td></td>
<td>Assault = 3, Other = 2</td>
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<tr>
<td>TBI - severity</td>
<td>Moderate = 3, Severe = 12</td>
<td>Mild = 2, Moderate = 3, Severe = 6</td>
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</table>
Appendix: 4.10: Scores for self-report mood and sleep measures for conservative GS and PS groups (median and range)

<table>
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<th>Variable</th>
<th>Good sleep group (N=15)</th>
<th>Poor sleep group (n=11)</th>
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<td>PSQI</td>
<td>2 (4)</td>
<td>13 (12)</td>
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<td>ISI</td>
<td>1(6)</td>
<td>18 (19)</td>
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<tr>
<td>HADS anxiety</td>
<td>6 (13)</td>
<td>13 (12)</td>
</tr>
<tr>
<td>HADS depression</td>
<td>3 (12)</td>
<td>6 (11)</td>
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</table>
Appendix 4.11: Sleep diary data for conservative GS and PS groups
(median and range, Mann-Whitney p value, two-tailed (p) and effect size r)

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<th>Poor sleep group (N=14)</th>
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<th>r</th>
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<td>SOL (min)</td>
<td>8.5 (45)</td>
<td>38.6 (50.4)</td>
<td>0.019</td>
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<td>WASO (min)</td>
<td>13 (38)</td>
<td>23.3 (116.5)</td>
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<td>TST (min)</td>
<td>481 (237)</td>
<td>450 (179.00)</td>
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<td>SE (%)</td>
<td>96.77 (25)</td>
<td>77.19 (25)</td>
<td>0.001</td>
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<td>How well felt in the morning</td>
<td>3 (2.2)</td>
<td>2 (3.05)</td>
<td>.023</td>
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<td>How enjoyable sleep was</td>
<td>3.07 (2)</td>
<td>1.71 (2.86)</td>
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<td>How alert felt in the morning</td>
<td>1.4 (3.3)</td>
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<td>How physically tense</td>
<td>0.93 (2)</td>
<td>1.56 (2.29)</td>
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Appendix 4.12: Actiwatch data for conservative GS and PS groups

(Median and range, Mann-Whitney p value, two-tailed (p) and effect size (r) are reported)

<table>
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<tr>
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<th>Good sleep group (N=19)</th>
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<td>SOL</td>
<td>16 (57)</td>
<td>27 (81)</td>
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<td>64 (99)</td>
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<td>84 (19)</td>
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