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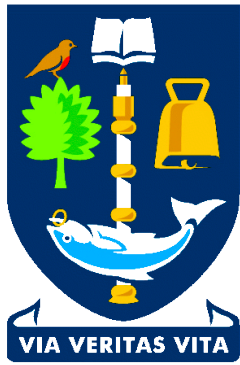
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University of Glasgow

Prevalence and types of sleep problems in head injury patients in rehabilitation

And

Clinical Research Portfolio

VOLUME I

(Volume II Bound Separately)

Eleni Morfiri

University of Glasgow

Mental Health and Wellbeing

August 2013

Submitted in part fulfilment of the requirements for the Degree of

Doctor in Clinical Psychology (D.Clin.Psy.)



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Chapter 1

Systematic literature review

Fatigue, mental effort and cognition after head injury: A systematic review.

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Fatigue, mental effort and cognition after head injury: A systematic review.

Abstract

Background: Fatigue is one of the most commonly reported symptoms after head injury (HI). The coping hypothesis suggests that HI patients are required to put greater effort when completing cognitive tasks due to attentional deficits and slowed processing and this leads to greater fatigue. This review synthesises findings on the relationship between fatigue, mental effort and cognition in HI patients.

Methods: Using a combined electronic and manual search, 10 articles which fulfilled inclusion and exclusion criteria were identified. Quality criteria were used to assess methodological quality and relevant data were extracted and synthesised.

Results: Two studies were rated as 'high' quality, six 'moderate' and two 'low'. HI samples were heterogeneous in terms of injury severity and time post-injury, controls were poorly matched, and insufficient consideration was given to confounding variables, limiting the confidence in findings. HI patients experience greater day-to-day fatigue than controls, but not greater of situational fatigue or effort when completing cognitive tasks. Fatigue and effort are associated with performance on vigilance, selective attention, and information processing speed tasks, but not on divided attention tasks.

Conclusions: This review provides partial support for the coping hypothesis. Fatigue is associated with cognitive performance in HI patients, particularly when performing tasks that are not self-paced. The direction of the association between fatigue and cognition is unclear.

Keywords: *head injury, fatigue, mental effort, attention, coping hypothesis.*

Introduction

Fatigue is one of the most commonly reported symptoms after head injury (HI). Fatigue is more common in HI patients than in healthy controls or orthopaedic injury patients (Ziino & Ponsford, 2006a; Stulemeijer et al., 2006). Indeed, up to 73% of HI patients report fatigue as a problem five years post-injury (Olver, Ponsford, & Curran, 1996). Fatigue appears to be independent of the severity of the HI and in most cases develops into a chronic problem (Ziino & Ponsford, 2005). Bushnik, Englander, and Wright (2008) examined the patterns of fatigue over the first two years after injury and found a decrease in self-reported fatigue in the first year and no changes thereafter. Many HI patients rate fatigue as one of their most distressing symptoms (LaChapelle & Finlayson, 1998). This is not surprising, considering that greater fatigue is associated with problems in concentration, motivation and activity and limitations in physical and social functioning (Stulemeijer et al., 2006). Experience of fatigue following HI can have a negative impact on self-perceived quality of life and on participation in activities (Cantor et al., 2008).

A common difficulty in the study of fatigue is that there is no universally accepted definition of fatigue. In the present review the definition of fatigue by Aaronson et al. (1999) is adopted, where fatigue is defined as *“the awareness of a decreased capacity for physical and/or mental activity due to an imbalance in the availability, utilization, and/or restoration of (physiological or psychological) resources needed to perform activity”* (p. 46). Within this framework, deficiencies of physiological resources resulting in impaired speed of processing, attention and/or arousal could arguably be causes of fatigue following HI (Ziino & Ponsford, 2006b). Another difficulty in the study of fatigue is the lack of objective methods to assess the experience of fatigue. To overcome this, self-assessment measures of fatigue have been developed and validated. A common distinction between these measures is that some aim to assess overall fatigue (day-to-day fatigue), whereas others focus on situational fatigue, aiming to assess fatigue in the present moment. Fatigue scales share many

similarities and most authors conceptualise fatigue as a multidimensional construct. However, there is considerable variability around the suggested dimensions of fatigue.

Despite the lack of a consensual definition of fatigue and the variability in the measurement of fatigue, in the last two decades an increasing number of studies have explored its mechanisms, correlates, measurement, consequences, and treatment in HI patients, as well as the associations between fatigue and cognition (for a review see Belmont, Agar, Hugeron, Gallais, & Azouvi, 2006). The present systematic review focuses on studies exploring the relationship between cognition and fatigue. The related concept of mental effort is also included in this review, as fatigue is assumed by some to be a consequence of overwhelming efforts made to compensate for cognitive limitations (Van Zomeren, Brouwer, & Deelman, 1984; Azouvi et al., 2004). Therefore, in some studies the relationship between mental effort and cognition has been investigated alongside fatigue or as an indicator of fatigue (Belmont, Agar, & Azouvi, 2009; Azouvi et al., 2004).

The coping hypothesis (Van Zomeren et al., 1984) has been an influential theoretical framework for studies that explore the relationships between fatigue and cognition. Van Zomeren et al. (1984) suggest that according to the coping hypothesis, cognitive deficits associated with HI (such as attentional deficits and slowed processing) may cause additional effort to be required in order to maintain a level of performance needed for daily tasks. The coping hypothesis postulates that increased effort leads to increased fatigue. Several studies in recent years have explored the merits of the coping hypothesis in HI patients, particularly the relationship between fatigue and performance on attentional tasks (Azouvi et al., 2004; Belmont et al., 2009; Ziino & Ponsford, 2006a). A few studies have explored the relationship between fatigue and other areas of cognitive functioning, such as executive functioning (Fry, Greenop, & Schutte, 2010).

As many studies in this review focus on attention, a brief description of different types of attention is provided. A number of models of attention have been developed, most of which argue that attention is a multidimensional construct involving overlapping processes or components, which interact dynamically (Ponsford, 2008). A common distinction made is between intensity and selectivity of attention. Ziino and Ponsford (2006a, p. 383) provide a concise description of the main components and processes of attention: “intensity involves the regulation of levels of attentional activation, encompassing the state of receptivity to stimulation and response preparedness (i.e., alertness) and attentional activation over longer monotonous tasks (i.e., vigilance). In contrast, selective attention incorporates focused and divided attention, where the process of filtering relevant sensory information from irrelevant information is required. While both divided attention and focused attention require selectivity, they are also different in that divided attention requires the dividing or sharing of resources between two or more kinds of information, sources, or mental operations (Davies, Jones, & Taylor, 1984). In contrast, focused attention requires selection of one source of information while withholding responses to irrelevant stimuli.” This typology of attentional tasks is adopted in this review when synthesising the findings of studies, which use attentional tasks.

A literature review (Belmont et al., 2006) summarised research findings on the prevalence, assessment, causative factors and treatments of fatigue after HI. However, no systematic reviews have been published in the area of fatigue, mental effort, and cognition. Cognitive testing is frequently used as part of the assessment process with HI patients to understand their needs and to inform clinical decisions, as well as for litigation or financial benefit claims for disability. It is well established that effort is an important determinant of performance on cognitive tests and the use of effort tests in routine practice is recommended (BPS, 2009). Fatigue during testing and patients’ perception of required mental effort to adequately meet the demands of a test can potentially influence performance on testing by depleting patients’ capacity to perform optimally and/or their motivation to engage with a cognitive test. The current review can enhance our understanding of

the potential influence of fatigue and mental effort on HI patients' performance on different types of cognitive tests.

Aims

To provide a synthesis of studies investigating relationships between fatigue, mental effort and cognition in HI patients. Results are discussed with reference to the coping hypothesis (Van Zomeren et al., 1984).

Research Questions

1. Do head injury patients experience greater day-to-day fatigue, mental effort and situational fatigue than controls with similar demographic characteristics?
2. Are fatigue and mental effort associated with cognitive function? In particular:
 - a) Vigilance
 - b) Selective attention
 - c) Divided attention
 - d) Executive functioning
 - e) Information processing speed

Method

Search Strategy

A systematic literature search was conducted using the OVID online interface to access the Medline, Embase and Embase Classic databases; the EBSCO host online interface to access the PsycINFO and CINAHL databases and the Web of Science database. Databases were searched March 2013 week 4 by combining MeSH terms and keywords relating to HI and fatigue (for full search strategy see Appendix 1.2). No publication cut-off date was applied. A sensitivity search was also carried out,

which involved screening references from identified papers and from review papers and conducting hand searches of relevant journals (Journal of Head Trauma Rehabilitation, Brain Injury, Neuropsychology).

Duplicates were removed. For each paper identified from the database searches, titles were screened against inclusion and exclusion criteria to allow for removal of irrelevant articles. Abstracts were reviewed for articles where it was unclear from the title whether or not they were suitable for inclusion in the review. Following exclusion of unsuitable articles, a total of 25 articles were left. Full text copies of these were obtained. Following review of the full text of the remaining 25 articles, a further 15 articles were excluded on the basis of the inclusion and exclusion criteria (for details on reasons of exclusion see Appendix 1.3). The combined electronic and manual search generated 10 articles for inclusion in this systematic review. The process for identifying papers is outlined in Figure 1.

Inclusion/Exclusion Criteria

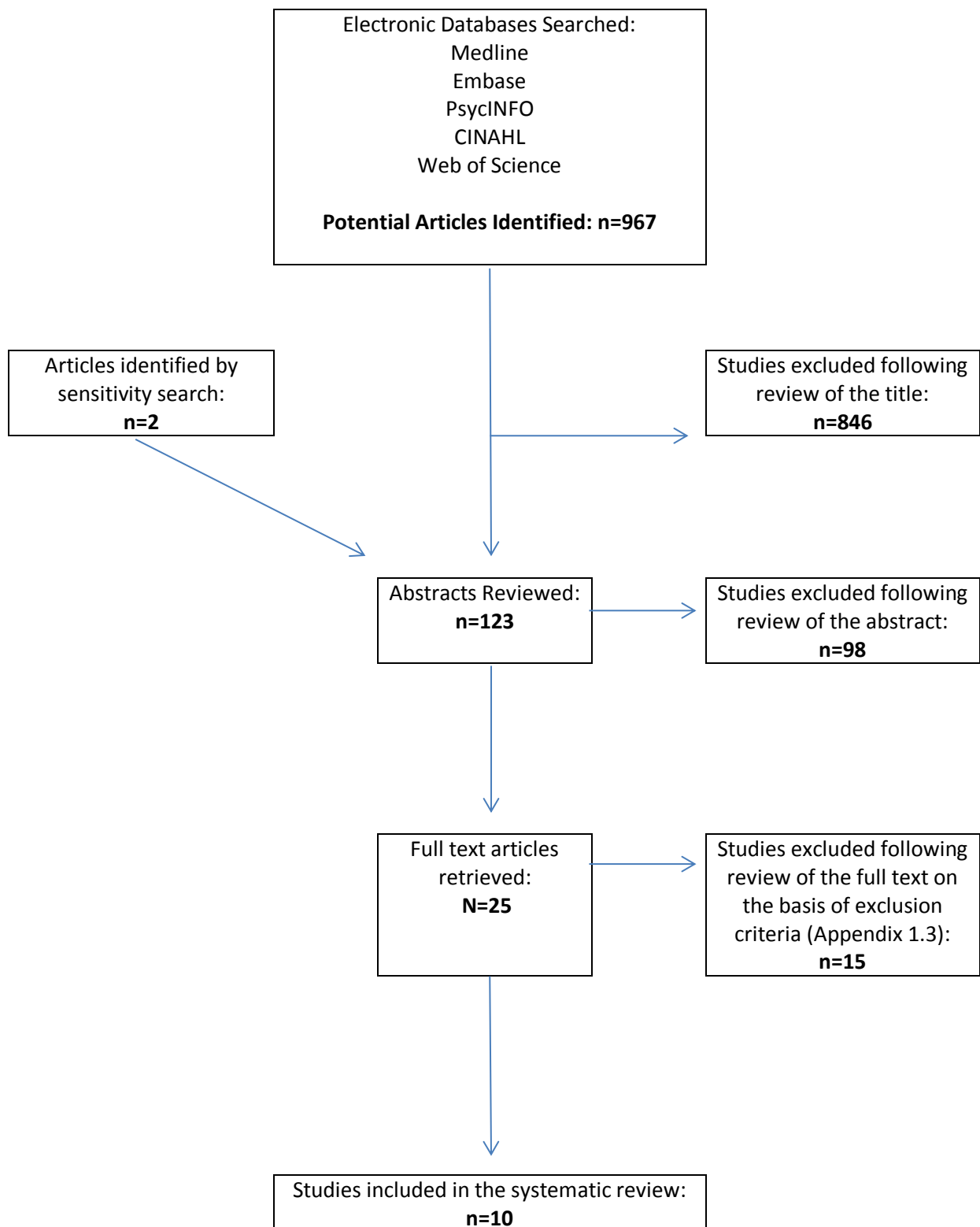
Inclusion criteria:

1. Participants with a HI of any severity, i.e. individuals who have experienced a head injury, which is thought to be related to a mild, moderate, or severe traumatic brain injury (TBI).
2. Participants aged 18 years or above
2. Use of subjective and/or objective measures of fatigue and/or effort
3. Objective measures of cognitive functioning
4. Published in English

Exclusion criteria:

1. Non traumatic brain injury patients (i.e. stroke)
2. Lack of subjective and/or objective measures of fatigue or mental effort, as idiosyncratic reports of fatigue and/or effort would not allow quantification and exploration of the experience of fatigue and/or mental effort and their relation to cognitive performance.
3. Use of self-report measures to assess cognitive functioning, as endorsement of cognitive symptoms is likely to be influenced by a number of factors, including patients' insight, which is frequently affected in HI patients.
4. Underlying pathophysiology of fatigue, such as studies focusing on endocrine functioning
5. Focus on validation of fatigue scales
6. Qualitative designs or single cases, as the effects of HI are diverse and generalisability of findings based on a single case is limited in this population
7. Unpublished studies, books, conference abstracts, review articles, commentaries, editorials, thesis
8. Animal studies

Figure 1: Flowchart outlining the process for the identification of papers



Quality criteria

The quality of the papers included in the review was assessed using a quality rating scale (see Appendix 1.4) developed specifically for this review. Guidelines published by the Scottish Intercollegiate Guidelines Network (SIGN, 2011) were used when developing the rating scale and quality criteria. Using the quality rating scale, each study was assessed on 28 items relating to the design and method. Studies were awarded a score of 0 to 56, with higher scores reflecting greater quality. To enable comparison of quality for the purpose of this systematic review, scores were converted to percentages and categorised as High (>75%), Moderate (50-74%), Low (25-49%) or Very Low (<24%). A detailed breakdown of scores is presented in Appendix 1.5. All papers were rated by the author and ranked according to the quality rating checklist. In addition, all papers were rated independently by a second rater. Full agreement on the overall quality rating was achieved on 8 of the 10 papers (80%). Rating of the two remaining papers was resolved following discussion.

Data extraction

Table 1 summarises key information from all 10 included articles including methodological quality, sample characteristics, assessment methods used for fatigue and/or mental and cognition, and main findings relating to the association between performance on cognitive tasks and fatigue and/or mental effort. Findings relating to the levels of day-to-day fatigue, mental effort and situational fatigue in HI patients and controls are discussed in the text.

Table 1. Summary of included studies

Author date and quality rating	Sample characteristics and matching 1. Sample size 2. Demographics in HI group: %males, mean age (SD) 3. Severity 4. Time post-injury 5. Matching	Fatigue (and/or mental effort) measures 1. Day-to-day 2. Situational 3. Mental effort *additional measures *sig. differences between HI and controls	Outcome Measures *HI group scored sig. poorer in comparison to controls	Study Design 1. Analysis 2. Confounders	Main findings relating to the association between fatigue (and/or mental effort) and cognition
Ziino & Ponsford (2006a) 83.9% high	1. 46 HI and 46 controls 2. 63% male, 35.28yrs (13) 3. severe, moderate, mild 4. sub-acute, chronic 5. No matching reported: no group differences found for age, gender, education, IQ	1. Fatigue Severity Scale* 2. Visual Analogue Scale for fatigue (vigour and fatigue subscales) 3. none *Causes of fatigue Questionnaire* -Mental effort -Physical effort	<i>Selective attention:</i> Complex Selective Attention Task (C-SAT) -Mean reaction times (RTs)*, Coefficient of variation, Errors, Misses <i>Divided attention:</i> Telephone Search(TS) and TS while counting (TSWC) -TS-time per target*, missed targets -TSWC-time per target, dual task decrement, missed targets, counting errors <i>Processing speed</i> Symbol Digit Modality Test (SDMT) -correct*, errors	1. Correlational and multiple regression 2. Time post- injury, Education, Anxiety, Depression	After controlling for the effects of anxiety and depression the following associations were found in the HI group: -VAS-F scores were associated with more errors on C-SAT -COF-ME scores were associated with higher RTs and more misses on C-SAT -FSS scores were associated with more misses on C-SAT

Author date and quality rating	Sample characteristics and matching 1. Sample size 2. Demographics in HI group: %males, mean age (SD) 3. Severity 4. Time post-injury 5. Matching	Fatigue (and/or mental effort) measures 1. Day-to-day 2. Situational 3. Mental effort *additional measures *sig. differences between HI and controls	Outcome Measures *HI group scored sig. poorer in comparison to controls	Study Design 1. Analysis 2. Confounders	Main findings relating to the association between fatigue (and/or mental effort) and cognition
Ziino & Ponsford (2006b) 75% high	Same as Ziino and Ponsford (2006a)	1. Fatigue Severity Scale 2. Visual Analogue Scale for fatigue (vigour and fatigue subscales) 3. none *Decrement on complex Selective Attention Task *Blood Pressure (systolic and diastolic*)	<i>Sustained attention:</i> Vigilance Task scores over 4 time periods: -Decision time* -Movement time* -Misses* -Variability	1. Correlational 2. Anxiety, Depression, Education, Time post-injury	After controlling for the effects of anxiety and depression the following associations were found in the HI group: -VAS-F fatigue scores were associated with more misses in 1st and 2nd time periods -VAS-F fatigue scores approached significance for misses -VAS-F vigour scores were associated with greater variability in 2nd and 4th time periods -increases in diastolic blood pressure were associated with higher FSS scores
Ashman et al. (2008) 71.4% moderate	1. 202 HI patients and 73 controls 2. 54% males, 47.7yrs (12.3) 3. Mild, moderate, severe 4. Chronic 5. Not matched, sig. differences in age and gender between HI and controls	1. Global Fatigue Index (GFI)* 2. Likert-type scale (pre- and post-*) 3. none	<i>Objective fatigue:</i> Changes in performance on a neuropsychological battery (CANTAB) administered 3 consecutive times (T ₁ , T ₂ , T ₃) 1. response speed* 2. accuracy 3. executive function*	1. Correlational 2. Age, gender	-Situational fatigue and day-to-day fatigue scores were associated with <i>slower response speed</i> in T ₁ , T ₂ , and T ₃ and T ₁ and T ₃ respectively in the HI group, but not in controls. - Situational fatigue and day-to-day fatigue were not associated with <i>accuracy</i> or <i>executive function</i> scores in either group.

Author date and quality rating	Sample characteristics and matching 1. Sample size 2. Demographics in HI group: %males, mean age (SD) 3. Severity 4. Time post-injury 5. Matching	Fatigue (and/or mental effort) measures 1. Day-to-day 2. Situational 3. Mental effort *additional measures *sig. differences between HI and controls	Outcome Measures *HI group scored sig. poorer in comparison to controls	Study Design 1. Analysis 2. Confounders	Main findings relating to the association between fatigue (and/or mental effort) and cognition
Sinclair et al. (2013) 69.6% Moderate	1. 20 HI and 20 controls 2. 70% male 3. severe, moderate, mild 4. 5. Matched for education, gender, age	1. Fatigue Severity Scale* 2. none 3. none *Epworth Sleepiness Scale *Pittsburgh Sleep Quality Index	<i>Sustained attention:</i> Psychomotor Vigilance Task -Reaction time* -Lapses* -Mean slowest 10% responses* -Variability in reaction times* -time-on-task decrement	1. Correlational and separate ANCOVAs 2. Depression, Severity, Time post-injury	-In the HI group there were no associations between any of the PVT summary statistics and fatigue, sleepiness, or sleep quality. - After controlling for fatigue there were no longer significant differences on any PVT summary statistics indicating that fatigue was globally related to sustained attention.
Belmont et al. (2009) 69.6% Moderate	1. 27 HI patients and 26 controls 2. 77% males, 31.7yrs (9.16) 3. Severe 4. Sub-acute and chronic 5. Matched for age, gender, education	1. Fatigue Severity Scale* 2. Visual analogue scale for fatigue (T ₀ , T ₁ , T ₂) 3. Visual analogue scale for mental effort (T ₀ , T ₁ , T ₂)	<i>Selective attention:</i> Go-no-go task administered 3 times (T ₀ , T ₁ , T ₂) 1. mean reaction times* 2. missed targets*	1. Correlational 2. Depression, time post-injury	-In the HI group FSS scores were associated with longer <i>reaction times</i> at T ₂ T ₁ and more <i>omissions</i> at T ₁ -Mental effort scores at T ₁ were associated with more misses at T ₁ . Mental effort scores at T ₂ were associated with more misses at T ₂ (r=.40, p≤.01).

Author date and quality rating	Sample characteristics and matching 1. Sample size 2. Demographics in HI group: %males, mean age (SD) 3. Severity 4. Time post-injury 5. Matching	Fatigue (and/or mental effort) measures 1. Day-to-day 2. Situational 3. Mental effort *additional measures *sig. differences between HI and controls	Outcome Measures	Study Design 1. Analysis 2. Confounders	Main findings relating to the association between fatigue (and/or mental effort) and cognition
Fry et al. (2010) 69.6% Moderate	1. 30 HI patients and 30 controls 2. 27.7yrs (9.43) 3. Moderate and Severe 4. sub-acute and chronic (over 6m and under 5yrs) 5. Not-matched, sig. differences in age and education	1. experimental manipulation of fatigue: 'fatigued' and 'non fatigued' conditions 2. Visual-analogue scale for fatigue 3. none	<i>Executive function:</i> Wisconsin Card Sorting Test 1. inductive reasoning (mean number of shorts)* 2. cognitive flexibility (perseverative errors)* 3. conceptual abilities (non-perseverative errors)*	1. two way ANOVA 2. none	-Inductive reasoning: no significant differences or interaction between group and condition. -Cognitive flexibility: HI patients scored sig. lower than controls. The fatigued groups scored similarly to the non-fatigued groups. There was an interaction effect indicating that fatigue impacted on cognitive flexibility to a greater extent in the HI group in comparison to controls. -Conceptual abilities: no significant differences or interaction between group and condition.
Azouvi et al. (2004) 62.5% moderate	1. 43 HI and 42 controls 2. 74% males, 26.7yrs (8.9) 3. Moderate, severe 4. Sub-acute and chronic 5. Matched for age, gender, education	1. none 2. none 3. Visual-analogue scale for mental effort	<i>Sustained attention:</i> 1. Visual go-no go task* 2. random number generation* <i>Divided attention:</i> 3. Both task- no emphasis* 4. Emphasis on random number generation* 5. Emphasis on go-no-go*	1. Correlational 2. Time post-injury	-Correlation coefficients were computed between performance and subjective mental effort on each task, but these were not reported. The authors note that most of these (10 out of 12) did not reach significance.

Author date and quality rating	Sample characteristics and matching 1. Sample size 2. Demographics in HI group: %males, mean age (SD) 3. Severity 4. Time post-injury 5. Matching	Fatigue (and/or mental effort) measures 1. Day-to-day 2. Situational 3. Mental effort *additional measures *sig. diff. between HI and controls	Outcome Measures *HI group scored sig. poorer in comparison to controls	Study Design 1. Analysis 2. Confounders	Main findings relating to the association between fatigue (and/or mental effort) and cognition
Riese et al. (1999) 51.8% Moderate	1. 8 HI patients and 8 controls 2. 100%males, 23.3yrs (5.9) 3. severe 4. over 9 m 5. Matched for sex, age, and education	1. none, 2. none 3. Rating Scale for Mental Effort *Cardiovascular assessment* +mental load (SEB)* + activation and irritation scale (GACL) +complaints related to working at PC screen (GVKL)*	<i>Divided attention:</i> Driving task -Lane tracking -Dot counting* -Peripheral detection 2 conditions: -50% of maximum performance -80% of maximum performance	1. Repeated measures ANOVA 2. Physiological distress differences	-No significant differences in effort were found.
Johansson et al. (2009) 42.8% Low	1. 58 HI patients and 40 controls 2. Mild HI (working): 43% male, 45.2yrs (2.4) Mild HI (sick leave): 23% male, 51.9yrs (1.1) HI (sick leave): 58% males, 42.9yrs (3.3) 3. Mild, Moderate and Severe 4. sub-acute and chronic 5. No matched, Mild HI sick leave group was significantly older	1. Self-report of mental fatigue and related symptoms* 2. none 3. none	<i>Information processing speed:</i> Digit symbol coding <i>Attention and Working memory:</i> Digit Span and Spatial Span <i>Verbal Fluency:</i> Verbal Fluency test (FAS) <i>Visual scanning, divided attention and motor speed:</i> Adapted Trail Making test <i>Reading Speed:</i> DLS reading speed test	1. Correlational and linear regression 2. Age, time post-injury	-The Self-report fatigue score correlated significantly with all cognitive tests. - <i>Information processing speed</i> was the most important predictor of fatigue scores.

Author date and quality rating	Sample characteristics and matching 1. Sample size 2. Demographics in HI group: %males, mean age (SD) 3. Severity 4. Time post-injury 5. Matching	Fatigue (and/or mental effort) measures 1. Day-to-day 2. Situational 3. Mental effort *additional measures *sig. differences between HI and controls	Outcome Measures *HI group scored sig. poorer in comparison to controls	Study Design 1. Analysis 2. Confounders	Main findings relating to the association between fatigue (and/or mental effort) and cognition
Chaumet et al. (2008) 39.3% Low	1. 22 HI patients and 22 controls 2. 73% males, 33yrs (10) 3. Severe 4. 90% over 1 year 5. Matched for sex and age	1. Fatigue Severity Scale* 2. none 3. none *Maintenance of Wakefulness Test (MWT) *Epworth Sleepiness Scale*	<i>Not defined:</i> Driving task (1 hour) Standard deviation of the vehicle position from the centre of the road*	1. Correlational and backward-stepwise-linear-regression 2. none	-Day-to-day fatigue and Body Mass Index explained 41.8% of the variance of the driving test scores. -Day-to-day fatigue scores correlated with subjective and objective sleepiness scores in the HI group, but not in controls.

Results

Day-to-day Fatigue, Situational Fatigue and Mental Effort in Head Injury patients and healthy controls

Day-to-day fatigue

Six out of the 10 studies with high (Ziino & Ponsford, 2006a), moderate (Ashman et al., 2008; Belmont et al., 2009; Sinclair, Ponsford, Rajaratnam, & Anderson, 2013) and low (Chaumet et al., 2008; Johansson, Berglund, & Ronnback, 2009) methodological quality assessed the severity of day-to-day fatigue in HI patients and controls. The Fatigue Severity Scale (FSS; Krupp et al., 1989) was used in four studies (Belmont et al., 2009; Sinclair et al., 2013; Ziino & Ponsford, 2006a; Chaumet et al., 2008). The Global Fatigue Index (GFI; Bormann et al., 2001) was used by Ashman et al. (2008), and a self-report scale of mental fatigue and related symptoms by Johansson et al. (2009). In all studies, HI patients reported significantly greater day-to-day fatigue severity in comparison to controls.

Situational fatigue

Situational fatigue was considered separately in five studies of high (Ziino & Ponsford, 2006a, 2006b) and moderate quality (Ashman et al., 2008; Belmont et al., 2009; Fry et al., 2010). The Visual Analogue Scale for Fatigue (VAS-F; Lee, Hicks, & Nino-Murcia, 1991) was used in all studies, apart from the Ashman et al. (2008) study, where a 5-point Likert-scale was used. The studies used a similar paradigm to explore the effect of completing demanding cognitive tasks in HI patients and in controls. Various tasks were used, depending on the research questions that the study wished to address. In three studies (Belmont et al., 2009; Ziino & Ponsford, 2006a; Fry et al., 2010), participants were asked to rate their situational fatigue after completing the experimental tasks. Situational fatigue did not differ significantly between HI groups and controls after the completion of cognitive tasks. Two studies assessed fatigue at two time points (Ziino & Ponsford, 2006b; Ashman

et al., 2004). In the Ziino and Ponsford (2006b) study situational fatigue did not differ between groups before or after the completion of cognitive tasks. In the Ashman et al. (2008) study, HI patients reported significantly greater fatigue severity after completing a computerised assessment battery three times.

Mental Effort

In three studies with moderate methodological quality, participants were asked to rate mental effort in relation to completing attentional tasks (Azouvi et al., 2004; Riese, Hoedemaeker, Brouwer, Mulder, Cremer, & Veldman, 1999; Belmont et al., 2009). In the Azouvi et al. (2004) and Belmont et al. (2009) studies Mental Effort was assessed using a Visual Analogue Scale, consisting of a 10-cm horizontal line. Riese et al. (1999) used the Rating Scale for Mental Effort (RSME; Zijlstra & Van Doorn, 1985). In the Azouvi et al. (2004) study participants rated their subjective sense of effort after completing a sustained attention and a divided attention task respectively. HI patients reported greater mental effort than controls during the sustained attention and the divided attention tasks. As expected, both groups rated effort as higher on divided attention tasks. Mental effort varied in a similar way across the two groups, i.e. there was no disproportionate increase of subjective mental effort in the HI group in relation to completing dual attention tasks. In the Riese et al. (1999) study participants rated their sense of effort in relation to completing a divided attention task with two levels of difficulty; one tailored to the lower end of participants' best performance and a second tailored to the high end of their best performance. There was no difference in mental effort between HI patients and controls in either condition. In the Belmont et al. (2009) study measures of mental effort were obtained, after the end of the first and second part of a selective attention task. The HI group and the control group did not differ significantly in self-ratings of effort at either time point.

Physiological arousal

In an attempt to objectively assess effort, two studies of high and moderate quality respectively included physiological measures (Ziino & Ponsford, 2006b; Riese, et al., 1999). In these studies participants' systolic and diastolic blood pressure (BP) were obtained before and after completing cognitive tasks. Riese et al. (1999) found differences in systolic BP between HI patients and controls. In HI patients BP increased, whereas in controls BP decreased over time. The same pattern was observed for diastolic BP, but differences were not significant. Ziino and Ponsford (2006b) found that diastolic BP increased significantly more in HI patients compared to controls. Similar to Riese et al. (1999) diastolic BP increased in the HI group, whereas in the control group diastolic BP decreased. The same pattern was observed for systolic BP, but was not significant. Additional analysis, by Ziino and Ponsford (2006b) found that diastolic, and not systolic, BP significantly correlated with subjective fatigue in the HI group.

Fatigue and Cognition

Vigilance and alertness

Three studies (Ziino & Ponsford, 2006b; Sinclair et al., 2013; Chaumet et al., 2008) of varied methodological quality (high, moderate and low respectively) explored associations between fatigue (and/or effort) and vigilance. Arguably, all tasks in the three studies required vigilance to detect relatively low frequency events and the memory load was low. In the Ziino and Ponsford (2006b) study, participants performed a vigilance task lasting 45 minutes, which required to press a button when target stimuli (but not foils) appeared on a computer screen. The HI group performed significantly worse across all three indicators of performance (decision time, movement time and missed items), but had comparable response times. The control group showed improved decision time over time. The same effect was not observed in the HI group. After controlling for anxiety and

depression, situational fatigue remained significantly associated with more misses on the vigilance task. Decision time and movement time were not significantly associated with situational fatigue. Day-to-day fatigue did not correlate with any aspect of performance. Further analysis found that a subgroup of HI patients who showed a decline in performance on the vigilance task also reported significantly greater increases in fatigue in comparison to HI patients whose performance remained stable.

Sinclair et al. (2013) used a short (10 min) auditory Psychomotor Vigilance Task (PVT). The HI group performed significantly worse on all indicators of performance (mean reaction times, average slowest 10% RTs, lapses) and had significantly greater variability in reaction times. However, the HI patients did not have significantly higher time-on task decrements in performance. There were no associations between any of the PVT summary statistics and fatigue using traditional correlational methods. Using Ancova analysis controlling for fatigue, there were no longer significant differences on any PVT summary statistics, indicating that day-to-day fatigue was globally related to vigilance. Similar but less global effects were found for sleepiness, as measured by the Epworth Sleepiness Scale (ESS; Johns, 1991) and sleep quality, as measured by the Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). Measures of situational fatigue were not employed in this study.

Chaumet et al. (2008) explored the relationship between alertness and fatigue. HI patients and controls performed an hour-long driving task at 130km/hour and the vehicle's distance from the middle of the road was measured. This long and monotonous task arguably requires alertness/vigilance skills. Subjective and objective sleepiness was assessed the Epworth Sleepiness Scale and maintenance of wakefulness tests (MWT). The standard deviation of the vehicle from the middle of the road was significantly higher in the HI group compared to controls. Regression analysis showed that day-to-day fatigue and BMI together predicted 41.8% of the variance in driving

performance. Day-to-day fatigue correlated with objective and subjective sleepiness in HI patients, but not in controls. Measures of situational fatigue were not employed.

Selective Attention

Two studies of high and moderate quality respectively (Ziino & Ponsford, 2006a; Belmont et al., 2009) explored associations between fatigue, mental effort and selective attention. Ziino and Ponsford (2006a) employed a computerised complex selective attention test (C-SAT). Participants were required to press one button if a green letter or red number appeared on the screen and a different button if a red letter or green number appeared. The HI group performed significantly slower, less accurately and their performance was more variable. After controlling for the effects of anxiety and depression, day-to-day fatigue was associated with more misses and situational fatigue was associated with more errors. Scores on a measure that relates to mental effort were associated with more misses and longer reaction times. Fatigue and effort were not associated with performance in the control group.

In the Belmont et al. (2009) study HI patients and controls performed a selective attention task (go-no-go) divided in two parts. Measures of speed and accuracy were collected for the first and the second part of the task. Ratings of fatigue and mental effort were collected at baseline and after completing the first and second part of the task. The HI group was slower and less accurate compared to controls. In both groups performance (speed and accuracy) did not reduce significantly over time. Mental effort and fatigue did not differ significantly between groups. In the HI group day-to-day fatigue was significantly correlated with speed, but not accuracy, on the second part of the task. Effort correlated with accuracy, but not speed, on both parts of the task.

Divided Attention

One study with high quality rating explored associations between fatigue and divided attention (Ziino & Ponsford, 2006a) and two of moderate quality explored the association between mental

effort and divided attention (Azouvi et al., 2004; Riese et al., 1999). Ziino and Ponsford (2006a) used the Telephone Search task (TS) and TS while counting (TSWC) task to measure divided attention. The HI group was slower on both tasks and both groups were slower on the divided attention task. HI patients did not perform disproportionately slower on the divided attention task. Higher situational fatigue ratings and higher scores on the causes of fatigue questionnaire were modestly associated with greater numbers of misses on the single task and slower response times, as well as greater dual-task-decrements on the divided attention task. However, when anxiety and depression were controlled for, these correlations were no longer significant.

In the Azouvi et al. (2004) study, HI and controls completed two sustained attention tasks (go-no-go and random number generation) and were then asked to perform the two tasks simultaneously under three conditions: with focus on the go-no-go task, with focus on the random number generation task, and with no focus. The dual tasks were hypothesised to measure divided attention. The HI group's performance was significantly slower and less accurate across all conditions. Both groups had significantly slower reaction times on the divided attention tasks. However, although the HI group performed overall worse, performance varied in a similar way across the two groups. Similarly, although the HI groups rated their subjective mental effort as higher on all conditions, subjective mental effort varied in a similar way across the two groups, with both groups reporting higher effort for the divided attentions tasks. Mental effort did not correlate with any indicator of performance in either group.

Riese et al. (1999) employed a driving task, where participants performed simultaneously three single tasks (lane tracking, dot counting and peripheral detection) at an individually adapted level of difficulty under two conditions, (one at 50% and a second at 80% of their highest performance level). The two groups were similar on all measures, apart from the dot counting task where the HI group had more misses. As expected, performance was slower and less accurate in the 80% condition in both groups. There were no differences in the two groups' ratings of mental effort, but differences

were found for diastolic BP and self-ratings of visual complaints and headaches. This study indicates that the HI group had greater psychophysiological reactivity. Correlations between performance, effort, or physiological measures were not reported in this study.

Executive function

Two studies of moderate methodological quality (Ashman et al., 2008; Fry et al., 2010) explored the association between fatigue and executive function. In the Ashman et al. (2008) study individuals with HI and controls completed consecutively three versions of a computerised cognitive test. Performance across the three time points was compared in relation to speed, accuracy, and executive function. The HI group performance was significantly poorer on the speed and executive function, but not the accuracy, sub-scales across all three time points. Changes in performance across administrations differed in the two groups. On the speed and accuracy subscale, the control group's performance improved across administrations, indicating that controls benefited from practice. The HI group's performance on the speed subscale did not vary significantly across administrations. On the accuracy subscale, the HI group's accuracy scores improved slightly on the second administration and decreased significantly in the third administration. No differences in the pattern of performance were found on the executive function subscale. Although the HI group scored worse, the pattern of performance was similar across the two groups, showing an initial increase from the first to the second administration and a slight decrease from the second to the third administration. Day-to-day fatigue and situational fatigue did not correlate with accuracy or executive function. Situational fatigue and day-to-day fatigue scores were significantly associated with slower response speed in the HI group, but not in controls.

Fry et al. (2010) divided a HI and a control group in two conditions. Two groups completed a task tapping into executive functioning (Wisconsin card sorting) after completing a two-hour session of neuropsychological testing. The remaining two groups completed the executive function task only. Prior to the start of the task, all individuals completed a measure of situational fatigue. Both groups

(HI and control) who had completed the two hour long assessment reported somewhat greater fatigue. Fatigue did not differ significantly between groups. The number of sorts, perseverative errors, and non-perseverative errors were the indicators of performance. The HI groups performed significantly worse on all three areas compared to controls. Despite the fact that self-ratings of fatigue increased in both the HI and controls in the 'fatigued' condition, this did not affect their actual performance, as there were no significant differences between the fatigued and the non-fatigued group on any of the three variables. Changes in performance varied in a similar way for both the HI group and the control group for number of sorts and for non-perseverative errors. However, performance decreased disproportionately more for the fatigued-HI group for perseverative errors. The authors did not examine the associations between performance and fatigue.

Processing speed

Two studies with high and moderate methodological quality respectively (Ziino & Ponsford; 2006a; Johansson et al., 2009) explored associations between fatigue and processing speed. Ziino and Ponsford (2006a) found that situational fatigue in HI patients correlated with processing speed on the Digit Symbol Modality Test (DSMT). The HI group performed significantly slower, but not significantly less accurately, on the processing speed task. Higher scores for day-to-day fatigue correlated with more errors on the processing speed task. However, the correlation between fatigue and errors was not significant after controlling for anxiety and depression.

Johansson et al. (2009) compared the performance of people with mild HI, who were working, individuals with mild HI who were on sick leave, and individuals with moderate or severe HI injury, who were on sick leave, and normal controls on neuropsychological tests (digit symbol coding, digit span and spatial span, FAS, Trail Making Test, reading speed). There were no significant differences on the digit span, spatial span, number of errors on the reading test, or the Trail Making Test. All HI groups performed worse on reading speed, digit-symbol coding, verbal fluency and TMT. A pattern emerged, where groups with more severe injuries performed worse overall. This 'dose-response'

relationship was particularly evident in reading speed performance, which was incrementally worse for higher levels of severity. Significant correlations were found between subjective ratings of overall fatigue and performance on all tests. Additional analysis showed that digit symbol coding, (a measure of information processing speed), was the best predictor of fatigue scores, explaining 35% of the variance. In addition to these two studies, the Ashman et al. (2008) study (described in detail in the executive function section) reported significant associations between situational or day-to-day fatigue scores and slower response speed in the HI group, but not in controls.

Discussion

Day-to-day fatigue, mental effort and situational fatigue

There is consistent evidence that self-reported day-to-day fatigue is higher in HI patients than in controls (Ashman et al., 2008, Belmont et al., 2009, Chaumet et al., 2008, Johansson et al., 2009, Sinclair et al., 2013, Ziino & Ponsford, 2006a). According to the coping hypothesis, HI patients should experience greater fatigue in relation to challenging cognitive tasks due to the increased effort that they need to apply in the face of attentional deficits and slowed processing speed. However, there is little evidence that situational fatigue is higher in HI patients in comparison to controls due to increased effort. A consistent finding is that situational fatigue increases after the completion of demanding mental tasks in HI patients and controls alike. With the exception of one study (Ashman et al., 2008), findings suggest that situational fatigue is comparable in HI patients and controls when performing cognitive tasks (Belmont et al., 2009; Ziino & Ponsford, 2006a; Ziino & Ponsford, 2006b; Fry et al., 2010). Findings in relation to effort in HI patients are inconsistent, as two studies did not find greater effort in HI patients during cognitive tasks compared to controls (Belmont et al., 2009; Riese et al., 1999) and one did (Azouvi et al., 2004). Two studies that included psychophysiological measures (Ziino & Ponsford, 2006b; Riese, et al., 1999) found increased blood pressure in HI patients

after cognitive tasks, whereas blood pressure decreased in the control group. These findings suggest a possible increase in psychophysiological reactivity for HI patients, which could be associated with the experience of fatigue. Further studies are needed to explore the relationship between fatigue and physiological arousal considering the small sample sizes in these studies.

Partial support for the coping hypothesis arises from the studies included in this review, as despite greater day-to-day fatigue overall, there is little evidence that HI patients experience greater effort and situational fatigue in relation to completing cognitive tasks. However, the constructs of 'fatigue' and 'effort' as conceptualised by the coping hypothesis may not be best measured by self-report, particularly after HI, where there can be difficulty with insight. It has been suggested that HI participants and controls may use different frames of reference when self-rating current fatigue. HI patients may rate situational fatigue in the context of their more general fatigue, which is typically reported as higher by HI patients in comparison to controls (Ziino & Ponsford, 2006b). Physiological measures such as blood pressure, cortisol levels and patterns of brain activation could be a more reliable and valid way of assessing any increased 'costs' associated performing cognitive tasks after a HI.

Fatigue, mental effort and cognition

HI patients consistently perform worse in comparison to controls on vigilance tasks (Ziino & Ponsford, 2006b; Sinclair et al., 2013; Chaumet et al., 2008); they have slower reaction times, more lapses of attention and greater variability in their performance. In all three studies fatigue (as measured by FSS or VAS-F) was associated with poorer performance on vigilance tasks. Studies on selective attention (Belmont et al., 2008; Ziino & Ponsford, 2006a) suggest that HI patients perform significantly worse in comparison to controls; they have slower reaction times, make more errors and have more misses. Situational, day-to-day fatigue and effort correlated with some aspects of performance in both studies. Lastly, fatigue is associated with reduced information processing speed

in HI patients (Ashman et al., 2008; Johansson et al., 2009; Ziino & Ponsford, 2006a). However, this relationship may be mediated by anxiety and depression (Ziino & Ponsford, 2006a).

The findings from three studies on divided attention (Ziino & Ponsford, 2006a; Azouvi et al., 2004; Riese et al., 1999) suggest that HI patients and controls alike perform more slowly and less accurately, when performing two tasks simultaneously. The HI group performed comparably to controls in the Riese et al. (1999) and Ziino and Ponsford (2006a) studies, but significantly worse than controls in the Azouvi et al. (2004) study. Arguably, the tasks in the latter study were more complex. These findings suggest that divided attention deficits in HI patients depend on the attentional demands of the task (Leclercq & Azouvi, 2002). Considering that HI patients' perform comparably to controls on divided attention tasks of lesser complexity, it has been suggested that the observed difficulties with divided attention of high complexity may relate to a reduction in available processing resources rather than to an impairment of strategic processes responsible for attentional allocation and switching between tasks (Azouvi et al., 2004). Mental effort and fatigue were not related to performance on divided attention tasks in any of the three studies.

Considering the findings from the two studies that focused on cognitive areas other than attention, (Fry et al., 2010; Johansson et al., 2010) it remains unclear whether performing other types of tasks that place demands on other domains of cognition (such as executive function, memory and language) leads to greater fatigue in HI patients. The Fry et al. (2010) study found that fatigue was associated with one aspect of executive functioning, perseverative errors, but not with cognitive flexibility or conceptual abilities. This was evident only in HI patients who had undergone a two-hour neuropsychological assessment process prior to completing the study task. The Johansson et al. (2009) study found that fatigue correlated with a verbal fluency task, a reading task and a Trail Making Task. The usual paradigm of these tasks arguably relates to processing speed. It is therefore possible that the associations between performance on these tasks and fatigue are mediated by processing speed.

Consistent with the coping hypothesis, fatigue is associated with performance on vigilance, selective attention, and processing speed tasks, but not with performance on divided attention tasks. This initially appears perplexing, as divided attention tasks used in the current studies were highly complex and resource demanding. However, an interesting characteristic of the tasks used to assess divided attention is that they were self-paced, whereas most tasks used to assess vigilance, selective attention, and processing speed required adequate performance under time-pressure. The most consistent finding in HI patients is mental slowness, related to a global, non-specific slowing of information processing (Leclercq & Azouvi, 2002). Van Zomeren and Brouwer (1994) claimed that, when slowed information processing is controlled for, there is little if any additional impairment of higher aspects of attention.

Whether attentional functions are additionally impaired if processing speed deficits are accounted for is unclear and beyond the scope of this review. However, the findings from the studies on vigilance, selective attention and information processing speed provide partial support for the coping hypothesis as fatigue was associated with performance in HI patients. According to the coping hypothesis, the association between performance and fatigue is because HI patients have to put more effort due to attentional difficulties and slowed processing and become mentally fatigued. However, Ziino and Ponsford (2006a) proposed an alternative explanation for the association between fatigue and performance on attention measures, which cannot be dismissed. These authors suggest that greater fatigue at time of testing may detrimentally affect performance on attention tasks, or that participants with HI cannot effectively compensate for existing attention deficits because of greater fatigue during testing. Some evidence for this hypothesis is provided by Sinclair et al. (2013). In this study a proportion of HI participants performed faster than controls. Interestingly, HI patients who performed faster than controls reported lower day-to-day fatigue, whereas the sub-group of HI patients who were slower than controls reported greater day-to-day fatigue. There were no other significant differences between the 'faster' and 'slower' sub-groups of HI participants in

terms of age, education, injury severity, time since injury, daytime sleepiness, sleep quality, or severity of depressive symptoms.

Strengths, limitations and future research

This is the first systematic review to focus specifically on the association between fatigue, mental effort and cognition. It is not possible to conclude whether increased fatigue is a result of cognitive deficits in HI patients due to a number of methodological issues. Variables that might explain or mediate the relationship between performance and fatigue, such as sleepiness, sleep problems, anxiety, depression, and time post-injury, were not included or controlled for in most studies. In addition, although control groups were included, these were not always adequately matched to the HI groups. Justification of sample size was only provided by one study (Ziino & Posford, 2006a), which raises questions as to whether other studies had enough power to detect significant findings.

There is an assumption in the literature that the experience and impact of fatigue is unrelated to severity of injury. Although there is some evidence that symptoms of fatigue are common across the spectrum of severity of injury (Ziino & Ponsford, 2005), there is no evidence to support a view that the mechanisms of fatigue, the underlying pathology and the associations with functioning are the same across the spectrum of severity. Therefore, analysed together results from heterogeneous groups in terms of injury severity may be 'masking' potential differences between patients with mild, moderate and severe HI. Similarly, time post-injury varied in most studies, ranging from a few days to years. Variability in time post-injury introduces complexity in the interpretation of their results, as the prevalence of fatigue and its' impact on functioning may be different at different times post-injury. Indeed, time post-injury has been found in a more recent study to be a significant predictor of day-to-day fatigue scores (Ponsford et al., 2012). Future studies should aim to address these issues.

Although there is some evidence that fatigue is associated with performance on certain cognitive tasks, particularly when a rapid response is required, the direction of this relationship is unclear and

it may be that fatigue impacts negatively on cognitive performance. Further studies, including HI patients who experience high levels of fatigue and HI patients who are not affected by fatigue could provide more clarity. A number of clinical factors, such as anxiety, depression, and sleep problems may mediate this relationship and future studies should control for these variables. Another area that requires further attention is that of learning. Some studies show that controls benefited from test practice, where HI patients did not show the same learning effects. This suggests that difficulties with learning may be indirectly contributing to poor performance and fatigue, as HI patients arguably need to process afresh stimuli that have been previously presented, whereas controls manage to 'automate' tasks to a greater extent. Lastly, the construct of 'effort' as conceptualised by the coping hypothesis may not be best measured by self-report, particularly for individuals with poor insight. It is therefore important to continue to explore better ways to measure fatigue and effort.

Clinical Implications

The current literature provides evidence that HI patients experience significant day-to-day fatigue and their performance on cognitive tasks, particularly under time pressure, is associated with fatigue. Considering the high prevalence and significant consequences of fatigue, it is important to assess fatigue in the context of rehabilitation. For HI patients who experience high levels of day-to-day fatigue, it is important to consider ways to manage the effects of fatigue, such as provision of rest breaks, distraction free environments, and treatment of underlying and/or contributing difficulties (e.g. anxiety, depression, sleep problems) with appropriate psychological or pharmacological interventions. In addition, in terms of return to work/education and engagement in rehabilitation it may be helpful to capitalise on individuals' ability to perform adequately when they have the opportunity to self-pace and to support over time their ability to perform adequately under time pressure.

Conclusions

HI patients experience greater day-to-day fatigue in comparison to controls, but not greater situational fatigue in relation to completing cognitive tasks. Fatigue is associated with HI patients' performance on vigilance, selective attention and processing speed tasks, but not with performance on divided attention tasks. Future research should control for confounding variables that might explain or mediate the relationship between performance and fatigue, such as sleepiness, sleep problems, anxiety, and depression. Homogeneous samples and clear characterisation of samples can help to explore possible injury-related factors, such injury severity and time post-injury.

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*The 10 articles included in this systematic review are preceded by an asterisk.

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Chapter 2
Major Research Project

Prevalence and types of sleep problems in head injury patients in rehabilitation.

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Lay Summary

Background and Purpose: Sleep problems are very common in head injury patients in the community. However, little is known about the sleep of head injury patients undergoing rehabilitation. The present study investigates how common sleep problems are in head injury patients in rehabilitation, what type of sleep problems they have and how these affect their recovery.

Methods: Twenty-three head injury patients undergoing inpatient rehabilitation were interviewed about their sleep and completed measures of sleep, mood, pain, and fatigue. In addition, they wore an actiwatch (a small watch-like device recording rest and activity patterns) and were asked to complete a sleep diary for a week. Information on their achievement of rehabilitation goals, frequency of aggression and engagement was collected from staff and casenotes.

Results: Fifteen participants (65%) had sleep problems. Of these, ten were diagnosed with a sleep disorder and no cause underlying sleep problems was found in five. Staff reported that sleep problems sometimes affect patients' ability to engage in rehabilitation activities. However, sleep was not significantly associated with rehabilitation variables. Poor sleep quality was associated with greater anxiety, fatigue, and daytime sleepiness.

Conclusions: This study found a high prevalence of sleep problems in a group of head injury rehabilitation inpatients. Sometimes poor sleep interferes with patients' rehabilitation. Implications of these results for understanding, assessing and treating sleep problems in head injury patients are discussed, along with suggestions for further research. Due to the small sample size, these conclusions are preliminary.

Abstract

Background: The prevalence of sleep problems in head injury (HI) patients in the community is high. Previous research suggests that HI patients with sleep problems require longer stays in rehabilitation units and that arousal disturbance disrupts engagement with rehabilitation activities. The present study explored the prevalence and types of sleep problem in patients with severe HI undergoing inpatient rehabilitation and whether sleep problems affect rehabilitation.

Methods: Actigraphy, a semi-structured sleep interview, and validated sleep measures were used to identify sleep problems (n=23). Information on rehabilitation, including percentage of goal achievement, frequency of aggressive behaviour, and engagement was collected retrospectively from staff and rehabilitation notes. Relevant factors including daytime sleepiness, fatigue, mood, and pain were explored.

Results: Fifteen participants (65.2%) had sleep problems, of which ten (43.8%) met diagnostic criteria for a sleep disorder, whereas in five cases (21.7%) no potential underlying cause for participants' sleep problems was identified. Sleep disorders in the sample were insomnia (21.7%), post-traumatic hypersomnia (8.7%), circadian rhythm disorder (8.7%), sleep apnoea (4.3%), periodic limb movement disorder (4.3%), and rhythmic movement disorder (4.3%). Sleep quality was not significantly associated with rehabilitation variables, but was estimated by senior staff as interfering with rehabilitation in 26% of the sample. Poor sleep quality was associated with greater anxiety, fatigue, and daytime sleepiness.

Conclusions: The majority of HI patients had sleep problems based on actigraphy and validated sleep measures. Poor sleep was associated with mood and arousal problems. Sleep problems may negatively affect the rehabilitation process and patients' wellbeing. However, the current study was not sufficiently powered to detect significant associations between sleep and rehabilitation. Due to the small sample size, these results are preliminary.

Introduction

There is a growing literature on sleep problems after head injury (HI). About 50% of HI patients experience a range of sleep problems including insomnia, post-traumatic hypersomnia, sleep apnoea, narcolepsy, and periodic limb movements (Mathias & Alvaro, 2012; Castriotta & Murthy, 2011). Although sleep problems are common in the general population, they are significantly more prevalent following HI. Mathias and Alvaro (2012) compared base rates from large-scale community studies with the prevalence of sleep disturbances in HI patients, and found that the HI group experienced significantly more sleep disturbances (50% vs 41%) and diagnosed sleep disorders (insomnia: 29% vs 10%, hypersomnia: 28% vs 10%, obstructive sleep apnea: 25% vs 2%, periodic limb movements: 8% vs 4%; narcolepsy: 4% vs .047%). Overall, it is estimated that HI patients are two to four times more likely to have sleep problems (Mathias & Alvaro, 2012). Some sleep disorders, such as sleep apnoea, have been linked with a high accident risk (Ellen et al., 2006) and may cause accidents on some occasions. However, on most occasions sleep difficulties in HI patients appear to develop or worsen post-injury (Rao et al., 2008; Ponsford, Parcell, Sinclair, Roper, & Rajaratnam, 2013) and frequently develop into chronic difficulties (Kempf, Werth, Kaiser, Bassetti, & Baumann, 2010).

The aetiology of sleep problems following HI is not fully understood, but it is likely to be multifactorial. Sleep problems in this population have been attributed to injury to specific brain regions, pathways, and neurotransmitter systems associated with sleep regulation (Ponsford et al., 2013). In addition to direct changes in brain structure and functioning, a number of secondary factors are associated with the presence of sleep disturbance in HI patients. In particular, anxiety and depression (Rao et al., 2008; Fichtenberg, Millis, Mann, Zafonte, & Millard, 2000; Parcell, Ponsford, Rajaratnam, & Redman, 2006; Quellet, Beaulieu-Bonneau, & Morin, 2006), fatigue (Clinchot, Bogner, Mysiw, Fugate, & Corrigan, 1998; Quellet et al., 2006) and pain (Beetar, Guilmette, & Sparadeo,

1996; Quillet et al., 2006) are associated with sleep problems in HI patients. A number of medications prescribed for pain, seizures, muscle relaxation or management of stress, anxiety or depressive symptoms can affect the quality, quantity, and architecture of sleep, for example by increasing or decreasing the amount of time spent in different sleep stages (Legros & Bazil, 2007). For inpatients, ward conditions, including lighting conditions, unusual noises, tense atmosphere, and loss of privacy may also be involved in the development of sleep problems (Cohen, Oksenberg, Snir, Stern, & Groswasser, 1992).

Sleep problems in rehabilitation

Although it is recognised by rehabilitation clinicians that many HI patients experience disturbed sleep-wake patterns, only two studies have investigated sleep problems in inpatient rehabilitation cohorts. In a questionnaire study of sleep complaints, Cohen et al. (1992) found that 73% of 22 HI patients reported sleep problems during rehabilitation. In this study HI inpatients in rehabilitation had more difficulties initiating and maintaining sleep, while discharged patients mostly suffered from excessive somnolence. Makley et al. (2008) reported disrupted sleep in 68% of 31 consecutive HI admissions to a rehabilitation unit. These findings suggest that the prevalence of sleep problems in HI rehabilitation inpatients is higher than in the general population or in HI patients in the community. However, they provide no information on the types of sleep problems experienced by rehabilitation inpatients after HI. Research regarding the types of sleep problems in HI rehabilitation inpatients is important to inform the assessment needs and the development of efficacious assessment methods and treatments.

It has been suggested that sleep problems can affect the rehabilitation process and outcomes. A survey found that disruption to rehabilitation activities was more frequent in acquired brain injury patients with sleep problems (Worthington & Melia, 2006). Another study found that HI patients with disturbed sleep had longer durations of rehabilitation (Makley et al., 2008). In addition, sleep

problems in HI patients are associated with poorer longer-term vocational outcomes (Clinchot et al., 1998) and exacerbated cognitive dysfunction (Mahmood, Rapport, Hanks, & Fichtenberg, 2004; Bloomfield, Espie, & Evans, 2010). The rehabilitation period is critical, as during this time a coordinated attempt is made to support patients to reach their optimal level of recovery. It is therefore important to understand whether sleep problems affect the rehabilitation process.

Aims and hypotheses

The primary aim of the present study is to examine the prevalence and types of sleep problems in patients with HI undergoing inpatient rehabilitation. The second aim of this study is to explore the relationship between sleep problems, patients' functioning and participation in the rehabilitation process. In addition, the associations between sleep quality, anxiety, depression, pain, sleepiness and fatigue will be explored.

Research Questions:

- What is the prevalence and types of sleep problems experienced by HI patients during inpatient rehabilitation?
- Do sleep difficulties affect the rehabilitation process? Specifically, three variables were selected and explored as indicators of engagement and progress with the inpatient rehabilitation process: percentage of goal achievement, staff-rated level of engagement, and frequency of aggressive behaviour.

Methods

Participants

Participants were recruited from two inpatient rehabilitation centres. Inclusion criteria were: (a) closed HI, (b) aged over 16 years old, (c) receiving rehabilitation for more than 2 weeks, (d) English as

first language. Exclusion criteria were: (a) undergoing rehabilitation for other types of brain injury, such as haemorrhagic stroke, (b) current severe mental illness, (c) learning disability, (d) neurodegenerative conditions, and (e) undergoing detoxification. Twenty-nine patients were identified by staff as suitable for the study. Six did not take part or were excluded; of these, two refused to take part, one did not meet the study criteria, one became unwell, one was discharged and one refused to wear the actiwatch and was excluded from the analysis. Therefore, the final sample included 23 participants, of which 19 had capacity to consent and 4 lacked capacity.

Procedure

Written information about the study and presentations to staff at the two rehabilitation centres were used to explain the aims of the study and inclusion/exclusion criteria. Rehabilitation staff identified potential participants and obtained verbal consent for the researchers to contact them. Staff provided information about potential participants' capacity to consent. Where participants were not thought to have capacity, verbal consent was obtained by staff from their next of kin/guardian for the researchers to contact them. Potential participants or their next of kin/guardian, for those who lack capacity to consent, were provided information about the study and a consent form to return should they wish to participate (see appendices 2.3 and 2.4 for examples of participants' information sheet and participants' consent form).

Participants with capacity: The interview and sleep measures were administered by the author and another Trainee Clinical Psychologist. Both researchers were trained in the administration of the interview, self-report measures, and actigraphy, and received regular research supervision. All participants were assessed in quiet rooms at the rehabilitation centres. The study measures were completed in one to three meetings lasting approximately 50 minutes each. Breaks were provided as required. Participants were provided with detailed guidance on the use of the actiwatch and on the completion of sleep diaries. A written reminder was placed at a prominent place in participants'

bedroom prompting them to complete their sleep diaries in the morning. In addition, staff were informed when the actigraphy/sleep data collection period started for participants and they were asked to prompt and support participants as required with the completion of diaries and with compliance with wearing the actiwatch. Staff were informed that participants have the right to withdraw any time and they were instructed to remove the actiwatch should they notice any disturbance or concern.

Participants lacking capacity: Self-report measures and sleep diaries were not administered in participants lacking capacity. Actigraphy and staff reports were used to gather information on their sleep and to support a sleep diagnosis, where relevant. This sub-group of participants was excluded from analyses pertinent to the second research question, which required completion of self-report measures.

Measures

Demographic, medical and injury information: Demographic, injury and medical information was collected from rehabilitation casenotes. Socio-economic status (SES) was rated using the Scottish Index of Multiple Deprivation (SIMD, 2009) on the basis of postcode prior to admission. The Glasgow Outcome at Discharge Scale (GODS) was used to assess disability. The scale is designed to assess disability after HI in an inpatient setting. It is derived from the Glasgow Outcome Scale-Extended (GOS-E), which assesses disability in the community after HI. The GODS has high inter-rater reliability (0.98) and high concurrent validity with the Disability Rating Scale ($r=0.73$). In terms of predictive validity the GODS is highly associated ($r=0.51$) with the GOS-E after discharge (McMillan, Weir, Ireland, & Stewart, 2013).

Sleep Interview: A semi-structured clinical interview based on the International Classification of Sleep Disorders (ICSD-II; American Academy of Sleep Medicine, 2005) was developed for the

purposes of the present study (Appendix 2.2). The interview was divided in three parts: (a) assessment of current sleep pattern, sleep changes post HI, historical and current sleep problems (b) screening for underlying sleep disorders, (c) attempted solutions for sleep problems.

The diagnostic process was based on the clinical interview in conjunction with actigraphy parameters, self-report measures, and staff reports. Where there were indications of potential sleep disorders, participants' symptoms were compared against the ICSD-II. In cases where participants met all required diagnostic criteria, a sleep disorder diagnosis was made. In cases where participants did not meet all the required criteria for a particular sleep diagnosis or where sleep problems were not consistent with any diagnostic category, a qualitative description of sleep characteristics is provided.

Actigraphy: Actigraphy is considered to be a valid objective measure of sleep patterns (Ancoli-Israel et al., 2003). The Actiwatch is a small wrist-worn device, which has an accelerometer and gathers information on activity levels. In the present study, the Actiwatch AW4 (Cambridge Nanotechnology) was used (figure 1). Stored data were downloaded to a computer for

Figure 1. Actiwatch



calculation of sleep measures using the relevant software (Actiwatch sleep analysis, 2001, version 1.9). Actigraphy data were used to obtain objective measures of sleep efficiency (SE: percentage of time asleep/total time spent in bed), sleep onset latency (SOL: time required for sleep initiation), total sleep duration (TST: total night-time sleep), and wake time after sleep onset (WASO: time spent awake after sleep initiation). Measures were gathered for a period of seven consecutive days.

Sleep diaries: Participants with capacity were asked to complete sleep diaries based on Morin and Espie (2003) for seven days in parallel with the actigraphy monitoring. Sleep diaries collected information on the timing and duration of sleep episodes during the day and night and on participants' perception of the quality of their sleep and their sense of feeling rested after sleep. Comparison of Actigraphic and diary data can assist with the interpretation of ambiguous data in Actigraphic recordings, for example by discriminating between nap and periods of inactivity.

Sleep quality: The Pittsburgh Sleep Quality Index (PSQI) was used to assess sleep quality. The PSQI comprises 19 items relating to seven components (sleep quality, sleep duration, sleep latency, habitual sleep efficiency, sleep disturbance, sleep medication and daytime dysfunction). High test-retest validity and reliability have been reported for the PSQI in patients with primary insomnia (Buysse et al., 1989) and it has been used to assess sleep in a HI population (e.g. Fichtenberg et al., 2000). Higher scores indicate poorer sleep quality with a global score >5 indicative of poor sleep quality.

Insomnia: The Insomnia Severity Index (ISI; Morin, 1993) is a seven-item self-report measure of subjective symptoms of insomnia. On a 5-point Likert-scale, the participant rates the degree of their difficulties over the last month. Scores range from 0-28 (0-7: no clinically significant insomnia, 8-14: sub-threshold insomnia, 15-21: clinical insomnia of moderate severity, 22-28: severe clinical insomnia). The scale has good internal consistency and concurrent validity (Bastien, Vallieres, & Morin, 2001) and has been used in research with HI patients (e.g. Quellet et al., 2006).

Sleepiness: The Epworth Sleepiness Scale (ESS) was used to assess daytime sleepiness (Johns, 1991). The ESS is an 8-item scale requiring participants to rate the likelihood of dozing in different situations on a four-point Likert-scale ranging from 0 (would never doze) to 3 (high chance of dozing). Scores range from 0-24 (0-9: normal range; 10-12 borderline; 12-24: abnormal). The scale

had good test-retest reliability (0.82) and internal consistency (0.88) (Johns, 1992) and it has been used with HI patients (e.g. Baumann, Werth, Stocker, Ludwig, & Bassetti, 2007).

Fatigue: The Barrow Neurological Institute (BNI) Fatigue Scale was used to assess fatigue. It consists of 10 items, each assessed on a scale ranging from 0 (rare problem) to 7 (problem present most of the time). The BNI has been developed for patients undergoing HI rehabilitation and has good internal consistency (0.94) and one factor explaining 65% of the variance (Borgaro, Gierok, Caples, & Kwasnica, 2004).

Pain: The Brief Pain Inventory (BPI) Short Form (Cleeland & Ryan, 1994) assesses pain intensity (severity) and the impact of pain on functioning (interference). The scale has good internal consistency, ranging from 0.80 to 0.87 for the severity items and from 0.89 to 0.92 for the interference items (Cleeland & Ryan, 1994).

Anxiety: The Hospital Anxiety and Depression Scale (HADS) was used to assess anxiety and depression symptoms (Zigmond & Snaith, 1983). The HADS is a brief 14-item self-report measure widely used to assess anxiety and depression in patients with medical conditions, which has been used widely with HI patients (for example Kempf et al., 2010). It consists of two subscales of seven items designed to measure levels of anxiety and depression. Responses are scored on a scale from 0 to 3, with a maximum of 21. The HADS is divided into four ranges to identify caseness: normal (0-7), mild (8-10), moderate (11-15), severe (16-21).

Engagement: The Hopkins Rehabilitation Engagement Scale (HRERS) is a 5-item staff-rated scale designed to assess engagement with inpatient rehabilitation. The items are rated on a 6-point scale, ranging from 'never' to 'always'. It assesses five dimensions of engagement: level of attendance, attitude toward therapy, need for verbal or physical prompts to facilitate initiation or maintenance

of engagement, acknowledgment of need for therapy, and level of active participation. The scale has high internal consistency ($\alpha=0.91$) and inter-rater reliability (0.733) and has been used to assess engagement with stroke, orthopaedic and spinal injury patients (Kortte et al., 2007). In the present study, the 'attendance' item was excluded, as for participants with higher levels of disability, attendance may not represent engagement. Therefore, the overall score was derived from 4 items and engagement scores ranged from 4-24 with higher scores representing better engagement.

Goal achievement: Information on participants' achievement of goals was collected retrospectively from the start of their admission until their exit from the study. Individualised person-centred goals were set for patients in both rehabilitation units within two weeks from their admission. Their progress was reviewed at six-week intervals. The percentage and nature of the goals achieved and not achieved was recorded and new goals were formulated by the rehabilitation teams. The percentage of goals achieved at each review was retrieved and the average number of goals achieved was calculated.

Aggression: The Modified Overt Aggression Scale (MOAS; Kay, Wolkenfeld, & Murrill, 1988) was used to assess aggressive behaviours displayed by the participants during the actigraphy period. The MOAS includes four scales: a. verbal aggression, b. aggression against property, c. autoaggression, d. physical aggression. The MOAS psychometric properties have been explored with psychiatric patients (Kay et al., 1988). The scale has good inter-rater ($r=0.85$) and test-retest reliability ($r=0.72$). The validity of the scale has been supported by its ability to discriminate between patients with a history of aggression, controls and patients without a history of aggression. The MOAS is used by many HI rehabilitation centres to monitor aggressive behaviour and to evaluate intervention outcomes.

Qualitative Information from staff: Senior rehabilitation staff completed a brief questionnaire for each participant focused on whether staff thought that participants had a sleep problem, whether poor sleep impacted on rehabilitation engagement and progress, and specific rehabilitation barriers related to poor sleep. The total number of participants who were perceived to have a sleep problem, the percentage of participants for whom sleep problems were considered to impact on their engagement and progress, and the frequency of different types of barriers was calculated.

Data Analysis

Justification of sample size: Previous studies on sleep problems in HI rehabilitation inpatients have sample sizes of 22 and 31 participants and found a prevalence of sleep problems in 68% and 73% of the sample respectively (Makley et al., 2008; Cohenet al., 1992). This study aimed to recruit 40 participants, of whom it was estimated (conservatively) that 20-30 would have sleep problems. No other studies comparing good and poor sleepers on engagement, goal achievement, or aggression were identified. The Makley et al. (2008) study looked into differences between participants with and without sleep problems on the Functional Independence Measure (FIM) at admission to rehabilitation. A very large effect size of $d=1.88$ was found. A more conservative estimate of a large effect size $d=1$ was adopted in the present study. Using a Bonferroni correction for multiple-comparisons, it was estimated that to detect statistically significant differences with power of 0.8 (one-tailed) with an alpha set at .0125 each group should have 21 participants. As the sample size ($N=23$) was smaller than planned and post-hoc power analysis indicated that the study was under-powered, correlational analysis rather than group comparisons was used.

Statistical analyses: The types and prevalence of sleep problems were calculated. The association between sleep self-report measures and rehabilitation variables was explored. Clinical variables highlighted by previous research as commonly co-occurring with sleep problems were explored, including anxiety, depression, fatigue, daytime sleepiness and pain. Associations between variables

were examined using Pearson's correlation for normally distributed variables and Spearman's for non-normally distributed variables. Cohen's (1992) criteria for effect sizes .1 (small effect), .3 (medium effect) and .5 (large effect) were adopted.

Ethical Approval

This study was approved by the Scotland A Research Ethics Committee (Appendix 2.5), the NHS Greater Glasgow and Clyde Research and Development Committee (Appendix 2.6), and ethics committees of the two rehabilitation centres.

Results

Demographic, Injury, and medical characteristics (see table 1)

Of the 23 participants, 4 (17.4%) lacked capacity to consent. Disability as assessed by the GODS was: lower severe disability (n=6), upper severe disability (n=10), upper moderate disability (n=3), and lower good recovery (n=4). Cause of injury included fall (47.8%), road traffic accident (26.1%), assault (21.7%) and other (4.3%). Four participants had a history of previous head injuries (17.4%). Eighteen participants (78.3%) had a history of drug and/or alcohol addiction. Medication use included anticonvulsants (69.6%), antidepressants (47.8%), anxiolytics (47.8%), antipsychotics (34.8%), regular pain medication (17.4%), thiamine (21.7%), hypnotics (17.4%) and other medication (60.8%) for physical health problems, such as heart conditions, diabetes, and hypertension. Four (17.4%) participants with poor sleep were prescribed sleep medication.

Table 1. Demographic, medical and injury information.

n=23 (100%)	
Age (in years)	43.91, SD=13.8
Gender	
Male	22 (95.6%)
Female	1 (4.4%)
Marital Status	
Married	1(4.4%)
Separated	6 (26%)
Single	16 (69.6%)
Employment status pre-injury	
Employed	6 (26.1%)
Unemployed	11 (47.8%)
Retired	3 (13%)
In education	3 (13%)
Education	
Secondary education	16 (69.6%)
Some post-secondary	6 (26.1%)
Degree	1 (4.4%)
Socioeconomic Deprivation	8.86, SD=6.30
Time post-injury (in months)	44.91, SD=69.62
Post-acute (<12 months)	11 (47.8%)
Chronic (>12 months)	12 (52.2%)
Epilepsy	9 (39.1%)

Research Question 1: Prevalence and types of sleep problems

Sleep problems: Actigraphy (for examples see Appendix 2.7) and subjective sleep measures (clinical interview, PSQI, ISI, ESS) were examined to identify sleep disorders in participants with capacity (n=19). Participants lacking capacity (n=4) could not complete self-report measures and sleep disorders were identified by Actigraphy and staff reports. Ten participants (43.4%) met diagnostic criteria for one or more sleep disorders. The prevalence of sleep disorders was insomnia 21.7%

(n=5), post-traumatic hypersomnia 8.7% (n=2), sleep apnoea 4.3% (n=1), rhythmic movement disorder 4.3% (n=1), irregular sleep-wake pattern 4.3% (n=1), and delayed sleep phase syndrome 4.3% (n=1). In addition, 5 participants (21.7%) had sleep problems, which did not meet diagnostic criteria. This sub-group included four participants who reported sleep problems and one participant who reported good sleep, but Actigraphy data and staff reports were suggestive of significant sleep problems. Hence, 15 out of 23 participants (65.2%) with sleep problems were identified of which 43.4% met diagnostic criteria for a sleep disorder (Table 2).

Table 2. Diagnoses of sleep disorders and descriptions of sleep problems not meeting diagnostic criteria (*italic*) found in the sample.

n=15	Type(s) of sleep problem(s) <i>or description of main sleep characteristics</i>	Sleep change post-injury	Sleep medication
01	Post-traumatic hypersomnia	Yes	Yes
02	Insomnia and sleep apnoea	No	No
03	<i>Delayed sleep onset</i>	Unclear	No
04	Post-traumatic hypersomnia	Yes	No
07	Irregular sleep pattern	Unclear	No
09	<i>Non-restorative sleep</i>	No	Yes
11	Insomnia	Yes	No
12	Insomnia	Yes	No
13	Periodic Limb Movement	No	No
14	Insomnia and rhythmic movement disorder	No	No
15	<i>Subclinical insomnia symptoms</i>	No	No
17	<i>Non-restorative sleep</i>	No	Yes
20	<i>Poor sleep quality and excessive sleepiness</i>	No	Yes
21	Insomnia	Yes	No
23	Delayed sleep phase syndrome	Unclear	No

Changes in sleep post-injury: Six participants (26.1%) reported that their sleep problems developed or worsened after the HI and six that their sleep problems preceded the HI (26.1%). In three cases (13%) it was unclear whether the onset of sleep problems was post- or pre-injury, as they lacked capacity and/or were unable to provide self-reports.

Association between Actigraphy and self-reported sleep quality: Correlational analysis was used to explore the congruence between participants self-reports and objective measures of sleep. Eleven out of 13 participants with sleep problems, who had capacity, self-rated their sleep quality as poor (>5). Two participants with sleep problems (periodic limb movements and delayed sleep onset) rated the quality of their sleep as good (PSQI=4). Pearson correlations were used to explore the association between self-reported sleep quality (PSQI; $n=19$, participants with capacity) and Actigraphy outcomes: Sleep efficiency, Sleep onset latency, Total sleep time, Wake time after sleep onset. Sleep efficiency was negatively correlated with higher PSQI scores, indicating that participants with lower sleep efficiency rated the quality of their sleep as poorer. Wake time after sleep was positively correlated with the PSQI, indicating that participants who spent more time in the night awake rated the quality of their sleep as poorer. Sleep onset latency and total sleep time were not significantly correlated with PSQI scores. Correlation coefficients varied between 0.421 and 0.464 indicating large effect sizes according to Cohen's (1992) indexes for correlation effect sizes (Table 3).

Table 3. Pearson correlations between Actigraphy and self-reported sleep quality

n=19	SE	WASO	SOL	TST
Pittsburgh Sleep	$r=-.458$	$r=-.464$	$r=.428$	$-.421$
Quality Index	$p=.048$	$p=.045$	$p=.068$	$p=.073$

Abbreviations: Sleep Efficiency (SE); Wake After Sleep Onset (WASO); Sleep Onset Latency (SOL);

Total sleep Time (TST).

Sleep diaries: Participants with capacity (n=19) completed sleep diaries for a week. Seven participants (30.4%) made entries during the weekdays with the support of a member of staff, but not on weekends when support was not available. One participant (4.3%) completed the sleep diary without staff support. Eleven participants, with no support from staff, did not make any diary entries. Due to the high volume of missing data, analyses on sleep diary data were not performed.

Sleep and rehabilitation

Associations between sleep and rehabilitation variables: Descriptive information on the percentage of goals achieved, the incidence of aggressive behaviour (MOAS), and scores on the engagement scale (HRERS) for participants with capacity is presented in Table 4.

Table 4. Goal achievement, Aggression, and Engagement Scores

	Goals Achieved (%) Mean (SD)	MOAS Mean (SD)	HRERS Mean (SD)
n=19	55.3 (18.24)	4.84 (10.83)	15.1 (4.83)

Abbreviations: Hopkins Rehabilitation Engagement Rating Scale (HRERS); Modified Overt Aggression Scale (MOAS)

Correlations (PSQI, Pearson; ISI; Spearman) were used to explore the associations between self-reported sleep measures on sleep quality and insomnia severity and rehabilitation variables (% of goals achieved, aggression, engagement). No significant associations were found between sleep quality or insomnia and percentage of goals achieved, aggression, or engagement. Correlation coefficients varied between 0.121 and 0.229, which represent small effect sizes according to Cohen's (1992) indexes for product-moment correlation effect sizes (Table 5).

Table 5. Correlations between self-report sleep and rehabilitation measures (PSQI, Pearson; ISI; Spearman).

n=19		HRERS	MOAS	Goals Achieved (%)
Pittsburgh	Sleep	r=-.180	r=-.169	r=.175
	Quality Index	p=.461	p=.904	p=.473
Insomnia	Severity	r=-.229	r=-.173	r=.121
	Index	p=.346	p=.479	p=.622

Abbreviations: Hopkins Rehabilitation Engagement Rating Scale (HRERS); Modified Overt Aggression Scale (MOAS)

Qualitative Information from rehabilitation staff: Senior rehabilitation staff provided opinions on participants' sleep and on the impact of sleep problems on rehabilitation. Staff correctly classified 10 out of 15 participants with sleep problems. The five participants (21.7%) where sleep problems were not identified by staff were two who met diagnostic criteria for insomnia, one who met diagnostic criteria for periodic limb movements, and two participants who reported experiencing sleep problems, which did not meet diagnostic criteria for a sleep disorder.

Staff perceived that sleep problems impacted negatively on participants' rehabilitation nearly always (n=1), most of the time (n=1), sometimes (n=4), seldom (n=2), never (n=2). Hence, sleep was thought to interfere with rehabilitation sometimes-nearly always in six out of 10 in this sub-group; that is 60% of participants perceived by staff as having sleep problems and in 26% of the whole sample. The most common sleep related barriers to rehabilitation identified by staff, were irritability/anger (n=8,) in bed during session times (n=6), sleepiness (n=5), excessive time in bed (n=2), low mood (n=2), concentration difficulties (n=1), and fatigue (n=1).

Exploratory Analysis: Clinical characteristics and sleep

Associations between clinical characteristics and self-report sleep measures: Descriptive information on anxiety, depression, fatigue, sleepiness and pain in participants with capacity is presented in Table 6.

Table 6. Anxiety, depression, fatigue, sleepiness and pain scores.

n=19	Anxiety	Depression	Fatigue	Sleepiness	Pain
Mean (SD)	8.37 (6.0)	7.68 (5.48)	2.84 (5.48)	5.16 (5.14)	.94 (1.54)

Correlational analysis (n=19; participants with capacity) was used to explore the associations between sleep self-report measures (PSQI, Pearson Test; ISI, Spearman's Rho) and clinical symptoms frequently co-occurring with sleep problems (pain, fatigue, sleepiness, anxiety and depression). PSQI scores were significantly associated with anxiety, fatigue and daytime sleepiness, indicating that participants with poorer self-reported quality of sleep tended to have greater anxiety, fatigue, and sleepiness. Higher insomnia severity scores were associated with higher levels of anxiety, depression, fatigue and pain. Correlation coefficients varied between 0.699 and 0.397, which indicate large effect sizes according to Cohen's (1992) indexes for product-moment correlation effect sizes (see table 7).

Table 7. Associations between sleep quality, insomnia severity, anxiety, depression, fatigue, sleepiness and pain (PSQI, Pearson Test; ISI, Spearman's Rho).

n=19	Anxiety	Depression	Fatigue	ESS	Pain
PSQI	r=.611 p=.005	r=.408 p=.083	r=.683 p=.001	r=.529, p=.032	r=.402 p=.088
ISI	r=.591 p=.008	r=.519 p=.023	r=.699 p=.001	r=.397 p=.093	r=.459 p=.048

Abbreviations: Pittsburgh Sleep Quality Index (PSQI), Epworth Sleepiness Scale (ESS); Insomnia Severity Index (ISI)

Discussion

Prevalence and types of sleep problems

The present study confirms and extends the findings of previous studies (Cohen et al., 1992; Makley et al., 2008) that sleep problems are very common in HI patients undergoing rehabilitation. Fifteen out of 23 participants (65.2%) had sleep problems, of which ten (43.8%) met diagnostic criteria for a sleep disorder, whereas in five cases (21.7%) no potential underlying cause for participants' sleep problems was identified. The overall prevalence of sleep problems in this study was similar to that reported in previous studies (72%, N=22; 68%, N=31), despite methodological differences. Makley et al. (2008) used staff-rated hourly sleep logs kept at night-time and Cohen et al. (1992) used a questionnaire screening to identify sleep problems. The present study is the first to use both validated self-report measures and Actigraphy to identify sleep problems in this population. However, the modest number of patients (n=23) only allows preliminary conclusions to be made about the prevalence of sleep problems in the population.

In this study, insomnia (21.7%), post-traumatic hypersomnia (8.7%), and circadian rhythm disorder (8.7%) were the most common sleep disorders. Sleep apnoea (4.3%) and periodic limb movement disorder (4.3%) were less common. In five participants (21.7%) no underlying disorder for sleep problems was identified. Similarly, a prospective study exploring sleep with HI patients with a range of injury severity six months post-injury found that in about half of the cases (43%) sleep problems did not fit criteria for a specific sleep disorder diagnosis (Baumann et al., 2007). A meta-analysis (Mathias & Alvaro, 2012) combined the results of nine studies which used formal diagnostic criteria and found that the prevalence of sleep disorders in HI patients with mixed severity of injury recruited predominantly from the community was: insomnia (29%), hypersomnia, (28%), sleep apnea (25%), and periodic limb movement disorder (8%). Typically, estimates of the prevalence of post-HI sleep disturbances range widely between studies, probably because of differences in

assessment methods and sample characteristics. The current study was the first to focus on severe HI patients in rehabilitation and provides a preliminary indication of prevalence rates in this population.

About one in three participants (31.6%; $n=19$) reported that their sleep problems developed or worsened after their HI. In previous studies self-reported sleep changes after HI are more commonly reported (80%) by patients with mixed severity of injury who have undergone rehabilitation (Parcell et al., 2006; Ponsford et al., 2013). However, the present study attempted to determine whether the onset of sleep problems was pre- or post-injury, where previous studies attempted to detect any reported changes to sleep post-injury, such as changes in bed-time and difficulties falling asleep. About one in three participants (31.6%; $n=19$) reported that their sleep problems pre-dated their injury. This finding suggests that for a proportion of HI patients in rehabilitation, sleep problems may be pre-morbid and not related to injury-related changes.

The percentage of self-reported history of drug and alcohol misuse in the sample was 78%. This is considerably higher in comparison to the general population in Scotland. According to a national survey by Information Services Scotland (ISD, 2011a) the estimated prevalence of problem drug (opiates and benzodiazepines) use amongst the 18-64 age group in 2009/10 was 1.71%. According to the Scottish Health Survey which used an alcohol screening tool (CAGE) to detect possible problematic drinking, the estimated prevalence of problem drinking is 14% for men and 9% for women over the age of 16 years old (ISD, 2011b). Although current substance use was unlikely to be directly related to sleep problems in this sample, as all participants were abstinent from drugs and alcohol during their rehabilitation admission, the high prevalence of drug and alcohol use in the sample raises questions about the possible relationship between substance misuse and the high prevalence of sleep problems. Research findings suggest that substances are frequently used to facilitate sleep initiation (Johnson, Roehrs, Roth, & Breslau, 1998), while at the same time alcohol

and drugs digestion has significant effects on the architecture and quality of sleep (Ebrahim, Shapiro, Williams, & Fenwick, 2013).

In addition to the high prevalence of drug and alcohol history, 70% of the sample were on anticonvulsant medication and the prescription of psychotropic medication was substantially higher than the estimated prevalence in the general population in Scotland (ISD, 2011c); anti-depressant (47.8% vs 11.3%) , anxiolytic (47.8% vs 3.2%), anti-psychotic (34.8% vs 0.97%) medication. Medication can affect the quality, quantity, and architecture of sleep, for example by increasing or decreasing the amount of time spent in different sleep stages (Legros & Bazil, 2007). As polypharmacy in severe HI patients is common, further research is required to explore whether and how medication use is implicated in the high prevalence of sleep problems and sleep disorders found in this population.

Senior rehabilitation staff identified most of the patients that had sleep disorders. Senior staff did not identify sleep problems in five participants, four of which reported during their interview that they had poor sleep quality, which significantly affected their daily functioning. Despite significant distress about their sleep, these participants had not communicated their sleep difficulties to rehabilitation clinicians. One participant under-reported his sleep problems, which possibly related to poor insight due to executive function problems (this was supported by his neuropsychological profile, history and staff reports). These findings suggest that some HI patients may not report or seek help spontaneously for sleep problems and some patients may not have insight into their sleep problems. Participants self-report of sleep quality (PSQI; n=19) was significantly associated with the average time spent awake during the night and sleep efficiency. These associations between self-reported sleep quality and Actigraphy measures indicate that HI patients' self-reports are congruent with objective sleep measures.

Sleep and rehabilitation

Exploratory analysis found no significant associations between self-report sleep measures and aggression, rehabilitation engagement or goal achievement. However effect sizes were small, and post-hoc power analysis using G-Power indicated that the power to detect an effect was also low (0.08 to 0.16). Therefore, the study may have failed to detect significant associations between sleep and rehabilitation variables, if they existed. Reports from senior staff suggest that sleep problems affect patients' ability to engage and benefit from rehabilitation frequently and in some cases sleep problems appear to have a significant impact on patients' ability to engage and benefit from rehabilitation.

Consistent with findings in studies with HI patients in the community (Ponsford et al., 2013; Parcell et al., 2006; Quillet et al., 2006), sleep problems were associated with anxiety, depression, fatigue, daytime sleepiness and pain. Overall, these findings indicate that a number of clinical problems tend to co-occur with poor sleep in HI rehabilitation inpatients. As the current study and previous studies have used correlational designs, the direction of these associations is unclear. Further studies are required to explore the extent to which poor sleep is secondary symptom to pain, fatigue and mood disorders or if it contributes to the development and maintenance of these difficulties.

It is frequently cited in the literature that poor sleep can affect patient rehabilitation, recovery, and outcomes. To date only one previous study (Makley et al., 2008) with a small sample (n=31) has explored this hypothesis with HI rehabilitation patients and found longer durations of rehabilitation in patients with poor sleep. A survey of acquired brain injury patients in rehabilitation found that disruption to rehabilitation activities was more frequent in patients with sleep problems (Worthington & Melia, 2006). It is unclear whether the rehabilitation variables explored in the present study were sensitive enough to detect whether sleep problems relate to difficulties in engagement with rehabilitation. The most commonly reported sleep-related barriers for staff were

irritability/anger, in bed during session times, and sleepiness. In the present study, it was not possible to explore disruptions in patients' attendance. Considering staff reports and the associations between sleep measures and mood, fatigue, and sleepiness together, the present study provides some preliminary indications for the hypothesis that sleep problems may potentially impact on rehabilitation. As the present study did not achieve adequate power it is not possible to conclude whether sleep problems affect HI patients' rehabilitation. Further exploration with larger samples is required to establish whether or not sleep problems contribute to difficulties in benefiting from rehabilitation, to rehabilitation progress and outcomes.

Clinical Implications

Sleep problems are very common in HI rehabilitation inpatients. Considering the frequent co-occurrence of sleep problems with anxiety, depression, fatigue, and daytime sleepiness, it may be beneficial to consider the assessment and treatment of sleep problems in conjunction with interventions aimed at improving the psychological wellbeing and cognitive functioning of HI inpatients (Ponsford et. al., 2013).

Senior rehabilitation staff are adept at identifying sleep problems in most patients. However, some severe HI cases are missed, perhaps because many of the symptoms associated with sleep problems overlap with those of HI and mood problems, and many severe HI patients in rehabilitation may not spontaneously report or seek help for sleep problems. Screening sleep quality in rehabilitation centres may be helpful in order to determine when there is a need for more detailed sleep assessments and treatment. In the present study, patients' scores on the PSQI were associated with Actigraphy measures, indicating that the PSQI may be a useful screening tool for sleep problems in most HI patients in rehabilitation.

When the need for more thorough assessment of sleep problems is identified, sleep diaries, which are routinely used in clinical practice as a cost-effective and reliable way of assessing sleep may not be suitable for this population unless sufficient support is provided from rehabilitation staff. Sleep charts and actigraphy may be suitable alternatives as they place less demands on HI patients' prospective memory skills and can be used with patients with communication difficulties and/or poor insight. The use of objective measures should be considered for patients with severe HI who are not able to communicate sleep problems verbally or who lack insight.

In cases where sleep problems affect patients' recovery and interventions are considered, accurate diagnosis of the possible sleep disorders underlying patients' poor sleep is important for the development of appropriate interventions. Findings from this study support that objective measures, in addition to self-reports and validated measures, are required in order to accurately identify sleep disorders. Symptoms of diverse disorders frequently overlap and patients self-reports alone are not sufficient for accurate differential diagnosis. For example, Ayalon, Borodkin, Dishon, Kanety, and Dagan (2007) used objective assessment methods and found that 36% of HI patients who had been diagnosed with insomnia, in fact suffered from circadian sleep disorders. As pharmacological and psychological treatments are distinct for different sleep disorders, it is important to develop evidence-based approaches for the assessment and management of sleep disorders after HI to support clinical practice.

Limitations and future directions

This study has several methodological limitations. The modest sample size limits the generalisability of the findings on the prevalence, types and correlates of sleep problems. Another consideration is that patients are frequently unaware of sleep apnoea and periodic limb movement disorder. As polysomnography (the gold standard for detecting these difficulties) could not be used in the current study for practical reasons, it is possible that the prevalence of these disorders may have been

underestimated. Individuals with HI may not be accurate in reporting the history of their sleep problems, which may have influenced findings on the onset of sleep problems. In addition, analysis of sleep diaries and comparison to actigraphy data was not possible due to poor completion of sleep diaries. As the sample was small and adequate power was not achieved, it is possible that significant relationships between sleep quality and rehabilitation variables may have been missed.

Further studies with larger samples are required to extend the results of the current study in relation to the prevalence, types, and correlates of sleep problems in HI rehabilitation settings and to further explore the impact of poor sleep on rehabilitation with adequate power. Second, prospective studies which include information over the course of rehabilitation (admission to discharge) may be more suitable for examining the impact of sleep on progress, including rehabilitation length and outcomes at discharge. Third, the complex interactions between sleep, depression, anxiety, fatigue, pain and sleepiness deserve further attention. Longitudinal studies would be better suited to explore the development of these interrelated difficulties. Lastly, consensus in assessment methods and clear characterisation of samples can assist future research with examining differences related to possible mediating variables, including severity of injury and time post-injury.

Conclusions

Sleep problems are common in severe HI patients undergoing rehabilitation. Sleep problems in this population are diverse and are associated with anxiety, depression, sleepiness, and fatigue. Staff perceive sleep problems to negatively affect patients' rehabilitation progress at times. Studies with larger samples are required, as the current study was not sufficiently powered to detect significant associations between sleep and rehabilitation progress. Use of objective measures, such as actigraphy, sleep charts, and/or use of sleep diaries with considerable support should be considered for the assessment and accurate diagnosis of sleep problems.

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Chapter 3

Advanced Clinical Practice I: Reflective Critical Account (Abstract only)

A reflective account on co-facilitating two Cognitive Stimulation Therapy groups.

Eleni Morfiri

Abstract

Continuous reflective practice is of vital importance during the process of training in Clinical Psychology, as well as post-qualification, as by facilitating learning from practice it leads to a process of continuous development. The basis for this reflective account is my experience of co-facilitating two Cognitive Stimulation Groups (CST) for people with dementia. I draw upon Kolb's Learning Cycle (1984) to structure my reflections, which relate broadly to four areas of my professional development: a. development of my skills in delivering CST, b. development of my ability in conducting joint work with colleagues from other professions, c. development of my understanding of issues related to the systems within which interventions are delivered, and d. development of my understanding of the exciting possibilities for Clinical Psychologists in shaping the care of people with dementia. Throughout this account, I refer to the multiple influences on my development, including learning from previous clinical experiences, from supervision, and from teaching, as well as from personal experiences. I proceed to consider how my learning from these specific experiences can be generalised to other contexts and roles and how it will inform my future practice. In doing so, I explore how these ideas can be linked with the National Occupational Standards for Clinical Psychologists (BPS, 2006), the New Ways of Working for Clinical Psychologists (BPS, 2007), and the SIGN guideline for patients with dementia (SIGN, 2006). Finally, I reflect on the process of writing this reflective account.

Chapter 4

Advanced Clinical Practice II: Reflective Critical Account (Abstract only)

Shifting cultures: A reflective account on the process of developing formulations to support clients' recovery within an Inpatient Multidisciplinary Team.

Eleni Morfiri

Abstract

Reflection is a systematic process that enhances the experience of learning by providing opportunities to think about one's own practice, to develop further one's insight into their ways of working, and the contexts within which practice takes place. Reflection is particularly valued by Clinical Psychologists as a profession, as there is wide recognition that it facilitates continuous professional development, as well as personal growth. The basis for this reflective account is my experience of working in a multidisciplinary Inpatient Child Service. I draw upon Gibb's model of reflection (1988) to structure my reflections, which relate to my experiences of using formal and informal opportunities to share formulations, to engage the team in a joint process of considering psychological explanations of dis-ease and to facilitate the team's reflecting thinking at times when psychological understandings were not considered. Throughout this account, I refer to the multiple influences on my development, including learning from previous clinical experiences, from supervision, and from teaching, as well as from personal experiences. I consider how my learning from these specific experiences can be generalised to other contexts and roles and how it will inform my future practice. At the same time, I explore how these ideas can be linked with the National Occupational Standards for Clinical Psychologists (BPS, 2006), the New Ways of Working for Clinical Psychologists (BPS, 2007), and the DCP good practice guidelines on the use of psychological formulations (BPS, 2011). Finally, I reflect on the process of writing this reflective account.

Appendix 1: Systematic Review

Appendix 1.1 Neuropsychological Rehabilitation, Instructions for Authors

General guidelines

- This journal accepts original (regular) articles, scholarly reviews, and book reviews.
- Manuscripts are accepted in English. British English spelling and punctuation are preferred. Please use double quotation marks, except where “a quotation is ‘within’ a quotation”. Long quotations of words or more should be indented without quotation marks.
- Manuscripts should be compiled in the following order: title page; abstract; keywords; main text; acknowledgements; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figure caption(s) (as a list).
- [Abstracts](#) of 150-200 words are required for all manuscripts submitted.
- Each manuscript should have up to 5 [keywords](#).
- The style and format of the typescripts should conform to the specifications given in the Publication Manual of the American Psychological Association (6th ed.).
- All parts of the manuscript should be double-spaced, with margins of at least one inch on all sides. Number manuscript pages consecutively throughout the paper.
- Search engine optimization (SEO) is a means of making your article more visible to anyone who might be looking for it. Please consult our guidance [here](#).
- Section headings should be concise.
- All authors of a manuscript should include their full names, affiliations, postal addresses, telephone numbers and email addresses on the cover page of the manuscript. One author should be identified as the corresponding author. Please give the affiliation where the research was conducted. If any of the named co-authors moves affiliation during the peer review process, the new affiliation can be given as a footnote. Please note that no changes to affiliation can be made after the manuscript is accepted. Please note that the email address of the corresponding author will normally be displayed in the article PDF (depending on the journal style) and the online article.
- All persons who have a reasonable claim to authorship must be named in the manuscript as co-authors; the corresponding author must be authorized by all co-authors to act as an agent on their behalf in all matters pertaining to publication of the manuscript, and the order of names should be agreed by all authors.
- Biographical notes on contributors are not required for this journal.
- Tables should be kept to the minimum. Each table should be typed double spaced on a separate page, giving the heading, e.g., "Table 2", in Arabic numerals, followed by the legend, followed by the table. Make sure that appropriate units are given. Instructions for placing the table should be given in parentheses in the text, e.g., "(Table 2 about here)".
- Results of statistical tests should be given in the following form:
"... results showed an effect of group, $F(2, 21) = 13.74$, $MSE = 451.98$, $p < .001$, but there was no effect of repeated trials, $F(5, 105) = 1.44$, $MSE = 17.70$, and no interaction, $F(10, 105) = 1.34$, $MSE = 17.70$."
Other tests should be reported in a similar manner to the above example of an F -ratio. For a fuller explanation of statistical presentation, see the *APA Publication Manual* (6th ed.).
- Abbreviations that are specific to a particular manuscript or to a very specific area of research should be avoided, and authors will be asked to spell out in full any such abbreviations throughout the text. Standard abbreviations such as RT for reaction time, SOA for stimulus onset asynchrony or other standard abbreviations that will be readily understood by readers of the journal are acceptable. Experimental conditions should be named in full, except in tables and figures.

- Footnotes should be avoided unless absolutely necessary. Essential footnotes should be indicated by superscript figures in the text and collected on a separate page at the end of the manuscript.
- Please supply all details required by any funding and grant-awarding bodies as an Acknowledgement on the title page of the manuscript, in a separate paragraph, as follows:
 - *For single agency grants:* "This work was supported by the [Funding Agency] under Grant [number xxxx]."
 - *For multiple agency grants:* "This work was supported by the [Funding Agency 1] under Grant [number xxxx]; [Funding Agency 2] under Grant [number xxxx]; and [Funding Agency 3] under Grant [number xxxx]."
- Authors must also incorporate a [Disclosure Statement](#) which will acknowledge any financial interest or benefit they have arising from the direct applications of their research.
- For all manuscripts non-discriminatory language is mandatory. Sexist or racist terms must not be used.
- Authors must adhere to [SI units](#) . Units are not italicised.
- When using a word which is or is asserted to be a proprietary term or trade mark, authors must use the symbol ® or TM.

Full details can be accessed at:

<http://www.tandfonline.com/action/authorSubmission?journalCode=pnrh20&page=instructions>

Appendix 1.2. Search Strategy

Head injury, traumatic brain injury, brain injury, TBI, intracranial injury, craniocerebral trauma, head trauma.

(head injur*, traumatic brain injur*, brain injur*, intracranial injur*, craniocerebral traum*, head traum*)

AND

Fatigue, mental fatigue, lassitude, tiredness, vigour, energy, effort, mental effort, exhaustion.

(fatig*, mental fatig*, lassitude*, tir*, vigo*, energ*, effort*, mental effort*)

Appendix 1.3. Excluded studies and reasons for exclusion

1	Borgaro, S. R., Baker, J., Wethe, J. V., Prigatano, G. P., & Kwasnica, C. (2005). Subjective reports of fatigue during early recovery from traumatic brain injury. <i>Journal of Head Trauma Rehabilitation</i> , 20(5), 416-425.	Use of screen for cognitive functions
2	Englander, J., Bushnik, T., Oggins, J., & Katznelson, L. (2010). Fatigue after traumatic brain injury: Association with neuroendocrine, sleep, depression, pain, and other subjective complaints. <i>Brain Injury</i> , 24(3), 390-391. <i>Journal of head trauma rehabilitation</i> , 23(1), 33-40.	Use of self-report measure (NFI memory)
3	Godefroy, O., Cabaret, M., & Rousseaux, M. (1994). Vigilance and effects of fatigability, practice and motivation on simple reaction time tests in patients with lesion of the frontal lobe. <i>Neuropsychologia</i> , 32(8), 983-990.	Unsuitable sample: Patients with frontal lesions related to operation for aneurism
4	Juengst, S., Skidmore, E., Arenth, P. M., Niyonkuru, C., & Raina, K. D. (2013). Unique contribution of fatigue to disability in community-dwelling adults with traumatic brain injury. <i>Archives of Physical Medicine and Rehabilitation</i> , 94(1), 74-79.	Self-report scale for executive functioning
5	Melamed, S., Rahamani, L., Greenstein, Y., Groswasser, Z., & Najenson, T. (1985). Divided attention in brain-injured patients. <i>Scandinavian Journal of Rehabilitation Medicine - Supplementum</i> , 12, 16-20.	No measure of fatigue or effort
6	Melamed, S., Stern, M., Rahmani, L., Groswasser, Z., & Najenson, T. (1985). Attention capacity limitation, psychiatric parameters and their impact on work involvement following brain injury. <i>Scandinavian Journal of Rehabilitation Medicine. Supplement</i> , 12, 21-26.	No measure of fatigue or effort
7	Ouellet, M. -, & Morin, C. M. (2006). Fatigue following traumatic brain injury: Frequency, characteristics, and associated factors. <i>Rehabilitation Psychology</i> , 51(2), 140-149.	Self-report on cognition

8	Stulemeijer, M., van der Werf, S., Bleijenberg, G., Biert, J., Brauer, J., & Vos, P. E. (2006). Recovery from mild traumatic brain injury: A focus on fatigue. <i>Journal of Neurology</i> , 253(8), 1041-1047.	Self-report on concentration problems
9	Stuss, D. T., Stethem, L. L., Hugenholtz, H., Picton, T., Pivik, J., & Richard, M. T. (1989). Reaction time after head injury: Fatigue, divided and focused attention, and consistency of performance. <i>Journal of Neurology, Neurosurgery & Psychiatry</i> , 52(6), 742-748.	Lack of fatigue measure
10	Tiersky, L. A., Cicerone, K. D., Natelson, B. H., & DeLuca, J. (1998). Neuropsychological functioning in chronic fatigue syndrome and mild traumatic brain injury: A comparison. <i>Clinical Neuropsychologist</i> , 12(4), 503-512.	Between group comparisons- No associations between fatigue and performance
11	Ponsford, J. L., Ziino, C., Parcell, D. L., Shekleton, J. A., Roper, M., Redman, J. R., et al. (2012). Fatigue and sleep disturbance following traumatic brain injury-their nature, causes, and potential treatments. <i>Journal of Head Trauma Rehabilitation</i> , 27(3), 224-233.	Review of 2 previous studies (included in the review) conducted by the same group.
12	Bushnik, T., Englander, J., & Wright, J. (2008). The experience of fatigue in the first 2 years after moderate-to-severe traumatic brain injury: A preliminary report. <i>Journal of Head Trauma Rehabilitation</i> , 23(1), 17-24.	Self-report scale on cognition
13	Bushnik, T., Englander, J., & Wright, J. (2008). Patterns of fatigue and its correlates over the first 2 years after traumatic brain injury. <i>Journal of Head Trauma Rehabilitation</i> , 23(1), 25-32.	Self-report scale on cognition
14	Bay, E., & De-Leon, M. B. (2011). Chronic stress and fatigue-related quality of life after mild to moderate traumatic brain injury. <i>Journal of Head Trauma Rehabilitation</i> , 26(5), 355-363.	No measure of cognition
15	Ponsford, J., & Ziino, C. (2003). Fatigue and attention following traumatic brain injury. <i>Zeitschrift Für Neuropsychologie</i> , 14(3), 155-163.	Published in German

Appendix 1.4. Methodological Quality Evaluation Criteria

Study ID (author, year):

Study Objectives	Ratings
Explains the scientific background and rationale for the study	Well covered=2 Partially or poorly addressed=1 Not addressed=0
The study addresses an appropriate and clearly focused question?	Well covered=2 Partially or poorly addressed=1 Not addressed=0
Specific study hypotheses are stated	Well covered=2 Partially or poorly addressed=1 Not addressed=0
Study design	
Study design is appropriate to test the hypotheses.	Yes=2 No=0
Control group included	Yes=2 No=0
Matching	Group matched on IQ and at least 2 demographic variables=2 Group not matched on IQ or at least 2 demographic variables=1 Not addressed=0
Sampling/recruitment	
Recruitment	Geographical cohort or random sample=2 Convenience or volunteer sample (i.e. rehabilitation setting)=1 Unclear how sample was obtained=0
The study indicated how many of the people who were asked to take part did so in each of the groups being studied	Yes=2 No=0
Inclusion and exclusion criteria were clearly defined and appropriate to test the study hypothesis	Yes=2 No=0
Method	
A description of the methodology used is included.	Well described=2 Partially or poorly described=1 Not described=0
Standardised procedural protocol used (i.e. same procedure/protocol was used within/between groups)	Use of standardised methods is reported for eliciting information from respondents <i>and</i> interviewer training, supervision, enlistment of respondents, processing data=2 Use of standardised methods is reported for eliciting information from respondents=1 No/not reported=0
Sample Characterisation	
The characteristics of the participants and controls included in the study were clearly described to allow adequate comparisons to be made.	Well described=2 Partially or poorly described=1 Not described=0
The study provided adequate description of head injury severity experienced by sample	Injury severity defined and diagnosed by appropriate methods (GCS) and a range is used (e.g. mild to severe)=2 One of the above reported=1

	Not reported=0
Measurement	
Fatigue (or mental effort) is clearly defined	Yes=2 No=0
Standardised and/or valid and reliable measures used for fatigue (or mental effort)	Well addressed =2 Partially or poorly addressed=1 Not addressed/reported=0
Measure of instantaneous fatigue (or mental effort) is included	Yes=2 No=0
Main dependent variable is clearly defined	Yes=2 No=0
Standardised and/or valid and reliable measures used for dependent variable	Well addressed =2 Partially or poorly addressed=1 Not addressed/reported=0
Analysis	
The statistical analysis employed is suitable to address the primary study question	Yes=2 No=0
Demonstrates that assumptions of statistical tests have been met	Well covered=2 Partially or poorly covered=1 No/not reported=0
Power calculation or effect sizes reported for main outcome variable	Yes=2 No=0
Consideration of cofounders (injury severity, time since injury, anxiety/depression, sleep problems)	Well addressed (3 or more taken into consideration)=2 Partially or poorly addressed (less than 3)=1 Not addressed/reported=0
Satisfactory confidence intervals are reported.	> 90%=2 < 90% / not reported=0
Results	
Reports outcome events unadjusted estimates and, if applicable, confounder-adjusted estimates)	Well described=2 Partially or poorly described=1 Not described=0
Discussion	
Provides summary of key results with reference to study Objectives	Yes=2 No=0
Summarises main results of the study taking into consideration results from other studies	Well described=2 Partially or poorly described=1 Not described=0
Acknowledges and discusses limitations of the study	Yes=2 No=0
Ethical approval	
Ethical approval obtained?	Yes=2 No/not reported=0
Total score: _____ /56 Score (%): _____ % Quality rating of study: _____	< 24% = poor 25 – 49% = low 50 – 74% = moderate >75% = high

Appendix 1.5. Detailed Breakdown of Checklist Ratings per Study

	Ashman et al (2008)	Azouvi et al (2004)	Belmont et al (2009)	Chaumet et al (2008)	Fry et al (2010)	Johansson et al (2009)	Riese et al (1999)	Sinclair et al (2013)	Ziino et al (2006a)	Ziino et al (2006b)
Background	2	2	1	1	2	1	2	2	2	2
Question	2	2	2	1	2	1	2	2	2	2
Hypotheses	2	2	2	0	2	0	1	1	2	2
Design	1	1	2	1	2	1	2	2	2	2
Control Group	2	2	2	2	2	2	2	2	2	2
Matched	0	1	1	1	0	1	1	1	0	0
Recruitment	1	1	1	1	1	1	1	1	1	1
Dropout	2	0	0	0	0	0	0	0	2	0
I/E criteria	2	2	2	2	2	2	2	2	2	2
Method	2	2	2	1	1	1	2	2	2	2
Protocol	1	1	1	1	1	1	1	1	1	1
Demographics	1	2	2	0	1	1	1	1	2	2
Severity	0	2	2	0	2	0	1	1	2	2
Fatigue Def.	2	0	0	0	2	0	0	0	2	2
Fatigue Meas.	2	0	2	2	0	0	0	2	2	2
Situational	2	2	2	0	2	0	2	0	2	2
OV Definition	2	2	2	0	2	0	2	2	2	2
OV Measure	1	2	2	0	2	0	1	1	1	1
Analysis	1	2	2	0	2	0	2	2	2	2
Assumptions	0	0	0	2	2	2	0	2	0	1
ES/Power	2	0	0	0	0	0	0	0	2	0
Confounders	1	1	1	0	0	1	0	2	2	2
Outcomes	1	2	2	1	1	2	1	2	2	2
Summary	2	2	2	2	2	2	2	2	2	2
Interpretation	2	2	2	2	2	1	1	2	2	2
Limitations	2	0	2	0	2	2	0	2	2	0
Ethics	2	0	0	2	2	2	0	2	2	2
Total	40-71.4%	35-62.5%	39-69.6%	22-39.3%	39-69.6%	24-42.8%	29-51.8%	39-69.6%	47-83.9%	42-75%
Rating	Moderate	moderate	moderate	low	moderate	low	moderate	moderate	high	high

Appendix 2: Major Research Project

Appendix 2.1. Journal of the International Neuropsychological Society Instructions for Authors

JOURNAL OF THE INTERNATIONAL NEUROPSYCHOLOGICAL SOCIETY

Instructions for Contributors

Aims and Scope: **JINS** is the official journal of the International Neuropsychological Society, an organization of over 3,700 international members from a variety of disciplines. Our editorial board is comprised of internationally known experts with a broad range of interests. **JINS** publishes empirically-based articles covering all areas of neuropsychology and the interface of neuropsychology with other areas, such as cognitive neuroscience. Theoretically driven work that has clinical implications is of particular interest. To assure maximum flexibility and to promote diverse mechanisms of scholarly communication, the following formats are available.

Regular Research: Maximum of 5,000 words (not including abstract, tables, figures, or references) and a 200 word abstract. Regular Research papers are original, creative, high quality papers covering all areas of neuropsychology; focus may be experimental, applied or clinical.

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Neurobehavioral Grand Rounds: Maximum of 5,000 words with an informative literature review (not including abstract, tables, figures, or references) and a 200 word abstract. Neurobehavioral Grand Rounds are unique case studies, which are usually published with an introduction by an expert in the field to put the case into a more global perspective.

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The use of abbreviations, except those that are widely used, is strongly discouraged. They should be used only if they contribute to better comprehension of the manuscript. Acronyms should be spelled out at first mention. Metric system (SI) units should be used. Pages should be numbered sequentially beginning with the Title Page.

The Title Page should contain the following: the full title of the manuscript, the full names and affiliations (department, institution, city, state) of all authors, a contact address with telephone and fax numbers and e-mail address, and the word count for abstract and for manuscript (excluding title page, abstract, references, tables, and figures).

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Abstract and Mesh Terms (Keywords) begin on page 2 and should include a brief statement of the problem, the method, the key findings, and the conclusions. Six mesh or key words not duplicated in the title should be provided, see <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db5mesh>.

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The Methods section should include the following: Compliance with institutional research standards for animal or human research (including a statement that the research was completed in accordance with the Helsinki Declaration http://www.wma.net/e/policy/17-c_e.html).

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Book:

Lezak, M.D., Howieson, D.B., Bigler, E.D., Tranel, D. (2012). *Neuropsychological Assessment*. New York: Oxford University Press.

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Report at a Scientific Meeting:

Weintraub, S. (2012, June). Profiles of dementia: Neuropsychological, neuroanatomical and neuropathologic phenotypes. International Neuropsychological Society, Oslo, Norway.

Manual, Diagnostic Scheme, etc.:

American Psychiatric Association (1994). *Diagnostic and Statistical Manual of Mental Disorders* (4th ed.). Washington, DC: American Psychiatric Association Press.

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Appendix 2.2. Semi-structured Sleep Interview

Semi-structured Sleep Interview

Name of Interviewer: _____ Date: _____
Site ID: _____ Time: _____
Participant's ID for the study: _____

PART I: General Information on sleep

1. SLEEP ROUTINE

At what time do you usually get into bed at night? _____ am / pm
At what time do you usually get out of bed in the morning? _____ am / pm
How long after going to bed do you usually turn out the lights? ____ hr ____ min
How long does it usually take you to fall asleep after the lights are off? ____ hr ____ min
How many times do you wake up during a typical night's sleep? ____ times
How long do you stay awake for? ____ hr ____ min
Do you usually feel refreshed after a typical night of sleep? ____ YES ____ NO
Do you nap during the day? ____ YES ____ NO
If yes, how many times per week do you take a nap? ____ times
How long does a typical nap last? ____ hr ____ min
Do you usually feel refreshed after napping? ____ YES ____ NO
Do you spend time in your bed at other times? ____ Yes ____ NO

2. SLEEP STATUS

Do you currently have problems with your sleep? ____ Yes ____ No
What seems to be the problem with your sleep?

How many night's per week are you affected by your sleep problem? ____night's per week

3. ONSET

When did your sleep problem/s start?

Has your sleep changed since your injury? ____Yes ____No ____Unsure/Maybe

If yes, could you specify in what way?

Were there any stressful events related to the onset of the sleep problem (e.g. divorce, exams, death of a loved one, divorce, retirement, medical or emotional problems, etc.)?

____Yes ____No ____Unsure/Maybe

If yes, could you specify the event?

4. SLEEP HISTORY

Have you had sleep problem/s in the past? ____Yes ____No

If yes, follow up with prompt questions (1) when, (2) symptoms, (3) duration, (4) impact:

Have you ever received a sleep disorder diagnosis in the past? ____Yes ____No

If yes, what type of sleep problem/s?

PART II: Information specific to potential sleep disorders

5. INSOMNIA (QUESTIONS COMPLEMENTING INSOMNIA SEVERITY INDEX QUESTIONNAIRE)

Do you find yourself worrying/ruminating before you go to sleep? ___ Yes ___ No

Do you watch the clock and worry as to when you will fall asleep? ___ Yes ___ No

Do you worry about the impact of not getting enough sleep? ___ Yes ___ No

If yes, describe nature of worries:

If yes, explore frequency, severity, duration:

If prior to injury, explore whether problems have worsened since injury ___ Yes ___ No

6. HYPERSOMNIA AND POST-TRAUMATIC HYPERSOMNIA

Do you feel sleepy during the day? ___ Yes ___ No

Do you think you are sleepier than other people your age? ___ Yes ___ No

Do you have difficulty staying awake during the day? ___ Yes ___ No

Do you feel the need to take naps during the day? ___ Yes ___ No

Do you sleep long hours during the night? ___ Yes ___ No

Do you find it difficult to wake up in the morning? ___ Yes ___ No

If yes, explore frequency, severity, duration:

If prior to injury, explore whether problems have worsened since injury ___ Yes ___ No

7. NARCOLEPSY (Note: Provide clear, concise explanations of the conditions below)

Do you find yourself falling asleep in situations where you need to be awake? ___ Yes ___ No

Sleep attacks ___ Yes ___ No

Sleep paralysis ___ Yes ___ No

Hypnagogic hallucinations ___ Yes ___ No

Cataplexy ___ Yes ___ No

If yes, explore frequency, severity, duration:

If prior to injury, explore whether problems have worsened since injury ___ Yes ___ No

8. SLEEP APNEA

Do you snore? ___ Yes ___ No

Does your bed-partner say that you snore? ___ Yes ___ No

Do you snore loudly or irregularly? ___ Yes ___ No

Do you or your partner notice that you sometimes stop breathing during your sleep? ___ Yes ___ No

If yes, explore frequency, severity, duration:

If prior to injury, explore whether problems have worsened since injury ___ Yes ___ No

9. PERIODIC LIMB MOVEMENT DISORDER

(Note: Provide clear, concise explanations of periodic limb movement disorder)

Leg twitches or jerks during the night? ___ Yes ___ No

If yes, explore frequency, severity, duration:

If prior to injury, explore whether problems have worsened since injury ___ Yes ___ No

10. RESTLESS LEGS SYNDROME (Note: Provide clear, concise explanations of RLS)

Crawling or aching feelings in the legs (calf) and inability to keep legs still ___ Yes ___ No

If yes, explore frequency, severity, duration:

If prior to injury, explore whether problems have worsened since injury ___ Yes ___ No

11. PARASOMNIAS (Note: Provide clear, concise explanations of the conditions below)

Nightmares ___ Yes ___ No

Night-terror ___ Yes ___ No

Sleep-walking ___ Yes ___ No

Sleep-talking ___ Yes ___ No

If yes, explore frequency, severity, duration:

If prior to injury, explore whether problems have worsened since injury ___ Yes ___ No

12. CIRCADIAN RHYTHM DISORDERS

If there is suspicion on circadian rhythm disorders from section 1, then follow-up with specific questions

Are you a morning or evening person? _____

At what time of the day do you start feeling sleepy? _____

If there were no restrictions, what time would you go to bed? _____

If there were no restrictions, what time would you naturally wake up? _____

Do you find it hard to function when you do not have the opportunity to go to bed/wake up at your preferred/natural times?

If yes, how does that affect you?

If yes, explore frequency, severity, duration:

If prior to injury, explore whether problems have worsened since injury ___Yes ___No

PART III: Information on remedial actions and consequences

13. REMEDIAL ACTION

How are you dealing with your current sleep problem? (Ask each and tick all that apply)

Prescribed medication ___

Over-the-counter medication ___

Drink alcohol ___

Catch up on sleep at weekend ___

Lie-in or go to bed early during the week ___

More caffeine than usual ___

Relaxation tapes / Meditation / Yoga ___

Less caffeine than usual ___

Exercise___

Psychological therapy___

Other (describe) _____

Nothing ___

Do you find any of these remedies helpful?

___Yes ___No ___Unsure/Maybe

If yes, any one in particular?

14. CONSEQUENCES

Does your current sleep pattern affect your day in any way? ___Yes ___No ___Unsure/Maybe

If yes, how? (For example do you feel tired, sleepy, and irritable or have poor concentration?)

2.3. Participant Information Sheet



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PARTICIPANT INFORMATION SHEET

Prevalence and types of sleep problems in head injury patients during the rehabilitation period

Introduction

We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being carried out and what is involved. Please take some time to read the following information carefully and discuss it with others if you wish. Please contact us if you would like more information or if there is anything that is not clear.

Purpose of the study

Many people who have sustained a head injury undergoing rehabilitation may experience sleep problems. Sleep problems are commonly associated with other difficulties, such as pain, fatigue and mood problems. Our main aim is to explore how common sleep problems are in people who are in rehabilitation centres after a head injury, what type of sleep problems they have, and what other difficulties may be associated with sleep problems. We also aim to explore whether sleep problems impact on people's ability to engage and participate in rehabilitation.

Why have I been invited?

You have been invited to take part in this study because you have recently sustained a head injury and you are currently undergoing rehabilitation for this.

Do I have to take part?

It is entirely up to you whether you take part or not. If you decide to take part you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw or not to take part will not affect the standard of care you receive or your future rehabilitation programme. If you decide to withdraw any data collected from you will be destroyed.

What does taking part involve?

If you decide to take part we will come along to meet with you at a time suitable for you at the rehabilitation centre where you stay. You will meet with the researcher, who will take an interview about your sleep and will complete six questionnaires with you. The interview should last about 20 minutes and the questionnaires take a few minutes each. Three questionnaires are about your sleep, one about your mood, one about levels of pain, and one about feelings of fatigue.

The main aim of this study is to monitor your sleep wake patterns when you are in the rehabilitation centre. Therefore, we would ask you to wear an Actiwatch (a small watch like device; photo below) on your wrist for a period of 7 days. For the same period of seven days we will ask you to keep sleep diaries. The researcher will provide you with sleep diaries and will explain to you how to use them.



This device measures movement and will give us an indicator of your sleep patterns. Also we would like to ask you to keep a diary of your sleep during this period.

Also, we would like your permission to access information from your medical notes. This will be information about your head injury, lifestyle factors and medical conditions. If your sleep is poor or very good we will also gather information on your participation and progress in rehabilitation.

Your General Practitioner (GP) will be informed of your participation in this study.

What happens to the information?

Your identity and personal information will be confidential and known only to the researchers. Your interview, questionnaires, diaries, Actiwatch data and information obtained from your medical notes will remain confidential and stored in electronic form in an NHS protected laptop and in paper copy in a locked cabinet. Your data will be kept in accordance with the Data Protection Act, which means to it will be kept safely and it will not be revealed to other without your permission. If we publish any findings from the study, this will be in the form where your results are combined with those of many other people and average scores are presented. We take great care not to publish any details from which you could be identified.

What are the possible benefits of taking part?

It is hoped that by taking part in this research you will be providing valuable information about the sleep problems that people who have sustained a head injury and are in rehabilitation experience and about the impact that these may have on the rehabilitation process.

Are there any disadvantages or risks of taking part?

There are no significant risks or disadvantages for taking part. You may feel a little tired, but there will be regular breaks during the study to minimise this.

Who is funding the research?

This research is being funded by the University of Glasgow Doctorate in Clinical Psychology.

Who is conducting this study?

This study is carried out by Eleni Morfiri (Trainee Clinical Psychologist) and Allan Thomson (Trainee Clinical Psychologist). The study is supervised by Professor Tom McMillan and Dr Maria Gardani from the Institute of Mental Health and Wellbeing of the University of Glasgow.

Who has reviewed the study?

This study has been reviewed by the Research Scotland A Ethics Committee, Edinburgh.

If I have any further questions?

Please do not hesitate to contact Ms Eleni Morfiri, Trainee Clinical Psychologist, tel. 0141 211 3920, e.morfiri.1@research.gla.ac.uk, should you like more information or if you would like to receive a summary of the main findings once the study has completed.

If you would like to contact someone who is not directly involved in the study to obtain independent information about the study, please do not hesitate to contact Dr Heather Woods, School of Psychology, University of Glasgow, heatherw@glasgow.ac.uk, Tel. 0141 330 3344.

What if something goes wrong?

If you have any concerns or if you want to complain about any aspect of the study, you can contact Dr (Brian O'Neill/Dr Roger Makepeace), Clinical Neuropsychologist at (Graham Anderson/Murdostoun), (tel. 0141 4046060/01698 385240). If you prefer to speak to someone outwith the Rehabilitation team, you can contact Dr Heather Woods, School of Psychology, University of Glasgow, heatherw@glasgow.ac.uk, Tel. 0141 330 3344.

Thank you for taking the time to read this information

2.4. Participant Consent form



University
of Glasgow



Eleni Morfiri
Trainee Clinical Psychologist
Mental Health and Wellbeing
Gartnavel Royal Hospital
1055 Great Western Road, Glasgow, G12 0XH

Tel. 0141 211 3920
Email: e.morfiri.1@research.glasgow.ac.uk

Researchers: Ms Eleni Morfiri, Mr Allan Thomson, Dr Maria Gardani, Prof. Tom McMillan

Participant Consent Form

Study title: Prevalence and types of sleep problems in head injury patients during the rehabilitation period.

Please initial box

1. I confirm that I have read and understand the information sheet dated *insert date*
(*version*) for the above study.
2. I have had the opportunity to consider the information provided, ask questions, and had these answered satisfactorily.
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
4. I agree to make anonymised information collected during this study available to related research projects at the Section of Psychological Medicine, University of Glasgow.
5. I understand that sections of my medical notes may be looked by the research team, where it is relevant for the study purposes, and by the Research and Development Service of NHS Greater Glasgow and Clyde, sponsor of the study, for audit purposes only. I give my permission for the researchers to have access to my notes.
6. I understand that my GP will be informed of my participation in the study.
7. I agree to take part in the above study.

Name of Participant

Date

Signature

Name of Researcher

Date

Signature

2.5. Ethics Approval letter

Scotland A Research Ethics Committee

Secretariat
2nd Floor Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone: 0131 465 5680
Fax: 0131 465 5789
www.nres.nhs.uk



Professor Thomas McMillan
Professor of Clinical Neuropsychology,
Mental Health and Wellbeing
MVLS, University of Glasgow
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Date: 24 August 2012
Your Ref.:
Our Ref.: 12/SS/0111
Enquiries to: Walter Hunter
Extension: 35680
Direct Line: 0131 465 5680
Email: walter.hunter@nhslothian.scot.nhs.uk

Dear Professor McMillan

Study title: Prevalence and types of sleep problems in head injury patients during the rehabilitation period

REC reference: 12/SS/0111

Thank you for your letter of 14 August 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

Adults with Incapacity (Scotland) Act 2000

I confirm that the Committee has approved this research project for the purposes of the Adults with Incapacity (Scotland) Act 2000. The Committee is satisfied that the requirements of section 51 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

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

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

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

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

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

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

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Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

The Committee specified the following condition:

The new line added to the continuing participant information sheet i.e. 'Data collected from this study may be published and may be used in future studies.' should be included in the participant information sheet for the welfare guardian.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.

Approved documents

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

Document	Version	Date
Covering Letter		15 July 2012
REC application: IRAS Form	3.4	13 July 2012
Protocol	2.0	02 July 2012
Investigator CV: McMillan		12 July 2012
Investigator CV: Gardani		12 July 2012
Investigator CV: Morfiri		12 July 2012
Investigator CV: Thomson		12 July 2012
Participant Information Sheet	2.0	02 July 2012
Participant Consent Form	3.0	06 July 2012
Participant Information Sheet: Guardian/Welfare Attorney	3.0	16 August 2012
Participant Consent Form: Guardian/Welfare Attorney	3.0	06 July 2012
Participant Information Sheet: Next of Kin	2.0	02 July 2011
Participant Consent Form: Next of Kin	3.0	06 July 2012
Participant Information Sheet: Continuing Participation	4.0	16 August 2012
Participant Consent Form: Continuing Participation	3.0	06 July 2012
GP/Consultant Information Sheets	1.0	15 July 2012
Interview Schedules/Topic Guides	1.0	05 July 2012

Questionnaire: PSQI		
Questionnaire: GODs		
Questionnaire: Insomnia Severity Index		
Questionnaire: Epworth Sleepiness Scale		
Questionnaire: BNI Fatigue Scale		
Questionnaire: BPI - Brief Version		
Questionnaire: HADDs		
Referees or other scientific critique report		01 June 2012
Summary/Synopsis	1.0	14 July 2012
Response to request for further information		14 August 2012

Statement of compliance

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

After ethical review

Reporting requirements

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

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

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

Feedback

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

Further information is available at National Research Ethics Service website > After Review

REC reference number: 12/SS/0111-Please quote this number on all correspondence

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




Yours sincerely



Dr Ian Zealley
Committee Chairman

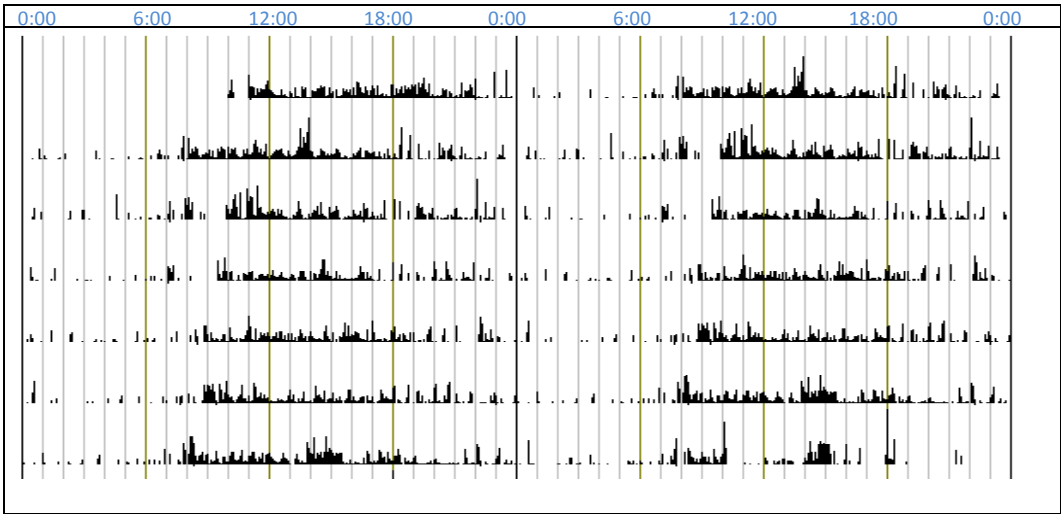
cc: Ms Eleni Morfiri
Dr Erica Packard, NHS Greater Glasgow and Clyde

2.6. Research and Development Approval Letter

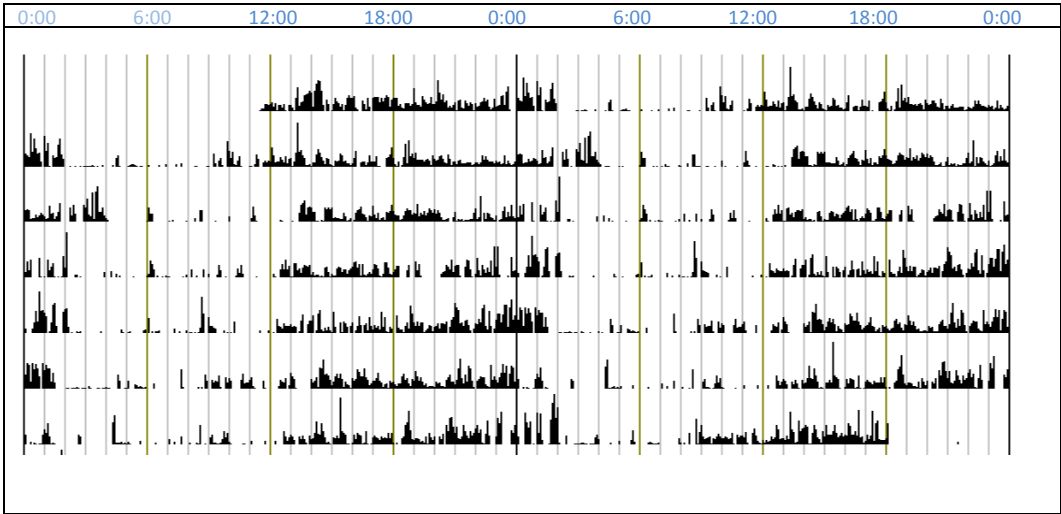
<div data-bbox="840 204 1021 336"></div> <div data-bbox="179 343 609 422"><p>Coordinator/Administrator: Dr Michael Barber/Mrs Elaine O'Neill Telephone Number: 0141 211 6208 E-Mail: michael.barber@ggc.scot.nhs.uk Website: www.nhs.org.uk/r&d</p></div> <div data-bbox="819 343 1001 442"><p>R&D Management Office Western Infirmary Tennent Institute 1st Floor 38 Church Street Glasgow, G11 6NT,</p></div> <div data-bbox="179 477 318 501" data-label="Text"><p>17 October 2012</p></div> <div data-bbox="179 523 432 665" data-label="Text"><p>Prof Tom McMillan Prof in Clinical Neuropsychology University of Glasgow Gartnavel Royal Hospital 1055 Great Western Road Glasgow G12 0XH</p></div> <div data-bbox="468 710 732 738" data-label="Section-Header"><h3>NHS GG&C Board Approval</h3></div> <div data-bbox="179 737 338 762" data-label="Text"><p>Dear Prof McMillan,</p></div> <div data-bbox="179 783 940 992" data-label="Text"><table border="0"><tr><td>Study Title:</td><td>Prevalence and types of sleep problems in head injury patients during rehabilitation period</td></tr><tr><td>Principal Investigator:</td><td>Prof Tom McMillan</td></tr><tr><td>GG&C HB site</td><td>n/a</td></tr><tr><td>Sponsor</td><td>NHS Greater Glasgow and Clyde</td></tr><tr><td>R&D reference:</td><td>GN12CP307</td></tr><tr><td>REC reference:</td><td>12/SS/0111</td></tr><tr><td>Protocol no:</td><td>V2.0; 02/07/12</td></tr><tr><td colspan="2"><small>(including version and date)</small></td></tr></table></div> <div data-bbox="179 1011 1023 1059" data-label="Text"><p>I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant Approval for the above study.</p></div> <div data-bbox="179 1080 378 1107" data-label="Section-Header"><h3>Conditions of Approval</h3></div> <div data-bbox="212 1115 983 1238" data-label="List-Group"><ol style="list-style-type: none">1. For Clinical Trials as defined by the Medicines for Human Use Clinical Trial Regulations, 2004<ol style="list-style-type: none">a. During the life span of the study GGHB requires the following information relating to this site<ol style="list-style-type: none">i. Notification of any potential serious breaches.ii. Notification of any regulatory inspections.</div> <div data-bbox="179 1273 1005 1347" data-label="Text"><p>It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhs.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.</p></div>	Study Title:	Prevalence and types of sleep problems in head injury patients during rehabilitation period	Principal Investigator:	Prof Tom McMillan	GG&C HB site	n/a	Sponsor	NHS Greater Glasgow and Clyde	R&D reference:	GN12CP307	REC reference:	12/SS/0111	Protocol no:	V2.0; 02/07/12	<small>(including version and date)</small>		<div data-bbox="1803 191 2002 323"></div> <div data-bbox="1187 397 1792 580" data-label="List-Group"><ol style="list-style-type: none">2. For all studies the following information is required during their lifespan.<ol style="list-style-type: none">a. Recruitment Numbers on a monthly basisb. Any change of staff named on the original SSI formc. Any amendments – Substantial or Non Substantiald. Notification of Trial/study end including final recruitment figurese. Final Report & Copies of Publications/Abstracts</div> <div data-bbox="1153 624 1919 647" data-label="Text"><p>Please add this approval to your study file as this letter may be subject to audit and monitoring.</p></div> <div data-bbox="1153 657 1798 683" data-label="Text"><p>Your personal information will be held on a secure national web-based NHS database.</p></div> <div data-bbox="1153 694 1529 719" data-label="Text"><p>I wish you every success with this research study</p></div> <div data-bbox="1153 775 1285 801" data-label="Text"><p>Yours sincerely,</p></div> <div data-bbox="1191 809 1433 888" data-label="Text"></div> <div data-bbox="1153 892 1350 940" data-label="Caption"><p>Dr Michael Barber Research Co-ordinator</p></div> <div data-bbox="1153 984 1314 1010" data-label="Text"><p>Cc: Ms Eleni Morfiri</p></div>
Study Title:	Prevalence and types of sleep problems in head injury patients during rehabilitation period																
Principal Investigator:	Prof Tom McMillan																
GG&C HB site	n/a																
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R&D reference:	GN12CP307																
REC reference:	12/SS/0111																
Protocol no:	V2.0; 02/07/12																
<small>(including version and date)</small>																	

Appendix 2.7. Dual-day display actograms of two participants with distinct sleep-wake patterns.

Actogram of participant with self-reported good sleep quality.



Actogram of participant who met diagnostic criteria for delayed sleep phase syndrome.



Appendix 3. Major Research Project Proposal

Prevalence and types of sleep problems in head injury patients during the rehabilitation period.

Abstract

Background: Identifying and managing sleep problems after brain injury has become an increasingly important issue. Sleep disturbance is very common after head injury. Previous studies in rehabilitation units have found that about 70% of patients experience sleep problems. Patients with sleep problems require longer stays in rehabilitation units and have poorer longer term outcomes.

Aims: This study will primarily explore the prevalence and types of sleep problems experienced after head injury and during the rehabilitation period. It will also explore whether people with sleep disturbances have more functioning problems and whether they experience additional difficulties engaging in the rehabilitation process in comparison to inpatients without sleep problems.

Methods: A semi-structured clinical screening interview, as well as objective and subjective assessment of sleep, will be used to identify the prevalence and types of sleep disturbances during rehabilitation. Factors thought to be associated with sleep disturbance will be explored. Poor sleepers will be compared with patients with good sleepers on their level of functioning and engagement in rehabilitation.

Applications: Findings from this study may strengthen the need for a thorough diagnosis and management of sleep problems in rehabilitation units for head injury patients and may improve current understanding of the implications of sleep problems on patients' progress in rehabilitation.

Introduction

Sleep problems in head injury patients during the rehabilitation period

It is clinically well recognized that many head injury patients in rehabilitation units experience disturbed sleep-wake patterns. However, although commonly seen, little is known about the prevalence and types of sleep problems that head injury patients experience during the rehabilitation period. A number of studies have explored problems with sleep in the chronic phase following head injury. In the chronic phase, about 50-70% of people with a head injury experience a diverse range of sleep problems including insomnia, post-traumatic hypersomnia, sleep apnoea, narcolepsy, and periodic limb movements (Dikmen, et al., 2010; Castriotta and Murthy, 2011). However, findings from studies looking into sleep problems in the chronic phase after head injury cannot be generalized to the early months post-injury, as sleep problems at these two time points possibly differ. Cohen, et al. (1992) in a questionnaire study of sleep complaints found that the nature of the sleep complaints differ between the post-acute and the chronic phase since injury. Patients with a recent injury had more difficulties initiating and maintaining sleep, while patients with older injuries suffered mostly from difficulties of excessive somnolence.

A small number of studies have focused on sleep problems during the rehabilitation period. Cohen, et al. (1992) found that 73% of 22 head injury patients in rehabilitation reported experiencing sleep problems. About 60% described having difficulties initiating and maintaining sleep and 14% reported experiencing excessive somnolence. Makley, et al. (2008) looked into 31 consecutive admissions in a rehabilitation unit. Similarly, disrupted sleep was observed in 23 (68%) of patients. These studies highlight the high prevalence of sleep problems in this population. However, as they have operationalised sleep problems using behavioural descriptions of the observed problems (such as sleep wake cycle disturbance, difficulties initiating and maintaining sleep), they do not fully describe the types of sleep problems experienced by this population and they do not identify potential underlying causes.

To date only one study (Bauman, et al., 2007) used a systematic approach to identify potential disorders underlying the observed sleep problems in the post-acute period after head injury. Out of 65 consecutive referrals, 47 patients (72%) qualified for a sleep disorder diagnosis. Of those, 18 presented with subjective excessive daytime sleepiness, 16 with objective excessive daytime sleepiness, 14 with post-traumatic hypersomnia, 11 with fatigue and 3 with insomnia. In 28 patients no specific underlying cause of their sleep problems could be identified. However, the results from this study cannot be generalized to patients in rehabilitation units, as the study included patients across the range of injury severity and included both inpatients and community dwelling patients.

On many occasions, sleep problems in head injury patients develop into chronic difficulties. There is a growing literature on the types of sleep problems in the chronic phase post-injury (Castriotta and Murthy, 2011). However, no study to date has attempted to identify potential sleep disorders that may underlie the sleep difficulties commonly experienced by head injury patients during the rehabilitation period. This can provide insights into how sleep problems present at the start of their development in patients with moderate and severe head injuries. In addition, it is clinically important as different types of sleep problems may be linked to different difficulties, may affect rehabilitation outcomes differently and individualised approaches to treatment may be required.

Factors associated with sleep disturbance in head injury patients during rehabilitation

It is unknown what proportion of patients experience sleep problems prior to their injury. Some sleep disorders, such as sleep apnoea, have been linked with a high accident risk (Ellen, et al., 2006) and on some occasions they may have been the underlying cause of the accident in the first place. However, on most occasions sleep difficulties appear to develop or worsen post-injury. Rao, et al. (2008) interviewed 54 patients 3 months post-injury and found significant increase in sleep problems post-injury in a number of domains on the Medical Outcome Scale for Sleep (MOS), such significantly more symptoms of sleep disturbance and daytime sleepiness.

A number of diverse factors have been associated with the presence of sleep disturbance in the early stages after head injury. Pathophysiological changes related to the head injury, such as focused or diffuse lesions may be affecting systems usually involved in the regulation of sleep. For example, low levels of hypocretin-1 have been found in the first months post injury of patients with poor sleep (Bauman, et al., 2007). Psychological factors seem to play an important role in the development of sleep problems. Rao, et al. (2008) in a study looking into risk factors for sleep problems following head injury found that symptoms of anxiety and depression were significant predictors of sleep difficulties. There is research evidence that pain can cause frequent night-time awakenings, which can lead to subjective perception of poor sleep quality (Moldofsky, 1989). Indeed, Beetar, Guilmette and Sparadeo (1996) in a study with head injury patients one year post-injury found that patients who experience pain had more sleep complaint, including difficulties falling asleep, maintaining sleep and daytime sleepiness. Fatigue has also been associated with poor sleep in the early phase post-injury too. Clinchot, et al. (1998) found that one year post-injury fatigue sleep complaint correlated with the presence of fatigue.

Lifestyle factors such as diet, drug and alcohol use, exercise, and sleep schedules can potentially impact on sleep and may play a role in the development of sleep disturbances during rehabilitation (Quellet, 2010). For example, caffeine, nicotine, and alcohol intake can affect sleep quality depending on the time, quantity and frequency of consumption. Additionally, obesity is linked to sleep disordered breathing, which can affect the quality of sleep or even lead to sleep disordered breathing, such as sleep apnoea. For hospitalised patients, hospital conditions, including lighting conditions, unusual noises, tense atmosphere, and loss of privacy may also be involved in the development of sleep problems (Cohen, et al., 1992). Medications prescribed during rehabilitation can affect the quality, quantity, and architecture of sleep. A number of medications prescribed for sleep, pain, seizures, muscle relaxation or management of stress, anxiety or depressive symptoms can interact with sleep processes, for example by increasing or decreasing the amount of time spent in different sleep stages (Quellet, 2010).

The Impact of Sleep Problems on Rehabilitation

In the general population, sleep difficulties are associated with reduced occupational, physical, cognitive, and emotional functioning (Steptoe, O'Donnell, Marmot and Wardle, 2008; Baglioni, et al., 2011). Similarly, sleep problems may be impacting further on the cognitive, affective, and behavioural difficulties that many people experience following a head injury. For example, Clinchot, et al. (1998) found that one year post-injury fatigue was more common among patients with sleep problems and Bloomfield, Espie and Evans (2010) found that poor sleepers with head injury had significantly poorer sustained attention in comparison to head injury patients without sleep problems.

The rehabilitation period is critical, as during this time a coordinated attempt is made to support patients to reach their optimal level of recovery. Sleep difficulties can potentially influence patients' alertness and can therefore decrease their ability to fully participate and benefit from a rehabilitation program. In a naturalistic study, Worthington and Melia (2006) found that sleep problems were associated with reduced ability to engage in rehabilitation activities and poorer rehabilitation outcomes. Makley, et al. (2008) found that patients with sleep problems had longer stays in a rehabilitation unit in comparison to patients without sleep problems, as they required longer periods of time to reach the same level of function at discharge. In the chronic phase, patients with sleep disturbance have poorer vocational outcomes, more behavioural problems and higher levels of cognitive and communicative dysfunction compared to patients with no sleep difficulties (Cohen, et al., 1992; Clinchot, et al., 1998).

Head injury patients with sleep problems appear to have poorer shorter and longer term rehabilitation outcomes. It is therefore important to understand how sleep problems are related to rehabilitation outcomes. Makley, et al. (2008) found that patients with sleep problems were functionally more impaired on admission to the rehabilitation centre. They suggested that the longer stay of patients with sleep disturbance in rehabilitation units may be due to the severity of injury or a combination of their injury and sleep disturbance. Worthington and Melia (2006) found that sleep problems during inpatient rehabilitation

were associated with disruptions, such as physical aggression and inability to stay awake during activities. The authors commented that their data strongly suggest a link between observable arousal disturbance and functional performance after head injury.

Aims and hypotheses

The primary aim of the present study is to examine the prevalence and types of sleep problems in patients with head injury during inpatient rehabilitation. In addition, it aims to provide a detailed description of factors that have been identified as common correlates of sleep problems in this population, including duration of post-traumatic amnesia, medication, alcohol intake, anxiety, depression, pain and fatigue.

The second aim of this study is to examine the relationship between sleep problems, patients' functioning and participation in the rehabilitation process.

Research Questions:

- What is the prevalence, types and correlates of sleep problems experienced by patients during rehabilitation following head injury?
- Do sleep difficulties relate to head injury patients' functioning and participation in the rehabilitation process?

Plan of investigation

Participants

Inclusion criteria:

- Participants with a closed head injury aged over 16 years old, who are undergoing rehabilitation in a rehabilitation unit will be recruited.

- Participants will need to have been in the unit for over 2 weeks, so that they have completed their initial assessment and collection of adequate data on their engagement/participation in rehabilitation is feasible.
- Participants included will have English as their first language and will be able to read and write.
- We estimate that a proportion of potential participants will be unable to provide informed consent. Previous research has suggested that the presence of sleep problems is a possible covariate of injury severity that increases with more severe injury (Makley, et al., 2008). This subset of participants is therefore of particular interest for the questions this study aims to address. The study will therefore include participants able to provide informed consent and participants who lack capacity to consent, where permission to do so is obtained from their next of kin/guardian. Participants will take part in tasks appropriate for their abilities. For example, data on their sleep will be collected with Actigraphy, but where appropriate, participants may not be required to complete the interview or to fill out the study questionnaires.

Exclusion criteria:

- Individuals with types of head injury other than closed head injury, such as haemorrhagic strokes, will not be included.
- Individuals with current severe mental illness, learning disability, neurodegenerative conditions or undergoing a process of detoxification will be excluded.
- Further exclusion criteria will be having a history of a diagnosed breathing condition that might affect sleep, such as asthma or COPD.

Recruitment Procedures:

Participants will be recruited from local rehabilitation centres, including the Huntercombe Service at Murdostoun, the Brain Injury Rehabilitation Trust-Graham Anderson House and potentially the Astley Ainslie Hospital in Lothian. Written information about the study will be provided to staff at the recruitment sites and where appropriate, presentations may be used to explain the aims of the study and to answer

potential questions. Rehabilitation centre staff will identify participants who potentially meet the inclusion criteria and will obtain verbal consent for the researchers to contact them. Information about capacity will be provided by staff in the rehabilitation centres. In addition, capacity will be assessed by participant's ability to understand the purposes of the study by the researcher. Staff will identify potential participants who do not have capacity to consent and will obtain verbal consent from their next of kin/guardian for the researchers to contact them. Potential participants or their next of kin/guardian, for those who lack capacity to consent, interested in the study will be provided information about the study and a consent form to return should they wish to take part in the study.

Design and Research Procedures

A cross-sectional design will be employed to explore the types and prevalence of sleep problems. In addition, the study aims to explore correlates of sleep disturbance that have been highlighted by previous research, including injury severity, medication, pain, fatigue, anxiety and depression. Descriptive, between-group and correlational analyses will be performed. The independent variable in all between group analyses will be whether participants have sleep problems.

Participant's or next of kin/guardian's consent will be sought in order to access relevant background information for their medical notes. Participants who have capacity will complete a semi-structured interview, the study questionnaires and will be given information on the use of the sleep diaries and Actigraphy. It is estimated that the interview will last about 20 minutes. The sum of the completion time for the study measures is estimated to be 30 minutes. Sleep will be monitored for a continuous period of 7 days using the sleep diaries and Actigraphy. The researcher will remain sensitive on issues of fatigue and will spread the completion of the measures and interview across a number of shorter sessions as required. Participants who lack capacity to consent to the study will not be required to complete the interview or study questionnaires. They will only be instructed in the use of the Actigraph and sleep diaries will be collected with support from rehabilitation staff.

A between subjects design will be employed to explore whether patients with poor sleep (PS) have poorer functioning and more difficulties engaging with their rehabilitation programme in comparison to patients with good sleep (GS). Information gathered from the semi-structured interview, review of the sleep diaries, sleep measures (Pittsburgh Sleep Quality Index, Insomnia Severity Index) and review of Actigraphy data will be used to allocate participant's into the GS and PS groups. If the participant meets the inclusion criteria for GS or PS as defined below, information on facets of engagement in the rehabilitation process will be collated by reviewing routinely-collected information in medical and unit notes.

Allocation of participants to PS or GS groups:

For the purposes of exploring the relationship between of sleep problems, functioning and engagement in rehabilitation, participants will be allocated to GS group or PS group on the basis of the following criteria developed with reference to Research Diagnostic Criteria (Edinger, et al., 2004). PS participants will be required to have a global score of five or above on the PSQI, sleep complaint present, even though they had had adequate opportunity to sleep, and they will also be required to meet one or more of the following Actigraphy parameters at least three times a week: total sleep time (TST) of less than 6.5 hours, a sleep efficiency (SE) score of less than 85%, or a sleep onset latency (SOL) of greater than 30 minutes. The GS group will be required to have a score of less than five on the PSQI and not to meet any of the Actigraphy criteria outlined. Participants who will not meet either of these groups of criteria will be classified as neither good nor poor sleepers and will not be included in this part of the study.

Data Analysis

In relation to the first research question of the study, descriptive statistics will be used to describe the data. The overall prevalence of sleep problems and the frequencies of specific sleep disorders will be calculated. Descriptive statistics on demographic information, level of functioning, medication use, measures of pain,

fatigue, anxiety and depression will be provided for the whole sample, as well as separately for participants with and without sleep problems. Spearman's or Pearson product-moment correlation will be used to explore whether sleep problems, as measured by the PSQI, correlate with measures of pain, fatigue, anxiety and depression.

In relation to the second question, a Multivariate Analysis of Variance (MANOVA) test will be employed to examine differences between the two groups (PS and GS) on the dependent variables (level of functioning, attendance, participation, goal achievement, and disruptive behaviour). If the difference between the two groups is significant, this will be followed-up by appropriate tests of difference for each dependent variable (t-test or Mann-Whitney). As previous research has suggested that the presence of sleep problems is a possible covariate of injury severity that increases with more severe injury (Makley, et al., 2008), it will be of particular interest to explore further whether there any interactions between sleep problems, injury severity and levels of functioning and engagement in rehabilitation.

Measures

Demographic Characteristics:

- Age
- Gender
- Employment status/ Marital status
- Socio-economic status (SES) will be rated using the Scottish Index of Multiple Deprivation (SIMD, 2009)
- Years in education

Injury related information:

- Glasgow Coma Scale (GCS; Teasdale and Jennett, 1974)
- Duration of post-traumatic amnesia (PTA)
- Duration of loss of consciousness (LOC)

- Time elapsed post injury
- Length of rehabilitation admission period

Medical information:

- Current Medication
- Medical diagnoses
- History of alcohol/drug abuse
- Epilepsy
- Smoking/ alcohol intake

Psychophysiological Measures:

- The Barrow Neurological Institute (BNI; Borgaro, Gierok, Caples and Kwasnica, 2004) Fatigue Scale, which has been designed specifically for head-injured patients, will be used to measure fatigue.

Administration time- 5 minutes

- Brief Pain Inventory (BPI) Short Form (Cleeland and Ryan, 1994)

Administration time- 5 minutes

- Hospital Anxiety and Depression Scale (HADS; Zigmond and Snaith, 1983)

Administration time- 5 minutes

Sleep related measures:

- A semi-structured clinical screening interview based on the International Classification of Sleep Disorders (ICSD-II; American Academy of Sleep Medicine, 2005) will be conducted.

Administration time-20 minutes

- Actigraphy will be used to obtain objective measures of sleep onset latency, number of awakenings, nocturnal restlessness, total sleep duration, and sleep efficiency. Measures will be gathered for a period of seven, preferably consecutive days, in the rehabilitation unit.
- Participants' self-reports on their quality of sleep and their subjective sense of feeling rested will be gathered using a sleep diary. Sleep diaries will be completed for 7 days in parallel with the

actigraphy monitoring. If participants are not able to record their sleep wake patterns staff will be asked to keep the sleep diaries.

- The Epworth Sleepiness Scale (ESS; Johns, 1991) will be used to measure daytime sleepiness.

Administration time- 5 minutes

- The Pittsburgh Sleep Quality Index (PSQI; Buysse, et al., 1989) will be used as a self-report measure of global sleep quality.

Administration time- 5 minutes

- The Insomnia Severity Index (ISI; Morin, 1993) will be used to provide a self-report measure of subjective symptoms of insomnia.

Administration time- 5 minutes

Functioning and Engagement with the Rehabilitation Process Measures:

- Glasgow Outcome at Discharge Scale (GODS). The Glasgow Outcome Scale at Discharge (currently under validation) is a measure of functioning that has been designed to be used at any point during rehabilitation or in acute settings (i.e. hospital wards). The reliability and validity of GODS are currently explored and preliminary results suggest that it is a sensitive and reliable measure for this population.

Administration time- 10 minutes (with staff)

- A questionnaire will be designed aiming to capture a number of indicators of participants' engagement and functioning during the rehabilitation period.

Data will be collected retrospectively from medical and unit notes from time of admission up to the date of collection.

Justification of sample size: Previous studies on sleep problems in head injury patients during rehabilitation have sample sizes ranging from 22 to 39 participants (Makley, et al., 2008; Bauman, et al., 2007, Cohen, et al., 1992) and have found a prevalence of sleep problems in 68%, 73% and 72% respectively. This study will aim to recruit 40 participants, of whom it is estimated (conservatively) that 20-30 will have sleep problems.

In relation to the second question, the planned analysis is MANOVA. Lauter (1978) has calculated sample size requirements for two-group MANOVA for small, medium and large effect size. One previous study has looked into differences in functioning as measured by the Functional Independence Measure (FIM) at admission in rehabilitation between participants with and without sleep problems (Makley, et al., 2008). A very large effect size of $d=1.88$ was found. No other prior study that looked at the effects of good and poor sleep on engagement with the rehabilitation process or functioning was identified. Makley, et al. (2008) assessed participants functioning at intake into rehabilitation. The present study will assess participants functioning and engagement at a later point in the rehabilitation process and therefore a more conservative estimate of a large effect size $d=1$ is expected. Using Lauter's tables it is estimated that 24-36 participants are required to detect statistically significant differences at a power of 0.8 (one-tailed) with an alpha level set at 0.5. We will therefore aim to recruit 12-18 participants per group.

Settings and Equipment: Where possible, assessment will occur in a quiet and secure place within the rehabilitation unit from which the individual was recruited. Equipment required includes encrypted NHS laptops, actigraphs, neuropsychological assessments, psychometric questionnaires, and relevant record forms.

Health and safety issues

Participant and Researcher Safety Issues: The study will be conducted within staffed settings during working hours. The researcher will re-arrange or discontinue an interview if a participant appears to be under the influence of alcohol or substances or if they are exhibiting signs of anger or distress. The interview rooms will be set-up to allow easy exit to the researcher. The researcher will comply with health and safety procedures at each rehabilitation centre. The researcher will be present at all times and will remain vigilant to levels of client distress. Breaks will be provided as required by the participant. Participants will be informed that they can withdraw from the study at any time.

Ethics issues

Ethical approval for this study will be sought from the NHS Scotland A Research Ethics Committee, from the NHS GG&C R&D department, and from the ethics and management committees of each rehabilitation unit. Written consent will be obtained from participants or their next of kin/guardian. Participants will be informed that they are free to leave the study at any point and that this will not affect any clinical treatment that they receive. Data will be coded and stored in accordance to NHS policies to ensure confidentiality.

Financial Issues

The overall cost of the study is estimated to be £150.42.

Timetable

We aim to apply for ethical approval in June 2012 and to begin recruitment in September 2012.

Practical Applications

Results may have implications for improving the identification of sleep problems in head injury patients during rehabilitation. The project may highlight additional barriers head injury problems with sleep problems face in participating in rehabilitation task and may highlight the need for accurate identification and management of sleep problems during the rehabilitation period.

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