Understanding sleep problems in rehabilitation inpatients after stroke

and

Clinical Research Portfolio

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CHAPTER 1

Systematic Review

A systematic review of the prevalence of insomnia in stroke patients

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Prepared according to instructions to authors for *Sleep Medicine Reviews* (see Appendix 1.1)

Abstract

Background and Purpose: A number of studies of sleep in stroke patients report high levels of insomnia and/or insomnia symptoms and highlight multiple factors that might influence prevalence. This review systematically reviews the evidence to address the question of what the prevalence of insomnia is after stroke. It also examines evidence relating to demographic and other factors to determine what factors are most closely related to the presence of insomnia following stroke.

Methods: A combined electronic and manual search identified 11 articles which fulfilled inclusion and exclusion criteria. Quality criteria based upon guidelines for evaluation of prevalence studies were used to assess each article and relevant data were extracted and synthesised.

Results: The highest quality rating was 'moderate', perhaps reflecting the paucity of research on insomnia prevalence in stroke patients. Methodological inconsistencies led to difficulties ascertaining insomnia prevalence. In the only study to employ formal diagnostic criteria prevalence was 37.6%, but prevalence varied widely in studies using less stringent criteria. Examination of potentially confounding factors highlighted a lack of reported information and inconsistent findings.

Conclusions: Current literature suggests that insomnia and insomnia symptoms are prevalent in stroke patients but further research – utilising more standardised classification systems and considering a range of potentially confounding factors – is required to more effectively inform assessment and treatment in this population.

Keywords: stroke; insomnia; sleep initiation and maintenance disorder; prevalence

Introduction

Stroke patients commonly experience sleep-related difficulties, with reviews describing evidence dating back to the 19th Century.[1] A wide range of sleep disorders are associated with stroke, including sleep-disordered breathing, insomnia, parasomnia, circadian rhythm disorder, sleep-related movement disorder, hypersomnia and excessive daytime sleepiness.[2],[3] Sleep problems can arise as a consequence of the stroke itself, in which brain areas involved in sleep regulation (including the hypothalamus, brainstem and thalamus) are impaired;[4] although the poor correlation between lesion site and sleep disturbance has been noted.[5] More commonly, sleep disturbances arise due to factors associated with stroke, such as sleep-disordered breathing, medication use, inactivity, environment, depression, stress and premorbid health problems.[2] However, the impact of such factors is complex, as highlighted by Taylor et al.[6] who reported not only a higher prevalence of insomnia in those with medical problems than those without, but also a higher prevalence of medical problems in those with insomnia than those without (see also Hayashino et al.[7]). Furthermore, sleep disturbance can be a risk factor for stroke;[3] for example, by significantly increasing the risk of ischemic stroke.[8] Such findings warn against investigating stroke and sleep in isolation and instead including exploration of possible confounding factors.

The wealth of research undertaken on the aforementioned range of sleep disorders is beyond the scope of this systematic review. The current focus is therefore on the prevalence of insomnia in stroke patients – prevalence being an estimation of the frequency and distribution of [insomnia] based on a sample from a larger group.[9] Definitions of insomnia differ across studies although published classification systems exist, including the International Classification of Sleep Disorders (ICSD-2);[10] Research Diagnostic Criteria for Insomnia

(RDC);[11] International Classification of Diseases (ICD-10);[12] and Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR).[13] Morin and Espie[14] summarise the main criteria for defining insomnia which relate to the severity, frequency, duration and impairment/distress involved (see Table 1). Insomnia can present as a primary complaint or secondary to a medical condition.[14] Acute/adjustment insomnia is precipitated by a specific circumstance, whilst chronic insomnia may be idiopathic, arise following psychophysiological factors, or within the context of psychiatric, medical or neurological disorders.[4] Hermann et al.[1] found that 20–40% of stroke patients experience sleep-wake disturbances, including insomnia. Insomnia is a particularly pertinent area of research from the perspective of clinical psychology in light of cognitive behavioural models offering an explanation of its maintenance[14] and thus opportunity for non-pharmacological treatment.

Table 1. Main criteria for defining insomnia[14, p.15]

1. Severity: Sleep latency or time awake after sleep onset greater than 30 min; or, last awakening occurring more than 30 min before desired time and before total sleep time reaches 6.5 hours; sleep efficiency is lower than 85%. May not be corroborated by polysomnography findings.
2. Frequency: Sleep difficulties present three or more nights per week
3. Duration: Insomnia present for more than 1 (i.e. DSM-IV; ICD-10; RDC) or 6 months (i.e. ICSD)
4. Daytime impairments/marked distress: Score of 2 or 3 on Insomnia Severity Index scale (items 5 and 7)

No known published systematic reviews have focussed on the prevalence of insomnia in stroke patients. However, a number of less comprehensive, review articles have explored the association between stroke and sleep problems, including some mention of insomnia prevalence. For example, most recently, reviews by Alberti[5] and Dyken et al.[15] discuss a study by Leppävuori et al.[16] which found that insomnia was reported by 56.7% of 277 stroke patients. A review by Wallace et al.[3] discusses diagnosis, epidemiology and treatment of

insomnia but does not review the prevalence of insomnia in stroke patients; nor does a more comprehensive review of sleep and stroke by Jennum et al.[4]

This review will contribute to the evidence-base by synthesising existing knowledge about insomnia in stroke patients, thus providing a broader and deeper understanding of insomnia prevalence and the factors potentially mediating the relationship between stroke and sleep. In practice, such understanding can inform the development of assessment approaches and allocation of time and resources in terms of enhancing the efficiency of screening tools in this population. Treatment can also be guided by an understanding of both stable and modifiable contributing factors. Insomnia can impact upon a patient's functioning, including excessive daytime sleepiness, fatigue, memory and attention – potentially leading to stress and depression.[5] Impaired functioning can in turn affect rehabilitation, as illustrated by Siengsukon and Boyd[17] who found that sleep can enhance the learning of implicit motor skills. Moreover, Wallace et al.[3] review findings of an association between insomnia and death. A significant positive association between suicidality and frequent awakening has also been reported.[18] For these reasons a systematic review exploring insomnia prevalence and confounding factors in stroke patients is timely and driven by theoretical and clinical importance.

Aims

Main research question:

What is the prevalence of insomnia in stroke patients?

Subsidiary research question:

What is the impact of potential confounding factors upon insomnia prevalence in stroke patients?

Specifically:

a. Demographic factors (e.g. age, gender, employment, education, environment)

b. Comorbidity (i.e. current/premorbid psychological, psychiatric or physical health problems, medication use)

c. Sleep quality preceding stroke

d. Time elapsed since stroke

e. Stroke type or severity

f. First or recurrent stroke event

Search methodology

Electronic and manual search process

First, relevant electronic databases were searched on 30th May 2012 by combining MeSH terms and keywords relating to stroke and insomnia (see Appendix 1.2), tailored to individual databases where necessary. No publication cut-off date was applied. The electronic search generated 1346 articles in total for which citations and abstracts were examined (see Figure 1). Duplicates were removed then articles were sorted by type (i.e. exclusion of book sections, case reports, meta-analyses, reviews, systematic reviews, erratum, letters, commentaries, journal notes, biographies, guidelines, reference guides, position statements, expert opinion/review, prefaces, conference abstracts and animal studies). Drug/treatment studies not including stroke/cardiovascular diseases and sleep problems were then excluded, followed by the remaining non-drug/treatment studies unrelated to stroke/cardiovascular diseases and sleep. Full text was obtained for the remaining 35 articles and 10 of these fulfilled the inclusion and exclusion criteria for this review. One further article was identified by searching the reference lists of these 10 articles and of four recent reviews which discuss

stroke and insomnia.[3-5], [15] The combined electronic and manual search generated 11 articles for inclusion in this systematic review.

Inclusion and exclusion criteria

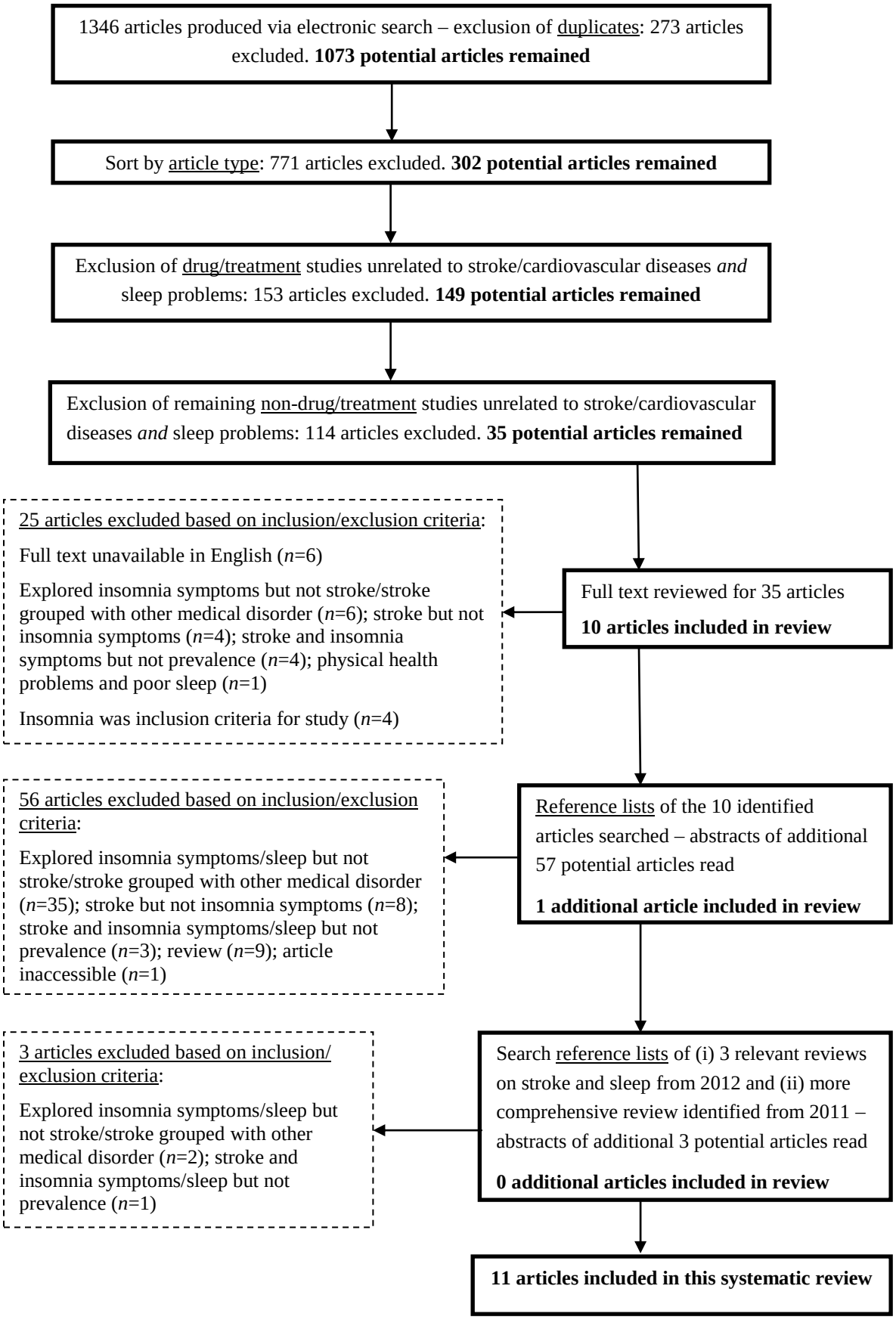
Inclusion

- Human participants aged 18 years or above
- Sample includes participants reported to have experienced stroke
- Sample includes participants reported to experience insomnia/insomnia symptoms
- Subjective and/or objective measure used to assess insomnia/insomnia symptoms
- Prevalence of insomnia/insomnia symptoms experienced by participants is reported
- Article appears in a peer-reviewed journal
- Article is accessible in English

Exclusion criteria

- Participants aged 17 years or below
- Drug/treatment study unrelated to stroke and insomnia/insomnia symptoms; or other irrelevant article type (see description of electronic and manual search process)
- Participants reported to have experienced Transient Ischemic Attack (TIA), other neurological disorder, or stroke results combined with those relating to other health disorder (e.g. heart problems)
- Participants reported to experience sleep disorder other than insomnia/insomnia symptoms
- No subjective and/or objective measure used to assess insomnia/insomnia symptoms
- No report of prevalence of insomnia/insomnia symptoms experienced by participants
- Article does not appear in a peer-reviewed journal
- Article is not accessible in English

Figure 1. Flowchart summary of search process



Quality evaluation and data abstraction

Quality evaluation of included studies

Quality evaluation criteria for the current systematic review (see Appendix 1.3) were generated based upon Boyle's[9] guidelines for evaluating prevalence studies, which were successfully applied in a previous systematic review focussing on traumatic brain injury. [19] The guidelines focus on sampling, measurement and analysis, which Boyle [9] describes as the basic elements. These guidelines were tailored to prevalence studies focussing specifically on insomnia in stroke patients and to the current research questions. Specifically, items were added to assess description of stroke and consideration of effects of stroke type and stroke as a first versus recurrent event upon sleep. Items were also adapted from Bloomfield's[19] review to assess description of stroke severity; definition of insomnia; instruments used to assess insomnia/insomnia symptoms; consideration of effects of stroke severity, sleep quality pre-stroke, time elapsed since stroke and other confounding factors upon sleep.

Finally, generic items were added relating to inclusion of a control group; consideration of demographic factors (following Bloomfield[19]); ethical approval and community based samples (following Giannakopoulos et al.[20]). The instrument by Giannakopoulos et al.[20] is presented in relation to the prevalence of temporomandibular disorder but was based on that of Boyle.[9] Relevant recent reviews were also explored for additional points to consider and already identified issues were reiterated (e.g. time elapsed since stroke and use of objective measures).[2],[3],[15] The final quality evaluation criteria included 21 items yielding a total score of 39. To also enable general comparison of quality for the purpose of this systematic review, scores were converted to percentages and categorised[19] as High (≥75%), Moderate (50-74%), Low (25-49%) or Poor (≤24%).

The 11 included articles in this review were scored according to the quality evaluation criteria, which also afforded the opportunity for clarification and refining of items. A second, independent rater then scored all articles and percentage agreement between the two raters (based on 231 items across 11 articles) was 89%. Discussion (e.g. further clarification of items) led to 100% agreement. Agreed ratings for all articles are shown in Appendix 1.4.

Data extraction

Table 2 summarises key information from all 11 included articles, which relates to sample characteristics (sample size, age, gender, recruitment strategy); assessment methods most relevant to this review for both stroke (measures of type and/or severity) and sleep (measures of insomnia symptoms; time elapsed post-stroke); main findings relating to prevalence of insomnia/insomnia symptoms (findings relating to subsidiary research question of confounding factors are discussed in the text); and quality evaluation (percentage score and qualitative description).

Table 2. Summary of included studies

Study	Sample characteristics	Key assessment methods – stroke	Key assessment methods – insomnia/insomnia symptoms	Main findings relating to prevalence of insomnia/insomnia symptoms	Quality evaluation
Palomäki et al.[21]	*N*=100 (68 female); mean age = 55.2 years (range 27–70); median = 56.0. Acute ischemic stroke patients consecutively hospitalised to a University Department of Neurology, Finland. Assigned to Miaserin (*n*=51) or placebo (*n*=49) group.	CT or MRI scan. SSS[22] & interview with neurologist to assess stroke severity. BI[23] to assess physical disability.	Defined as insomniac if one or more positive ratings for: initiation, maintenance or early wakening problems (items from HDS[24]). Initial assessment upon admission (average 14 days post-stroke).	At least one positive HDS sleep item reported by 63 of 93 (67.7%) patients (initiation 41.5%; maintenance 44.1%; early wakening 32.3%). 7 patients not assessed due to severe aphasia.	Moderate 62%
Chen et al.[25]	*N*=508; mean age = 65.7 years ±11.7. Selected cases from 874 first/recurrent ischemic stroke patients consecutively admitted to a hospital acute stoke unit 2004–2007, Hong Kong.	MRI. Stoke severity scores on NIHSS[26] obtained. BI to assess functional ability.	Published questionnaire used previously with elderly Chinese population.[27] Asked about sleep problems over past month (hrs spent asleep per night; hrs of sleep required; sleep initiation; maintenance; early wakening; self-perceived insomnia; sleeping medication; daytime tiredness). Assessment 3 months after stroke.	186 (36.6%) patients reported insomnia symptoms (i.e. "frequent" initiation or maintenance or early wakening problem). 64 (12.6%) patients had insomnia symptoms with daytime consequences (i.e. frequently feeling tired in daytime).	Moderate 62%
Leppävuori et al.[16]	*N*=277 (49.1% female); mean age = 70.7 years ±7.5. Selected cases from 486 consecutive ischemic stroke patients participating in a wider	MRI. Ischemic stroke type categorised according to published criteria for multi-centre clinical trials.[28]	Insomnia complaint present if patient reporting delayed sleep (at least 1hr), night-time insomnia (at least 1hr), or early wakening (at least 1hr), poor sleep quality and/or use of sleep-promoting drugs week prior to interview.	157 (56.7%) patients reported insomnia complaints; of these 104 (37.6% of all patients/66.2% of insomniacs) met DSM-IV criteria for insomnia and 53 (19.1/33.8%) did not. Of *post*-stroke insomniacs, 30 (60%) met DSM-IV criteria for insomnia; 20 (40%) only fulfilled criteria for insomnia complaint.	Moderate 62%

	stroke ageing memory study, Helsinki.	SSS to assess stroke severity. BI to assess physical disability.	Insomnia present if insomnia complaints lasted at least 1 month and impact on patient's daily life; following DSM-IV[29] criteria A–C for insomnia. Insomnia complaint/insomnia recorded as pre-stroke or post-stroke-onset. Evaluation 3–4 months post-stroke.	Of *pre*-stroke insomniacs, 74 (69.2%) met DSM-IV criteria for insomnia; 33 (30.8%) only fulfilled criteria for insomnia complaint. 4 (1.4%) patients diagnosed with hypersomnia, 7 (2.5%) with nightmares and 2 (0.7%) with disorder of the sleep-wake schedule.	
Vock et al.[30]	*N*=27 (16 female); median age = 49 years (range 18–76). First-time hemispheric ischemic stroke patients selected from admissions to a University Department of Neurology, Switzerland. Control: 11 patients (5 female) hospitalised in neurology (*n*=10) or dermatology (*n*=1) during study period; and published non-hospitalised age- and gender-matched norms. Median age = 43 years (range 26–67).	MRI & stroke volume assessed. NIHSS to assess stroke severity. BI & modified Rankin Scale[31] to assess stroke outcome.	Clinical interview, sleep questionnaire (including snoring & estimated sleep time per 24hrs) & ESS at hospital admission. EEG in acute i.e. 1–8 days post-stroke (all stroke patients), sub-acute i.e. 10–35 days post-stroke (*n*=13) & chronic i.e. 5–24 months (*n*=15) phases.	In 24 patients assessed, no change in median estimated sleep time (EST) before stroke and long-term follow-up (8hrs); increased EST in 9 (38%) patients. In 23 patients assessed, no change in median ESS score (4) pre-and post-stroke; increased in 11 (48%) patients post-stroke. Abnormal sleep EEG found in acute phase (67% patients), sub-acute phase (54%) and chronic phase (53%) compared to published norms. However, chronic phase EEG sleep pattern very similar between stroke patients and hospitalised controls.	Moderate 62%
Sterr et al.[32]	*N*=20 (7 female); mean age = 52 years (*SD* = 13; range 23–69).	Not reported.	PSQI.[33] ESS.[34]	9 (45%) participants reported potential sleep problems based on PSQI. 9 participants reported sleep-onset latency $\geq$ 30min; poor sleep efficiency (<85%); sleep duration within normal range;	Moderate 51%

	Opportunity sample from a cohort of patients attending University of Surrey motor rehabilitation trial following first-time stroke. Comparison with published norms.		Medical Outcome Study Short Form 36 (SF-36).[35] Time elapsed since stroke 12–180 months (mean = 51, *SD* = 10).	generally good sleep efficacy. 7 (40%) participants reported severe daytime sleepiness. Compared to normative data, sleep quality significantly poorer and daytime sleepiness significantly higher in stroke patients.	
Foley et al.[36]	Baseline (*N*=9282) and third annual follow-up data (*N*=6899). Age range = 65+ years. Data derived from a longitudinal aging study, recruiting from New Haven, East Boston, Iowa and Washington 1982–1985.	Participants asked whether they had been told by a physician or other health professional that they had a chronic medical condition, including stroke (noted at baseline and follow-up).	Participants rated problems with sleep onset; waking too early and not being able to fall asleep again (most of the time; sometimes; rarely; never). Time elapsed since stroke not reported.	Of those *without* insomnia symptoms at baseline assessment: Higher rates of incident insomnia found in those who reported stroke at baseline (18.9% of 233 reported insomnia at 3-year follow-up) or who reported stroke at follow-up (26.3% of 133 reported insomnia at 3-year follow-up), compared to those who reported no stroke (13.9% of 4590 reported insomnia at 3-year follow-up). Of those *with* insomnia symptoms at baseline: Higher retention of insomnia in those who reported stroke at baseline (63.5% of 104 reported insomnia at 3-year follow-up), compared to those who reported stroke at follow-up (50% of 54 reported insomnia at 3-year follow-up) and those who reported no stroke (50% of 1785 reported insomnia at 3-year follow-up).	Low 31%
Habte-Gabr et al.[37]	*N*=3097 aged 65+ years; *n*=1155 male (mean age = 73.7 years); *n*=1942 female (mean age = 74.8 years). Sample derived from a longitudinal population-based health survey in two	Lifetime history of physician-diagnosed stroke.	Participants were asked four questions relating to usual time for going to bed, falling asleep, getting out of bed in morning; and rated how often feel rested upon waking (responses divided into most of time or less than most of time).	History of stroke was significantly associated with decreased likelihood of women feeling rested in the morning compared to women with no stroke (68.4% vs. 79.1% feeling rested). History of stroke in men was significantly associated with increased likelihood of sleep latency >30min compared to men without stroke (21.8% vs. 10.6% reporting >30min).	Low 31%

	Iowa counties started in 1982 (total *N*=3673).		Sleep latency responses divided into >30min & ≤30min. Total sleep time also recorded (*n*=139 excluded from usual sleep time, sleep latency & total sleep time analyses). Time elapsed since stroke not reported.		
Stroe et al.[38]	*N*=2612 (50.4% female); age range 18–65 years (mean = 42.61 ±12.53). Sub-set of a larger epidemiologic study drawn from the general population of Detroit, recruited via random digital dialling technique; 1% (*n*=36) of sample had experienced stroke (mean age = 53.36 ±10.96 years; 41.7% male).	Participants asked about specific and current medical disorder(s) diagnosed by their doctor.	Frequency of problems with sleep onset and frequent awakenings over previous 2 weeks assessed with two rating scale items completed by participants. Assessed TST and TIB per 24 hours, and sleep efficiency. ESS. Time elapsed since stroke not reported.	Significantly higher percentage of participants who reported stroke had difficulty falling asleep (33.3%) and frequent awakenings (41.7%) compared to participants (*n*=867) who reported no medical disorder (9.3% and 19.7% respectively). TST (6.13hrs) and sleep efficiency (81.09%) significantly lower in stroke group than no medical disorder group (6.92hrs and 90.92% respectively). Mean ESS score (8.03) and TIB (7.6hrs) higher (but non-significant) in participants who reported stroke than participants reporting no medical condition (7.31 and 7.53hrs respectively).	Low 33%
Küçükdeveci et al.[39]	*N*=46 Selected cases from 85 stroke patients consecutively admitted to a hospital rehabilitation unit, Leeds, over 20 month period. Control: 47 age- and gender-matched participants with no history of stroke and no acute/serious medical	Information of cerebrovascular accident (date, type, side) was recorded; hospital files used if necessary. BI to assess current functional disability.	4-item self-report sleep questionnaire to rate frequency of insomnia symptoms in the past month (problems with initiation, maintenance, early wakening, waking feeling tired and worn out). Participation 3.1–38.2 months (median 15.9) after stroke & minimum 1.5 months after discharge.	Frequency of sleep disturbances revealed patients reported significantly more problems with sleep initiation than controls (22 patients & 16 controls reported initiation problem occurring at least 1 day in past month). No significant differences between patients and control group regarding problems with sleep maintenance (30 patients & 28 controls reported problem); waking several times per night (18 patients & 22 controls reported problem); or waking up tired (22 patients & 21 controls reported problem).	Low 28%

	problems (*n*=18 research group volunteers; *n*=29 selected alphabetically from GP practice).			Patient total sleep score higher (but non-significant) compared to control group.	
Ito et al.[40]	*N*=518 (263 female). Age = all 65 years old. Population-based health check-up programme open to residents in N City, Japan 1996-97 (total 1144 residents eligible). Of 255 males, 5.5% (*n*=14) reported prior stroke; of 263 females, 2.7% (*n*=7) reported prior stroke – remainder reported no stroke history.	Self-administered questionnaire included question about medical history. Clinical and physical examination upon entry to study.	Self-administered questionnaire asked about average sleep duration (hrs) per night, sleep-onset time (>30 min classified as a difficulty), number of wakenings per night (>2 classified as frequent), whether feel 'good'/'bad' when wake up ('bad' classified as feeling not rested). Time elapsed since stroke not reported.	Males with history of stroke (*n*=14): problem with sleep initiation (30.8%); frequent awakening (30.8%); not feeling rested (15.4%); any of the 3 disturbances (66.7%). Females with history of stroke (*n*=7): problem with sleep initiation (28.6%); frequent awakening (14.3%); not feeling rested (27.3%); any of the 3 disturbances (42.9%). However, no significant differences in prevalence of sleep disturbances between those with and without past history of stroke, in males or females.	Poor 21%
Popoviciu et al.[41]	*N*=70; age = not reported in article. Ischemic vertebro-basilar stroke cases selected from a total 271 cases studied over the previous 20 years.	Transcranial Doppler ultrasound; EEG recordings; computerised EEG mappings (cortical cartography); intracranial artery blood flow velocity.	Continuous night PSG recording (duration 6, 8, 12, 24 hours – or to death in some patients). Time elapsed since stroke not reported.	5 cases accompanied by insomnia – identified with "bulbontomesencephalic diffuse signs and sleep disorganisation: total absence of DSWS [deep slow wave sleep] and frequent fragmentation during the night of the LSWS [light slow wave sleep] stages by wakefulness periods" (p.288).	Poor 23%

Key to abbreviations: CT = computerised tomography; MRI = magnetic resonance imaging; SSS = Scandinavian Stroke Scale; BI = Barthel Index; HDS = Hamilton Depression Scale; NIHSS = National Institute of Health Stroke Scale; ESS = Epworth Sleepiness Scale; EEG = electroencephalogram; *SD* = standard deviation; PSQI = Pittsburgh Sleep Quality Index; TST = total sleep time; TIB = time in bed; PSG = polysomnography.

Results

The most relevant findings from each article are described alongside comment regarding key methodological strengths and limitations. Increased weight is attributed to articles assigned higher quality ratings.

What is the prevalence of insomnia in stroke patients?

As also found by Bloomfield[19], variations in the definition of insomnia exist across studies – likely a pivotal influence upon reported prevalence rates. With this in mind, four studies with a 'moderate' quality rating of 68%[16],[21],[25],[30] all include ischemic stroke patients, although differ on additional factors; for example, sample size, recruitment strategy, inclusion of control group, assessment of stroke and sleep and time elapsed post-stroke, which prevents clear conclusions being drawn about insomnia prevalence. Leppävuori et al.'s[16] study of 277 patients revealed 56.7% patients reported insomnia complaints; however 37.6% of all participants met DSM-IV criteria A–C for insomnia, illustrating from the outset the effect of insomnia definition upon prevalence. The authors also made a distinction between pre- and post-stroke insomniacs (see Table 2). This study has a number of strengths, including standard methods for assessing sleep and stroke; sampling of consecutive patients; comparison of included and excluded participant characteristics; and comparison of pre- and post-stroke insomniacs. However, there is no report of a control group without stroke against which to assess prevalence of insomnia and evaluation did not take place at the same time-point (3-4 months post-stroke) for all participants.

Both Chen et al.[25] and Palomäki et al.[21] report utilisation of published questionnaires for assessment of insomnia symptoms, although the authors do not discuss the reliability or

validity of these measures. Chen et al.'s[25] assessment of consecutively hospitalised participants at three months post-stroke revealed 36.6% of patients reported insomnia symptoms whilst 12.6% reported insomnia symptoms with daytime consequences (i.e. frequently feeling tired). This study reports inclusion and exclusion criteria, utilised standard methods for assessing stroke, but does not refer to a sleep classification system or include a healthy control group and also attained a low response rate. The authors acknowledge further limitations including possible selection bias (i.e. 41.9% excluded, including those with severe aphasia), lack of more accurate sleep measures such as polysomnography, no full psychiatric assessment (e.g. anxiety with insomnia might have inflated insomnia prevalence) and cross-sectional design with lack of information about sleep pre-stroke, preventing conclusions to be made about stroke lesions and insomnia.

Palomäki et al.[21] extracted items from a depression scale to assess insomnia symptoms in consecutively hospitalised patients, this time an average of 14 days post-stroke. They found 67.7% of 93 participants reported at least one insomnia symptom. A high response rate is reported and, again, standard methods were utilised for assessment of stroke but there is no report of a non-stroke control group, inclusion criteria or sleep classification system (they state the insomnia definition "resembles" ICSD-R[42] (p.60) but also that one might query whether it is too sensitive). Additionally, time elapsed between stroke and assessment is inconsistent across participants.

Vock et al.[30] selected 27 eligible consecutive patients for their study which, although revealed abnormal sleep EEG in the acute phase (1–8 days post-stroke), showed no significant differences in sleep EEG between stroke patients and hospitalised patients in the chronic phase. Key strengths of this study include the hospitalised control group (although small in number and compensated by addition of non-hospitalised norms); reported inclusion

and exclusion criteria; standard stroke and sleep assessment methods; established sleep assessment methods and consideration of sleep pre-stroke. However, the response rate is not reported, time elapsed post-stroke at assessment is inconsistent, a sleep classification system was not employed when describing insomnia symptoms and the authors comment on a small sample size. Sterr et al.'s[32] study was also rated 'moderate' but attained a lower score of 51%. From an opportunity sample of 20 participants, 45% reported potential sleep problems and 40% reported severe daytime sleepiness, based on standard sleep questionnaires. Additionally, the authors noted these problems with sleep and daytime sleepiness were significantly poorer when compared to normative data. However, details of inclusion criteria, response rate and stroke assessment are not reported; there is no reference to a sleep classification system; and time elapsed post-stroke varies from 12–180 months.

Küçükdeveci et al.,[39] Foley et al.,[36] Habte-Gabr et al.[37] and Stroe et al.[38] were rated 'low' quality articles. Only Küçükdeveci et al.[39] focus specifically on stroke by following up 46 of 85 consecutively admitted patients. They found a significantly higher proportion of sleep initiation problems compared to a non-stroke control group, but no significant differences regarding maintenance, night-time wakening or waking up tired. The authors included a control group and stroke information was "recorded" (p.168), although this information is not reported; sleep assessment involved non-standardised rating scales; response rate was 54%; and time elapsed post-stroke varied from 3.1–38.2 months. Foley et al.'s[36] longitudinal study included data relating to participants who claimed they had, or had not been, told they had experienced stroke. For participants reporting no insomnia symptoms at baseline, higher rates of insomnia symptoms were found in those reporting stroke at baseline (18.9%) or at 3-year follow-up (26.3%) compared to those reporting no stroke (13.9%). For participants who did report insomnia symptoms at baseline, a higher retention of symptoms was found in those reporting stroke at baseline (63.5%) than those reporting stroke at 3-year follow-up, or no

stroke (both 50%). Despite being a general population based study with a 70% response rate and comparison with non-stroke participants, stroke presence is based only upon self-report and sleep problems upon non-standardised rating items with no sleep classification system; age, inclusion and exclusion criteria are not defined; and time elapsed post-stroke is not reported. The authors also state that a lack of insomnia measurement over the 3-year follow-up makes it difficult to ascertain whether the insomnia was acute or chronic.

Habte-Gabr et al.[37] report an association between history of stroke in females with a decreased likelihood of reporting feeling rested in the morning (68.4% compared to 79.1% of females without stroke reporting feeling rested). A higher proportion of males with stroke had increased sleep latency (21.8%) compared to those without stroke (10.6%). Both associations were significant. A response rate of 84% is reported, however the source of the physician diagnosis of stroke is unclear (e.g. case file review, self-report, or other); the number of participants with stroke is unclear; sleep assessment is based on non-standardised rating items without inclusion of a sleep classification system or timescale; and time elapsed post-stoke and inclusion and exclusion criteria are not outlined. The authors also comment on over-estimations of sleep latency and under estimations of sleep time that can arise from self-report.

Stroe et al.'s[38] sample of 2612 participants from a larger epidemiological study revealed that, compared to those without a medical disorder, those with stroke included a significantly higher percentage of participants with sleep initiation and awakening problems and also had a significantly lower total sleep time and sleep efficiency. Although the ESS was employed to assess sleepiness, onset and awakening problems are based on non-standardised criteria; stroke presence is based on self-report; response rate was 70%; only exclusion criteria are reported; and there is no report of time elapsed since stroke. The authors state that limitation

of age to 18–65 years prevents generalisation of findings to some extent. They also discuss the inability to make causal inferences about the relationship between medical diseases and sleep problems from cross-sectional design research (cf. Ito et al.[40]) and comment on the potential to include objective measures such as polysomnography.

Articles by Ito et al.[40] and Popoviciu et al.[41] were rated as 'poor' quality. Ito et al.'s[40] sample of 518 residents from a population-based health check-up programme included a small number of males (*n*=14) and females (*n*=7) reporting prior stroke and found no significant differences in the prevalence of sleep problems between those who did and did not report prior stroke. Despite being population based, the response rate was only 45.3%; inclusion and exclusion criteria are not outlined; medical history and sleep are based on self-report (with no detail of the clinical and physical examination); and there is no note of time elapsed since stroke. Popoviciu et al.[41] outline objective stroke and sleep assessment methods in their study of 70 selected stroke cases and briefly mention five cases with insomnia symptoms but without reference to a sleep classification system for insomnia. In addition, the article does not include inclusion and exclusion criteria; details of recruitment or age of participants; a control group; or a note of time elapsed post-stroke.

What is the impact of potentially confounding factors upon insomnia prevalence in stroke patients?

A number of included articles explored one or more factors which might affect the prevalence of insomnia/insomnia symptoms in stroke patients. Article limitations outlined previously will not be repeated here. Articles without exploration of mediating factors relating specifically to stroke and sleep[37],[38][40],[41] or such results included in the remaining articles are not discussed here.

Demographic factors (e.g. age, gender, employment, education, environment)

Leppävuori et al.[16] found insomnia/insomnia complaints to be significantly more frequent in females than males and a higher mean age of those with insomnia than those without. This contrasts with Palomäki et al.'s[21] finding of a lack of significant gender effect and also lack of age effects found by Palomäki et al.[21] and Sterr et al.[32] It is suggested by Palomäki et al.[21] that a lack of significant effect of age may be due to including only those aged 71 and below in their study. Living alone was reported by Palomäki et al.[21] as a predictor of insomnia complaints from multiple logistic regression analysis and Leppävuori et al.[16] reported those with post-stroke insomnia were found more often to have a low level of education than pre-stroke insomniacs. No significant association between marital status and insomnia complaints was reported by Palomäki et al.[21] and, additionally, Sterr et al.[32] found caffeine and alcohol intake were not significantly associated with nocturnal sleep or sleepiness. In Leppävuori et al.'s[16] study, sleep assessment did not relate to the same environment (e.g. hospital versus at home) across all participants and the impact of this is unclear.

Comorbidity (i.e. current/premorbid psychological, psychiatric or physical health problems, medication use)

Leppävuori et al.[16] explored the broadest range of comorbidities. Of the *n*=157 with insomnia complaints, 66% were classified as having primary insomnia whilst for 21% it was attributed as a consequence of stroke or other physical illness (migraine was more significant in insomniacs than non-insomniacs). In 12.1% it was best explained by a depressive or anxiety disorder. Based upon DSM-IV criteria, depression was reported for 51.6% insomniacs but only 25% of non-insomniacs; in line with this, Palomäki et al.[21] report depression emerged as an independent predictor of early wakening insomnia at their baseline

assessment (based on the Beck Depression Inventory[43]) in multiple logistic regression analyses and Chen et al.[25] found scores on a Chinese version of the Geriatric Depression Scale[44] were significantly higher in those with insomnia symptoms than those without. They highlight that, despite excluding those with DSM-IV depression as a potential influence on insomnia, subclinical depression still appeared to be a strong predictor of insomnia symptoms and insomnia symptoms with daytime consequences. Leppävuori et al.[16] also report a significant difference in the prevalence of anxiety disorder diagnosis for insomniacs (31.2%) compared to non-insomniacs (9.2%). However, Sterr et al.[32] describe anxiety, depression (based on the Hospital Anxiety and Depression Scale[45]) and general psychological health (based on the Medical Outcome Study Short Form 36) as an improbable explanation of sleep and sleepiness problems in long-term stroke survivors. Similarly, Küçükdeveci et al.[39] report that, despite significantly higher anxiety and depression in stroke patients versus healthy controls, no significant increase in insomnia symptoms was found in patients apart from problems falling asleep (which they suggest may be due to use of sleep medication). Leppävuori et al.[16] also note a significant difference in the prevalence of DSM-III-R[46] dementia diagnosis in insomniac (24.2%) compared to non-insomniac (13.3%) stroke patients.

In terms of physical health, a significantly higher prevalence of diabetes mellitus (as recorded in the hospital stroke registry) was found in those with insomnia symptoms than those without (Chen et al.[25]) and a significant positive association reported between participant-rated bodily pain and longer sleep duration (Sterr et al.[32]). In addition, Küçükdeveci et al.[39] revealed that stroke patients with shoulder pain (assessed via patient report and joint examination) reported significantly higher sleep disturbance than patients without shoulder pain; in contrast, pain was significantly less frequently reported by age- and gender-matched controls without acute/serious medical health problems and was not associated with increased

sleep disturbance. Palomäki et al.[21] suggest that exclusion of severe diseases (e.g. dementia, severe cardiovascular disorders, alcoholism) from their study as a potential confound might have led to under-estimation of insomnia complaints. Leppävuori et al.[16] found no significant difference in snoring and apnoea between those with insomnia and those without, although assessment of snoring and apnoea is not outlined in the article. In contrast, Vock et al.[30] excluded sleep apnoea in their study due to its potential effect on sleep change post-stroke. Leppävuori et al.[16] suggest insomnia prevalence might have been under-estimated due to the fact excluded individuals were often more severely physically disabled (based on the Barthel Index) and dependent on daily assistance. The authors also note use of sleep-prompting medication by 48% of stroke patients with insomnia (commenced pre-stroke in 26.4% of patients) and that two-thirds of patients using medication reported sleep satisfaction. Vock et al.[30] attempted to avoid sedative and hypnotic use in their study although note usage by some patients, which may confound their results.

Sleep quality preceding stroke

Vock et al.[30] found no significant overall change in estimated sleep time (EST) or Epworth Sleepiness Scale scores between pre-stroke and long-term follow-up (median 12 months post-stroke). In terms of prevalence, Leppävuori et al.[16] note that 38.6% of stroke patients reported pre-stroke onset of insomnia/insomnia complaints while 18.1% reported post-stroke onset.

Time elapsed since stroke

Although time elapsed since stroke varies across articles, so too do study design, assessment methods and other confounding variables, making cross-study comparison unreliable. However, some results are reported within articles. For example, increased time since stroke

has been significantly associated with increased daytime sleepiness and bodily pain (Sterr et al.[32]). Vock et al.[30] explored sleep in the acute, sub-acute and chronic stage post-stroke compared to hospitalised control patients and found similar sleep EEG in the two groups within the chronic phase. However, in the acute phase, patients demonstrated significantly shorter total sleep time (for the first three hours of sleep), significantly higher waking after sleep onset and significantly lower sleep efficiency compared to the sub-acute and chronic phase.

Stroke type or severity

Leppävuori et al.[16] reported that post-stroke insomniacs had a significantly more physically disabling stroke (as measured by the Scandinavian Stroke Scale; SSS) and presented with major dominant stroke syndrome significantly more often than non-insomniacs (non-insomniacs most often presented with minor non-dominant syndrome). They found no other significant associations between stroke severity or syndrome and insomnia. Chen et al.[25] found frontal lobe infarction was significantly associated with insomnia symptoms but not insomnia with daytime consequences, which the authors suggest illustrates a link between infarction site and insomnia in stroke. Chen et al.[25] relate their findings to Leppävuori et al.'s[16] study, which predominantly involved anterior (vs. posterior) major dominant hemispheric strokes. This contrasts with Palomäki et al.'s[21] findings of no significant effect of stroke location (hemispheral vs. brainstem) or severity (using the SSS) on frequency of insomnia complaints. However, Vock et al.[30] note a significant inverse correlation between amounts of wakefulness after sleep onset (WASO) and stroke outcome at discharge (using the Barthel Index; a higher score indicates higher independence); additionally, a significant positive relationship was found between WASO and stroke outcome at long-term follow-up (using the modified Rankin scale; a higher score indicates worse outcome).

First or recurrent stroke event

Chen et al.[25] found no significant association between previous stroke (as recorded in the hospital stroke registry) and frequent insomnia symptoms or insomnia with daytime consequences. However, the authors did not compare patients with previous stroke and patients with first time stroke.

Discussion

Summary of research findings

The main aim of this systematic review was to explore the prevalence of insomnia in stroke patients but this is very difficult to ascertain due to methodological inconsistencies and omitted information across articles, even within studies rated 'moderate' quality. Only Leppävuori et al.[16] explicitly based insomnia assessment upon diagnostic criteria (DSM-IV) which produced a prevalence rate of 37.6%, increasing to 56.7% based on reported insomnia complaints. However, other 'moderate' quality articles based on more subjective measures revealed prevalence rates of insomnia symptoms ranging from 12.6% (sleep questionnaire; Chen et al.[25]) to 45% (PSQI; Sterr et al.[32]) to 67.7% (sleep items from a depression scale; Palomäki et al.[21]).

However, not only insomnia definition and assessment differed across articles, therefore the specific methodological factor(s) accounting for the variation in insomnia prevalence is unclear (i.e. sample size, recruitment strategy and time elapsed since stroke are all potential key contributing factors). For example, time elapsed since stroke was found to influence sleep in stroke patients (Sterr et al.;[32] Vock et al.[30]) and this was not only inconsistent across articles adding to difficulties comparing the studies, but was inconsistent or unreported

in some articles. Researchers should at least record time elapsed since stroke and, ideally, maintain consistency across participants. Inconsistencies were also found in terms of whether sleep problems were worse in stroke patients compared to control data (Sterr et al.;[32] Foley et al.;[36]Habte-Gabr et al.; [37] Küçükdeveci et al.;[39] Stroe et al.[38]) or there were no differences (Vock et al.;[30] Ito et al.;[40] Küçükdeveci et al.[39]). As an aside, by way of gross comparison, Morin et al.[47] report a prevalence of 9.5% for insomnia syndrome in a general population-based study using DSM-IV and ICD-10 criteria, which is lower than the prevalence rates found in stroke patients by Leppävuori et al.,[16] who also utilised DSM-IV criteria.

There were contradictory findings for age and gender as mediating factors and corroborative research is also required regarding other demographic variables (e.g. living alone, education, marital status, caffeine and alcohol). This systematic review includes participant samples from different countries and Chen et al.[25] state the effect of ethnicity in the development of insomnia is unknown, therefore cross-cultural comparison could be an area for further research. No articles reported the effect of environment on sleep in stroke patients, yet the hospital environment presents numerous factors that can disturb sleep.[48] The results suggest medical problems are more prevalent in stroke patients and can be associated with insomnia symptoms. In addition, depression and anxiety were associated with insomnia, but again there are contradictory results.

Additional articles in this review explored demographic factors, but meaningful conclusions could not be drawn from them as the results did not relate specifically to stroke (Habte-Gabr et al.;[37] Ito et al.;[40] Popoviciu et al.;[41] Stroe et al.[38]). Further research is required to explore the impact of first versus recurrent stroke and also premorbid sleep on insomnia prevalence (although Chen et al.[25] highlight the potentially unreliable retrospective reporting

of sleep pre-stroke). Further research is also required regarding the effect of time elapsed since stroke, stroke type and stroke severity, which yielded mixed results. Due to the high rate of medication use in stroke patients[16] and the potentially disruptive effects of medication, caffeine and alcohol on sleep,[14] researchers should also be mindful of these factors when undertaking insomnia studies with stroke patients. Due to the limited and contradictory findings identified at this stage, it is not possible to clearly establish the theoretical basis of insomnia in stroke patients but, as suggested by Chen et al.,[25] it is likely to be multi-factorial.

Methodological quality of the research

In addition to the aforementioned issues, the overall low quality rating of articles included in this review may possibly reflect a dearth of research designed specifically to explore insomnia prevalence in stroke patients. Indeed, in some articles stroke per se was not the predominant patient population of interest but were included in this review because they mentioned relevant prevalence data. This in itself highlights a gap in the current research literature. Such research should employ consistent criteria for insomnia classification to enable cross-study comparisons;[19] Sterr et al.[32] also recommend more objective measures such as actigraphy and EEG. Many articles in this review employed subjective self-report measures for not only sleep but also stroke presence and potentially confounding variables (e.g. medical conditions). Habte-Gabr et al.[37] acknowledge the possible unreliable nature of self-report but also highlight that most often this is the method by which clinicians are made aware of sleep problems in practice. Furthermore, Chen et al.'s[25] report that sub-clinical depression is a strong predictor of insomnia further illustrates the role of less stringent classification methods in clinical practice (cf. Elwood et al.[8]).

Caveats of this systematic review

There are no known published systematic reviews focussing on insomnia prevalence in stroke patients. Therefore, the results of this review are a first step in terms of reviewing the findings thus far and highlighting possible methodological and mediating factors contributing to the inconsistencies amongst them in order to facilitate future research. It is particularly difficult to disentangle the findings from articles not specifically focussing on stroke and insomnia due to the multiple other factors involved. However, again this relates back to the fact that few pure prevalence studies on stroke and insomnia were identified, which also limits generalisation of results. It is possible that relevant articles have been excluded due to the limited remit of this systematic review and consequent stringent exclusion and inclusion criteria. However, these criteria were at the same time necessary due to the expanse of research exploring stroke and sleep disorders generally.[2],[3]

Clinical implications and directions for future research

This systematic review raises implications for both clinical practice and research. As highlighted at the outset, sleep problems can impair functioning and rehabilitation post-stroke and the articles reviewed highlight further potential consequences for patients' adjustment and well-being. For example, social isolation may arise following stroke and further impact upon sleep[39] and an association between insomnia in stroke and impaired psychosocial functioning has been reported.[16] Therefore, insomnia symptoms may have consequences reaching beyond rehabilitation in the hospital ward. Screening of sleep disorders has been suggested as a routine aspect of stroke care (also supported by the current review), along with increased awareness of the impact of sleep problems in patients, families and neurologists-in-training.[49] This review highlights it is important not to assess insomnia symptoms in isolation as there are multiple other potential mediating factors. However, causal inferences

cannot arise from cross-sectional research – to facilitate understanding, longitudinal designs are recommended.[40],[38] Treatment of insomnia in stroke patients will then be able to focus on the factors underpinning it.[1] There is evidence of cognitive behavioural therapy (CBT) being as effective as pharmacological interventions for insomnia,[3] although this research does not relate to stroke patients. Through a deeper understanding of the factors precipitating and maintaining insomnia in stroke patients it may be possible to tailor CBT specifically to this population. This is particularly valuable for patients who are already involved in complex medication regimes[6] and due to potential negative side-effects of pharmacological interventions which may also exacerbate sleep problems in the long-term.[39]

Conclusions

Inconsistencies in methodology across studies have generated a very broad estimate of prevalence of insomnia symptoms but which supports screening for insomnia in stroke patients by clinicians – particularly in light of the potentially detrimental impact of sleep problems on stroke outcome. Future research should strive towards standardised classification systems for assessment of insomnia when exploring prevalence in this area, whilst being mindful of the multiple factors potentially contributing towards insomnia (which in themselves open many avenues of further research). Adherence to these basic principles will help inform the development of an effective assessment and treatment process for every stroke patient and potentially improve recovery post-stroke.

Practice points

1. There is a paucity of research on insomnia prevalence in stroke patients;
2. Methodological inconsistencies cause difficulty in ascertaining the prevalence of insomnia and insomnia symptoms in this population;
3. Based on formal diagnostic criteria, the prevalence of insomnia was 37.6%, although this varied widely in studies utilising less stringent criteria;
4. Exploration of demographic and other factors potentially related to insomnia prevalence following stroke revealed inconsistent findings and a lack of reported information across studies.

Research Agenda

1. Studies on insomnia prevalence in stroke patients should utilise more formal insomnia classification criteria and acknowledge the range of factors that might influence prevalence;
2. Longitudinal research design may facilitate a deeper understanding of the factors contributing to insomnia and insomnia symptoms in stroke patients;
3. Research is required to explore the effectiveness of CBT for insomnia following stroke.

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*The 11 articles included in this systematic review are preceded by an asterisk.

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CHAPTER 2

Major Research Project

Understanding sleep problems in rehabilitation inpatients after stroke

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Keywords: stroke; sleep disorder; pre-sleep cognition; arousal; fatigue

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Prepared according to instructions to authors for *Stroke* (see Appendix 2.1)

Lay summary

Background and Purpose: Sleep problems are commonly reported by stroke patients. Poor sleep quality can impair mood, physical health, mental processes and the rehabilitation process itself. However, we do not fully understand why some patients sleep well after stroke while other patients do not. Worries, racing thoughts and physical symptoms of anxiety at bed-time can lead to sleep problems in the general population and this novel study investigates whether these factors might also help explain sleep quality in stroke patients.

Methods: Twenty-one stroke patients residing within inpatient rehabilitation wards were classified as good or poor sleepers using a questionnaire (Pittsburgh Sleep Quality Index; PSQI) which assessed their sleep pattern, sleep quality, sleep medication use and daytime performance. Good and poor sleepers were compared in terms of level of worries, racing thoughts and physical symptoms they reported experiencing at bed-time since the stroke. Good and poor sleepers were also compared in terms of their experience of daytime sleepiness, fatigue, mood and disturbance due to the environment since the stroke, as these factors can also affect sleep quality.

Results: Poor sleepers reported a significantly higher level of worries, racing thoughts, fatigue and mood difficulties than good sleepers. The level of daytime sleepiness and perceptions of environmental disturbance did not differ significantly between groups.

Conclusions: This study revealed a high level of poor sleep within a group of stroke rehabilitation inpatients (48%) based on the PSQI. Worries and racing thoughts at bed-time appear potentially important factors related to sleep quality in stroke patients. Implications of these results for understanding, assessing and treating sleep problems in stroke patients are discussed, along with suggestions for further research.

Abstract

Background and Purpose: Sleep problems are commonly reported by stroke patients. Poor sleep quality can detrimentally impact upon multiple clinical variables, including mood, physical health, cognition and the rehabilitation process itself. However, the relationship between sleep and stroke is complex and not fully understood. Pre-sleep cognitions and pre-sleep arousal have been proposed as contributing factors in sleep disturbance within the general population and this novel study investigates these variables as potential factors associated with sleep post-stroke.

Methods: Stroke rehabilitation inpatients (N=21) were classified as good or poor sleepers using the Pittsburgh Sleep Quality Index (PSQI) and compared using measures of pre-sleep cognitions and pre-sleep arousal; relevant factors including daytime sleepiness, fatigue, mood and environmental disturbance were also explored.

Results: Poor sleepers reported a significantly higher level of pre-sleep cognitions, pre-sleep cognitive arousal, fatigue and mood disturbance than good sleepers. The level of daytime sleepiness and perceptions of environmental disturbance did not differ significantly between groups.

Conclusions: This study revealed a high level of poor sleep within the current sample (48%) based on the PSQI and pre-sleep cognitions and cognitive arousal appear potentially important factors in sleep quality post-stroke. Theoretical and practical implications and future directions for research are discussed.

Introduction

Stroke is a leading cause of mortality worldwide and also incurs high economic costs as a major cause of long-term disability.[1] Consequences of stroke can involve motor deficits, aphasia, impaired cognitive ability and perceptual deficits.[2] Consequently, research exploring modifiable factors that might impact upon stroke outcome is of high clinical importance. Sleep is one such factor. Sleep is both a potential risk factor and outcome associated with stroke, involving a complex relationship not yet fully understood.[3] The current study contributes to the literature by investigating factors associated with sleep quality post-stroke within rehabilitation inpatients, focussing particularly upon sleep-related cognitions and pre-sleep arousal, which have received little attention to this point within the stroke population.

Sleep is "…as necessary as food and water".[4, p.7] Disturbance to sleep quantity, quality or timing has a bi-directional relationship with mood disturbance and can also lead to impaired physical health, mortality, reduced quality of life and cognitive impairment – particularly speed of processing and attention and, to a lesser extent, memory, language, mental arithmetic and executive functions.[5] Deficits in sleep may impact upon the rehabilitation process by reducing motivation, energy and concentration,[3] highlighting the clinical importance of sleep quality for stroke patients. Indeed, sleep has been found to enhance the learning of implicit motor skills post-stroke.[6]

Specific sleep disorders are commonly reported by stroke patients, including sleep disordered breathing problems (sleep apnoea, habitual snoring and Cheyne-Stokes respiration); sleep-wake disorders (insomnia, hypersomnia; excessive daytime sleepiness; parasomnia; circadian rhythm disorder); and sleep-related movement disorder (restless legs syndrome and periodic

limb movements).[3],[7],[8] As part of this study, specific sleep problems experienced by patients were explored. Bassetti and Hermann[8] review possible accounts for sleep disturbance post-stroke, including lesions in brain areas regulating sleep and/or breathing; consequences of the stroke itself (e.g. pain, mood disturbance, stress); environmental factors (e.g. noise, light, temperature, medical intervention); and stroke-related comorbidities (e.g. infections, cardiac failure, medication use).

No known published studies have investigated sleep-related cognitions and pre-sleep arousal in relation to sleep quality post-stroke. Within a cognitive model of insomnia, Harvey[9] proposes that worry about sleep and the consequences of sleep loss leads to autonomic arousal and distress, which activates selective attention towards – and monitoring of – internal and external sleep-related threat cues. Consequently, perceived deficits in sleep and daytime performance are over-estimated and the cycle is maintained by counter-productive safety behaviours (e.g. thought control) and inaccurate beliefs about sleep and the benefits of worry; ironically, escalation of this cycle can lead to real deficits in sleep and daytime functioning.[9] Similarly, Morin and Espie[4] describe how sleep problems can persist if interpreted as a sign of danger or loss of control. Compared to good sleepers, poor sleepers report more negative cognitions about sleep (e.g. thoughts about not falling asleep), engage in more monitoring and safety behaviours (e.g. clock watching) and have more dysfunctional beliefs and attitudes about sleep.[4] For example, people with insomnia have been found to report a significantly higher frequency of pre-sleep thoughts than good sleepers using the Glasgow Content of Thoughts Inventory (GCTI).[10]

In addition, Nicassio et al.[11] found an association between higher pre-sleep arousal and increased likelihood of reported sleep disturbance (e.g. describing oneself as an insomniac, increased sleep onset latency, night awakenings and daytime listlessness); they also report

people with insomnia scored significantly higher on every item of the Pre-Sleep Arousal Scale (PSAS) compared to normal sleepers. The current study explored whether these phenomena – based upon research in the general population – can facilitate understanding of sleep post-stroke.

Additional factors that might be associated with sleep post-stroke were also explored. A specific measure of daytime sleepiness was included, as previous research found daytime sleepiness in stroke was higher compared to age- and gender-matched healthy control participants and a higher level of daytime sleepiness was associated with increased time since stroke.[12] Fatigue is common post-stroke and can be associated with sleep problems[13] therefore was also explored. Mood and environment have also been identified as potentially important mediating variables in previous studies, therefore were examined. In addition to the aforementioned relationship between sleep and mood,[5] anxiety and depression have been found to be significantly higher in stroke patients compared to healthy controls.[14] As participants in the current study were recruited across multiple wards, participants' perceptions of the impact of environment upon sleep were explored, as factors such as noise, physical environment and routine have previously been reported as disruptive by patients.[15]

Two further variables, medical problems and pain, were also recorded in this study. In a community-based study, a higher prevalence of insomnia was found in those with medical problems than those without and, in turn, a higher prevalence of medical problems in those with insomnia than those without.[16] Furthermore, exclusion of stroke patients with other health problems may have led to a non-representative sample in the current study. Küçükdeveci et al.[14] revealed that pain was significantly more frequently reported by stroke patients than healthy controls and, importantly, patients with shoulder pain reported significantly higher sleep disturbance than patients without shoulder pain, whilst pain was not

associated with increased sleep disturbance in controls. Finally, the current study explored participants' perceptions of the factors they believed to be contributing to their sleep quality to explore any additional, or contrasting, variables.

To summarise, literature to date suggests sleep post-stroke to be multi-faceted. The current study focuses on a novel investigation of sleep-related cognitions and pre-sleep arousal in stroke patients and also takes into consideration a number of stroke-related and other non-specific factors.

Aims and hypotheses

Main aim

1. To explore factors that might impact upon sleep quality post-stroke by comparing 'good' and 'poor' sleepers in terms of pre-sleep cognitions, pre-sleep arousal, daytime sleepiness, fatigue; whilst also exploring mood, environment and pain.

Subsidiary aims

2. To explore the sleep pattern and type of sleep problems experienced post-stroke based on the report of patients and Consultant Stroke Physicians.

3. To explore patients' beliefs about the factors contributing to their sleep quality post-stroke.

Hypotheses

Primary hypothesis

Stroke patients classified as ‘poor’ sleepers will report a higher frequency of pre-sleep thoughts than ‘good’ sleepers.

Secondary hypotheses

Stroke patients classified as ‘poor’ sleepers will report higher levels of pre-sleep arousal, daytime sleepiness and fatigue than ‘good’ sleepers.

No hypotheses were proposed for self-reported mood, perceptions of environment, medical problems or pain. However, based on aforementioned literature, it is suggested that poor sleepers would report lower mood than good sleepers.

Methods

Participants

Patients were recruited from four NHS post-acute rehabilitation inpatient hospital wards (A, B, C and D) within Glasgow, United Kingdom. Eligible patients were identified by Consultant Stroke Physicians in each ward based on study inclusion and exclusion criteria. Inclusion criteria were (a) patients residing in an inpatient stroke rehabilitation ward following a stroke; and (b) aged 18 years or older. Exclusion criteria were (a) inability to provide informed consent; (b) perception or language problems of sufficient severity to likely prevent participation in study tasks (following Bloomfield et al.[17]); (c) history of aggression; (d) drug or alcohol addiction; (e) post-stroke dementia; and (f) usage of sedatives and

hypnotics (where administered after entry into the study, this information would be reported, following Vock et al.[18]).

Sample size estimation was based on the Glasgow Content of Thoughts Inventory (GCTI)[10] as the primary outcome measure. The GCTI is reported to have discriminant validity, based on a comparison of people with insomnia (M = 58.0, SD = 10.08) and good sleepers (M = 35.2, SD = 8.37); $t(56) = 9.40$, $p < .001$.[10] This generated an effect size of $d = 2.46$ using G*Power[19] (input parameters: one-tailed t-test with independent means). Adopting a more conservative approach with $d = .80$ (large effect size)[20] and statistical power $\beta = .80$, G*Power estimated 21 participants in each group were required to detect significant differences if they existed (i.e. a total of 42 participants).

The total number of stroke patients admitted during the recruitment period for each ward[1] was retrospectively recorded: ward A (32), B (45), C (134) and D (18). Thirty-seven patients were identified as eligible; of these, 24 consented to participate, 10 declined to participate, one patient was already taking sleep medication, one patient became too physically unwell and one patient died. Of the 24 who consented to take part, three completed only part of the study and were excluded from analysis. Therefore the final sample included 21 participants (10 male, 11 female) with mean age 68.14 years (SD = 12.43, range 47–94 years).

[1] Relates to date of interviewing first participant in each ward (ward A: 27th January 2012; ward B: 10th February 2012; ward C: 24th February 2012; ward D: 14th April 2012) to date overall recruitment process ceased (28th May 2012). Record of total number of stroke patients admitted to ward B was only available from 27th January 2012.

Design

In a quasi-experimental between-participants design, stroke patients classified as 'good' or 'poor' sleepers were compared in terms of pre-sleep cognitions and pre-sleep arousal, whilst also exploring differences in daytime sleepiness, fatigue, mood, environmental disturbance and pain. Additionally, observations were made across the whole sample regarding (i) the sleep pattern and type of sleep problems experienced post-stroke; and (ii) participants' beliefs about the factors contributing to their sleep quality post-stroke.

Measures

Demographic and stroke data

Data was collated on age, gender, cohabitation, years of formal education;[21], [22] alcohol and caffeine use;[12] and work status pre-stroke, as part of an initial interview with participants (see Appendix 2.2). Whether participants were residing within a single or shared ward room was recorded as part of the Pittsburgh Sleep Quality Index (PSQI). A questionnaire was completed by the ward health care team to gather data on stroke type;[23] date of stroke; date of admission to current ward; whether it was a first or recurrent stroke; current use of sleep or anxiety/depression medication; known current mental and physical health conditions (including sleep disorders); and typical number of days rehabilitation undertaken per week (see Appendix 2.3). Generation of these items was informed by previous related research[12],[21], [24] and discussion with Consultant Stroke Physicians.

Initial Interview

A modified version of the University of Glasgow Sleep Centre Interview (UGSCI) collated background information about sleep and related factors pre- and post-stroke (e.g. energy,

fatigue, pain, daytime sleepiness, impact of sleep pattern; see Appendix 2.2). Items relating to perceived sleep quality,[25] energy[22], fatigue[22] and pain[14] were identified as relevant from previous studies. Pre-stroke items were reported retrospectively.

Identified sleep problems

In addition to the Consultants' reports of known current sleep problems, participants were interviewed using a diagnosis algorithm, comprising a set of Yes/No questions to screen for narcolepsy; sleep breathing disorder; periodic limb movements in sleep/restless legs syndrome; circadian rhythm disorder; and parasomnia.[26]

Patients' beliefs about factors contributing to sleep quality post-stroke

Participants were asked (i) Since your stroke, what helps you to get a good night's sleep? (ii) Since your stroke, what makes it difficult for you to get a good night's sleep?

Classification of 'good' and 'poor' sleepers

The PSQI comprises 19 self-report items relating to seven components (sleep quality, sleep duration, sleep latency, habitual sleep efficiency, sleep disturbance, sleep medication and daytime dysfunction).[27] High test-retest validity and reliability have been reported for the PSQI in patients with primary insomnia[28] and it has been used to assess sleep in a stroke population.[12],[21] Higher scores indicate poorer sleep quality – a cut-off score of 5 is proposed, whereby 'poor' sleep quality is indicated by a score of $\geq$ 6. [27] However, a cut-off score of 6 was applied in the current study for the following reasons: (i) Backhaus et al.[28] argue the cut-off score should be set at 6 to maximise specificity with only a modest reduction in sensitivity; (ii) within a stroke patient sample, Bakken et al.[21] report a PSQI mean score of 6.9 which they highlight as higher than the cut-off of 5 used in other populations (consistent with this, the mean PSQI score across all participants in the current

study was 7.47); (iii) following Bloomfield et al.,[17] and due to the small sample size, the median PSQI score (6) was used as the cut-off score to classify good and poor sleepers.

Clinical outcome variables relating to main study aim

Pre-sleep cognitions. Frequency of pre-sleep thoughts was assessed using the GCTI,[10] which comprises 25 self-report items relating to different thoughts that are rated on a four-point scale ("not at all" to "a great deal"). A higher GCTI total score indicates a higher frequency of pre-sleep cognitive intrusions, with a cut-off score of 42 for high frequency cognitive events. Reliability and validity of the GCTI has been demonstrated in adults with insomnia;[10] it can discriminate between poor sleepers with insomnia and good sleepers.

Pre-sleep arousal. The PSAS[11] was used to assess pre-sleep arousal – a 16-item self-report questionnaire comprising 8 cognitive arousal items and 8 somatic arousal items. Each item is rated on a five-point scale ("not at all" to "extremely") and a higher total (or sub-scale) score indicates a higher level of pre-sleep arousal. The PSAS has been shown to be both valid and reliable using general population samples.[11]

Daytime sleepiness. Daytime sleepiness was assessed using the Epworth Sleepiness Scale (ESS).[29] 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). A higher ESS total score indicates a higher level of daytime sleepiness with a score $\geq$ 16 indicative of a high level of daytime sleepiness. Reliability and internal consistency of the ESS has been demonstrated in relation to daytime sleepiness in adults[30] and the ESS has been used with stroke patients.[12],[18]

Fatigue. There is no specific scale to measure post-stroke fatigue[13] but the Fatigue Severity Scale (FSS)[31] is one of the most frequently used measures to assess fatigue in stroke patients.[22] Lerdal and Kottorp[32] propose the FSS-7 – a shortened version which excludes two of the original nine items and is reported to have better psychometric properties based on their stroke research. Participants rate seven items on a 7-point Likert scale ranging from 1 (completely disagree) to 7 (completely agree). A mean FSS score indicates level of interference of fatigue on daily functioning: no fatigue (mean score < 4); moderate fatigue (mean score 4–4.9); severe fatigue (mean score ≥ 5).[22]

Additional factors considered: Mood, environment and pain

In addition to Consultants' reports of known current mental and physical health conditions (including sleep problems), anxiety and depression were assessed using the Hospital Anxiety and Depression Scale (HADS)[33] – a 14-item self-report measure comprising two 7-item sub-scales to assess anxiety and depression (a score of ≤ 7 indicative of non-cases, 8–10 for probable cases and ≥ 11 for definite cases). The HADS has been used previously to assess mood in research exploring sleep problems in stroke patients.[12],[14] The HADS has also been reported as a valid and reliable screening measure for mood in stroke patients irrespective of sleep pattern.[34] The impact of environment on sleep was assessed using a modified version of the Factors Influencing Sleep Questionnaire (FISQ),[35] in which participants rate how disruptive they perceive 35 environmental factors on a five-point Likert scale ranging from 0 (not at all) to 4 (extremely). For this study, items relating to pain, anxiety and inability to lie comfortably were excluded from the total FISQ score to produce a score reflecting only external environmental factors (see Appendix 2.4). Participants also reported whether or not they experienced pain pre- or post-stroke (see Appendix 2.2).

Procedure

Patients identified as eligible were provided with an Information Sheet (see Appendix 2.5) describing the study purpose, tasks involved and issues relating to confidentiality and anonymity. Those who had expressed willingness to participate were approached by the researcher who discussed the information provided and addressed any questions. All participants who wished to take part were required to provide written consent (see Appendix 2.6) and recruited individually (all interviews were held in a private ward room). First, participants completed the modified UGSCI, diagnosis algorithm, were asked about their beliefs as to factors contributing to their sleep quality post-stroke and completed the PSQI.

Next, the GCTI, PSAS, ESS, FSS-7, HADS and FISQ were administered (the order of these six measures was randomised across participants using a randomisation plan generator programme[36]). Participants were instructed to respond to these six measures in terms of sleep since their recent stroke (with specific time scales instructed by the GCTI, FSS-7 and HADS adhered to). To ease burden on participants, breaks were scheduled at least every 45 minutes and the session was split over two days if necessary. Upon completion, participants were verbally debriefed further regarding the purpose of the study with the opportunity to ask any additional questions. Consultants then completed the questionnaire collating descriptive data for each participant. If a Consultant was unavailable to complete this questionnaire in the first instance (e.g. due to work demands), it was completed by a member of the patient's healthcare team (e.g. junior doctor, nurse or clinical psychologist) then verified by the Consultant.

Data analyses

Non-parametric, independent-samples Mann-Whitney *U* Tests (two-tailed) were used to explore differences between good and poor sleepers on the GCTI, PSAS, ESS, FSS-7, HADS, FISQ and variables relevant to sleep pattern derived from the PSQI (i.e. sleep onset latency and total sleep time) and UGSCI (i.e. wake time and maximum number of awakenings after sleep onset). Mann-Whitney *U* Tests (two-tailed) were also applied to ratings of sleep quality and energy levels pre- and post-stroke. An approximate value of *r* (*r* = *z*/square root of *N*), was calculated to examine effect sizes, with Cohen's[20] criteria of .1 (small effect), .3 (medium effect) and .5 (large effect). Key variables relating to the current hypotheses were extracted from the UGSCI and FISQ for analysis. Mann-Whitney *U* Tests and tests of association (two-tailed) explored participant characteristics data. Main themes were summarised from qualitative responses (i.e. open-response questions in the FISQ and participants' beliefs about factors influencing sleep and rest).

Ethical approval

This study was approved by the West of Scotland Research Ethics Service (WoSRES) and NHS Greater Glasgow and Clyde Research and Development Committee (see Appendices 2.7–2.9).

Results

Participant characteristics

Demographics, stroke and clinical information

All participants (*N*=21) completed the PSQI (median = 6; interquartile range, *IQR* = 9). Based on the median PSQI cut-off score of 6, 11 participants were classified as good sleepers

(median = 3; *IQR* = 3) and 10 as poor sleepers (median = 12; *IQR* = 4). Patient demographics (Table 1), stroke and additional clinical variables (Table 2) are presented for good and poor sleepers. The numbers of good and poor sleepers recruited from each ward were as follows: Ward A (good = 4; poor = 4); Ward B (good = 5; poor = 3); Ward C (good = 1; poor = 1); Ward D (good = 1; poor = 1). Mann-Whitney *U* Tests and tests of association revealed no significant differences between good and poor sleepers, or any significant associations in relation to participant characteristics (see Appendices 2.10 and 2.11 respectively).

Table 1. Patient demographics for good and poor sleepers

	Good sleepers (*n*=11)	Poor sleepers (*n*=10)
Age – mean (*SD*)	72.73 (11.36)	63.10 (12.09)
– median (*IQR*)	73 (17)	60.00 (16)
Gender		
Number of males	5	5
Number of females	6	5
Formal education, years (median; *IQR*)	10 (7)	11 (3)
Work status pre-stroke		
Employed	3	4
Unemployed	0	2
Retired	8	4
Cohabitation at home		
With partner and/or other family	7	6
Alone	4	4
Time since stroke, days (median; *IQR*)	37 (34)	22 (37)
Time in current ward, days (median; *IQR*)*	27 (43)	25 (37)
Number of patients resident in:		
Shared ward room	5	8
Single ward room	6	2
Total alcohol use post-stroke (total units)	0	1.5 [2]
Total recreational drug use post-stroke	None	None
Caffeine drinks consumed post-stroke, mg caffeine per day (median; *IQR*)[3]	225 (167)	190 (171)

* This data item was unavailable for 2 poor sleepers; therefore they were not included in this analysis.

[2] Total of one half-pint reported; units based on NHS Choices estimate for high strength lager/beer/cider (http://www.nhs.uk/Livewell/alcohol/Pages/alcohol-units.aspx)
[3] Based on Food Standards Agency caffeine level estimates (http://www.food.gov.uk/multimedia/pdfs/fsis5304.pdf)

Table 2. Stroke and additional clinical variables for good and poor sleepers

	Good sleepers (*n*=11)	Poor sleepers (*n*=10)
Stroke data		
a. Left hemisphere	1	2
Right hemisphere	10	7
Left and right hemisphere	0	1
b. Haemorrhagic stroke	0	0
Ischemic stroke *	11	9
c. Cortical stroke	5	5
Subcortical stroke	6	4
Cortical and subcortical	0	1
d. Classification †		
LACS	3	3
PACS	5	4
TACS	3	3
POCS	0	0
e. First stroke	10	8
Recurrent stroke	1	2
Clinical data		
a. Number of patients:		
With known mental health problems	2 (1 anxiety/depression; 1 anxiety agoraphobia)	3 (1 alcohol excess; 2 depression)
With known physical health problems (including sleep problems)‡	9	8
Using mood medication	2	2
Using sleep medication	0	0
b. Number of days per week involving rehabilitation (median; *IQR*)	5 (0)	5 (0)

* Report of haemorrhagic/ischemic stroke was not provided for 1 poor sleeper, hence only 9 poor sleepers included for this classification item.

† LACS = Lacunar syndrome; PACS = Partial anterior circulation syndrome; TACS = Total anterior circulation syndrome; POCS = Posterior circulation syndrome.

‡ Only 1 participant (good sleeper) was reported to have a sleep problem (restless legs syndrome) by a Consultant Stroke Physician.

Aim 1: Pre-sleep cognitions, pre-sleep arousal, daytime sleepiness and fatigue

In terms of the main study aim, poor sleepers reported a significantly higher level of pre-sleep cognitive events (GCTI), pre-sleep arousal (PSAS total score and cognitive subscale) and fatigue (FSS-7) than good sleepers (Table 3). Large effect sizes were found for pre-sleep cognitive events and fatigue, with medium-large effect sizes for pre-sleep arousal. Exploration of median ratings for each GCTI item (see Appendix 2.12) revealed poor sleepers reported that thoughts about their health kept them awake to the greatest extent, whilst median ratings for good sleepers were consistent across all 25 GCTI items. There was no significant difference between daytime sleepiness (ESS) reported by good and poor sleepers, which revealed a small effect size.

Table 3. Comparison of median (*Md*) scores for good and poor sleepers on the GCTI, PSAS, ESS and FSS-7

	Good sleepers (*n*=11) *Md* (*IQR*)	Poor sleepers (*n*=10) *Md* (*IQR*)	*U*	*Z*	*p*	*r*
GCTI	29 (6)	42 (24)	19.00	-2.54	.011	.55
PSAS total score	21 (10)	29.5 (15)	27.00	-1.98	.048	.43
Cognitive subscale	13 (7)	19.5 (8)	26.00	-2.05	.040	.45
Somatic subscale	9 (4)	10 (7)	46.50	-0.61	.542	.13
ESS	9 (6)	9.5 (9)	47.00	-0.57	.572	.12
FSS-7	1.14 (0.57)	3.36 (4.76)	15.50	-2.80	.005	.61
HADS total score	7 (9)	17 (12)	29.50	-1.80	.071	.39
Anxiety subscale	3 (5)	8.5 (4)	23.00	-2.28	.023	.50
Depression subscale	4 (4)	8 (8)	37.00	-1.28	.201	.28
FISQ	13 (35)	10 (14)	51.50	-0.25	.808	.05

Mood, environment and pain

Mood and environment were explored statistically as subsidiary factors (Table 3). There was no significant difference in the level of general psychological distress between good and poor sleepers, as reflected by the HADS total score; although the effect size was medium-large. HADS subscales revealed poor sleepers reported a significantly higher level of anxiety than good sleepers (large effect size) but the difference between levels of depression was not significant (small-medium effect size). There was also no significant difference between groups for perceived disturbance due to environmental factors in the FISQ. Similar numbers of good and poor sleepers reported having experienced pain pre-stroke (*n*=5 and *n*=6 respectively) and post-stroke (*n*=9 and *n*=8 respectively).

Comparisons pre- and post-stroke

As additional contextual information, good and poor sleepers self-rated perceptions of sleep (0 = poor; 10 = excellent) and energy level (0 = total lack of energy/total fatigue; 10 = full of energy/energy surplus) pre- and post-stroke (see Table 4). Poor sleepers retrospectively rated their sleep quality pre-stroke significantly lower than good sleepers (large effect size). However, there were no significant differences between group ratings for sleep post-stroke (medium effect size) or energy levels pre- and post-stroke (small-medium effect sizes). All 11 good sleepers reported 'Yes' when asked if they slept well as an adult pre-stroke, while five poor sleepers said 'Yes' and five said 'No'. Five good sleepers and four poor sleepers reported 'Yes' when asked if they experienced daytime sleepiness pre-stroke, while three good sleepers and four poor sleepers reported 'Yes' when asked if they experienced fatigue pre-stroke (the remainder responded 'No').

Table 4. Comparison of pre- and post-stroke median (*Md*) ratings for good and poor sleepers

	Good sleepers (*n*=11) *Md* (*IQR*)	Poor sleepers (*n*=10) *Md* (*IQR*)	*U*	*Z*	*p*	*r*
Sleep quality						
Pre-stroke, at home	10 (2)	5.50 (4)	19.50	-2.57	.010	.56
Post-stroke, in hospital	6 (5)	5 (2)	34.00	-1.50	.133	.33
Energy levels						
Pre-stroke, at home	8 (3)	8 (5)	43.50	-0.83	.406	.18
Post-stroke, in hospital	6 (4)	5.50 (3)	43.00	-0.86	.392	.19

Aim 2: Sleep pattern and type of sleep problems experienced post-stroke

In addition to the Consultants' report of any participants experiencing physical health or sleep problems (Table 2), participants' self-report was also used to explore sleep pattern and sleep problems post-stroke. First, Table 5 shows that poor sleepers reported significantly longer time awake after sleep onset, less total sleep time (large effect sizes) and longer sleep onset latency (medium-large effect size) than good sleepers. There was no significant difference between groups regarding the maximum number of awakenings after sleep onset but a medium-large effect size.

Table 5. Comparison of median (*Md*) sleep onset latency, wake time after sleep onset, maximum number of awakenings after sleep onset and total sleep time reported in good and poor sleepers

	Good sleepers (*n*=11) *Md* (*IQR*)	Poor sleepers (*n*=10) *Md* (*IQR*)	*U*	*z*	*p*	*r*
Sleep onset latency (minutes)	15 (20)	52.50 (48)	23.50	-2.25	.025	.49
Wake time after sleep onset (minutes)	5 (30)	52.50 (51)	17.00	-2.69	.007	.59
Maximum number of awakenings after sleep onset	2 (3)	3 (2)	31.50	-1.69	.091	.37
Total sleep time (minutes)	450 (120)	270 (203)	18.50	-2.58	.010	.56

Second, the diagnosis algorithm screen (Table 6) revealed both good and poor sleepers self-reported within each sleep disorder category, with the exception of parasomnia (there were no significant associations between good and sleepers and type of sleep problems; Appendix 2.13).

Table 6. Number of good and poor sleepers meeting criteria for each type of sleep problem based on the diagnosis algorithm screen

	Good sleepers (*n*=11)		Poor sleepers (*n*=10)	
	Yes	No	Yes	No
Narcolepsy	3	8	4	6
Sleep breathing disorder	1	10	3	7
Periodic Limb Movements in Sleep/Restless Legs Syndrome	5	6	3	7
Circadian Rhythm Sleep Disorder	1	10	4	6
Parasomnia	0	11	0	10

Aim 3: Participants' beliefs about factors contributing to sleep quality post-stroke

When asked what helps them get a good night's sleep since the stroke, 17 participants provided a response (reporting one or more factors). Factors reported and the number of participants who reported each were as follows: same routine as home (*n*=1); consistent bed- and getting-up -time (*n*=2); engaging in activity during the day (*n*=2); no disruptions by staff (*n*=1); quiet environment (*n*=3); cool/warm temperature (*n*=3); dim lighting (*n*=2); specific food/drink consumed at night (*n*=2); pain/sleep medication (*n*=3); watching television (*n*=4); positive thinking about recovery (*n*=1); positive mood (*n*=1); reminiscing (*n*=1); news/visits from family (*n*=1); and going home at weekends (*n*=1).

When asked what makes it difficult for them to get a good night's sleep since the stroke, 15 participants provided a response (reporting one or more factors). Factors reported and the number of participants who reported each were as follows: staff/patient noise (*n*=6); patient behaviours (*n*=2); concern about other patients (*n*=2); anxiety, worrying thoughts (*n*=3); pain (*n*=2); requiring the toilet (*n*=1); requiring a drink of water (*n*=1); uncomfortable mattress (*n*=1); catheter causing discomfort (*n*=1); specific food/drink consumed at night (*n*=1); and disorientation due to not knowing the time (*n*=1).

Additional qualitative information: Perceived effect of sleep on rehabilitation

One good sleeper and three poor sleepers reported 'Yes' when asked whether their sleep pattern affected their ability to do rehabilitation, as part of the UGSCI (three participants reported this as an effect on attention/concentration and one reported physical unsteadiness following naps).

Discussion

Main findings and theoretical implications

Consistent with the primary hypothesis, poor sleepers reported a significantly higher frequency of pre-sleep cognitions than good sleepers. This finding is consistent with a higher frequency of pre-sleep cognitions found in people with insomnia in the general population, compared to good sleepers.[10] Harvey's[9] cognitive model proposes excessive sleep-related worries lead to anxiety and selective attention towards sleep-related threat cues, engagement in counter-productive safety behaviours (e.g. thought control) and inaccurate beliefs about sleep and the benefits of worry. In line with this, poor sleepers in the current study reported significantly higher anxiety than good sleepers and significantly higher pre-sleep cognitive arousal. However, preliminary exploration of thought content using the GCTI indicated thoughts relating to health had kept poor sleepers awake to the greatest extent the previous night. Therefore, thought content associated with sleep disturbance in stroke patients may be different to that of the general population.

At this stage, it is unclear whether poor sleepers reported a higher frequency of pre-sleep cognitions as part of a general experience of anxiety, insomnia symptomology, or both. An inherent difficulty in the current area of research is that, despite reports of sleep problems by participants in this study, sleep screening is not a standard component of stroke assessment procedures in practice. Therefore the prevalence of insomnia in this sample cannot be ascertained. However, poor sleepers in this study did report significantly more difficulty than good sleepers regarding multiple defining features of insomnia, including sleep onset latency, wake time after sleep onset and total sleep time.[4] In any case, this study importantly highlights a potentially important role of pre-sleep cognitions in sleep post-stroke.

Poor sleepers also reported a significantly higher level of fatigue than good sleepers, supporting previous research in this area.[13] However, good and poor sleepers did not differ significantly regarding daytime sleepiness. In the Sterr et al.[12] study, a higher level of daytime sleepiness was associated with increased time since stroke and time elapsed since stroke was much shorter in the current study. Therefore, it may be that differences in daytime sleepiness may emerge over time. Participants reported a number of environment-related factors when asked what makes it difficult for them to get a good night's sleep since the stroke, although environment-related items in the GCTI (i.e. thoughts about temperature, lighting and noise) received relatively lower ratings by good and poor sleepers. The FISQ was included as a control measure to assess perceived disturbance due to environmental factors, which revealed no significant differences between good and poor sleepers. However, objective measures such as actigraphy may reveal differences in sleep quality across environmental contexts[21] and could be included in future research.

This study raises difficulties regarding assessment of sleep pre-stroke. Poor sleepers retrospectively rated their sleep quality at home pre-stroke as significantly poorer than good sleepers. Indeed, it may be that they were poor sleepers before the stroke – this is a possibility for any study of sleep following a neurological disorder without a longitudinal design. However, it is also possible that such a retrospective rating of sleep pre-stroke is not reliable (cf. Chen et al.[37]) particularly based only on one item (as opposed to use of the standard measure, PSQI, to assess sleep post-stroke); or recall may have been biased by experience of poor sleep at the time of the study. In addition, the rating naturally represented not only sleep pre-stroke, but also sleep at home and therefore could be a function of differences in sleep between home and hospital environments. Moreover, the median rating of poor sleepers was 5.5 out of 10 (10 = excellent sleep quality), which lies above the scale mid-point. Finally,

both pain and other physical health problems were reported for 82% of good sleepers and 80% of poor sleepers – these factors were not a main focus of this study but are reported as acknowledgement that they too may have impacted upon sleep. However, as similar rates were reported for both groups, it appears likely other factors (e.g. pre-sleep cognitions, pre-sleep arousal and fatigue) more probably account for the difference in sleep quality.

Clinical implications

First, broad clinical considerations arise from this study. Within a small sample of stroke inpatients, approximately half the participants were experiencing poor sleep according to an established measure of sleep quality (PSQI) and a more conservative cut-off score of 6. In itself, concerns arise for such patients due to the importance of sleep for rehabilitation and recovery post-stroke and general quality of life – even greater concerns would arise were this pattern of results to be found across larger samples of stroke inpatients. Indeed, a similar prevalence of sleep disturbance was reported by Leppävuori et al.[38] who found that 56.7% of 277 stroke patients reported insomnia complaints (37.6% of all participants met DSM-IV[39] criteria A–C for insomnia) at 3–4 months after stroke. The median score for poor sleepers lay exactly on the cut-off score for high frequency cognitive events.

In addition, both anxiety and depression median HADS scores for poor sleepers lay within the 'probable' case range, while the median score for overall psychological distress on the HADS lay well within the 'definite' case range. Furthermore, the median score for poor sleepers on the FSS-7 (3.36) was just below the moderate fatigue range (4–4.9). This is important in terms of the relationships between sleep, pre-sleep cognitions, mood and fatigue.[13] Therefore, although only four participants reported perceived detrimental effects of sleep quality on rehabilitation in the current study, the impact of sleep upon rehabilitation

and additional factors such as mood and fatigue documented in the literature suggests a detrimental effect of poor sleep on rehabilitation outcome remains possible for such patients.

Consequently, this study raises two more specific clinical issues. First, this study supports Waters and Bucks'[5] recommendation of sleep screening as a routine part of assessment in stroke patients. The authors highlight that poor cognitive performance may otherwise be erroneously attributed to factors other than sleep (e.g. an organic or comorbid disorder, poor effort or motivation) but that the frequency of such errors are unknown. Waters and Bucks[5] describe screening tools that could be used (including the PSQI), the role of training to increase awareness of the impact on sleep on cognition and an urgent need to target sleep problems as part of intervention. There is already consensus and developed protocols for routine mood screening of stroke inpatients.[40] As the second issue, this current study highlights pre-sleep cognitions as a potentially important aspect of intervention (e.g. health-related thoughts). In this respect, clinical psychology has a potentially key role for rehabilitation and recovery post-stroke. A review by Wallace et al.[3] describes cognitive behavioural therapy (CBT) as being as effective as pharmacological interventions for insomnia but states convincing evidence relating to stroke patients is unavailable. The current study suggests an increased need for high-quality research on cognitive interventions for stroke patients.

Strengths and limitations

This is the first known sleep study to investigate pre-sleep cognitions and pre-sleep arousal in stroke patients. Despite a small sample size, significant results for pre-sleep cognitions, pre-sleep cognitive arousal, fatigue and mood were accompanied by medium to large effect sizes. Stroke is a very heterogenous phenomenon which can limit generalisability of results;[41]

however, the current study did not apply stringent inclusion criteria in an attempt to recruit a broad sample of patients. The use of self-report methods are clinically relevant as it is through this method that sleep problems are most often highlighted to clinicians[42] but they can be unreliable; for example, narcolepsy is an uncommon sleep disorder[43] yet a third of participants in the current study met criteria for this disorder based on the diagnostic algorithm, which potentially raises issues regarding accuracy when using this assessment approach with this population. A next step for this research could be to include more objective measures of sleep (e.g. actigraphy) and environment (e.g. for light, temperature, noise, humidity and carbon dioxide). Such measures were considered for the current study but the recruitment strategy did not enable consistent and meaningful measurements across all participants. It is also acknowledged that no conclusions can be made regarding the direction of causality (e.g. mood may influence sleep and vice-versa). Longitudinal research is recommended to further understand relationships between sleep and comorbid factors.[44]

Future directions

First, replication of the current findings with a larger sample would add support for the important role of pre-sleep cognitions and pre-sleep arousal in stroke patients indicated in this study. Second, further exploration of a cognitive model of insomnia[9] is required in relation to stroke patients (e.g. selective attention to sleep-related threat cues, utilisation of counterproductive safety behaviours and dysfunctional beliefs about sleep and the benefits of worry). Third, a qualitative study could further explore the content of patients' thoughts and worries; questionnaire measures have provided a useful quantitative measure and starting point to highlight cognitive factors as worthy of further research and a follow-up study involving interviews with patients would help detail the specific content of these thoughts and worries to tailor cognitive intervention specifically to this population (e.g. during this

study, worries were freely reported in relation to stroke re-occurring during sleep). Finally, a comparison study involving both hospital- and community-based patients post-stroke would enable monitoring of factors such as pre-sleep cognitions, pre-sleep arousal, fatigue and mood over time. Such a study is important as sleep quality may appear to improve in the home environment[21] or, alternatively, sleep-wake disorders may be more prominent when patients return to their living conditions pre-stroke.[8]

Conclusions

The current study suggests pre-sleep cognitions are associated with sleep quality in stroke rehabilitation inpatients – in addition to pre-sleep cognitive arousal, fatigue and mood disturbance. Screening for sleep disorders by both researchers and clinicians is recommended as standard for stroke patients. Particular consideration of pre-sleep cognitions is suggested during assessment and intervention for identified sleep problems in this population.

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CHAPTER 3

Advanced Clinical Practice I: Reflective Critical Account

(Abstract only)

Acute by name, acute by nature: An experience of personal and professional development within a specialist NHS acute neuropsychology service

Susan Dixon

Abstract

In this account I reflect upon a perceived parallel between my internal affective experience and the external working environment within a specialist NHS clinical psychology service. I employ Gibbs' (1988) model of reflection to explore personal, client-specific and systemic factors contributing to the emotional and professional experiences arising from this unique, challenging and invaluable learning environment and relate these to standards of ethics, practice and communication. The reflective process continues with discussion of the potential implications of my observations for service provision, the role of clinical psychology within acute care and the evolution of this role over time. Finally, the impact of my learning experience upon future practice is considered.

CHAPTER 4

Advanced Clinical Practice II: Reflective Critical Account

(Abstract only)

Two sides of the same coin? Reflective comparisons between specialist NHS acute and rehabilitation neuropsychology services

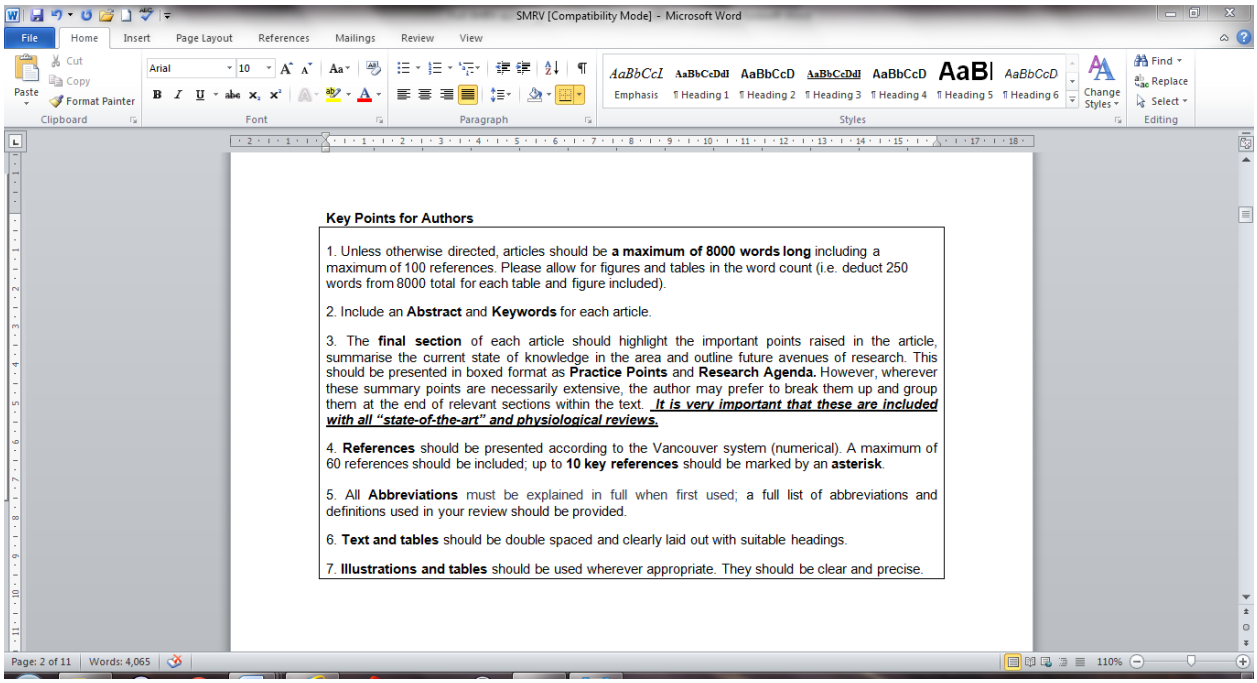
Susan Dixon

Abstract

Building upon my previous placement within a specialist acute neuropsychology service, this reflective account describes my transition to working within a specialist rehabilitation service. I utilise a framework for reflexive practice proposed by Rolfe, Freshwater and Jasper (2001) to identify and explore my reflective comparisons across the two services. The account leads to an action-orientated (reflexive) level of reflection in which I consider the impact of this learning process on my personal and professional development. Particular focus is placed upon my experience of different therapy modalities, inter-disciplinary team working, service management and training.

Appendix 1: Systematic Review

Appendix 1.1. Instructions to authors for *Sleep Medicine Reviews*



Key Points for Authors

1. Unless otherwise directed, articles should be **a maximum of 8000 words long** including a maximum of 100 references. Please allow for figures and tables in the word count (i.e. deduct 250 words from 8000 total for each table and figure included).

2. Include an **Abstract** and **Keywords** for each article.

3. The **final section** of each article should highlight the important points raised in the article, summarise the current state of knowledge in the area and outline future avenues of research. This should be presented in boxed format as **Practice Points** and **Research Agenda.** However, wherever these summary points are necessarily extensive, the author may prefer to break them up and group them at the end of relevant sections within the text. ***It is very important that these are included with all "state-of-the-art" and physiological reviews.***

4. **References** should be presented according to the Vancouver system (numerical). A maximum of 60 references should be included; up to **10 key references** should be marked by an **asterisk**.

5. All **Abbreviations** must be explained in full when first used; a full list of abbreviations and definitions used in your review should be provided.

6. **Text and tables** should be double spaced and clearly laid out with suitable headings.

7. **Illustrations and tables** should be used wherever appropriate. They should be clear and precise.

Those interested in writing for the journal must contact the Editors-in-Chief:

http://www.smrv-journal.com/authorinfo

Appendix 1.2. Electronic search MeSH terms and keywords

Database	Stroke		Insomnia	
	MeSH terms	Keywords	MeSH terms	Keywords
Medline (R) In-Process & Other Non-Indexed Citations and Ovid Medline (R) 1946 to Present	Stroke OR Cerebrovascular disorders	*Stroke OR Stroke*	Sleep initiation and maintenance disorders	Insomnia*
Embase Classic & Embase 1947 to 2012 Week 21	Stroke	*Stroke Stroke*	Insomnia	Insomnia*
PsychInfo	Cerebrovascular accidents OR Apoplexy	*Stroke OR Stroke*	Insomnia	Insomnia*
CINAHL	Stroke	*Stroke OR Stroke*	Insomnia	Insomnia*
PsychARTICLES	n/a	*Stroke OR Stroke*	n/a	Insomnia*
Web of Science	n/a	*Stroke OR Stroke*	n/a	Insomnia*
Cochrane Central Register of Controlled Trials	n/a	*Stroke Stroke*	n/a	Insomnia*

Appendix 1.3. Quality Evaluation Criteria

Ethical approval

1. Ethical approval obtained?
   0 = No/not reported
   1 = Yes

Sampling/recruitment

2. Is the sample community (general population) based?
   0 = No/not reported
   1 = Yes (e.g. consecutive hospitalised patients)

3. Was probability sampling used to identify potential respondents?
   0 = No/not reported
   1 = Simple (i.e. predetermined number of individuals selected from the sampling frame with equal chance of being chosen)
   2 = Complex (e.g. stratified, cluster, multistage, or multiphase)

4. Are the inclusion and exclusion criteria clearly defined?
   0 = No/not reported
   1 = Inclusion *or* exclusion criteria reported
   2 = Inclusion and exclusion criteria reported
   3 = Inclusion and exclusion criteria reported; *and* number of excluded individuals estimated as a proportion of the target population

5. Adequate response rate?
   0 = less than 70% *or* not reported
   1 = equal to or greater than 70%
   2 = equal to or greater than 70% *and* it is reported that respondents and non-respondents, and/or the study sample and the target population have similar socio-demographic characteristics
   3 = equal to or greater than 80%

6. Adequate description of stroke type experienced by the sample?
   0 = No/not reported
   1 = Minimal detail reported (e.g. left/right hemisphere *or* ischemic/haemorrhagic)
   2 = Yes (i.e. more than one of: left/right hemisphere; ischemic/haemorrhagic; classification using Oxford Stroke Classification System; or similar)

7. Adequate description of stroke severity experienced by sample?
   0 = No/not reported
   1 = Severity is based on outcome measure (e.g. The Rankin Scale; The Barthel Index) and/or subjective report (e.g. mild/moderate/severe)
   2 = Severity is based on objective measure (e.g. National Institutes of Health Stroke Scale; Oxford Classification Scheme; Canadian Stroke Scale; Scandinavian Stroke Scale)

8. Control group included?
   0 = No/not reported
   1 = Yes – not matched/no detail
   2 = Yes – matched

Measurement

9. Adequate definition of insomnia provided?
   0 = No (e.g. general sleep complaint; participant self-reported sleep problems) *or* not reported
   1 = Definition partially maps onto classification system (i.e. reference is made to problem(s) with sleep initiation, maintenance, early awakenings, nonrestorative sleep, impaired daytime functioning)
   2 = Definition of insomnia maps onto classification system (i.e. reference is made to Diagnostic and Statistical Manual of mental disorders – IV; Research Diagnostic Criteria for Insomnia; International Classification of Diseases – 10; or International Classification of Sleep Disorders – version 2)

10. Are the data collection methods standardised across all participants?
    0 = No/not reported
    1 = Use of standardised methods is reported for eliciting information from respondents
    2 = Use of standardised methods is reported for eliciting information from respondents *and* interviewer training, supervision, enlistment of respondents, processing data

11. Type of instrument(s) used to assess insomnia/insomnia symptoms?
    0 = Non-standardised (e.g. rating scales, participant self-report, questionnaire)
    1 = Standardised subjective (e.g. clinical interview; sleep questionnaire such as PSQI) *or* objective (e.g. actigraphy, polysomnography)
    2 = Standardised subjective *and* objective

12. Reliability reported for instrument(s) used to assess insomnia/insomnia symptoms?
    0 = No/not reported
    1 = Reliability of instrument(s) reported

13. Validity reported for instrument(s) to assess insomnia/insomnia symptoms?
    0 = Not reported
    1 = Validity of instrument(s) reported

Analysis

14. Consideration of demographic factors?
    0 = Not reported
    1 = Reported (e.g. age, gender, language, ethnicity, employment status, residency)
    2 = Reported ***and*** included in statistical analyses to assess impact upon sleep

15. Consideration of sleep quality preceding stroke?
    0 = Not reported
    1 = Sleep quality preceding stroke reported
    2 = Sleep quality preceding stroke reported ***and*** either homogenous group, or included in statistical analyses to assess impact upon sleep

16. Consideration of stroke as a first or recurrent event?
    0 = No/not reported
    1 = Stroke as first/recurrent event reported
    2 = Stroke as first/recurrent event reported ***and*** either homogenous group, or included in statistical analyses to assess impact upon sleep

17. Consideration of impact of stroke type?
    0 = No/not reported
    1 = Stroke type reported
    2 = Stroke type reported ***and*** either homogenous group, or included in statistical analyses to assess impact upon sleep

18. Consideration of impact of stroke severity?
    0 = Not reported
    1 = Stroke type reported
    2 = Stroke type reported ***and*** either homogenous group, or included in statistical analyses to assess impact upon sleep

19. Consideration of time elapsed since stroke?
    0 = Not reported
    1 = Time elapsed reported
    2 = Time elapsed reported ***and*** either homogenous group, or included in statistical analyses to assess impact upon sleep

20. Consideration of other potential confounding factors which might impact upon sleep post-stroke (e.g. current/premorbid psychological, psychiatric or physical health problems; environment; medications)?
    0 = Not reported
    1 = Potentially confounding factors reported
    2 = Potentially confounding factors reported *and* either excluded, or included in statistical analyses to assess impact upon sleep

21. Satisfactory confidence intervals?
    0 = < 90% / not reported
    1 = ≥ 90%

Total score: _____ / 39

Score (%): _____ %

≤ 24% = poor
25 – 49% = low
50 – 74% = moderate
≥75% = high

Quality rating of study: _____

Appendix 1.4. Quality Criteria Ratings for included articles

	Article*										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
1. Ethical approval	1	1	1	1	1	1	1	1	0	0	0
2. Community sample	1	1	1	1	1	1	1	0	1	1	0
3. Probability sampling	1	0	0	0	2	0	0	0	0	0	0
4. Inclusion/exclusion	1	2	2	1	1	0	2	1	0	0	0
5. Response rate	0	0	0	2	2	0	1	0	3	1	0
6. Description – stroke type	0	2	2	2	0	0	2	1	0	0	2
7.Description – stroke severity	0	2	2	2	0	0	2	1	0	0	1
8. Control group	2	0	0	0	1	0	1	1	2	2	0
9. Definition – insomnia	1	1	2	1	1	1	0	1	1	1	1
10. Data collection	1	2	1	2	1	1	1	1	1	2	0
11. Insomnia measures	0	0	1	1	0	0	2	1	0	0	1
12. Reliability	0	0	0	0	0	0	0	1	0	0	0
13. Validity	0	0	0	0	0	0	0	1	0	0	0
14. Demographics	1	2	2	2	1	2	2	2	2	2	0
15. Sleep pre-stroke	0	0	2	2	0	0	0	0	0	0	0
16. First/recurrent stroke	0	2	0	0	0	0	2	2	0	0	0
17. Stroke type	0	2	1	2	0	0	2	1	0	0	2
18. Stroke severity	0	2	2	2	0	0	2	1	0	0	2
19. Time elapsed	1	2	2	1	0	0	1	2	0	0	0
20. Other confounds	1	2	2	1	1	2	2	2	2	2	0
21.Confidence Intervals†	0	1	1	1	1	0	0	0	0	1	0
Total score (maximum = 39)	**11**	**24**	**24**	**24**	**13**	**8**	**24**	**20**	**12**	**12**	**9**
Score (%)	28%	62%	62%	62%	33%	21%	62%	51%	31%	31%	23%
Quality rating‡	L	M	M	M	L	P	M	M	L	L	P

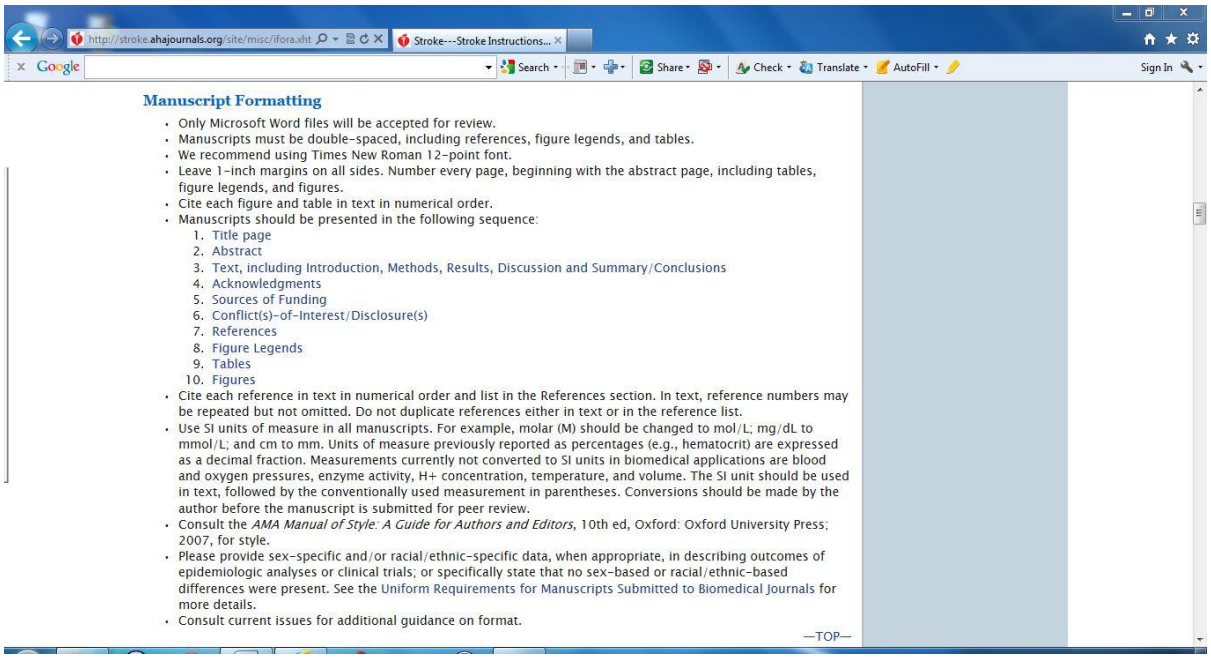
***Key to article identification**: 1 = Küçükdeveci et al.[28]; 2 = Chen et al.[22]; 3 = Leppävuori et al.[16]; 4 = Palomäki et al.[21]; 5 = Stroe et al.[27]; 6 = Ito et al.[29]; 7 = Vock et al.[23]; 8 = Sterr et al.[24]; 9 = Habte-Gabr et al.[26]; 10 = Foley et al.[25]; 11 = Popoviciu et al.[30]

†Only Leppävuori et al.[16] included confidence intervals relating specifically to prevalence of insomnia symptoms.

‡**Key to quality rating**: P = Poor; L = Low; M = Moderate; H = High.

Appendix 2: Major Research Project

Appendix 2.1. Instructions to authors for *Stroke*



Manuscript Formatting

- Only Microsoft Word files will be accepted for review.
- Manuscripts must be double-spaced, including references, figure legends, and tables.
- We recommend using Times New Roman 12-point font.
- Leave 1-inch margins on all sides. Number every page, beginning with the abstract page, including tables, figure legends, and figures.
- Cite each figure and table in text in numerical order.
- Manuscripts should be presented in the following sequence:
  1. Title page
  2. Abstract
  3. Text, including Introduction, Methods, Results, Discussion and Summary/Conclusions
  4. Acknowledgments
  5. Sources of Funding
  6. Conflict(s)-of-Interest/Disclosure(s)
  7. References
  8. Figure Legends
  9. Tables
  10. Figures
- Cite each reference in text in numerical order and list in the References section. In text, reference numbers may be repeated but not omitted. Do not duplicate references either in text or in the reference list.
- Use SI units of measure in all manuscripts. For example, molar (M) should be changed to mol/L; mg/dL to mmol/L; and cm to mm. Units of measure previously reported as percentages (e.g., hematocrit) are expressed as a decimal fraction. Measurements currently not converted to SI units in biomedical applications are blood and oxygen pressures, enzyme activity, H+ concentration, temperature, and volume. The SI unit should be used in text, followed by the conventionally used measurement in parentheses. Conversions should be made by the author before the manuscript is submitted for peer review.
- Consult the *AMA Manual of Style: A Guide for Authors and Editors*, 10th ed, Oxford: Oxford University Press; 2007, for style.
- Please provide sex-specific and/or racial/ethnic-specific data, when appropriate, in describing outcomes of epidemiologic analyses or clinical trials; or specifically state that no sex-based or racial/ethnic-based differences were present. See the Uniform Requirements for Manuscripts Submitted to Biomedical Journals for more details.
- Consult current issues for additional guidance on format.

—TOP—

Full details available to download from:

http://stroke.ahajournals.org/site/misc/ifora.xhtml

Appendix 2.2.

University of Glagsow Sleep Centre Interview (Modified)

Modified with permission of Professor C.A. Espie, University of Glasgow

Participant number:	**Gender:**	**Age:**
Years of formal education (school, college, university):	**Cohabitation (living alone/with partner?):**	
Work status before stroke:	**Today's date:**	

a) Sleep pattern

Participant's pattern of sleep on a typical night since the stroke	
How long does it take you to fall asleep (minutes)?	
How many times do you wake up during the night?	
How long are you awake during the night because of these awakenings (hours/minutes)?	
About how long do you sleep altogether (hours/minutes)?	
How many nights a week follow this pattern?	
Do you sleep during the day? (Yes/No) If YES, for how long (hours/minutes)?	

b) Daytime effects

Effect of sleep pattern since the stroke on participant's daytime functioning	
Does it affect your energy/feeling tired (Yes/No)? If YES, in what way?	
Does it affect problems staying awake (Yes/No)? If YES, in what way?	
Does it affect problems concentrating (Yes/No)? If YES, in what way?	
Does it affect your mood (Yes/No)? If YES, in what way?	
Does it affect your relationships with other people (Yes/No)? If YES, in what way?	
Does it affect getting things done (Yes/No)? If YES, in what way?	
When are your worst times in the day?	

c) Impact on your life

Effect of sleep pattern since the stroke on participant's quality of life	
What consequences – if any – does your sleep pattern since the stroke have for you?	
Is there anything you are not able to do because of your sleep pattern, since the stroke (Yes/No)? If YES, please specify?	
Does your sleep pattern affect your ability to do your rehabilitation; for example, occupational therapy, physiotherapy, psychology, speech & language therapy (Yes/No)? If YES, in what way?	

d) Lifetime history of sleep

Quality of sleep throughout the participant's life	
Did you sleep well as a child (Yes/No)?	
Did you sleep well as a teenager (Yes/No)?	
Did you sleep well as a younger adult (Yes/No)?	
Did you sleep well as an adult before the stroke (Yes/No)?	
Have you slept well as an adult since the stroke (Yes/No)? If NO, in what way?	

e) History of daytime sleepiness and fatigue

Participant's experience of daytime sleepiness and fatigue before and after the stroke	
Did you experience daytime sleepiness before the stroke (Yes/No)? If YES, for how long (days/weeks/months/years)?	
Have you experienced daytime sleepiness since the stroke (Yes/No)? If YES, for how long (days/weeks/months)?	
Did you experience fatigue before the stroke (Yes/No)? If YES, for how long (days/weeks/months/years)?	
Have you experienced fatigue since the stroke (Yes/No)? If YES, for how long (days/weeks/months)?	

f) Intake of alcohol, caffeine and other drugs

Participant's intake of alcohol, caffeine and other drugs	
Since the stroke, how much alcohol do you normally drink? (type of drink & number per day) What about other (recreational) drugs (type, quantity & frequency)?	
Since the stroke, how much caffeine do you normally drink? (cups per day)	

g) Current and previous treatments for sleep problems

Anything the participant is taking or has tried to help him/her sleep	
What have you taken in the past?	
Are you taking anything you have bought over the counter?	
What (if any) sorts of things have you tried to do yourself to help you sleep?	
What (if anything) have you found has worked and not worked?	

h) Additional information

1. Did you experience any **physical pain** before you had the stroke? (Y/N)

   If YES…

   For how long (days/weeks/months/years)? _____

   Was the pain experienced at rest, with movement, or both? _____

   Please rate the level of physical pain, before you had the stroke:

   0 1 2 3 4 5 6 7 8 9 10

   No pain Extreme pain

2. Have you experienced any **physical pain** since you had the stroke? (Y/N)

   If YES…

   For how long (days/weeks/months)? _____

   Was the pain experienced at rest, with movement, or both? _____

   Please rate the level of physical pain, since you had the stroke:

   0 1 2 3 4 5 6 7 8 9 10

   No pain Extreme pain

3. Please rate your **sleep quality at <u>home</u>**, <u>before</u> you had the stroke:

0 1 2 3 4 5 6 7 8 9 10

Poor Excellent

4. Please rate your **sleep quality in <u>hospital</u>**, <u>since</u> you had the stroke:

0 1 2 3 4 5 6 7 8 9 10

Poor Excellent

5. What statement best describes your **sleep quality at <u>home</u>**, <u>before</u> you had the stroke?(tick)

I was a good sleeper □

I was a poor sleeper □

6. What statement best describes your **sleep quality in <u>hospital</u>**, <u>since</u> you had the stroke? (tick)

I am a good sleeper □

I am a poor sleeper □

7. Please rate your **level of energy at <u>home</u>**, <u>before</u> you had the stroke:

0 1 2 3 4 5 6 7 8 9 10

Total lack of energy/total fatigue Full of energy/ energy surplus

8. Please rate your **level of energy in hospital**, <u>since</u> you had the stroke:

0 1 2 3 4 5 6 7 8 9 10

Total lack of energy/total fatigue Full of energy/ energy surplus

Appendix 2.3.

Participant number:	**Today's date:**

Questionnaire for member of participant's ward health care team

1. Participant age at time of study (time of study = ……..…) ……..…years

2. Type of stroke:
   a. Left or right hemisphere? ……...
   b. Haemorrhagic or ischemic? .....
   c. Cortical or subcortical? ……....
   d. If available, participant dominant hemisphere? .....
   e. Oxford Stroke Classification System: LACS, PACS, TACS, or POCS? …….....

3. Date of stroke?

   ……..….
   ..…….....

4. Date participant admitted to this ward? ……

5. Participant's first stroke? (if not, how many previous to this stroke?)

   ……...
   ……...

6. What (if any) medication participant taking to aid sleep (i.e. sedatives)?

   ……..….
   ..…….....

7. What (if any) medication participant taking for anxiety/depression (e.g. anti-depressants)?

   ……..…
   ..…….....

8. Known mental health conditions at time of study?

   ……..…
   ..…….....

9. Known physical health conditions at time of study (including sleep disorders)?

   ……..…
   ..…….....

10. Typical number of days per week participant spent doing rehabilitation?

    ……..…
    ..…….....

Please ensure Consultant Stroke Physician reviews information provided

Thank you

Appendix 2.4.

Participant number:	**Today's date:**

Factors Influencing Sleep Questionnaire (Modified)

How tired are you right now? (circle the number below that best indicates how tired you are right now)

0	1	2	3	4	5	6	7	8	9	10
Not at all Tired										The most tired I've ever felt

Here is a set of responses I'd like you to consider for some factors that may have bothered your sleep or rest:

0 = not at all

1 = somewhat

2 = moderately

3 = quite a bit

4 = extremely

How much does each of the following bother your sleep or rest whilst you are in this stroke rehabilitation ward?

1. Loud talking in the hallway at night _____
2. Patient sounds such as coughing, snoring, gagging, moaning _____
3. Talking in the hallway during the day _____
4. Doors opening, closing, slamming _____
5. Falling objects such as pans; patient charts _____
6. Socialising at the nurses' station _____
7. Squeaking parts on beds or equipment _____

0 = not at all 1 = somewhat 2 = moderately 3 = quite a bit 4 = extremely

8. Alarms on equipment _____

9. Conversations between hospital personnel at the bedside _____

10. Air conditioning, heating, or ventilation systems _____

11. Telephones _____

12. Cleaning equipment such as vacuum cleaners _____

13. Intercom and call lights _____

14. Paging system _____

15. Radios _____

16. Equipment used for patients _____

17. Televisions _____

18. Medicine and linen carts _____

19. Toilets flushing _____

20. Footsteps _____

21. Meal trays and eating utensils _____

22. Visitors _____

23. Handwashing at nearby sink _____

24. Traffic outside the hospital _____

25. Unfamiliar bed _____

26. Interruptions by nurse _____

27. Interruptions by physician _____

0 = not at all 1 = somewhat 2 = moderately 3 = quite a bit 4 = extremely

28. Interruptions by other health care personnel _____

29. Bright lights _____

30. Pain _____

31. Procedures performed on you _____

32. Procedures performed nearby you (on someone else) _____

33. Anxiety _____

34. Inability to lie comfortably or to get comfortable _____

35. Inability to perform my usual routine before going to sleep _____

36. Other (specify)_____ _____

What strategies would you suggest to promote sleep while you are in the hospital recovering from stroke?

……
……
……
……
……
……

Was there a phase in the recovery process since your stroke when sleep disruption was the worst? (e.g., acute stroke unit, when pain is the worst, etc)

……
……
……
……
……
……

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Appendix 2.5. Participant Information Sheet

University of Glasgow
Mental Health and Wellbeing
Gartnavel Royal Hospital
Administration Building
Trust HQ, 1st floor
1055 Great Western Rd
G12 0XH

Email: s.dixon.1@research.gla.ac.uk

Telephone: (0141) 211 0690 or 211 3927

Study title: Understanding sleep problems in rehabilitation inpatients after stroke

Participant Information Sheet

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask the researcher, Susan Dixon (Trainee Clinical Psychologist) if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

Sleep problems are common after stroke. However, not all stroke patients are poor sleepers but research into the reasons for sleep problems after stroke is limited. This study will explore the patterns of sleep experienced by people who have had a stroke and who are in hospital. This study will also compare 'good' and 'poor' sleepers to investigate factors that might affect sleep after stroke. Such factors include thoughts and worries about sleep, fatigue, daytime sleepiness, pre-sleep arousal, mood, other health conditions, pain and the hospital environment. This study will explore whether any of these factors can help explain why some people sleep well while others have sleep difficulties after stroke.

Why have I been invited to take part?

We are inviting people who have had a stroke to take part in this study. This study compares **good and poor sleepers**, therefore we require both people who have sleep difficulties and people who do not have sleep difficulties. Overall, approximately 42 patients from post-acute stroke rehabilitation wards in Glasgow will be recruited for this study.

Do I have to take part?

Participation in this study is completely voluntary. It is up to you to decide whether or not to take part.

If you do decide to take part, you will be asked to sign a consent form to show you have agreed to take part. The consent form will include a request that the researcher can provide the health care professionals involved in your care at the stroke rehabilitation ward with information about any sleep problems or any other health-related problems you are experiencing, which are identified during the study. You will receive a copy of the consent form to keep. Please take time to decide whether you would like to participate.

If you do not wish to take part in this study but want advice regarding any sleep problems you are experiencing, you should contact the ward doctor/GP.

What is involved in taking part?

For the first part of this study, you will be asked to meet with the researcher for an initial interview about your sleep and demographic information. You will also be asked about the factors you think might be contributing to any sleep problems you are experiencing. This will take approximately 45 minutes.

With your consent, the researcher will also obtain relevant information from a member of your health care team at the ward, which will be used for the purpose of this study (i.e., information about your current stroke and any previous strokes; medication use; admission date; other medical/mental health conditions; and ward routine).

The second part of the study will involve completing some questionnaires relating to thoughts and worries about sleep, fatigue, mood, health, pain and the hospital environment. Each of these questionnaires will be explained to you by the researcher. This will take approximately 45 minutes.

Participating in the study would therefore involve a total of approximately 90 minutes. You can decide whether you want to complete the interview and questionnaires on the same day, or complete them over more than one day. There is no time limit for you to complete the interview or questionnaires and you can take breaks at any point.

What are the possible benefits of taking part?

There is no direct benefit to you from taking part in this study. However, whether you are a good or poor sleeper, the information you provide by taking part in this study will be valuable, by contributing towards a better understanding of sleep problems experienced by stroke patients and enhancing ways we assess and treat these.

Are there possible disadvantages or risks of taking part?

It is not anticipated that taking part in this study will cause you any physical or psychological harm, nor cause any significant disruption to your life.

It is acknowledged that people who have experienced a stroke can experience fatigue or difficulties with attention, therefore regular breaks will be offered to ensure participation progresses at your own pace.

What if I want to withdraw from the study at any time?

You are free to withdraw from the study at any time and you do not have to give a reason for doing so. Any data collected from you for the study would be destroyed. Withdrawal from the study would not affect the standard of care you receive or your future treatment.

Would my results be kept confidential?

All information collected about you during this study will remain strictly confidential and will be stored within a locked cabinet. Your information will be anonymous and coded using a number so that it will not be possible to recognise you.

As part of participant safety, if you become distressed or report thoughts/acts of harm to yourself or others while taking part, the researcher will report this to a health care professional at the stroke rehabilitation ward in the first instance, and also the study supervisors. If you disclose sensitive information, or the researcher has any other concerns, this will be discussed with the project supervisors.

What happens to the results from the study?

The results will be used in the researcher's thesis for the degree of Doctorate in Clinical Psychology, which will be submitted in July 2012. It is also hoped that the study will be submitted for publication in a scientific journal. Your information will remain anonymous and you will not be identified in the thesis or any publication.

What happens after I have taken part?

When the study is complete, a summary of the overall results from the study will be sent to the health care team of the wards that have taken part in the study. If you would like to receive a copy, please tell the researcher who will ask your ward health care team to forward a copy on to you.

What if I have a complaint about any aspect of the study?

If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance but the normal NHS complaint procedures are also available to you.

Who is organising and funding the study?

The study is being organised by Susan Dixon, Trainee Clinical Psychologist, University of

Glasgow. The study is being supervised by Professor Jon Evans, Professor of Applied Neuropsychology, Professor Colin Espie, Professor of Clinical Psychology (University of Glasgow) and Dr Niall Broomfield, Consultant Clinical Psychologist (Head of NHS Greater Glasgow and Clyde Stroke Neuropsychology Service; University of Glasgow).

The study is sponsored by NHS Greater Glasgow and Clyde.

Who has reviewed the study?

The study has been reviewed by the West of Scotland Research Ethics Committee.

If I do decide to take part, what happens next?

If you decide you do wish to take part, please tell the ward Consultant Stroke Physician [name of Consultant(s)] as soon as possible so that he/she can inform the researcher. Alternatively, tell one of the nursing team you wish to take part and he/she can advise the Consultant.

The researcher will meet with you to go through this participant information sheet and you will be able to ask any questions you have about the study. If you still wish to take part, you will be asked to sign a consent form, which you will also receive a copy of. The researcher will then arrange a time convenient for you to complete the interview and questionnaires involved in the study.

If you have any further questions?

If you would like more information or have a query about the study please contact the researcher:

Susan Dixon

University of Glasgow
Mental Health and Wellbeing
Gartnavel Royal Hospital
Administration Building
Trust HQ, 1st floor
1055 Great Western Rd
G12 0XH

Email: s.dixon.1@research.gla.ac.uk

Telephone: (0141) 211 0690 or 211 3927

If you wish to speak about this research to someone **not** closely linked to the study, please contact the Consultant Stroke Physician for the ward [name of Consultant(s)].

Thank-you for your time.

Appendix 2.6. Consent Form

University of Glasgow
Mental Health and Wellbeing
Gartnavel Royal Hospital
Administration Building
Trust HQ, 1st floor
1055 Great Western Rd
G12 0XH

Email: s.dixon.1@research.gla.ac.uk

Telephone: (0141) 211 0690 or 211 3927

Study title: Understanding sleep problems in rehabilitation inpatients after stroke

Consent Form

Name of researcher: **Susan Dixon**

Participant number: _____

Please initial the box

1. I confirm that I have read and understand the information sheet dated 18.12.11 (Version 2) for the above study and have had the opportunity to ask questions. ☐

2. 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. ☐

3. I agree to the researcher obtaining information from members of my health care team at the stroke rehabilitation ward, for the purpose of this study (i.e., information about my current stroke and any previous strokes; medication use; admission date; other medical/mental health conditions; and ward routine). ☐

4. I understand that if I become distressed or report thoughts/acts of harm to myself or others while taking part in the study, the researcher will report this to a health care professional at the stroke rehabilitation ward in the first instance, and the study supervisors. I also understand that if I disclose sensitive information, or the researcher has any other concerns, this will be discussed with the project supervisors to identify whether any support or advice might be appropriate and beneficial to me. ☐

5. I agree that the researcher can provide the health care professionals involved in my care at the stroke rehabilitation ward with information about any sleep problems or any other health-related problems I am experiencing, which are identified during the study. ☐

6. I agree to take part in the above study. ☐

_____	_____	_____
Participant Name	Participant signature	Date
_____	_____	_____
Researcher Name	Researcher signature	Date

1 copy to the patient; 1 copy to the researcher; 1 Original for the patients' notes

Appendix 2.7. Ethics Service approval letter for study

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 3
Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT
www.nhsggc.org.uk

Dr Niall Broomfield
Consultant Clinical Psychologist,
Stroke Neuropsychology Service
Clinical Psychology Department
3rd Floor, G Block
Western Infirmary
Dumbarton Road,
Glasgow
G11 6NT

Date 21st December 2011
Your Ref
Our Ref
Direct line 0141 211 2123
Fax 0141 211 1847
E-mail Liz.Jamieson@ggc.scot.nhs.uk

Dear Dr Broomfield

Study title: **Understanding sleep problems after stroke.**
REC reference: **11/WS/0120**

Thank you for your letter of 18 December 2011, 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

The Sub Committee agreed that the issues outlined in the Provisional Opinion letter had been adequately addressed.

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.

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).

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

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).

Approved documents

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

Document	*Version*	*Date*
Advertisement	2	18 December 2011
Covering Letter	1	18 November 2011
Investigator CV		
Other: Student CV Miss Susan Dixon	1	18 November 2011
Other: Academic Supervisor Professor Jonathan Evans		
Other: Academic Supervisor Professor Espie		
Participant Consent Form	2	18 December 2011
Participant Information Sheet: X 4 - 1 for each hospital	2	18 December 2011
Protocol	2	18 December 2011
Questionnaire: Algorithm to Screen for Sleep Disorder other than insomnia	2	18 December 2011
Questionnaire: Aim 2: Participants Beliefs regarding factors contributing to sleep quality post stroke	2	18 December 2011
Questionnaire: Epworth Sleepiness Scale	2	18 December 2011
Questionnaire: Factors Influencing Sleep		
Questionnaire: Fatigue Severity Scale (FSS-7)	2	18 December 2011
Questionnaire: The Glasgow Content of Thoughts Inventory	2	18 December 2011
Questionnaire: HADS		
Questionnaire: Pre-Sleep Arousal Scale	2	18 December 2011
Questionnaire: Pittsburgh Sleep Quality Index	2	18 December 2011
Questionnaire: Interview for Member of Participant's Ward Healthcare Team	2	18 December 2011
REC application	1	18 November 2011
Response to Request for Further Information		18 December 2011

Statement of compliance

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

After ethical review

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

11/WS/0120	**Please quote this number on all correspondence**

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

Yours sincerely

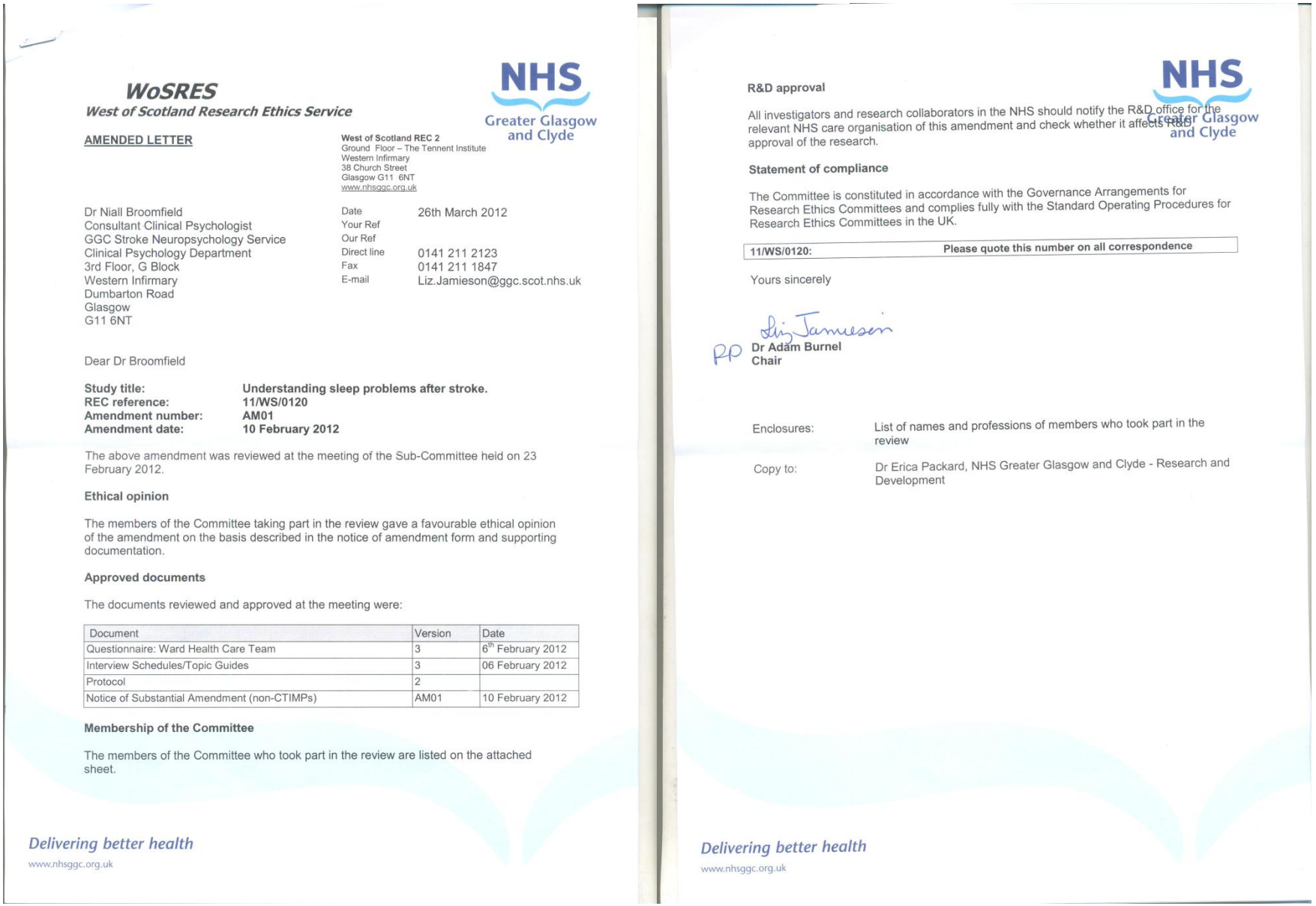
Liz Jamieson
Committee Co-ordinator
On behalf of Dr Adam Burnel, Chair

Enclosures: List of names and professions of members who were involved in the review.

"After ethical review – guidance for researchers"

Copy to: Dr Erica Packard, NHS Greater Glasgow and Clyde - Research and Development

Appendix 2.8. Ethics Service approval letter for study amendments



WoSRES
West of Scotland Research Ethics Service

NHS Greater Glasgow and Clyde

AMENDED LETTER

West of Scotland REC 2
Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT
www.nhsggc.org.uk

Dr Niall Broomfield
Consultant Clinical Psychologist
GGC Stroke Neuropsychology Service
Clinical Psychology Department
3rd Floor, G Block
Western Infirmary
Dumbarton Road
Glasgow
G11 6NT

Date 26th March 2012
Your Ref
Our Ref
Direct line 0141 211 2123
Fax 0141 211 1847
E-mail Liz.Jamieson@ggc.scot.nhs.uk

Dear Dr Broomfield

Study title: **Understanding sleep problems after stroke.**
REC reference: **11/WS/0120**
Amendment number: **AM01**
Amendment date: **10 February 2012**

The above amendment was reviewed at the meeting of the Sub-Committee held on 23 February 2012.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Questionnaire: Ward Health Care Team	3	6th February 2012
Interview Schedules/Topic Guides	3	06 February 2012
Protocol	2	
Notice of Substantial Amendment (non-CTIMPs)	AM01	10 February 2012

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Delivering better health
www.nhsggc.org.uk

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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.

11/WS/0120: **Please quote this number on all correspondence**

Yours sincerely

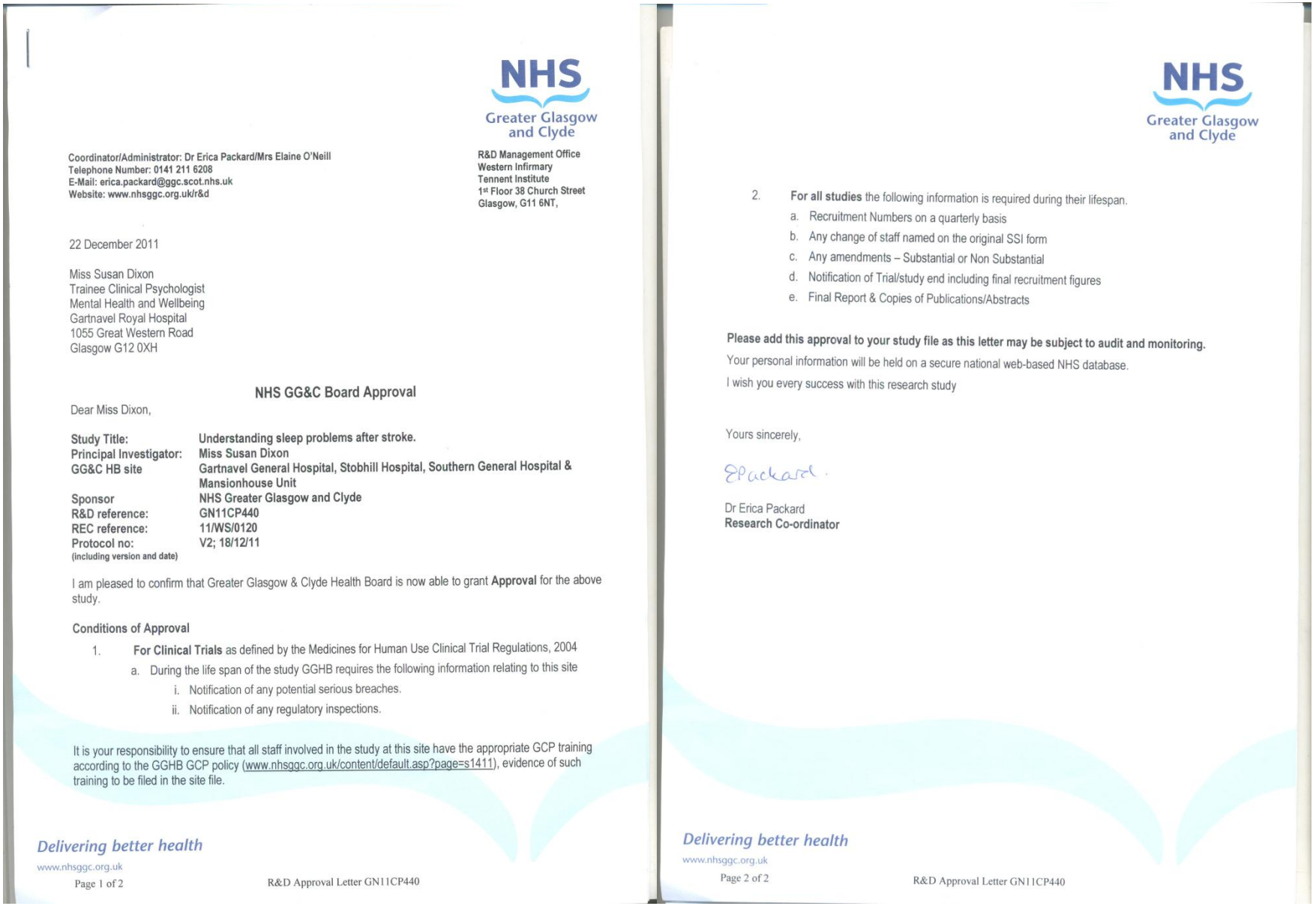
pp Liz Jamieson
Dr Adam Burnel
Chair

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Erica Packard, NHS Greater Glasgow and Clyde - Research and Development

Delivering better health
www.nhsggc.org.uk

Appendix 2.9. Research and Development approval letter for study



NHS
Greater Glasgow and Clyde

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22 December 2011

Miss Susan Dixon
Trainee Clinical Psychologist
Mental Health and Wellbeing
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow G12 0XH

NHS GG&C Board Approval

Dear Miss Dixon,

Study Title:	**Understanding sleep problems after stroke.**
Principal Investigator:	**Miss Susan Dixon**
GG&C HB site	**Gartnavel General Hospital, Stobhill Hospital, Southern General Hospital & Mansionhouse Unit**
Sponsor	**NHS Greater Glasgow and Clyde**
R&D reference:	**GN11CP440**
REC reference:	**11/WS/0120**
Protocol no: (including version and date)	**V2; 18/12/11**

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

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.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

NHS
Greater Glasgow and Clyde

2. **For all studies** the following information is required during their lifespan.
   a. Recruitment Numbers on a quarterly basis
   b. Any change of staff named on the original SSI form
   c. Any amendments – Substantial or Non Substantial
   d. Notification of Trial/study end including final recruitment figures
   e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.
Your personal information will be held on a secure national web-based NHS database.
I wish you every success with this research study

Yours sincerely,

EPackard.

Dr Erica Packard
Research Co-ordinator

Appendix 2.10. Mann-Whitney *U* tests comparing good and poor sleeper participant characteristics (two-tailed)

	Good sleepers (*n*=11) *Md* (*IQR*)	Poor sleepers (*n*=10) *Md* (*IQR*)	*U*	*z*	*p*	*r*
Age	73 (17)	60 (16)	29.00	-1.83	.067	.40
Formal education, years	10 (7)	11 (3)	48.50	-0.47	.641	.10
Time since stroke, days	37 (34)	22 (37)	34.00	-1.48	.139	.32
Time in current ward, days*	27 (43)	25 (37)	38.50	-0.53	.595	.12
Caffeine, mg per day	225 (167)	190 (171)	41.00	-0.99	.323	.22
Rehabilitation per week, days	5 (0)	5 (0)	49.50	-1.05	.294	.23

* This data item was unavailable for 2 poor sleepers; therefore they were not included in this analysis.

Note. r interpreted using Cohen's (1988) criteria of .1 (small effect), .3 (medium effect) and .5 (large effect)

Appendix 2.11. Tests of association between good and poor sleepers and participant characteristics (two-tailed)

	χ^2	*df*	*N*	*p*	Effect size
Number from each ward	0.79	3	21	.852	.19†
Number of males and females	0.04	1	21	1.00	-.05*
Work status pre-stroke	3.44	2	21	.179	.41†
Cohabitation at home	6.63	3	21	.085	.56†
Resident in single/shared room	2.65	1	21	.183	.36*
Hemisphere of stroke (left/right/both)	1.82	2	21	.403	.29†
Haemorrhagic/ischemic	1.16	1	20	.476	.24*
Cortical/subcortical/both	1.36	2	21	.508	.25†
Stroke classification	0.06	2	21	.969	.06†
First/recurrent stroke	0.51	1	21	.586	.16*
Known mental health problems	0.40	1	21	.635	-.14*
Known physical health/sleep problems	0.01	1	21	1.00	.023*
Using mood medication	0.01	1	21	1.00	-.02*

*Based on Fisher's Exact Test and Phi (φ); φ interpreted using Cohen's (1988) criteria of .1 (small effect), .3 (medium effect) and .5 (large effect).

†Based on Cramér's V, interpreted using Cohen's (1988) criteria for df = 1 (.1 = small; .3 = medium; .5 = large); df = 2 (.07 = small; .21 = medium; .35 = large); df = 3 (.06 = small; .17 = medium; .29 = large)

Note. 'Using sleep medication' not computed as this variable was a constant (i.e. no participants across whole sample).

Appendix 2.12. Median (*Md*) and interquartile range (*IQR*) for good and poor sleepers on individual Glasgow Content of Thought Inventory (GCTI) items

GCTI item	Good sleepers (n=11) *Md* (*IQR*)	Poor sleepers (n=10) *Md* (*IQR*)
1. Things in the future	1 (0)	1 (1)
2. How tired/sleepy you felt	1 (1)	1.50 (2)
3. Things that had happened that day	1 (0)	1 (1)
4. How nervous/anxious you felt	1 (0)	1 (2)
5. How mentally awake you felt	1 (1)	2 (2)
6. Checking the time	1 (1)	1 (2)
7. Trivial things	1 (1)	1 (1)
8. How you couldn't stop your mind from racing	1 (0)	1 (1)
9. How long you'd been awake	1 (0)	1 (1)
10. Your health	1 (1)	2.50 (2)
11. Ways you could get to sleep	1 (0)	1.50 (2)
12. Things you had to do tomorrow	1 (0)	1 (1)
13. How hot/cold you felt	1 (0)	1.50 (1)
14. Your work/ responsibilities	1 (0)	1 (0)
15. How frustrated/ annoyed you felt	1 (0)	1.50 (2)
16. How light/dark the room was	1 (1)	1 (1)
17. Noises you heard	1 (1)	1 (0)
18. Being awake all night	1 (0)	1.50 (2)
19. Pictures in your mind	1 (0)	1 (0)
20. The effects of not sleeping well	1 (0)	1 (2)
21. Your personal life	1 (0)	1.50 (3)
22. How thinking too much was the problem	1 (0)	2 (2)
23. Things in your past	1 (0)	1 (2)
24. How bad you were at sleeping	1 (0)	2 (2)
25. Things to do to help you sleep	1 (0)	1.50 (2)

Appendix 2.13. Tests of association between good and poor sleepers and type of sleep problem based on the diagnosis algorithm screen (two-tailed; Fisher's Exact Test)

	χ^2	*df*	*N*	*p*	Φ
Narcolepsy	0.38	1	21	.659	-.14
Sleep breathing disorder	1.49	1	21	.311	-.27
Periodic Limb Movements in Sleep/Restless Legs Syndrome	0.53	1	21	.659	.16
Circadian Rhythm Sleep Disorder	2.76	1	21	.149	-.36

Note. φ interpreted using Cohen's (1988) criteria of .1 (small effect), .3 (medium effect) and .5 (large effect). 'Parasomnia' not computed as this variable was a constant (i.e. no participants across whole sample).

Appendix 3: Major Research Project Proposal

Understanding sleep problems in rehabilitation inpatients after stroke

Abstract

Background: Stroke patients commonly present with sleep-related problems which can detrimentally impact upon rehabilitation. However, the factors maintaining sleep-related problems post-stroke are unclear.

Aims: (i) identify the type of sleep-related problems experienced post-stroke; (ii) explore patients' beliefs about the maintaining factors; and (iii) compare specific factors which might impact upon sleep post-stroke in 'good' and 'poor' sleepers, including sleep-related cognitions, pre-sleep arousal, daytime sleepiness and fatigue.

Methods: Stroke patients (N=42) will be recruited from post-acute rehabilitation wards. A diagnosis algorithm and clinical interview will explore the type of sleep-related problems experienced and patients' beliefs about maintaining factors. 'Good' and 'poor' sleepers will be categorised using clinical interview and self-report measure. Self-report measures will assess sleep-related cognitions, pre-sleep arousal, daytime sleepiness, fatigue and other related factors.

Applications: This area of research can help enhance assessment and treatment of sleep-related problems post-stroke, which may positively impact upon patient well-being, quality of life and rehabilitation whilst also facilitating efficient allocation of National Health Service resources. This study also has the potential to identify important new avenues of future research in both sleep and stroke.

Introduction

Sleep problems and ageing

Sleep is "...as necessary as food and water" (Morin & Espie, 2003, p.7). Understanding sleep problems within an ageing population is particularly important because vulnerability to sleep disturbance increases with age (Espie, 2002). Foley et al.'s (1995) assessment of over 9000 participants aged 65 years and above revealed more than 50% of participants reported at least one sleep complaint most of the time (see Ancoli-Israel & Kripke, 1991 for a review). Older adults also experience daytime sleepiness, which is associated with fragmented sleep (Carskadon, Brown & Dement, 1982). Medical and psychosocial comorbidities (e.g., hypertension, cardiovascular disease and depression) and multi-medication use are suggested as major contributors to sleep problems in older adults, as opposed to the ageing process itself (Bloom et al., 2009). Sleep deprivation can negatively impact upon psychological well-being and quality of life (Alapin et al., 2000; Morin & Espie, 2003). Therefore, sleep problems are common in older age and health conditions typically associated with ageing can further impact upon sleep. The current study aims to enhance current understanding of sleep problems following stroke.

Sleep problems experienced after stroke

Stroke is common amongst older adults (Hickey et al., 2009) and patients often present with a variety of sleep-related problems post-stroke (see Bassetti & Hermann, 2011 for a review), particularly sleep-related breathing disorders (SRBD; Bassetti, 2005; Bonnin-Vilaplana Bonnin-Vilaplana, Arbiox, Parra, Garcia-Eroles, & Montserrat, 2009; Johnson & Johnson, 2010), which has been highlighted as a possible risk factor for stroke (Bassetti, 2005). Insomnia is also common post-stroke; furthermore, patients may have experienced symptoms of insomnia pre-stroke (Leppävuori, Pohjasvaara, Vataja, Kaste & Erkinjuntii, 2002), which is important to explore in the current study.

In addition, Sterr, Herron, Dijk and Ellis (2008) report that a literature review they conducted suggested "sleep disturbances and excessive daytime sleepiness are common co-morbidities of acute stroke" (p. 575). Their own results revealed long-term stroke survivors (chronicity of 12–180 months) self-reported poorer sleep and more daytime sleepiness compared to a normative healthy population. The current study extends this work by (a) identifying the types of sleep-related problems experienced across a sample of stroke rehabilitation patients; (b) exploring patients' beliefs about factors contributing to their sleep quality; (c) investigating a wider range of factors that might impact upon sleep problems post-stroke, including sleep-related cognitions, pre-sleep arousal, daytime sleepiness, fatigue, mood,

comorbidity, pain and environmental factors; and (d) recruiting patients within hospital.

Why is it important to investigate sleep problems after stroke?

Research highlights the detrimental impact that sleep-related problems can have on the post-stroke rehabilitation process. Siengsukon and Boyd (2008) found that sleep enhanced the learning of implicit motor skills post-stroke and Kociuba et al. (2010) revealed that poor sleep was associated with reduced cognitive function. Following a stroke, sleep-related problems may not initially be identified or recognised as a significant problem. A better understanding of these problems could enhance assessment and intervention, and also impact upon rehabilitation outcome.

Understanding the maintenance of post-stroke sleep problems

Although a number of studies have explored the prevalence of sleep problems experienced by stroke patients, the maintaining factors remain unclear. The current study will initially ask stroke rehabilitation patients what factors they believe to be contributing towards the quality of their sleep. This will be followed by an investigation of the role of possible specific stroke-related factors, as discussed below.

The current focus: Sleep-related cognitions, pre-sleep arousal, daytime sleepiness and fatigue

Existing knowledge about the maintenance of sleep problems is predominantly based on research on insomnia in the general population. Within a cognitive behavioural model, Morin and Espie (2003) propose that sleep problems can persist if interpreted as a sign of danger or loss of control. Through monitoring one's sleep pattern and worrying about the consequences of sleep loss, emotional distress and increased sleep disturbance can arise; this in turn leads to physiological and emotional hyperarousal, which exacerbates the sleep problem. When compared to good sleepers, poor sleepers report more negative cognitions about sleep (e.g., thoughts about not falling asleep), engage in more monitoring and safety behaviours (e.g., clock watching) and have more dysfunctional beliefs and attitudes about sleep (see Morin & Espie, 2003, for a discussion of this research). For example, Harvey and Espie (2004) found that people with insomnia reported a significantly higher frequency of pre-sleep thoughts then good sleepers on the Glasgow Content of Thoughts Inventory (GCTI). Unlike other measures of cognitive arousal, the GCTI assesses both frequency and content of thoughts (Harvey & Espie, 2004). Information about both frequency and content of sleep-related cognitions in stroke patients could specifically guide assessment and treatment following stroke.

To explore the theory of arousal further in the current study, the Pre-Sleep Arousal Scale (PSAS; Nicassio, Mendlowitz, Fussell & Petras, 1985) will also be employed due to previous research highlighting the important role of both cognitive and somatic symptoms. Nicassio et al. (1985) reported that higher pre-sleep arousal was associated with increased likelihood of reported sleep disturbance (e.g., describing oneself as an insomniac, increased sleep onset latency, night awakenings and daytime listlessness). Further, people with insomnia scored significantly higher on every item of the PSAS than normal sleepers. This study will explore whether pre-sleep arousal contributes to sleep disturbances in stroke rehabilitation patients.

The current study also explores daytime sleepiness. In the study by Sterr et al. (2008) described previously, the Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman & Kupfer, 1989) was used to categorise participants as 'good' and 'poor' sleepers and daytime sleepiness was assessed using the Epworth Sleepiness Scale (ESS; Johns, 1991). In addition to self-reported poorer sleep and increased daytime sleepiness in stroke patients compared to a normative healthy population, daytime sleepiness (but not nocturnal sleep) was associated with chronicity (number of months since the stroke). Furthermore, use of the Medical Outcome Study Short Form 36 (SF-36; McHorney, Ware & Raczek, 1993) revealed nocturnal sleep was associated with physical factors (e.g., pain and changes in physical role functioning) while daytime sleepiness was associated with vitality. Therefore, different factors might underpin sleep and sleepiness problems.

Finally, fatigue is one of the most common symptoms post-stroke and can be associated with sleep problems (Lerdal et al., 2009). There is no specific scale to measure post-stroke fatigue (Lerdal et al., 2009). Although fatigue is a multi-dimensional variable, the one-dimensional Fatigue Severity Scale (FSS; Krupp, Nicholas, LaRocca, Muir-Nash & Steinberg, 1989) is one of the most frequently used measures to assess fatigue in stroke patients (Lerdal et al., 2011). Lerdal and Kottorp (2011) propose instead the FSS-7 – a shorter, modified version of the FSS excluding two of the original nine items and reported to have better psychometric properties (Lerdal & Kottorp, 2011). The FSS-7, referred to as a 'fatigue interference scale', is recommended when aiming to control for fatigue while exploring relationships between other variables (Lerdal, personal communication July 11, 2011).

Mood, comorbid conditions and pain

The current study also incorporates exploratory analyses of additional, stroke-related factors. First, anxiety and depression have been found to be associated with stroke (Hackett & Anderson, 2005; Küçükdeveci, Tennant & Chamberlain, 1996) and poor sleepers have been found to report lower mood than good sleepers (Bloomfield, Espie & Evans, 2010). The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) is a 14-item self-report measure which assesses anxiety and depression using four-point Likert scales. The

HADS has been used to assess mood when exploring sleep problems in stroke patients (Küçükdeveci et al., 1996; Sterr et al., 2008) and preliminary research suggests it is a useful screening tool for use in a cognitively intact stroke population (Hanlon, 2010). Second, Hayashino, Yamazaki, Takegami, Nakayama & Sokejima (2010) found a positive correlation between poor sleep and number of comorbid medical conditions (e.g., hypertension, gastrointestinal disease, musculoskeletal disease, blood disease, respiratory disease, diabetes, cancer, and so on). Therefore, other medical conditions will be recorded in this study. A third factor to consider is pain. Küçükdeveci et al. (1996) found stroke patients were more likely to experience pain than participants who had not had a stroke. Furthermore, sleep disturbance was more frequent amongst stroke patients with pain than patients without pain. Mood, comorbidity and pain experienced by participants will all be acknowledged in the current study.

The hospital environment

The hospital environment will be assessed across all participating wards. Tranmer, Minard, Fox and Rebelo (2003) used 24 items from the original 36-item Factors Influencing Sleep Questionnaire (FISQ; Simpson, Lee & Cameron, 1996) to explore patients' perceptions of the impact of unit noise, unit physical environment, unit activity and patient perception or care on sleep disruption. Tranmer et al. (2003) revealed that other patients, loud noises and an uncomfortable environment were reported as moderately to extremely disturbing on the first night in hospital. However, personal factors (e.g., unfamiliar bed, inability to perform usual routine and anxiety/pain) were more disruptive. A literature review by Ulrich, Quan, Zimring, Joseph and Choudhary (2004) highlights the impact of noise, light and climate on sleep.

To summarise, multiple factors may maintain sleep-related problems post-stroke. The current study will focus on the role of sleep-related cognitions (i.e., worries about sleep), pre-sleep arousal, daytime sleepiness and fatigue. In particular, no known previous studies have investigated cognitions of stroke patients in relation to sleep-related problems. Additional measures will explore other relevant stroke-related factors and potential avenues for future research.

Aims and hypotheses

Aims

1. Observational: Explore the sleep pattern and type of sleep problems experienced across a whole sample of stroke patients undergoing hospital based post-acute stroke rehabilitation

2. Observational: Explore stroke patients' beliefs about factors contributing to their sleep pattern, including any sleep problems experienced

3. Quasi-experimental: Investigate factors that might impact upon sleep quality post-stroke by comparing stroke patients classified as 'good' and 'poor' sleepers in terms of self-reported unhelpful sleep-related cognitions, pre-sleep arousal, daytime sleepiness and fatigue.

Hypotheses

Primary hypothesis

Stroke patients classified as 'poor' sleepers will report a higher frequency of sleep-related cognitions on the GCTI than stroke patients classified as 'good' sleepers.

Secondary hypotheses

Compared to 'good' sleepers, 'poor' sleepers will report a higher level of pre-sleep arousal on the PSAS, a higher level of daytime sleepiness on the ESS and a more severe level of fatigue on the FSS-7.

In terms of the observational aspect of this study, it is anticipated that a high frequency – and wide range – of sleep-related problems will be reported across the sample as a whole, based on previous research (e.g., Bassetti & Hermann, 2011; Leppävuori et al., 2002) and comparison with relevant cut-off scores on the measures employed.

Plan of investigation

Participants

Stroke patients residing in post-acute rehabilitation wards will be invited to participate. Reasons for recruiting within hospital (as opposed to the community following discharge) include (a) the applied clinical importance of facilitating assessment and treatment of sleep problems at an early stage of development post-stroke; (b) increased opportunity to assess participants at a similar point in time post-stroke; (c) increased access to participants; (d) decreased attrition rate; and (e) decreased variability in environmental conditions across the sample.

Inclusion and exclusion criteria

Inclusion criteria include (a) patients residing in an inpatient stroke rehabilitation ward following a stroke; (b) age 18 years or older. Exclusion criteria include (a) inability to provide informed consent, (b) perception or language problems, of sufficient severity to likely prevent participation in study tasks (following Bloomfield et al., 2010); (c) history of aggression; (d) drug or alcohol addiction; (e) post-stroke dementia; and (f) patients administered sedatives and hypnotics; where administered after entry into the study, this information will be reported (following Vock et al., 2002). Following these criteria, eligibility to participate will be based on the opinion of the referring clinician.

Recruitment procedures

Participants will be recruited from four NHS post-acute stroke rehabilitation wards within Glasgow. Patients reside in such wards for approximately 6-8 weeks. Patients eligible to participate in the study will be identified (based on the inclusion and exclusion criteria) by the Consultant Stroke Physician for each ward. Note that, due to limited availability of Consultants on the ward, other members of the ward healthcare team (e.g., junior doctors, nurses, or clinical psychologists) will assist with the identification of possible eligible participants but the Consultant will make the final decision regarding patient eligibility. Next, eligible patients will be provided with the participant information sheet by the Consultant (or other member of the ward health care team, if the Consultant is unavailable but has confirmed a participant's eligibility) so that the participant can make an informed decision about whether they wish to take part. If participants do wish to take part, the participant information sheet states patients should tell the Consultant so that he/she can inform the principal investigator – or alternatively, tell one of the nursing team they wish to take part and he/she can advise the Consultant. The Consultant, or other member of the ward health care team will inform the researcher of patients both eligible and willing to take part in the study and the researcher will meet with these participants to go over the participant information sheet. At this point, participants will be able to ask any questions about the study and all participants will be asked to sign a consent form which participants will receive a copy of.

As this study explores the potential impact of environmental factors on sleep, eligible participants who wish to take part will be identified as soon as possible upon their admission to the ward but will take part approximately two weeks post admission. This two week delay is aimed to ensure all participants experience a similar length of stay in the ward and the associated environmental factors prior to taking part, thus minimising time on the ward as a confounding variable and allowing better comparison across the sample.

Measures

Descriptive data

A questionnaire will be administered to each participant's ward health care team (e.g., Consultant stroke physician, junior doctor, nurse, or clinical psychologist) to collate information relating to stroke type (i.e., left/right; haemorrhagic/ischemic; cortical/subcortical; and, if available, a note of the participant's dominant hemisphere), time since stroke (Bakken, Lee, Kim, Finset & Lerdal, 2011; Sterr et al., 2008) and stroke history (i.e., whether it is a first stroke). Stroke type will be categorised using the Oxford Stroke Classification System (Mead, Lewis, Wardlaw, Dennis & Warlow, 2000). This questionnaire will also ask about patient use of sleeping medications (i.e., sedatives), number of days since hospital admission (following Bakken et al., 2011), medications for anxiety/depression, known mental health and/or medical conditions, typical daily routine and type of ward the patient resides in (e.g., single/shared room). Note that the information provided in these questionnaires will be checked by the Consultant, if the Consultant is not the one to complete the questionnaire in the first instance (e.g., due to being unavailable on the ward or not having time to do so because of other work demands).

A modified version of the University of Glasgow Sleep Centre Interview will be administered to participants to collate sleep-related background information (sleep pattern, quality, daytime effects, impact on life, lifetime history of sleep, history of daytime sleepiness and fatigue, current and previous treatments for sleep problems). This interview will ask about stimulant use (i.e., caffeine, alcohol and other drugs); age, gender, years of formal education, cohabitation status (Bakken et al., 2011; Lerdal et al., 2011); and work status pre-stroke. Participants will be asked whether they sleep during the day and, if so, for how long. Perceived sleep quality both at home and hospital will be rated by participants on a 10-point Likert scale (0 = poor; 10 = excellent; based on Freedman, Kotzer & Schwab, 1999) and participants will be asked whether they have been good/poor sleepers pre- and post-stroke. Participants will also be asked to rate their level of fatigue pre- and post-stroke (0 = total lack of energy/total fatigue; 10 = full of energy/energy surplus; following Lerdal et al. (2011). Finally, this interview asks about the presence of pain pre- and post-stroke and asked to rate this (0 = no pain; 10 = extreme pain; based on Küçükdeveci et al., 1996). All information obtained from the interview will be recorded in written format only.

AIM 1: *Type of sleep problems experienced by patients post-stroke*.

Sleep problems will be classified using items from the Glasgow Sleep Centre Interview (GSCI) and a diagnosis algorithm (Wilson et al., 2010) administered to participants, which provides a list of questions to screen for insomnia and other sleep disorders. Participants will

be classified as 'good' and 'poor' sleepers using the GSCI and PSQI. The PSQI comprises 19 self-report items relating to seven components (sleep quality, sleep duration, sleep latency, habitual sleep efficiency, sleep disturbance, sleep medication and daytime dysfunction); higher scores indicate poorer sleep quality (Buysse et al., 1989). A score of five or above on the PSQI indicates poorer sleep (following Bakken et al., 2011; Lerdal et al., 2011; Sterr et al., 2008). High test-retest validity and reliability have been reported for the PSQI in patients with primary insomnia (Backhaus, Junghanns, Broocks, Riemann & Hohagen, 2002) and it has been used to assess sleep in a stroke population (Bakken et al., 2011; Sterr et al., 2008).

AIM 2: *Patients' beliefs about the factors potentially maintaining their sleep problems*.

Qualitative data will be collated using two open-ended questions to explore the factors participants believe contribute to their sleep pattern post-stroke (i.e., what they believe helps them get a good night's sleep and also what they believe makes this difficult).

AIM 3: *Exploration of specific factors that might impact upon sleep problems post-stroke – sleep-related cognitions, somatic arousal, daytime sleepiness and fatigue*

The frequency of sleep-related cognitions in good and poor sleepers will be assessed using the GCTI. Harvey and Espie (2004) demonstrated reliability and validity of the GCTI in adults with insomnia; it can discriminate between poor sleepers with insomnia and good sleepers (Harvey & Espie, 2004). The GCTI comprises 25 self-report items relating to different thoughts, which are rated in terms of frequency on a four-point scale ("not at all" to "a great deal"). A higher mean GCTI score indicates a higher frequency of pre-sleep cognitive intrusions. Pre-sleep arousal will be assessed using the PSAS (Nicassio et al., 1985), which is a 16-item self-report questionnaire comprising 8 items relating to cognitive arousal and 8 items relating to somatic arousal. Each item is rated on a five-point scale ("not at all" to "extremely") and a higher mean total score (or individual cognitive/somatic domain score) indicates a higher level of pre-sleep arousal. The PSAS has been shown to be both valid and reliable (Nicassio et al., 1985).

Daytime sleepiness will be assessed using the ESS (Johns, 1991). The ESS is an eight item self-report scale, which requires 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). A higher mean ESS score indicates a higher level of daytime sleepiness. Johns (1992) demonstrates reliability and internal consistency of the ESS when assessing daytime sleepiness in adults and this measure has been used with stroke patients (Sterr et al., 2008; Vock et al., 2002).

Fatigue will be assessed using the FSS-7, which has also been used with stoke patients (Lerdal & Kottorp, 2011). The FSS-7 is a self-report scale which assesses the interference of fatigue on daily functioning based on participant ratings of seven items using a seven-point Likert scale ranging from 1 (completely disagree) to 7 (completely agree). A higher mean FSS-7 score is indicative of increased fatigue interference.

Background factors: Mood, comorbid conditions and pain

All participants will be administered the HADS to assess mood, which has been used in sleep research involving stroke patients (Sterr et al., 2008). To avoid generating an unrepresentative sample, patients with known comorbid mental health and/or medical conditions will not be excluded from the current study but this information will be recorded. All participants will be asked about the presence of shoulder pain during movement and rest (following Küçükdeveci et al., 1996) or any other pain.

The hospital environment

As a control measure, the perceived impact of environmental factors upon sleep will be assessed across each ward using the FISQ. Participants rate each item on a five-point Likert scale ranging from 0 (not at all) to 4 (extremely). Objective measurements of environmental conditions (i.e., noise, temperature, humidity, light and carbon dioxide) will be sampled within each ward to supplement the self-report FISQ measure.

Design

The first part of the study employs an observational design, to explore the sleep pattern and sleep problems experienced by rehabilitation stroke patients. Participants will also be asked what factors they believe contribute to their sleep quality post-stroke. The second part of the study employs a quasi-experimental design; two independent groups of stroke patients (those classified as ‘good’ sleepers and ‘poor’ sleepers) will be compared in terms of (i) frequency of sleep-related cognitions; (ii) pre-sleep arousal (somatic and cognitive); (iii) level of daytime sleepiness; and (iv) severity of fatigue. Scores on each of these domains will also be reported for the whole sample to assess sleep pattern generally in stroke rehabilitation patients. Background factors (mood, comorbidity and pain) will be explored between the two groups and the potential impact of environmental factors upon sleep will be assessed.

Research procedures

Participants will be interviewed on an individual basis within the hospital. First, the researcher will conduct an initial interview with participants to collate descriptive data, information about sleep pattern and quality (Aim 1) and patients' beliefs about factors contributing to their sleep quality (Aim 2). Self-report measures will also be administered (Aim 3).

Justification of sample size

Sample size estimation is based on the GCTI as the primary outcome measure. Harvey and Espie (2004) report that the GCTI has discriminant validity, based on a comparison of people with insomnia (M = 58.0, SD = 10.08) and good sleepers (M = 35.2, SD = 8.37); $t(56) = 9.40$, $p < .001$. Using G*Power (Faul, Erdfelder, Lang, & Buchner, 2007), this generates an effect size of $d = 2.46$ (input parameters: one-tailed t-test with independent means). The current study will adopt a more conservative approach. Instead, with $d = .80$ (which Cohen, 1988, suggests as a 'large' effect size) and statistical power $\beta = .80$, G*Power estimates 21 participants in each group are required to detect significant differences if they exist. Therefore, a minimum of 42 participants will be recruited for the current study.

Settings and equipment

Participants will undertake the study in hospital, during their admission to the post-acute rehabilitation ward. Equipment includes (i) recording sheets for interview information; (ii) self-report measures; (iii) participant information sheets, consent forms and posters to advertise the study; and (iv) pens suitable for patients to use. Noise, temperature, humidity, light and carbon dioxide within each ward will be sampled using equipment borrowed from the University of Glasgow.

Raw data will be recorded in a written (interview and questionnaire) format. A code (e.g., number) will be assigned to each participant ensuring data collated from participants are anonymous and that participants are not identifiable from the data. All raw data (i.e., questionnaires and interviews) will be stored in a locked cabinet on NHS premises and a code will be allocated to each participant to anonymise data so that individual patients cannot be identified. The anonymised data will be entered onto an electronic database on an encrypted laptop from the University of Glasgow and a back-up copy will be stored on the principal investigator's NHS computer network. A copy of the data set will be stored by the study supervisors. All computers will be password protected.

Data analysis

Classification of sleep problems will be coded categorically (Aim 1). Qualitative data regarding participants' beliefs about factors contributing to their sleep quality will be analysed using content analysis (Aim 2). Independent samples *t*-tests will be employed to analyse GCTI, PSAS, ESS and FSS-7 data (Aim 3); scores on each of these domains will also be reported for the whole sample (for comparison with cut-off scores where provided and previous research) to assess sleep pattern generally in stroke rehabilitation patients (Aim 1). Exploratory analyses will be undertaken in relation to background factors (mood, comorbidity and pain) and hospital environment, which might also impact upon sleep.

Health and safety issues

Researcher safety issues

Participants will be recruited during evening, weekend and weekday hours. It has been identified that patients have increased free time during evenings and weekends. Key hospital staff (e.g., ward manager and charge nurse) will be identified should assistance be required.

Participant safety issues

The purpose of the study will be explained to participants in verbal and written format and questions about the procedure addressed from the outset. If a participant becomes visibly distressed during assessment, the session will cease and assistance will be sought from ward staff in the first instance and the researcher will discuss the matter with the project supervisors. If a participant discloses sensitive information, or the researcher has any other concerns, this will be discussed with the project supervisors. The participant information sheet will highlight the duty of the researcher to report disclosure of thoughts/acts of harm to the self or others immediately to ward staff. The researcher will also inform the project supervisors of such disclosures.

Ethical issues

This proposal will be considered by the University of Glasgow for submission for ethical approval by the West of Scotland Research Ethics Committee. It is not anticipated that patients will experience physical or psychological harm by participating in this study, nor any significant disruption to their lives. Due to potential difficulties experienced by stroke rehabilitation patients (e.g., fatigue and sustained attention problems), assessment sessions

will likely take place over two sessions to reduce the burden on participants (following Bakken et al., 2011), each lasting approximately 45 minutes. Regular breaks will also be offered. An information sheet administered to all patients prior to participating will provide details of the tasks involved, estimated duration of tasks, anonymity, confidentiality and the right to withdraw from the study at any time. Patients will be required to provide signed consent prior to participating, including consent for the researcher to provide feedback to ward staff regarding sleep problems or other health-related problems identified during the study. Any participant requests for psychological input relating to difficulties experienced will be discussed with the supervisors to identify appropriate sources of support. Patients will be debriefed after participating (i.e., reiterate the purpose of the study, ask if they have any questions, ensure they have a copy the information sheet with contact details) and relevant feedback regarding the study outcome will be available for dissemination to participants and involved NHS staff if appropriate.

Financial issues

Equipment costs

A total estimated cost of £89.93 for materials to undertake this study relates to:

1. Photocopying of self-report measures (£49.40), information sheets, consent forms (£7.80) and sheets for interview questions (£10.40)
2. Good quality pens with rubber grip for participants (7 x packs of 3 = £22.33).

Travel

Participants will not incur any travel expenses. The researcher will travel to hospital wards and an application for reimbursement of travel expenses will be made to NES. As outlined in the researcher's Clinical Psychology Trainee guide, *Training in NHS Greater Glasgow & Clyde: A Guide for Trainees and Supervisors within NHS Greater Glasgow & Clyde* (p.18), "NES will resource trainees for expense incurred by them for the academic component of their training. NES have defined academic travel as travel from your base in the service to the academic course base for training and training related activities."

Timetable

Recruitment, data coding and analysis is estimated to be completed within approximately nine months.

Practical applications

Despite existing research examining the prevalence of sleep-related problems post-stroke, the maintaining factors are unclear. Within clinical practice, further understanding of these factors could more specifically guide assessment and treatment of sleep-related problems experienced post-stroke, which may positively impact upon patient well-being, quality of life and rehabilitation, whilst also facilitating efficient allocation of National Health Service resources. This study also has the potential to open new avenues in sleep and stroke research.

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