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**Does a Pennebaker-like writing intervention reduce cognitive arousal  
and sleep onset latency in poor sleepers?**

**& Research Portfolio**

**Part One**

(Part Two bound separately)

**Patricia Mooney B.A. Hons**

Section of Psychological Medicine

Division of Community Based Sciences

University of Glasgow

Submitted in partial fulfilment of the requirement for the degree of Doctor of Clinical  
Psychology

July 2006

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SMALL SCALE SERVICE RELATED PROJECT

**User Satisfaction with a Psychoeducation Group for Patients with  
Schizophrenia/Psychosis and their Carers**

Published as:

Mooney P., Stallard A., & Alexander F. (2006). User satisfaction with a Psychoeducation Group for People with a Diagnosis of Schizophrenia/ Psychosis and their Carers. *Clinical Psychology, 164*, 11-16.

Small Scale Service Related Project submitted in partial fulfilment of the requirement for the degree of Doctor of Clinical Psychology

Prepared in accordance with the guidelines for submission to Clinical Psychology (Appendix 1.1)

## Summary

This study assessed user satisfaction with a psychoeducation group programme for patients with schizophrenia/psychosis and their carers. Results were found to be positive. Recommendations for future changes to the group and the audit process are made.

## Introduction

UK clinical guidelines recommend that patients with a diagnosis of schizophrenia/psychosis and their carers should be provided with information/education regarding their problem (e.g. SIGN, 1998; NICE, 2002). Notably, the Clinical Standards Board for Scotland (2001) advise that “giving users and carers information about the illness and available services/treatments available improves understanding, helps maintain vital relationships and improves outcomes for users and carers in the longer term”.

Theoretical accounts of schizophrenia and empirical evidence support these recommendations. The vulnerability stress model of schizophrenia proposes that a range of biological, psychological and psychosocial factors interact and determine the course and outcome (Nuechterlein et al, 1994). The principle of this formulation, that psychological and social stressors and mediators can influence the course of schizophrenia, lends impetus to psychosocial management strategies to modify these factors and hence bring about positive change in the course of the disorder. A recent review of research involving both clients and carers concluded that “psychoeducational approaches are useful as part of the treatment programme for people with Schizophrenia and related illnesses” (Pekkala and Merinder, 2001).

The nature and method of delivery of these approaches can vary. Some programmes go beyond the provision of information and take an educational approach to skills training or problem solving (Hogarty et al, 1991). Birchwood et al (1992) found that simple information giving is less effective than interactive sessions. In addition, the importance of the family environment has long been recognised, with supportive familial relationships been shown to enhance treatment compliance (Oehl et al, 2000) and to reduce the likelihood of relapse (Bebbington and Kuipers, 1994). A recent review by Pharoah et al (2004) found that family interventions may decrease the frequency of relapse, encourage compliance of medication and improve general social impairment. Furthermore, family work to address problems may not be effective if the patient is not included (Bruchremer et al, 1995). Carrying out such work in a group setting has been shown to be advantageous (Birchwood et al, 1992). Group work can be cost effective and can offer a source of social support for members.

There is evidence that negative experiences of contact with psychiatric services can impair engagement (Tarrier and Barrowclough, 1988). This highlights the importance that any psychoeducation programme is delivered clearly, is understandable and paced appropriately for all recipients. This is particularly important for people with schizophrenia/psychosis, given the cognitive impairments such as information processing deficits often evident in this population (Silverstein et al, 1998). Thus, clinical standards for Schizophrenia state that “information should be given in a way that the person can understand to the best of their ability at the time” (Clinical Standards Board for Scotland, 2002).

The review of clinical practice through audit is a well established means of promoting the quality of clinical care by identifying shortfalls in performance against standards and best practice. However, although outcomes in schizophrenia/psychosis such as relapse rates are commonly measured, patients' and carers' satisfaction with services provided are often not carried out in any formal way (Scottish Intercollegiate Guidelines Network, 1998). Encouraging patients/carers to make comments, suggestions and complaints about services allows the organisation to gain a patient's perspective which should inform the review and development of services, practices and procedures. Thus, feedback is paramount to ensuring quality and improving performance. As such, the Clinical Standards Board for Scotland (2002) regards it essential that user and carer satisfaction are audited.

This study aims to solicit feedback from users of a psychoeducation group for people with schizophrenia/psychosis and their carers. More specifically, this study aims:

1. To investigate whether the practical arrangements of the group were acceptable
2. To assess helpfulness of individual sessions
3. To investigate what participants found most or least beneficial about attending the group
4. To investigate whether participants have made any positive lifestyle changes as a result of attending the group

## Method

### **Population**

Adult outpatients with a diagnosis of schizophrenia or psychosis and their carers attending a psychosocial education programme run by a Community Mental Health Team in Inverclyde were invited to participate in the study. A total of 30 participants attended this programme in 4 separate groups of 6 to 8 people. 16 group members agreed to take part in this research by completing the study questionnaire. No demographic details are available for participants.

### **Materials**

A questionnaire was developed to investigate patient satisfaction (Appendix 1.2). This included items that can be categorised according to the themes identified in the aims of this study (see Figure 1 below). Response formats varied.

Readability of the questionnaire was assessed using the Flesch (1948) scoring procedure which yielded a score of 75.8 (reading level 5th grade), placing it above the 'normal' range of 60-70 (range 0-100). However, this was considered acceptable.

**Figure 1. Categorisation of Questions**

Category	Question	Response Format
Whether the practical arrangements of the group were acceptable	Did you find it beneficial to attend the group together? Would it have been more useful to attend a group on your own? Did you find the handouts useful? Do you still refer to the handouts? Would you be interested in attending a self-help group or a carers' forum? Was the time of the group suitable? Was the location of the group suitable?	Yes/ No
Helpfulness of individual sessions	How helpful did you find each of the eight sessions? Session 1 – Introduction, outline of sessions Session 2 – What is schizophrenia? Session 3 – Symptoms of schizophrenia Session 4 – Medication issues Session 5 – Stress/relaxation Session 6 – Problem solving Session 7 – Relapse prevention Session 8 – Ongoing topics/ evaluation	Very helpful/ Quite helpful/ Not helpful / N/A
What participants found most or least helpful about attending the group	What did you find most helpful about attending the group? What did you find least helpful about attending the group?	No choice – free text
Whether participants have made any positive lifestyle changes since attending the group	Have you made any lifestyle changes since attending the group? Indicate which: Having a greater understanding of condition; feeling more able to control symptoms and manage relapse; feeling more able to discuss difficulties with family/ friends; feeling more able to discuss aspects of care with professionals; using relaxation techniques; using problem solving techniques; meeting other people in similar situations; improving relationships between person with diagnosis and carer attending group.	Yes/ No

## Group

Groups consisted of eight weekly sessions each lasting approximately one and half-hours, including a break for refreshments. In order to be more convenient and accessible, sessions were held in the evening at 5.45pm at the offices of the Community Mental Health Team, which are centrally located by a shopping precinct. Groups were staffed primarily by Community Psychiatric Nurses, but other disciplines such as occupational therapists and clinical psychologists also had considerable input.

The group postulated clearly defined goals which are summarised below:

1. Integration of the psychotic experience
2. Acceptance of the vulnerability to further episodes
3. The importance of psychotropic medication for symptom control
4. The significance of stressful life events as triggers for reoccurrence of symptoms
5. Distinguishing personality from disorder
6. Increasing participants' social support network.

Groups were run in an informal manner, encouraging all attending to participate and help shape the content of discussions. Sessions followed a format similar to that used by Atkinson et al (1996) and included an information session (short presentation and discussion) followed by a problem solving exercise. Each session was allocated to a specific topic. The first three focussed on education regarding the nature of schizophrenia (aetiology, symptoms and prognosis), as well as treatment and management. Subsequent sessions incorporated work on stress management, problem solving and relapse identification/ prevention drawing on the work of authors such as Falloon (1986) and Goldstein (1994). A final session was included to cover any areas of continuing concern to participants. Handouts were provided at each meeting which included all topics covered.

## **Procedure**

Participants were asked to complete the questionnaire at the end of the eight week programme. The researcher did not obtain written informed consent as this information was routinely collected as part of clinical practice. However, participants were informed by

staff that involvement was voluntary, anonymous and that results would be used to improve future groups. They were also notified that the information obtained may be disseminated through academic channels but that there would be no identifiers in this work.

Data was anonymised at source, as participants were not required to complete their name on the questionnaire. The results were then forwarded on to the researcher by staff facilitating the group. The researcher was blind to the identity of the participants of the group. The data was collected from several groups running between March 2002 and January 2004. Analysis was carried out between February 2004 and July 2004.

## Results

Results were analysed descriptively according to the aims stated.

**Aim 1: To investigate whether the practical arrangements of the group were acceptable**

Responses were converted into frequencies and are presented in Table 1.

**Table 1. Practical Arrangements of Group**

Question	No	Yes	Don't know
Beneficial to attend group together	1	13	1
More useful to attend a group alone	9	2	3
Handouts useful	1	13	0
Still refer to handouts	4	10	0
Interested in self-help or carers' forum	2	13	0
Time suitable	2	14	0
Location suitable	0	14	0

14 participants reported the time (87.5 %, n=16) and location (100%, n=14) of the group suitable. 13 people (86.7%, n=15) felt it useful to attend the group together. 13 respondents (86.7%, n=15) found the handouts useful and 10 (71.4%, n=14) acknowledged that they still referred to them. 13 group members (86.7%, n=15) expressed an interest in attending a future self-help group or carers forum.

### **Aim 2: To assess helpfulness of individual sessions**

Once again, the results were converted into a frequency chart according to the feedback ratings of each individual session. The results are presented in Table 2.

**Table 2. Ratings of session**

Session No.	Very Helpful	Quite Helpful	Not Helpful	N/A
1	7	6	0	3
2	10	5	0	0
3	10	5	0	0
4	8	6	0	0
5	10	4	1	0
6	6	7	0	2
7	8	7	0	0
8	5	7	0	0

The modal response for all sessions, with the exception of sessions 6 and 8, was ‘very helpful’. Indeed, with regards to sessions 2, 3 and 5, 10 respondents (66.7%, n=15) found these sessions very helpful. Only one person reported finding any of the sessions unhelpful (session 5).

**Aim 3: To investigate what participants found most or least beneficial about attending the group**

The qualitative data was analysed according an idiographic case study approach, drawing on principals of Interpretative Phenomenological Analysis (Smith, 1996). Inter rater reliability for this data was calculated and found to be satisfactory. Both raters agreed in 79.2% of cases in the first instance. After reanalysing the data by means of collapsing some categories, agreement reached 89.6%. Some of the common themes found are reported here.

### **Most Beneficial**

The most common theme emerging in response to this question was that of social support. Half of those who gave an answer indicated that they found the social support received from others in the group was one of the most helpful components of the group. Comments included “talking with and meeting others in the same position” and the “group sharing how they coped in their situation with the illness”. Another common theme found to be helpful was the education component, with session topics commonly being raised as the most helpful aspect of the programme. A broad range of topics were highlighted as being useful, for example, “problem solving” and “symptoms of schizophrenia”.

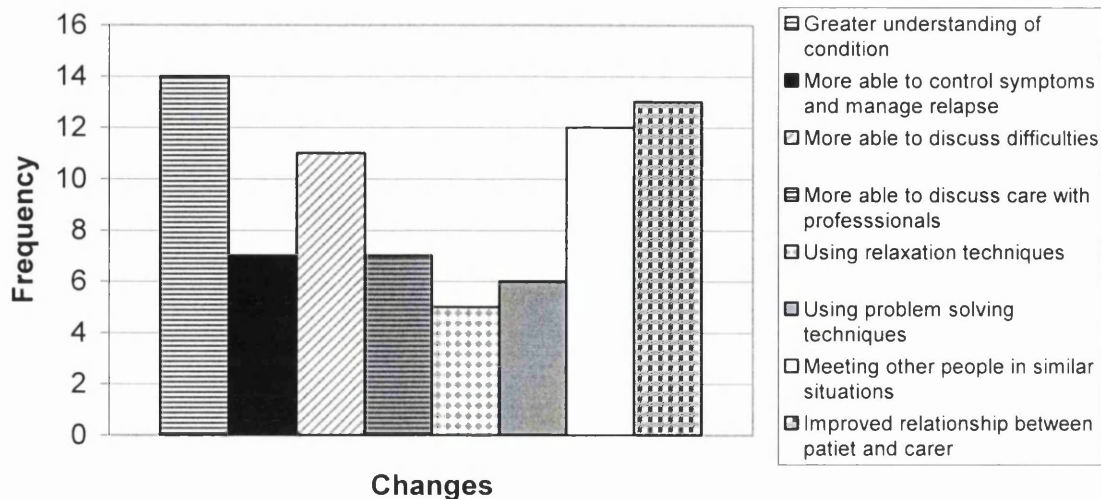
### **Least Beneficial**

The most predominant response to this question was “nothing”, with replies including “(I) thought it was all helpful” and “there were helpful facts at all the meetings”.

### **Aim 4: To investigate whether participants have made any positive lifestyle changes as a result of attending the group**

11 participants (73.3 %, n=15) reported having made positive lifestyle changes as a result of attending the group. The frequencies of each change made are demonstrated graphically in Figure 2.

**Figure 2. Positive Changes Made Since Attending Group**



The largest proportion, 14 (93.3%, n=15), reported one of the positive lifestyle changes as having a greater understanding of the condition. 13 people (86.7%, n=15) reported an improved relationship between patient and carer and 12 (80%, n=15) identified meeting other people in similar situations. However, only 7 participants (46.7%, n=15) acknowledged feeling more able to discuss care with professionals. Fewer made changes by using skills taught in the group. 5 (33.3%, n=15) reported using relaxation techniques and 6 (40%, n=15) using problem solving techniques taught in the group.

### Discussion

This study intended to solicit feedback with four specific aims.

**Aim 1: To investigate whether the practical arrangements of the group were acceptable**

Analysis of results assessing the practical arrangements of the group found these to be acceptable. The majority of respondents endorsed the location and timing of sessions. Most preferred the opportunity to attend a group with both patients and carers. These results should be interpreted with caution as it could be argued that those who found these arrangements unsuitable are less likely to have attended the group. In addition, a large majority expressed an interest in attending a future self-help group or carers forum. As a result of this feedback, both carers and client support groups have been developed in this service.

**Aim 2: To assess helpfulness of individual sessions**

Overall, sessions were found to be helpful. The sessions found to be most helpful appear to be those discussing the aetiology and symptoms of schizophrenia and the session teaching stress management and relaxation.

**Aim 3: To investigate what participants found most or least beneficial about attending the group**

The social support received in these groups appeared to be the most often cited benefit of attending. This result is pleasing, given that individuals with psychosis or schizophrenia and their families often become socially isolated (Bengtsson et al, 2001) and that social support is predictive of quality of life and can serve as a protective factor against

psychological distress (Ritsner et al, 2000). Session topics were also commonly cited as being the most beneficial thing about attending the group. Overall, it appears that little was found not to be beneficial to participants.

**Aim 4: To investigate whether participants have made any positive lifestyle changes as a result of attending the group**

The majority of participants reported having made positive lifestyle changes as a result of attending the group and many report having made multiple changes. The most common changes include improved relationships between patient and carer. This may have positive consequences, given the importance of the family environment on compliance and outcome (Oehl et al, 2000; Bebbington and Kuipers, 1994). A further change commonly reported was meeting others in the same situation. This potentially has far reaching implications when bearing in mind the role of social support in protecting against psychological distress.

Among the least common changes reported was implementing some of the techniques taught in the sessions, namely utilising problem solving and relaxation skills. This highlights a disparity between how helpful sessions on these topics were found to be and whether participants utilised the techniques after the group had ended. One explanation could be that perhaps the participants did not fully understand the methods or rationale for using these techniques and, as such, session content may require revision. This appears unlikely as it is anticipated that any misunderstanding in these areas would have been reflected in the ratings of these sessions. However, it must be borne in mind that participants may report sessions to be helpful in order to please staff even if they do not

fully understand, remember or use the strategies taught. Thus, further investigation as to why this disparity exists may be merited. Perhaps ‘booster sessions’ carried out after the programme has ended would reinforce the usefulness of these techniques, refresh participants memories regarding the methods used and encourage individuals to engage in these activities in the future.

In addition, feeling more able to discuss aspects of care with health/ social care professionals was also less commonly reported. Although the group is multidisciplinary in nature, in reality it could be argued that it is primarily led by nursing and support staff. Perhaps involving staff from other disciplines and agencies more frequently may go some way to alleviating concerns and helping individuals feel more comfortable conversing with different professional groups.

### **Methodological Considerations**

These results should be interpreted with the following caveats in mind. Not least is the fact that the numbers in this sample are small and, as such, conclusions or generalisations should be made tentatively. Furthermore, as questionnaires were anonymised at the point of completion, there is no way of ascertaining which respondents are patients or carers. Future work may wish to consider analysing data from patients and caregivers separately while continuing to ensure anonymity. This would identify if both patients and carers opinions’ were equally represented.

In addition, feedback was solicited on the last of the eight weekly sessions. Given the cognitive difficulties commonly experienced by people with schizophrenia (Silverstein et

al, 1998) already discussed, this may affect the accuracy of feedback and increase the anxieties of those providing feedback. Therefore, a further refinement could be to solicit feedback on individual sessions at the end of that session. It may also be beneficial to check that group members have understood and recalled information learned in sessions to ensure that it has been remembered before assessing whether it has had the desired impact.

More specifically, the question regarding positive lifestyle changes may have been confusing to some respondents. This question asked respondents to indicate yes or no to whether they had made any positive lifestyle changes since attending the group. If participants responded yes, they were prompted to indicate what changes they made from a selection of items. However, some of the options offered in this section were similar to topics discussed in sessions and may have been misinterpreted as asking participants what they enjoyed about the group. As a result, on three occasions, participants responded no to “Have you made any lifestyle changes since attending the group?”, but subsequently went on to select some of the choices of lifestyle changes. Rephrasing this question may overcome some of these difficulties.

## **Conclusion**

Changes may be made in the audit process to make it more robust. However, the sample studied appears to be satisfied with the practicalities, content and social support offered by the group. Thus, not only is there a strong evidence base for this type of work but it is also found to be useful and acceptable to participants. Future groups may wish to draw on features of the current one, remaining cognisant of the recommendations for change suggested.

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## SYSTEMATIC LITERATURE REVIEW

### **A Systematic Review of the Effectiveness of Non-pharmacological Interventions for Sleep Maintenance Insomnia**

Systematic Literature Review submitted in partial fulfilment of the requirement for the degree of Doctor of Clinical Psychology

Prepared in accordance with the guidelines for Clinical Psychology Review (Appendix 2.1).

## ABSTRACT

Non pharmacological interventions are fairly well established in the treatment of initial insomnia. However, the effectiveness of non pharmacological treatments for sleep *maintenance* insomnia is not clear. This review assessed the effectiveness of non-pharmacological interventions for sleep maintenance insomnia in adult and older adult populations ( $\geq 18$  years). Ten articles that examined the use of non pharmacological interventions (two bright light therapy and eight psychological interventions) were identified following a systematic search of electronic databases, and hand searching of relevant journal titles. Generally, the quality of the studies was variable. There was little evidence for the effectiveness of bright light therapy. In contrast, there was evidence to suggest that psychological interventions are effective in treating sleep maintenance insomnia. It was not, however, possible to delineate which components are most effective.

# 1. INTRODUCTION

## *1.1 Insomnia*

Primary insomnia (PI) is a heterogeneous disorder and debilitating sleep problem (Association of Sleep Disorders Centers, 1979; Coleman et al, 1982). PI is defined as difficulty initiating or maintaining sleep, or non-restorative sleep, which is associated with significant distress and daytime impairment and not due to other medical, psychiatric or sleep disorders (APA, 1994). In other nosologies, it is referred to as ‘psychophysiologic insomnia’ (ASDA, 1997). Prevalence estimates vary, but approximately 10% to 15% of the adult population (Mellinger et al, 1985; Ford & Kamerow, 1989) experience PI on a chronic basis. This rate increases to between 12 and 40% in people over age 65 (Montgomery & Dennis, 2004).

Chronic PI can have several adverse affects. These may be psychosocial, occupational, health and economic in nature (Morin, 1993). For example, PI patients experience more psychological distress compared to healthy controls, show impairments to daytime functioning, make use of health care services more often than good sleepers, and show increased absences from work (Mellinger et al, 1985; Ford & Kamerow, 1989; Gallup, 1991; Kales et al, 1984).

Complaints of PI are typically divided into problems of falling asleep (sleep-onset or initial insomnia), problems staying asleep (sleep-maintenance insomnia) and problems awakening too early in the morning (terminal insomnia; Morin, 1993). There is now a reasonably large insomnia treatment literature, which demonstrates non-pharmacological

interventions as fairly well established in the treatment of initial insomnia (Harvey, 2005; Smith et al, 2002; Morin et al, 1999; Murtagh & Greenwood, 1995). The past ten years has also witnessed an expanding experimental cognitive literature, concerned with cognitive factors associated with sleep onset difficulties (Espie, 2002; Broomfield et al, 2005). However, despite this body of work, there has been a relative lack of research attention focused specifically on sleep-maintenance difficulties. This is surprising, particularly given that maintenance problems are a more common complaint among adults than sleep-onset insomnia, especially those of middle and older age (Karacan et al, 1983; Bixler et al, 1979).

### *1.2 Pharmacology*

The most common treatments for PI are pharmacological (Morin et al, 1999; Walsh & Schweitzer, 1999; Kupfer & Reynolds, 1997). Benzodiazepines, sedative anti depressants and ‘Z drugs’ are the most commonly prescribed (National Institute of Clinical Excellence, 2004). In 1999, the NHS in England spent £33.6 million on anxiolytics and hypnotics (Department of Health, 1999). Furthermore, a disproportionate number of older adults with PI receive sedative hypnotic medications as their primary or sole treatment (Dement et al, 1982). However, whilst hypnotic medications may be useful in the short-term management of sleep maintenance difficulties, they provide only symptomatic relief, and do not address underlying mechanisms that maintain these difficulties. Consequently, patients who use hypnotics on a long-term basis often experience drug tolerance, dependence, “daytime hangover” effects, rebound insomnia and a gradual return of their sleep problems (Hauri, 1982; Johnson & Chernik, 1982; Kales et al, 1974). Iatrogenic effects may be particularly problematic among older individuals who are at increased risk for toxic drug interactions

and serious falls as a result of over sedation (Dement et al, 1982; Ray et al, 1987). Clearly, therefore, safe alternative therapies which are effective in the long term are required to treat younger and older adults with sleep maintenance difficulties.

### *1.3 Non-pharmacological Interventions*

Non-pharmacological interventions are now well established in the treatment of PI (Espie, 2002). Various cognitive and behavioural therapies have been developed for the treatment of sleep onset difficulties and PI in general (e.g. Morin & Espie, 2003; Espie et al, 2001; Edinger & Samson, 2003). Cognitive and behavioural therapy (CBT) treatments include a range of interventions, ranging from educational packages to behavioural techniques to cognitive interventions. Most contain more than one component. Specific treatments will be discussed later in this paper. Suffice to say, these approaches target the mechanisms presumed to maintain sleep difficulties e.g. oversleeping, poor stimulus control and ‘trying hard’ to get to sleep. They also aim to improve sleeping habits and challenge thoughts, attitudes and beliefs about sleep to varying degrees.

Non-psychological treatments such as bright light therapy (BLT) aim to re-establish appropriate phase relationship between the temperature rhythm and timing of sleep, thereby improving maintenance of sleep.

Practice guidelines established by American Academy of Sleep Medicine (Morin et al, 1999) routinely recommend the use of certain non-pharmacological approaches in this population. Cognitive Behaviour Therapy (CBT) is the most effective psychological intervention for PI. Meta analyses report moderate to large effect sizes (Morin et al, 1999; Murtagh & Greenwood, 1995), with 70% to 80% of patients benefiting (Morin et al, 1999).

These effects hold for older adults, although not on all outcomes (Montgomery & Dennis, 2004). Although CBT based interventions show slower effects than pharmacology, they produce much more durable improvements (Morin et al, 1999; Hauri, 1997; McClusky et al, 1991).

However, whilst current evidence would suggest CBT is the treatment of choice for PI in general, the effectiveness of these treatments specifically for sleep maintenance problems, is less clear. Whereas several treatment reviews and guidelines have been published in the area of PI (e.g. Edinger & Mearns, 2005; Murtagh & Greenwood, 1995; Montgomery & Dennis, 2004; Morin et al, 1999), not all of these include the differing insomnia's (initial versus maintenance versus terminal). Of those that do, many either do not carefully delineate or report sleep maintenance effects from sleep onset effects, only assess the efficacy of one treatment (e.g. CBT; Edinger & Mearns, 2005) or only consider one specific population (e.g. older adults; Montgomery & Dennis, 2004). Others do not provide a comprehensive review comparing effect sizes of the relative interventions, or have been rendered 'out of date' by a burgeoning literature since their publication (Morin et al, 1994; Murtagh & Greenwood, 1995). There is therefore a clear need to systematically review the effectiveness of non-pharmacological interventions specifically for sleep maintenance insomnia using carefully delineated maintenance insomnia patient populations. This should usefully inform clinicians of the best evidence based practice in this field.

## 2. OBJECTIVE

The objective of the present review, therefore, was to assess the effectiveness of non-pharmacological interventions for sleep maintenance insomnia in adult and older adult

populations ( $\geq 18$  years). Specifically, the review examined reductions in wake time after sleep onset (WASO) and number of nocturnal awakenings (NOA). As interventions aimed at reducing sleep maintenance problems may also have an effect on other sleep parameters, total sleep time (TST), sleep efficiency (SE) and sleep onset latency (SOL) were also recorded.

### 3. METHODS

#### 3.1 Search Strategy

PsychINFO, MEDLINE, EMBASE, and The Cochrane Library of Systematic Reviews were searched from 1980 until Week One January 2006, using the terms *insomnia*, *sleep maintenance*, *intervention*, and *treatment*. In addition, Behavioural Sleep Medicine, Sleep, Journal of Sleep Research, Sleep Medicine Reviews and Sleep Medicine were hand searched to identify trials not electronically indexed. All were searched from 1980 or their first issue (if after 1980). Citation lists from other relevant studies were also examined to identify any relevant studies not cited elsewhere.

#### 3.2 Types of Studies

- *Inclusion criteria:* Randomised controlled trials, controlled trials, controlled single-case series designs, uncontrolled case-series and uncontrolled single-case designs where the main purpose of the study was to evaluate the effectiveness non-pharmacological interventions for sleep maintenance insomnia. All studies assessed

changes in sleep according to recognised objective (e.g. polysomnography; PSG) and/or subjective (e.g. sleep diaries) criteria.

- *Exclusion criteria:* Studies in which insomnia was secondary to any other medical or psychiatric conditions. Studies which also included sleep onset difficulties. Studies which primarily aimed to assess variables other than sleep (e.g. the proposed effective mechanisms of interventions).

### *3.3 Types of Participants*

- *Inclusion criteria:* 18 years and above; diagnosis of sleep maintenance insomnia.
- *Exclusion criteria:* <18 years old; organic condition; mental health problems; disordered breathing; other health problem which could influence sleep (e.g. pain, cardiac problems).

### *3.4 Results of Literature Search*

Searching the electronic databases using the terms above (with a restriction of adult human only studies) initially retrieved 152 results. Removing duplicate studies reduced this number to 91. Further removing those which did not specifically relate exclusively to sleep maintenance insomnia, non-pharmacological treatment, where studies involved a pharmacological treatment arm, or where it was explicitly stated that sleeping difficulties were secondary to physical or mental health problems, reduced this figure by 74 to 17. On further scrutiny, 8 articles were excluded for the following reasons: involved a benzodiazepine reduction programme (one study); included sleep onset and sleep maintenance difficulties (two studies); acknowledged that at least one (out of three)

participant's difficulties were secondary to depression (one study); difficulties due to sleep disordered breathing (one study); primary aim not to assess efficacy of treatment with results of sleep parameters reported elsewhere (two studies); baseline and treatment grouped together (ergo not allowing analysis of efficacy of treatment; one study). This left a total of 9 studies, with one further study being identified via hand-searching and consultation of reference lists (Edinger et al, 1992). This process was repeated by electronically searching the term sleep maintenance insomnia exclusively. No further studies were identified, giving a final total of 10 studies.

### *3.5 Data Extraction*

The data extracted from each article included subject demographics; format and duration of treatment; and method of sleep assessment. In addition, sleep parameters reported included pre and post measures; wake time after onset (WASO); number of nocturnal awakenings (NOA); total sleep time (TST); sleep efficiency (SE); and sleep onset latency (SOL). Furthermore, data relating to study eligibility, quality and outcomes was derived. Due to the diversity of the study designs, and in order to make any comparison of studies meaningful, only immediate data were considered. Follow up data were not used for the purpose of this review.

### *3.6 Non-pharmacological Interventions Considered*

Several non-pharmacological interventions were considered in this review. **Bright light therapy** (BLT; Campbell et al, 1993; Suhner et al, 2002) uses exposure to bright light timed to delay the circadian clock and thereby re-establish an appropriate phase

relationship between the temperature rhythm and the timing of sleep to alleviate maintenance problems. **Stimulus control therapy** (SC; Bootzin et al, 1991) aims to train people with insomnia to reassociate the bed and bedroom with rapid sleep onset by restricting sleep incompatible behaviours that serve as cues for staying awake and by enforcing a consistent sleep-wake schedule. **Sleep restriction** (SR; Spielman et al, 1987) curtails the amount of time spent in bed to almost the amount of time asleep and creates a mild state of sleep deprivation which promotes more efficient sleep. **Relaxation therapies** (RT; Hoelscher et al, 1986) such as progressive muscle relaxation (tensing and relaxing muscles) are used to reduce arousal levels which people with PI often display. **Paradoxical intention** (PI; Broomfield & Espie, 2003) asks individuals with insomnia to engage in gently staying awake. This therapy draws on the basic premise that when an individual stops trying to sleep, performance anxiety and sleep effort are reduced and sleep comes more easily. **Sleep hygiene** education (SH; Hauri, 1991) targets health practices (e.g. exercise, substance use) and environmental factors (e.g. light, temperature) that may be either detrimental or beneficial to sleep.

Each of the above interventions includes only one component. Multi component **cognitive behaviour therapy** (CBT; e.g. Edinger et al, 2001; referred to as behaviour therapy in one early study in this review) employs a range of techniques, typically sleep restriction therapy, stimulus control, sleep hygiene education and cognitive restructuring. CBT aims to break the vicious circle of insomnia, emotional distress, dysfunctional cognitions, and further sleep disturbance. The cognitive restructuring element consists of identifying dysfunctional sleep cognitions, challenging their validity, and replacing them with more adaptive substitutes (Morin, 1993).

### *3.7 Quality Ratings for Studies Considered*

Two (complementary) measures were used to assess the methodological quality of the studies included. Firstly, the Methodological Quality Instrument (MQI; Cho & Bero, 1994) was used, an instrument which has been utilised successfully to assess the quality of pharmacological and non-pharmacological (Detsky et al, 1987) studies. The measure rates each study on several factors including design, inclusion/exclusion criteria, blinding of participants and raters, and statistical merit (see Figure 1). The MQI yields an overall score between zero and one, with one representing the highest possible quality.

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INSERT FIGURE 1 HERE

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Secondly, the Sleep Study Quality Measure (SSQM; Mendleson, 1997) was used. This is a measure specific to sleep, used successfully in a recent review (McMahon et al, 2005), and was employed here to determine quality of sleep-related aspects of the studies. The instrument takes into account subjective and objective measures of sleep, and examines details of reporting of sleep parameters. The SSQM also yields a score between zero and one, with one representing the highest quality (see Figure 2).

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INSERT FIGURE 2 HERE

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A random sample of studies (n=4) were also evaluated by a second rater. Intra-class correlation co-efficients were calculated between both sets of ratings, and were high (0.99 for the MQI and 1.00 for SSMQ). Disagreements between raters were discussed and a consensus on quality score reached for each measure.

### *3.8 Synthesis of Results*

Effect sizes were also calculated (where possible and not already available) as an indicator of treatment outcome. A standard mean difference score was calculated for each outcome variable by using Cohen's d index of an individual effect size (Cohen, 1977), with the contribution of each study considered with respect to its quality rating.

## 4. RESULTS

Details of the papers that met criteria for inclusion are shown in Table 1. A summary of the sleep parameters extracted from each study is given in Table 2.

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INSERT TABLE 1 HERE

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### *4.1 Bright Light Therapy (BLT)*

Two studies reported using BLT (Campbell et al, 1993; Suhner et al, 2002). One was a randomized placebo controlled trial (RCT; Campbell et al, 1993) and one was a

randomized controlled relapse prevention trial (Suhner et al, 2002). These studies received quality ratings of 0.57 and 0.72 respectively on the MQI and 0.5 and 0.63 respectively on the SSQM.

Campbell et al (1993) carried out a placebo controlled trial with participants (mean age 70.4 years) receiving 2 hrs of BLT each day for 12 days. Sleep parameters were measured using an electroencephalogram (EEG) and demonstrated a significant decrease in WASO from a mean of 102.8 mins to 43.2 mins in the active treatment group, as well as mean increase in SE of 17%, producing large effect sizes of 2.77 and 2.96, respectively. However, it is worth noting that even with this increase in SE, participants continued to spend an average of 43 minutes awake per night.

Campbell et al (1993) concluded their findings demonstrate the effectiveness of timed exposure to bright light in the treatment of this problem, and that with some refinements, BLT may prove useful in a large proportion of elderly people with sleep maintenance insomnia. However, the method of 'randomisation' employed is in particular a potential weakness in the study design. Participants were allocated to either treatment or control on an alternate basis. Thus, the sample was not truly randomized to condition. Furthermore, the investigators were not blind to this. Therefore, whilst the data suggests that BLT may significantly reduce time awake in bed, the study design may have introduced bias in terms of the allocation of participants to groups.

Suhner et al (2002) also used BLT in a relapse prevention study involving 15 participants aged 80 or over. In an open label phase, participants were given two hours exposure (at home) per day for 11-13 days, with sleep parameters primarily measured using

polysomnography (PSG). According to the PSG data from the open label phase, no significant difference in WASO, SE or TST between the baseline and end of acute treatment phase was found. Furthermore, no significant difference between the active and control groups was observed on any sleep parameters after the maintenance phase.

Suhner et al (2002) therefore reported that no valid conclusion could be made about the efficacy of the maintenance treatment. Contrary to hypotheses, the acute light treatment phase did not improve sleep. A particular limitation of this study was the failure of the authors to use recognised subjective measures of sleep (e.g. sleep diary; Espie, 1991). A further limitation was the relatively small number of participants and, in particular, the relatively poor compliance of some participants. Finally, Suhner et al (2002) used paid volunteers, a potential confounding variable had any significant effect been found.

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INSERT TABLE 2 HERE

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#### *4.2 Psychological Interventions*

Eight studies using a combination of cognitive and behavioural techniques were reviewed. Seven used stimulus control (SC), three used sleep restriction (SR), three used education training (sleep requirements, effects of aging, circadian rhythms), one used relaxation therapy (RT), two used imagery training (IT), and one used sleep hygiene (SH). The quality ratings of these studies varied from 0.44 to 0.94 on the MQI, and 0.05 to 0.89 on the SSQM (see Table 1). To aid comprehension, studies are reported in accordance with

their design. Four studies used randomised controls designs, one used a randomised design without a control, two used multiple baseline case series designs and one was a case study.

#### *4.21 Randomised Controlled Trials*

Edinger et al (2001) carried out a randomised double blind placebo controlled trial with 75 participants, comparing CBT to RT and a placebo condition (quasi-desensitisation). Interventions consisted of 6 individual weekly sessions and sleep parameters were measured by subjective and objective means (sleep diary and PSG, respectively). CBT produced the largest improvements across the majority of outcome measures; sleep diaries showed that CBT-treated patients achieved an average 54% reduction in their WASO compared to 16% and 12% reductions for RT and placebo-treated patients, respectively. Recipients of CBT also showed a greater normalization of sleep and objective symptoms than the other groups, with an average sleep time of more than 6 hours and SE of 85.1% at treatment end.

In terms of quality, Edinger et al (2001) rated highly (0.94 on the MQI and 0.89 on the SSQM). They concluded that CBT represents a viable intervention for primary sleep-maintenance insomnia which should promote clinically significant sleep improvements within 6 weeks. Notable strengths of this study were the double blind design and the inclusion of a measure of treatment credibility, the Therapy Evaluation Questionnaire (Borkovec & Nau, 1972).

Lacks et al (1983) in their RCT compared SC to a credible placebo (quasi desensitisation) delivered in a small group format, with 15 participants. Sleep diaries were used for outcome measures. Both groups showed significant decrements in WASO and NOA, and

there were no significant between group differences on any of the main dependant measures. They, however, noted that these non-significant differences were in the expected direction of SC being more effective.

A particular failing of this paper, aside from the small numbers, was the questionable conclusions regarding the results. Despite the lack of significant differences between treatment and control conditions, the authors later in the paper referred to the control group as a 'control *treatment*' after analysis of results, which prior to analysis had been described as the control *group*. Furthermore, the authors failed to confirm any of their sleep log data with objective measures. This is reflected in the poor quality rating of 0.18 on the SSQM. To their credit, the authors did attempt to account for both therapist effect and treatment credibility. However, participants were also required to pay for postage and a 'deposit' for taking part, which could be 'earned back' through participation in sessions. This may have increased participants' investment in symptoms improving. These design limitations meant this study attracted a lower quality score on the MQI (0.58) than the Edinger et al (2001) study.

Morin and Azrin (1987) compared the efficacy of SC and IT to a wait list control (WLC). Seven participants formed each of the three groups (total N=21), with treatments delivered in a small group setting. Results showed that SC produced a larger and quicker impact on awakening than IT. The SC group's mean WASO reduced by 65% compared to 16% in the IT group and 25% in the WLC. Furthermore, both the SC and IT group showed a greater reduction in NOA compared to WLC. However, there was no significant difference between SC and IT on this variable.

Morin and Azrin (1987) concluded that behavioural and cognitive procedures such as SC and IT may provide substantial benefits in alleviating maintenance insomnia. The study had several limitations, however, and was of moderate quality according to the MQI, with a rating of 0.66. One obvious limitation is the small numbers per group ( $N = 7$ ). The absence of objective sleep data to confirm the subjective sleep results (diary) also led to the low quality rating attracted on the SSQM (0.21). Moreover, reporting of data was vague, with exact figures per group for each outcome measure not reported.

Morin and Azrin (1988) also completed a randomised controlled trial comparing SC and IT with WLC. This study used a similar group format as their previous trial, although this time only participants specifically aged 55 and over were recruited. Furthermore, on this occasion, an objective sleep assessment device was employed (SAD; a remote hand-held switch which participants pressed whilst awake, which was connected to a clock). Both SC and IT produced a significant improvement on sleep diary measures, with large effect sizes on WASO of 0.84 and 0.61 respectively. WASO for the SC group reduced significantly relative to WLC, although the IT group did not differ significantly from either group on this measure. In this respect, the mean WASO was reduced for the SC group by 33.86 min compared to a 16.22 min reduction in the IT group, and an increase in the WLC's of 3.9 mins. Similarly, the SC group's TST increased significantly more than either of the other groups. Furthermore, satisfaction with treatment progress was higher for the SC than IT group and was perceived to be more 'credible'.

The authors therefore concluded that SC and IT can effectively treat maintenance difficulties in older adults. However, although the study made an attempt to use objective measures, these were not included as outcome data and were only used to correlate with

subjective measures (these correlations were significant). In addition, the interventions were ‘superimposed’ on drug intake for some participants, thereby confounding treatment outcome results. Moreover, participants with physical illnesses were included if their insomnia was not considered secondary to a physical illness. And participants were required to pay a deposit before participation. This may have confounded the results, as any remitting of physical symptoms may have had a secondary effect on sleep independent of intervention. Furthermore, financial investment may have meant participants had a vested interest in symptoms improving. This study yielded quality scores of 0.70 and 0.29, respectively on the MQI and SSQM.

#### *4.22 Randomised Trials*

Schoicket et al (1988) compared meditation, SC, and SH in 65 adults in a four week treatment programme conducted in small groups. Outcome was measured using sleep diaries. There was no control condition but, notably, both the SC and meditation group were also given SH instructions. Participants were also given counterdemand instructions “not to expect improvement to sleep until after the fourth treatment session” to reduce demand effects (Steinmark & Borkovec, 1974). Results were analysed in week 3 and 4 because of the counterdemand instructions. Participants in all three groups achieved significant improvement from baseline during the 4 weeks of treatment. There were no statistical differences between any of the groups. Taken together, the treatments produced a 31% decrease in WASO and a 20% decrease in the NOA after 4 weeks (see Table 4 for individual results). Furthermore, it appears these findings were not the result of demand characteristics; a significant difference was gained first at week 3 and maintained at week 4, despite instructions not to expect improvement until week 4. Indeed, meditation and SC

produced large effect sizes of 0.95 and 0.78, respectively. SH produced an effect size of 0.47.

The authors, therefore, concluded that improvement can be attained in a brief period by group treatment using either of these techniques. This study was limited by the lack of objective measures of sleep (reflected in its low quality rating of 0.18 according to the SSQM), and the lack of control group. Furthermore, like the some of the previous studies reviewed, participants were required to pay postage and a deposit in advance of participation. The authors did at least attempt to control for demand characteristics, and measured treatment compliance and credibility/acceptability. This study therefore gained a larger quality rating on the MQI (0.74) than the SSQM (0.18).

#### *4.23 Case Series*

Hoelscher & Edinger (1988) used a multiple baseline design to evaluate a behavioural treatment (BT) package which included SR, SE and SC in four 'older adults' aged 59 to 72. Intervention was delivered via 4 individual weekly sessions. Diary and SAD measured sleep. A clinically significant reduction in WASO was found in three participants. Mean subjective and objective WASO reduced by 52.3 min (ES = 1.44) and 53.8 min (ES = 1.30), respectively. SE also increased on both measures, however, these benefits did not translate to increased TST. Moreover, one participant failed to make improvements, although using PSG, the authors identified a fragmented sleep pattern secondary to periodic leg movements.

Hoelscher & Edinger (1988) described their results as "encouraging" but called for further controlled evaluations. The study was not of particularly high quality according to the MQI

and SSQM (0.51 and 0.50, respectively). The limitations of this study are rather obvious, in that they used only a very small sample (N=4) and no control group.

Edinger et al (1992) also used a multiple baseline design to treat seven 'older adults' aged 55 to 68 years sequentially with RT and then a CBT package (which included SE, SC and SR). They delivered both interventions on a weekly basis for four weeks each. Sleep diaries and SAD measured change. Only modest improvements in WASO and SE were found after RT. This compared to significant improvements observed following CBT. On sleep diaries, mean WASO reduced from 103.7 min in the baseline condition to 37.9 min post CBT (ES = 1.62) and SE increased by 13.6% (ES = 13.85). This difference was more pronounced according to the SAD data which saw mean WASO reduced from 167.0min to 48.5min and SE increase by 22%.

Edinger et al (1992) described their results as promising in terms of CBT efficacy, but conceded the limitations of their study as the small sample size and relatively high educational levels of participants. Furthermore, the study appears to use PSG which is arguably a more robust objective measure of sleep. However, PSG data were not fully reported and analysed. This study gained scores of 0.45 and 0.61 on the MQI and SSQM respectively.

#### *4.24 Case Study*

Espie and Lindsay (1987) reported a case study using time series analysis of a 33 year old man with sleep maintenance insomnia. They used Paradoxical Intention (PI) weekly, over 6 weeks, followed by worry control (WC) for 3 weeks. WC comprised of elements of

cognitive restructuring and behavioural problem solving. PI made little impact upon WASO. However, WASO fell from a mean of 52 minutes at baseline to 14 minutes during WC. Statistical analysis using time series analysis confirmed the visual impression of a significant change resulting from WC but not PI.

The authors concluded results did not support the use of PI but strongly favoured WC as a means of reducing mental arousal and WASO. This study gained one of the lowest scores of 0.44 and 0.05 on the MQI and SSQM respectively, which is perhaps not surprising given the case study design. The obvious limitations of generalising from a case study are applicable. Furthermore, the study did not detail sleep parameters at onset. However, the authors did attempt to use formal, recognised statistical procedures in the form of time series analysis.

## 5. SUMMARY

### *5.1 Limitations of Research*

Consideration of the evidence for the non-pharmacological interventions reviewed here must be taken in context of the general limitations to the currently available literature. When looking at the literature overall it is striking to note that, in general, many of the studies focused on (poorly defined) older adult samples. Yet maintenance problems also predominate in middle aged samples. Indeed, no studies of BLT have been completed using younger adults with maintenance problems.

Furthermore, the quality of the studies varies considerably. This can be seen in the range of MQI and SSMQ ratings. Overall, the MQI ratings vary from 0.44 to 0.94 and the SSQM ranges from 0.05 to 0.89. Only two of the studies reviewed (Suhner et al, 2002; Campbell et al, 1993; Edinger et al, 2001) used formal diagnostic criteria to identify sleep maintenance insomnia. Several studies paid participants, or asked *them* to pay for postage or a deposit which could be earned back in treatment (Suhner et al, 2002; Lacks et al, 1983; Shoicket et al, 1988; Morin & Azrin, 1988). This may very well have influenced the investment that participants had in these interventions improving their sleep. This is of particular relevance given that many studies comparing different treatment components found significant effects for all groups, with no significant differences between them. Many studies also involved small numbers of participants and, without fail, all studies failed to report a power calculation. Only a minority of studies used both objective and subjective measures of sleep (Campbell et al, 1993; Hoelscher & Edinger, 1988; Edinger et al, 1992).

Future research should consider focussing on more carefully controlled trials with larger sample sizes, explicitly stating diagnostic criteria used for inclusion, and using power calculations to detect the likelihood of identifying change. They should also ensure the use of unpaid volunteers and carefully delineate intervention components using control groups as comparisons.

## *5.2 Bright Light Therapy*

Only two RCT's of BLT met criteria for this review with a total of only 31 participants. Evidence was contradictory and the quality of the evidence was variable and, at best, reasonable. Campbell et al (1993) found BLT to be effective compared to a placebo but

Suhner et al (2002) did not. Indeed, the one study which found a significant effect for BLT (Campbell et al, 1993) was the poorer in quality of the two. Further research is required to replicate the study designs of those reviewed using larger samples whilst clearly defining the diagnostic criteria used and ensuring that investigators are also blind to the nature of intervention given. Finally, there is a clear need for research in the area of BLT with younger adults suffering from maintenance insomnia.

### *5.3 Psychological Interventions*

The primary aim of this review was not to compare individual psychological interventions, rather to identify whether these interventions may be of benefit. However, evidence for each intervention was not equivalent and, therefore, it appears appropriate to discuss the evidence of each intervention in turn.

There is some evidence for the use of multi component CBT for maintenance problems. It was found to have significant benefits in three studies (one RCT and two case series) with a total of 86 participants of mixed age. In two of these studies CBT was found to be superior to RT (Edinger et al 1992; Edinger et al, 2001), with no control group in the remaining study (Hoelscher & Edinger, 1988). Although the quality on these studies varied greatly (from 0.45 to 0.94 on the MQI and 0.5 to 0.89 on the SSQM), it is noteworthy that one of these studies (Edinger et al, 2001) had the highest quality rating of all the studies reviewed. Furthermore, these three studies were the only in this review to use both subjective and objective measures to identify change.

There is also evidence for the specific use of SC, but it is not clear whether this is more effective alone than other interventions. Four studies totalling 128 participants, 3 of which

were RCT's, compared SC to various other interventions and placebos. SC was found to significantly improve WASO without exception, as well as various other sleep parameters to varying degrees. However, in all but one of these studies (Morin and Azrin, 1987), no significant differences were found between SC and other interventions/controls. Nevertheless, one study showed a trend toward improvement compared to a placebo (Lacks et al, 1983) and another yielded greater (though not significant) improvements compared to IT (Schoicket et al, 1988). These studies varied in quality from reasonable to good on MQI (0.58 to 0.74) but low rates according to the SSQM (0.18 to 0.29). This reflects the fact that none of the studies used objective measures. However, all studies with the exception of Morin and Azrin (1987), required participants to pay for postage and a deposit. It is interesting to note that the only study which did not was also the only one that found a significant difference between SC and the other conditions. This could indicate that the significant results for *all* interventions in other studies may partially be reflective of an investment participants made in 'getting better'.

There is at present insufficient evidence for the use of SH and meditation. Both were shown to have significant effects in a study involving 65 participants. This work found significant improvements delivering SH and meditation in small groups (Schoicket et al, 1988). However, no benefit was found with these interventions, relative to SC. This study was a randomised trial, albeit without a placebo and as such was judged to be of good quality on MQI (0.74). Again however, it did not assess sleep parameters objectively required participants to pay a deposit/ postage and packaging, reflected in its low quality rating on SSQM (0.18).

Evidence for the use of IT or WC is also insufficient at present. IT was found to be of benefit in one RCT with 27 participants (Morin & Azrin, 1988), although results were not superior to SC on WASO. However, the same improvements were not replicated in a similar study with 21 participants (Morin & Azrin, 1987) of comparable (if slightly lower) quality. WC was found to be of significant benefit in one case study (Espie & Lindsay, 1987) in that reductions of WASO were found while engaging in WC but not PI. However, given the poor quality and the nature of the design, this is considered insufficient evidence for the use of this intervention in this population.

#### *5.4 Review Limitations*

The limitations of the current review should be borne in mind when considering its conclusions. The volume of literature reviewed was small, with a total of ten studies reviewed in total. Furthermore, this paper did not rate evidence according to the 'levels of evidence approach' (c.f. Morin et al, 1999), although it does discuss the relative quality of each study. Hence, conclusions are given with the above caveats in mind.

#### *5.5 Conclusions*

Non-pharmacological interventions are fairly well established in the treatment of initial insomnia but effects on sleep *maintenance* problems are unclear. This review assessed the effectiveness of non-pharmacological interventions for sleep maintenance insomnia in adult and older adult populations. The quality of studies reviewed varied greatly. Many involved small samples and a surprising amount required participants to 'pay to take part'. There was very little convincing evidence for the effectiveness of BLT from the limited

studies reported here, and both studies reviewed used older adults exclusively. There appears sufficient evidence to suggest that psychological interventions, in general, are effective in treating sleep maintenance insomnia. In particular, there appears stronger, better quality, evidence for the use of multi component CBT. However, there is less evidence to indicate which specific components of CBT treatment packages are the most effective, with almost all being found effective in at least one study, but little difference between them. Further controlled trials of unpaid volunteers of mixed ages are therefore required to carefully delineate which intervention components are most effective in the management of maintenance insomnia difficulties.

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Figure 1.

**Methodological Quality Instrument (Cho & Bero. 1994)**

Reviewer:

Article Number:

1. Study Design (choose 1 only):

*Experimental, randomised Placebo-controlled trial* \_\_ *Comparative trial, no placebo* *Time series trial*  
*Crossover trial*

*Nonexperimental* \_\_ *Cohort, prospective* \_\_ *Cohort, retrospective*  
*Cross-sectional* *Case-control*  
\_\_ *Case reports or case series*

\_\_ *None of the above (describe below):*

2. What was the study question? (please use the space below)

[possible responses to items 3-24: \_ Yes \_ Partial \_ No \_ (Not applicable)]

3. Was the study question sufficiently described?
4. Was the study design appropriate to answer the study question?
5. Were both the inclusion and exclusion criteria specified? (if case study check N/A)
6. For case studies only: Were participant characteristics adequately reported? (If not case study, check N/A)
7. Were participants appropriate to the study question?
8. Were control participants appropriate? (If no controls were used, check N/A.)
9. Were participants randomly selected from the target population?
10. If participants were randomly selected, was the method of random selection sufficiently well-described? (If participants were not randomly allocated, check N/A.)
11. If participants were randomly allocated to treatment groups, was the method of random allocation sufficiently described? (If participants were not randomly allocated, check N/A.)
12. If blinding of investigators to intervention was possible, was it reported? (If not possible, check N/A.)
13. If blinding of participants to intervention was possible, was it reported? (If not possible, check N/A.)
14. Was measurement bias accounted for by methods other than blinding?
15. Were known confounders accounted for by study design? (If no known confounders, check N/A.)
16. Were known confounders accounted for by analysis? (If no known confounders, check N/A.)
17. Was there a sample size justification before the study?
18. Were post-hoc power calculations or confidence intervals reported for statistically non-significant results?
19. Were statistical analyses appropriate?
20. Were the statistical tests stated?
21. Were exact *p* values or confidence intervals reported for each test?
22. Were attrition of participants and reasons for attrition recorded?
23. For those participants who completed the study, were the results completely reported?
24. Do the findings support the conclusions?

Figure 2.

**Sleep Study Quality Measure (Derived from Mendelson. 1997)**

Reviewer:

Article Number:

1. Self-report measure used to assess sleep quality (1 point)  
  
Sleep parameters reported for PI studies only (0.5 points for each): WASO, SOL, TST  
  
Sleep parameters reported for DSPS studies only (0.5 points for each): Sleep Onset and Sleep Offset, TST
2. Objective measure PSG (2 points) and/or actigraphy (1 point) used (Maximum 3 Points)  
  
Sleep parameters reported for PI studies only (0.5 points for each): WASO, SOL, TST  
  
Sleep parameters reported for DSPS studies only (0.5 points for each): Sleep Onset and Sleep Offset, TST
3. Appropriate diagnostic measures used to assign diagnosis, and clear assessment and exclusion of other sleep disorders; e.g., apnoea. (2 points for Yes; 1 for Partial)
4. Measures of clinical significance reported (1 Point) or sufficient data quoted to be able to calculate (0.5 points).

Weighting Scheme:        Points in 1, 2 and 3 multiplied by two.  
                                     Points in 4 multiplied by one.

Total Possible Points: 19

Quality Rating:            Actual Score/ 19

Table1. Summary of Studies.

Study	Type of Study	MQI	SSQM	Number of Participants	Age of Participants	Diagnostic criteria	Assessment Instruments	Type of Intervention	Mode and Timing of Intervention	Limitations	Results	Authors' Conclusions
Campbell et al (1993)	Placebo Controlled Trial	0.57	0.50	16 (7 male)	62-81 (X=70.4)	ICSD <sup>1</sup>	NS	BLT	12 days @ 2hrs Tx per day	Small N. Randomisation method. No subjective measure of sleep variables.	Significant reduction in WASO. Significant increase in SE.	Timed exposure to bright light effective.
Suhner et al (2002)	Relapse Prevention	0.72	0.63	15 (8 male)	63-84 (X=71.5)	No formal criteria specified	Self report (sleep diary)	BLT	3mo x 2hrs Tx twice weekly	Small N. Pts paid. No subjective measure of sleep variables.	No improvements in any parameters after intensive phase. No difference in parameters after maintenance phase.	No valid conclusion can be made.
Edinger et al (2001)	Double-blind randomised placebo controlled	0.94	0.89	75 (40 male)	Actual range not stated – inclusion criteria 40-80 X=55.3	DSM-III	PSG Self –report (structured clinical interview)	CBT (SC, SR, Education) RT Placebo	6 weekly 30-60 min individual sessions		Larger improvements across majority of outcome measures with CBT than RT or placebo.	CBT represents viable intervention.
Lacks et al (1983)	Randomised Placebo Controlled Trial	0.55	0.18	15 (6 males)	31-59 (X=43)	No formal criteria stated	Self report (sleep diary)	SC Placebo (IT)	4 weekly small group (N= 3-5) 60-90 min sessions	Small N. P's required to pay 'postage' and a 'deposit'.	Significant improvements for both groups. Trend towards SC.	Psychological interventions useful.
Morin & Azrin (1987)	Randomised WLC Trial	0.66	0.21	21 (7 male)	Range not stated (X=57, SD=9.85)	No formal criteria stated	Self report (clinical interview)	SC, IT, WLC	4 weekly small group (N= 3-5) 60 min sessions	Small N. No objective measures. Exact figures not quoted.	WASO significantly reduced for SC. NOA reduced for SC and IT.	Behavioural and cognitive procedures beneficial.
Morin & Azrin	Randomised WLC Trial	0.70	0.29	27 (10 male)	Range not stated (X=67.4,	No formal criteria	Self report (clinical)	SC, IT, WLC	6 bi weekly/ weekly small group (N= 3-5)	P's provided refundable deposit.	Improvements in WASO and TST for SC compared	Psychological interventions

<sup>1</sup> Participants met criteria for advanced sleep phase syndrome – intrinsic type, although referred to throughout title, abstract and text of paper as sleep maintenance insomnia.

(1988)						SD=5.6)	stated	interview)	60-75 min sessions	Objective measures not analyses in own right. No exclusion of hypnotics	to controls. No diff in WASO compared with IT but SC yielded greater improvements.	effective.
Schocket et al (1988)	Randomised Trial	0.74	0.18	65 (28 male)	28-75 (X=52.14)	No formal criteria stated	Self report (sleep diary)	SC, SH, M	4 weekly small group (N= 5-7) sessions	Small N. P's required to pay 'postage' and a 'deposit'. No objective measures.	All made significant improvements. No differences between groups.	Self reported improvement can be gained by any of the interventions.
Hoelscher & Edinger (1988)	Multiple baseline	0.51	0.50	4	59-72	No formal criteria stated	Self report (sleep diary)	BT (SC, SR, education)	4 weekly 60min individual sessions	Small N.	Reductions in WASO concurrent with intervention.	Further controlled evaluations required.
Edinger et al (1992)	Multiple baseline	0.45	0.61	7 (3 male)	55-68 (X=61.9)	No formal criteria stated	Self report (clinical interview and sleep diary)	RT and CBT (SC, SR, education)		Small sample size. Relatively high education level. PSG not fully reported.	Modest improvements after RT. Significant improvements after CBT.	Promising for CBT.
Espie & Lindsay (1987)	Case study	0.44	0.05	1 male	33	No formal criteria stated	Self report (clinical interview)	Paradoxical instruction, worry control	9 weekly sessions	Initial difficulties inadequately quantified. No objective measures. Inadequate reporting of sleep parameters.	Significant reduction in WASO from worry control but not paradoxical intention.	Results strongly favour worry control as intervention.

BLT= Bright Light Therapy, SC= Stimulus Control, WLC= Wait List Control, M= Meditation, SR= Sleep Restriction, SH=, Sleep Hygiene, IT= Imagery Training, RT= Relaxation Therapy, CBT= Cognitive Behaviour Therapy, BT= Behaviour Therapy, PI= Paradoxical Intention, EEG= Electroencephalography, PSG= Polysomnography, SAD= Sleep Assessment Device.

Table 2. Summary of Sleep Parameters (Standard Deviations).

Study	Group	Measure	Pre WASO	Post WASO	WASO ES	Pre TST	Post TST	TST ES	Pre NOA	Post NOA	NOA ES	Pre SE	Post SE	SE ES
Campbell et al (1993)	BLT	EEG	102.8 (21.4)	43.2 (21.6)	2.77	352.7 (19.9)	398.3 (40.9)	1.4179	25.12	14.7		77.5 (3.2)	90.1 (5.1)	2.96
Suhner et al (2002)	BLT	PSG <sup>2</sup>	112 (48.8)	93.9 (35.7)	0.42	358.8 (48.5)	355.3 (65.7)	0.06	NS	NS		74.06 (9.8)	74.89 (8.85)	0.09
Edinger et al (2001)	CBT	Sleep Diary <sup>3</sup>	103.9	49.2		336.8	360.0 (8.4)					72.0	84.3 (1.7)	
		PSG	64.9	34.3		352.1	372.4 (10.6)					77.8	85.1 (1.9)	
	RT	Sleep Diary	103.9	80.06		336.8	362.0 (8.6)		NS	NS		72.0	78.1 (1.6)	
		PSG	64.9	60.8		352.1	337.9 (10.6)					77.8	78.1 (1.9)	
Lacks et al (1983)	SC	Sleep Diary	60.24 (22.71)	25.49 (21.67)	1.57	NS	NS		1.73 (0.82)	1.57 (0.92)	0.18	NS	NS	
Morin & Azrin (1987)	SC	Sleep Diary	NS	NS		NS	NS		NS	NS		NS	NS	
	IT	Sleep Diary	NS	NS		NS	NS		NS	NS		NS	NS	
Morin & Azrin (1988)	SC	Sleep Diary	76.74 (36.31)	42.88 (43.57)	0.84	289.76 (67.66)	354.40 (83.26)	0.85	2.49 (0.83)	1.92 (1.13)	0.57	NS	NS	
	IT	Sleep Diary	72.97 (28.87)	56.75 (23.69)	0.61	351.08 (48.27)	360.63 (64.69)	0.17	3.04 (1.30)	2.46 (1.24)	0.46	NS	NS	

<sup>2</sup> Open label data reported.<sup>3</sup> Intention to treat analysis reported (as per original paper). Baseline data averaged for objective and subjective measures separately across all groups.

Schocket et al (1988)	SH	Sleep Diary	81.05 (36.73)	61.76 <sup>d</sup> (44.66)	0.47	NS	NS	1.50 (0.67)	1.48 (1.10)	0.02	NS	NS	
	M	Sleep Diary	82.05 (41.92)	49.77 (23.80)	0.95	NS	NS	1.85 (0.77)	1.46 (0.78)	0.48	NS	NS	
	SC	Sleep Diary	84.82 (43.92)	52.68 (37.82)	0.78	NS	NS	1.81 (1.00)	1.11 (0.92)	0.73	NS	NS	
Hoelscher & Edinger (1988)	BT	Sleep Diary	103.6 (44.2)	51.3 (25.0)	1.44	364.6 (66.8)	366.7 (37.1)	2.8 (1.3)	2.3 (0.9)	0.45	72.2 (10.5)	83.3 (6.5)	1.27
		SAD	125.2 (51.0)	71.4 (28.7)	1.30	340.7 (59.9)	339.1 (43.7)	4.3 (1.9)	3.3 (1.4)	0.30	68.3 (8.1)	78.8 (7.2)	1.37
	RT	Sleep Diary	103.7 (52.4)	93.6 (38.3)	0.22	338.0 (64.9)	339.7 (50.4)	3.6 (0.3)	2.6 (0.5)	2.43	72.0 (1.2)	75.4 (0.9)	3.21
Edinger et al (1992)		SAD	167.0 (55.0)	131.0 (38.6)	0.76	275.4 (5.6)	292.0 (5.3)	4.2 (1.8)	3.6 (1.8)	0.33	60.1 (1.1)	66.6 (0.9)	6.47
	CBT	Sleep Diary	103.7 (52.4)	37.9 (23.4)	1.62	338.0 (64.9)	312.3 (39.9)	3.6 (0.3)	1.9 (0.5)	4.12	72.0 (1.2)	85.6 (0.7)	13.85
		SAD	167.0 (55.0)	48.5 (21.1)	2.84	275.4 (5.6)	292.6 (4.0)	4.2 (1.8)	2.1 (1.1)	1.41	60.1 (1.1)	82.1 (0.6)	24.83
Espie & Lindsay (1987)	PI	Sleep Diary	52	44		NS	NS	NS	NS		NS	NS	
	Worry Cont.	Sleep Diary	44	14		NS	NS	NS	NS		NS	NS	

BLT= Bright Light Therapy, SC= Stimulus Control, WLC= Wait List Control, M= Meditation, SR= Sleep Restriction, SH= Sleep Hygiene, IT= Imagery Training, RT= Relaxation Therapy, CBT= Cognitive Behaviour Therapy, BT= Behaviour Therapy, PI= Paradoxical Intention, EEG= Electroencephalography, PSG= Polysomnography, SAD= Sleep Assessment Device

<sup>4</sup> Week 3 figures reported. Counterdemand present.

MAJOR RESEARCH PROJECT PROPOSAL

**Does a Pennebaker-like writing intervention reduce cognitive arousal  
and sleep onset latency in poor sleepers?**

Major Research Proposal submitted in partial fulfilment of the requirement for the degree  
of Doctor of Clinical Psychology (Appendix 3.1)

## Summary

This study draws on several areas of literature including the role of cognitive arousal in sleep difficulties and a cognitive model of insomnia implicating inhibition and suppression as maintaining insomnia. The Pennebaker writing task requires people to write about their innermost thoughts and emotions regarding traumatic or significantly emotional events and is thought to promote emotional processing or facilitate cognitive changes that increase insight. This task has had significant effects in several areas of psychological and physical ill health. Furthermore, a pilot study using a Pennebaker-like writing task with poor sleepers proved successful. This study aims to test the notion that a Pennebaker-like writing task will reduce pre sleep cognitive activity and the length of time it takes for individuals to fall asleep (sleep onset latency; SOL). This study will do this by replicating and extending on an existing pilot study. A minimum of 28 participants will be randomised, following a one night baseline, to three nights of Pennebaker writing, or a control condition. A mixed models ANOVA design will be employed with the between participants factor of condition (Pennebaker, Control) and within group factor of Time (Baseline, Treatment). It is hypothesised that, following a one night baseline, participants randomised to the experimental condition (Pennebaker - like writing task), when compared with participants randomised to the control condition will show reduced pre-sleep cognitive arousal and reduced SOL.

***Databases searched include:*** PsycINFO, Medline, All EBM Reviews, Social Sciences Citation Index.

***Keywords searched include:*** insomnia, Pennebaker writing, cognitive arousal and various authors' names.

## **Background**

### ***Cognitive arousal in sleep difficulties***

The role of cognitive arousal is well established in sleep difficulties (Espie, 2002). There is an emerging consensus that pre sleep cognitive activity of people with insomnia is typically negatively toned and covers a broad range of topics (Harvey, 2000; Wicklow and Espie, 2000). Most individuals with sleep onset insomnia “complain that the sleep onset period is dominated by unwanted thoughts and worries, as well as periods of rumination about past or future life events, or concerns about the plactions of not being able to fall asleep” (Harvey, 2003, p. 594; Borkovec, 1982; Espie, 1991). Furthermore, these individuals frequently perceive this activity as a major barrier to sleep (Espie, Brooks and Lindsay, 1989; Harvey, 2000). For example, Lichstein and Rosenthal (1980) found that people with insomnia are ten times more likely to quote cognitive arousal as central to their sleep disturbance compared to somatic arousal. However, there is evidence that such cognitive arousal can be reduced. A study by Harvey and Payne (2002) found that thinking about a specific interesting and engaging cognitive task to be an effective method of managing unwanted pre-sleep thoughts among people with insomnia in the short term.

### ***Inhibition and suppression in insomnia***

There is also some evidence that insomniacs inhibit or internalise their emotions (Kales, Caldwell, Soldatos, Bixler and Kales, 1983; Kales and Kales, 1984). Kales et al (1983) used the Minnesota Multiphasic Personality Inventory (MMPI) to assess personality patterns of 528 patients with chronic insomnia. The profiles these patients were

consistently characterised by, amongst other things, inhibition of emotions. Harvey's (2002) cognitive model of insomnia draws on these findings and suggests that "it is possible that inhibition and suppression may be a strategy adopted to cope with excessive cognitive activity and escalating anxiety throughout the day" (Harvey, 2002, p.884). According to this model, as a result, the unwanted pre sleep cognitive activity reported by those with insomnia may (in part) be a consequence of this inhibition and incomplete emotional processing of daily stressors. It is proposed that the resulting 'unfinished' business from the day intrudes during the pre sleep period, fuelling negatively toned pre sleep cognitive activity and interfering with sleep onset. This proposal is by and large untested, although Harvey (2001) did find that suppression was employed more by insomniacs than good sleepers when dealing with intrusive thoughts or worries when trying to get to sleep. Nevertheless, emotional processing theory by Rachmann (1980) would support such a view and Bootzin and Rider (1997), amongst others, acknowledge that bed time might possibly be the first quiet time during the day that an individual has to think about the day's events as well as to worry and plan for the next day.

Further evidence in line with the idea that people with insomnia do not adequately process events of the day are results from studies indicating that insomniacs engage in problem solving (Harvey, 2000) and reappraisal (Harvey, 2001) whilst trying to get to sleep. For example, Harvey (2001) compared the strategies employed to manage cognitive activity during the pre sleep period of 30 insomnia sufferers with 29 good sleepers and found that one of the most frequently used strategies for insomnia sufferers, but not good sleepers, was reappraisal. Thus, it could be argued that insomniacs engage in these strategies in order to compensate for their failing to process these worries adequately during the day.

The experimental work of Pennebaker and his colleagues (e.g. Pennebaker and Beall, 1986; Pennebaker, Kiecolt-Glaser and Glaser, 1988) has consistently found that inducing participants to write about their innermost thoughts and emotions regarding traumatic or significantly emotional events resulted in health improvements. Respondents who were asked to disclose their emotional reactions to past traumatic events or recent upsetting experiences subsequently made fewer visits to physicians than did individuals who had been instructed to write about neutral topics (Pennebaker and Beall, 1986).

With specific regards to psychological wellbeing, recent results show that written disclosure buffered the effects of social constraints on stress in cancer patients at 6-month follow-up (Zakowski, Ramati, Johnson, Morton and Flanigan, 2004). This study randomised participants to a written emotional disclosure task or a 'non emotional' writing task. Their results showed that written disclosure buffered the effects of social constraints (negative social responses to patients' expressions of emotion regarding their cancer) on distress such that patients with high levels of constraint at study intake exhibited distress levels comparable to patients with low levels of constraint, if they were given the opportunity to express their emotions in writing. Those at high constraint levels who were not given that opportunity (control condition) continued to exhibit heightened levels of distress at follow-up.

Although the expressive writing paradigm has generally produced positive outcomes, a recurring puzzle concerns how and why it works (Pennebaker, 2004; Bootzin, 1997). No single theory or theoretical perspective has convincingly explained its effectiveness

(Pennebaker, 2004), although two theories predominate the literature. One theory is that writing about emotions reverses emotional inhibition and facilitates emotional processing. A second theory argues that writing facilitates cognitive changes that increase insight (Pennebaker, 1997). Nevertheless, Bootzin (1997) has highlighted the potential utility of Pennebaker's writing intervention to be a component for treatment of some disorders, but emphasised the need for prior systematic research into its benefit with specific clinical problems.

### *Writing in sleep difficulties*

Several investigations have looked at the role of writing in sleep difficulties. Espie and Lindsay (1987) have described a technique (cognitive control) which aims to reduce the influence of cognitive activity upon sleep which includes pre sleep writing. However, the task instructions in this study were different to that of a Pennebaker-like writing task and included focussing on the days worries and evaluating them as well as creating a 'to do list'. Furthermore, the overall aims of this intervention were different to that of the Pennebaker task, primarily being to remove mental activity from the bed and bedroom environment (Morin and Espie, 2003), rather than facilitating emotional processing.

In addition, Krakow et al (2001) and Neidhardt et al (1992) found that exposure interventions for nightmare sufferers that include writing were successful in reducing the frequency of nightmares and improved sleep quality. These data further suggest that nocturnal writing tasks may have potential in the amelioration of sleep disturbance via facilitation of emotional processing.

With regards to the work of Pennebaker and colleagues, a pilot study carried out by Harvey and Farrell (2003) found that a Pennebaker-like writing task led to shorter estimated sleep onset in poor sleepers when compared to individuals who did not engage in this task. As this study was pilot in nature, there were several methodological limitations that preclude drawing strong conclusions from this work.

Firstly, the sample were poor sleepers, which were employed as an analogue of insomnia. Thus, firm conclusions cannot be drawn regarding the implications of the results of this study for understanding and treating insomnia. Secondly, the rationale given to the group completing the Pennebaker-like writing task explicitly led them to expect that the writing task would be beneficial to sleep. This could mean that results reflect a placebo effect (Bootzin, Herman and Nicassio, 1976). Thirdly, sleep onset latency was exclusively measured using the subjective reports of participants. The accuracy of any results measured by this means might be questioned as individuals with insomnia are known to be inaccurate in their estimation of sleep onset latency (Coates et al, 1982). Fourthly, no baseline period was employed in this study. Although no pre intervention differences were found between groups in terms of sleep onset latency, this measure was taken retrospectively for an average night. Given the inaccuracy of insomniac in reporting sleep onset latency (Coates et al, 1982) and the fact that sleep has much inter-subject and inter-night variability (Speilman, Yang and Glovinsky, 2001), this makes it difficult to exclude the explanation that the change in sleep variables are not simply an artefact of inter-subject variability or change to habitual bedtime/wakening. Finally, no measures were included in this study to clearly determine the mechanism by which the intervention group experienced shorter sleep onset latency, for example, pre sleep cognitive arousal.

## ***Summary***

In summary, the following points should be considered:

- The evidence for the role of cognitive arousal in sleep difficulties.
- Harvey's (2002) model implicating inhibition and suppression as maintaining insomnia.
- The proposed theoretical underpinnings of the utility of the Pennebaker writing task.
- The significant effects of Pennebaker writing in other areas, along with the (limited) evidence of therapies utilising writing in sleep.
- The pilot study using a Pennebaker-like writing task with poor sleepers.

Taken together, these factors could indicate that engaging individuals with insomnia in Pennebaker-like writing task would lead to a reduction in pre sleep cognitive activity as well as a reduction in sleep onset latency.

## **Study Aim**

This study aims to test the notion that a Pennebaker-like writing task will reduce pre sleep cognitive activity and the length of time it takes for individuals to fall asleep (sleep onset latency; SOL). This study will do this by replicating and extending on the existing pilot work of Harvey and Farrell (2003), by addressing the methodological limitations mentioned above.

## **Design**

The independent variable is the 'condition'; participants will be randomised, following a one night baseline, to three nights of Pennebaker writing, or a control condition. The dependent variables are SOL and pre sleep cognitive activity. A mixed models ANOVA design will be employed with the between participants factor of condition (Pennebaker, Control) and within group factor of Time (Baseline, Treatment).

## **Hypothesis**

It is hypothesised that, following a one night baseline, participants randomised to the experimental condition (Pennebaker - like writing task), when compared with participants randomised to the control condition will show:

1. Reduced pre-sleep cognitive arousal.
2. Reduced SOL.

## **Participants**

The minimum number of participants required in a study of this nature to ensure that any significant result would be of a meaningful magnitude is 28 (N = 14 per group). This number was derived from a two sample normal distribution with unequal variances power calculation by means of a t-test using Welch's approximation for the degrees of freedom. A website power calculator (<http://calculators.stat.ucla.edu/powercalc/>) was used to carry out this analysis. The extant data of means and standard deviations of SOL from both the

experimental and 'sleep as usual' condition from Harvey and Farrell (2003) was used as a template, with the power set at 0.8 and the alpha level being  $p < 0.05$ .

Participants will be recruited via notices placed locally and emails sent to University and Health Service Staff via a mass mailing system asking for volunteers with sleep difficulties, a method which has previously proved successful (e.g. Broomfield and Espie, 2003). Current third year trainees are successfully recruiting in this manner also. Participants will be aged between 16 and 65, be required to meet formal criteria for sleep onset insomnia according to the revised version of the International Classification of Sleep Disorders (American Sleep Disorder Association, 1997; i.e. SOL greater than 30 minutes on at least 4 nights a week, with or without disruption to other sleep variables), and complain of poor sleep due to excessive pre sleep worry/cognition. Exclusion criteria will include failure to comply with instructions of the task, the use of alcohol or sleep medication during the experimental period, severe depression or physical illness during the study period.

## **Measures**

- A structured clinical interview that includes questions to establish the presence or absence of each ICSD criteria for insomnia and to exclude other mental health problems or sleep disorders. This interview has been developed by members of the Sleep Group at Glasgow University and will be used to screen for insomnia and mental health problems, in the absence of a psychometrically validated alternative.
- The Insomnia Severity Index (Morin, 1993). The ISI is an index of insomnia severity. It has been validated against both polysomnographic and prospective sleep

diary measures and demonstrates convergence with clinical interview criteria. It demonstrates face and criterion validity, and other adequate psychometric properties. It provides a cut-off score which is considered useful as a guideline for clinicians in evaluating the clinical significance of the insomnia complaint. A cut-off score of 14 demonstrates a sensitivity of 94% and a specificity of 94% in distinguishing individuals diagnosed with primary insomnia from good sleeper controls. This measure will also be used to screen for insomnia.

- Pittsburgh Sleep Quality Index – PSQI (Buysse et al, 1993). The PSQI requests information regarding the number of hours spent in bed and asleep, frequency and reasons for awakening, and difficulty returning to sleep after awakening. The PSQI has been shown to be a valid and reliable assessment to overall sleep quality and disturbance, with good test-retest reliability ( $r = 0.85$ ) and internal consistency ( $[\alpha] = 0.83$ ). This is would also be used to screen for insomnia, alongside the semi structured interview.
- The Beck Depression Inventory II (BDI-II; Beck, Steer & Brown, 1996) will be used to aid screening for severe depression. This is a self-administered 21 item self-report scale measuring supposed manifestations of depression. It has good psychometric properties and there are widely agreed cut-offs based on scores indicating from no depression or minimal depression to mild, moderate, or severe depression.
- A daily sleep diary (Espie, 1991) to measure sleep onset latency and pre sleep cognitive activity. This diary requests information on: time to bed, time to fall asleep, and total sleep time.
- The cognitive subscale of the Pre Sleep Arousal Scale (PSAS; Nicassio et al, 1985). The PSAS contains 16 items tapping eight symptoms of cognitive (e.g.,

racing mind) and eight symptoms of somatic (e.g., muscle tension) arousal experienced at bedtime. Ratings range from 1 (not at all) to 5 (extremely). A total score ranging from 8 to 40 is computed for each subscale; a high score indicates a high arousal. The internal consistency and the test-retest reliability of this questionnaire are adequate. Participants will be instructed to complete the cognitive subscale of this measure on rising in the morning, along with the sleep diary.

- “Actiwatch” (model AW2; Cambridge Neurotechnology Ltd). This wrist actigraph recording provides objective estimates of SOL and sleep efficiency. This measure assesses levels of movement which is known to be a good predictor of wakefulness and sleep (America Sleep Disorders Association, 1995; Mullaney et al., 1980). Actigraph measures correlate highly with polysomnographic (PSG) data for sleep duration and total wake time (Sadeh et al., 1995; Mullaney et al., 1980).
- A rating of ‘emotional processing’ using a 4 point scale (“I worked through some upsetting issues”; anchor points 0 “not at all”, 3 “a lot”). In the absence of any psychometrically validated alternative, this will be used as a measure of the extent to which individuals thought that they emotionally processed information after engaging in the writing task
- The Penn State Worry Questionnaire (PSWQ; Meyer et al, 1990). This questionnaire will not be used for diagnostic or analysis purposes, it will solely be used to ensure that the control group are focussed upon worry for a similar length of time of the experimental group.
- The Worry Domains Questionnaire (WDQ; Tallis, Eysenk, and Mathews, 1992). As with the PSWQ, the results from this will not be analysed, but will be used to ensure that the control group was focussed on worry for the same amount of time as the experimental group.

## Procedure

After screening, participants will be given instructions in how to complete the sleep diary and use the actiwatch. Participants will be instructed to wear the actigraph watch every day and complete the sleep diary on waking.

Participants will have previously been randomised to either the experimental task or the 'sleep as usual' condition using a 'random number generator' website such as <http://www.Random.org>. Participants will be given two envelopes containing instructions for day 1 and instructions for days 2 to 4 (which they will be told not to open until that day), as well as sleep diaries and copies of the relevant questionnaires.

Participant's sleep will be monitored for a 1 day baseline period (day 1). Participants will then be asked to follow the instructions below, relevant to their particular condition, for a further 3 days (days 2 – 4). Such a timescale has proved sufficient to find adequate results in similar experimental studies manipulating novel interventions (e.g. Harvey and Payne, 2002; Haynes et al, 1981; Harvey, 2003). Indeed, Harvey and Farrell (2003) found a significant effect over 3 days in their pilot study using the same task.

As patients' expectations have been known to influence response to other interventions (Espie and Lindsay, 1985; Broomfield and Espie, 2003), all participants will be told that they should not expect any improvement in sleep. Adherence to the experimental condition will be monitored using a manipulation check to similar to that of Harvey and

Farrell (2003). This would ask participants to rate the content of their writing on a scale from -5 (about sad/anxiety related things) to +5 (about happy things).

At the end of the study, all participants will be debriefed and thanked. Participants will also be issued with the 'Good Sleep Guide', a leaflet describing behavioural advice for home practice (National Medical Advisory Committee, 1993).

### ***Experimental condition***

Participants in the experimental condition will be given written instructions based on those used by Harvey and Farrell (2003) and Pennebaker (1997). See Appendix 4.5 for a copy of the participants' instructions. Participants will be asked to write about any thoughts, concerns, worries for 20 minutes in the early evening (between 6pm and 8 pm). This time was chosen as it was thought that engaging in such a task at bedtime may be activating, and would therefore be too arousing to be effective. In addition, Espie and Lindsay (1987) suggested targeting pre sleep worry in the early evening might be more effective than procedures at bedtime. Participants will be instructed to engage in this activity outwith the bedroom, in order to ensure that the worries they write about (which are incompatible with sleep) do not become associated with the bedroom environment (Bootzin, 1972). Participants will also be asked to complete the 'emotional processing rating' after engaging in this task.

Participants will be instructed that they can write about either the same or different traumatic events during each writing session. Despite suggestions by Harvey and Farrell (2003) to the contrary, participants will not be required to show anyone what they write (to

encourage honest and free emotional expression), and this will be made explicit to them in the first instance.

### ***Control group***

The control group will be instructed to complete a PSWQ and WDQ between 6pm and 8pm in order that they spend approximately the same amount of time focussed on their worries as the experimental group, but without facilitation of emotional processing that the Pennebaker task is hypothesised to facilitate. In addition, the control group will be asked to carry on with their normal sleeping practices, to continue wearing their Actiwatch and to continue completing their sleep diary.

### **Analysis**

An average SOL will be calculated for both the baseline and experiments phase. Both groups would then be compared on this, and the PSAS cognitive subscale, by means of a two way mixed ANOVA with the independent variables being Condition (writing task v control) and Time (Baseline vs Experimental Phase). Separate ANOVAs for SOL and cognitive activity will be computed.

### **Discussion**

The results of this study will provide further evidence for the efficacy of this intervention and its effects on pre sleep cognitive arousal. If results of this study were significant, then this would indicate that the treatment is efficacious in the short term and further studies

over a longer term should be carried out. Success in the long term may mean that this treatment could be included in existing treatment packages for insomnia.

## **Ethical Considerations**

It is anticipated that no ethical considerations apply beyond those that are common to research where experimental variables are manipulated. Informed consent will be gained and will follow the guidelines proposed by COREC. It is anticipated that ethical approval will be gained from both Greater Glasgow and Argyll and Clyde Health Boards (where the primary investigator is employed), although no NHS patients will be solicited for, or included in, this study (see Appendices 3.2 and 3.3 for copies of ethical approval and research sponsorship).

## **Timescale**

Ethical approval will be sought during June or July 2005. A minimum of 2 Actigraph watches will be available for sole use in this study. This will allow 2 participants to be recruited per week. This will mean that the minimum possible time for data collection is 14 weeks. Allowing extra time for 'slippage', a conservative estimate for the data collection phase is 20 weeks, starting from the time ethical approval is received.

## **Health and Safety Issues**

Where possible, a room on NHS property would be booked to be used to recruit and interview participants. Participants will not have previously been known to NHS

Psychology services, referrals will not have been through the usual routes e.g. GP's, and no previous risk assessment would be carried out on participants. However, all participants will have been vetted in some form by nature of their employment status within the NHS or University of Glasgow.

### **Proposed Costs/ Outlays**

The proposed costs and outlays for this study are estimated in the attached proforma (see Appendix 3.4).

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MAJOR RESEARCH PROJECT

**Does a Pennebaker-like writing intervention reduce cognitive arousal  
and sleep onset latency in poor sleepers?**

Major Research Project submitted in partial fulfilment of the requirement for the degree of  
Doctor of Clinical Psychology

Prepared in accordance with the guidelines for Behavioral Sleep Medicine (Appendix 4.1).

## Abstract

The present study considered the role of pre sleep cognitive arousal, inhibition and suppression in sleep onset difficulties. The Pennebaker writing task, which promotes emotional processing by asking people to write about their deepest thoughts, worries, and emotions, has proven effective in several areas of health, including oncology and Post Traumatic Stress Disorder. Here, the paradigms ability to reduce pre sleep cognitive arousal and sleep onset latency in people with insomnia was tested. 28 people with insomnia were randomised to three nights of Pennebaker writing or a control condition, following a one night baseline. The outcomes of change over baseline at day 4 in pre sleep cognitive arousal and sleep onset latency were compared between groups using analysis of variance normal linear models (ANOVA). Writing significantly reduced pre sleep cognitive arousal according to one out of two measures but did not significantly reduce sleep onset latency. The implications and possible explanations of the results are discussed.

Keywords: insomnia, cognitive arousal, emotional processing, writing intervention

Primary or psychophysiologic insomnia (PI) involves difficulty initiating or maintaining sleep, in the absence of underlying medical or psychiatric causes (APA, 1994). PI is fairly common, with approximately 10% to 15% of the adult population (Mellinger et al, 1995; Ford & Kamerow, 1989) experiencing the disorder on a chronic basis. The disorder typically results in psychological distress, and can significantly impact social occupational and cognitive functioning (e.g. Mellinger et al, 1995; Ford & Kamerow, 1989; Gallup, 1991).

The role of cognitive arousal is well established in sleep difficulties (Espie, 2002). Recent research indicates the pre sleep cognitive activity of people with insomnia (PWI) is excessive and uncontrollable, negatively toned, and covers a broad range of topics (e.g. Harvey, 2000). Wicklow and Espie (2000), for instance, directly sampled the pre sleep thoughts of PWI using tape recorders, and found that worry and thinking about sleep most strongly predicted delayed sleep onset. Importantly however, not all thinking amongst PWI is worrisome and negative (Wicklow & Espie, 2000). Furthermore, PWI perceive this activity as a major barrier to sleep (e.g. Espie et al, 1989; Harvey, 2000; Lichstein & Rosenthal, 1980). Lichstein and Rosenthal (1980) found that people with PI (PWI) are ten times more likely to quote cognitive arousal as central to their sleep disturbance compared to somatic arousal.

There is also evidence that such pre sleep cognitive arousal (PSCA) in PWI can be reduced by brief and novel interventions (e.g. Harvey & Payne, 2002; Carney & Waters, 2006). For example, Carney and Waters (2006) found that in a cohort of 33 undergraduate students, that engaging in “Constructive Worry” for five nights had a positive significant effect on PSCA according to the Pre Sleep Arousal Scale (Nicassio et al, 1985).

Evidence suggests that PWI inhibit or internalise their emotions (Kales et al, 1983; Kales & Kales, 1984). For example, Kales et al (1983) used the Minnesota Multiphasic Personality Inventory (MMPI) to assess personality patterns of 528 patients with chronic insomnia. The profiles of these patients were consistently characterised by, amongst other things, inhibition of emotions. Furthermore, Harvey (2001) found that thought suppression was employed more by PWI than good sleepers, when dealing with intrusive thoughts or worries at bedtime. Harvey's (2002) cognitive model of the maintenance of PI draws on such evidence. Harvey suggests that unwanted PSCA amongst PWI may be a consequence of such inhibitive processes, causing the incomplete emotional processing of daily stressors. According to this hypothesis, 'unfinished business from the day' intrudes during the pre sleep period in PWI, fuelling PSCA and delaying sleep onset.

Other authors from the PI literature also acknowledge that bed time might possibly be the first time during the day that an individual has time to think about the day's events, and worry and plan for the next day (Bootzin & Rider, 1997). Furthermore, Harvey's explanation is commensurate with Rachman's (1980) model of emotional processing. In this model, emotional processing is the method whereby emotional disturbances are absorbed, and subsequently decline, so that other behaviour can proceed without disruption. According to this model, suppressing emotional expression impedes emotional processing, and incomplete emotional processing can result in PI (Rachman, 1980).

Inducing PWI to write about thoughts and worries before they get to bed might therefore, in theory, improve sleep by facilitating emotional processing and ameliorating PSCA. One approach to achieve this is the Pennebaker writing task. The task asks people to write

about their deepest thoughts, worries, and emotions for 15 to 20 minutes (e.g. Pennebaker & Beall, 1986; Pennebaker et al, 1988). Two meta analyses (Smyth, 1998; Frisina et al, 2004) have found beneficial effects of the task with non clinical and clinical populations, (e.g. Post Traumatic Stress Disorder and oncology patients) on a range of physical and psychological outcomes, including sleep.

A recurring puzzle concerns how and why this paradigm works (Pennebaker, 2004; Bootzin, 1997). No single theory or theoretical perspective has convincingly explained its effectiveness (Pennebaker, 2004), although two theories predominate the literature. One is that writing about emotions reverses emotional inhibition and facilitates emotional processing. The second hypothesises that translating experiences into language by writing promotes organisation of problem descriptions into coherent stories, thereby facilitating cognitive changes that increase insight (Pennebaker, 1997). Despite this ambiguity, Bootzin (1997) has highlighted the potential utility of Pennebaker's writing intervention as a component for treatment of mental health problems including PI, but emphasises the need for prior systematic research into its benefits for individual problem areas.

Despite extensive research on the Pennebaker paradigm, and converging evidence that PWI frequently experience PSCA (Harvey, 2000; Wicklow & Espie, 2000) which delays sleep onset (Lichstein & Rosenthal, 1980; Gross & Borkovec, 1982; Hall et al, 1996), surprisingly, only one study has specifically used the intervention in a population exclusively with sleeping difficulties. Harvey and Farrell (2003), in a recent pilot study, found that PWI who wrote about problems and worries prior to bed using the Pennebaker task, experienced shorter estimated SOL compared to PWI who did not.

The Harvey & Farrell (2003) data are encouraging, and highlight the potential to improve PI with a simple intervention designed to facilitate processing of pre sleep cognitions and worries. Cognitive behaviour therapy for PI (CBTI) has a strong evidence base (Morin et al, 1999; Murtagh & Greenwood, 1995), but typically, includes no worry-specific cognitive components (Carney & Waters, 2006). Clarification of the efficacy of the Pennebaker task in treating PI may allow its inclusion in CBT for PI treatment packages.

However, several methodological limitations of Harvey and Farrell's (2003) study preclude any definitive conclusions about the task's clinical utility with PWI. Not least is the fact that the rationale given to the writing task group may have led to expected sleep improvement. PWI who took part were informed that previous research had showed benefits for sleep in writing down thoughts and concerns, and that this task would similarly help them organise and process their thoughts. Results may therefore reflect a placebo effect relating to demand expectations (Bootzin et al, 1976). Furthermore, Harvey and Farrell (2003) employed no objective SOL measure, and no baseline period was employed. The observed changes in sleep may therefore reflect an artefact of errors in subjective estimation, inter-subject variability or change to habitual bedtime/wakening unrelated to the experimental (Pennebaker) intervention. Finally, no measures were included to clearly delineate whether effects were indeed mediated by a reduction in PSCA.

The current study therefore aimed to replicate and extend this and other previous research, by applying the Pennebaker task to PWI. Drawing on the extant cognitive PI literature, and on studies of the Pennebaker writing task in health and, in particular, sleep, the hypothesis that an early evening writing task designed to facilitate processing of cognitions and worries would reduce (i) PSCA and (ii) SOL, was tested. Importantly, the

methodological limitations inherent in the Harvey and Farrell pilot study outlined above, were directly addressed. In this respect, an objective measure of sleep was employed (actigraphy), PSCA was measured (Pre Sleep Arousal Scale; Nicassio et al, 1985), and counter demand instructions were given to participants (“do not expect any improvement to sleep”). It was hypothesised that, following a one night baseline, participants randomised to the experimental condition (Pennebaker writing task), would show reduced PSCA and SOL, compared to participants randomised to a control condition. Importantly, the work described here was not designed as a treatment study, rather as an experimental examination of the applicability of the paradigm to PI.

## Method

### **Participants**

Participants were recruited using a group email sent to university students and health service staff (c.f. Broomfield and Espie, 2003). Prior to inclusion, and in the absence of any psychometrically validated alternative, for inclusion participants were assessed by a locally developed semi structured clinical interview (see Appendix 4.2), and using standardised questionnaires. In this respect, participants also completed screening questionnaires assessing sleep (PI Severity Index [ISI] - Morin, 1993; Pittsburgh Sleep Quality Index [PSQI] - Buysse et al, 1989) and mood (Beck Depression Inventory II [BDI-II] – Beck et al, 1996). The ISI and PSQI are widely used to determine inclusion in PI studies (e.g. Broomfield & Espie, 2003; Harvey & Farrell, 2003; Carney & Waters, 2006; Harvey & Payne, 2002; Marchetti et al, 2006).

Respondents were included if they were aged between 16 and 65, and complained of clinically significant difficulties falling asleep which were the result of excessive PSCA (“experience persistent thoughts when trying to sleep”; “racing thoughts in bed that prevent falling asleep”). Following International Classification of Sleep Disorders (Second Edition) criteria for PI (American Sleep Disorder Association, 2005), clinically significant sleeping difficulties were defined as SOL > 30 minutes on four plus nights per week for at least for 4 weeks, with or without disruption to other sleep variables. In addition, participants scored > 5 on the PQSI and > 8 on the ISI, both recognised cut-off criteria for identifying clinical PI (Morin, 1993; Buysse et al, 1989). Participants with sleep maintenance difficulties were included only if they reported concomitant initiation difficulties. Participants were excluded if they were receiving treatment for sleeping difficulties (either psychological and/or pharmacological) or were suffering from any co morbid sleep (apnoea, restless legs syndrome, etc), medical, or psychiatric condition known to influence sleep.

Thirty two participants were identified, all of whom met criteria for PI. Three failed to attend their initial meeting and one person withdrew during baseline, leaving twenty eight who completed the experiment. This sample size was adequate for power purposes, on the basis that a sample of 28 participants (14 per group) would have 80% power to successfully detect a difference between groups at  $p < 0.05$ . Data for this calculation were extracted from the experimental and ‘sleep as usual’ conditions of the Harvey and Farrell study (2003).

## **Design and Procedure**

Participants who replied to the group email declaring an interest in the study were sent copies of the information sheet and consent form by email. Those who responded expressing a desire to participate were contacted by email or telephone (dependent on preference) to arrange an initial meeting. At the initial meeting, written informed consent was obtained (see Appendices 4.3 and 4.4) and participants were screened to identify whether they met inclusion criteria using the semi structured clinical interview.

Participants who met inclusion criteria were then blindly randomised to either the experimental task or the control condition by an independent person. Group allocation was determined using a random number generator.

Participants were then shown how to complete the sleep diary and how to use the actigraph watch. They were asked to button press the actiwatch once at lights out, and again on rising. Participants were also requested to limit their alcohol intake to a maximum of 4 units and to carry on with their normal sleeping practices, while wearing their actigraph watch at all times (with the exception of during wet activities). As patients' expectations can influence response to other interventions (Espie & Lindsay, 1985; Broomfield & Espie, 2003), and unlike Harvey and Farrell (2003), all participants were explicitly told not to expect any improvement in sleep during the experiment.

Participants were then given four envelopes marked days 1, 2, 3 and 4. Envelopes contained instructions for each day according to the relevant condition, as well all materials required for that day. Following Harvey and Farrell (2003), experimental nights

were scheduled for weekday nights, to increase the likelihood that participants would have a regular sleeping routine and follow alcohol intake guidelines.

Participants' sleep and PSCA was first monitored for a 1 day/night baseline period (day 1). Participants were then asked to follow the instructions described below, relevant to their group, for a further 3 days/nights (days 2 – 4). These timescales are typical of the Pennebaker literature (e.g. Pennebaker & Beall, 1986; Pennebaker et al, 1988), and in experimental studies manipulating novel interventions for PI (e.g. Harvey & Payne, 2002; Haynes et al, 1981; Harvey, 2003).

Following four nights, a final meeting with the researcher was convened. Adherence to protocol was assessed for all participants, alongside treatment credibility for the writing group only. Participants were thanked, debriefed and issued with the 'Good Sleep Guide', a leaflet describing cognitive behavioural PI advice for home practice (National Medical Advisory Committee, 1993).

### *Experimental Condition*

Participants in the experimental condition were given written instructions based on those used by Harvey and Farrell (2003) and Pennebaker (1997; see Appendix 4.5). Participants were asked to "*spend 20 minutes writing about any thoughts, concerns, or worries in the early evening (between 6pm and 8 pm)*". This time was chosen as it was thought that engaging in such a task nearer to bedtime might prove activating, and therefore too arousing to be effective (Harvey & Farrell, 2003; Espie & Lindsay, 1987). Participants were instructed to engage in the writing task outwith the bedroom, to ensure that worries they wrote about did not become associated with the bedroom environment (Bootzin,

1972). Participants could write about the same or different concerns during each writing session. As with Harvey and Farrell (2003), participants were not required to show the researchers their writings, to encourage honest and free expression.

### *Control Group*

The control group were instructed to “*complete two questionnaires about your worries between 6pm and 8pm*” (c.f. Carney & Waters, 2006): the Penn State Worry Questionnaire (PSWQ; Meyer et al, 1990) and the Worry Domains Questionnaire (WDQ; Tallis et al, 1992). These questionnaires were timed during piloting of the study to take approximately 15 to 20 minutes to complete. In addition, Carney and Waters (2006) found these to take on average approximately 15 minutes to complete. This ensured controls spent approximately the same amount of time focussed on their worries as the experimental group, but without the hypothesised facilitation of emotional processing as per the experimental task. Again, control participants were asked to complete the questionnaires outwith the bedroom environment (c.f. Bootzin 1972).

## **Measures**

### *Sleep*

For both groups, a daily sleep diary (Espie, 1991) was completed on rising for each study day. Sleep diaries are the gold standard measure of subjective sleep (Chesson et al, 2000). The diary data provided subjective measures of sleep onset latency (SOL) as well as data regarding alcohol intake.

Additionally, wrist actigraphy (Actiwatch model AW2; Cambridge Neurotechnology Ltd) provided an objective estimate of SOL. Wrist actiwatches were worn at all times except during wet activities, and assess nocturnal movement levels. Movement at night is known to be a good predictor of wakefulness and lack of movement a good predictor of sleep (America Sleep Disorders Association, 1995; Mullaney et al, 1980). Several reviews (Lichstein et al, 2006; Littner et al, 2003; Sadeh et al, 1995; Mullaney et al, 1980) indicate actigraphy correlates highly with polysomnographic (PSG) data, particularly for sleep continuity variables e.g. sleep efficiency, and that it is considered a useful outcome measure in intervention studies using PWI.

### *Cognitive Arousal*

The cognitive subscale of the Pre Sleep Arousal Scale (PSAS-C; Nicassio et al, 1985) contains 8 items examining symptoms of PSCA experienced at bedtime (e.g. racing mind; being distracted by sounds and noise in the environment; worry about falling asleep). PSAS-C was completed by all participants alongside the sleep diary, with respect to the previous evening. In addition, a 5 point Likert scale provided an additional measure of PSCA (see Appendix 4.6). This required participants to rate “How mentally alert you felt last night while you were trying to get to sleep” (anchor points 1 “not at all”, 5 “extremely”) and has been used successfully in previous studies of PSCA (Robertson, Broomfield & Espie, submitted).

### *Emotional Processing in Writing Group*

In the absence of a psychometrically validated alternative, the extent to which individuals emotionally processed the worries they wrote about was assessed using three Likert scales (“I worked through some upsetting issues”; “Writing helped me organise my thoughts”;

“My thoughts/opinions have changed regarding the subject I wrote about”; anchor points 0 “not at all”, 3 “a lot”). These were also completed in the morning along with the sleep diaries and measures of PSCA (see Appendix 4.7).

#### *Adherence to Writing Task*

Adherence to the writing instructions was monitored at the final meeting using a manipulation check akin to Harvey and Farrell’s (2003). Participants rated the content of their writing on a scale from –5 (about sad/anxiety related things) to +5 (about happy things). Participants also estimated how long they wrote for in general over the three days.

#### *Writing Task Credibility and Utility*

Treatment credibility and utility of the writing task was assessed using four questions based on Borkovec and Nau’s (1972) Therapy Evaluation Questionnaire. These assessed the perceived logic of, and confidence in, the writing intervention, participant willingness to repeat the intervention, and the perceived likelihood the intervention would help others. Three of these questions used a 6 point Likert scale (anchor points 0 “not at all”, 6 “very much”). The fourth question asked participants to respond “yes” or “no” to whether they would use the task again. These data were collected at the final meeting for the Pennebaker group.

#### *Adherence to Study Protocol*

Finally, all participants rated adherence to the study protocol, at the final meeting using a 6 point Likert scale (c.f. Broomfield and Espie, 2003; “To what extent did you comply with the experimental instructions given to you during the study?”; anchor points 0 “not at all”,

6 “very much”). The total number of nights each participant correctly followed the study protocol was also recorded.

## **Data Analysis**

After checking the appropriateness of the data, a one way ANOVA model was employed using difference scores (Day 4 – Day 1) on each of the dependent variables with the between participants factor of Condition (Pennebaker; Control). The independent variable was ‘Condition’. The dependent variables were PSCA (PSAS-C and alertness scale) and SOL (diary and actigraphy).

## **Results**

### **Participant Characteristics**

Table 1 presents the mean scores for participant characteristics overall, and by group. Overall mean age of the participants was 32.89 (SD = 13.96) and the overall ratio of females to males was 18:10. Groups were compared using a one way analyses of variance (ANOVA) or Chi-square (for gender). No significant differences were found on any of the variables reported (all  $p > 0.10$ , NS; see Table 1).

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Insert Table 1 about here

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## **Manipulation Checks and Adherence to Experimental Instructions**

Participants reported correctly following experimental instructions on a mean of 3.96 nights ( $SD = 0.19$ ) out of four. Mean adherence rating was 5.96 ( $SD = 0.19$ ; scale 0-6). This included pressing the Actiwatch, and completing the various study tasks. Only one participant reported anything other than maximum adherence on all days.

One way ANOVA compared adherence and task acceptability in both groups. No significant differences were found between the writing and control group in terms of extent of adherence ( $F [1, 26] = 1.00, p = 0.327, NS$ ), number of nights adhered ( $F [1, 26] = 1.00, p = 0.327, NS$ ) or acceptability/sensibility of tasks ( $F [1, 26] = 1.00, p = 0.327, NS$ ). Together, these analyses indicate no differences between the groups in terms of adherence to study protocol.

Thirteen of the 14 writing group participants complied with the recommended writing time, as per task instructions (15-20 minutes). Participants reported a mean rating of -3.58 ( $SD = 1.98$ ) with regards to the content of their writing (scale -5 to +5; sad/anxiety related to happy). This indicates that participants in the writing group followed the writing instructions in that they wrote about worrisome or negative topics.

## **Credibility of Writing Task**

Only one participant in the writing group indicated that they would not engage in the writing again to help their sleep. The mean scores for confidence in using the task in the

future and recommending the task to a friend experiencing sleeping difficulties were 5.00 (SD = 1.41) and 5.17 (SD = 1.40), respectively (scale 0-6). Participants thus found the task credible and of use.

## **Outcome Variables**

Outcome data were first examined for kurtosis, skewness and homogeneity of variance and was considered suitable for parametric analysis (Field & Hole, 2003). In this respect, the primary outcome data (PSAS-C; alertness rating; SOL diary; SOL actigraphy) were considered normally distributed according to Kolmogoroc-Smirnov Z tests of normal distribution  $\{D(27) = 0.680, p = 0.744, \text{NS}; D(27) = 1.019, p = 0.250, \text{NS}; D(28) = 0.876, p = 0.426, \text{NS}; D(25) = 1.328, p = 0.059, \text{NS}, \text{respectively}\}$ . In addition, normal Q-Q plots were produced which supported these analyses.

The outcomes of change over baseline at day 4 in PSCA (PSAS-C and alertness scale) and SOL (diary and actigraphy) were compared between the two groups using normal linear models (one way ANOVA). Change score analyses were employed to account for the variability in participants' scores at baseline. This method has been used successfully employed in both sleep and nonsleep related experimental studies (e.g. Roehrs et al, 1999; Carlson & Garland 2005; Gumley et al, 2003; Cohen-Zion et al, 2001), and was carried out both with and without adjustment for the mean of that variable at baseline. Baseline rates were covaried out using the same model described above (i.e. ANOVA), but imputing the baseline rate of the dependent variable as a covariate. Covarying the baseline rates of dependent variables out in this manner accounted for their effect on scope for improvement. As such, two separate one way ANOVAs both with a Between Factor of

Group (Writing Task x Control) were carried out for each of the four dependent variables (PSAS-C, alertness, SOL diary, SOL actigraph); one ANOVA involved the initial change score, a second ANOVA involved the adjusted change score. Results of both are outlined below.

For each of these variables, Table 2 illustrates data for baseline and day 4, change over baseline, and the adjusted change figures after the baseline rates for the variables had been accounted for. Figures 1-4 indicate group baseline (day1) and day 4 rates for each variable.

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Insert Table 2 about here

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*Cognitive Arousal*

Analysis of PSAS-C revealed a non significant main effect of Group ( $F [1, 25] = 0.963, p = 0.336, NS$ ). The writing group did not show significantly greater reduction in PSCA on PSAS-C relative to controls. On analysis of alertness ratings, there was a significant main effect of Group ( $F [1, 25] = 6.766, p = 0.015$ ). This confirmed the initial hypothesis in that the writing group showed a significantly greater decrease in PSCA according to alertness ratings relative to controls. This increase yielded a small effect size ( $ES = 0.21$ ).

These findings for PSAS-C and alertness were confirmed after adjustment for baseline rates. For PSAS-C, the main effect of Group was again non significant ( $F [1, 24] = 0.380, p = 0.543, NS$ ). Whereas analysis of alertness ratings again revealed a significant main

effect of Group ( $F [1, 24] = 7.20, p = 0.013$ ), indicating reduced PSCA on this measure amongst the writing group, relative to controls.

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Insert Figures 1-4 about here  
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*Sleep Onset Latency*

Analysis of SOL diary data revealed a non significant main effect on Group ( $F [1, 26] = 1.494, p = 0.233, NS$ ). The writing group did not show significantly greater reduction in SOL, relative to controls, according to diary data. Analysis of actigraphy data also revealed a non significant main effect on group ( $F [1, 23] = 1.058, p = 0.314, NS$ ). This confirmed the diary data in that the writing group did not show a significantly greater reduction in SOL relative to controls according to actigraphy data.

Once again, these findings were confirmed after adjustment for their rates at baseline. For SOL diary data, the main effect of Group was non significant ( $F [1, 25] = 0.265, p = 0.611, NS$ ). Again, the SOL actigraphy data revealed a non significant main effect on Group ( $F [1, 22] = 0.037, p = 0.848, NS$ ). Thus, these adjusted scores confirmed that results did not show a significant reduction in SOL relative to controls on either measure.

**Emotional Processing in Writing Group**

To coordinate with the primary analyses of PSCA and SOL, results from the emotional processing questionnaire for the last day of writing (day 4 overall) are reported in Table 3.

As is evident, nine participants reported their writing to be ‘at least some benefit’ in helping them work through issues ( $N = 12$ ), eleven thought that writing ‘helped them organise their thoughts to some degree’ ( $N = 12$ ), and seven reported that ‘their thoughts had changed on the topic they wrote about at least to some extent’ ( $N = 12$ ). Therefore, it seems the writers believed that the task had some effect on the organisation and emotional processing of their chosen concerns.

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Insert Table 3 about here

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## Discussion

The current study tested the notion that a Pennebaker-like writing task would reduce PSCA and SOL in PWI. Supporting the initial hypotheses, the writing task significantly decreased PSCA according to participants’ self rating of alertness relative to the control condition. However, contrary to the initial hypotheses, the experimental manipulation did not reduce PSCA at bedtime on PSAS-C. Nor did it significantly reduce SOL on either subjective or objective estimates of sleep.

Adherence was high amongst the experimental participants, with respect to length and content of writing. Moreover, credibility ratings of the writing task indicated that generally, participants found the task of use to them. Participants reported high rates of confidence that the task would work for them in the future, and indicated a high possibility that they would recommend the writing task to a friend suffering from PI. Indeed, results

from the writing task questionnaire indicated that more than half of the experimental group felt that it benefited them to use the writing task to work through issues, organise thoughts and change opinions. Furthermore, both groups were similar with regards to the acceptability of the experimental rationale and adherence.

The observed decrease in PSCA on self-rated alertness, and the findings that participants reported this task to be of benefit, were observed however in the absence of any corresponding decrease in SOL. This might be because the present study was too brief for any decrease in PSCA to translate into change on SOL. Carney and Waters (2006) compared a “Constructive Worry” writing paradigm in PWI with a control task similar to the one used in this study over 5 days. “Constructive Worry” required participants to record worries they anticipated would keep them awake at night, and write down steps that could contribute to the resolution of the problem. They observed change on PSAS-C but did not find the proposed changes on all measures (e.g. State Trait Anxiety Inventory – State Version; Spielberger, 1983). And more pertinently, Carney and Waters (2006) considered their study of 5 nights duration “too brief to detect any meaningful change on sleep”, and suggested that a longer study would be required for change to be observed on SOL. In support of this, there is evidence from psychological treatment studies of CBTI which suggests that sleep changes are not immediate (Hauri, 1997; McCluskey et al, 1991; Morin et al 1999; Edinger et al, 2001).

The lack of parallel PSCA decrease amongst writers on PSAS-C might be explained by the fact that the two measures of PSCA tap into different processes. On closer examination, the alertness scale appears to measure general cognitive arousal whereas the PSAS-C is significantly correlated with anxiety and depression and is therefore considered to measure

negatively toned activity (Nicassio et al, 1985). It is possible therefore, that the processing purported to accompany the writing task decreases alertness without necessarily affecting negatively toned cognitive activity. However, at present, there is no evidence to suggest that this is the case. Rather, it may be that given the number of data points observed for these respective measures, it was more difficult to statistically detect changes on the PSAS-C.

The differing results regarding SOL in this study to that of Harvey and Farrell (2003) may be explained in two ways. Firstly, a demand characteristic may account for the significant reduction in SOL which was observed following their writing task. In their study, groups completed a writing task similar to the current one, wrote about hobbies, or did not engage in writing. However, unlike here, the rationale given to both the problem and writing hobbies groups explicitly led participants to expect their tasks would benefit sleep. This may be why, although the problem writing group differed significantly from the control group, there was in fact no significant difference between problem writers and the hobbies group. Therefore, the significant sleep findings in Harvey and Farrell's (2003) study may not reflect a true improvement in SOL as a result of this task. Rather, they may reflect a 'placebo' effect (Bootzin et al, 1976) which was controlled for in the present study. Taken along with the lack of effect on sleep in the present study, this could indicate that this task is of limited clinical utility.

Second, the discrepant results may also relate to differences between the respective samples and methodologies. The mean age in the current study was higher than that of Harvey and Farrell (2003). In this respect, the mean age of 32.89 (SD = 13.96) was found in the current study, compared with means of 23.7 (SD = 7.2), 21.9 (SD = 4.9), and 22.1

(SD = 4.1), respectively for the three groups in Harvey and Farrell's (2003) study. This is important. Thirty six years was the mean age of patients treated for PI in England between 2002 and 2003 (Department of Health, 2003). Moreover, typically, the mean age of participants in studies of clinical PI is usually forty and above (see e.g. Espie et al, 2001; Lacks et al, 1983; Unger et al, 2004). Also, despite their inclusion criteria, approximately a quarter of Harvey and Farrell's (2003) sample did not even meet the criteria for clinical PI, scoring below 5 on PSQI. This is interesting. Even in PI studies employing analogue non-patient samples, mean PSQI scores often exceeds 7 (e.g. Marchetti et al, 2006; Broomfield & Espie, 2003; Nelson & Harvey, 2003). Finally, there may also be a difference in the distressing nature of topics written about. Mean affect ratings for writing content were higher in the current study than in the Harvey study ( $M = -3.58$ ,  $SD = 1.98$ ; and  $M = -1.8$ ,  $SD = 2.0$ , respectively).

Perhaps then, the sample studied here were more akin to a clinical population than were the Harvey and Farrell (2003) cohort. And by implication, participants who experience complex sleep problems may be less likely to display sleep change over this short period. It may also be possible that the Pennebaker writing paradigm is less helpful for clinical populations of PWI, or those suffering from more severe difficulties. This latter hypothesis would be supported by a recent meta analysis by Frisina et al (2004). They recognized the effect of the Pennebaker writing task on sleep, but found that the mean weighted effect size of clinical populations was modest ( $d = 0.19$ ) in comparison to that found in a meta analysis of Pennebaker writing tasks for healthy people ( $d = 0.47$ ; Smyth, 1998). Further research comparing response of an analogue and true clinical PI samples will be necessary to clarify this.

Taking the above factors into account, the limitations of the present study should be borne in mind when interpreting the results. Although the number of writing sessions in Pennebaker tasks appears unrelated to improvement (Smyth, 1998), it has been argued that lengthening the time course over which the writing task is spaced, may be beneficial (Smyth, 1998). Notably, the present study closely followed the original protocol used by many authors (e.g. Sloan et al, 2005; Sloan and Marx, 2004; Norman et al, 2004; Kloss et al, 2002; Zakowski et al, 2004) in that the writing task took place over three consecutive days. Nevertheless, it may be prudent in future research to conduct a lengthier study (e.g. 21 nights) with more widely spaced sessions (e.g. 3 writing sessions at weekly intervals) to maximise any effects.

The current study, given its application to PWI, followed Harvey and Farrell's (2003) protocol by only measuring the immediate effects of the task. However, some researchers employing the Pennebaker task in other fields have tended not to consider immediate effects, concentrating instead on longer term impact. For example, Zakowski et al (2004) examined the effects of this paradigm on 104 patients with cancer and found that the task buffered the effects of social constraint on stress at 6 month follow up. Therefore, it may be that any benefit of this task with respect to PWI is typically not immediate. Broderick et al (2005) found no significant effect on fatigue and psychological wellbeing amongst fibromyalgia patients immediately post writing, but did find a significant improvement in psychological wellbeing at 4 months follow up.

However, this hypothesis does not sit easily with the pattern of results obtained here on PSCA, the fact that participants in this study mostly reported the task helpful, and indeed the Harvey and Farrell's (2003) results. Perhaps the most parsimonious explanation to

reconcile these findings may be that the demand characteristics of Harvey and Farrell (2003) served to accelerate or magnify any true benefit of the task. As such, future Pennebaker studies of PWI should assess outcome some time after completing the paradigm, as well as immediately, to fully capture any effects.

The present study also drew on the premise that PWI often experience uncontrollable cognitive arousal at night (Harvey, 2000). Accordingly, participants were included only if they complained of excessive PSCA. However, no attempt was made to select participants who specifically experienced *negatively toned* pre sleep cognitions. This may have minimised any likely effects. Indeed, some participants' reported to the researcher that their pre sleep cognitive activity was not necessarily negatively toned. This would be consistent with studies of PWI directly sampling thinking patterns at night. Wicklow & Espie (2000) have shown, for example, that not all thinking amongst PWI is worrisome and negative.

The Pennebaker task has shown success in physical health worries (Broderick et al, 2005; Rosenberg et al, 2002) and trauma (Schoutrop et al, 2002). It has also shown greater effects in participants who display higher levels of catastrophisation (Norman et al, 2004). Therefore, the paradigm may be more beneficial to PWI who specifically report high rates of worrying and negatively toned PSCA rather than those who simply complain of general PSCA at night. Furthermore, given that effects of this task are not equivalent across all areas of application (Smyth, 1998; Frisina et al, 2004), it is entirely possible that this task is more effective on some 'types' of problems, worries or concerns than others. The effect of these issues on the current study, however, may be limited. Harvey and Farrell (2003) did not select on this criteria and yet still found significant effects. Selecting participants

on this more specific aspect of pre sleep cognition or comparing PWI who display high and low levels of negatively toned PSCA might be a next step in examining this paradigm.

Consistent with this failure to select on negatively toned PSCA, the PSAS-C ratings obtained in the current study were not as high as expected. For example, Nicassio et al (1985) obtained mean ratings of 25.5 in their sample 30 of PWI. In addition, Carney and Waters (2006) who produced significant effects in their study on PSAS-C, reported higher mean baseline rates for their sample than was reported here. They reported mean PSAS-C scores in their control and “Constructive Worry” groups of 30.97 (SD = 5.58) and 31.72 (SD = 5.46), respectively, compared to 19.86 (SD = 6.22) and 21.92 (SD = 6.59) in the control and writing groups here. Thus, there may have been a greater initial scope for improvement than in this study. However, it should be noted that they do not report selecting on this and, once again, failing to select on this criteria did not have an adverse effect on Harvey and Farrell’s (2003) results. Future research will be required to clarify this.

In summary, as hypothesised, PSCA according to self rated mental alertness decreased, but PSAS-C scores remained unchanged following a Pennebaker writing task. However, the present study failed to support Harvey and Farrell’s (2003) results regarding SOL in that no significant change was found on objective or subjective SOL measures. Several factors may account for these results. Notably, the study period may have been too brief to detect sleep changes (c.f. Carney & Waters, 2006). Alternatively, demand characteristics from the Harvey and Farrell (2003) paper may have accelerated or aided sleep effects in their study. Along with these issues, limitations such as the selection of participants may also

have precluded a more positive finding. Further research using a longer follow up should help better clarify the potential efficacy of this paradigm with PWI.

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Table1. Mean scores and standard deviations for participant characteristics and estimates of sleep onset latency at intake.

	Writing Group	Controls	Total
Sex (F: M ratio)	8:6	10:4	18:10
Age	33.29 (12.32)	32.50 (15.89)	32.89 (13.96)
Usual SOL	75.00 (44.03)	95.36 (61.16)	85.18 (53.31)
PSQI	9.93 (2.87)	11.00 (2.60)	10.46 (2.74)
ISI	14.71 (3.97)	15.29 (4.21)	15.00 (4.03)
BDI	7.07 (7.14)	10.21 (7.13)	8.64 (7.18)

**Standard deviation in parenthesis.**

Table 2. Mean scores and standard deviations for outcome variables at baseline, day 4, change over baseline, and change (adjusted).

Measure	Baseline		Day 4		Change scores		Adjusted change scores	
	Writing	Control	Writing	Control	Writing	Control	Writing	Control
PSAS-C	21.92 (6.59)	19.86 (6.22)	18.31 (6.03)	18.57 (6.26)	-3.62 (6.06)	-1.29 (6.26)	-3.08 (SE=1.50)	-1.79 (SE=1.45)
Alertness	3.15 (1.14)	2.86 (0.86)	2.38 (0.87)	3.29 (0.99)	-0.77 (1.09)	0.43 (1.28)	-0.65 (SE=0.26)	0.32 (SE=0.25)
SOL (diary)	52.86 (35.88)	84.29 (57.74)	51.07 (41.43)	64.79 (52.81)	-1.79 (21.63)	-19.50 (49.73)	-6.98 (SE=9.78)	-14.30 (SE=9.78)
SOL (act)	22.17 (18.86)	71.62 (140.25)	58.25 (62.19)	65.23 (84.20)	36.08 (51.15)	-6.38 (134.09)	16.96 (SE=20.92)	11.27 (SE=20.08)

Negative score indicates an improvement in variables. Standard deviation in parenthesis unless otherwise indicated.

Table 3. Descriptive results of the writing questionnaire for day 4

Question	Very much	To some extent	Not at all
I worked through some upsetting issues	1	8	3
Writing helped me organise my thoughts	4	7	1
My thoughts/opinions have changed regarding the subject I wrote about	1	6	5

Figure 1. Writing and Control PSCA - Day 1 and Day 4 Alertness Scores

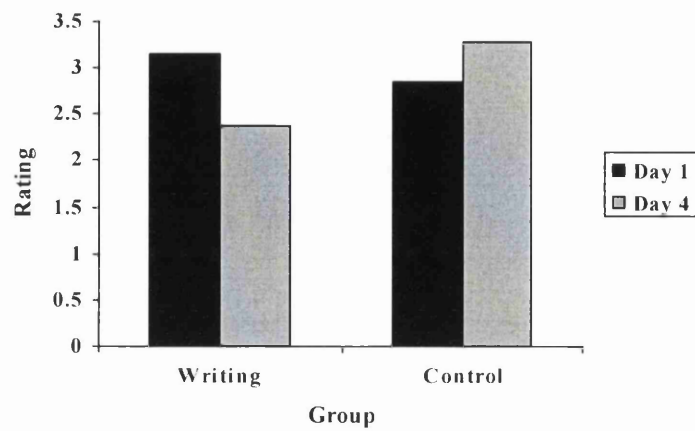


Figure 2. Writing and Control PSCA- Day 1 and Day 4 PSAS-C Scores

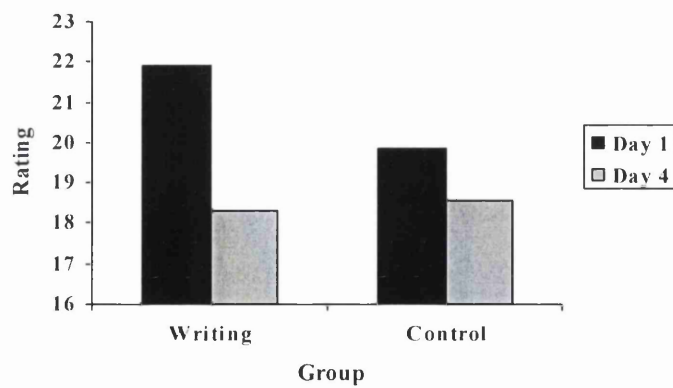


Figure 3. Writing and Control SOL - Day 1 and Day 4 Diary

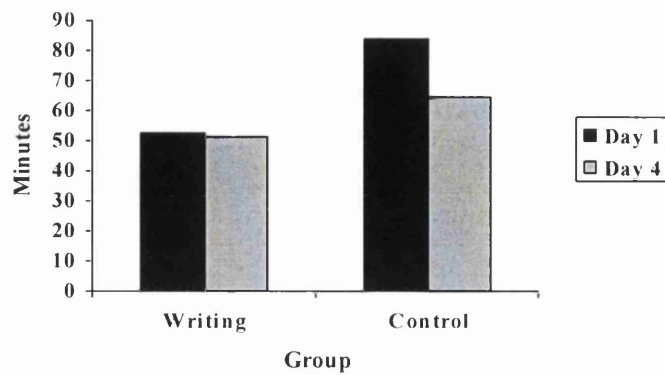
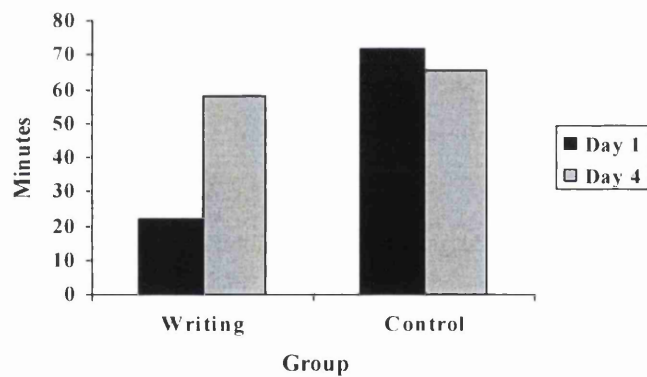


Figure 4. Writing and Control SOL - Day 1 and Day 4 Actigraphy



SINGLE CASE RESEARCH STUDY

**Challenging behaviour or PTSD? Using single case methodology to inform psychological formulation in a woman with a learning disability.**

Single Case Research Study submitted in partial fulfilment of the requirement for the degree of Doctor of Clinical Psychology

Prepared in accordance with the guidelines for Journal of Intellectual Disability Research (Appendix 1 - bound separately in Part Two).

## ABSTRACT

### **Background**

Challenging behaviour ranges widely in topography and underlying processes. However, behaviour which others describe as ‘challenging’ may also be an atypical presentation of a mental health problem. Thus, behavioural function cannot be clearly determined from topography. The present study used an experimental functional analysis to assess the accuracy of two hypotheses of screaming and arm flapping in a severely learning disabled woman while travelling by car.

### **Method**

An ABAC within series reversal design was employed to test whether screaming and arm flapping was: an atypical presentation (or secondary feature) of a traumatic reaction to being in the car; or challenging behaviour as a result of frustration at the car stopping or slowing down.

### **Results**

Rates of screaming were higher when the car was stopped compared to baseline. No such elevated rates were found when the car was moving. A similar result was found for arm flapping although data were somewhat more equivocal.

### **Conclusions**

The behaviour appeared to result from frustration at being delayed in obtaining a desired outcome. Results informed the psychological formulation of these difficulties. Subsequent management guidelines were developed to reduce this behaviour.

## Chapter 6

### APPENDICES FOR CHAPTERS 1-4

## Appendix 1.1 Authors' Instructions for Contributing to Clinical Psychology

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### Submitting to *Clinical Psychology*

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- When sending copy, make sure it is double spaced, in a reasonably sized font and that all pages are numbered.
- Give a 40-word summary at the beginning of the paper.
- Contributors are asked to use language which is psychologically descriptive rather than medical and to avoid using devaluing terminology; i.e. avoid clustering terminology like 'the elderly' or medical jargon like 'person with schizophrenia'. If you find yourself using quotation marks around words of dubious meaning, please use a different word.
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refereeing. They will then communicate directly with authors.

- We reserve the right to shorten, amend and hold back copy if needed.
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- Spell out all acronyms the first time they appear.
- Include the first names of all authors and give their employers, and remember to give a full postal address for correspondence.
- Give references in *Clinical Psychology* style, and if a reference is cited in the text make sure it is in the list at the end.
- Don't include tables and figures unless they save space or add to the article.
- Ask readers to request a copy of your questionnaire from you rather than include the whole of it in the article.

**Psychosocial Education on Schizophrenia/Psychosis**  
**For people with a diagnosis of Schizophrenia and their carers**  
**Evaluation Form**

1. How helpful did you find each of the eight sessions:-

	Very Helpful	Quite Helpful	Not Helpful	N/A
Session 1 - Introduction, outline of sessions				
Session 2 - What is Schizophrenia?				
Session 3 - Symptoms of Schizophrenia				
Session 4 - Medication issues				
Session 5 - Stress/Relaxation				
Session 6 - Problem solving				
Session 7 - Relapse prevention				
Session 8 - Ongoing topics/evaluation				

2. If you were unable to attend for any of the sessions, can you briefly indicate why?

-----

3. What aspect of the group did you find most helpful?

-----

-----

4. What did you find least helpful?

-----

5. Is there any topics that you would have included or spent more time on?

-----

-----

6. Have you made any positive lifestyle changes since attending the group?

YES

☐

NO

☐

If yes please indicate below: -

- Having greater understanding of condition
- Feeling more able to control symptoms and manage relapse
- Feeling more able to discuss difficulties with family/friends
- Feeling more able to discuss aspects of care with health/social care Professionals e.g. consultant psychiatrist
- Using relaxation techniques
- Using problem solving techniques
- Meeting other people in similar situations
- Improving relationship between person with diagnosis and carer  
Attending group

☐☐☐☐☐☐☐☐

7. Do you feel it was beneficial to attend the group together (person and carer)?

YES

☐

NO

☐

DON'T KNOW

☐

8. Would it have been more useful to attend a group on your own?

YES

☐

NO

☐

DON'T KNOW

☐

Comment \_\_\_\_\_

9. Did you find the handouts useful?

YES

☐

NO

☐

Please explain \_\_\_\_\_

10. Do you still refer to the handouts?

YES

☐

NO

☐

Please explain \_\_\_\_\_

11. Would you be interested in attending a self-help group or carers' forum?

YES

☐

NO

☐

12. Did you think the length of each session was?

too long

☐

adequate

☐

too short

☐

13. Was the time of the group suitable?

YES

☐

NO

☐

Please explain

14. Was the location of the group suitable?

YES

NO

Please explain

15. Please use this space to indicate any suggestions or comments that may improve the group.

---

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Thank you for your co-operation.

## Clinical Psychology Review

### Guide for Authors

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## Appendix 3.1

### Guidelines for Submission of Major Research Project Proposal

This can be written in the form of an application to a Local Research Ethics Committee and be presented, in full, in the final Research Portfolio. A copy of the letter(s) of ethical approval received from the LREC must also be included in the Research Portfolio. In circumstances where the completed project deviated from the original approved plan, the trainee must insert a clear explanation of these changes. Any further correspondence with the LREC, which relates to such changes must also be appended. The Major Research Project Proposal should include the following headings.

- Full title of project
- Summary of Project
- Introduction
- Aims and hypotheses

Aims

Hypotheses

- Plan of Investigation

Participants

Recruitment

Measures

Design and Procedures

Settings and Equipment

Power Calculation

Data Analysis

- Practical Applications
- Timescale
- Ethical Approval
- References

## Primary Care Division

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**NHS**  
**Greater  
Glasgow**

Ms P Mooney  
Trainee Clinical Psychologist  
Department of Psychological Medicine,  
Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow  
G12 0XH

Date 17 August 2005

Your Ref  
Our Ref

Direct line 0141 211 3824  
Fax 0141 211 3814  
E-mail [anne.mcmahon@gartnavel.gla.ac.uk](mailto:anne.mcmahon@gartnavel.gla.ac.uk)

Dear Ms Mooney

**Full title of study:** Does a Pennebaker-like writing intervention reduce cognitive arousal and sleep onset latency in poor sleepers?

**REC reference number:** 05/S0701/81

Thank you for your letter of 27 July 2005, responding to the Committee's request for further information on the above research and submitting revised documentation]

The further information was considered at the meeting of the Committee held on 11 August 2005. A list of the members who were present at the meeting is attached.

#### Confirmation of ethical opinion

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

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

#### Conditions of approval

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

#### Approved documents

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

Document	Version	Date
Application		26 June 2005
Investigator CV		26 June 2005
Protocol		26 June 2005
Protocol	two	27 July 2005
Peer Review		26 June 2005
Compensation Arrangements		26 June 2005



D161181

Copy of Questionnaire	two	27 July 2005
Copy of Questionnaire		26 June 2005
Copy of Questionnaire	Non-Valid. Questionnaire	26 June 2005
Copies of Advertisements		26 June 2005
Letters of Invitation to Participants		26 June 2005
Participant Information Sheet		26 June 2005
Participant Information Sheet	two	27 July 2005
Participant Consent Form	two	28 July 2005
Participant Consent Form	two - researcher	27 July 2005
Participant Consent Form		26 June 2005
Response to Request for Further Information		27 July 2005

### **Management approval**

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

### **Membership of the Committee**

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

### **Notification of other bodies**

The Committee Administrator will notify the research sponsor that the study has a favourable ethical opinion.

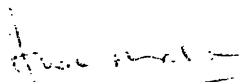
### **Statement of compliance**

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.

<b>05/S0701/81</b>	<b>Please quote this number on all correspondence</b>
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With the Committee's best wishes for the success of this project,

Yours sincerely



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

Email: Anne.McMahon@gartnavel.gla.comen.scot.nhs.uk

Enclosures:

Attendance at Committee meeting on 11 August 2005  
Standard approval conditions  
Site approval form (SF1)

Primary Care Division

Research & Development Directorate



Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow G12 0XH  
Tel: 0141 211 3600  
[www.nhsgg.org.uk](http://www.nhsgg.org.uk)

Ms P Mooney  
Trainee Clinical Psychologist  
Department of Psychological Medicine  
Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow  
G12 0XH

Date 27 September 2005  
Your Ref  
Our Ref BR/AW/approve  
Direct Line 0141 211 3661  
Fax 0141 211 3814  
Email [annette.watt@gartnavel.gla.ac.uk](mailto:annette.watt@gartnavel.gla.ac.uk)

Dear Ms Mooney

**Project Reference Number:** 05CP14  
**Project Title:** Does a Pennebaker-like writing intervention reduce cognitive arousal and sleep onset latency in poor sleepers?

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

- You should notify me of any changes to the original submission and send regular, brief, interim reports including recruitment numbers where applicable.
- Your research must be conducted in accordance with the National Research Governance standards. (see CSO website: [www.show.scot.nhs.uk/cso](http://www.show.scot.nhs.uk/cso)) Local Research Governance monitoring requirements are presently being developed. This may involve audit of your research at some time in the future.
- You must comply with any regulations regarding data handling (Data Protection Act).
- Brief details of your study will be entered on the National Research Register (NRR). You will be notified prior to the next submission date and asked to check the details being submitted.
- A final report, with an abstract which can be disseminated widely within the NHS, should be submitted when the project has been completed.

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

Thank you again for your co-operation.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Brian Rae'.

**Brian Rae**  
**Research Manager**



D161181

**RESEARCH EQUIPMENT, CONSUMABLES AND EXPENSES**

Trainee ...Patricia Mooney.....

Year of Course .....2nd..... Intake Year...2003.....

Please complete the list below to the best of your ability:

Item	Amount Required	Approximate Cost
Plain Paper / Headed paper / envelopes	120 sheets headed paper 500 sheets plain paper 100 envelopes	
Postage	100 second class stamps	
Photocopying	500 (using paper above)	
Acetates	N/A	
Equipment		
<b><u>Miscellaneous:</u></b> Travel costs: Follow-up costs Phone calls Software Computing equipment	480 miles travel (20 x journeys to Gartnaval Hospital from base)	

Possible sources .....

Supervisor's Signature ..... Date .....

### **Behavioral Sleep Medicine - Instructions to Contributors**

The editorial scope of Behavioral Sleep Medicine is given above. In brief, the journal publishes original research on the application of behavioral/cognitive science to the study of normal and disordered sleep. Submission of manuscripts presumes that the work has not been previously published in whole or in substance and is not simultaneously being considered for publication by another journal.

Manuscripts should be prepared in accordance with the Publication Manual of the American Psychological Association (5th edition). The manual sets forth guidelines for referencing, preparation of abstracts (maximum 120 words), bias-free language, spacing (double-spaced throughout), margins (1 inch, 2.54 cm, on four sides), formatting tables and figures, etc. To briefly summarize APA format for references, sources are cited in the text by author and year (e.g., Loomis, Harvey, & Hobart, 1937), and the reference list is arranged alphabetically. Examples of reference format for articles, chapters, and books are as follows.

Loomis, A. L., Harvey, E. N., & Hobart, G. A., III. (1937). Cerebral states during sleep, as studied by human brain potentials. *Journal of Experimental Psychology*, 21, 127-144.

Webb, W. B. (1970). Individual differences in sleep length. In E. Hartmann (Ed.), *Sleep and dreaming* (pp. 44-47). Boston: Little, Brown and Company.

Kleitman, N. (1939). *Sleep and wakefulness*. Chicago: University of Chicago Press.

Submit manuscripts to the Editor, Kenneth L. Lichstein, Sleep Research Project, Department of Psychology, The University of Alabama, Box 870348, Tuscaloosa, AL 35487-0348. The copies should be complete with all tables and figures. Do not send original figures until the manuscript is accepted for publication. The submission should be accompanied by a cover letter requesting review and providing the address, phone, fax, and email of the corresponding author. The cover letter must also include the statement that research participants were treated in compliance with the ethical standards of one's discipline.

Submit two paper copies and an electronic copy of the manuscript. Submit a paper copy and an electronic copy of the cover letter as well. Electronic copies should be saved either as Adobe PDF files or in rich text format (rtf). Send electronic copies as email attachments to lichstein@ua.edu.

If the first author is 5 years or less post Ph.D. (or post residency for physicians) and wishes to be considered for the Early Career Distinguished Research Award, this should be stated in the cover letter (see announcement below).

**Early Career Distinguished Research Award:** The editorial leadership of BSM periodically encounters a particularly outstanding article from an early career investigator. Such articles are characterized by a level of methodological maturity and importance of findings more commonly associated with accomplished senior scientists. BSM will honor research that satisfies these standards with the Early Career Distinguished Research Award. The award

comprises featured recognition in the journal and invited commentary by a distinguished scholar on the merits of the research. This award reflects the Journal's interest in honoring outstanding early career scientists, encouraging high quality research, and elevating the visibility of particularly important research for the readership. To be eligible, the first author must be 5 years or less post Ph.D. (or post residency for physicians) at the time of submission and should indicate in the submission cover letter that he/she wishes to be considered for this award.

The editorial scope of Behavioral Sleep Medicine is given above. In brief, the journal publishes original research on the application of behavioral/cognitive science to the study of normal and disordered sleep. Submission of manuscripts presumes that the work has not been previously

**University of Glasgow Sleep Research Group  
Sleep Clinic Screening Form**

**ID**            **Date:**

**Age:**

**Marital status:** married: single: divorced: widowed

**Occupation:**

Does this involve working nightshifts?

**Retired:** Yes: No

**Gender:** Male/Female

1.        How long have you had your sleep problem (number of years/months)?  
  
          i) Did this start before you were 10 years old?  
  
          ii) If yes to i), was there any identifiable precipitant to this?  
  
          iii) If yes to i) have your experience of sleeping difficulties been persistent since this time?
2.        How many nights per week do you have difficulties sleeping?
3.        How much sleep do you get on an average night?
4.        Do you have difficulty falling asleep at night?
5.        On average, how long (hours/minutes) does it take you to fall asleep each night?
6.        Do you have difficulty staying asleep?
7.        On average, how long in total (hours/minutes) are you usually awake at night (after you have been asleep for the first time)?
8.        Are you ever awake all night (not intentionally)?

If yes, how often?

After such nights, do you nap the next day?

9. Occasionally, do you find that you get what you would consider a 'normal' night's sleep?

If yes, how often?

10. On average, what time do you wake up in the morning?

11. On average, how long (hours/minutes) do you wake before you are required to?

12. How would you rate the quality of your sleep

Very good                      Fairly good                      Fairly bad                      Very bad

13. Other than difficulties in sleeping, is there anything that prevents you getting as much sleep as you would like e.g. having a young child, a partner who snores?

14. Do you experience any of the following in the day time due to your sleep problem?

Fatigue/malaise    Yes/no

Attention, concentration, or memory impairment    Yes/no

Social/vocational dysfunction or poor school performance    Yes/no

Mood disturbance/irritability    Yes/no

Daytime sleepiness    Yes/no

Motivation/energy/initiative reduction    Yes/no

Proneness for errors/accidents at work or while driving    Yes/no

Tension, headaches and/or GI symptoms in response to sleep loss  
Yes/no

Concerns or worries about sleep    Yes/no

15. Do you feel that you spend a disproportionate amount of time thinking and worrying about your sleep?    Yes/no

16. Do you have difficulty falling asleep in bed at the desired bedtime or during planned naps, but fall asleep with relative ease during monotonous activities e.g. watching TV or reading when not intending to sleep?  
Yes/no

17. Do you find that you sleep better away from home than at home?  
Yes/no
18. Do you experience persistent thoughts in bed when trying to sleep that seem to come out of the blue?  
Yes/no
19. Do you experience 'racing' thoughts in bed that prevent you falling asleep as they are impossible to control?  
Yes/no
20. Do you find it almost impossible to relax enough in order to fall asleep at bedtime?  
Yes/no
21. Does pain or physical discomfort interrupt your sleep at night?  
Yes/no
- If yes, does taking pain medication help this? Yes/no
21. Do you think that pain is the main cause of your sleeping problem?  
Yes/no
22. Do any other physical health problems interrupt your sleep at night?  
Please give details.
23. Have you suffered from any physical health problems in the past that have disrupted your sleep?  
Yes/No
24. When did your current sleeping difficulties occur in relation to these physical health problems?
25. Have you felt particularly 'down' or 'sad' or 'empty' about things in the past two weeks?  
☐ Never      ☐ Sometimes      ☐ Usually      ☐ Always
26. Does your doctor know about this?
27. Are these low feelings a change from what is normal for you?
28. When did these feelings start?
29. In the past two weeks :  
Have you lost pleasure in your usual activities? Yes/No

Has your appetite changed?	Yes/No
Have you lost or gained weight?	Yes/No
Have you lacked energy?	Yes/No
Have you felt agitated?	Yes/No
Have you felt slowed down?	Yes/No
Have you thought about harming yourself?	Yes/No
Have you felt excessively guilty or worthless?	Yes/No
Has your concentration been poor?	Yes/No

30. Are you currently being treated for depression? If yes, please give details.

31. Are you currently suffering from emotional or mental health problems (if not mentioned above)?

Yes/No

Please provide some details

32. Have you suffered from emotional or mental health problems in the past?

33. When did your current sleeping difficulties occur in relation to these mental health difficulties?

34. Please provide details of any medication that you are currently taking (or have been taking in the past three months) for sleep difficulties or any other purpose.

35. Are you currently receiving psychological help for sleeping difficulties?

Yes/no

36. Do you drink alcohol? Yes/No

If yes, what do you usually drink?

How many of these alcohol drinks do you usually have per day (if not daily, how many in a week)?

Do you feel that your alcohol use disrupts your sleep?

37. Do you use illicit drugs? Yes/No
- If yes, what do you usually use?
- How much do you have in a day (if not daily, in a week)?
- Do you feel that your drug use disrupts your sleep?
38. Do you find that you fall asleep at the 'wrong' time?
- ☐ Never ☐ Sometimes ☐ Usually ☐ Always
39. In what way do you feel that it is wrong?
40. Do you have difficulties waking up at a set time in the morning (or would you if you are currently not required to) in order for example to be ready to leave for work at for 8.15 am?
- Yes/No
- If yes, in what way (e.g. keep falling asleep again, feel you need to sleep more due to a bad night)?
41. If you had no social constraints (e.g. work) is there particular times that would optimise your chances of having a good sleep? Yes/No
- If yes, what would these be?
- Sleep at..... Get up at.....
42. Do you snore during your sleep?
- ☐ Never ☐ Sometimes ☐ Usually ☐ Always
43. If you do, how do you know? For example, has your partner been awoken?
44. Do you hold your breath, have breathing pauses or stop breathing in your sleep?
- ☐ Never ☐ Sometimes ☐ Usually ☐ Always
- If you do, how do you know? For example, has your partner noticed this?
45. Do you think breathing difficulties may be the main cause of your sleeping problem? Why do you think this is the case?
46. Do you fall asleep unintentionally or have to fight to stay awake during the day?
- ☐ Never ☐ Sometimes ☐ Usually ☐ Always
47. When you wake up in the morning do you feel unrefreshed and groggy?

☐ Never      ☐ Sometimes      ☐ Usually      ☐ Always

48. Please indicate how likely you are to fall asleep in the following situations. Use the scale below to indicate how likely you are to fall asleep in each situation:

0 = would never doze  
1 = slight chance of dozing  
2 = moderate chance of dozing  
3 = high chance of dozing

Situation	Record chance of dozing 0, 1, 2, 3
-----------	------------------------------------

Sitting and reading	_____
---------------------	-------

Watching TV	_____
-------------	-------

Sitting, inactive in a public place (e.g. a theatre or a meeting)	_____
--	-------

As a passenger in a car for an hour without a break	_____
---	-------

Lying down in the afternoon to rest when circumstances permit	_____
--	-------

Sitting and talking to someone	_____
--------------------------------	-------

Sitting quietly after lunch without alcohol	_____
---	-------

In a car, while stopped for a few minutes in the traffic	_____
---	-------

49. Do you experience repeated, uncontrollable leg jerks or leg twitches during your sleep?

☐ Never      ☐ Sometimes      ☐ Usually      ☐ Always

50. Do you think such uncontrolled limb movements may be the main cause of your sleeping problem?

51. Do you experience restless or "crawling" feelings in your legs at night which go away if you move your legs?

☐ Never      ☐ Sometimes      ☐ Usually      ☐ Always

52. Do you think such restless legs may be the main cause of your sleeping problem?

53. Do you experience excessive sleepiness and sudden muscle weakness?

54. Do you experience any of the following:

- nightmares
- inability to perform voluntarily movements before going to sleep, or upon waking
- grinding/clenching teeth

- sleepwalking/talking
- night terrors (waking up screaming or with an intense feeling of terror)  
How often?

55. Do you feel that you have any other difficulties related to sleeping that have not been covered in this interview?
56. Are you physically well at present?



## **Investigating Bedtime Thoughts of People Who Have Difficulty Falling Asleep**

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

*Thank you for reading this.*

### **What is the purpose of the study?**

Most individuals who experience difficulties falling asleep complain that their mind is dominated by unwanted thoughts and worries while trying to get to sleep which they think is a barrier to them falling asleep. It is possible that 'unfinished' business from the day intrudes during the pre sleep period and interferes with the process of falling asleep.

Some research has found that asking participants to write about their innermost thoughts and emotions regarding traumatic or significantly emotional events has resulted in health and psychological improvements. Although there are a few theories as to why this works, no one knows for certain.

This study aims to investigate whether asking people who experience difficulties falling asleep to write about their worries will reduce the time it takes them to fall asleep and reduce the amount of unwanted thoughts and worries they experience while trying to fall asleep.

### **Why have I been chosen?**

You are one of 28 people who have been asked to take part in this study because you experience difficulty falling asleep.

### **Do I have to take part?**

*It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form (which you will also be given a copy of to complete). If you decide to take part you are still free to withdraw at any time and without giving a reason.*

### **What will happen to me if I take part?**

You will be asked to take part for four days, although the research study will last for approximately 8 months. You will need to visit Gartnavel Royal Hospital twice for about one hour each time. The first time you visit, the researcher will ask you some questions about your sleep and your mental health and will be asked to complete some questionnaires. You will also be given an envelope with instructions in it telling you exactly what you should do for the next four nights and a special 'watch' which will automatically measure when you fall asleep and when you wake up.

Sometimes because we do not know which way of dealing with problems is best, we need to make comparisons. People will be put into two groups and then compared. The groups are selected by a computer which has no information about the individual – i.e. selection is by chance. People in each group have to do something different and then their results are compared. You have a 50/50 chance of being in either group.

### **What do I have to do?**

Everyone will be asked to wear the special 'watch' at all times during the study (except when bathing) and to complete a questionnaire and a diary recording details regarding their sleep (e.g. when you got to sleep) in the morning. This should take approximately 10 minutes. Everyone should do this and go to sleep as usual on the first night. On the next three nights, you will be asked to either write about your worries for approximately 20 minutes per evening (which you will not need to show to anyone) or you will be asked to fill in some questionnaires about your worries (which will also take about 20 minutes per evening). You will be asked not to drink alcohol for the four nights while taking part. You can continue to take any usual prescription medications etc.

### **What are the alternatives for diagnosis or treatment?**

If you do not wish to take part, you may still contact your doctor for advice regarding your sleeping difficulties.

### **What are the side effects of taking part?**

There are no side effects of taking part, although you should not expect any improvement in sleep by doing so.

### **What are the possible disadvantages and risks of taking part?**

There are also no disadvantages, except that it will take time out of your day to complete the questionnaires etc with no benefit to your sleep. There are no risks to you from taking part in this study.

### **What are the possible benefits of taking part?**

There is no direct benefit to you from taking part in this study. The information we get from this study may help us to understand more about sleep difficulties and treat future patients with problems falling asleep better.

### **What if new information becomes available?**

Sometimes during the course of a research project, new information becomes available. If this happens, the researcher will tell you about it and discuss with you whether you want to continue in the study. If you did decide to continue in the study you will be asked to sign an updated consent form. Also, on receiving information your researcher might consider it to be in your best interests to withdraw you from the study and he/she will explain the reasons.

### **What happens when the research study stops?**

When the research study stops, you will be given an information leaflet which contains advice on things that you can do to possibly help you sleep better.

### **What if something goes wrong?**

*If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you.*

### **Will my taking part in this study be kept confidential?**

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you will have your name and address removed so that you cannot be recognised from it. Your GP will not be notified of your participation and no one from the study will have access to your medical records.

### **What will happen to the results of the research study?**

The results of the research will be published in an academic journal in approximately one year's time. You will not be identified in any report/publication. You can obtain a copy of the published results from the address below.

### **Who is organising and funding the research?**

This research is organised by Patricia Mooney, Trainee Clinical Psychologist (see contact details below) and sponsored by Greater Glasgow Primary Care NHS Research and Development Department.

### **Who has reviewed the study?**

This study has been reviewed by Greater Glasgow Primary Care Research Ethics Committee.

### **Contact for Further Information**

If you should require further information, please contact:

Patricia Mooney  
University of Glasgow  
Department of Psychological medicine  
Garthnavel Royal Hospital  
1055 Great Western Road  
Glasgow  
G12 0XH  
Email: [0309254m@student.gla.ac.uk](mailto:0309254m@student.gla.ac.uk)  
Telephone: 0141 211 0607

Thank you for taking part in this study!

Version 2 25/7/05



Patient Identification Number for this trial:

## CONSENT FORM

### Investigating Bedtime Thoughts of People Who Have Difficulty Falling Asleep

Researcher: Patricia Mooney

Please initial box

1. I confirm that I have read and understand the information sheet dated 25/07/05.  
(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 take part in the above study.

☐

\_\_\_\_\_  
Name of Patient

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent  
(if different from researcher)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

1 for patient; 1 for researcher

### Writing Task Instructions

*“For the next **3 days**, in the early evening (between **6pm and 8pm**), I would like you to spend **20 minutes** writing about any thoughts, concerns, worries, or things on your mind. In your writing, I’d like you to be really honest, so that you can explore your very deepest thoughts and emotions. **You are not going to be asked to show anyone what you write.** Take the opportunity to explore your deepest thoughts and feelings about something that is emotionally important to you and is bothering you at the moment. Please write in as much detail as you can and explore every aspect of the topics you are writing about. You can write about the **same issue** every evening, or you may decide to cover **several topics** over the 3 sessions.”*

Participant Number \_\_\_\_\_

\*\*\*\*\**Complete in morning*\*\*\*\*\*

## Alertness Scale

Please rate *how **mentally alert** you felt last night while you were trying to get to sleep* by circling one number on the scale.

1	2	3	4	5
Not at all	Slightly	Moderately	A lot	Extremely

Participant Number \_\_\_\_\_

\*\*\*\*\**Complete in morning*\*\*\*\*\*

**Writing Task Questionnaire**

Please think about your writing *last night* when answering the next 3 questions and circle the most appropriate response.

**I worked through some upsetting issues:**

Very much      To some extent      Not at all

**Writing helped me organise my thoughts:**

Very much      To some extent      Not at all

**My thoughts/opinions have changed regarding the subject I wrote about:**

Very much      To some extent      Not at all