A double-blind randomised controlled study of a brief intervention of bedtime restriction for adult patients with primary insomnia

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ABSTRACT

INTRODUCTION: Bedtime restriction is effective for volunteer patients with primary insomnia.

AIM: To determine the effectiveness of bedtime restriction in adult volunteers with primary insomnia.

METHODS: Patients were recruited in response to articles in local newspapers. The study hypothesis was not given in the articles. Patients were assessed as to whether or not they had primary insomnia. They completed a two-week sleep diary after which they met the investigators and were randomised to either bedtime restriction and basic sleep hygiene or the control group with basic sleep hygiene only. A total of 224 potential participants applied to be in the study. Of the 52 who had primary insomnia, 45 were randomly allocated to either control or intervention group and only two did not complete the study. Randomisation was concealed and participants were blinded regarding the treatment. The primary outcome was also measured in a blinded fashion.

RESULTS: The outcome evaluated was patient description of 'better' or 'much better' quality of sleep versus the 'same', 'worse' or 'much worse' quality of sleep at six weeks. Overall, 73% (16/22) of those in the intervention group were either having better or much better quality of sleep after treatment, while in the control group this was 35% (8/23). The number needed to treat was 3 [95% CI 2–11] for bedtime restriction and sleep hygiene versus sleep hygiene alone.

DISCUSSION: This is the first study using bedtime restriction designed to be feasible in primary care by using a brief intervention and a patient-oriented outcome.

KEYWORDS: Insomnia; primary health care; randomized controlled trial

Introduction

Primary insomnia accounts for 12% of insomnia in primary care.[1] It is defined as self-reported difficulty in sleep initiation or maintenance for at least one month and does not have a specific cause, such as anxiety, depression, a medical condition or other sleep disorder.[2] In addition to poor functioning the following day, the risk for developing depression and anxiety from untreated insomnia has been reported.[3,4]

Cognitive-behavioural therapy for insomnia (CBT-I) has been shown to be an effective treatment for primary insomnia in randomised trials[5] and aims at addressing the cognitive and behavioural aspects of insomnia using a combination of various interventions. These include behavioural strategies (e.g. bedtime restriction, stimulus control therapy, relaxation-based interventions), education (e.g. sleep hygiene), and cognitive strategies (cognitive therapy).[5] Although effective, CBT-I is not designed as a treatment that can be administered by primary care clinicians (typically it is administered as a 6–8 session model)[5] and thus it remains underutilised in primary care. One of the authors (AF) had noted in his private practice that patients with primary insomnia had

J PRIM HEALTH CARE
2013;5(1):5–10.

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improved quality of sleep after one or two sessions with bedtime restriction, without the other components of CBT-I.

Bedtime restriction requires the clinician to work out how many hours a patient spends in bed at night and how many hours they perceive they actually sleep (average sleep time). Average sleep time can be calculated from the patient's history and/or a sleep diary. The patient is then asked to limit their time in bed to their calculated average sleep time (with a minimum time in bed of five hours). Anecdotally, the common response found was that patients reported a more satisfying sleep experience. When planning this study, the authors found three studies of bedtime restriction in elderly patients.[6–8] However, each study required four or more visits and use of objective measures of sleep, such as polysomnography (overnight sleep studies) or actigraphy (movement watches).

As neither these means of assessment nor the repeated visits are feasible in primary care, the question of the efficacy of this treatment for the primary care population of interest remained unanswered. The authors considered a subjective effectiveness measure in primary care would be more appropriate, as insomnia is defined using subjective reports. If bedtime restriction was an effective treatment for primary insomnia, it would have the potential to be used alone in primary care as a treatment for patients with primary insomnia, without resorting to the need for input from a CBT therapist. Therefore, it was decided to test a brief version of bedtime restriction that, if effective in a population of volunteers, could be evaluated further in a primary care population.

Methods

Patients were eligible for this study if they had primary insomnia. Primary insomnia was defined as having trouble with sleep initiation or maintenance on at least three nights per week for more than one month and with no other causes of insomnia identified.[2] Inclusion criteria were: aged 16 years or older, Hospital Anxiety and Depression Scale (HADS) score for depression of ≤8,[9] ability to read and understand the participant information sheet written in English, and competent to sign the consent form.

Recruitment was undertaken through articles about the first author in local newspapers, with interested individuals contacting him directly asking to be in the study. There was no mention of bedtime restriction in the articles. Initially, patients were interviewed by telephone by the authors (AF and BA) to determine if they had primary insomnia. As this became very time-consuming, patients were later recruited by mailing out the ASQV1 (Auckland Sleep Questionnaire Version 1), a seven-page paper questionnaire asking about the common causes of insomnia.[10] This made the process of selecting those with primary insomnia a much easier task because it was possible to make a provisional diagnosis of primary insomnia from the questionnaire.

Those who had a provisional diagnosis of primary insomnia attended a face-to-face interview with either AF or BA or both for confirmation of the diagnosis. During this attendance, a participant information sheet was provided and the consent form was signed. The information sheet stated each participant would be receiving instruction about one of two non-drug treatments for insomnia and that the alternate treatment would not be revealed until the end of the six-week study. The treatments were bedtime restriction plus basic sleep hygiene or basic sleep hygiene alone.

Participants were sent a sleep diary to be completed in the two weeks prior to their interview and they were asked to stop any hypnotic medication for a month before the study and to stay off medication for the six weeks of the study. Using the sleep diary, it was determined how long each participant reported spending in bed and how long they felt they actually were asleep during time in bed.

Randomisation was done by one of the investigators (BA) using an Microsoft Office Excel spreadsheet before any patients were recruited. Allocation to one of the two groups was sealed in numbered opaque envelopes which were opened in order, usually in the presence of two investigators (BA and AF), once the patient had

given consent for participation in the study. This ensured that randomisation was concealed. The patients were randomised to two parallel groups.

Written instructions regarding sleep hygiene were given to both groups. Based on their sleep diary information, the bedtime restriction group received personalised instructions on bedtime and wake time to be adhered to over the following six weeks. Some negotiation was permitted regarding bedtime allocation in the bedtime restriction group if initiated by the participant. Care was taken not to disclose which group each participant was in (i.e. intervention or control group). There was a visit at two weeks to check that the patients had understood the instructions given at the first visit. At six weeks, a staff member of The University of Auckland Department of Psychological Medicine phoned the patients and asked how well they had been sleeping in the past month in comparison to prior to the study: 'much worse', 'worse', 'same', 'better' or 'much better'. The staff member was instructed not to ask about the patient's intervention and so remained blind to the intervention. This was a second level of blinding.

The study was conducted according to the CONSORT statement[11] and data collection was from March 2006 until January 2008. The only aspect of the CONSORT statement that the study did not fulfil was that it was not registered with a trials register, as it commenced in 2006 and the Australian and New Zealand Clinical Trials Registry was not started until 2007. The sample size calculation expected a 40% effect size with 90% of the intervention group getting better with bedtime restriction and 50% with sleep hygiene, *p*-value 0.05 and beta 0.2, two-sided, which required 24 participants in each group. The 40% effect size was based on a conservative estimate of the private practice patients of author AF. Analysis was done using Chi-square and intention-to-treat analysis.[12] Ethics approval was obtained from the Northern Ethics Committee on 19 December 2005, reference number NTX/05/09/117. Analysis of the data was done using the website at the Centre for Evidence-Based Medicine at the University of Toronto.

WHAT GAP THIS FILLS

What we already know. Bedtime restriction has been shown to be effective for elderly patients with primary insomnia, usually in studies using actigraphy and polysomnography.

What this study adds: Bedtime restriction is effective for adults with primary insomnia, using resources available to primary care practitioners. This study also used an outcome measure that is relevant to primary care clinicians and their patients, rather than equipment such as polysomnography or actigraphy, which is not routinely available to primary care practitioners.

Figure 1. Flow diagram of study participants through randomised controlled trial of bedtime restriction for primary insomnia

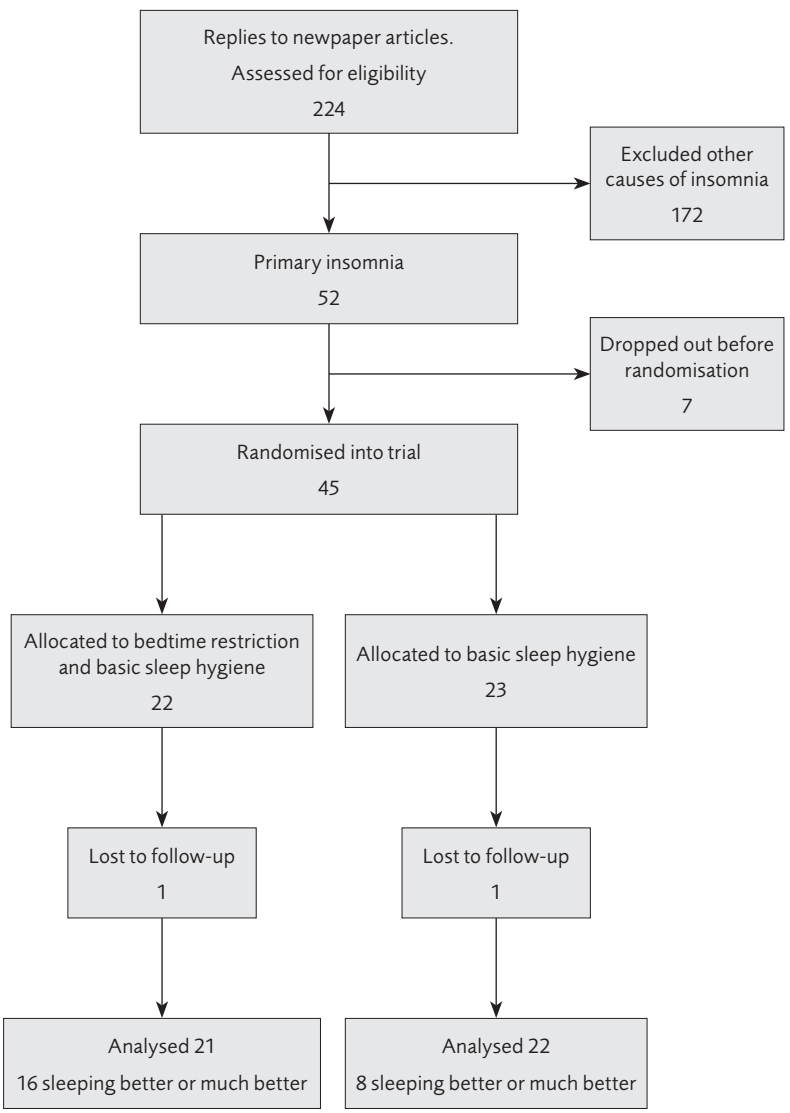

Table 1. Baseline characteristics of participants

		Intervention group (n=22)	Control group (n=23)
Age (median)		58 years (range 35–70 years)	53 years (range 29–84 years)
Gender	**Women**	15	13
	Men	7	10
Sleep quality (median)*		3	3
Ethnicity		20 NZ European 1 Indian 1 Tongan	22 NZ European 1 Indian
HADS† depression score (median)		2 (range 0 to 8)	3 (range 0 to 8)
HADS anxiety score (median)		5 (range 2 to 11)	4 (range 0 to 14)

* Sleep quality rated as 1 'very good', 2 'fairly good', 3 'fairly bad', 4 'very bad'

† HADS: Hospital Anxiety and Depression Scale

Results

A total of 224 people replied to the newspaper articles, of whom 52 had primary insomnia. Of these, seven dropped out before randomisation (see Figure 1). Table 1 shows the demographics of the participants. Table 2 shows the results of the two interventions. Two people were lost to follow-up after randomisation, one from the intervention group and one from the control group. For the intention-to-treat analysis, those who were lost to follow-up were allocated their baseline status, i.e. 'same/worse/much worse'. Those who scored either 'better' or 'much better' were considered to have improved sleep. In the intervention group, 16 participants were either 'better' or 'much better' compared with eight participants in the control group.

The absolute risk of benefit was 38% [95% CI 8.8–59%] with the intervention group having 73% getting better (experiencing improved sleep) and 35% in the control group getting better. The number needed to treat (NNT) to get one person to experience improved sleep at six weeks was 3 [95% CI 2–11] for the intervention with sleep hygiene versus sleep hygiene alone. Using a Chi-square analysis,[12] the *p*-value was = 0.0107. Taking into account the two who were lost to follow-up, the per protocol analysis was statistically significant (p=0.0085) and the NNT stayed the same. The study was stopped at 45 participants as we had no further candidates from our initial advertising and were very close to our sample size calculation of 48. The only harm reported was a patient in the intervention group scraping her car on a fence on two occasions when backing out of a driveway.

Discussion

This study shows that time-in-bed restriction leads to improvement in sleep, with a numbers needed to treat of 3. The control group showed improvement, with 35% of participants sleeping 'better' or 'much better', but the intervention group had 73% sleeping 'better' or 'much better'. This suggests that for a third of patients with primary insomnia, basic sleep hygiene may be effective while another third will benefit further with the addition of bedtime restriction.

*Table 2. Outcome of blinded telephone call to participants**

	'Better' or 'much better'	'Same', 'worse', or 'much worse'	Total
Intervention group	16	6	22
Control group	8	15	23

* Assumes those lost to follow-up were sleeping 'worse'

We chose a patient-oriented outcome that was relevant to patients, rather than sleep diary outcomes or more technical measures, such as polysomnography or actigraphy. However, there are some limitations with the simple outcome measure used. It may over-estimate the efficacy of each of the treatments. For example, someone responding that their sleep was 'better' may still experience poor quality sleep or be unhappy with their sleeping (thus still being regarded as experiencing insomnia). Although describing their sleep as better, they may not experience good sleep or feel that the treatment was particularly effective for them. Another limitation is the short timeframe for the study, with a follow-up period of only six weeks; however, this reflects the intention of the study as a pilot precursor to a larger study. The study population was also likely to be both those with more severe insomnia and those who were particularly motivated to improve their sleep, as it involved responding to an article calling for those with poor sleep to contact the investigator. The numbers in the study are relatively small, but the recruiting was very time intensive. The study was conducted with no external funding and was stopped when the initial supply of participants ran out. The study was powered for the small sample size as clinical experience suggested that the intervention was quite powerful.

A strength of this study was that it was a randomised controlled trial conducted according to the CONSORT statement. It was also a double-blind study, with the patients being blind to their allocation and the outcome assessor being blind to the intervention group. The short intervention (two sessions) without the use of actigraphy or polysomnography was deliberate to assess an intervention that would be appealing to primary care physicians.

Sleep restriction was first proposed as an effective treatment for insomnia by Spielman and colleagues in the 1980s.[8] Since then, recommendations developed and published by the American Academy of Sleep Medicine in 2006[5] have described sleep restriction as an empirically supported treatment. Two randomised controlled trials of sleep restriction were included in their systematic review.[6,7] Both these studies were in community-dwelling older adults. In the study by Friedman et al.,[6] 39 subjects were randomised to either sleep restriction plus sleep hygiene, sleep restriction with napping plus sleep hygiene, or sleep hygiene alone (as an active control). Actigraphy and sleep diary data were used as outcome measures and polysomnography was conducted in a subgroup. All subjects met with a therapist for six sessions. Both sleep restriction conditions produced an increase in sleep efficiency, with reduced time spent in bed compared to the control group, but no difference in effect was found between the sleep restriction therapy groups and the control group on actigraphy or polysomnography measures. In contrast with the current study, the above study did not include clinical report of patient perception of improvement. It is not clear whether an improvement in sleep efficiency would be correlated with any clinically significant (patient perception of improved sleep) improvement in sleep and no subjective outcomes apart from sleepiness were investigated.

In the study by Lichstein et al.,[7] 89 older adults with primary insomnia were randomised to either sleep restriction (called 'sleep compression' in the paper), relaxation therapy or a placebo group. All subjects underwent two consecutive polysomnography tests prior to treatment for diagnosis and met with a therapist weekly for six sessions. Both treatment groups were more effective than placebo for reducing wake time after sleep onset (WASO), with sleep restriction producing the best outcome at one-year follow-up. All groups showed improvements on measures of fatigue and insomnia impact.

A recent trial, again in elderly patients, used brief behavioural treatment for insomnia which included a reduction of time in bed, getting up at the same time each day (regardless of sleep duration) and not going to bed unless sleepy.[13] Polysomnography and actigraphy were used to assess diagnosis and sleep and the results showed a benefit at four weeks, with an NNT of 2.4. The intervention included a follow-up visit at two weeks and two telephone calls at weeks one and three.

There is little research on the use of bedtime restriction alone as an intervention in the general adult population and existing studies mostly do not report clinically meaningful outcomes (which the authors believe should include subjective perception of sleep improvement). The trial designs, in requiring multiple therapist sessions, also limit generalisability and translation into most primary care settings.

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In the authors' primary care practice (BA and KF), patients are asked to turn up early to sleep consultations and complete the ASQV1[10] which takes about 20 minutes. It is then a fairly straightforward process to decide the cause of their insomnia. The majority of cases are patients with depression or anxiety or physical health issues.[1] For those with primary insomnia, sleep restriction (referred to as bedtime restriction by the authors to avoid negative associations patients may ascribe to 'restricting their sleep') is discussed, with a preliminary sleep schedule set based on patient estimates of average time spent in bed and average sleep duration. A handout on how to follow the bedtime restriction is also given to reduce time spent in the consultation process.

Conclusion

This study gives strong support to the brief intervention of bedtime restriction being effective for improving sleep in adult volunteers with primary insomnia. The intervention, using two visits, is feasible in primary care. The bedtime restriction method is relatively simple and could easily be managed in primary care, thereby saving the time and cost of CBT-I for the majority of patients. We are currently conducting a larger trial of this brief intervention in a primary care population.

COMPETING INTERESTS
None declared.

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