Research

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Simplified sleep restriction for insomnia in general practice:

a randomised controlled trial

Abstract

Background
Insomnia is common in primary care. Cognitive behavioural therapy for insomnia (CBT-I) is effective but requires more time than is available in the general practice consultation. Sleep restriction is one behavioural component of CBT-I.

Aim
To assess whether simplified sleep restriction (SSR) can be effective in improving sleep in primary insomnia.

Design and setting
Randomised controlled trial of patients in urban general practice settings in Auckland, New Zealand.

Method
Adults with persistent primary insomnia and no mental health or significant comorbidity were eligible. Intervention patients received SSR instructions and sleep hygiene advice. Control patients received sleep hygiene advice alone. Primary outcomes included change in sleep quality at 6 months measured by the Pittsburgh Sleep Quality Index (PSQI), Insomnia Severity Index (ISI), and sleep efficiency (SE%). The proportion of participants reaching a predefined 'insomnia remission' treatment response was calculated.

Results
Ninety-seven patients were randomised and 94 (97%) completed the study. At 6-month follow-up, SSR participants had improved PSQI scores (6.2 versus 8.4, $P<0.001$), ISI scores (8.6 versus 11.1, $P=0.001$), actigraphy-assessed SE% (difference 2.2%, $P=0.006$), and reduced fatigue (difference −2.3 units, $P=0.04$), compared with controls. SSR produced higher rates of treatment response (67% [28 out of 42] versus 41% [20 out of 49]); number needed to treat = 4 (95% CI = 2.0 to 19.0). Controlling for age, sex, and severity of insomnia, the adjusted odds ratio for insomnia remission was 2.7 (95% CI = 1.1 to 6.5). There were no significant differences in other outcomes or adverse effects.

Conclusion
SSR is an effective brief intervention in adults with primary insomnia and no comorbidities, suitable for use in general practice.

Keywords
behaviour therapy; general practice; sleep initiation and maintenance disorders.

INTRODUCTION

The symptom of insomnia affects approximately 40% of adults in the general population, with between 7% and 22% meeting the criteria for an insomnia disorder.[1–3] Insomnia is often chronic,[4,5] and is associated with an increased risk of depression and anxiety,[6,7] cardiovascular disease,[8,9] and reduced quality of life.[10] GPs are consulted more frequently than other health professionals for sleep problems,[11] and patients typically prefer non-pharmacological treatment strategies.[12] In general practice, approximately 12% of adults with insomnia experience primary insomnia.[13,14] Primary insomnia is diagnosed when there is no other identified cause, such as obstructive sleep apnoea or other contributing medical condition.[15] In 2014, the third edition of the *International Classification of Sleep Disorders* combined primary and secondary insomnia under the single diagnosis of chronic insomnia disorder;[16] although the current study only included those with primary insomnia as defined above.

Cognitive behavioural therapy for insomnia (CBT-I) is effective but its use in general practice is limited because of the time and training required for its delivery.[17,18] Recent research has focused on briefer, more accessible treatments. These include studies by Buysse *et al* using the behavioural components of CBT-I (sleep restriction and stimulus control),[19] Edinger and Sampson using an abbreviated form of CBT-I,[20] and Espie *et al* using CBT-I delivered by nurses in the primary care setting.[21] The results have been promising.

The sleep restriction component of CBT-I consolidates fragmented sleep by reducing the time allowed in bed (the sleep opportunity); thereby inducing mild sleep deprivation to enhance the endogenous sleep drive.[22] The aim of the current study was to assess whether an even shorter intervention than those mentioned above (simplified sleep restriction) designed to fit into two GP consultations could improve sleep among patients with primary insomnia.

METHOD

Study setting and patients

A parallel design randomised controlled trial was conducted in Auckland, New Zealand. Fourteen general practices participated. Primary care patients were eligible if they were between 16 and 75 years old with primary insomnia lasting >6 months, did not have obstructive sleep apnoea, a mental health or other significant comorbidity that may have led to secondary insomnia, and were not taking hypnotic medication for at least 2 weeks prior to baseline assessment.[23] All enrolled adult patients were sent a form to screen for insomnia and to invite potentially

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eligible patients to participate. Those who responded were further assessed using a longer questionnaire (to determine the cause of the sleep disorder), physical examination (blood pressure, pulse, body mass index, neck circumference, inspection of face, nose, tongue, tonsils, and palate, and auscultation of heart and lungs) and a sleep diary (requiring difficulty sleeping on at least 3 nights a week) to ensure they had primary insomnia and were fit for participation. Patients on prescription sleep medication and unwilling or unable to discontinue regular use during the study, were excluded.

Intervention

After randomisation, participants in both the simplified sleep restriction (SSR) and control groups received verbal advice about sleep hygiene, including information such as avoiding caffeine, relaxing before bedtime, and creating a pre-bed routine,[24] at a visit with the study GP. Those in the SSR group also received verbal and written instructions (sleep prescription) setting both bedtime and wake-up times based on a preceding 2-week daily sleep diary.

The study GP (one of the authors) developed the intervention design and algorithm used in the trial after reviewing the literature and existing evidence for CBT-I and sleep restriction. All intervention instructions were delivered by the study GP. The total time in bed allowed in the sleep prescription was equal to the average total sleep duration plus 50% of the total time spent awake in bed (therefore reducing the total additional 'wake time' by half), with a minimum time in bed of 5 hours. Actual bedtime and wake-up times were negotiable. Participants were asked to continue with a sleep diary until the next visit.

Participants attended a second visit 2 weeks later. If participants were sleeping for <85% of the time they spent in bed (according to their diary), the time allowed in bed was further reduced to total sleep duration plus 30 minutes. If patients felt excessively sleepy, they were advised to spend 30 minutes more in bed each night. Wherever possible, wake-up time was kept constant, and any changes required were made to bedtime. Participants were also given a written flowchart summarising change options (available from authors on request) and asked to self-adjust their sleep every 2 weeks thereafter. Control participants also attended a second visit after 2 weeks where their general sleep progress according to sleep hygiene guidelines was discussed. Scripts were used for the delivery of instructions to both groups.

Randomisation and blinding

Computer-generated block randomisation was performed by a biostatistician not involved in recruitment or assessment. A central telephone system was used to implement the random allocation sequence following enrolment and baseline assessment, maintaining allocation concealment. Because of the nature of the intervention, participants could not be completely blinded to the intervention; however, they were only aware that they would receive some advice about their sleep but were not told the exact nature. For the first 40% of participants (37 out of 91), a research assistant blind to allocation assessed follow-up measures. However, because of funding constraints, the study GP, who was not blind to allocation, followed up the remaining 60% of participants (54 out of 91). Standard scripts, objective measures, and self-completed questionnaires were used wherever possible to minimise the risk of assessment bias. The study GP gave no assistance to the participants when completing their questionnaires.

Outcome measures

Sleep quality was measured by the Pittsburgh Sleep Quality Index (PSQI)[25] and Insomnia Severity Index (ISI)[26] at baseline, 3 months, and 6 months, and change in sleep efficiency from baseline to 6 months (total sleep time/time in bed [from lights out] x 100% from 2-week diaries and actigraphy).[27] Secondary outcomes measured at baseline and 6 months included sleep-onset latency, wakefulness after sleep-onset, and total sleep time, assessed from 2-week sleep diaries[27] and actigraphy (Minimitter Actiwatch®-64; Minimitter, Bend, Oregon);[28–30] sleepiness using the Epworth Sleepiness Scale;[31]

fatigue using the Flinders Fatigue Scale;[32] depression using the Patient Health Questionnaire (PHQ-9),[33] and anxiety using the Generalised Anxiety Disorders (GAD-7) questionnaire.[34,35] Actigraphy used 30-second epochs, analysed with Actiware software (version 5.70.1; medium wake threshold).

Demographic information was collected by self-administered questionnaire. Medical status, medication use, hypnotic use, and caffeine or other substance use, were evaluated using interviewer-administered questionnaires. Potential adverse effects were assessed at 2 weeks, 3 months, and 6 months, including blood pressure, history of accidents, angina, myocardial infarction, stroke or other condition resulting in hospitalisation, and extreme sleepiness (such as while driving, operating machinery, cooking, or in other unsafe situations).

Statistical tests

Sample size calculations used data from a 6-week pilot trial ($n = 45$) of sleep restriction.[36] To detect an absolute difference in the proportion with a treatment response between intervention and control of 30%, at least 45 participants in each group would be required ($\alpha = 0.05$, 80% power)

The results were analysed using SAS software (version 9.3). All available data were used and no missing data imputation was performed. Mixed models for repeated measures were used for PSQI and ISI with two post-baseline time points (3 and 6 months), and multiple linear regression was used to analyse continuous outcomes with one post-baseline time point (6 months). All analyses used an intention-to-treat approach and were adjusted for age, sex, and baseline insomnia severity (ISI score).

The definition of treatment effect described by Buysse *et al*[19] was used to determine treatment responses of remission, response, partial response, and non-response. These four categorical outcomes were then collapsed into two categories: 'remission' or 'response' versus 'partial response' or 'non-response'. The absolute risk reduction, number needed to treat (NNT), and the corresponding 95% confidence intervals (CIs) were calculated using unadjusted data. The four and two category outcomes were then analysed using ordinal and logistic regression, respectively, adjusting for age, sex, and baseline insomnia severity. From this modelling, adjusted odds ratios and 95% CIs were obtained. Complete case sensitivity analysis and analysis adjusting for hypnotic use at 6 months were also performed.

RESULTS

Participant flow and recruitment

Of the 28 978 screening letters sent out, 2740 responses were received from those potentially eligible and interested in participating in the trial. Of these, 1302 (48%) met general criteria for insomnia and were sent the comprehensive sleep disorders screening questionnaire to identify those with possible primary insomnia, and of these, 720 (55%) completed the second

Figure 1. CONSORT diagram showing flow of study participants through the randomised controlled trial of simplified sleep restriction for primary insomnia.
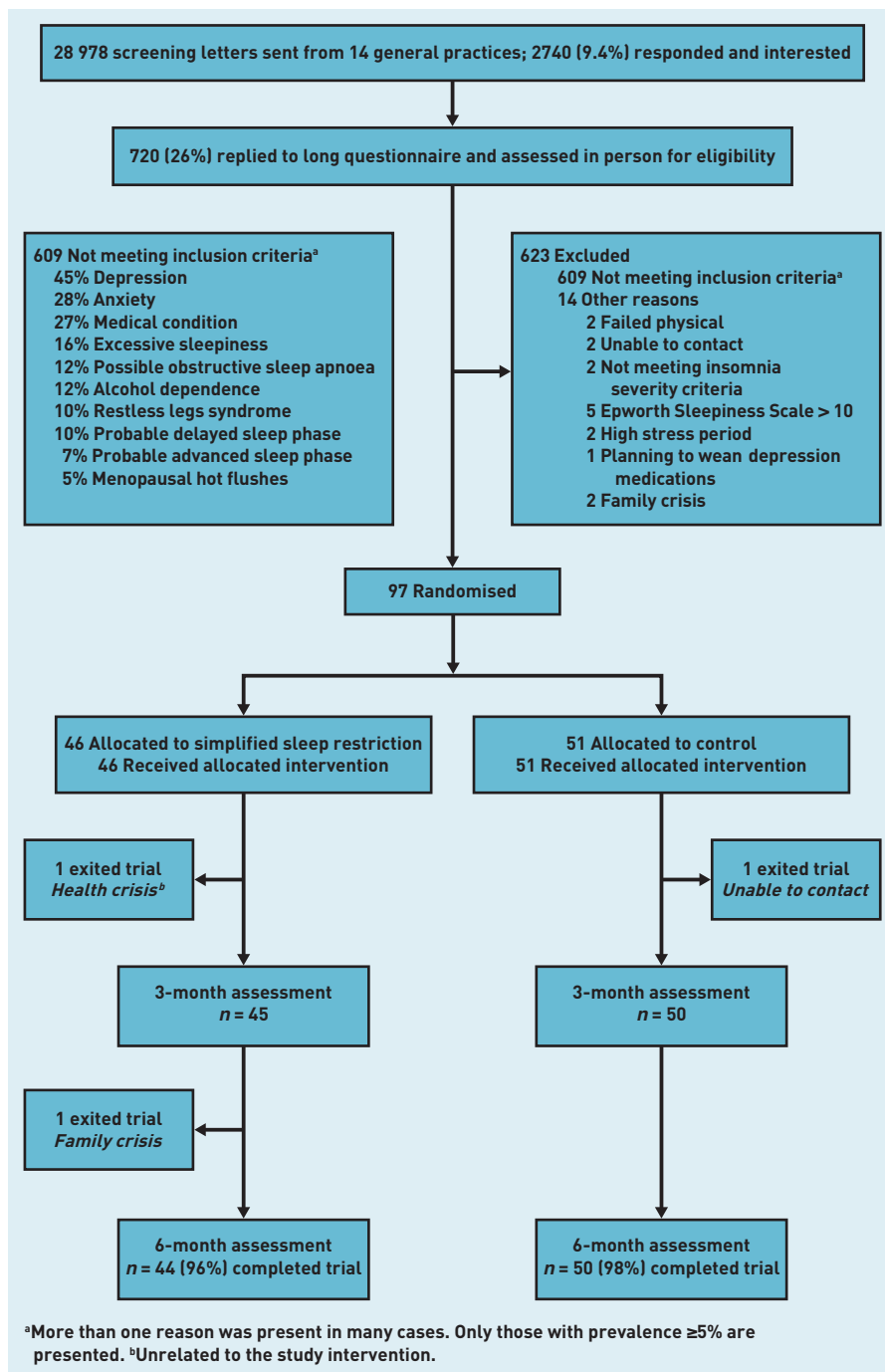

28 978 screening letters sent from 14 general practices; 2740 (9.4%) responded and interested

720 (26%) replied to long questionnaire and assessed in person for eligibility

609 Not meeting inclusion criteria[a]
45% Depression
28% Anxiety
27% Medical condition
16% Excessive sleepiness
12% Possible obstructive sleep apnoea
12% Alcohol dependence
10% Restless legs syndrome
10% Probable delayed sleep phase
7% Probable advanced sleep phase
5% Menopausal hot flushes

623 Excluded
609 Not meeting inclusion criteria[a]
14 Other reasons
2 Failed physical
2 Unable to contact
2 Not meeting insomnia severity criteria
5 Epworth Sleepiness Scale > 10
2 High stress period
1 Planning to wean depression medications
2 Family crisis

97 Randomised

46 Allocated to simplified sleep restriction
46 Received allocated intervention

51 Allocated to control
51 Received allocated intervention

1 exited trial
Health crisis[b]

1 exited trial
Unable to contact

3-month assessment
***n* = 45**

3-month assessment
***n* = 50**

1 exited trial
Family crisis

6-month assessment
***n* = 44 (96%) completed trial**

6-month assessment
***n* = 50 (98%) completed trial**

[a]More than one reason was present in many cases. Only those with prevalence ≥5% are presented. [b]Unrelated to the study intervention.

Table 1. Baseline characteristics of participants

Characteristic	Sleep restriction (*n* = 46) Mean (SD)	Control (*n* = 51) Mean (SD)
Age, years	55.4 (12.7)	51.8 (13.4)
Female, *n* (%)	39 (85)	36 (71)
Duration of insomnia, years	15 (14)	14 (13)
Primary outcomes		
Pittsburgh Sleep Quality Index[25]	10.43 (3.08)	10.29 (3.02)
Insomnia Severity Index[26]	14.76 (3.85)	14.51 (3.36)
Sleep efficiency [sleep diary],[a] %	73.32 (11.80)	74.15 (11.05)
Sleep efficiency [actigraphy], %	82.68 (4.66)	82.37 (4.67)
Secondary outcomes — sleep		
Epworth Sleepiness Scale[31]	5.17 (3.70)	6.45 (3.29)
Flinders Fatigue Scale[32]	12.74 (6.83)	12.53 (5.11)
Sleep-onset latency, minutes		
Sleep diary	31.50 (23.00)	29.55 (22.48)
Actigraphy	16.10 (14.47)	14.66 (12.42)
Wake after sleep onset, minutes		
Sleep diary	44.82 (28.92)	47.84 (30.14)
Actigraphy	47.59 (13.88)	51.81 (19.51)
Total sleep time, minutes		
Sleep diary	369.59 (65.27)	376.93 (61.08)
Actigraphy	415.68 (34.17)	418.36 (39.36)
Secondary outcomes — mental health		
PHQ-9 depression score[33]	4.98 (2.76)	5.31 (2.80)
GAD-7 anxiety score[34]	3.33 (3.06)	3.41 (2.45)
Physiological measures		
Systolic blood pressure, mmHg	122.24 (13.98)	123.88 (13.20)[b]
Diastolic blood pressure, mmHg	75.52 (10.35)	75.62 (8.98)[b]
Heart rate, beats per minute	68.91 (9.82)	73.29 (10.86)
Body mass index, kg/m^2	25.84 (3.89)	25.16 (4.28)

[a]Using data averaged from sleep diary recordings for a 2-week period. Sleep efficiency is calculated as total sleep time/time spent in bed x 100%. [b]n = 50 due to equipment malfunction. PHQ-9 = Patient Health Questionnaire-9. GAD-7 = Generalised Anxiety Disorders-7.

Baseline data

There were no obvious differences between groups in baseline characteristics (Table 1). The overall attrition rate during the trial was 3% (two lost to follow-up from SSR, one from control).

The mean duration of the advice given at the initial visit was 20 minutes for SSR and 11 minutes for control participants. The duration of the advice given at the second visit was 14 and 11 minutes, respectively.

Outcomes and estimation

Compared with control, the SSR intervention led to statistically significant improved PSQI scores (−2.14, 95% CI = −3.15 to −1.13); improved ISI scores (−2.50, 95% CI = −3.97 to −1.03); improved sleep efficiency (2.22%, 95% CI = 0.65 to 3.79), and improved sleep-onset latency (−6.13 minutes, 95% CI = −11.82 to −0.44) as measured by actigraphy; and a reduction in feelings of fatigue (−2.27, 95% CI = −4.42 to −0.13) (Table 2 and Table 3). Using the two treatment outcome categories,[19] the NNT was four (95% CI = 2.0 to 19.0). There were no statistically significant differences between the groups in change in sleep efficiency (sleep diary), in the other sleep parameters, perceived sleepiness, depression, anxiety, or blood pressure (Table 3 and Table 4). However, heart rate reduced significantly more in the control than in the intervention group (*P* = 0.02), although baseline heart rate was higher in the control group. Similar results to the main analysis were obtained for the primary outcome measures when adjusted for hypnotic use at 6 months and with a complete cases analysis for PSQI and ISI. By 6 month follow-up, two participants in the sleep restriction group and 10 in the control group reported using hypnotic medication at least 3 times a week.

Adverse events

No adverse events were recorded in the SSR group in the initial 2 weeks and there were

questionnaire and were potentially eligible. Ninety seven (13%) participants fulfilled all inclusion and no exclusion criteria and were randomised (Figure 1). Recruitment and follow-up occurred between March 2009 and November 2012.

Table 2. Pittsburgh Sleep Quality Index and Insomnia Severity Index for simplified sleep restriction versus control at baseline, 3 months, and 6 months. Data presented as mean (SD)

Primary outcomes	Intervention (simplified sleep restriction)			Control			Difference between the groups (95% CI), *P*-value[b]
	Baseline score[a] *n* = 46	3-month score[a] *n* = 45	6-month score[a] *n* = 43	Baseline score[a] *n* = 51	3-month score[a] *n* = 49	6-month score[a] *n* = 50	
Pittsburgh Sleep Quality Index[25]	10.43 (3.08)	6.24 (3.11)	6.49 (3.52)	10.29 (3.02)	8.71 (3.32)	8.10 (3.49)	−2.14 (−3.15 to −1.13) **<0.0001**
Insomnia Severity Index[26]	14.76 (3.85)	8.47 (4.45)	8.28 (4.41)	14.51 (3.36)	11.51 (3.94)	10.50 (3.72)	−2.50 (−3.97 to −1.03) **0.001**

Statistically significant results are in bold. [a]Observed (raw) data. [b]Mixed model for repeated measures adjusted for age, sex, and baseline insomnia severity (using ISI score).

Table 3. Sleep results for simplified sleep restriction versus control at baseline and 6 months. Data presented as mean (SD)

	Intervention (Simplified sleep restriction)			Control			Difference between the groups,[b,d] (95% CI) P-value
	Baseline score[a] n = 46	6-month score[a] n = 43	Mean change (95% CI)[b,c]	Baseline score[a] n = 51	6-month score[a] n = 50	Mean change (95% CI)[b,c]	
Primary outcomes							
Sleep efficiency % (sleep diary)	73.32 (11.80)	80.46 (10.66)[e]	6.72 (3.90 to 9.54)	74.15 (11.05)	78.24 (10.52)[f]	4.28 (–6.70 to 1.86)	2.44 (–0.96 to 5.84) 0.200
Sleep efficiency % (actigraphy)	82.68 (4.66)	83.74 (4.94)[g]	1.75 (0.42 to 3.09)	82.37 (4.67)	81.96 (5.38)[f]	–0.46 (–1.58 to 0.65)	2.22 (0.65 to 3.79) **0.006**
Secondary outcomes							
Epworth Sleepiness Scale	5.17 (3.70)	3.70 (2.93)	–1.62 (–2.72 to –0.53)	6.45 (3.29)	4.86 (3.28)	–1.55 (–2.50 to –0.61)	–0.07 (–1.40 to 1.27) 0.900
Flinders Fatigue Scale	12.74 (6.83)	7.30 (5.49)	–5.39 (–7.16 to –3.63)	12.53 (5.11)	9.08 (4.96)	–3.12 (–4.65 to –1.59)	–2.27 (–4.42 to –0.13) **0.040**
Sleep onset latency, minutes							
Sleep diary	31.50 (23.00)	22.77 (19.60)	–6.29 (–12.75 to 0.16)	29.55 (22.48)	25.21 (19.38)[e]	–2.84 (–8.38 to 2.70)	–3.45 (–11.23 to 4.32) **0.400**
Actigraphy	16.10 (14.47)	13.37(7.91)[f]	–5.08 (–9.90 to –0.26)	14.66 (12.42)	15.61 (12.74)[e]	1.06 (–2.97 to 5.08)	–6.13 (–11.82 to –0.44) **0.040**
Wake after sleep onset, minutes							
Sleep diary	44.82 (28.92)	29.47 (31.71)	–13.37 (–22.69 to –4.05)	47.84 (30.14)	40.02 (27.00)[e]	–7.61 (–15.60 to 0.39)	–5.76 (–17.00 to 5.47) **0.300**
Actigraphy	47.59 (13.88)	44.33 (15.44)[f]	–4.54 (–8.99 to –0.08)	51.81(19.51)	51.59 (17.50)[e]	–1.46 (–5.18 to 2.27)	–3.08 (–8.35 to 2.18) **0.200**
Total sleep time, minutes							
Sleep diary	369.59 (65.27)	397.30 (63.29)	23.71 (9.51 to 37.90)	376.93 (61.08)	398.17 (64.91)[e]	18.99 (6.81 to 31.67)	4.72 (–12.39 to 21.83) **0.600**
Actigraphy	415.68 (34.17)	407.20 (36.92)[f]	–7.00 (–15.94 to 1.95)	418.36 (39.36)	415.05 (38.45)[e]	–7.10 (–14.58 to 0.38)	0.10 (–10.47 to 10.67) **0.990**

Statistically significant results are in bold. [a]Observed (raw) data. [b]Multiple linear regression adjusted for age, sex, and baseline insomnia severity (using Insomnia Severity Index score[26]). [c]Least square mean for change from baseline to 6-month score. [d]Least square mean difference for change from baseline to 6-month score between sleep restriction and control group. [e]n = 43. [f]n = 49. [g]n = 42.

Table 4. Mental health and physiological outcomes for simplified sleep restriction versus control at baseline and 6 months. Data presented as mean (SD)

	Simplified sleep restriction			Control			Difference between the groups[b,d,e] (95% CI) P-value
	Baseline score,[a] n = 46	6-month score,[a] n = 43	Mean change (95% CI)[b,c,d]	Baseline score,[a] n = 51	6-month score,[a] n = 50	Mean change (95% CI)[b,c,d]	
Mental health outcomes							
PHQ-9 depression score	4.98 (2.76)	2.93 (2.39)	2.19 (–3.21, –1.17)	5.31 (2.80)	3.62 (2.69)	–1.66 (–2.54 to –0.78)	–0.53 (–1.77 to 0.71) 0.40
GAD-7 anxiety score	3.33 (3.06)	1.47 (1.88)	–1.76 (–2.59 to –0.92)	3.41 (2.45)	2.56 (2.35)	–0.84 (–1.56 to –0.12)	–0.92 (–1.93 to 0.10) 0.08
Physiological measures							
Systolic blood pressure, mmHg	122.24 (2.06)	121.21 (2.15)	–1.33 (–4.28 to 1.63)	123.88 (1.87)[f]	125.06 (1.97)[g]	0.25 (–3.48 to 3.98)[h]	–1.58 (–6.34 to 3.19) 0.50
Diastolic blood pressure, mmHg	75.52 (1.53)	74.51 (1.42)	–1.30 (–3.29 to 0.68)	75.62 (1.27)	74.92 (1.48)[g]	–1.46 (–3.97 to 1.05)[h]	0.16 (–3.05 to 3.37) 0.90
Heart rate, beats per minute	68.91 (1.45)	69.47 (1.57)	0.72 (–1.98 to 3.43)	73.29 (1.52)	69.61 (1.37)[g]	–3.82 (–6.45 to–1.19)[g]	4.54 (0.81 to 8.27) **0.02**

Statistically significant results are in bold. [a]Observed (raw) data. [b]Multiple linear regression adjusted for age, sex, and baseline insomnia severity (using Insomnia Severity Index score[26]). [c]Least square mean for change from baseline to 6-month score. [d]Differences in physiological measures calculated from t-test procedure in SAS. [e]Least square mean difference for change from baseline to 6-month score between sleep restriction and control group. [f]n = 50 due to machine error. [g]n = 49. [h]n = 48. PHQ-9 = Patient Health Questionnaire-9. GAD-7 = Generalized Anxiety Disorders-7.[34]

Table 5. Adverse events experienced by participants

Adverse event n (%)	Baseline[a]		Week 3[b]		6 months[c]	
	Sleep restriction n = 46	Control n = 51	Sleep restriction n = 45	Control n = 51	Sleep restriction n = 43	Control n = 48
Motor vehicle accident	3 (7)	4 (8)	0	1 (2)	2 (5)	5 (10)
Injury						
Medical attention	9 (20)	5 (10)	0	1 (2)	4 (9)	6 (13)
No medical attention	7 (15)	5 (10)	0	2 (4)	2 (5)	8 (17)
Worsening angina	0	0	0	1 (2)	0	0
Myocardial infarction	0	0	0	0	0	0
Stroke	0	0	0	0	0	0
Hospitalisation	3[d](7)	1[e](2)	0	0	3[f](7)	3[g](6)
Sleepiness						
Driving	1 (2)	3 (6)	1 (2)	0	0	2 (4)
Childcare	0	3 (6)	1 (2)	0	0	0

[a]Baseline questionnaire asks about occurrence of adverse events over preceding 6 months. [b]Week-3 questionnaire asks about sleepiness in the preceding 2 weeks (that is, from time of treatment initiation). [c]6-month questionnaires asks about sleepiness in the preceding 6 months (that is, the duration of the trial). [d]Panic attack, faint, pacemaker insertion. [e]MRI, deafness, and loss of balance. [f]Finger surgery, knee replacement, gallstones. [g]Broken arm, ankle surgery, pneumonia.

no obvious differences between groups over time. Statistical testing was not performed because of the small number of events (Table 5).

DISCUSSION

Summary

The simplified sleep restriction (SSR) intervention delivered over two brief visits by a GP was effective in improving primary insomnia over 6 months, compared with modified sleep hygiene advice alone. There were improvements in patients' perceptions of sleep quality and fatigue, and objectively measured sleep efficiency.

The difference in change of the PSQI score between participants in the SSR and control groups over 6 months was statistically significant, with the intervention group improving by an average of 3.94 PSQI points and 6.48 ISI points. An improvement of 3 PSQI points and 6 ISI points are considered clinically significant improvements in primary insomnia.[19,37] The clinical meaningfulness of the results is also demonstrated by 67% (28 out of 42) in the SSR group experiencing insomnia remission or treatment response at 6 months compared with 41% (20 out of 49) in the control group (NNT = 4, 95% CI = 2.0 to 19.0). The adjusted odds of getting an insomnia remission or treatment response for those in the SSR group was 2.7 times more likely (95% CI = 1.12 to 6.48) than for those in the control group.

There were no statistically significant differences between groups for sleep efficiency or sleep-onset latency as measured by sleep diary, or for wake after sleep-onset and total sleep time measured by both actigraphy and sleep diary. The reason for this is not entirely clear. Possibly, measures of global sleep quality such as the PSQI and the ISI are more sensitive to change, or represent a more meaningful reflection of a subjective insomnia complaint than minutes spent asleep or awake as recorded by a sleep diary or actigraphy.

Strengths and limitations

Strengths of this study included recruitment from general practice and delivery of the intervention by a GP. Although the study GP had an interest in insomnia, no specialised training in behavioural sleep medicine was undertaken. Instructions were delivered within the time frame of two slightly extended GP consultations meaning the time and expense for both patient and practitioner may be realistic for primary care. The written sleep prescription and the sleep self-adjustment algorithm were two novel components, which may have enhanced adherence. While standardised delivery of the intervention by one GP ensured good fidelity of the intervention, further research is needed to assess the generalisability of this effect when delivered by a wide range of GPs.

Limitations included a large number of exclusion criteria to define a primary insomnia population. Future trials should consider having fewer exclusion criteria to extend the generalisability of the results. Information regarding socioeconomic status, education, and literacy levels was not collected. This may also limit the generalisability of the results. Most follow-up outcome assessments were not blinded. However, the use of objective measures where possible, countersigning digital data readouts and self-report questionnaires, was used to minimise the risk of assessment bias. As insomnia is a chronic condition, a longer follow-up time would have been informative about the durability of treatment effect. Polysomnography was not used to screen participants; therefore it is possible that those who did not respond to the sleep restriction intervention may have been suffering from obstructive sleep apnoea, although attempts were made to screen for this using interviews and physical examination.

The outcomes used in this trial were those recommended for insomnia trials.[28] With multiple outcomes there is a risk of a type 1 error. However, only two primary

outcomes were defined, both of which found significant improvement, so type 1 error is unlikely. As sample size calculations were not carried out on the basis of all the outcomes, the trial may have been underpowered to detect small differences as statistically significant in outcomes such as the sleep diary measures.

Comparison with existing literature
The current study found slightly lower treatment response rates than were seen in the pilot trial, which involved volunteers recruited by advertisement, who may have been more motivated than those routinely screened in primary care.

The results are consistent with other research into brief interventions for insomnia. In the study by Edinger and Sampson,[20] participants attended two individual 25-minute sessions and were followed up after 3 months. The authors found significant improvements compared with control in awakenings after sleep onset and sleep efficiency measured by sleep diaries, as well as insomnia symptoms measured by the Insomnia Symptom Questionnaire. However, this was a small study (n = 20) and, in contrast to most other insomnia research trials, consisted mostly of males (90%), which may limit the generalisability. In the study by Espie et al[21] participants attended five group sessions and were followed up after 6 months. Significant improvements in wake after sleep onset (measured by actigraphy) were found compared with control.

The results found in this trial were also similar (but of smaller magnitude) to those found by Buysse et al,[19] who compared sleep restriction therapy plus stimulus control (brief behavioural treatment for insomnia) to an 'information only' control; although follow-up was only 6 weeks.

Although not all outcome measures improved significantly, Aikens and Rouse[38] suggested that patients may be satisfied by an improved functional outcome even if their sleep is not perfectly normalised by treatment. When viewed from this perspective, the current trial demonstrated that SSR was superior to control on several measures of importance including improved global sleep quality, reduced insomnia severity, and reduction in daytime fatigue.

Implications for research and practice
This trial showed that SSR can produce clinically meaningful improvements in insomnia symptoms at 6 months. It has the potential for primary care delivery (by a GP or nurse) to a significant number of people who have chronic primary insomnia and are seen in general practice. Treating insomnia could improve quality of life and potentially reduce associated morbidity.[39] Patients who have an inadequate response could still be referred for specialist assessment if desired. Future research should also examine delivery within the real-world practice setting, and include those with comorbid insomnia. Larger trials could assess whether the use of SSR also reduces the use or need for hypnotic medication.

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