Psychological treatment for insomnia in the management of long-term hypnotic drug use: a pragmatic randomised controlled trial

Kevin Morgan, Simon Dixon, Nigel Mathers, Joanne Thompson and Maureen Tomeny

SUMMARY

Objective: *To evaluate the clinical and cost impact of providing cognitive behaviour therapy (CBT) for insomnia (comprising sleep hygiene, stimulus control, relaxation and cognitive therapy components) to long-term hypnotic drug users in general practice.*

Design: *A pragmatic randomised controlled trial with two treatment arms (a CBT treated 'sleep clinic' group, and a 'no additional treatment' control group), with post-treatment assessments commencing at 3 and 6 months.*

Setting: *Twenty-three general practices in Sheffield, UK.*

Participants: *Two hundred and nine serially referred patients aged 31–92 years with chronic sleep problems who had been using hypnotic drugs for at least 1 month (mean duration = 13.4 years).*

Results: *At 3- and 6-month follow-ups patients treated with CBT reported significant reductions in sleep latency, significant improvements in sleep efficiency, and significant reductions in the frequency of hypnotic drug use (all* $P<0.01$*). Among CBT treated patients SF-36 scores showed significant improvements in vitality at 3 months (*$P<0.01$*). Older age presented no barrier to successful treatment outcomes. The total cost of service provision was £154.40 per patient, with a mean incremental cost per quality-adjusted life-year of £3416 (at 6 months). However, there was evidence of longer term cost offsets owing to reductions in sleeping tablet use and reduced utilisation of primary care services.*

Conclusions: *In routine general practice settings, psychological treatments for insomnia can improve sleep quality and reduce hypnotic consumption at a favourable cost among long-term hypnotic users with chronic sleep difficulties.*

Keywords: *cognitive behaviour therapy; insomnia, sleep; randomised controlled trials; hypnotics; cost-utility.*

K Morgan, PhD, professor of gerontology, Loughborough University, Loughborough; S Dixon, MSc, lecturer in health economics, University of Sheffield, Sheffield; N Mathers, MB ChB, professor of general practice; J Thompson, MSc, research assistant, University of Sheffield, Sheffield; M Tomeny, D Clin Psych, consultant clinical psychologist, Nottinghamshire Healthcare Trust, Mansfield.

Address for correspondence

Professor K Morgan, Sleep Research Centre, Department of Human Sciences, Loughborough University, Leicestershire LE11 3TU. E-mail: k.morgan@lboro.ac.uk

Submitted: 12 September 2002; Editor's response: 28 April 2003; final acceptance: 3 September 2003.

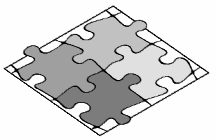
Introduction

CHRONIC insomnia is both frequently reported and widely treated in general practice,[1] where hypnotic drugs are the treatment of choice.[1,2] As a result, while hypnotic therapy beyond 3–4 weeks is widely regarded as clinically undesirable,[3,4] long-term use remains common in primary care settings.[2,5] This mismatch between the needs of patients with chronic sleep problems, and the short-term value of hypnotic drug therapy could be addressed by cognitive behaviour therapy (CBT) for insomnia. In clinical trials cognitive behavioural treatments have produced lasting improvements in sleep quality among 70–80% of treated patients,[6,7] and have proved effective in supporting hypnotic reduction and withdrawal among selected chronic users.[8] However, most of this research has been conducted by sleep specialists working in secondary care settings. Little is known about the clinical effectiveness or cost utility of CBT for insomnia when delivered in routine primary care settings by non-sleep specialists to typical general practice patients.[7] In the UK the need to develop services in this area has recently been emphasised by the National Service Frameworks (NSFs) for Mental Health[9] and Older People,[10] both of which emphasise the need for benzodiazepine prescribing to meet clinical guidelines. In medicines-related guidelines relevant to all NSFs the Department of Health recommends that primary care agencies should both invite patients to 'come off' long-term hypnotics and provide support for them to do so.[11] Psychological (cognitive behavioural) approaches to sleep management appear well placed to deliver this support. However, a major factor inhibiting the wider provision of psychological interventions for insomnia in primary care is the lack of an evaluated and fully costed service delivery model. Indeed, in contrast to the growing research literature addressing the efficacy of CBT treatments for insomnia,[7] relatively little research attention has been paid to issues of service delivery, particularly the issues of who should deliver the treatments, and how such treatments are best integrated within existing primary care structures.

In the present study, therefore, we evaluated the clinical effectiveness and cost utility of a 'sleep clinic' offering cognitive behaviour therapy to long-term (1 month) hypnotic users with chronic insomnia in general practice. This pragmatic trial addressed two key research questions:

- Can CBT treatments for insomnia be delivered effectively in routine general practice settings using existing primary care staff?
- Can effective psychological treatments for insomnia promote significant and sustained reductions in drug consumption among long-term hypnotic users?

HOW THIS FITS IN



What do we know?

Long-term benzodiazepine drug use represents a significant burden on primary care resources. However, while drug reduction and/or withdrawal programmes have typically emphasised anxiety management, most benzodiazepines are now prescribed as hypnotics.

What does this paper add?

No previous study has examined the use of psychological treatment for insomnia as a means for improving sleep quality and thereby reducing the need for hypnotic drugs in primary care. In the present study conducted among long-term hypnotic users with chronic sleep problems, psychological treatment for insomnia delivered in routine general practice settings was associated with improved sleep quality, reduced drug consumption, and cost advantages.

Method

Participants

The study was approved by the North Sheffield Research Ethics Committee. General practices were eligible to participate if they were not currently running a benzodiazepine reduction programme and were able to provide a suitable room for psychological treatment. From 96 general practices in the Sheffield area we randomly selected 42, and of these 23 met the study criteria and agreed to participate (Figure 1). Practice participation was divided into two phases: a 'sleep clinic' (SC) phase; and a control (C) phase, with phase order (SC-C or C-SC) randomised across practices. This division of phases had the important effect of precluding the need for 'control-only' practices, as would have been the case had practices been randomly assigned to either the clinic or control conditions. In this way all practitioners were provided with an incentive to participate (the incentive being access to the SC phase). Patients were eligible for the trial if they: had been consuming hypnotics for at least the previous month; were not taking neuroleptic medication; were requesting or due for a repeat hypnotic prescription; and were able to travel to the surgery for appointments. To ensure adequate representation of older patients (the most likely consumers of long-term hypnotics), and to exclude those (generally younger adults) whose sleep disturbance is often lifestyle-related, the selection criteria also included a lower age of 30 years, but no upper age limit.

Invitations to participate in the study were made to consecutive patients by the general practitioner (GP) during a consultation or by letter before the issue of a repeat prescription. Following this, patients were contacted by project staff, who repeated the invitation and made a first appointment. Patients recruited during the control phase were visited at home and asked to complete baseline and follow-up assessments 'In order to gain a better understanding of your sleep problem and how it responds to treatment'. Patients recruited during the SC phase were offered six appointments with '… a practice counsellor with special training in the treatment of insomnia'. At recruitment, all patients received their prescription

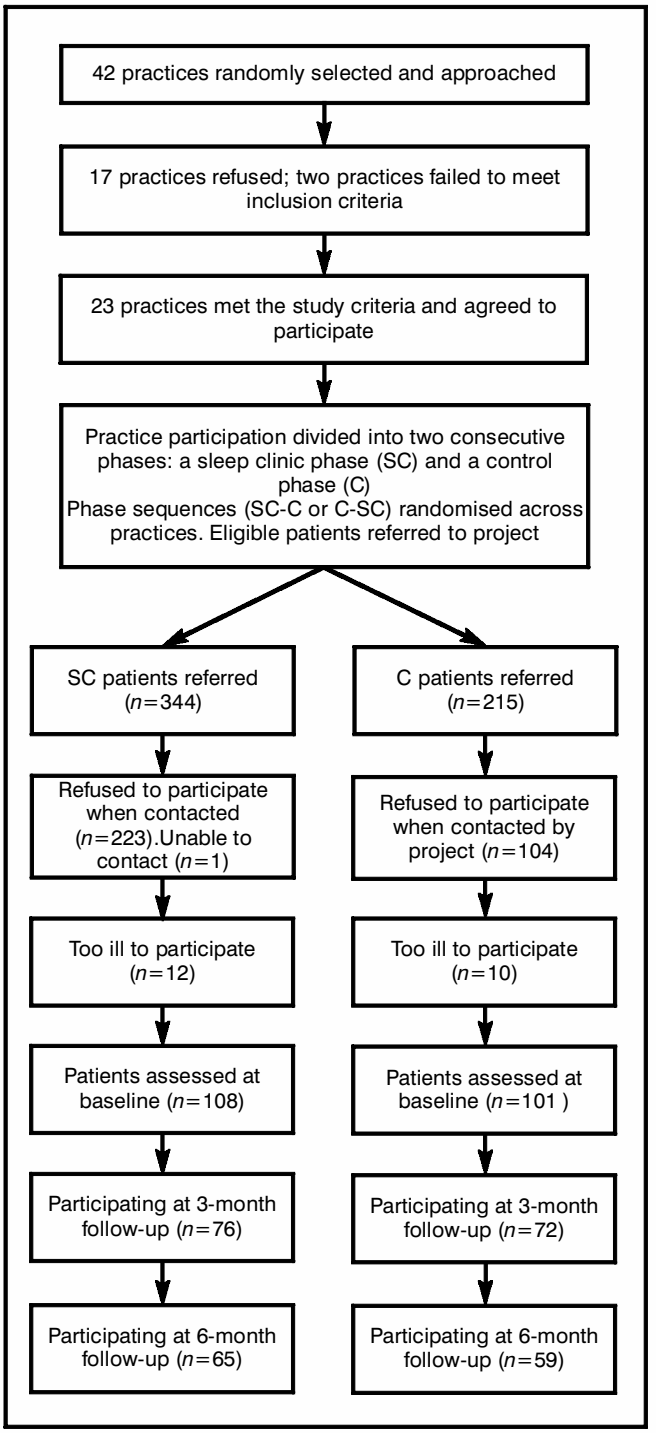


Figure 1. Recruitment and progress of patients through the trial.

hypnotics as usual. While it was made clear to SC patients that the aim of treatment was to improve their sleep quality, they were also informed that psychological therapy '… can help to reduce the number of sleeping tablets you take, and may, if you choose, replace your sleeping tablets altogether'. For patients who wished to discontinue hypnotics, a programme of tapered withdrawal was agreed with the GP. All patients were recruited between January 1999 and August 2000. To allow for the late return of follow-up questionnaires, 6-month assessments continued to April 2001.

Table 1. Characteristics of patients completing baseline assessments.

Characteristic	Clinic group	Control group	*P*-value
Number at baseline	108	101	
Men	38	30	0.46[a]
Women	70	71	
Mean age (range)	63.3 (31–89)	67.7 (39–92)	0.02[b]
Mean age at onset of sleep problem: years (SD)	51.3 (15.1)	49.9 (16.1)	0.19[b]
Mean duration of hypnotic drug use: years (SD)	12.5 (10.2)	14.3 (11.2)	0.001[b]
Per cent consuming hypnotics continuously (nightly)	59.3	56.4	0.68[a]
Global PSQI Score	12.9 (3.4)	12.3 (3.2)	0.25[b]
HADS Anxiety Score: mean (SD)	9.8 (4.6)	8.5 (4.7)	0.04[b]
HADS Depression Score: mean (SD)	6.8 (4.2)	6.1 (4.5)	0.24[b]

[a]Significance of Pearson χ^2. [b]Significance of independent samples *t*-value. SD = standard deviation.

Cognitive behaviour therapy

Psychological treatment was provided by experienced primary care counsellors following 40 hours of classroom-based training in cognitive-behavioural approaches to insomnia management. The counsellors were recruited from outside the Sheffield area, and worked exclusively for this project. Treatment sessions were offered on a weekly basis within the surgery of the referring doctor at a time convenient for the patient. Most patients were seen within 2 weeks of referral. Throughout the trial counsellors received fortnightly clinical supervision from a consultant clinical psychologist (MT). Psychological treatment was based on existing protocols[12,13] and distributed over six 50-minute sessions addressing assessment, information and sleep hygiene, stimulus control procedures, relaxation procedures, cognitive therapy, and review and discharge, respectively. (For further details see Supplementary Box 1.) Hand-outs summarising key therapeutic points were provided after sessions 2–5, and an audiotape of relaxation instructions was provided after session 4.

Assessment and outcome measures

Baseline assessments, completed at home for the control group and in the first session for the SC group, included: the Pittsburgh Sleep Quality Index (including global and sub-scale or 'component' scores);[14] the SF-36;[15] the Hospital Anxiety and Depression Scale;[16] a health-related events schedule (covering contacts with primary and secondary care services); a sleep history questionnaire; and a 7-night hypnotic drug record (recording drug use for consecutive nights). Follow-up assessments commenced at 3 and 6 months, and included all baseline measures except the Hospital Anxiety and Depression Scale, and the sleep history questionnaire. Trial outcomes were: Pittsburgh global scores (range 0–21 with lower scores indicating reduced severity of sleep disturbance); the Pittsburgh component scores 'total sleep time' (estimated actual sleep per night), 'sleep efficiency' (percentage of time in bed spent asleep), and 'sleep latency' (time taken to get to sleep); SF-36 scores; frequency of hypnotic drug use (as a percentage of baseline value); healthcare costs and cost utility. Additional outcomes included the number of hypnotic drug-free nights per week, and the mean hypnotic dose (expressed as a percentage of the maximum dose prescribed).

Costs were estimated from the NHS perspective and covered counsellor sessions, hypnotic drug use, and all GP and other primary care contacts. Hospitalisations associated with benzodiazepine use are very rare and are not considered here. We estimated the cost of a counsellor session at £26.25, which included salary, on-costs, training, supervision, travel, clerical support, equipment and capital costs. Other unit costs were taken from standard sources.[17,18] Health-related utility, and hence quality-adjusted life-years (QALYs) were measured using the SF-6D, which is calculated using a sub-set of questions from the SF-36.[19]

Statistical analysis

Analyses included all available data from SC patients regardless of adherence. Outcomes were analysed as change scores (baseline minus follow-up) and compared using general linear models adjusted for baseline score, age and GP practice. Sleep efficiency scores and hypnotic-free nights per week were non-normally distributed and analysed using the Kruskal–Wallis test. Change in SF-36 and SF-6D scores was measured by area under the curve defined by the scores at baseline, 3 and 6 months, net of the baseline score.[20] A further analysis of costs and health related utility was undertaken that included withdrawals by inputing missing data through last observation carried forward. For the trial outcomes the minimum level of statistical significance was set at 0.01; for all remaining comparisons alpha was set at 0.05. Standardised differences (clinic versus control) calculated during the trial indicated that the present sample sizes (at 3 and 6 months) would deliver adequate (>80%) statistical power.

Results

Recruitment and patient characteristics

Of 537 patients invited to join the trial, 209 (38.9%) agreed to take part (SC group = 108; control group = 101; Figure 1). Since actual consultations before the issue of a repeat prescription proved to be the exception rather than the rule, most patients were initially invited by letter. Refusal was not significantly associated with sex ($\chi^2 = 3.02$, degrees of freedom [df] = 1, $P = 0.08$), but did increase significantly with age across the tertile groupings 31–61 years, 62–75 years, and 75+ years ($\chi^2 = 7.02$, df = 2, $P = 0.03$). All recruited patients met DSM IV criteria for insomnia.[21] Mean age ($P = 0.02$) and duration of hypnotic drug use ($P = 0.001$) were significantly higher, and

Table 2 Main sleep quality outcome measures at baseline and follow-up (values compared in multivariate ANOVA models unless otherwise stated).

	Baseline mean (SD)		3-month follow-up mean change (*n*)			6-month follow-up mean change (*n*)		
	Clinic group *n* = 108	Control group *n* = 101	Clinic group	Control group	*P*-value	Clinic group	Control group	*P*-value[a]
Outcome measure (continuous)								
Pittsburgh Sleep Quality Index (range 0–21)[a]	12.8 (3.4)	12.3 (3.2)	2.8 (73)	-0.9 (72)	0.002	1.9 (65)	-1.4 (57)	0.04
Sleep latency (minutes)[a]	55.9 (49.1)	55.6 (47.3)	27.7 (73)	3.5 (72)	<0.001[b]	29.6 (65)	1.7 (57)	0.003[b]
Sleep efficiency score[a]	2.2 (1.0)	1.9 (1.2)	0.7 (73)	-0.1 (72)	<0.001[d]	0.7 (65)	-2.4 (57)	<0.001[d]
Total sleep time (hours)[c]	6.2 (1.2)	5.6 (1.3)	-0.6 (73)	-0.1 (72)	0.04	-0.6 (65)	-0.1 (57)	0.18
Hypnotic-free nights/week[c]	1.6 (2.3)	1.8 (2.3)	-2.2 (76)	-0.4 (75)	<0.001[d]	-2.4 (62)	-0.2 (62)	<0.001[d]
Mean hypnotic dose (as proportion of maximum dose prescribed)[a]	0.90 (0.19)	0.96 (0.13)	-7.9 (54)	-4.2 (67)	0.21	-4.4 (48)	1.4 (57)	0.41
Outcome measure (categorical)								
Low frequency hypnotic use (50% of baseline) at follow-up: *n* yes (% yes)			36 (47.4)	13 (17.3)	<0.001[e]	39 (54.2)	11 (17.7)	<0.001[e]
Continuous (nightly) hypnotic use: *n* yes (% yes)	64 (59.3)	57 (56.4)	23 (30.3)	44 (58.7)	<0.001[e]	24 (33.3)	39 (62.9)	0.001[e]
Zero hypnotic use during assessment period: *n* yes (% yes)	2 (2.1)	7 (6.5)	22 (29)	8 (10.7)	0.005[e]	24 (33)	5 (8.1)	<0.001[e]

[a]Positive change scores indicate improvement. [b]Data log transformed for ANOVAs. [c]Negative change scores indicate improvement. [d]Kruskal-Wallis test. [e]Pearson χ^2. SD = standard deviation.

mean anxiety scores significantly lower ($P = 0.04$) in the control group (Table 1). Other indices of sleep history, including mean age at onset of problem ($P = 0.19$), levels of continuous hypnotic drug use ($P = 0.93$), global Pittsburgh scores ($P = 0.25$), and depression scores ($P = 0.24$) showed no significant differences between the groups at baseline (Table 1).

Clinic attendance and follow-up

Most SC patients (66%; 71/108) attended six sessions. A further 16% (17/108) attended three to five sessions, while 19% (20/108) attended two sessions only. Follow-up data were provided by 70% (76/108) of clinic patients and 71% (72/101) of control patients at 3 months, and by 60% (65/108) of clinic patients and 57% (58/101) of control patients at 6 months. In the outcome data reported here, variations in these group sizes are owing to partially completed assessments returned by a minority of patients.

Clinical outcomes: 3 months

At 3-month follow-up (Table 2) SC patients showed a significant improvement in global Pittsburgh scores (mean difference = -3.8, 95% confidence interval [CI] = -4.8 to -2.8, $P = 0.002$) reflecting reductions in sleep latency (mean difference = -24.1, 95% CI = -37.2 to -11.1, $P<0.001$) and improvements in sleep efficiency (mean difference = -0.9, 95% CI = -1.2 to -0.6, $P<0.001$). Increases in total sleep time (mean difference = 0.5, 95% CI = 0.1 to 0.8, $P = 0.04$) failed to reach the criterion level of significance. SC patients also reported marked reductions in hypnotic drug use. For the SC and control groups, respectively, 47.4% (36/76) versus 17.3% (13/75) reported 'low frequency' use (difference = 0.30, 95% CI = 0.16 to 0.44, $P<0.001$); 28.9% (22/76) versus 10.7% (8/75) reported zero hypnotic consumption over the 7-day follow-up assessment period (difference = 0.18, 95% CI = 0.06 to 0.31, $P = 0.005$); and 30.3% versus 58.7% reported continuous hypnotic drug use during the assessment period (difference = 0.59, 95% CI = 0.13 to 0.44, $P = 0.001$). The number of drug-free nights showed a reciprocal and significant increase among SC patients (mean difference = 1.8, 95% CI = 1.1 to 2.6, $P<0.001$), but the mean hypnotic dose consumed showed no significant difference between the groups ($P = 0.21$). Consistent with improvements in sleep quality, scores on the SF-36 dimension 'vitality' improved significantly at 3-month follow-up ($P<0.001$). (For further data see Supplementary Table 1.)

Clinical outcomes: 6 months

Within the SC group significant improvements in sleep latency (mean difference = -27.9, 95% CI = -43.4 to -12.6, $P = 0.003$) and sleep efficiency (mean difference = -1.0, 95% CI = -1.3 to -0.6, $P = 0.001$) were maintained at 6 months (Table 2). However, differences in global Pittsburgh scores did not achieve the 1% level of significance (mean difference = -3.3, 95% CI = -4.7 to -1.8, $P = 0.04$). Significant reductions in hypnotic use were maintained at the 6-month follow-up. For the SC and control groups, respectively, 54.2% (39/72) versus 17.7% (11/62) reported low frequency use (difference = 0.37, 95% CI = 0.22 to 0.51, $P<0.001$); 33.3% (24/72) versus 8.1% (5/62) reported zero hypnotic use during the assessment week (difference = 0.25, 95% CI = 0.12 to 0.38, $P<0.001$); and 33.3% (24/72) versus 62.9% (39/62) reported continuous

Table 3.Costs and health related utility from baseline to 3-month and 6-month follow-ups (£1999–2000).

	3-month follow-up					6-month follow-up				
	Clinic group		Control group			Clinic group		Control group		
Source of cost	Mean (SE)	*n*	Mean (SE)	*n*	*P*-value	Mean (SE)	*n*	Mean (SE)	*n*	*P*-value
Primary care costs[a]	44.3 (10.0)	71	77.5 (13.1)	73	0.09	106.6 (21.6)	65	133.4 (30.4)	57	0.55
Prescription costs	6.7 (0.6)	71	7.6 (0.8)	73	0.41	11.1 (1.2)	65	13.7 (1.6)	57	0.28
Counsellor costs	154.4 (3.3)	71	-	-	-	154.7 (3.4)	65	-	-	-
Total costs[b]	198.7 (9.6)	71	97.9 (12.6)	73	<0.01	272.4 (21.7)	65	142.6 (30.5)	57	<0.01
Health related utility[c]						0.024[d] (0.01)	64	-0.014 (0.02)	59	0.13
Including withdrawals										
Total costs						263.6 (16.1)	108	162.4 (21.1)	101	<0.01
Health related utility						0.007[d] (0.01)	108	-0.014 (0.01)	101	0.26

[a]Includes GP surgery visits, GP domiciliary visits, practice nurse and district nurse contacts. [b]Columns do not sum to the total as each is estimated using separate analyses of variance. [c]Measured by area under the curve relative to baseline. [d]Positive values indicate improvements over baseline. SE = standard error.

hypnotic drug use during the assessment week (difference = 0.29, 95% CI = 0.13 to 0.46, $P<0.001$). Again, the mean dose of hypnotics consumed did not differ between the groups ($P = 0.41$). While two SF-36 dimensions approached significance: 'physical functioning' ($P = 0.04$) and 'mental health' ($P = 0.02$), neither met the criterion alpha level. (For further data see Supplementary Table 1.)

Cost outcomes

The mean cost of the counselling was £154.40 per patient (Table 3). However, reductions in primary care utilisation among the clinic group at 3 months, and sustained reductions in hypnotic drug use (Table 3), suggest longer-term cost offsets. At 6 months the mean incremental cost per QALY was £3416. Inclusion of withdrawals through data imputation pointed to a reduction in treatment effect, and produced a mean incremental cost per QALY of £4819 (Table 3).

Discussion

Summary of main findings

Sleep quality. Despite the long-term prescribing of drugs ostensibly to improve sleep quality, all patients referred into this trial met DSM IV criteria for insomnia. It seems reasonable to conclude at the outset, therefore, that hypnotic drugs appear to offer poor value in the management of chronic insomnia. Evidence from the present study indicates that appropriately structured and supervised psychological therapy for insomnia can be effectively delivered in routine general practice settings by non-specialists. Among patients reporting chronic sleep difficulties, long-term hypnotic consumption, and high levels of comorbidity, cognitive behavioural treatment was associated with significant improvements in sleep latency, sleep efficiency and global sleep quality. Most improvements in sleep quality were maintained from the 3- to the 6-month follow-up. Sleep latency in particular showed a substantial improvement, reducing by an average of 27.7 minutes at 3 months and 29.6 minutes at 6 months. Such a magnitude of change meets widely accepted criteria for clinical significance (a post treatment sleep latency of ≤30 minutes with a reduction in sleep latency of at least 10 minutes).[22]

Hypnotic drug use. Low-frequency hypnotic use (defined as ≤50% of baseline drug-use frequency) was achieved by 47.4% of clinic patients at 3 months, and 54.2% at 6 months. Two other trends are clear from the results. First, the proportion of continuous (nightly) drug users declined sharply within the clinic group, from 59.3% at baseline, to 30.3% at 3 months (difference = 0.28, 95% CI = 0.13 to 0.44), and 33.3% at 6 months (difference = 0.3, 95% CI = 0.13 to 0.46). These changes reflect a significant post-treatment shift towards intermittent drug use among the most hypnotic-dependent patients; that is, continuous users. Importantly, this 'shift' was not associated with compensatory dose increases, with the mean hypnotic dose consumed remaining similar in both groups at 3- and 6-month follow-ups (Table 2). Second, the substantially increased proportions of clinic patients reporting zero drug use at 3- and 6-month follow-ups (Table 2) strongly suggests that many patients discontinued hypnotic drug use altogether. Since no direct pressure was placed on clinic patients to discontinue hypnotics, the present trial emphasises the value of addressing *sleep* needs when dealing with hypnotic dependency. Given that the present trial recruited a proportion of patients showing low levels of treatment adherence, it is likely that targeting the more motivated patients could produce greater levels of drug reduction and total withdrawal.

This overall profile of treatment outcomes, particularly the marked improvement in sleep latency, is consistent with the findings of two trials evaluating CBT for insomnia reported while the present study was being carried out (and both using self-selected patients showing relatively low levels of comorbidity). In the first of these Morin *et al*[12] demonstrated the effectiveness of CBT insomnia treatments when delivered to elderly patients in specialised sleep medicine facilities. More recently Espie *et al*[13] reported significant and sustained improvements in sleep quality among a broad age-range of insomniacs following group CBT sessions delivered by health visitors in general practice settings. Collectively, then, these findings serve to emphasise the potential value of CBT treatments for insomnia in both promoting sleep quality, and in addressing the still unresolved issue of chronic hypnotic dependence in general practice.

Cost effectiveness

As a professional group, primary care counsellors were selected to deliver treatment in the present study because of their experience in providing 'talking therapies', and because of their growing availability throughout general practice in the UK.[23] The present clinical and economic results indicate that service delivery by counsellors is practical, effective and affordable. At 6 months the mean incremental cost per QALY of £3416 is well within the limits of cost-effectiveness currently thought acceptable in the UK.[24] This result is insensitive to changes in unit costs and inclusion of study withdrawals. With appropriate investment in training and supervision, targeted cognitive behaviour therapy for insomnia could be made widely available within existing primary care services.

Limitations of the present study

As a pragmatic trial conducted among patients known to be resistant to change in their drug regime, the present results should be cautiously interpreted, and the possibility of selection and attrition bias recognised. Of the 17 practices that refused (Figure 1), most cited workload and/or current satisfaction with hypnotic drug management as the main reason. Fifty-nine per cent of eligible patients declined to participate in the trial (65% of those referred to the SC arm, and 48% of those referred to the control arm). Suspicion that involvement would threaten future hypnotic drug prescribing, particularly among those invited into the SC arm, emerged as a typical, and wholly expected concern of many patients. As a result, refusals tended to be highest in the SC arm. While inability to travel to the surgery may, in theory, have biased the clinic sample towards greater mobility and health, no systematic differences emerged between the groups at baseline on measures reflecting physical functioning.

Factors systematically associated with attrition have been identified. Levels of comorbidity were high in both groups (as indexed by SF-36 scores). It is unsurprising, therefore, that poor overall health, acute illness episodes, and hospitalisations were the most commonly cited reasons for dropout (two clinic patients died before the 6-month follow-up). These relationships between health status and attrition were confirmed in a series of multivariate models reported elsewhere, which showed that in both groups dropout was most associated with lower health status at baseline.[25] However, clinic patients who withdrew before 3 months did attend significantly fewer SC sessions, indicating lower adherence even during treatment.

Recommendations for primary care

Targeted cognitive behaviour therapy for insomnia should be considered by primary care commissioners and practitioners when addressing the insomnia management needs of patients with longer term sleep difficulties. Such initiatives could utilise and develop the skills of existing primary healthcare professionals.

References

1. Simon GE, VonKorff M. Prevalence, burden, and treatment of insomnia in primary care. *Am J Psychiatry* 1997; **154(10):** 1417-1423.
2. Ohayon MM, Caulet M, Priest RG, Guilleminault C. Psychotropic medication consumption patterns in the UK general population. *J Clin Epidemiol* 1998; **51(3):** 273-283.
3. Lader M. Benzodiazepines — a risk-benefit profile. *CNS Drugs* 1994; **1(5):** 377-387.
4. Kramer M. Hypnotic medication in the treatment of chronic insomnia: non nocere! Doesn't anyone care? *Sleep Med Rev* 2000; **4(6):** 529-541.
5. Morgan K, Clarke D. Longitudinal trends in late-life insomnia: implications for prescribing. *Age Ageing* 1997; **26:** 179-184.
6. Morin CM, Culbert JP, Schwartz SM. Nonpharmacological interventions for insomnia: a meta-analysis of treatment efficacy. *Am J Psychiatry* 1994; **151:** 1172-1180.
7. Morin CM, Hauri PJ, Espie CA, *et al*. Nonpharmacologic treatment of chronic insomnia. *Sleep* 1999; **22:** 1134-1156.
8. Morin CM, Colecchi CA, Ling WD, Sood RK. Cognitive-behavior therapy to facilitate benzodiazepine discontinuation among hypnotic-dependent patients with insomnia. *Behav Ther* 1995; **26(4):** 733-745.
9. Department of Health. *Mental health modern standards and service models: A national service framework for mental health.* London: HMSO, 2000.
10. Department of Health. *National service framework for older people.* London: HMSO, 2001.
11. Department of Health. *Medicines and older people: implementing the medicines-related aspects of the NSF for older people.* London: HMSO, 2001.
12. Morin CM, Colecchi C, Stone J, *et al*. Behavioral and pharmacological therapies for late-life insomnia - a randomized controlled trial. *JAMA* 1999; **281:** 991-999.
13. Espie CA, Inglis SJ, Tessier S, Harvey L. The clinical effectiveness of cognitive behaviour therapy for chronic insomnia: implementation and evaluation of a sleep clinic in general medical practice. *Behav Res Therap* 2001; **39:** 45-60.
14. Buysse DJ, Reynolds CF III, Monk TH, *et al*. The Pittsburgh sleep quality index for psychiatric practice and research. *Psychiatry Res* 1989; **28:** 193-213.
15. McHorney CA, Ware JE, Lu JFR, Sherbourne CD. The MOS 36-item short-form health survey (SF-36) III. Test of data quality, scaling assumptions, and reliability across diverse patient groups. *Med Care* 1994; **32:** 40-66.
16. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand* 1983; **67:** 361-370.
17. British Medical Association and the Royal Pharmaceutical Society of Great Britain. *British National Formulary.* London: BMA and The Pharmaceutical Press, 2000.
18. Netten A, Curtis L. *Unit costs of health and social care*. Canterbury: PSSRU, 2000.
19. Brazier J, Roberts J, Deverill M. The estimation of a preference-based measure of health from the SF-36. *J Health Econ* 2002; **21:** 271-292.
20. Matthews JNS, Altman DG, Campbell MJ, Royston P. Analysis of serial measurements in medical research. *BMJ* 1990; **300:** 230-235.
21. American Psychiatric Association. *Diagnostic and statistical manual of mental disorders: DSM-IV.* Washington, DC: American Psychiatric Association, 1994.
22. Riedel BW, Lichstein KL, Dwyer WO. Sleep compression and sleep education for older insomniacs: self-help versus therapist guidance. *Psychol Aging* 1995; **10:** 54-63.
23. Sibbald B, Addington-Hall J, Brenneman D, Freeling P. Counsellors in English and Welsh general practices: their nature and distribution. *BMJ* 1993; **306:** 29-33.
24. Raftery J. NICE: faster access to modern treatments? Analysis of guidance on health technologies. *BMJ* 2001; **323:** 1300-1303.
25. Morgan K, Thompson J, Tomeny M, *et al*. Predicting longer-term outcomes following psychological treatment for hypnotic dependent chronic insomnia. *J Psychosom Res* 2003; **54:** 21-29.

Acknowledgements

We thank Anne Truefitt and Joan Davies who delivered the cognitive-behavioural treatment programme, Professor Colin Espie for technical advice, and Beth Fawcett, who provided secretarial support throughout the trial. We also thank the GPs, practice staff and patients who supported this research. This research was funded by the NHS Health Technology Assessment Programme (project 95/30/02). The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the NHS executive.

Supplementary information

Additional information accompanies this paper at http://www.rcgp.org.uk/rcgp/journal/supp/index.asp