*Health Technology Assessment* 2004; Vol. 8: No. 8

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February 2004

**Health Technology Assessment**
**NHS R&D HTA Programme**



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# Psychological treatment for insomnia in the regulation of long-term hypnotic drug use

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**Declared competing interests of authors:** none

Published February 2004

This report should be referenced as follows:

Morgan K, Dixon S, Mathers N, Thompson J, Tomeny M. Psychological treatment for insomnia in the regulation of long-term hypnotic drug use. *Health Technol Assess* 2004;**8**(8).

*Health Technology Assessment* is indexed in *Index Medicus*/MEDLINE and *Excerpta Medica*/EMBASE.

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The research reported in this monograph was funded as project number 95/30/02.

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ISSN 1366-5278



Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.
Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.

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# Abstract

## Psychological treatment for insomnia in the regulation of long-term hypnotic drug use

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**Objectives:** To evaluate the clinical and cost impact of providing, in routine general practice settings, a cognitive-behaviour therapy (CBT) package for insomnia to long-term hypnotic drug users with chronic sleep difficulties; and to identify factors associated with variations in clinical outcomes.
**Design:** A pragmatic cluster randomised controlled trial with two treatment arms (a CBT-treated 'sleep clinic' group, and a 'no additional treatment' control group), with post-treatment assessments starting at 3, 6 and 12 months.
**Setting:** Twenty-three general practices in Sheffield, UK.
**Participants:** In total, 209 patients (aged 31–92 years) with chronic sleep problems who had been receiving repeat hypnotic drug prescriptions for at least 1 month (mean = 13.4 years) were recruited into the trial.
**Interventions:** The intervention consisted of six 50-minute sessions as follows: introduction and sleep assessment, basic sleep hygiene, stimulus control and sleep restriction procedures, progressive relaxation, cognitive treatments, and review and discharge.
**Main outcome measures:** These included: global sleep quality [as measured by the Pittsburgh Sleep Quality Index (PSQI)], frequency of hypnotic drug use, mean dose of hypnotics consumed, health-related quality of life [as measured by the Short-Form 36 (SF-36)], NHS service costs and overall cost utility.
**Results:** At 3- and 6-month follow-ups, patients treated with CBT showed improved global PSQI scores as well as improvements in the SF-36 dimensions of vitality at 3 months and physical functioning and mental health at 6 months. CBT-treated patients also reported reductions in the frequency of hypnotic drug use compared with the control group, with many CBT-treated patients reporting zero drug use at the follow-up assessments. Clinical improvements were maintained within the CBT group at the 12-month follow-up, with PSQI scores and the frequency of hypnotic drug use continuing to show significant reductions relative to the control group. Multiple regression analyses of PSQI scores within the sleep clinic group alone indicated that the magnitude of pre- to post-treatment change in overall sleep quality was closely related to Hospital Anxiety and Depression Scale depression scores at 3-, 6-and 12-month follow-ups. In each model higher depression scores at baseline were associated with poorer treatment outcomes. No significant relationship was found between the patient's age and PSQI outcomes in any of these analyses. Within the sleep clinic group, reductions in drug use showed no significant association with the hypnotic product consumed. At the 3-month follow-up low-frequency drug use was reported by 22.9% (8/35) of temazepam users, 33.3% (5/15) of nitrazepam users and 38.9% (7/18) of zopiclone users. The total cost of service provision was £154.40 per patient (1999/2000 prices). The mean incremental cost per quality-adjusted life-year (QALY) at 6 months was £3418; this figure was insensitive to changes in costs. A simple model also showed that extending the evaluation period beyond 6 months may improve the cost-effectiveness of CBT. The incorporation of hidden costs associated with hypnotic drug treatment (e.g. accidents) also reduces the cost per QALY ratio, although to a much lesser degree.
**Conclusions:** In routine general practice settings, psychological treatment for insomnia can improve sleep quality, reduce hypnotic drug use, and improve health-

related quality of life at a favourable cost among long-term hypnotic users with chronic sleep difficulties. These positive outcomes appear robust over time, persisting for at least 1 year among the more treatment-adherent patients. While these benefits may be reduced among those patients presenting with higher levels of psychological distress, the present study clearly indicates that older age per se presents no barrier to successful treatment outcomes. Further research should assess the long-term clinical and cost-effectiveness of psychological treatments for insomnia among non-hypnotic-using patients, and establish the minimum psychological treatment input required.

# Contents

# List of abbreviations

| | |
|---|---|
| ANOVA | analysis of variance |
| BAC | British Association for Counselling |
| BACP | British Association for Counselling and Psychotherapy |
| BNF | British National Formulary |
| C | control phase |
| CAN | counsellor cancellations |
| CBT | cognitive-behaviour therapy |
| CC | counsellor contacts |
| CEAC | cost-effectiveness acceptability curve |
| CI | confidence interval |
| CMS | Counselling in Medical Settings |
| DNA | did not attend |
| DSH | deliberate self-harm |
| DSM-IV | Diagnostic and Statistical Manual of Mental Disorders |
| HADS | Hospital Anxiety and Depression Scale |
| HYP | hypnotics |
| IC | incremental costs |
| ICD-10 | International Classification of Diseases-10 |
| ICER | incremental cost-effectiveness ratio |
| IPQ | Illness Perception Questionnaire |
| MAU | multiattribute utility |
| OTC | over the counter |
| PC | non-general practitioner primary contacts |
| PHS | Psychological Health Sheffield |
| PPA | Prescription Pricing Authority |
| PSQI | Pittsburgh Sleep Quality Index |
| PSSRU | Personal Social Services Research Unit |
| QALY | quality-adjusted life-year |
| QoL | quality of life |
| RTA | road traffic accident |
| SC | sleep clinic phase |
| SD | standard deviation |
| SE | standard error |
| SF-36 | Short-Form 36 |
| SPSS | Statistical Package for the Social Sciences |

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

# Executive summary

## Objective

This study was designed: (1) to evaluate the clinical and cost impact of providing, in routine general practice settings, a cognitive-behaviour therapy (CBT) package for insomnia (comprising information, sleep hygiene, stimulus control, relaxation and cognitive therapy components) to long-term (≥ 1 month) hypnotic drug users with chronic sleep difficulties; and (2) to identify factors associated with variations in clinical outcomes.

## Methods

The study was designed as a pragmatic cluster randomised controlled trial with two treatment arms (a CBT-treated 'sleep clinic' group, and a 'no additional treatment' control group), with post-treatment assessments starting at 3, 6 and 12 months. All patients entered the trial receiving prescription hypnotic drugs.

The study was conducted within 23 general practices in Sheffield. In total, 209 patients (aged 31–92 years) with chronic sleep problems who had been receiving repeat hypnotic drug prescriptions for at least 1 month (mean = 13.4 years) were recruited into the trial.

The intervention consisted of six 50-minute sessions as follows: session 1, introduction and sleep assessment; session 2, basic sleep hygiene; session 3, stimulus control and sleep restriction procedures; session 4, progressive relaxation; session 5, cognitive treatments; session 6, review and discharge. Treatments were delivered by primary care counsellors eligible for accreditation by the British Association for Counselling and Psychotherapy.

Main outcomes included: global sleep quality [as measured by the Pittsburgh Sleep Quality Index (PSQI)], frequency of hypnotic drug use, mean dose of hypnotics consumed, health-related quality of life [as measured by the Short-Form 36 (SF-36)], NHS service costs and overall cost utility.

## Results

All patients met Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria for insomnia. At 3- and 6-month follow-ups, patients treated with CBT showed improved global PSQI scores ($p < 0.002$ and $p < 0.04$, respectively), and improvements in the SF-36 dimensions of vitality at 3 months ($p < 0.01$), and physical functioning ($p < 0.04$) and mental health ($p < 0.02$) at 6 months. CBT-treated patients also reported reductions in the frequency of hypnotic drug use (both $p < 0.001$) compared with the control group, with many CBT-treated patients (29% at 3 months and 33% at 6 months) reporting zero drug use at the follow-up assessments. Clinical improvements were maintained within the CBT group at the 12-month follow-up, with PSQI scores ($p < 0.01$) and the frequency of hypnotic drug use ($p < 0.001$) continuing to show significant reductions relative to the control group.

Multiple regression analyses of PSQI scores within the sleep clinic group alone indicated that the magnitude of pre- to post-treatment change in overall sleep quality was related to Hospital Anxiety and Depression Scale depression scores at 3-month ($n = 71$; $\beta = -0.24$, $p = 0.03$), 6-month ($n = 66$; $\beta = -0.40$, $p = 0.001$) and 12-month ($n = 60$; $\beta = -0.30$, $p = 0.02$) follow-ups. In each model higher depression scores at baseline were associated with poorer treatment outcomes. No significant relationship was found between the patient's age and PSQI outcomes in any of these analyses.

Within the sleep clinic group, reductions in drug use showed no significant association with the hypnotic product consumed. At the 3-month follow-up low-frequency drug use (defined as ≤ 50% of the baseline drug-use frequency) was reported by 22.9% (8/35) of temazepam users, 33.3% (5/15) of nitrazepam users and 38.9% (7/18) of zopiclone users ($\chi^2 = 1.61$, df = 2, $p = 0.45$).

The total cost of service provision was £154.40 per patient (1999/2000 prices). The mean incremental cost per quality-adjusted life-year (QALY) at

6 months was £3418; this figure, within a range that has previously been considered to represent acceptable value for money by NHS decision-makers, was insensitive to changes in costs (varying from £3074 to £4679 per QALY when counsellor unit costs were changed). While the incremental gain in utility was not statistically significant, when combined with the incremental cost data, the probability that the cost per QALY of treatment would be considered cost-effective if decision-makers are willing to pay less than around £12,500 per QALY, is greater than 80%. A simple model also showed that extending the evaluation period beyond 6 months is likely to improve the cost-effectiveness of CBT. The incorporation of hidden costs associated with hypnotic drug treatment (e.g. accidents) also reduces the cost per QALY ratio, although to a much lesser degree.

## Conclusions

Despite chronic hypnotic drug use ostensibly to manage persistent insomnia, patients in the trial reported very high levels of sleep disturbance and very low levels of sleep quality. In routine general practice settings, psychological treatment for insomnia can improve sleep quality, reduce hypnotic drug use, and improve health-related quality of life at a favourable cost among long-term hypnotic users with chronic sleep difficulties. These positive outcomes appear robust over time, persisting for at least 1 year among the more treatment-adherent patients. While these benefits may be reduced among those patients presenting with higher levels of psychological distress, the present study clearly indicates that older age per se presents no barrier to successful treatment outcomes.

CBT for insomnia should be considered by primary care commissioners and practitioners when implementing National Service Framework recommendations for benzodiazepine use, and when addressing the insomnia management needs of patients with longer term sleep difficulties.

## Recommendations for research

Additional research should assess:

- the clinical and cost-effectiveness of psychological treatments for insomnia when delivered to long-term hypnotic drug users as part of a targeted hypnotic drug withdrawal programme
- the long-term clinical and cost-effectiveness of psychological treatments for insomnia when delivered to non-hypnotic-using general practice patients presenting with chronic insomnia
- the minimum psychological treatment input required to achieve a clinically significant improvement in sleep outcomes among general practice patients presenting with chronic insomnia.

# Chapter 1
# Background

## Introduction

Insomnia affects between 5 and 10 per cent of the adult population[1] and is both widely reported and widely treated in general practice.[2–4] A variety of effective treatment options has been developed in recent years,[5,6] but hypnotic drugs have remained the treatment of choice in primary care settings.[7,8] In England, for example, the total volume of general practice prescriptions for hypnotics [British National Formulary (BNF 4.1.1)] showed only a modest decline from 13.6 million in 1980 to 10.6 million in 2000 (a 22% fall).[9–10] During the same period, prescriptions for anxiolytics (BNF 4.1.2) fell from 18.9 million to 5.8 million (a 69% fall).[10,11] Similar trends have been reported elsewhere in Europe.[12] As a result of these differential trajectories, since the early 1990s most prescriptions for benzodiazepines have been for hypnotic rather than for anxiolytic products. These prescribing trends clearly indicate (1) a robust demand for insomnia management among NHS patients; (2) a commitment to insomnia management among NHS clinicians; and (3) a clear need to recognise the role of insomnia management in benzodiazepine reduction. Nevertheless, while benzodiazepine dependency research and practice continue to emphasise anxiolytics and anxiety management, opportunities for reducing the more widely used hypnotics through improved NHS insomnia management have not been fully explored.

While hypnotics have long been associated with unwanted behavioural side-effects, the research evidence increasingly suggests that untreated insomnia can also significantly impair daytime functioning. Thus, in epidemiological studies both the principal symptom associated with insomnia (daytime sleepiness) and hypnotic drug consumption have been independently associated with reduced work performance, absenteeism,[2,13] and road traffic accidents (RTAs)[13,14] in the general population. Among elderly people, sleepiness[15] and hypnotic drug use[16–18] have also been specifically implicated as causes of falls and fractured neck of femur. Therefore, to optimise the quality of life (QoL) of chronic insomniac drug users and to reduce the risks associated with untreated insomnia, effective hypnotic drug reduction programmes must address underlying issues of insomnia management.

## Long-term hypnotic use

It is now widely accepted that hypnotic drug therapy beyond 4–6 weeks in duration is undesirable at all ages.[19–21] Nevertheless, trends in the duration of hypnotic drug use indicate that long-term use (≥ 4 years+) remains common, with new hypnotic drug use showing an annual incidence of 1.5% [95% confidence interval (CI) 1.3 to 1.6] among patients aged 65 years or older.[7] This clear mismatch between the long-term needs of patients with chronic sleep difficulties and the short-term value of pharmacological treatment further emphasises the need for flexible, enduring approaches to insomnia management that can both prevent long-term drug use and support hypnotic drug reduction programmes. This is particularly important among continuous long-term hypnotic drug users who, as a result of tolerance, may still experience disturbed sleep while taking their medication, but who may also experience some degree of rebound (i.e. a worsening of their sleep quality) when doses are reduced or omitted.[22] In the UK the need to develop services in this area has recently been emphasised by the National Service Framework for Older People,[23] which recommends that primary care agencies should both invite patients to come off long-term hypnotics and provide support for them to do so. At present, psychological (cognitive–behavioural) approaches to sleep management appear well placed to deliver this support.

## Psychological treatments for insomnia

Reviews and meta-analyses of the clinical trials evidence show that an average of 5 hours' psychological treatment (combining stimulus control, progressive relaxation and cognitive approaches) produces reliable and lasting improvements in both sleep structure (as indexed by sleep latency, continuity and duration) and subjective sleep satisfaction among 70–80% of

treated patients.[24,25] Psychological treatments targeting insomnia have also been successful in significantly reducing hypnotic intake and encouraging total withdrawal.[26] However, despite the potential for improved insomnia management and reduced hypnotic drug dependence through psychological treatments, such approaches are rarely deployed in non-specialised primary care settings. Emphasising this point, a recent review of psychological treatments for insomnia concluded "… research is needed to examine the effectiveness of treatment when it is implemented in clinical settings (primary care, family practice), by non-sleep specialists, and with insomnia patients presenting medical or psychiatric comorbidity."[25] In the UK a major factor inhibiting the wider provision of psychological interventions for insomnia is the lack of an evaluated and fully costed service delivery model. In contrast to the growing research literature addressing the efficacy of cognitive-behaviour therapy (CBT) treatments for insomnia, 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.

A recent uncosted model,[27] however, clearly shows that effective CBT for insomnia need not be delivered by clinical psychologists (the traditional therapists in clinical trials), and may instead be offered by practitioners more closely associated with primary care settings (health visitors in this particular trial). However, since health visitors show both an increasing commitment to working with the under-fives, and diminishing contacts with older patients,[28] they may not be well placed to address, on a national scale, a clinical problem most prevalent in middle and later life. Primary care counsellors, in contrast, are widely available in general practice,[29] experienced in the delivery of 'talking therapies' and, as a result, well placed to deliver the CBT packages typical of current psychological approaches.[27,30]

The present trial, therefore, aimed to assess: (1) whether psychological treatments for insomnia can be effectively delivered in routine NHS general practice settings by non-sleep specialists; and (2) whether improvements in sleep quality achieved through psychological treatment can produce significant and sustained reductions in hypnotic drug use among long-term (≥ 1 month) hypnotic users. To meet these broad objectives, the trial was designed:

- to evaluate the impact of CBT for insomnia on sleep quality and hypnotic drug use among long-term (≥ 1 month) hypnotic users with chronic sleep problems
- to evaluate the cost utility of providing CBT for insomnia to long-term (≥ 1 month) hypnotic users with chronic sleep problems
- to evaluate, among long-term hypnotic users receiving CBT for insomnia, factors associated with variations in post-treatment outcomes
- to identify the training and support needs of counsellors providing a sleep and insomnia management service in primary care settings.

# Chapter 2
# Methods

This study was approved by the North Sheffield Research Ethics Committee. Consent and patient information sheets are shown in Appendix 1.

## Sampling strategy

Since the participation of the prescribing general practitioner (GP) was integral to the study design, the direct recruitment of patients from the community was rejected in favour of recruitment through consenting general practices. In selecting an appropriate sampling strategy which minimised bias and optimised recruitment, several factors were then taken into consideration. First, to generate a large enough sample of patients with what is, at the practice population level, a relatively low-frequency characteristic (i.e. hypnotic drug use ≥ 1 month), access to a number of practices was required. Second, as one of the main aims of the study was to develop a service which, if effective, could be rolled out into existing practice settings, a representative range of general practices was required. These considerations resulted in the adoption of cluster sampling, with individual general practices providing the unit of sampling, and all registered practice surgeries in the Sheffield area ($n$ = 96) providing the sampling frame. Assuming (in the absence of data indicating seasonal variations in hypnotic prescribing) constant demand over time for insomnia management at the primary care level, serial referral from these randomly selected practices would (other things being equal) deliver a similarly representative sample of patients meeting the study criteria. General practices were eligible to participate if they were not currently running a benzodiazepine reduction programme and were able to provide suitable on-site facilities for psychological treatment. From 96 general practices in the Sheffield area 42 were randomly selected, of which 23 met the study criteria and agreed to participate.

### Patient recruitment

Cluster sampling allowed the option of dividing practices along control group/psychological treatment group lines, with 50% of practices referring only control patients and 50% referring only into the study 'sleep clinic'. Early discussions with experienced GPs, however, suggested that the 'control only' option lacked incentives, and would be unlikely to encourage or maintain practice participation. To avoid bias arising from asymmetrical incentives, therefore (i.e. some practices receiving the 'benefit' of a clinic, while others receive nothing) practice participation was divided into two discrete phases: a sleep clinic phase (phase SC) and a control phase (phase C), with the phase order (SC-C or C-SC) randomised across practices. (Such a division was considered preferable to alternating control and sleep clinic referrals from the same practice, since the latter option would have been difficult to administer and prone to error, and required the study counsellors to provide simultaneous sessions over a much larger geographical area.) It was originally estimated that phases SC and C would run consecutively for 6 months each across all practices, giving a total recruitment time of 12 months. However, slow rates of referral and an uneven flow of eligible patients necessitated an extension of the recruitment period by 6 months, giving a total recruitment time of 18 months. Where repeat prescriptions were issued in the absence of a consultation, a (circa) 50% sample of patients due for repeat prescriptions was contacted by the practice and invited to participate in either the clinic or control phase as appropriate. All patients were recruited between January 1999 and August 2000. To allow for the late return of follow-up questionnaires, 12-month assessments continued until November 2001.

To ensure adequate representation of older patients (the most likely consumers of long-term NHS insomnia management) and to exclude those (generally younger adults) whose sleep disturbance is often lifestyle related, the selection criteria included a lower age of 30 years, but no upper age limit. Patients were therefore eligible for the trial if they: (1) were aged 30 years or over; (2) met Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)/International Classification of Diseases-10 (ICD-10) criteria for insomnia [i.e. a persistent (≥ 1 month) complaint of difficulty initiating or maintaining sleep (or of non-restorative sleep) which causes the individual significant distress and is associated with impaired

social or occupational functioning]; (3) had been consuming hypnotics for at least the previous month; (4) were not taking neuroleptic medication; (5) were requesting or due for a repeat hypnotic prescription; and (6) were able to travel to the surgery for appointments with the project counsellor. Invitations to participate in the study were made to consecutive patients by the general practitioner either during a consultation or by letter before the issue of a repeat prescription. Patients were then contacted by project staff, who repeated the invitation and made a first appointment.

## Clinical assessments

Control patients were visited at home by the project research assistant (a graduate psychologist with substantial interviewing experience) who explained the study, provided the information sheet (Appendix 1a) and obtained consent. Baseline assessments (see below) were also completed at this visit. Control patients were then provided with a drug log on which they were asked to record the dose of hypnotic consumed each night for the next 7 nights. When completed, these logs were returned to the project in a stamped addressed envelope provided at the home visit.

Following the invitation to participate, sleep clinic patients were sent (by post) self-completion daily sleep diaries (Appendix 3) which they were asked to complete for the nights before their first appointment. Most patients were seen within 2 weeks of referral. At the first appointment sleep clinic patients were seen by the project counsellor, who explained the study, provided the information sheet (Appendix 1b) and obtained consent. Baseline assessments were also provided at this time, together with a stamped addressed envelope for their return.

For both control and sleep clinic patients baseline clinical assessments included the following published scales.

### The Pittsburgh Sleep Quality Index (PSQI)[31]

This 11-item questionnaire, widely used as an outcome measure in sleep medicine,[25] covers qualitative (sleep quality, daytime fatigue, etc.) and quantitative (sleep latency, total sleep time, etc.) aspects of sleep, and delivers both an overall (global) score and domain-specific component scores. The global PSQI score ranges from 0 to 21, with lower scores indicating a reduced severity of sleep disturbance. Global PSQI scores are calculated as the sum of component scores for seven domains: Sleep Quality, Sleep Latency, Sleep Duration, Sleep Efficiency, Sleep Disturbance, Use of Medication, and Daytime Dysfunction.

### The Epworth Sleepiness Scale[32]

This is a self-completion measure of daytime sleep tendency which requires the patient to rate the likelihood of their falling asleep in eight different situations (e.g. when watching television, talking to someone or waiting in traffic). Ratings are made on a 0–3 scale (with 0 = 'never' and 3 = 'a high chance'), giving an overall score range of 0–24. The scale has proved useful in quantifying the excessive daytime somnolence associated with sleep apnoea syndrome, but has been less used in insomnia research.

### The Hospital Anxiety and Depression Scale (HADS)[33]

HADS requires patients to rate their level of agreement with 14 mood-related statements (e.g. 'I feel tense or "wound up"' or 'I feel cheerful') on a 0–3 scale. Each of the two seven-item subscales (A: anxiety; D: depression) has a score range of 0–21, with the higher scores indicating a greater severity of anxiety/depression symptoms. Cut-points for clinical 'caseness' have varied in the literature, although a recent review suggests that the sensitivity and specificity of both subscales is optimal when caseness is defined at the score of 8 or above.[34]

### The Short Form 36 (SF-36)[35]

This 36-item questionnaire addresses both physical and emotional health states, and provides validated scores indicating health variations in eight domains: Physical Functioning, Social Functioning, Physical Role Limitation, Emotional Role Limitation, Mental Health, Energy/Vitality, Pain, and General Health Perception. In addition to these domain-specific scores, health utility values for a patient's given health outcomes (modelled from utility values derived from a representative sample of the UK population) can be estimated from the SF-36 responses.[36]

When baseline assessments were returned, sleep clinic patients were sent a modified Illness Perception Questionnaire (IPQ).[37] This modification required patients to rate their level of agreement with 26 sleep-related statements (e.g. 'My sleep problem is a serious condition'; 'Other people played a large role in causing my sleep

problem') on a scale from 0 (strongly agree) to 4 (strongly disagree). The IPQ comprises five subscales, each presumed to contribute to the patient's cognitive representation of illness: Identity (the symptoms the patient associates with the illness), Cause (personal ideas about aetiology), Time-line (the perceived duration of the illness), Consequences (expected effects and outcome), and Cure/Control (how one controls or recovers from the illness).

## CBT

Psychological treatment was provided by two experienced primary care counsellors recruited specifically for this study. Both were eligible for accreditation by the British Association for Counselling [BAC; now the British Association for Counselling and Psychotherapy (BACP)]. Both counsellors received 40 hours of classroom-based training in psychological (cognitive–behavioural) approaches to insomnia management. The counsellors worked exclusively for the project, attending surgeries only for booked treatment sessions. Following the first appointment, treatment sessions were offered on a weekly basis within the surgery of the referring doctor at a time convenient for the patient. Throughout the trial counsellors received fortnightly clinical supervision from a consultant clinical psychologist experienced in the cognitive–behavioural treatment of chronic insomnia (MT). Supervision was provided both to maintain the quality of treatment and to provide clinical support for the counsellors. Psychological treatment was based on existing protocols[27,30] and distributed over six 50-minute sessions, with printed information sheets provided after each session. Sessions were structured as follows.

### Session 1: assessment

In this session the nature, duration and impact of the sleep problem were fully explored, a process augmented by the prior completion of sleep diaries (Appendix 3) and a 20-item sleep questionnaire (Appendix 4). During this session the structure of the behavioural sleep management programme was explained and questions were invited. While it was made clear to sleep clinic 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". An information sheet was provided at the end of this session (Appendix 2a).

### Session 2: information, sleep hygiene and sleep restriction

Sleep hygiene refers to the systematic process of encouraging those behaviours that optimise sleep quality, while discouraging those behaviours that antagonise sleep. In clinical trials, improvements in sleep hygiene have been associated with significant and sustained improvements in sleep quality when combined with psychological therapies.[38,39] In this session the principles of sleep hygiene were explained, and any specific contraindicated habits (tea/coffee drinking close to bedtime, inappropriate exercise regimens, etc.) were addressed. Guided by estimates of sleep efficiency (i.e. the proportion of time spent in bed asleep) available from the patient's sleep diaries, optimal bedtimes and getting-up times were also proposed in this session, and a target reduction for 'time in bed' was agreed. This sleep restriction[40] aims to reduce the amount of time spent in bed awake, and to align more closely the patients' estimated total sleep time (available from the sleep diaries) per night with the amount of time they actually spend in bed.

The issue of drug reduction was also addressed at this session. Where patients expressed an interest in reducing the volume of hypnotics taken, low-frequency drug use was encouraged, where low frequency was defined as ≤ 50% of the baseline drug-use frequency. For all patients who wished to discontinue or modify their hypnotic drug use, the GP was informed and a programme of tapered dose reduction/withdrawal agreed. This programme was monitored by the counsellor throughout the treatment programme. An information sheet was provided at the end of this session (Appendix 2b).

### Session 3: stimulus control procedures

Stimulus control treatments presume the influence of both operant and classical learning in the onset and maintenance of insomnia. According to stimulus control theory, sleep onset, as an operant behaviour reinforced by sleep itself, becomes associated with a number of factors (getting into bed, switching off the light, settling down to sleep), which ultimately become discriminative stimuli for reinforcement, in the presence of which sleep onset becomes more probable. In chronic insomnia, however (whatever the cause), where long periods in bed are increasingly associated with wakefulness, associations between these stimuli and sleep onset can be significantly weakened. Furthermore, through the repeated pairing of bedroom cues with the frustration of sleeplessness, these same stimuli can now, through the mechanisms of classical

conditioning, become conditioned stimuli for negative emotional responses which sustain episodes of insomnia. Stimulus control approaches, therefore, aims to maximise the stimulus control properties of the bedroom and recondition the environmental cues.[41] Using a model of stimulus control described by Espie,[42] patients were advised on: (1) appropriate presleep activities; (2) the management of delayed sleep onset, and (3) the management of episodes of intervening wakefulness (see Appendix 2c).

### Session 4: relaxation procedures

In this session, and again guided by information supplied in the sleep diaries, sleep management was reviewed and therapeutic messages from earlier sessions were reinforced. The patient was then introduced to, and instructed in, progressive relaxation techniques. Among older patients who found the muscle tension components of progressive relaxation uncomfortable, autogenic training techniques were used instead. (Autogenic training is essentially a mental exercise during which the patient is encouraged to repeat, in a monotonous fashion, self-suggestions of physical heaviness in a particular limb, alternating with suggestions of physical warmth in that limb.[43]) Both relaxation procedures were administered according to standardised instructions.[44] An audiotape of the relaxation instructions was provided at the end of this session, together with an information sheet (Appendix 2d).

### Session 5: cognitive therapy

This session focused on the control of presleep mentation and provided the patient with strategies for dealing with intrusive and ruminative thoughts that delay sleep onset. The principal techniques used (cognitive restructuring and thought blocking) are described elsewhere.[44] A detailed information sheet was provided at the end of this session (Appendix 2e)

### Session 6: review of all procedures and discharge

At this session the patient's overall treatment was reviewed and advice offered on the management of future episodes of insomnia. Using information from the sleep diaries, which were maintained throughout treatment in this arm of the trial, particular attention was drawn to areas of sleep improvement. Those patients who had started a drug reduction/withdrawal programme were encouraged to maintain the regimen. All discharged patients were provided with an information sheet (Appendix 2f) and told that follow-up assessment material would be sent in 3 months.

### Practice evaluation

On completion of the study all practices were sent a brief evaluation questionnaire (Appendix 2g) which they were invited to return anonymously.

## Statistical analysis

Ten outcome measures were derived from the clinical assessments (five reflecting key aspects of sleep quality and five reflecting key aspects of drug use). These outcomes were:

- the PSQI global score
- sleep latency (the time taken to get to sleep) in minutes
- the sleep efficiency (percentage of time in bed spent asleep) component score from the PSQI
- total sleep time (estimated actual sleep per night) in hours
- total Epworth Sleepiness Scale score
- the number of hypnotic-free nights per week during the 7-night assessment periods
- the mean hypnotic dose (expressed as a percentage of the maximum dose prescribed for that patient)
- achievement (yes/no) of low-frequency hypnotic drug use at follow-up (where low frequency was defined as ≤ 50% of the baseline drug-use frequency)
- continuous (nightly) hypnotic drug use during the 7-night assessment periods (yes/no)
- zero hypnotic drug use during the 7-night assessment periods (yes/no).

Data were analysed on an intention-to-treat basis, with comparisons including all available data from sleep clinic patients regardless of adherence. Non-categorical clinical outcomes were converted to change scores (baseline minus follow-up) and compared using one-way analysis of variance (ANOVA) with trial group (sleep clinic versus control) as a fixed factor and baseline value (for that change score) and age as covariates. Since patients were randomised in clusters, the referring general practice was included in the model as a random factor. Because of variations in individual follow-up periods resulting from delays in the return of postal assessments, follow-up time was entered into the models as a three-category fixed effect (shorter, intermediate and longer delay). To improve symmetry in the score distribution, sleep latency data were log-transformed for analysis. Sleep efficiency scores, Epworth Sleepiness Scale scores and hypnotic-free nights per week departed substantially from a normal distribution, and were therefore analysed using the Mann–Whitney

U-test. The categorical variables low-frequency hypnotic use, continuous hypnotic use and zero hypnotic use were analysed using the chi-squared statistic.

Multivariate analyses were then conducted to examine factors that may be associated with sleep quality outcome variations, treatment adherence and study attrition. In each of these analyses the independent variables were selected specifically to represent physical health, mental health, sleep quality and relevant personal characteristics.

## Outcome variations

Within the sleep clinic group, relationships between selected pretreatment characteristics and subsequent change in sleep quality were assessed in three separate multiple regression models for the 3-, 6- and 12-month follow-up data. In each model PSQI global change scores were dependent, and age, gender, HADS depression and anxiety scores, the General Health Perception score from the SF-36 (a five-point self rating of health from 1 = excellent to 5 = poor) and the baseline PSQI score were independent. Stepwise procedures were used, with entry into the model set at $p < 0.05$ and removal set at $p > 0.10$.

### *Drug-use outcomes and hypnotic products*

To assess possible associations between drug-use outcomes and specific hypnotic products, relationships between low-frequency hypnotic use/zero hypnotic use and the most frequently prescribed hypnotic drugs (temazepam, nitrazepam and zopiclone) were analysed using the chi-squared statistic. Owing to low cell frequencies at 6 months and 12 months, only 3-month follow-up data were explored in this way.

## Adherence and attrition

To assess factors associated with treatment adherence, sleep clinic patients were divided into two groups: (1) those completing all six sessions ($n = 71$); and (2) those completing fewer than six sessions ($n = 37$). Membership of these groups was then analysed in a discriminant model with age, gender, HADS depression and anxiety scores, the General Health Perception score from the SF-36, and the baseline global PSQI scores as independent variables. Stepwise procedures were used, with entry into and removal from the model determined by the significance of the *F*-statistic (for change in Wilks' lambda) and set at 0.05 and 0.10, respectively.

Within the sleep clinic group the relationship between adherence (as indexed by the number of sleep clinic sessions attended) and subsequent attrition (at 3 months) was then analysed in a further discriminant model in which completion/non-completion of 3-month follow-up assessments (i.e. dropout versus non-dropout) provided the grouping variable, and age, gender, PSQI score, HADS anxiety and depression scores, the General Health Perception score from the SF-36 and the number of sessions attended were independent variables. Stepwise procedures were used, with entry into and removal from the model determined by the significance of the *F*-statistic (for change in Wilks' lambda) and set at 0.05 and 0.10, respectively.

Finally, to explore factors associated with attrition across both arms of the trial, clinic and control patients with appropriately complete datasets (total $n = 202$) were combined in a discriminant analysis in which those who did and those who did not complete follow-up assessments at 3 months provided the grouping variables (i.e. 'dropouts' versus 'non-dropouts'). Independent variables for the analysis were age, gender, PSQI score, HADS anxiety and depression scores, the General Health Perception score from the SF-36 and study arm (clinic or control). Again, stepwise procedures were used, with entry into and removal from the model determined by the significance of the *F*-statistic (for change in Wilks' lambda) and set at 0.05 and 0.10, respectively. In each of the discriminant models the equality of the covariance matrices was tested using Box's *M*-statistic. All analyses were conducted using the Statistical Package for the Social Sciences (SPSS, version 10) for Windows.

# Chapter 3

# Patient recruitment

## Study size

Sample size estimates were originally based on the proportion of patients returning to their GP actively seeking insomnia treatment. Assuming a 20% difference between the clinic and control groups, and setting alpha at 5% and power at 80%, 93 patients were required in each arm. Two factors, however, necessitated a revision of these estimates. First, the use of return rates as an outcome proved impractical owing to the extensive use of computerised repeat prescribing, resulting in fewer actual consultations. Second, although baseline recruitment had met the original sample size targets, high levels of attrition between baseline and follow-up had diminished patient numbers in both the clinic and control arms. As a result, sample size was re-estimated based on the related binary outcome: achievement/non-achievement of low frequency hypnotic drug use at follow-up (with low frequency defined as ≤ 50% of the baseline drug-use frequency). Since drug-use frequency is a 'weaker' outcome than return rate, the estimated difference was increased from 20% to 25%. With low-frequency use predicted for 45% of the clinic group and 20% of the control group, two-sided significance at 0.05 and power at 0.9, 75 patients per arm were required. Standardised differences (clinic versus control) in low-frequency drug use calculated during the trial indicated adequate (≥ 80%) power using smaller sample sizes at the 6-month and 12-month follow-ups.

## Patient characteristics

Of 537 patients invited to join the trial between January 1999 and August 2000, 209 (38.9%) agreed (sleep clinic group = 108; control group = 101; *Figure 1*). Refusal was not significantly associated with gender ($\chi^2 = 3.02$, 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, $p = 0.03$). Recruited patients were predominantly women. Mean age ($p = 0.02$) and duration of hypnotic drug use ($p = 0.001$) were significantly higher, and mean anxiety scores ($p = 0.04$) and Epworth Sleepiness scores ($p < 0.001$) significantly lower in the control group. Other indices of sleep history and clinical status, including mean age at onset of problem ($p = 0.19$), levels of continuous hypnotic drug use ($p = 0.93$), global PSQI scores ($p = 0.25$), estimated sleep latency ($p = 0.54$), estimated total sleep time ($p = 0.71$) and depression scores

***TABLE 1*** *Characteristics of participants completing baseline assessments*

| Characteristic | Clinic group | Control group | *p* Value |
|---|---|---|---|
| No. at baseline | 108 | 101 | |
| Men | 38 | 30 | 0.46* |
| Women | 70 | 71 | |
| Age (years)[a] | 63.3 (31–89) | 67.7 (39–92) | 0.02† |
| Age at onset of sleep problem (years)[b] | 51.3 ± 15.1 | 49.9 ± 16.1 | 0.19† |
| Duration of hypnotic drug use (years)[b] | 12.5 ± 10.2 | 14.3 ± 11.2 | 0.001† |
| % consuming hypnotics continuously | 59.3 | 56.4 | 0.68* |
| Global PSQI score[b] | 12.9 ± 3.4 | 12.3 ± 3.2 | 0.25† |
| Sleep latency (minutes)[b] | 55.9 ± 47.3 | 55.6 ± 49.1 | 0.54†‡ |
| Total sleep time (hours)[b] | 5.5 ± 1.4 | 5.6 ± 1.8 | 0.71† |
| HADS anxiety score[b] | 9.8 ± 4.6 | 8.5 ± 4.7 | 0.04† |
| HADS depression score[b] | 6.8 ± 4.2 | 6.1 ± 4.5 | 0.24† |
| Epworth Sleepiness Scale score[c] | 4.6 (3.0) | 2.9 (2.0) | 0.001§ |

Data are shown as [a] mean (range), [b] mean ± SD or [c] mean (median).
* Significance of Pearson $\chi^2$.
† Significance of independent samples *t*-value.
‡ *t*-Test performed on log-transformed values.
§ Significance of Mann–Whitney U tests.

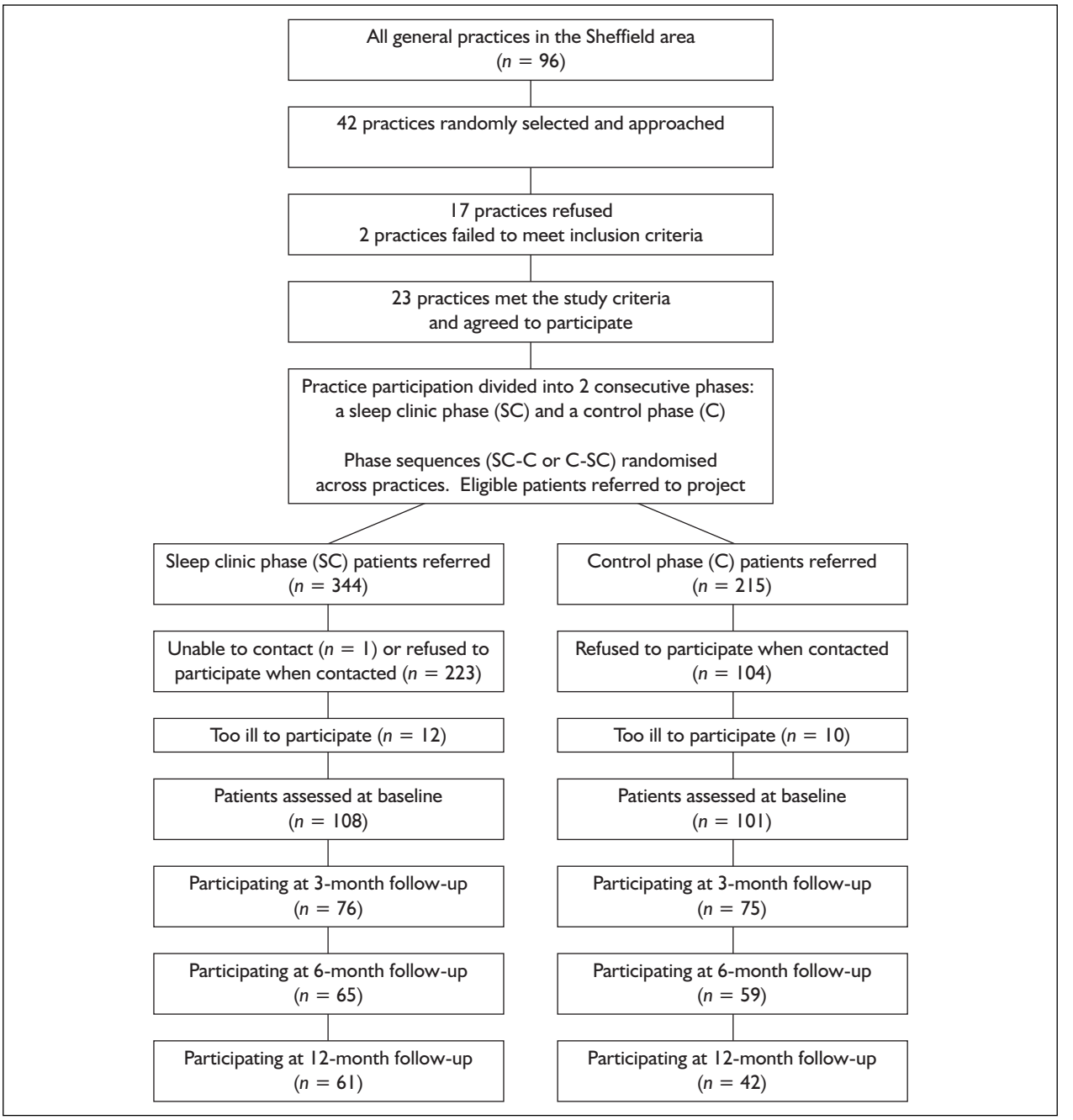


***FIGURE 1*** *Recruitment and follow-up*

($p = 0.24$) showed no significant differences between the groups at baseline (*Table 1*).

## Clinic attendance and follow-up

Most sleep clinic patients (66%; 71/108) attended six sessions. A further 16% (17/108) attended three to five sessions, and 19% (20/108) attended two sessions only (*Table 2*). Follow-up data were provided by 70% (76/108) of clinic patients and 74% (75/101) of control patients at 3 months, by 60% (65/108) of clinic patients and 57% (58/101) of control patients at 6 months, and by 57% (61/108) of clinic and 42% (42/101) of control patients at 12 months.

## Incomplete assessments and sample size

In the outcome data reported here, variations in sample sizes are due to partially completed assessments returned by a minority of patients. In most of these cases either the responses provided on the postal assessments were ambiguous, or no

***TABLE 2*** *Number of clinical sessions completed by patients recruited into the sleep clinic arm*

| No. of sessions attended | No. (%) of patients attending | Cumulative % of patients attending |
|---|---|---|
| 2 | 20 (18.5) | 18.5 |
| 3 | 10 (9.3) | 27.8 |
| 4 | 2 (1.9) | 29.6 |
| 5 | 5 (4.6) | 34.3 |
| 6 | 71 (65.7) | 100.0 |

responses were provided at all. For the most part, questionnaire content did not overlap. However, information on the frequency of sleep medication use provided in the PSQI (item 7) was used when drug log data were missing or unclear. Where even minimal information was missing from scales, scores for that scale were not computed and the whole scale was treated as missing.

## Limitations on follow-up

The original intention was to conduct follow-up assessments at 3, 6, 12 and 24 months. Two factors, however, made the 24-month follow-up impractical. First, progressive attrition, particularly in the control group, had already resulted in very low returns at 12 months, with the likelihood that further attrition would render the results unreliable. Second, because the recruitment period had been extended, virtually all 24-month follow-ups would have been due well outside the funded period of the study. On balance, therefore, it was decided to abandon the 24-month follow-up and instead to direct project resources towards optimising returns from the 12-month postal assessments.

# Chapter 4

# Results: clinical outcomes

All differences reported here are between sleep clinic and control group values. Unless stated otherwise, analyses were performed using baseline minus follow-up change scores (as described in Chapter 2).

## Clinical outcomes: 3 months

At 3-month follow-up (*Table 3*) sleep clinic patients showed a significant improvement in global Pittsburgh scores (mean difference –3.8, 95% 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, $p < 0.001$), increases in total sleep time (mean difference 0.5, 95% CI 0.1 to 0.8, $p = 0.04$) and improvements in sleep efficiency (mean difference -0.9, 95% CI –1.2 to –0.6, $p < 0.001$). Among sleep clinic patients, Epworth Sleepiness Scale scores showed a significantly greater improvement relative to baseline (mean difference = –1.8, 95% CI –2.8 to –0.8, $p < 0.001$).

Sleep clinic patients also reported marked reductions in hypnotic drug use. For the sleep clinic and control groups, respectively: 47.4% (36/76) versus 17.3% (13/75) reported 'low-frequency' use (difference between proportions 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

***TABLE 3*** *Main sleep-related outcome measures at baseline and 3-month follow-up*

| | Baseline mean ± SD | | 3-month follow-up mean change (*n*) | | |
|---|---|---|---|---|---|
| | **Clinic group (*n* = 108)** | **Control group (*n* = 101)** | **Clinic group** | **Control group** | ***p*-Value** |
| **Outcome measure (continuous)** | | | | | |
| PSQI (range 0–21)[a] | 12.8 ± 3.4 | 12.3 ± 3.2 | 2.8 (72) | –0.9 (72) | 0.002 |
| Sleep latency (minutes)[a] | 55.9 ± 49.1 | 55.6 ± 47.3 | 27.7 (73) | 3.5 (72) | <0.001[c] |
| Sleep efficiency score[a] | 2.2 ± 1.0 | 1.9 ± 1.2 | 0.7 (73) | –0.1 (72) | <0.001[d] |
| Total sleep time (hours)[b] | 6.2 ± 1.2 | 5.6 ± 1.3 | –0.6 (73) | –0.1 (72) | 0.04 |
| Epworth Sleepiness Scale | 4.6 ± 4.2 | 2.9 ± 3.3 | 0.2 (72) | –1.6 (70) | <0.001[d] |
| Hypnotic-free nights/week[b] | 1.6 ± 2.3 | 1.8 ± 2.3 | –2.2 (76) | –0.4 (75) | <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 |
| **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] |
| Continuous (nightly) hypnotic use: *n* yes (% yes) | 64 (59.3) | 57 (56.4) | 23 (30.3) | 44 (58.7) | <0.001[e] |
| Zero hypnotic use during assessment period: *n* yes (% yes) | 2 (2.1) | 7 (6.5) | 22 (29.0) | 8 (10.7) | 0.005[e] |

Data are clinic versus control group values compared in univariate ANOVA models unless otherwise stated.
[a] Positive change scores indicate improvement.
[b] Negative change scores indicate improvement.
[c] Data log-transformed for ANOVAs.
[d] Mann–Whitney U-test.
[e] Pearson $\chi^2$.

between proportions 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 between proportions 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 sleep clinic patients (mean difference 1.8, 95% CI 1.1 to 2.6, $p < 0.001$), but the mean hypnotic dose consumed showed no 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 ($p < 0.001$; see Chapter 6).

## Drug-use outcomes and hypnotic products

At baseline the most frequently prescribed hypnotics were temazepam (51%; 107/209), nitrazepam (23%; 47/209), zopiclone (15%; 31/209) lorazepam (2.9%; 6/209) and diazepam (1.9%; 4/209). Of these only temazepam, nitrazepam and zopiclone were included in the drug-use outcomes analyses. Patterns of drug reduction showed no significant association with hypnotic product, with low-frequency drug use reported by 22.9% (8/35) of temazepam users, 33.3% (5/15) of nitrazepam users and 38.9% (7/18) of zopiclone users ($\chi^2 = 1.61$, df = 2, $p = 0.45$) at the 3-month follow-up. Similarly, levels of zero drug use at 3 months were reported by 17.6% (13/74) of temazepam users, 18.9% (7/37) of nitrazepam users and 30.4% (7/23) of zopiclone users ($\chi^2 = 1.85$, df = 2, $p = 0.40$).

# Clinical outcomes: 6 months

Within the sleep clinic group significant improvements in global Pittsburgh scores (mean difference –3.3, 95% CI –4.7 to –1.8, $p = 0.04$), 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 4*).

***TABLE 4*** *Main sleep-related outcome measures at baseline and 6-month follow-up*

| | Baseline mean ± SD | | 3-month follow-up mean change (*n*) | | |
|---|---|---|---|---|---|
| | **Clinic group (*n* = 108)** | **Control group (*n* = 101)** | **Clinic group** | **Control group** | ***p*-Value** |
| **Outcome measure (continuous)** | | | | | |
| PSQI (range 0–21)[a] | 12.8 ± 3.4 | 12.3 ± 3.2 | 1.9 (65) | –1.4 (57) | 0.04 |
| Sleep latency (minutes)[a] | 55.9 ± 49.1 | 55.6 ± 47.3 | 29.6 (65) | 1.7 (57) | 0.003[c] |
| Sleep efficiency score[a] | 2.2 ± 1.0 | 1.9 ± 1.2 | 0.7 (65) | –2.4 (57) | <0.001[d] |
| Total sleep time (hours)[b] | 6.2 ± 1.2 | 5.6 ± 1.3 | –0.6 (65) | –0.1 (57) | 0.18 |
| Epworth Sleepiness Scale | 4.6 ± 4.2 | 2.9 ± 3.3 | 0.2 (66) | –2.2 (58) | <0.001[d] |
| Hypnotic-free nights/week[b] | 1.6 ± 2.3 | 1.8 ± 2.3 | –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 | –4.4 (48) | 1.4 (57) | 0.41 |
| **Outcome measure (categorical)** | | | | | |
| Low-frequency hypnotic use (≤ 50% of baseline) at follow-up: *n* yes (% yes) | – | – | 39 (54.2) | 11 (17.7) | <0.001[e] |
| Continuous (nightly) hypnotic use: *n* yes (% yes) | 64 (59.3) | 57 (56.4) | 24 (33.3) | 39 (62.9) | 0.001[e] |
| Zero hypnotic use during assessment period: *n* yes (% yes) | 2 (2.1) | 7 (6.5) | 24 (33) | 5 (8.1) | <0.001[e] |

Data are clinic versus control group values compared in univariate ANOVA models unless otherwise stated.
[a] Positive change scores indicate improvement.
[b] Negative change scores indicate improvement.
[c] Data log-transformed for ANOVAs.
[d] Mann–Whitney U-test.
[e] Pearson $\chi^2$.

Total sleep time, however, did not differ significantly between the groups at this time ($p = 0.18$). Among sleep clinic patients significant reductions in Epworth Sleepiness Scale scores were also maintained at 6 months (mean difference = –2.3, 95% CI –3.5 to –1.1, $p < 0.001$).

Significant reductions in hypnotic use were also maintained at the 6-month follow-up. For the sleep clinic and control groups, respectively: 54.2% (39/72) versus 17.7% (11/62) reported low-frequency use (difference between proportions 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 between proportions 0.25, 95% CI 0.12 to 0.38, $p < 0.001$), and 33.3% (24/72) versus 62.9% (39/62) reported continuous hypnotic drug use during the assessment week (difference between proportions 0.29, 95% CI 0.13 to 0.46, $p < 0.001$). Clinic patients continued to show an increase in drug-free nights at the 6-month follow-up (mean difference 2.2, 95% CI 1.3 to 3.0, $p < 0.001$).

Again, the mean dose of hypnotics consumed did not differ between the groups ($p = 0.41$). Six-month health gain among sleep clinic patients was indicated by two dimensions of the SF-36 (see Chapter 6), Physical Functioning ($p = 0.04$) and Mental Health ($p = 0.02$). Earlier differences in Vitality, however, failed to reach conventional significance ($p = 0.08$).

## Clinical outcomes: 12 months

Clinical results from the 12-month follow-up are shown in *Table 5*. For sleep clinic patients significant improvements in global Pittsburgh scores (mean difference –3.6, 95% CI –5.1 to –2.2, $p < 0.01$), sleep latency (mean difference –29.7, 95% CI –47.7 to –11.6, $p = 0.02$) sleep efficiency component scores (mean difference –0.95, 95% CI 0.2 to –1.4, $p < 0.001$), and Epworth Sleepiness Scale scores (mean difference –2.3, 95% CI 0.5 to –3.23, $p < 0.001$) were maintained at 12 months. Again, however, total sleep time, did not differ

***TABLE 5*** *Main sleep-related outcome measures at baseline and 12-month follow-up*

| | Baseline mean ± SD | | 3-month follow-up mean change (*n*) | | |
|---|---|---|---|---|---|
| | **Clinic group (*n* = 108)** | **Control group (*n* = 101)** | **Clinic group** | **Control group** | ***p*-Value** |
| **Outcome measure (continuous)** | | | | | |
| PSQI (range 0–21)[a] | 12.8 ± 3.4 | 12.3 ± 3.2 | 3.3 (61) | –0.4 (42) | 0.01 |
| Sleep latency (minutes)[a] | 55.9 ± 49.1 | 55.6 ± 47.3 | 32.2 (61) | 2.5 (42) | 0.02[c] |
| Sleep efficiency score[a] | 2.2 ± 1.0 | 1.9 ± 1.2 | 0.7 (61) | –0.1 (42) | <0.001[d] |
| Total sleep time (hours)[b] | 6.2 ± 1.2 | 5.6 ± 1.3 | –0.8 (61) | –8.9 (42) | 0.22 |
| Epworth Sleepiness Scale | 4.6 ± 4.2 | 2.9 ± 3.3 | 0.4 (61) | –1.8 (42) | <0.001[d] |
| Hypnotic-free nights/week[b] | 1.6 ± 2.3 | 1.8 ± 2.3 | –2.0 (60) | –0.2 (42) | 0.001[d] |
| Mean hypnotic dose (as proportion of maximum dose prescribed)[a] | 0.90 ± 0.19 | 0.96 ± 0.13 | 0.2 (40) | 0.1 (38) | 0.57 |
| **Outcome measure (categorical)** | | | | | |
| Low-frequency hypnotic use (≤ 50% of baseline) at follow-up: *n* yes (% yes) | – | – | 27 (45.0) | 6 (14.3) | <0.001[e] |
| Continuous (nightly) hypnotic use: *n* yes (% yes) | 64 (59.3) | 57 (56.4) | 23 (38.3) | 30 (71.4) | <0.001[e] |
| Zero hypnotic use during assessment period: *n* yes (% yes) | 2 (2.1) | 7 (6.5) | 19 (31.7) | 4 (9.5) | 0.008[e] |

Data are clinic versus control group values compared in univariate ANOVA models unless otherwise stated.
[a] Positive change scores indicate improvement.
[b] Negative change scores indicate improvement.
[c] Data log-transformed for ANOVAs.
[d] Mann–Whitney U-test.
[e] Pearson $\chi^2$.

significantly between the groups at this time ($p = 0.22$).

Significant reductions in hypnotic drug use seen at 3 and 6 months were also maintained at the 12-month follow-up. For the sleep clinic and control groups, respectively: 45% (27/60) versus 14.3% (6/42) reported low-frequency hypnotic use (difference between proportions 0.31, 95% CI 0.14 to 0.47, $p < 0.001$), 31.7% (19/60) versus 9.5% (4/42) reported zero hypnotic use during the assessment week (difference between proportions 0.25, 95% CI 0.12 to 0.38, $p = 0.008$), and 38.3% (23/60) versus 71.4% (30/42) reported continuous hypnotic drug use during the assessment week (difference between proportions 0.33, 95% CI 0.15 to 0.51, $p < 0.001$). At 12 months sleep clinic patients continued to show an increase in drug-free nights/week (mean difference –2.0, 95% CI –0.8 to –3.1, $p < 0.001$). As at the earlier follow-ups, the mean dose of hypnotics consumed did not differ between the groups at this time ($p = 0.41$).

## Sleep outcome variations

Results from the multiple regression analyses of possible predictors of outcome variations in PSQI scores are shown in *Table 6*. In each of the three analyses (for PSQI change scores at 3, 6 and 12 months), only baseline PSQI scores and HADS depression scores achieved the criterion level of significance for entry into the models. In combination, these variables collectively explained 22.5%, 29% and 19.2% of the variance in PSQI outcomes at 3, 6 and 12 months, respectively.

## Adherence (sleep clinic patients)

In the discriminant analysis of treatment adherence only baseline PSQI scores discriminated significantly between the two groups, with those attending for all six sessions showing a significantly greater severity of sleep disturbance (lambda = 0.89, $F = 13.17$, $p < 0.001$). The final model correctly classified 65.7% of cases. However, the Box's $M$-statistic for this model ($M = 5.0$, $p = 0.03$) indicates significant inequality in the population covariance matrices.

## Attrition (sleep clinic patients)

For the discriminant analysis of attrition among clinic patients at the 3-month follow-up, full datasets were available for 102 cases (28 dropouts and 74 non-dropouts). In the discriminant model only the number of treatment sessions significantly discriminated between these groups (lambda = 0.67, $F = 48.7$, $p < 0.001$), with non-dropouts showing a higher frequency of clinic attendance than dropouts (5.5 sessions versus 3.5 sessions, respectively). Although the model successfully classified 81.5% of cases, the Box's $M$-statistic ($M = 5.0$, $p = 0.3$) indicated significant inequality in the population covariance matrices.

## Attrition (all patients)

For the discriminant analysis of attrition among all patients at the 3-month follow-up, full datasets were available for 202 cases (54 dropouts and 148 non-dropouts). Only one independent variable, SF-36 General Health Perception, contributed significantly to the discriminant function, with dropouts showing lower levels of self-rated health (lambda = 0.98, $F = 4.7$, $p = 0.03$). However, while the model covariance matrices did not differ significantly ($M = 0.17$), the discriminating power of the model was weak, classifying only 52.7% of cases.

***TABLE 6*** *Predictors of PSQI change scores at 3, 6 and 12-month follow-up: summary of stepwise multiple regressions*

| Dependent variable | Predictor variables[a] | Standardised $\beta$ | $p$ | $R^2$ | $R^2$ change |
|---|---|---|---|---|---|
| PSQI change at 3 months | Baseline PSQI score | 0.469 | <0.001 | 0.169 | 0.169 |
| | HADS depression score | –0.244 | 0.03 | 0.225 | 0.056 |
| PSQI change at 6 months | Baseline PSQI score | 0.487 | <0.001 | 0.141 | 0.141 |
| | HADS depression score | –0.402 | 0.001 | 0.29 | 0.149 |
| PSQI change at 12 months | Baseline PSQI score | 0.415 | 0.001 | 0.114 | 0.114 |
| | HADS depression score | –0.289 | 0.02 | 0.192 | 0.078 |

[a] Only predictors significant at $p < 0.05$ are included in the table. All models included age, gender, HADS anxiety and depression scores, baseline PSQI and SF-36 General Health Perception scores as independent variables.

## Practice evaluation

Of the 23 practices sent the evaluation questionnaire (Appendix 2g), 19 returned them. Of these, seven (37%) indicated that they would 'probably' ($n$ = 5) or 'definitely' ($n$ = 2) offer the sleep clinic as a service if resources were made available, eight (42%) were unsure, and four practices indicated that they would 'probably' ($n$ = 3) or 'definitely' ($n$ = 1) not offer the service. The reason given by all of these latter four was 'no demand from patients'.

# Chapter 5
# Economic analyses

## Introduction

This chapter examines the cost-effectiveness of counsellor-delivered CBT for insomnia among patients who are chronic users of hypnotic drugs. An economic evaluation of CBT is important as the therapy may have profound effects on costs and patient outcomes. The cost of counselling in other patient groups has been estimated at around £40 per patient,[45] yet if effective, this investment could reduce prescription costs over the lifetime of the patient. Likewise, previous work has outlined the poor health-related QoL in patients with insomnia[46] and so any health improvement would also be welcome. Changes in these costs and in health-related QoL can be estimated directly from the trial, and form the basis of a cost–utility analysis.

There are other potential benefits from reducing hypnotic prescriptions. Epidemiological and clinical studies have shown higher rates of RTAs,[47] falls[48] and deliberate self-harm (DSH)[49] in patients receiving hypnotics, all of which will have associated costs and morbidity. Longitudinal outcome studies have also shown increased mortality in patients receiving hypnotic drugs.[50] Reductions in dependence may also reduce the number of patients who go on to enter formal withdrawal programmes, which could require intensive therapy.[51] However, capturing these effects in a trial would be difficult because the size and length of the trial would not provide sufficient power to estimate with confidence any differences in the occurrence of these rare events.

Consequently, the economic evaluation in the present trial was designed to consist of two parts. First, an evaluation alongside the trial using only cost and effectiveness data from the trial was conducted. This was based on accepted principles and methods of economic evaluations alongside controlled trials.[52] Second, a modelling exercise of long-term costs and outcomes was undertaken by extrapolating the trial data then supplementing them with external sources of data such as the relative risk of fractured neck of the femur. This modelling exercise is presented in Appendix 7.

This evaluation was undertaken from the NHS and Personal Social Service perspective, as this coincides with the decision-maker's viewpoint. Such a perspective is recommended by the National Institute for Clinical Excellence for the appraisal of health technologies.[53] The present analyses examine costs and outcomes up to the 6-month follow-up.

## Methods

Estimates of cost were based on individual patient level data and focused on a small set of resources. The resources targeted were based on discussions with GPs who recognised the target population as patients whose only contacts with the health service were GP consultations (for insomnia, and related psychiatric and physical conditions) and repeat prescriptions.

Resource use data were collected primarily by patient questionnaire, although the counsellors' diaries were used as a more accurate source of the number of counselling sessions attended (and cancelled) by patients. Unit costs for counselling sessions were seen as a key part of the evaluation and so bottom–up costs were estimated by a variety of methods (Appendix 5). Other costs were taken from a variety of standard sources, including the BNF[9] and the annual Personal Social Services Research Unit (PSSRU) publication.[54] An outline of the cost components and their associated data sources is shown in *Table 7*.

Economic assessment questionnaires were given to participants either at the first clinical session (for clinical patients) or at the first home visit (for control patients). All participants were sent follow-up questionnaires at 3 and 6 months. These questionnaires, developed and piloted during the first 3 months of the study, included items on the use of primary care services and the consumption of OTC sleep medication. Data on prescription hypnotic use was collected on a separate questionnaire as part of the clinical study. Use of OTC medication was collected to assess whether any reductions in prescription hypnotics were compensated for by an increase in non-prescription sleep aids. These data were not costed, but the results are presented within this chapter.

***TABLE 7*** *Within-trial cost study summary*

| Resource | Measure | Source of data | Valuation |
|---|---|---|---|
| **Psychological therapy** | | | |
| Staff<br>Training<br>Counsellor and practice overheads | No. of sessions | Counsellor diaries | National salary estimates plus local overheads (see Appendix 5) |
| **Drug therapy** | | | |
| Hypnotics | Dose and frequency | Self-completed records | BNF plus dispensing on-cost from PPA |
| **Other health services** | | | |
| GP contacts<br>Other primary care contacts | No. of contracts | Self-completed records | PSSRU |
| **Other costs** | | | |
| OTC medication | No. of type | Self-completed records | Market prices |

OTC, over-the-counter; PPA, Prescription Pricing Authority.

***TABLE 8*** *Unit costs (1999/2000 prices)*

| Resource | Source | Central estimate | Lower limit | Upper limit |
|---|---|---|---|---|
| Hypnotic standard daily dose | BNF, PPA and trial data (see Appendix 6 for details) | 9.1p | 5.1p | 26.7p |
| GP contact in surgery | PSSRU | £25 | – | – |
| GP contact at home | PSSRU | £45 | – | – |
| Other primary care attendance | PSSRU[b] | £19 | £9 | £25 |
| Counsellor session | Bottom–up costing (see Appendix 5 for details) | £26 | £24 | £34 |
| DNA counsellor session[a] | See section on counsellor costs (Appendix 5) | £26 | – | – |
| Cancelled counsellor session | See section on counsellor costs (Appendix 5) | £0 | £0 | £26 |

[a] Sessions where the patient did not attend (DNA).
[b] Estimates are based on different types of staff used in the care of these patients. The central estimate represents a home nurse/district nurse. The lower limit is the cost of a consultation with the practice nurse. The upper limit is the cost of a community psychiatric nurse home visit. These represent the cheapest and most expensive primary care contacts that are likely to be used by this patient group.

All unit costs are in 1999/2000 prices, with any adjustments for inflation carried out using the Hospital and Community Pay and Prices Index (*Table 8*). No discounting is used as costs fall within one year of treatment commencing. CBT training for counsellors was annuitised over 30 years and incorporated into the unit cost of a counselling contact (see Appendix 5).

In addition to the various outcome measures collected as part of the trial, health utility values for the patient's health outcomes were derived from the SF-36 responses.[36] These values are modelled from utility values given by a representative sample of the UK population. The utility values allow a cost–utility analysis to be performed.

## Data analysis

The resource use and unit costs data were used to produce a cost for each patient, and mean

differences between treatments tested for, using one-way ANOVA with trial group (sleep clinic versus control) as a fixed factor and baseline value and age as covariates. Since patients were randomised in clusters, referring general practice was included in the model as a random factor. Because of variations in individual follow-up periods resulting from delays in the return of postal assessments, follow-up time was entered into the models as a three-category fixed effect (shorter, intermediate and longer delay; see Chapter 2). Data were analysed using the general linear models programme in SPSS (version 10) for Windows.

Changes in quality-adjusted life-years (QALYs) were estimated for each patient by calculating the area under the curve relative to baseline. Mean differences between the two groups were tested for using the same general linear model as before, including an adjustment for baseline utility.

Mean differences are used in the economic analysis as these are the summary values of interest;[55] means multiplied by the size of the intended programme calculate the cost of the intended programme. Confidence intervals, calculated by the SPSS general linear model, were derived parametrically. Non-parametric methods were not used as the general linear models produced residuals that were approximately normal.

One-way sensitivity analysis was undertaken using upper and lower limits of the estimated unit costs (see *Table 8* for values). This analysis looked at methodological uncertainties (e.g. the cost of non-attendance to the NHS), data uncertainties (e.g. what type of primary care contacts took place) and uncertainty over the generalisability of the costs (e.g. variation in the grade and cost of counsellors).

GP costs were not subject to sensitivity analysis as the data collection and quality control methods were thought adequate. Accessing patient records would be possible, although time-consuming and costly. Longer term costs associated with hypnotic drug use were investigated in the modelling work (Appendix 7).

Sampling uncertainty of the incremental cost per QALY was investigated by estimating a cost-effectiveness acceptability curve (CEAC).[56] This curve maps out the probability that the intervention is cost-effective for all possible threshold values of incremental cost per QALY that society wishes to pay. The CEAC was produced through simulation. A set 10,000 mean population costs and effects were calculated for each group based on their mean values and their associated standard deviations produced from the general linear models. These group-specific population values were then randomly matched to produce 10,000 population incremental cost-effectiveness ratios (ICERs). The CEAC was then plotted from these data once the observations in the north-west and south-east quadrants of the cost-effectiveness plane had been excluded.

# Chapter 6

# Results: economic outcomes

For those patients followed up to 3 months, the mean number of counsellor sessions was 5.56, while DNAs and cancellations amounted to 10% of appointments (*Table 9*). Clinic patients had a lower mean daily dose at 3 months ($p = 0.02$) and fewer GP ($p = 0.66$) and other primary care attendances ($p = 0.01$) over the preceding 3 months. The reduced GP and other primary care attendances amounted to approximately two contacts. A similar pattern emerged at 6 months, although differences in primary care contacts reduced to around 1.5 contacts, and were no longer statistically significant. Use of OTC medications to help with sleep was minimal and was not included in the costs (*Table 10*).

The mean cost of the CBT intervention was £154 (*Table 11*); however, differences in the cost of hypnotics at 3 and 6 months were small and not statistically significant. Primary care costs (GP and other primary care) were around £30 lower in the clinic group, but not statistically significant. Total NHS costs were higher in the clinic group by £130 per patient at 6 months (95% CI £42 to £218).

The mean difference in costs was only sensitive to changes in the unit costs of counsellor contacts. Using a national survey of counsellor salaries as the basis for upper and lower limits, the mean difference could potentially vary between £117 and £178 per patient, owing to different counsellor grades and salaries (*Table 12*).

The general pattern of changes in health-related QoL was for the control group to deteriorate and the clinic group to improve (*Table 13*). The most notable change at 3 months was the increase in Energy/Vitality in the clinic group ($p < 0.001$), although this was not maintained up to 6 months. By 6 months, there were three statistically

***TABLE 9*** *Resource use from baseline to 3- and 6-month follow-ups (1999/2000 prices)*

| Source of cost | 3-month follow-up | | | | | 6-month follow-up | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Clinic group | | Control group | | | Clinic group | | Control group | | |
| | Mean ± SE | *n* | Mean ± SE | *n* | *p*-Value | Mean ± SE | *n* | Mean ± SE | *n* | *p*-Value |
| Mean daily drug dose[a] | 0.42 ± 0.05 | 71 | 0.67 ± 0.07 | 73 | 0.02 | 0.44 ± 0.06 | 65 | 0.77 ± 0.09 | 57 | 0.01 |
| Counsellor contacts[b] | 5.56 ± 0.14 | 73 | – | – | – | 5.58 ± 0.14 | 65 | – | – | – |
| Counselling DNAs | 0.16 ± 0.05 | 73 | – | – | – | 0.15 ± 0.05 | 65 | – | – | – |
| Counselling cancellations | 0.45 ± 0.08 | 73 | – | – | – | 0.48 ± 0.10 | 65 | – | – | – |
| GP contacts | 1.65 ± 0.30 | 71 | 1.91 ± 0.39 | 73 | 0.66 | 3.13 ± 0.59 | 65 | 4.03 ± 0.89 | 57 | 0.46 |
| Other primary care visits | 0.04 ± 0.32 | 70 | 1.62 ± 0.42 | 73 | 0.01 | 1.02 ± 0.79 | 65 | 1.55 ± 1.14 | 56 | 0.75 |

[a] Expressed as a percentage of the maximum dose prescribed for that patient. This is dose at the follow-up point, and does not take into account changes during the preceding months and the length of time to follow-up.
[b] The rows do not sum to the total as each is estimated using separate ANOVAs.

***TABLE 10*** *Use of OTC medications to help with sleep in the past 3 months*

| | 3-month follow-up | | 6-month follow-up | |
|---|---|---|---|---|
| | Clinic group | Control group | Clinic group | Control group |
| Used OTC medications[a] | 4 | 2 | 7 | 2 |
| Not used OTC medications | 67 | 69 | 59 | 56 |
| Total | 71 | 71 | 66 | 58 |

[a] Medications used were: Nytol ($n = 5$), Piriton ($n = 2$), St John's wort ($n = 1$), Sominex ($n = 1$), Valerian ($n = 1$), Natrasleep ($n = 1$), Panadol ($n = 1$) and 'herbal' medication ($n = 1$). No description was available for two observations.

***TABLE 11*** *NHS costs from baseline to 3- and 6-month follow-ups (1999/2000 prices)*

| Source of cost | 3-month follow-up | | | | | 6-month follow-up | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Clinic group | | Control group | | | Clinic group | | Control group | | |
| | Mean ± SE | *n* | Mean ± SE | *n* | *p*-Value | Mean ± SE | *n* | Mean ± SE | *n* | *p*-Value |
| 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[a] | 154.4 ± 3.3 | 71 | – | – | – | 154.7 ± 3.4 | 65 | – | – | – |
| Primary care costs | 44.3 ± 10.0 | 71 | 77.5 ± 13.1 | 73 | 0.09 | 106.6 ± 21.6 | 65 | 133.4 ± 30.4 | 57 | 0.55 |
| 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 |

[a] Actual costs, not estimated using ANOVA.
[b] The rows do not sum to the total as each is estimated using separate ANOVAs.

***TABLE 12*** *One-way sensitivity analysis of costs at 6 months*

| | Baseline mean difference (£) = +129.9 | | CC = £26, CAN = £0, PC = £18, HYP = 8.8p |
|---|---|---|---|
| Unit costs | Mean difference based on lower limit | Mean difference based on upper limit | |
| CC | +116.8 | +177.8 | Lower: CC = £24<br>Upper: CC = £34 |
| CAN | Same as baseline | +148.2 | Lower: CAN = £0<br>Upper: CAN = £26 |
| PC | +135.5 | +126.5 | Lower: PC = £9<br>Upper: PC = £25 |
| HYP | +131.0 | +124.7 | HYP = 5.1p<br>HYP = 26.7p |

CC: counsellor contracts; CAN: counsellor cancellations; PC: non-GP primary contracts; HYP: hypnotics

***TABLE 13*** *Change in SF-36 and SF-6D scores 3- and 6 months from baseline*

| | 3-month follow-up | | | 6-month follow-up | | |
|---|---|---|---|---|---|---|
| | Mean change (*n*) | | | Mean change (*n*) | | |
| | Clinic group | Control group | *p*-Value | Clinic group | Control group | *p*-Value |
| **SF-36 dimension** | | | | | | |
| Physical Functioning | +1.4 (73) | –1.7 (72) | 0.19 | +2.5 (66) | –4.7 (59) | 0.04 |
| Social Functioning | +1.6 (73) | –8.6 (72) | 0.09 | +1.1 (66) | –7.6 (59) | 0.17 |
| Physical Role Limitation | –4.3 (72) | –1.8 (69) | 0.70 | –5.0 (64) | –8.3 (59) | 0.69 |
| Emotional Role Limitation | +3.2 (72) | –9.1 (69) | 0.10 | +7.2 (64) | –16.3 (59) | 0.01 |
| Mental Health | +2.9 (73) | –0.9 (70) | 0.14 | +4.5 (66) | –4.0 (59) | 0.02 |
| Energy/Vitality | +7.0 (73) | –4.5 (70) | <0.001 | +4.8 (66) | –1.6 (59) | 0.08 |
| Pain | +0.7 (73) | –0.3 (72) | 0.75 | +1.0 (66) | +1.7 (59) | 0.86 |
| General Health Perceptions | +1.8 (73) | –1.0 (69) | 0.29 | +2.2 (65) | –0.7 (57) | 0.38 |
| **SF-6D** | | | | | | |
| Health-related Utility | | | | +0.024 (64) | –0.014 (59) | 0.13 |

significant differences in SF-36 dimensions (Physical Function, Role Limitation due to Emotional Problems, and Mental Health), all in favour of the clinic group. In terms of health-related utility, the clinic group improved by 0.024 QALYs, whereas the control group deteriorated by 0.014 QALYs. The incremental gain in the clinic group of 0.038 QALYs is not statistically significant (95% CI –0.011 to +0.088).

***TABLE 14*** *One-way sensitivity analysis of mean incremental cost per QALY at 6 months*

| Unit costs | Baseline mean incremental cost per QALY (£) = 3418[a] | |
|---|---|---|
| | Mean difference based on lower limit | Mean difference based on upper limit |
| CC | 3074 | 4679 |
| CAN | Same as baseline | 3900 |
| PC | 3566 | 3329 |
| HYP | 3447 | 3282 |

[a] Incremental cost = £129.9, incremental QALYs = 0.038.

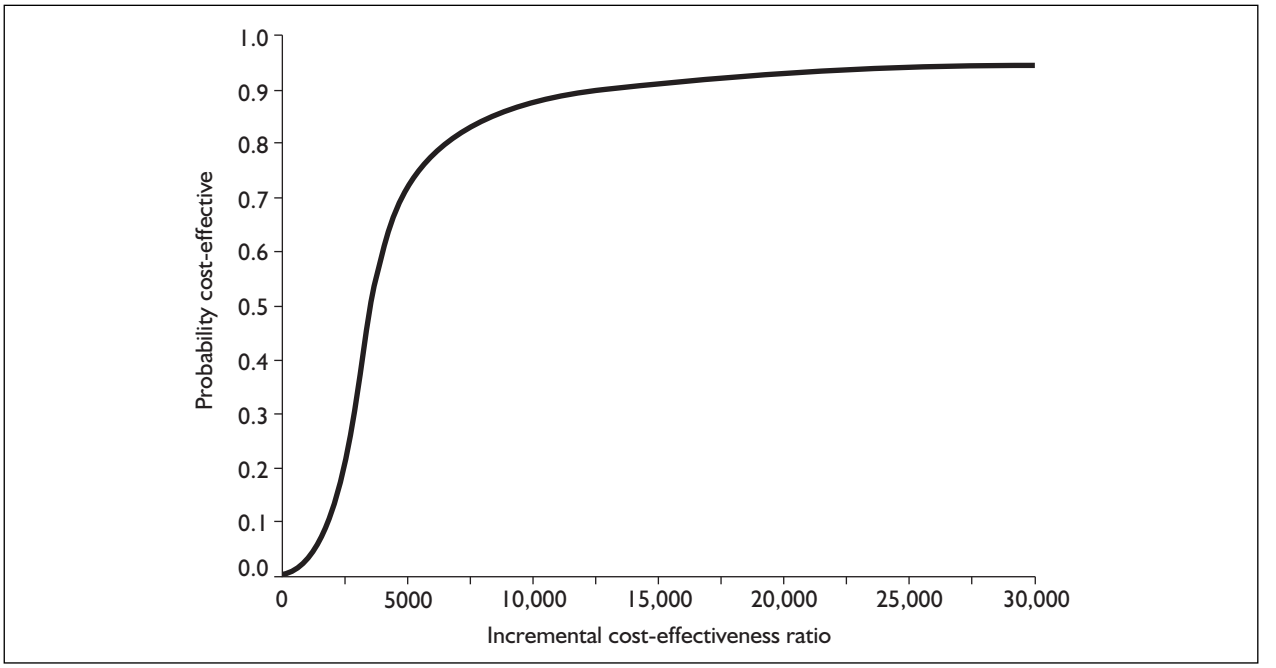


***FIGURE 2*** *Cost-effectiveness acceptability curve (CEAC)*

Combining the mean cost difference and mean QALY difference produces an incremental cost per QALY of £3418. When unit costs are allowed to change in line with the previous sensitivity analysis of costs, this ratio varies between £3074 per QALY and £4679 per QALY (*Table 14*).

When looking at sampling uncertainty, rather than the methodological uncertainties of the sensitivity analysis, the CEAC shows that the intervention appears cost-effective at low levels of cost per QALY (*Figure 2*).The longer term cost-effectiveness of treatment was investigated using a simple economic model. The results of this exercise (see Appendix 7) show that any increase in the time-frame of the evaluation is likely to produce substantial reductions in the incremental cost per QALY. This is caused primarily by sustained treatment effects rather than the incorporation of hidden costs (e.g. accidents associated with benzodiazepine use). The trial based analysis implicitly assumes that there are no sustained treatment effects after 6 months, and could therefore be considered a worst-case scenario.

# Chapter 7
# Discussion

## Clinical outcomes

### Patient characteristics

Baseline assessments clearly indicated that, despite the long-term prescribing of drugs ostensibly to improve sleep quality, all patients referred into this trial met DSM-IV[57] criteria for insomnia, reporting both high levels of sleep disturbance and low levels of sleep satisfaction. It seems reasonable to conclude at the outset, therefore, that from both the NHS and the patient perspectives, this study supports the view that hypnotic drugs offer poor value in the management of chronic insomnia.

Levels of comorbidity were high in both groups, with most patients reporting additional symptoms which, they felt, caused or exacerbated their present sleep difficulty. The distribution of these symptoms showed no significant relationship with trial group ($\chi^2 = 6.1$, df = 5, $p = 0.3$). The most common symptoms were worry/mental activity, reported by 34% (71/209) of all patients, pain/discomfort, reported by 24% (50/209), and bereavement/loneliness, reported by 11% (23/209). For both groups, however, depression scores fell within the normal range, while anxiety scores were only mildly elevated (*Table 1*).[33,34] Given both the age range of study participants and the high levels of presenting comorbidity, and also the length of the follow-up periods, it is important to recognise that for some patients in both arms of the trial changes in sleep quality occurred against a background of declining health.

### Clinical effectiveness

Evidence from the present study indicates that psychological therapy for insomnia can be effectively delivered in routine general practice settings by non-specialist primary care counsellors. Among patients reporting chronic sleep difficulties, long-term hypnotic consumption and high levels of comorbidity, CBT was associated with significant improvements in sleep quality, significant reductions in hypnotic drug use and significant gains in health-related QoL. Most improvements were maintained from the 3-month to the 6- and 12-month follow-ups. Sleep latency in particular showed a substantial improvement, reducing by an average of 27.7 minutes at 3 months, 29.6 minutes at 6 months and 32.2 minutes at 12 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)[58] and is consistent with improvements found in clinical trials involving younger[27] and healthier[30] people with insomnia. Total sleep time, however, showed a significant increase in the clinic group only at 3 months. Given this, the consistent improvement in sleep efficiency is mainly due to a decreased time spent in bed, consistent with sleep restriction instructions. Overall, PSQI scores showed a 2–3 point reduction across all follow-ups for the clinic group, indicating a range of improvements in factors relevant to sleep quality.

Changes in the daytime impact of sleep treatment are less clear. Epworth Sleepiness Scale scores show changes consistent with improved daytime arousal in the clinic group at all three follow-ups. However, these scores differed between the groups at baseline, with control group patients showing significantly lower levels of sleepiness. Subsequent differences in change scores resulted not so much from reduced sleepiness scores among the clinic group as from increased levels of sleepiness reported by the control group (relative to baseline). It appears likely, therefore, that labile baseline values have distorted results on this scale. While valuable in assessing hypersomnia arising from sleep apnoea or narcolepsy,[32] it is possible that the Epworth scale lacks sensitivity in insomniac patients, many of whom do not complain of excessive daytime sleepiness (the modal score at baseline in this study was zero). Certainly, Epworth Sleepiness Scale scores in the present study provide poor evidence that treatment significantly reduced daytime sleep tendency.

Overall, the trial achieved its revised target of promoting low-frequency drug use in over 45% of treated patients, with many sleep clinic patients reporting zero drug use at the follow-up assessments (*Tables 3–5*). Continuous use, too, declined sharply within the clinic group, accounting for 30.3% of clinic patients at 3 months (difference between proportions 0.28, 95% CI 0.13 to 0.44), 33.3% at 6 months (difference

between proportions 0.3, 95% CI 0.13 to 0.46) and 38.3% at 12 months (difference between proportions 0.33, 95% CI 0.15 to 0.51), indicating significant benefits among the most hypnotic-dependent patients. Importantly, there was no evidence of compensatory dose increases among intermittent drug users in the clinic group patients. Similarly, there was little evidence of systematic compensatory use of OTC medications (*Table 10*), with non-prescription sleep aids used by only a small minority of patients in both the clinic and control groups. 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 and strongly suggests that, in practice, targeting the more motivated patients (see below) could produce greater levels of drug reduction and total withdrawal.

## Drug-use outcomes and hypnotic products

The present trial was not designed to test outcome differences between hypnotic products, although the data did allow for exploratory analyses. Relative to the benzodiazepines temazepam and nitrazepam, the cyclopyrrolone zopiclone did appear to be associated with higher levels of both 'low-frequency' and 'zero' use at 3 months, although these differences did not exceed chance expectation. Notwithstanding the absence of statistical significance, it should be emphasised that hypnotic drug groupings reflect more than differences in pharmacology. Since chronic hypnotic users tend to stick with the same generic product over time despite the introduction of newer compounds,[7] drug types can become proxies for both the age of the user and the duration of drug use. At baseline in the present study the three most frequently prescribed drugs showed significant associations with age (mean ages: nitrazepam users 70.8 years, temazepam users 66.3 years, zopiclone users 54.5 years, $F = 17.7$, df = 2, 185, $p < 0.001$) and duration of use (mean durations: nitrazepam users 20.8 years; temazepam users 11.5 years; zopiclone users 8.8 years; $F = 18.1$, df = 2, 174, $p < 0.001$) consistent with each drug's 'lifetime' in the BNF. A more rigorous comparison of drug-use outcomes, therefore, should control for these obvious confounds.

## Outcome variations

Few of the tested variables showed a significant association with treatment outcome (*Table 6*). Nevertheless, the present analyses clearly show that variations in treatment response were consistently associated with pretreatment levels of depression (as measured by the HADS). However, HADS anxiety and depression scores were highly correlated ($r = 0.7$, $n = 203$ at baseline) and, when entered separately into the regression analysis, both contributed significantly to the final model (along with baseline PSQI). [HADS depression scores also correlated significantly with IPQ subscale scores ($r = 0.43$; $p < 0.001$) which, in turn, significantly predicted PSQI outcomes at 3 months in a separate regression analysis.[59] Because of missing IPQ data, this latter model included only 55 of the 108 clinic patients, and is not reported in detail here.] A safe conclusion, therefore, is that sleep outcomes are significantly influenced by underlying affective status at baseline. Relationships between insomnia and anxiety and depression have been reported in the clinical outcome literature. Edinger and colleagues,[60] for example, found that lower levels of anxiety were characteristic of older insomniacs who, in turn, showed a more positive treatment response, while in the epidemiological literature lower levels of depression have been associated with longer-term insomnia remission.[61]

Negative results in the present analyses also merit attention. The finding that outcome variations were age independent (after controlling for mood and baseline values of the dependent variable) reinforces the conclusion from other trials (e.g. Ref. 30) that, in and of itself, older age presents no barrier to successful behavioural treatment for insomnia. Since insomnia prevalence and hypnotic drug use rise steadily with age, the public health implications of this result are clear.

## Treatment adherence

The present trial was designed in response to the NHS HTA programme priority area 'Management of patients on long-term benzodiazepine medication', which specifically emphasised the inclusion of patients "… not wishing to cease taking benzodiazepine medication". The present intervention was designed to reduce the need for hypnotic (mostly benzodiazepine) medication through improved sleep quality (achieved by psychological treatment). To meet the terms of the call, recruitment was non-selective and many of the patients referred into the treatment arm of the present trial initially expressed resistance (and some hostility) to the notion of reconsidering their insomnia treatment. High levels of non-adherence, therefore, are not surprising. It is nevertheless interesting to note that the patients with the greatest degree of sleep disturbance (as indexed by the PSQI) were those most likely to

complete treatment. Non-adherence was also significantly associated with subsequent attrition (within the clinic group), with the most adherent patients (i.e. those completing all six therapy sessions) more likely to participate in the follow-ups. Collectively, these findings reinforce the conclusion that some degree of selection in order to identify and include patients with higher motivation would, in future interventions, optimise therapeutic resources and treatment impact.

## Sampling and attrition

The possibility of selection and attrition bias must be considered when interpreting these findings. 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 clinic arm and 48% of those referred to the control arm). Whereas refusal appears independent of gender ($\chi^2 = 3.02$, df = 1, $p = 0.08$), older patients were significantly more likely to decline the invitation to participate ($\chi^2 = 7.02$, df = 2, $p = 0.03$). It is possible that this latter finding may reflect the impact of growing frailty, an impact symmetrically distributed between the arms of the trial. Suspicion that involvement would threaten future hypnotic drug prescribing, particularly among those invited into the sleep clinic arm, emerged as a typical and wholly expected concern among many patients. As a result, refusals tended to be highest in the sleep clinic 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.

Attrition between baseline and follow-up was high overall. However, similar levels of attrition in both groups at 3 months (*Figure 1*) suggest that withdrawal was not disproportionately influenced by sleep clinic factors, a conclusion reinforced by the outcome of the discriminant analysis of attrition. While earlier treatment adherence emerged as a factor predictive of attrition (at 3 months) from the sleep clinic group, overall health emerged as a significantly influential factor when both arms of the trial were considered. In general, levels of comorbidity within the trial participants were higher than expected from epidemiological studies,[2,3,7] and substantially higher than those reported in recent insomnia trials.[27,30] Poor overall health, acute illness episodes and hospitalisations were the most commonly cited reasons for dropout (two clinic group patients died between baseline and 6-month follow-up). The weak, though significant association between lower self-rated health at baseline and attrition at 3-month follow-up again reinforces the conclusion that health status contributed systematically to dropout in this trial. The authors acknowledge, however, that after the 3-month follow-up, attrition became greater in the control group, possibly reflecting the fact that these patients received no benefit from, and perhaps developed no loyalty to the trial.

## Treatment delivery

As a professional group, primary care counsellors were selected to deliver treatment in the present study both because of their experience in providing 'talking therapies', and because of their growing availability throughout general practice in the UK.[29] Although the present counsellors were experienced in primary care settings and had previous experience in CBT approaches, they clearly appreciated the early investment in training. Subsequent supervision sessions were found to be therapeutically supportive (by the counsellors), and also helped to maintain standardisation and quality in the delivery of the CBT package.

Clinical skills and availability similarly influenced the choice of a consultant clinical psychologist to provide fortnightly supervision. All clinical psychologists are familiar with both the theory and practice of CBT, and the accessibility of these skills for primary care initiatives is clearly indexed by NHS activity data. Summary information for England, for example, shows a steady rise in GP referrals to clinical psychology services from 33,000/year in 1998/90 to 42,000 in 1999/2000.[62] As used in the present trial, therefore, clinical supervision provides a mechanism for amplifying existing NHS expertise in CBT treatments, enabling that expertise to feed into the assessment and treatment of patients with chronic sleep problems.

However, it should also be recognised that the delivery and supervision of treatment need not be restricted to these professions, but could involve any agency or group with appropriate core skills (e.g. psychotherapists, nurse specialists), and appropriate training in the assessment and management of insomnia. Given this availability of staff and expertise, the present study offers a credible model of NHS insomnia management and hypnotic drug reduction. Such a model, supported by appropriate investment in training,

could allow targeted CBT for insomnia to be made widely available within existing primary care services.

#### *Training needs*

The counsellor training programme used in the present trial was designed to develop competence in three key areas: (1) knowledge of sleep and insomnia, (2) theory and practice in assessment, and (3) theory and practice in clinical management. Although the structure and learning objectives of the programme had been decided in advance, the duration of training was agreed only after the project counsellors had been appointed. In this way, the existing skills of the appointees could be taken into consideration when deciding on the appropriate intensity and pitch of the training programme. Both of the counsellors appointed had some CBT experience. The resulting 40-hour programme (4 hours per day for 2 weeks), therefore, was able to develop these skills with a specific focus on insomnia. Training involved formal didactic classroom-based sessions, practical sessions (particularly in the administration and scoring of assessment materials), structured group discussions, role play, case-study tutorials and supervised training interviews conducted with external volunteers. The time distribution for each of the three key areas was, approximately, knowledge 15%, assessment 25% and management 60%. Feedback provided by the trainees and conclusions drawn from project discussions suggest that the 40-hour programme, subsequently supported by weekly (for 1 month) then fortnightly supervision sessions, adequately met the training needs of these counsellors. Furthermore, as an interactive and flexible programme with considerable opportunities for practical skills transfer, it should be suited to a range of existing healthcare professionals.

#### *Practice evaluation*

The brief practice evaluation questionnaire (Appendix 2g) was included mainly as part of the practice debriefing at the end of the trial, and can be regarded as little more than a 'straw poll' of practice attitudes. While the large majority of responses were supportive or neutral, two conclusions can be cautiously drawn from the distribution of responses. First, the inclusion of neutral and negative attitudes would suggest that recruitment did not result in a sample of practices positively biased towards CBT treatments. Second, the uniform explanation for negative responses ('no patient demand') draws attention to the possibility that long-term hypnotic drug use is not always recognised as a significant clinical issue.

## Economic outcomes

The economic evaluation conducted alongside the trial shows that NHS costs increased by approximately £130 over 6 months for patients receiving counselling (95% CI £42 to £218). The mean cost of the counselling sessions was approximately £150. However, there appear to be small cost offsets due to reductions in drug use and primary care services (*Table 11*).

### Costs

Resource-use data for the counselling sessions are considered to be very accurate, as they are based on the counsellors' diaries. Other resource-use data are less accurate, but based on short periods of patient recall. Unit costs for counselling were calculated using a variety of methods and are considered here to be an improvement over previously published estimates (see Appendix 5). The unit costs of counselling are based around a national survey of counsellor salaries and should therefore be generalisable. Sensitivity analysis showed that incremental costs (IC) were most sensitive to changes in the unit costs of counselling services (IC £117 to £178), this being a consequence of the intervention dominating the costs to the NHS of these patients.

Incremental costs may also vary if the time-frame of the study is increased or the perspective changed. An extended evaluation period would allow any sustained effect on hypnotic use to reduce the incremental cost by around £5 per annum (using 6-month figures from *Table 11*). The same argument could be made with other primary care costs, although this would be more open to question. There may also be further cost reductions though the prevention of adverse events associated with hypnotic use (e.g. RTAs, falls). Any sustained reduction in hypnotics and/or any reduction in adverse sequelae will reduce the incremental cost of CBT.

Adopting a societal perspective would introduce production costs (sometimes referred to as indirect costs) into the study design. The two main effects of this would be increased production costs in the short term associated with attending counselling sessions, and reduced production costs in the longer term associated with greater well-being and hence reduced absenteeism and primary care utilisation. The effect of this changed perspective are therefore not predictable, but thought to be small.

### Outcomes

Effects of treatment on health-related QoL were varied (*Table 13*), although generally show a short-

term improvement at 3 months followed by a tailing-away. The control group showed a consistent reduction in QoL over the period of the study. Estimating utilities allowed these changes to be synthesised into a QALY difference of 0.038 (95% CI –0.011 to +0.088).

The estimated QALY difference is limited to the trial period, and so any sustained effect of treatment is not included in this model. Furthermore, QoL and life-expectancy decrements associated with adverse events of hypnotic drug use are likely to increase the QALY gains of treatment. Any sustained effect and/or any reduction in adverse sequelae will increase the QALY gains of treatment. However, the tailing-off of the treatment effect and the rare and delayed nature of the adverse events mean that these changes are thought to be small.

### Cost–utility analysis

The mean incremental cost–utility ratio of £3418 per QALY is well within the range traditionally funded in the NHS[63] and is insensitive to changes in costs (which vary at most from £3074 to £4679 per QALY when counsellor unit costs are changed). As discussed previously, any extension of the time-frame of the evaluation is likely to reduce the incremental cost of CBT and increase its incremental QALY gains, thus improving the incremental cost per QALY further.

The main uncertainty over the cost per QALY ratio is that within the trial, the QALY gains do not reach conventional levels of significance. Consequently, although the mean cost per QALY is £3418 there is a small probability (about 1 in 10) that CBT is not cost-effective at a ceiling ratio of £30,000 per QALY. A larger sample would increase the power of the study and help to remove this uncertainty, although, overall, the CEAC is considered very favourable for CBT.

The other area of uncertainty is the longer term cost-effectiveness of treatment. The modelling work, albeit simple, emphasises that the central cost per QALY estimate of £3418 should be considered a worst-case scenario; any treatment effect beyond 6 months improves the cost-effectiveness of treatment. Of less importance is the uncertainty associated with the hidden costs. However, the modelling work shows that the incorporation of these improves the cost-effectiveness of CBT yet further. Overall, although the trial failed to show a statistically significant benefit in terms of utility, the cost-effectiveness of CBT is likely to be similar to or less than that which has previously been considered by decision-makers to represent acceptable value for money to the NHS.

The QALY estimates are based on utility estimates produced from the SF-36 using a multiattribute utility (MAU) approach. Consequently, the validity of the QALY estimates is reliant on the validity of the SF-36 descriptive system, the validity of MAU approach used to develop the utility algorithm and the validity of the QALY model in general. Each of these has their critics; other descriptive systems are available, the utility algorithm could have been derived using other methods (in terms of both utility elicitation techniques and statistical modelling techniques) and some of the assumptions of the QALY model can be seen to be violated. The SF-6D was used as it was thought to be the best descriptive system for this patient group and its values are produced from established techniques (i.e. standard gamble and statistical inference).

## Overall conclusions

CBT packages for insomnia (comprising information, sleep hygiene, stimulus control, relaxation and cognitive therapy components) should be considered by primary care commissioners and practitioners when implementing National Service Framework[23] recommendations for benzodiazepine use, and when addressing the insomnia management needs of all patients with longer term sleep difficulties. Such initiatives could utilise and develop the skills of existing primary healthcare professionals. Since drug reductions in the present trial were achieved through improved sleep quality, the current approach lends itself to a wider strategy of early sleep management in primary care which could prevent long-term hypnotic use developing. Economic evaluation of CBT for insomnia shows that treatment is likely to be considered cost-effective if decision-makers are willing to pay less than around £12,500 per QALY (there is a greater than 80% probability that the ICER would be less than this value), taking into account the uncertainty in parameters included in the model. Modelling longer term effects, and the impact of rare events, increases the cost-effectiveness of treatment further. Service delivery by appropriately trained counsellors clinically supervised by an appropriately experienced clinical psychologist, therefore, offers a model which is flexible, practical and cost-effective.

# Acknowledgements

We thank Professor Colin Espie for technical advice, Beth Fawcett for providing secretarial support throughout the trial, and Anne Truefitt and Joan Davies who delivered the cognitive-behavioural treatment programme. We also thank the GPs, practice staff and patients who supported this research.

## Contributions of authors

KM and MT adapted the CBT package for delivery within the present study; KM, SD, MT and NM developed the study protocol; JT, KM and NM recruited the practices; MT, KM, NM and JT trained the counsellors; MT provided clinical supervision throughout the trial; JT carried out the fieldwork with support from KM and MT; KM analysed the clinical data. SD analysed the economics data; KM and SD prepared the report and all authors commented on drafts. KM and SD are guarantors.

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# Appendix 1a

# Consent form/information sheet (control group)

## Insomnia management in general practice: patient information

In collaboration with the University of Sheffield, this practice is currently participating in a study of how sleep problems like yours are managed within the Health Service. The aim of this study, which is supported by the National Health Service Executive, is to help patients and general practitioners to get the most out of available treatments for persistent insomnia. In the course of this study, two approaches to treatment are being compared: sleeping tablet therapy; and psychological (talking) therapy. While both treatments are known to offer effective relief from insomnia, the actual cost and the long-term benefits of these treatments within the Health Service have never been fully evaluated.

Your doctor is offering you sleeping tablet therapy. In order to gain a better understanding of your particular sleep problem and how it responds to treatment, we would like your co-operation in two ways. First, we would like you to complete some simple assessments of your sleeping patterns and general health both now, and after the present course of sleeping tablets is completed. These assessments, which take only a few minutes to complete, can be returned to the Northern General Hospital in stamped-addressed envelopes provided. And second, we would like your permission to use information from your NHS health records in our analyses. All we are interested in is how your sleep problem and its treatment affect your general health. All information provided by you will be treated in confidence, and will be made anonymous (which means that our records will not show from whom the information came). Participation is, of course, entirely voluntary. If you do not wish to participate, this will not in any way affect the quality of treatment you will be offered by your doctor

If you are willing to participate, please sign the attached form. You will then be contacted by the project co-ordinator, who will arrange to deliver the brief assessments. Please keep a copy of this sheet for your own information. If you have any queries, or would just like to discuss the project further, please telephone the project office on: (number provided).

## Insomnia management in general practice: consent form

**The Insomnia Treatment Study has been explained to me, and I have been given the opportunity to ask questions about this research. I understand the aims of the study, and agree to participate. I also understand that I can withdraw from the study at any time.**

Name _____ Date _____

# Appendix 1b

# Consent form/information sheet (sleep clinic group)

## Insomnia management in general practice: patient information

In collaboration with the University of Sheffield, this practice is currently participating in a study of how sleep problems like yours are managed within the Health Service. The aim of this study, which is supported by the National Health Service Executive, is to help patients and general practitioners to get the most out of available treatments for persistent insomnia. In the course of this study, two approaches to treatment are being compared: sleeping tablet therapy; and psychological (talking) therapy. While both treatments are known to offer effective relief from insomnia, the actual cost and the long-term benefits of these treatments within the Health Service have never been fully evaluated.

In addition to sleeping tablets, your doctor is offering you psychological (talking) therapy which can help to reduce the number of sleeping tablets you take, and may, if you choose, replace your sleeping tablets altogether. This treatment, which can begin within the next 2 weeks, will involve up to six visits to the surgery where you will be seen by a practice counsellor with special training in the treatment of insomnia. During these visits your sleep problem will be personally assessed and treated by the counsellor.

If you decide to accept your doctor's offer, then we would like your co-operation in two ways. First, we would like you to provide us with information on your health and sleeping patterns while you are undergoing therapy, and for a period afterwards. These assessments, which take only a few minutes to complete, can be handed in at your appointment, or returned to the Northern General Hospital in stamped-addressed envelopes provided. And second, we would like your permission to use information from your NHS health records in our analyses. All we are interested in is how your sleep problem and its treatment affect your general health. All information provided by you will be treated in confidence, and will be made anonymous (which means that our records will not show from whom the information came). Participation is, of course, entirely voluntary. If you do not wish to participate, this will not in any way affect the quality of treatment you will be offered by your doctor.

If you are willing to participate, please sign the attached form. You will then be contacted by the project staff who will arrange your first appointment at a time convenient to you. Please keep this sheet for your own information. If you have any queries, or would just like to discuss the project further, please telephone the project office on: (number provided).

## Insomnia management in general practice: consent form

**The Insomnia Treatment Study has been explained to me, and I have been given the opportunity to ask questions about this research. I understand the aims of the study, and agree to participate. I also understand that I can withdraw from the study at any time.**

Name _____ Date _____

# Appendix 2a

## Patient information sheet 1

Thank you for agreeing to participate in the University of Sheffield Sleep Clinic Project. Our aim is to improve the quality of your sleep by introducing you to methods that have already helped many people with insomnia. During treatment you can also get advice and help if you wish to reduce, or discontinue, your current sleeping tablets.

In this session your counsellor explained what the clinic will offer. Your treatment will be spread over a further 5 appointments, each lasting about 50 minutes. At each appointment you will have an opportunity to discuss your progress, and any problems which might arise, before moving on to the next stage of treatment.

In order to get the best out of this treatment, please try to

- complete and return all the questionnaires you have been given
- attend all your appointments.

If, for any reason, you wish to cancel or change your appointment, or if you have any other query, please ring the sleep clinic on [number provided].

# Appendix 2b

## Patient information sheet 2

Whatever the cause of your present sleep problem there are still things you can do that will help you get the most out of your sleep *now*. This sheet is to remind you of the advice given at the sleep clinic.

- Don't expect **too** much from your sleep. As you get older it is quite normal for sleep to become shorter, lighter, and more broken. You may also find that your normal sleep routines are more easily disturbed. Rather than changing your sleep, you may need to adjust your expectations and your habits. For example, you may be going to bed too early. Do you really need as much sleep as you think?
- Avoid those things which can prevent or disrupt sleep (even if these things have never been a problem in the past). Learn to take more care of your sleep. For example, try drinking less tea or coffee (especially close to bedtime). If you have to get up in the night to go to the toilet, perhaps it is best to avoid late night drinking altogether.
- Is your bed comfortable and warm enough, and is your bedroom quiet enough?
- It is extremely important to keep regular habits. In particular, avoid excessive daytime napping, or long lie-ins in the morning.
- Try to keep at least *fairly* active during the day, but allow time to 'wind down' in the evening.
- If you have a medical complaint that seems to interfere with your sleep (for example, a condition that causes pain or breathlessness at night), see your doctor and explain the problem.

# Appendix 2c

## Patient information sheet 3

Beds and bedrooms are very important 'signals' for sleep, and actually make a lot of people feel quite sleepy. For those with insomnia, however, these important signals may be lost. In this session we discussed how these signals or 'cues' can be strengthened so that your sleep gradually improves. The main aim of this treatment is to reduce the amount of time you spend awake in bed each night.

Listed below are the rules we agreed.

- Try to go to bed at the agreed time each night and settle down to sleep as soon as possible.
- If you have not gone to sleep after about 20 minutes, get up and leave the bedroom until you feel tired again.
- It is important that you do not use your bed for anything except sleep. Avoid activities like reading, smoking, or listening to the radio or watching TV in bed. If you can't sleep, get up.
- Get up at the agreed time even if you feel tired or in need of more sleep.
- Try to keep active during the day and avoid napping.
- Go to bed at the agreed time.

Before putting these rules into practice, you may find it helpful if you first prepare a room where you can sit during sleepless periods, and tell other people in your household about your sleep treatment.

# Appendix 2d

## Patient information sheet 4

In today's session we discussed how both physical and mental relaxation are a normal and natural part of good sleep. As we drift into sleep we experience several changes, both in our physical arousal and in our thinking pattern.

With sleep –

- Breathing slows down
- Heart rate slows down
- Muscles relax
- Patterns of thinking change from problem solving which is usually in words, to thoughts in pictures and images.

These changes are a normal and natural part of good sleep, just as it is normal for our heart rate and breathing to speed up when we take exercise. When we prepare for sleep we begin the process of putting our minds and bodies to bed. Over the last two weeks you have begun to help this process by keeping exercise to the day and making space to wind down at night. You have begun to remove or reduce those things which can get in the way of good sleep, such as coffee, tea, daytime naps and sleep incompatible behaviours in your bedroom. Now you can build upon this and give the natural process a helping hand, by learning a good, deep relaxation. This will help you to reduce your physical arousal, by slowing down your heart rate and breathing and by reducing muscle tension. By focusing on the relaxation you will also stop your mind from racing, you will keep out thoughts which might otherwise get in the way of sleep and you will help the natural shift in your thinking from words to pictures.

This will help you to achieve a relaxed state and allow you to drift into sleep.

PRACTICE

- Set aside 25 minutes, at a convenient time when you will not be disturbed, each day. Practise the relaxation using your tape or from memory if preferred. The more you practise the deeper your relaxation will become and the more it will help you to achieve a good night's sleep.
- Once in bed, settle down prepared to sleep and again go through the relaxation. At the end try to hold in your mind the details of your pleasant image. Hold this as vividly as you can, see the colours and movements and hear the sounds, etc.

REMEMBER

- Beware of excuses which prevent you from practising every day.
- Don't fall asleep during practice in the daytime.
- Don't expect changes in your sleep just yet, it takes time. Just enjoy the relaxation.

# Appendix 2e

## Patient information sheet 5

In the last session we discussed how an active mind or body can get in the way of good sleep. We began to tackle this with the help of relaxation. In today's session we considered how we can put our minds to bed and stop thoughts getting in the way of good sleep. We can now build upon our earlier work, using other techniques, which keep arousing thoughts at bay. Thoughts which get in the way of sleep might be worrying thoughts, but more often are just thoughts about the day that has gone, or the day to come. They may be negative or positive, but either way they get in the way of good sleep.

### Put the day to rest

In today's session we discussed ways of putting the day to rest. It is helpful to pre-empt bedtime thoughts by rescheduling them to earlier in the day. Set aside time to pay attention to these thoughts; a good way is to write them down, perhaps in the form of an end of day note. We can write details of the day past and the day to come, and we can try to tie up loose ends.

### Change *troublesome* or *negative* thoughts into *trouble-free realistic* thoughts

We can use special techniques to challenge and change particularly troublesome thoughts. These thoughts may be about anything at all, but very often they are about sleep itself.

### For example:

| *negative thoughts* | *realistic thoughts* |
|---|---|
| I am never going to sleep tonight | I always fall asleep eventually |
| I won't cope tomorrow | I will be tired but I will cope |
| I will get sick if I don't sleep | Insomnia does not cause illness |
| Everyone else is asleep | I am not alone, as many as 1 in 5 adults have difficulty sleeping |

### Change *negative thoughts* to *realistic thoughts* by challenging your beliefs

Catch the thoughts you want to block or challenge. Although these thoughts are unhelpful they are often involuntary, habitual, negative, exaggerated or even defeatist. You can change these into more realistic thoughts by asking yourself:

1. Is this thought or fact?
2. Am I jumping to conclusions?
3. What is the evidence to support this thought?
4. What is a more realistic alternative to this thought?

Remember for every negative thought there is usually a more realistic alternative. Use this to help challenge thoughts during your 'pre-emptive thinking time' in the late afternoon or early evening.

### A calm mind at bedtime

Once in bed settle down quickly and go through your relaxation as last week. Use *imagery* by holding a pleasant scene in your mind. If you are troubled by repetitive, unimportant thoughts use the *thought blocking* technique we discussed. Repeat the word 'THE' every two seconds in your head. This will block out other thoughts and help you drift into sleep or return to sleep if you have awakened during the night. Remind yourself that you have already put your thoughts to bed during your thinking time. If any disruptive thoughts should enter your mind remind yourself of the realistic alternative which you identified during the day. Then use your imagery or thought blocking to distract yourself and drift off into sleep.

### No need to try to sleep

Remember there is no need to try to sleep. Sleep is natural and if we remove the things that keep us awake we will go off to sleep, even if we try to stay awake! GOOD sleepers never *try* to sleep; they just let it happen. You can join them with the techniques you have learned over the last few weeks. Don't expect too much too quickly, it takes time.

# Appendix 2f

## Patient information sheet 6

Your treatment with the Sheffield Sleep Clinic is now complete, and in today's session we considered your progress, and reviewed the advice you have been offered so far. Perhaps there were some treatments that you found particularly helpful. If so, we would encourage you to use that particular approach in future. At this stage it is important to emphasise, however, that all the advice you have been given can help to both *treat* and *prevent* episodes of poor sleep. The following points, therefore, are intended to help you manage your own sleep.

- Try to avoid, as best you can, those things which are likely to disturb your sleep.
- Remember that, if you do experience periods of poor sleep, there are many things that you can do to help yourself.
- Continue to practise the relaxation techniques you learned in the clinic.
- Continue to use the thinking techniques which help to control unhelpful thoughts.
- Keep all your information sheets in a safe place, and refer to them if necessary.
- Finally, it is realistic to expect some poor nights in the future. This does not mean that your insomnia is out of your control. Remember, **you are still in a position to help restore satisfactory sleep**.

### And don't forget:

- Please return your current sleep diaries and other forms, when completed, in the envelope provided.
- While your treatment at the clinic is now complete, the project team will contact you again (by post) over the next 2 years in order to monitor your progress.

Thank you for your co-operation over the past weeks.

# Appendix 2g

# Practice evaluation questionnaire

## Sleep clinic evaluation questionnaire

We are interested in your views about the sleep clinic as a service.

1. If resources were available would you offer the sleep clinic as an integrated clinical service (as opposed to a randomised controlled trial) at your practice?
   Yes – definitely _____
   Yes – probably _____
   Not sure _____
   Probably not _____
   No – definitely not If not why not?
   Clinically unsatisfying _____
   Impractical on the ground _____
   No demand/interest from patients _____
   Other (please specify) _____

2. Were there any elements to the sleep clinic that you were dissatisfied with?

3. Which aspects, if any could have been improved? (please specify).

4. Did the sleep project increase the workload for any of the following?

   (a) GP workload _____
   (b) Practice manager workload _____
   (c) Reception staff workload _____
   (d) Other (please specify) _____

# Appendix 3

# Daily sleep diary

## Daily sleep diary

| **Initials:** | **Date of Birth:** | | | **Date of Day 1:** | | | |
|---|---|---|---|---|---|---|---|
| | **Day 1** | **Day 2** | **Day 3** | **Day 4** | **Day 5** | **Day 6** | **Day 7** |
| 1 At what time did you go to bed last night? | | | | | | | |
| 2 After settling down, how long did it take you to fall asleep? | | | | | | | |
| 3 After falling asleep, for how long were you awake during the night *in total*? | | | | | | | |
| 4 At what time did you finally wake up? | | | | | | | |
| 5 At what time did you get up? | | | | | | | |
| 6 Did you take a sleeping tablet last night? (give dosage) | | | | | | | |
| 7 How much alcohol did you drink yesterday? (in Units) | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 How well do you feel this morning?<br>**0 1 2 3 4**<br>not at all moderately very | | | | | | | |
| 2 How enjoyable was your sleep last night?<br>**0 1 2 3 4**<br>not at all moderately very | | | | | | | |
| 3 How active was your mind in bed last night?<br>**0 1 2 3 4**<br>not at all moderately very | | | | | | | |
| 4 How physically tense were you in bed last night?<br>**0 1 2 3 4**<br>not at all moderately very | | | | | | | |
| 5 How anxious were you in bed last night?<br>**0 1 2 3 4**<br>not at all moderately very | | | | | | | |

# Appendix 4

## 20-Item sleep questionnaire

| | | | |
|---|---|---|---|
| Below are some questions concerning your sleep. Please answer all the questions. If your times for going to bed and so on vary greatly, give ranges (e.g. 10–11pm, 30–60 mins) | | | |
| 1 | For how long do you usually sleep at night? | | |
| 2 | After settling down, how long does it usually take you to fall asleep? | | |
| 3 | How often do you wake up too early in the morning? (tick one) | Never<br>Seldom<br>Sometimes<br>Often<br>All the time | ☐<br>☐<br>☐<br>☐<br>☐ |
| 4 | Do you usually wake up during the night? | Yes<br>No | ☐<br>☐ |
| 5 | If Yes: What usually awakes you? (answer in your own words) | | |
| 6 | How many times (on average) do you awake each night? | | |
| 7 | For how long are you awake on each of these occasions? | | |
| 8 | At what time do you usually go to bed? | | |
| 9 | At what time do you usually wake up (in the morning)? | | |
| 10 | At what time do you usually get up? | | |
| 11 | How refreshed do you usually feel when you wake up in the morning (tick one)? | Very refreshed<br>Quite refreshed<br>Unrefreshed<br>Tired<br>Shattered | ☐<br>☐<br>☐<br>☐<br>☐ |
| 12 | In general, how much sleep do you think a person your age needs? | | |
| 13 | How long have you had your present sleep problem? | | |
| 14 | What do you think is the cause of your present sleep problem? (answer in your own words) | | |
| 15 | Have you ever had serious trouble with your sleep in the past? | Yes<br>No | ☐<br>☐ |
| 16 | Have you gained or lost weight in the last few months? (tick one) | Yes I have gained weight<br>Yes I have lost weight<br>No, I'm about the same | ☐<br>☐<br>☐ |
| 17 | Before the present problem how would you have described yourself? (tick one) | A very good sleeper<br>A good sleeper<br>An average sleeper<br>A poor sleeper<br>A very poor sleeper | ☐<br>☐<br>☐<br>☐<br>☐ |
| 18 | How would you describe yourself now? | A very good sleeper<br>A good sleeper<br>An average sleeper<br>A poor sleeper<br>A very poor sleeper | ☐<br>☐<br>☐<br>☐<br>☐ |
| 19 | Do you usually take a nap during the day? | Yes<br>No | ☐<br>☐ |
| 20 | When do you usually nap? (give length of each nap) | | |
| *Thank you for completing this questionnaire* | | | |

# Appendix 5

## Counsellor unit costs

The unit costs for counsellor sessions were developed from several sources. First, a bottom–up costing exercise was undertaken using a methodology adapted from a local NHS provider. Second, data from a national survey of counsellor pay rates was used to give information on salary scales. Finally, these data were compared against other sources, including Counselling in Medical Settings (CMS) guidelines and previously published unit costs.

Together, these data provide a justifiable central estimate of the cost of counselling (£26.25), together with upper (£34.28) and lower (£24.06) bounds on what could reasonably be expected in other locations (1998/99 prices).

### Bottom–up costing

A local provider, Psychological Health Sheffield (PHS), was approached for details on the cost of a counselling service. A costing framework was developed from discussion with PHS and is shown in *Table 15*. The issue of salaries is discussed in the next section.

Starting with a salary, employer's on-costs are added to produce a salary-only hourly rate. Added to this are the costs of administration, supervision, travel, training and clerical support. Training costs were adapted to include the specialist training required to deliver this particular intervention, which was calculated as 5.5 days of staff costs annuitised over 30 years. GP practice costs then need to be added, and have been gathered from two sources. First, several practices within the trial were approached for their own estimates of providing a room and clerical support for counsellors, and second, overhead estimates for a practice nurse were adapted from a renowned source (PSSRU 2000).[54] The difference between

***TABLE 15*** *Unit costs of counselling*

| | | Baseline (£) | Lower (£) | Upper (£) |
|---|---|---|---|---|
| **Costs of counselling service** | | | | |
| Salary[a] | | 20,979 | 18,548 | 29,890 |
| Salary plus on-costs | 10.95% | 23,276 | 20,579 | 33,163 |
| Hourly cost | 46 weeks, 37.5 hours | 13.49 | 11.93 | 19.22 |
| Direct costs | Hours | | | |
| Counselling | 3.00 | 40.48 | 35.79 | 57.67 |
| Clinical administration | 0.50 | 6.75 | 5.96 | 9.61 |
| Supervision | 0.25 | 3.37 | 2.98 | 4.81 |
| Non-clinical administration | 0.20 | 2.70 | 2.39 | 3.84 |
| Travel | 0.25 | 3.37 | 2.98 | 4.81 |
| Indirect costs | Annual cost | | | |
| Supervisor | £2250 | 5.48 | 5.48 | 5.48 |
| Training[b] | £825 | 2.01 | 2.01 | 2.01 |
| Clerical and equipment | £1500 | 3.65 | 3.65 | 3.65 |
| Subtotal | | 67.81 | 61.25 | 91.88 |
| Counsellor cost per appointment | | 22.60 | 20.42 | 30.63 |
| **General practice costs** | | | | |
| Capital and overheads per appointment[c] | | 3.65 | 3.65 | 3.65 |
| Total cost per appointment | | 26.25 | 24.06 | 34.28 |

[a] Baseline, lower and upper figures are median, lower and upper quartile salaries for patient and family counsellors employed by NHS Trusts, respectively. More extreme upper and lower figures were not used as such salaries would not reflect the level of staff used to deliver this intervention.
[b] Training includes continuing professional development, plus specific training for the intervention delivered in this trial (with an annual equivalent cost of £75).
[c] Mean figure of estimates produced by two practices within the trial.

these two sources was small (£3.65 versus £4.39 per appointment, respectively).

## Counsellor salaries

The terms and conditions of employment for counsellors vary dramatically across the UK, and this has led to recommendations for grading and pay.[64] However, a recent survey of pay rates for counsellors[65] provides a good source of information for describing actual practice. Although the survey is restricted to counsellors working in NHS Trusts, and as such excludes primary care, it is thought the best source of data.

Patient and family counsellors employed by NHS Trusts had a median salary of £20,979. Lower and upper quartiles (£18,584 and £29,890) were used as upper and lower bounds for the sensitivity analysis. Using the bottom–up costing framework and local GP overheads, the mean salary translates to £26.25 per appointment, with upper and lower limits of £34.28 and £24.06, respectively.

The Pay and Workforce Research Survey also looked at staff who are paid through sessional payments. Session rates varied between £15 and £30 per hour, with a median rate of £20; however, these do not include other costs to the NHS such as the overhead and capital costs. Once these are included, and consideration is given to the need for more experienced counsellors to provide the service studies here, the sessional rates are similar to those produced through bottom–up costing.

## Other sources

### CMS salary scales

CMS, a division of the BAC, made proposals for grading criteria and pay scales in October 1998.[64] These guidelines only recommend pay scales to employers and make no attempt to cost a counselling service, which necessitates the inclusion of non-salary costs.

The proposals were partly made in response to low pay rates and therefore give recommended salaries in excess of actual salaries. The recommended salary scales are grade 1 £15,577 to £20,497, grade 2 £19,709 to £28,052 and grade 3 £26,937 to £34,406. The counsellors who delivered the intervention in the study were experienced and BAC accredited. This would broadly put them on the grade 2 scale, and consequently would produce a salary range similar to that taken from the Pay and Workforce Research Survey.

## Previous studies

Harvey and co-workers[66] undertook an economic evaluation alongside a controlled trial of counselling in primary care. In this study, a simple top–down figure of £11 per hour is estimated. This is based on £18,000 gross salary, 20% employers' on-costs, 37.5 hour week and, implicitly, a 52 week working year (£21,600/1950 = £11 per hour).

A study looking at the use of counselling in irritable bowel syndrome at the University of Sheffield (Mathers N, personal communication) used the counsellor's sessional payment as the basis of costing. A sessional payment of £30 per hour was used as the basic cost, with an additional 20% added for supervision. As such, the gross cost of £36 per hour includes all incidental costs and expenses.

## Non-attendance: DNAs

The cost of appointments when a patient does not attend is open to debate. A common practice is to cost this at the cost of a filled appointment. This approach is sometimes criticised as it does not take into account the use of the time for other productive uses, such as administration or time with another patient. However, in the context of the service provided in this study, where counsellors travel between practices and provide a structured intervention, substitution possibilities are small. Consequently, DNAs are costed at the normal rate in the baseline estimate, while cancellations are attributed a zero cost. Sensitivity analysis is undertaken by applying the full cost to cancellations as well.

# Appendix 6

## Hypnotic drug costs

Hypnotic drug-use data, quantified in terms of 'percentage of maximum prescribed dose', were available at baseline, 3-, 6- and 12-month follow-ups. Unit costs per tablet were derived from the BNF,[9] using prices of the lowest-dose tablet, then inflated by 4% to cover community dispensing costs.[67]

The study groups were not well balanced in terms of the types of hypnotics prescribed, resulting in the clinic group being more expensive (see *Table 16*). Therefore, a standard cost reflecting the average cost of hypnotics across all patients was used, and percentage doses applied to this standard cost. The average annual cost for all patients based on the prescribed dose at baseline is £33.32, or 9.1p per day.

Hypnotic costs over a given period are estimated by applying the standard cost (9.1p per day) to the percentage dose at the start of the period for half of the length of the period, then adding the estimated cost of the second half of the period based on the percentage dose at the end of the period.

***TABLE 16*** *Mean annual cost of drugs and numbers in each group*

| Drug name | Clinic group | Control group | Mean annual cost at baseline dose (£) |
|---|---|---|---|
| Temazepam | 58 | 49 | 18.68 |
| Nitrazepam | 25 | 22 | 22.79 |
| Zopiclone | 6 | 25 | 97.45 |
| Diazepam | 3 | 1 | 23.04 |
| Lorazepam | 1 | 5 | 6.09 |
| Chloral hydrate | – | 1 | 123.07 |
| Oxazepam | 4 | – | 11.02 |
| Loprazolam | 1 | – | 60.51 |
| Total | 98 | 103 | 33.32 |
| Mean cost per day | | | 0.09 |

In the sensitivity analysis, rather than taking estimates based on the distribution of the hypnotic costs, it was thought more clinically meaningful to base upper and lower limits on commonly used drugs. Consequently, the cheapest and most expensive of the three most commonly used drugs were used as the limits. These are temazepam (5.1p per day) and zopiclone (26.7p per day).

# Appendix 7

# Cost-effectiveness model

A simple spreadsheet model was produced to examine the effect of extrapolating the cost-effectiveness analysis beyond 6 months and incorporating the hidden costs of hypnotic treatment.

## Methods

Two models were produced: first, a model that assumed that the costs and effects seen up to 6 months would continue into the future, and second, a model that assumed that costs, dose and effect would exhibit an exponential decay (i.e. the difference between the two groups would be one half of the first year amount in the second year, quarter in the third year, one-eighth in the fourth year, etc.).

### Assumptions of the model

- Effect (i.e. QALYs), excess costs and excess mortality are proportional to dose. Constant doses produce constant effects, excess costs and mortality (if undiscounted). A reduced difference in hypnotic doses produces reduced effects, excess costs and mortality.
- Estimated using the following data:
  - an odds ratio of an RTA requiring hospitalisation associated with hypnotic use of 6.5, and a rate of RTAs requiring hospitalisation of 1.2 per 10,000 person-years (source: Neutel[68]); cost of hospitalisation following an RTA equal to £1227 (source: HES 1998/99, ICD external causes V40–V49[69])
  - a relative risk of a fall requiring hospitalisation associated with hypnotic use of 3.6, and a rate of falls requiring hospitalisation of 9.0 per 10,000 person-years (source: Neutel and colleagues[70]); cost of a hospitalisation following a fall equal to £2408 (source: HES 1998/99, ICD external causes W01[69])
  - an odds ratio of DSH requiring hospitalisation associated with hypnotic use of 8.2, and a rate of DSH requiring hospitalisation of 0.7 per 10,000 person-years (source: Neutel and Patten[49]); cost of hospitalisation following DSH equal to £446 (source: HES 1998/99, ICD external causes X60–X84[69])
  - combining these produces an excess cost of hypnotic users over non-users of £6.67 per annum (or £3.33 per half-year)
  - excess costs estimated proportional to dose with full excess costs assumed for the control group.
- The excess mortality associated with hypnotic use is estimated using an annual hazard ratio of 1.35 for 'high benzodiazepine use' (source: Kripke and colleagues[50]) and applied to the successive annual probabilities of death from the UK Government Actuary's Department (2001) for a female aged 65 years. Excess mortality is estimated proportional to dose with full excess mortality assumed for the control group.
- The mean utility of a patient is 0.646, which is taken from an analysis of baseline patient data. This figure is needed to estimate the effect of excess mortality on QALYs.
- The increased risk of the accidents was described by various measures: excess mortality was described by a hazard ratio, the excess risk of falls was described by a relative risk, and the excess costs of RTAs and DSH were described by odds ratios. However, when the incidence of the outcome of interest is uncommon (< 10%), the adjusted odds ratio derived from a logistic regression approximates the risk ratio.[71] It is therefore assumed that for these very rare events, all three measures will produce similar estimates of excess risk.
- Costs are discounted at 6% per annum and QALYs at 1.5% per annum.

## Results

The first lines of *Tables 17* and *18* replicate the results from *Tables 9*, *11* and *13* in the report, and consequently produce the same ICER of £3418 per QALY.

*Table 17* shows a simple extrapolation where the savings generated in the first year (excluding counsellor costs) are rolled forward to successive years. The reducing incremental cost is merely due to discounting. Under these assumptions, the intervention becomes cost saving in the fourth year. Likewise, the QALY effects in the first year

***TABLE 17*** *Simple extrapolation of the 6-month results*

| Year | Cost (£) | | Dose | | IC | CIC | XsAccid | CIC (Accid) | DFC | CBT | Ctl | IQ | CIQ | XsMort | CIQ (Mort) | DFQ | ICER | ICER (XsAccMort) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | CBT | Ctl | CBT | Ctl | | | | | | QALY difference | | | | | | | | |
| 1 | 272 | 143 | 0.44 | 0.77 | 130 | 130 | 1.43 | 128 | 1.00 | 0.024 | –0.014 | 0.038 | 0.038 | 0.0022 | 0.040 | 1.00 | 3418 | 3199 |
| 1 | 118 | 143 | 0.44 | 0.77 | –24.8 | 105 | 1.43 | 104 | 1.00 | 0.024 | –0.014 | 0.038 | 0.076 | 0.0043 | 0.080 | 1.00 | 1383 | 1291 |
| 2 | 111 | 134 | 0.44 | 0.77 | –23.4 | 82 | 1.35 | 80 | 0.94 | 0.024 | –0.014 | 0.037 | 0.113 | 0.0067 | 0.120 | 0.99 | 720 | 669 |
| 2 | 111 | 134 | 0.44 | 0.77 | –23.4 | 58 | 1.35 | 57 | 0.94 | 0.024 | –0.014 | 0.037 | 0.151 | 0.0090 | 0.160 | 0.99 | 386 | 356 |
| 3 | 105 | 127 | 0.44 | 0.77 | –22.1 | 36 | 1.27 | 35 | 0.89 | 0.023 | –0.014 | 0.037 | 0.188 | 0.0116 | 0.199 | 0.97 | 193 | 175 |
| 3 | 105 | 127 | 0.44 | 0.77 | –22.1 | 14 | 1.27 | 13 | 0.89 | 0.023 | –0.014 | 0.037 | 0.225 | 0.0142 | 0.239 | 0.97 | 63 | 54 |
| 4 | 99 | 120 | 0.44 | 0.77 | –20.8 | –7 | 1.20 | –8 | 0.84 | 0.023 | –0.013 | 0.036 | 0.261 | 0.0171 | 0.278 | 0.96 | –26 | –28 |
| 4 | 99 | 120 | 0.44 | 0.77 | –20.8 | –28 | 1.20 | –29 | 0.84 | 0.023 | –0.013 | 0.036 | 0.297 | 0.0199 | 0.317 | 0.96 | –93 | –91 |

CBT, cognitive-behaviour therapy; Ctl, control; IC, incremental cost; CIC, cumulative incremental cost; XsAccid, excess cost in the control group produced by accidents associated with hypnotic use; CIC (Accid), cumulative incremental costs net of excess cost of accidents; DFC, discount factor for costs; IQ, incremental QALYs; CIQ, cumulative incremental QALYs; XsMort, excess mortality associated with hypnotic use; CIQ (Mort), cumulative incremental QALYs net of excess mortality; DFQ, discount factor for QALYs; ICER, incremental cost-effectiveness ratio; ICER (Xs AccMort), incremental cost-effectiveness ratio net of excess cost of accidents and excess mortality.

***TABLE 18*** *Extrapolation with diminishing effectiveness and cost reductions*

| | Cost (£) | | Dose | | IC | CIC | XsAccid | CIC (Accid) | DF | CBT | Ctl | IQ | CIQ | XsMort | CIQ (Mort) | DF | ICER | ICER (XsAccMort) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | CBT | Ctl | CBT | Ctl | | | | | | QALY difference | | | | | | | | |
| 1 | 272 | 143 | 0.44 | 0.77 | 130 | 130 | 1.43 | 128 | 1.00 | 0.024 | –0.014 | 0.038 | 0.038 | 0.0022 | 0.040 | 1.00 | 3418 | 3199 |
| 1 | 118 | 143 | 0.44 | 0.77 | –24.8 | 105 | 1.43 | 104 | 1.00 | 0.024 | –0.014 | 0.038 | 0.076 | 0.0043 | 0.080 | 1.00 | 1383 | 1291 |
| 2 | 123 | 134 | 0.61 | 0.77 | –11.7 | 93 | 0.67 | 93 | 0.94 | 0.005 | –0.014 | 0.019 | 0.095 | 0.0055 | 0.100 | 0.99 | 986 | 925 |
| 2 | 123 | 134 | 0.61 | 0.77 | –11.7 | 82 | 0.67 | 81 | 0.94 | 0.005 | –0.014 | 0.019 | 0.113 | 0.0067 | 0.120 | 0.99 | 720 | 674 |
| 3 | 121 | 127 | 0.69 | 0.77 | –5.5 | 76 | 0.32 | 76 | 0.89 | –0.004 | –0.014 | 0.009 | 0.123 | 0.0073 | 0.130 | 0.97 | 621 | 583 |
| 3 | 121 | 127 | 0.69 | 0.77 | –5.5 | 71 | 0.32 | 70 | 0.89 | –0.004 | –0.014 | 0.009 | 0.132 | 0.0080 | 0.140 | 0.97 | 536 | 503 |
| 4 | 117 | 120 | 0.73 | 0.77 | –2.6 | 68 | 0.15 | 68 | 0.84 | –0.009 | –0.013 | 0.005 | 0.136 | 0.0083 | 0.145 | 0.96 | 499 | 469 |
| 4 | 117 | 120 | 0.73 | 0.77 | –2.6 | 65 | 0.15 | 65 | 0.84 | –0.009 | –0.013 | 0.005 | 0.141 | 0.0087 | 0.150 | 0.96 | 464 | 436 |
| 5 | 112 | 113 | 0.75 | 0.77 | –1.2 | 64 | 0.07 | 64 | 0.79 | –0.011 | –0.013 | 0.002 | 0.143 | 0.0089 | 0.152 | 0.94 | 448 | 422 |
| 5 | 112 | 113 | 0.75 | 0.77 | –1.2 | 63 | 0.07 | 63 | 0.79 | –0.011 | –0.013 | 0.002 | 0.145 | 0.0091 | 0.155 | 0.94 | 433 | 407 |
| 6 | 106 | 107 | 0.76 | 0.77 | –0.6 | 62 | 0.03 | 62 | 0.75 | –0.012 | –0.013 | 0.001 | 0.147 | 0.0092 | 0.156 | 0.93 | 426 | 400 |
| 6 | 106 | 107 | 0.76 | 0.77 | –0.6 | 62 | 0.03 | 62 | 0.75 | –0.012 | –0.013 | 0.001 | 0.148 | 0.0093 | 0.157 | 0.93 | 419 | 394 |
| 7 | 100 | 100 | 0.76 | 0.77 | –0.3 | 62 | 0.02 | 62 | 0.70 | –0.012 | –0.013 | 0.001 | 0.148 | 0.0093 | 0.158 | 0.91 | 415 | 391 |
| 7 | 100 | 100 | 0.76 | 0.77 | –0.3 | 61 | 0.02 | 61 | 0.70 | –0.012 | –0.013 | 0.001 | 0.149 | 0.0094 | 0.158 | 0.91 | 412 | 387 |
| 8 | 95 | 95 | 0.77 | 0.77 | –0.1 | 61 | 0.01 | 61 | 0.67 | –0.012 | –0.013 | 0.000 | 0.149 | 0.0094 | 0.158 | 0.90 | 410 | 386 |
| 8 | 95 | 95 | 0.77 | 0.77 | –0.1 | 61 | 0.01 | 61 | 0.67 | –0.012 | –0.013 | 0.000 | 0.149 | 0.0095 | 0.159 | 0.90 | 409 | 384 |
| 9 | 89 | 89 | 0.77 | 0.77 | –0.1 | 61 | 0.00 | 61 | 0.63 | –0.012 | –0.012 | 0.000 | 0.149 | 0.0095 | 0.159 | 0.89 | 408 | 384 |
| 9 | 89 | 89 | 0.77 | 0.77 | –0.1 | 61 | 0.00 | 61 | 0.63 | –0.012 | –0.012 | 0.000 | 0.150 | 0.0095 | 0.159 | 0.89 | 407 | 383 |
| 10 | 84 | 84 | 0.77 | 0.77 | 0.0 | 61 | 0.00 | 61 | 0.59 | –0.012 | –0.012 | 0.000 | 0.150 | 0.0095 | 0.159 | 0.87 | 407 | 382 |
| 10 | 84 | 84 | 0.77 | 0.77 | 0.0 | 61 | 0.00 | 61 | 0.59 | –0.012 | –0.012 | 0.000 | 0.150 | 0.0095 | 0.159 | 0.87 | 406 | 382 |

See Table 17 for abbreviations.

are rolled forward, with the diminishing incremental QALYs the result of discounting. Combining costs and QALYs produces a rapidly diminishing ICER, and if a 4-year time-frame is considered, CBT is dominant, that is, more effective and less costly. When the hidden costs of hypnotic treatment are considered, the incremental costs are reduced further and the incremental QALYs are increased further. These effects, however, are relatively small.

*Table 18* shows a model where CBT has a diminishing effect with costs and dose of the CBT group converging with the control group. The first two lines of the model are identical to *Table 17*, then differences are apparent. However, the same patterns are seen with the ICER reducing substantially as a longer time-frame is considered. Under this scenario, CBT does not become dominant, but at 10 years, the ICER is around £270 per QALY.

## Discussion

The results show that any increase in the time-frame of the evaluation produces substantial reductions in the ICER. This would be true for any scenario that incorporated any amount of sustained effect. The effect of hidden costs is very small.

The choice of risk estimates from the studies of hidden costs is somewhat subjective as they vary with type of drug, age of patients, length of time between prescription and accident, and dose of drug. The most appropriate estimate was used on each occasion, and in any case, all estimates were of the same magnitude and consequently, a different choice of risk estimates would not materially affect the results of the model.

A more complex model based around a Markov formulation was experimented with which, for example, explicitly modelled dose changes for individual patients. However, the conclusions were essentially the same: an increased time-frame increases the cost-effectiveness of CBT.

These results are produced by CBT incurring costs only in the first 6 months of the model, but exhibiting cost savings in subsequent years. The trial-based analysis implicitly assumes that there are no sustained treatment or cost effects after 6 months. This must be considered a worst-case scenario. The only way that the ICER could increase is if CBT caused hypnotic use to increase after 6 months or caused patients to increase their use of health services through extra demands on the GP or counsellors for continued support. There was no evidence of this in the trial.

The model did not cover all hidden costs of hypnotic use. The cost of withdrawal programmes was not included; however, this was thought to be negligible as no such formal programmes existed with local providers. Instead, patients withdrawing from treatment tend to seek support through self-help groups such as Tranx. Such resources, although incredibly important, would produce low costs within the perspective of this evaluation as private and production costs are excluded.

## Conclusion

The model examined the effect of extrapolating the results of the trial beyond 6 months. Two formulations were examined and both showed that the cost-effectiveness of CBT improved even when the effects of treatment were reduced dramatically over time. The effect of hidden costs was negligible. The trial-based results should be considered a worst-case scenario, as they assume that there is zero effect beyond 6 months.

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ISSN 1366-5278