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

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Patients with chronic sleep problems, who had been using hypnotic drugs for at least 1 month, were given a course of cognitive-behaviour therapy (CBT) to help with their insomnia. The CBT consisted of 6 sessions with a practice counsellor specially trained to treat insomnia, handouts were given after sessions 2 - 5, and an audiotape was provided after session 4. For patients who wanted to discontinue taking hypnotics, a programme of gradual withdrawal was agreed with the general practitioner (GP). The comparator group carried on with the treatment they had been receiving before the study began.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis; cost-utility analysis.

Study population
Patients with chronic insomnia who had been prescribed hypnotics by their GP for at least 1 month were eligible for inclusion in the study. Patients were not eligible if they were taking neuroleptic medication. The patients had to be due for, or had to have requested a repeat prescription of hypnotics and had to be able to travel to the surgery. The patients also had to be at least 30 years old. All patients were registered with a general practice that could offer a room suitable for psychological treatment and was not currently running a benzodiazepine reduction programme.

Setting
The setting was primary care. The economic study was conducted in Sheffield, UK.

Dates to which data relate

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The same patients provided the effectiveness data and the cost data. It was unclear whether or not the costing was carried out prospectively.
Study sample
No power calculations to determine the sample size were reported. Forty-two general practices were randomly selected from a total of 96 in the Sheffield area. Seventeen of these practices refused to participate in the study and 2 did not meet the inclusion criteria. Each of the 23 participating practices was randomised to either a sleep clinic (SC) phase followed by a control (C) phase, or a C phase followed by an SC phase. This meant that the treatment group to which the patients were assigned depended on when they were recruited into the study. There were 108 patients in the SC group. A total of 344 patients were invited to participate, but 223 refused, 1 could not be contacted and 12 were too ill. There were 101 patients in the C group. A total of 215 were invited to participate, but 104 refused and 10 were too ill. Refusal to participate in the trial was significantly associated with age, (p=0.03).

Study design
This was a multi-centre, crossover randomised trial. The unit of randomisation was the general practice. Follow-up was at 3 and 6 months. At 3 months, 76 (70%) of the SC patients and 72 (71%) of the C group provided data. At 6 months, 72 (60%) of the SC patients and 59 (57%) of the C group provided data.

Analysis of effectiveness
The basis of the analysis was intention to treat. The primary health outcomes used were:

- the Pittsburgh Sleep Quality Index (PSQI),
- sleep latency,
- sleep efficiency score (percentage of time in bed spent asleep),
- total sleep time,
- hypnotic-free nights per week,
- mean hypnotic dose (as a proportion of the maximum dose prescribed),
- the percentage of patients at 50% or more of baseline use,
- the percentage of patients taking hypnotics every night,
- the percentage of patients taking zero hypnotics,
- the MOS 36-item short-form health survey (SF-36) and the SF-6D (derived from a sub-set of SF-36).

The authors stated that 0.01 was taken as the target level of significance for the trial outcomes.

The two groups were assessed at baseline for the gender ratio, age, age at onset of sleep problems, duration of hypnotic use, percentage taking hypnotics nightly, Hospital Anxiety and Depression (HADS) scores and the SF-36. All patients met the DSM-IV criteria for insomnia. The patients in the C group were significantly older, (p=0.02), had longer duration of hypnotic drug use, (p=0.001), and had significantly lower mean anxiety scores, (p=0.04). There was no significant difference between the two groups for other aspects of sleep history.

Effectiveness results
Results for the 3-month follow-up.

The change in PSQI was 2.8 for the SC group and -0.9 for the C group, (p=0.002).

The change in sleep latency was 27.7 minutes for the SC group and 3.5 for the C group, (p<0.001).
The change in the sleep efficiency score was 0.7 for the SC group and -0.1 for the C group, (p<0.001).
The change in total sleep time was -0.6 hours for the SC group and -0.1 hours for the C group, (p=0.04).
The change in hypnotic-free nights per week was -2.2 for the SC group and -0.4 for the C group, (p<0.001).
Low-frequency hypnotic use was 47.4% in the SC group and 17.3% in the C group, (p<0.001).
The proportion taking hypnotics nightly was 30.3% in the SC group and 58.7% in the C group, (p<0.001).
The proportion on zero hypnotics was 29% in the SC group and 10.7% in the C group, (p=0.005).
Scores on the SF-36 assessing vitality improved in the SC group, (p<0.001).

Results at 6 months.
The change in PSQI was 1.9 in the SC group and -1.4 in the C group, (p=0.04).
The change in sleep latency was 29.6 minutes in the SC group and 1.7 in the C group, (p=0.003).
The change in the sleep efficiency score was 0.7 in the SC group and -2.4 in the C group, (p<0.001).
The change in hypnotic-free nights per week was -2.4 in the SC group and 0.2 in the C group, (p<0.001).
Low-frequency hypnotic use was 54.2% in the SC group and 17.7% in the C group, (p<0.001).
The proportion taking hypnotics nightly was 33.3% in the SC group and 62.9% in the C group, (p=0.001).
The proportion on zero hypnotics was 33% in the SC group and 8.1% in the C group, (p<0.001).
The improvements in SF-36 for the SC group were not statistically significant (0.04 versus 0.02; p<0.001) (odds ratio: 12 - 34).

Clinical conclusions
The authors concluded that CBT did improve sleep quality, as shown by the reduction in hypnotic drug use and the improvement in sleep latency, sleep efficiency and global sleep quality.

Measure of benefits used in the economic analysis
The measure of benefit used was the quality-adjusted life-years (QALYs). These were measured using the SF-6D, which was derived using a sub-set of questions from the SF-36. The authors did not explain where the utility weights came from. The SF-6D utility values were calculated at 6 months' follow-up.

Direct costs
Discounting was not carried out since the costs were incurred during less than 2 years. The costs of the health service were calculated, which was consistent with the NHS perspective adopted. The costs were measured for primary care, prescriptions and counsellor sessions. The primary care costs covered GP surgery visits, GP domiciliary visits, practice nurse and district nurse contacts. The costs were not broken down into prices and quantities. The costs were calculated using actual data. Resource use appears to have come from the trial. The unit costs were mostly taken from the British National Formulary (2000) and the Unit Costs of Health and Social Care (2000). The price year was given as 1999/2000.

Statistical analysis of costs
No sensitivity analysis was carried out.

**Indirect Costs**
No indirect costs were calculated.

**Currency**
UK pounds sterling (UK).

**Sensitivity analysis**
The authors stated that the results were insensitive to changes in the unit costs, but they did not provide any information about how this conclusion was reached.

**Estimated benefits used in the economic analysis**
At 6 months, when withdrawals were not considered, the mean change in health-related utility was 0.024 (standard error, SE=0.01) for the SC group and -0.014 (SE=0.02) for the C group. When withdrawals were accounted for, the mean change in health-related utility was 0.007 (SE=0.01) for the SC group and -0.014 (SE=0.01) for the C group.

**Cost results**
At 6 months, the mean costs for the 6-month period were 272.4 (SE=31.7) for the SC group and 142.6 (SE=30.5) for the C group. The costs of adverse effects were included in the costing.

**Synthesis of costs and benefits**
The incremental cost per QALY at 6 months was 4,819 when withdrawals were included and 3,416 when withdrawals were excluded.

**Authors’ conclusions**
Cognitive-behaviour therapy (CBT) in a primary care setting can improve sleep quality for chronic insomniacs, as measured by all the indicators of sleep quality and reduced drug use. The authors concluded that the cost of that improvement, in terms of the cost per quality-adjusted life-year (QALY) gained, was reasonable. They also pointed out that appropriate targeting of CBT would improve the outcomes since there was a high drop-out rate. The cost per QALY gained went down when withdrawals were not included.

**CRD COMMENTARY - Selection of comparators**
The selection of the comparator, carrying on with existing treatment, was valid as this describes the common treatment offered by GPs in the NHS. You should decide if the comparator represents current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The source of the effectiveness data was a multi-centre, crossover randomised trial in general practice. The study design was appropriate for the study question. The authors did not show that the study sample was representative of the study population. All patients meeting the inclusion criteria from the participating general practices were initially included. The only reason why they would not be generalisable would be if the participating general practices were unrepresentative of general practices as a whole. However, the high refusal rate meant that the results cannot necessarily be generalised to all chronic insomniacs.

**Validity of estimate of measure of benefit**
Limited information was given on the derivation of the measure of benefit. The authors referred to the SF-6D, which was used to derive the measure of health-related utility.

**Validity of estimate of costs**
From the cost perspective adopted, all the relevant categories of cost appear to have been included. However, with the exception of one counsellor session, the costs were not reported separately from the quantities. The other costs were taken from published sources. The price year was given, which enables reflation exercises.

**Other issues**
The authors made appropriate comparisons of their results with the findings of those from other studies. However, they did not address the generalisability of their results beyond the UK NHS setting. It would have been helpful to have access to the data referred to in the paper, but which could not be accessed using the URL given.

**Implications of the study**
The authors concluded that CBT in a general practice setting can definitely improve the sleep quality and health-related quality of life for some patients. Although the cost per QALY was considered reasonable, the authors advocate targeting the CBT on patients who are least likely to withdraw from treatment, which would result in a significantly lower cost per QALY. The authors pointed out that dropping out from treatment is related to low initial health status.

**Source of funding**
Funded by the NHS Health Technology Assessment Programme, project number 95/30/02.

**Bibliographic details**

**PubMedID**
14960215

**Other publications of related interest**

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Adult; Aged; Aged, 80 and over; Chronic Disease; Cognitive Therapy; Drug Administration Schedule; Female; Follow-Up Studies; Health Care Costs; Humans; Hypnotics and Sedatives /administration & dosage; Male; Middle Aged; Sleep Initiation and Maintenance Disorders /drug therapy /therapy

**AccessionNumber**
22004008017

**Date bibliographic record published**
31/07/2004

**Date abstract record published**