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

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K Morgan,[1*] S Dixon,[2] N Mathers,[3] J Thompson[3] and M Tomeny[4]

[1] Loughborough Sleep Research Centre, Department of Human Sciences, Loughborough University, UK
[2] Sheffield Health Economics Group, ScHARR, University of Sheffield, UK
[3] Institute of General Practice and Primary Care, Community Sciences Centre, University of Sheffield, UK
[4] Department of Clinical Psychology, Nottinghamshire Healthcare Trust, Mansfield, UK

* Corresponding author

Executive summary

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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.

Publication

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NHS R&D HTA Programme

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Initially, six HTA panels (pharmaceuticals, acute sector, primary and community care, diagnostics and imaging, population screening, methodology) helped to set the research priorities for the HTA Programme. However, during the past few years there have been a number of changes in and around NHS R&D, such as the establishment of the National Institute for Clinical Excellence (NICE) and the creation of three new research programmes: Service Delivery and Organisation (SDO); New and Emerging Applications of Technology (NEAT); and the Methodology Programme.

This has meant that the HTA panels can now focus more explicitly on health technologies ('health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care) rather than settings of care. Therefore the panel structure was replaced in 2000 by three new panels: Pharmaceuticals; Therapeutic Procedures (including devices and operations); and Diagnostic Technologies and Screening.

The HTA Programme will continue to commission both primary and secondary research. The HTA Commissioning Board, supported by the National Coordinating Centre for Health Technology Assessment (NCCHTA), will consider and advise the Programme Director on the best research projects to pursue in order to address the research priorities identified by the three HTA panels.

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