Insomnia

'Doctor, I haven’t slept for days…you’ve got to do something!' Having done house jobs at a time when we did 56 hour weekends without sleep, I can remember how that feels. Somehow her immaculate make-up suggested that she may be exaggerating just a little…however, lack of sleep, whether real or perceived is a source of great distress to people.

A BMJ clinical review helpfully looked at some of the causes and some treatment strategies (BMJ Clinical Review 2011;342:d2899) and I have also added information from a review in the NEJM (NEJM 2015;373:1437) and a BMJ review (BMJ 2016;353:i2123).

The NEJM review suggests 20% of Americans use a sleeping tablet of some sort at least once a month, and many more use alcohol to achieve the same aim!

A Scottish cross-sectional population study that showed that (BJGP 2016;66(647):e410):

- 12% of over 65s were prescribed benzodiazepines or Z-drugs.
- This rose to 28% for those in care homes.

Sleep requirements do fall with age – older people may spend more time in bed but report poorer quality and quantity of sleep.

Diagnosis

- Careful history to exclude secondary causes, which include:
  - Anxiety/depression
  - Physical health problems (e.g. pain, dyspnoea)
  - Obstructive sleep apnoea (risk increased if BMI ≥30 or neck circumference ≥40cm)
  - Excess alcohol or illicit drugs
  - Parasomnias (restless legs, sleep walking/talking/sleep terrors/teeth grinding (bruxism), etc.)
  - Circadian rhythm disorder (especially in shift workers).
- Sleep diaries may help (see Useful websites) in that they may show erratic sleep patterns, difficulty getting off to sleep or early morning waking and can be used to personalise advice.
- Examination to exclude other physical causes as indicated by history.
- Investigations: you may want to do an FBC for anaemia, ferritin (restless legs) or TSH (hyperthyroidism). Polysomnography (sleep studies) may be indicated if severe problems/sleep apnoea suspected. This assesses brain activity, oxygen levels and muscle activity. Sleep apnoea is discussed in the ENT chapter online.

Remember there are different elements to sleep problems (International Classification of Sleep Disorders):

- Difficulty initiating sleep.
- Difficulty maintaining sleep.
- Waking earlier than desired.
- Resistance in going to bed on an appropriate schedule. (Isn’t this all children? Read the poem ‘Bedtime’ by Eleanor Farjeon!)
- Difficulty sleeping without a parent or caregiver.

The issues may be acute or chronic (defined as one of the above for at least 3d a week for at least 3m) (BMJ 2016;355:15819). A review of chronic insomnia confirmed that drugs should be used only as a last resort, particularly in the elderly for whom side-effects are more common, and that all the non-drug managements outlined below should be used as first line treatments for chronic insomnia (BMJ 2016;355:15819).

Secondary insomnia

When assessing people with insomnia, always look for and treat causes of secondary insomnia including anxiety/depression:

- For those with delayed sleep disorder melatonin may help (2 RCTs) – although if this is related to shift work, then changing shift patterns may be more helpful.
- For restless legs massage/stretching/exercise and warm baths before bed are suggested (the BMJ clinical review makes no comment about the evidence base for these suggestions!!) with non-ergot dopamine agonists reserved for more severe cases (e.g. pramipexole). Ergot-derived dopamine agonists (e.g. pergolide, cabergoline) have gone out of favour, with the concerns expressed some years ago about heart valve disease. There is an article on restless leg syndrome in the Neurology chapter online.
- The other parasomnias (sleep walking/talking/sleep terrors, etc.) need referral for specialist assessment and management.

Non-drug management of insomnia
There are many elements to this, many of which have been combined together into a package of cognitive behavioural therapy for insomnia, called CBT-I.

CBT-I is the mainstay of non-pharmacological treatment. In trials CBT-I is consistently better than any drug therapy in chronic insomnia, for both effectiveness and long-term benefits. CBT-I works in those with co-morbidities, such as chronic pain, depression and cancer as well as in those without co-morbidities. CBT-I can be delivered one-to-one or in groups and computerised CBT-I packages also exist, and have been shown to be as effective as one-to-one therapy. Importantly, although it can take 4–8w for CBT to work, its benefits last over 12m, and helping patients see the long-term benefits over the short-term benefit of benzodiazepines is important, because many people have long term, not short term sleep problems.

CBT-I combines:

- Sleep hygiene.
- Stimulus control.
- Sleep restriction.
- Relaxation training.
- Cognitive restructuring.

Most effective when offered together as part of CBT-I these elements may be offered alone. Each element is described below.

**Sleep hygiene**

For all, sleep hygiene will help, and for some this will be all that is needed. For those with primary insomnia (no underlying cause), 30% will get better with sleep hygiene alone. There is a good leaflet on sleep and sleep hygiene on the patient.co.uk website (see the Useful websites box).

**Stimulus control**

Sleep hygiene involves the CBT technique of **stimulus control** – trying to re-associate bed with sleep, rather than a place you lie anxiously waiting for sleep not to come!. Stimulus control involves 5 simple rules:

1. Go to bed only when sleepy.
2. Get out of bed if you are not asleep within 15–20min (repeat as often as necessary).
3. Use the bed and bedroom only for sleeping.
4. Get up at the same time every day.
5. No napping.

**Sleep restriction**

The BMJ review concluded that sleep restriction was the most important element of CBT-I. The idea behind this is that people spend too long in bed, not sleeping. Using sleep diaries they are supposed to work out how long they actually spend sleeping in bed. For example, let's say they go to bed at 11pm but don't get off to sleep until 1am, and then they sleep through to 7am. Total sleep = 6h, total time in bed = 8h. They then need to restrict their time in bed to the total sleep time (6h), so, if their usual getting up time is 7am they have to stay out of bed, up and about, until 1am, then go to bed. Daytime naps are banned. Over a 2w period people apparently report better sleep (deeper, better quality) and more consolidated sleep. If at the end of a fortnight they are not sleeping better, they can knock a further 30min off their 'in bed' time. If they are sleeping better but still feeling sleep deprived, they can add 30min to their 'in bed' time. Those who drive/operate machinery should do this over a holiday period because in the short term they are often sleep deprived before the benefits kick in.

**Relaxation training**

There is some evidence for yoga and Tai Chi.

**Cognitive re-structuring**

Many people who can't sleep lie in bed worrying about how tired they will be the next day and how terrible they will feel. Cognitive re-structuring can help them view their insomnia differently. For example, mindfulness-based approaches to insomnia can help because they aim to reduce excessive rumination and worrying, improve selective attention and efforts to sleep. Using this approach people can develop a new relationship with their insomnia – experiencing it non-judgementally.

**Exercise**

Exercise improves sleep. Exercise in the 4h before bed used to be advised against, the thinking being that this might keep people awake. Lately research has shown this not to be true. However, trials have shown that although exercise at any time helps, exercise in the morning tends to produce the best sleep. Aerobic exercise is better than resistance-based exercise.

**Sleep tracking devices**

Compared with clinical measurements of sleep, a trial showed that the commonly used devices (Fitbit One, Jawbone UP, Nike+ FuelBand, GENEactiv and LUMO Black) mis-reported total sleep time by 10–50min and inaccurately assessed arousal during major sleep periods. The BMJ review suggested patients should be discouraged from using them as the main measure of sleep quality.
Drugs for insomnia

This comes from the NEJM review (NEJM 2015;373:1437).

- **Diphenhydramine** (sold in the UK OTC as Nytol) is the most commonly used drug for insomnia. In trials it showed moderate benefit and caused daytime sedation and anticholinergic side-effects (like dry mouth, constipation, and of course concern has been expressed about anticholinergics and dementia).

- **The benzodiazepines and Z-drugs** (which are not benzodiazepines but do work on benzodiazepine receptors) have varying half-lives (temazepam 8–10h, zolpidem 2.5h) and have shown benefit for insomnia but are of course addictive and may cause daytime sleepiness (remember the DVLA rules on driving and drugs apply to all these agents as well!). A recent link has also been made between long-term use of benzodiazepines and Alzheimer’s, although of course unpicking the cause in all this is much more complicated than saying that one causes the other. More on the Z-drugs below!

- **Sedating antidepressants.** These are widely used but unlicensed (trazodone is used as a treatment for insomnia by 1% of Americans!). They also have anticholinergic side-effects and may cause daytime sleepiness.

- **Melatonin.** Slow release melatonin is licensed in the UK for use for short-term insomnia in those aged 55y or more, for less than 13w duration. Trials suggest it can help improve sleep onset but not total sleep time. Next day sleepiness was the main side-effect and this was rarely reported.

- **Gabapentin** is sometimes used for sleep, but is unlicensed. Remember this is also a drug of abuse.

The Z-drugs in primary insomnia

Drugs work, but the effect is not long lasting and there are significant concerns about side-effects. Practical measures (sleep hygiene, stimulus control, CBT, etc.) tend to have a longer duration of action. In fact one RCT showed CBT was better than zopiclone (more efficient sleep, less wakefulness, although no change in total time asleep).

A meta-analysis of trials submitted to the FDA in the US for drug licensing purposes (thus avoiding publication bias) (65 trials, 4300 patients) showed that the Z-drugs reduced time to getting off to sleep by 22min (CI 11–33min) compared to placebo, but when adjusting for varying factors this may increase to falling asleep about 42min earlier than with placebo (BMJ 2012;345:e8343).

Way back in 2005, when the ‘Z-drugs’ were relatively new for insomnia, NICE issued guidance reminding us to use them only where insomnia was severe and interfered significantly with everyday life (NICE 2005, TA77). Problems with them include rebound wakfulness, perception of tolerance developing, and withdrawal effects. Also there is potential for abuse (often used to enhance the ‘high’ of other drugs) and concerns about impact on performance (especially driving) the next day, and falls in the elderly. NICE also reminded us that if one Z-drug didn’t work, we should not use the others, because it tends to be a class effect.

An editorial in the NEJM highlights the fact that there is increasing concern about driving risk the day after using Z-drugs (NEJM 2013;369:689). Research on zolpidem, which is available both in lower doses and controlled release formulations in the US, has shown two important things:

- **Women metabolise the drug differently and tend to have significantly higher blood levels than men, even 8h after taking it.**

- **In both sexes there was also a concern about driving performance, and importantly lack of awareness of impairment of driving skills.** The editorial acknowledges that reduced performance on a driving assessment doesn’t necessarily translate into more accidents, but with lack of awareness to reduced performance, any impaired performance should be taken seriously.

In the US, the FDA now recommends lower doses for women on the basis of the research (5mg not 10mg).

The European Medicines Agency Pharmacovigilance Risk Assessment Committee has recommended the following (DTB 2014;6:63):

- Dose: 10mg except in older patients and liver impairment when 5mg should be used (‘older’ unhelpfully not defined!).

- Never to be used at higher doses than this. Do not take a second dose later in the night if you wake again.

- Use the lowest effective dose.

- Do not driveoperate machinery for 8h after taking it.

- Be especially aware of the potential for increased impairment if taken with other drugs that slow reaction times, including alcohol.

The Z-drugs: what does this mean in practice?

There are currently no recommendations about using lower doses of zolpidem in women in the UK. However, I think I’ll be cautious about using 10mg in women, and I’ll ensure I follow, and my patients are aware of, the European recommendations.

I’ll be particularly clear with patients that there is evidence of impairment in tasks such as driving the day after use and, most importantly, lack of awareness of this impairment.

How much this applies to the other Z-drugs we don’t know because there isn’t the evidence, but concerns about next day performance, in particular, may occur with the other Z-drugs, and other drugs used to treat insomnia.

I’ll continue to use the Z-drugs only in cases of severe insomnia with significant impact on everyday life (not difficult – I can’t
We make every effort to ensure the information in these articles is accurate and correct at the date of publication, but it is of necessity of a brief and general nature, and this should not replace your own good clinical judgement, or be regarded as a substitute for taking professional advice in appropriate circumstances. In particular check drug doses, side-effects and interactions with the British National Formulary. Save insofar as any such liability cannot be excluded at law, we do not accept any liability for loss of any type caused by reliance on the information in these articles.

### Shift work, insomnia and health risks

A BMJ State of the Art Review reminds us that (BMJ 2016;355:i5210) (apologies that the statistics quoted vary from odds ratios to risk ratios – this was all that was given in the original paper):

- Shift workers, unsurprisingly have more sleep problems that normal workers.
- Shift workers have a small increased risk of cardiovascular disease (RR 1.23, CI 1.15–1.31) and very small increased risk of stroke (RR 1.05, CI 1.01–1.09) and an increase risk of metabolic syndrome (OR 1.15, CI 1.08–1.22).
- The data on breast cancer risk is mixed.

The authors outlined things individuals and organisations can do to reduce the impact of shifts on workers:

- Having at least 11h recovery time between shifts.
- Avoid long working weeks (>60h/w).
- Giving workers a high degree of flexibility about individual working times whilst limiting excessive overtime/work during night shifts.
- Regularly screening and treating those with sleep problems.
- Educating workers about sleep hygiene, and the need to prioritise sleep and recovery time above other activities during and after runs of night shifts.
- Using bright light and caffeine to promote adaptation and performance.
- Healthy lifestyle for all, with limited night-time eating.

### Insomnia

- Look for treatable secondary causes.
- Use of sleep hygiene (combining stimulus control) may be all that is needed.
- CBT-I is the most effective treatment. Consider sleep restriction in motivated individuals who spend long hours in bed but not asleep.
- Drugs are a last resort.
- Be aware of the new US and European guidance on zolpidem doses in women. Warn patients that one of the problems with next day driving impairment is the lack of awareness of a problem.

Can you access CBT-I (face-to-face or online)?

**How often do we assess how much time is spent in bed awake vs. in bed and asleep?**

Is sleep restriction worth a try in those who spend a disproportionate amount of time lying in bed but not actually sleeping and who are willing to try this drug-free approach?

Audit your use of the Z-drugs. Do you, as an individual or as a practice, use the Z-drugs a lot?

Do you use them in line with the NICE guidance (severe insomnia with significant impact on everyday life) and is this clearly documented in the notes at initiation and each medication review? How often do you use alternatives (amitriptyline, trazodone) for sleep?

In the light of the issues highlighted above you may want to consider offering women a trial of 5mg rather than 10mg (the 10mg tablets are scored) either by writing to women using zolpidem or by flagging their notes for a discussion next time you see them.

**Sleep diaries are available from:**


**Sleep hygiene advice is available at:**

[www.patient.co.uk/health/Insomnia-Poor-Sleep.htm](http://www.patient.co.uk/health/Insomnia-Poor-Sleep.htm)

An online form of CBT-I (available on the NHS in some areas or to purchase privately (£99 for the course in May 2017)) can be found at:

[https://sleepstation.org.uk/how_it_works/find_out_more](https://sleepstation.org.uk/how_it_works/find_out_more)
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