

INSOMNIA

A HOME MEDICINES REVIEW CASE STUDY

CASE SCENARIO – HOME MEDICINES REVIEW

Mrs Somnum, aged 72 years, has been referred by her general practitioner (GP) for a Home Medicines Review (HMR). She was recently diagnosed with chronic insomnia, mainly experiencing trouble getting to sleep (starting 4 months ago).

Her GP has requested that you review her current medicines to identify any contributing factors and make recommendations where possible for its management.

Mrs Somnum's medical history includes: hypercholesterolaemia, hypertension, depression, anxiety and polymyalgia rheumatica. Her current medicines are listed in Table 1. She takes the paracetamol three times daily, but all other medicines are taken with dinner. She drinks 1–2 coffees a day (often consuming one in the late afternoon) but does not drink alcohol or smoke. She has heard she can get melatonin without a prescription and explains that she started valerian tablets after a friend recommended them.

NB: The management of insomnia, and identifying non-pharmacological and pharmacological contributing factors, can be a consideration in medication management reviews. The case study highlights this, noting that it is not a complete HMR and only includes those aspects relating to insomnia.

Introduction

Insomnia is characterised by self-reported difficulty in falling or staying asleep despite adequate opportunity, resulting in subjective daytime impairment and distress. Insomnia often occurs alongside other mental and physical medical conditions; however, it should not be viewed as a secondary symptom to these conditions. Insomnia can be acute (usually due to short-term stressors) or chronic (present on more than 3 days per week for at least 3 months or longer).^{1,2}

Pharmacists can play an important role in assisting in the management of insomnia by reviewing medicine use, identifying and providing advice on potential contributing factors, recommending appropriate management options (such as Cognitive Behavioural Therapy for insomnia [CBTi]) and referring patients to their general practitioner (GP) when necessary.

Insomnia

A national survey in 2016 estimated that 39.8% of Australian adults experience inadequate sleep, and a 2019 survey highlighted that the prevalence of chronic insomnia disorder in Australian adults was 14.8%.^{3,4} »

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QUMISH* STEERING COMMITTEE
***Quality Use of Medicines for Insomnia and Sleep Health**

SPONSORSHIP INFORMATION



A national education program for pharmacists funded by the Australian Government under the Quality Use of Diagnostics, Therapeutics and Pathology program.

LEARNING OBJECTIVES

After reading this article, pharmacists should be able to:

- Explain factors that contribute to insomnia
- Discuss Cognitive Behavioural Therapy for insomnia (CBTi)
- Discuss pharmacological management options for insomnia
- Describe the role of the pharmacist in insomnia management.

Competency (2016) standards addressed:
 1.1, 1.4, 1.5, 2.1, 2.2, 2.3, 3.1, 3.2, 3.5

Accreditation number: CAP2405AMVS

Accreditation expiry: 30/04/2027

Clinical features

Insomnia is a subjective complaint, and assessment should be made to determine the initial causes and to identify any long-term psychological and behavioural factors. Assessment should involve taking a sleep history using a sleep diary (templates available online or in app form) or a sleep questionnaire (such as the Insomnia Severity Index). See the *Australasian Sleep Association Primary Care* resources for more information.^{5,6}

Chronic insomnia is associated with reduced quality of life and cognitive performance, and increased risk of accidents, hypertension, cardiovascular disease, depression, diabetes and mortality.^{5,7–13}

Contributing factors

Insomnia is more common in people who are female, older, have medical conditions or mental health disorders, or are socioeconomically disadvantaged.^{14,15}

Short-term insomnia can be triggered by many psychological, physical and environmental factors. These include^{5,16–18}:

- stress
- mental health conditions such as depression and anxiety
- medical conditions (e.g. gastro-

oesophageal reflux disorder [GORD], menopause, pain, hyperthyroidism, dyspnoea, nocturia)

- sleep health behaviours (also called 'sleep hygiene')
- sleep disorders (e.g. sleep apnoea, restless legs syndrome) or circadian rhythm disorders
- genetics

- substances (e.g. alcohol, caffeine, nicotine)
- many medicines, such as some antidepressants, corticosteroids, adrenergic agonists (e.g. pseudoephedrine), psychostimulants (e.g. dexamfetamine, methylphenidate), diuretics, beta blockers and statins
- dependence on sleep medicines.

For most people, sleep improves after initial precipitating triggers have been managed or have subsided. However, in about 20–30% of people, psychological and behavioural perpetuating factors can cause insomnia to persist over time.

In many patients, a pattern of 'conditioned insomnia' develops, where the bedroom environment can become a learned trigger for feeling alert, awake and anxious.¹⁹

Pathophysiology

The pathophysiology of insomnia is complex and involves psychological factors (e.g. hyperarousal/anxiety), behavioural factors (e.g. spending more time in bed than required, resulting in more time awake) and a 'conditioned' insomnia response to

Table 1 – Current medications for Mrs Somnum

MEDICINE NAME AND STRENGTH	DIRECTIONS	DURATION OF THERAPY
Atorvastatin 20 mg	1 tablet daily	5 years
Docusate/senna 50/8 mg	2 tablets daily when required	3 years
Escitalopram 20 mg	1 tablet daily	3 years
Prednisolone 5 mg	1 tablet daily, on reducing dose regimen	6 months
Paracetamol 665 mg MR	2 tablets 3 times daily	2 years
Telmisartan 40 mg	1 tablet daily	5 years
Valerian extract equivalent to dry root & rhizome 2,000 mg	1 tablet daily	2 months





the bed environment), and neurobiological sleep-wake mechanisms (including circadian rhythm and sleep pressure).^{3,19}

Insomnia management

CBTi is the recommended first-line treatment for insomnia and is used for both acute and chronic insomnia.^{5,20,21}

However, patients with insomnia that has persisted for <4 weeks (caused by an obvious underlying trigger, such as work stress, acute pain or jet lag) may find reassurance and ongoing monitoring adequate to prevent the development of chronic insomnia.^{5,20}

Cognitive behavioural therapy for insomnia

CBTi aims to identify and target the underlying causes of insomnia, and it can lead to large and sustained improvements in insomnia and associated mental/physical symptoms after just 4–8 therapy sessions.^{21,22}

CBTi treatment includes components such as sleep and healthy sleep behaviour education, stimulus control therapy, bedtime restriction therapy and relaxation therapy.^{19,23}

Chronic insomnia often leads to, and may be caused by, anxiety. It can be a vicious cycle of worrying about sleep quality and next-day consequences, which then prevents a person getting to sleep, and inadequate sleep that can exacerbate anxiety during the day. CBTi aims to break the cycle by using psychological techniques and psychoeducation to change unhelpful thoughts, beliefs and behaviours about sleep.²⁴

As treatment from a psychologist can be costly, a Medicare GP Mental Health Treatment Plan referral can be used to access subsidised sessions with a psychologist. CBTi from a suitably trained sleep psychologist is the gold standard modality; however, due to the costs and time involved (and availability of practitioners), other delivery methods have been developed and may be suitable for some patients.^{23,25} CBTi can also be accessed via self-guided online programs and from other health professionals such as GPs and nurses.^{21,23} For example, *This way up: managing insomnia* is a free online program based on CBTi, and can be recommended if appropriate, especially if

cost of therapy is an issue.²⁶

Of note, in a 2015 feasibility study in NSW, pharmacists provided a modified version of CBTi therapy which found some positive effect on insomnia severity. This highlights the potential role and impact pharmacists can have in recommending behavioural interventions with appropriate training and remuneration.²⁷

For more information regarding CBTi and its components, and evidence-based resources to supplement and further explain the below information, go to www.sleepprimarycareresources.org.au/insomnia/cbti

Healthy sleep behaviours and sleep education

Patients should be provided with evidence-based information about sleep to challenge common myths and misconceptions that can cause anxiety and sleep difficulties.¹⁹ For more information, go to www.sleephealthfoundation.org.au/sleep-topics/sleep-myths

Patients should be informed of the cyclical nature of normal sleep and that brief awakenings during the night are a normal occurrence. A night of normal sleep includes 5–6 cycles each lasting for approximately 90 minutes, and includes light (stage 1), moderate (stage 2), deep (stage 3) and Rapid Eye Movement (REM) sleep. Most deep sleep occurs in the first half of the night, and most light and REM sleep occurs in the second half of the night.^{28,29}

Healthy sleep behaviours (or 'sleep hygiene') should be encouraged for all patients. However, many patients with chronic insomnia have already implemented healthy sleep hygiene practices to limited benefit. Consequently, these recommendations are not an adequate 'standalone' treatment for insomnia and should be provided alongside other CBTi components.²⁹ Examples of recommendations include^{19,29–31}:

- regular exercise (moderate evening exercise is okay, but intensive »



- exercise should be avoided within 4 hours of bedtime)
- regular sleep and wake times, with morning sunlight exposure
 - avoiding long naps, particularly after 4 pm
 - avoiding caffeine after midday
 - avoiding screen use in bed
 - making the bedroom cool, quiet and dark.

Stimulus control therapy

Stimulus control therapy aims to treat the 'conditioned' insomnia response to the bedroom environment and re-establish an association between bed and sleep. Stimulus control therapy is particularly effective at reducing sleep onset difficulties.^{19,32}

Stimulus control therapy includes instructions to use the bedroom only for sleep and intimacy, and to go to bed only when sleepy, and to get up and leave the bedroom if not asleep after about 15 minutes (then returning to bed when feeling sleepy again).^{19,32} Patients are encouraged to get out of bed at the same time each morning, irrespective of how much sleep they obtained.^{19,32}

Bedtime restriction therapy

Bedtime restriction therapy is the most

effective CBTi component, and leads to improvements in sleep, mood and daytime function within 3–4 weeks.^{19,25,33} Bedtime restriction requires motivation sustained over several weeks, but if applied appropriately may result in sustained improvement in insomnia symptoms.^{19,25,33}

Bedtime restriction aims to temporarily reduce time in bed over several consecutive nights and weeks to increase sleep pressure, consolidate sleep periods and reduce time spent awake in bed. After sleep improves, time in bed is gradually extended each week until a comfortable balance is achieved.^{19,33}

Bedtime restriction therapy should be provided by specialist sleep clinicians in the presence of specific comorbidities, and occupational and lifestyle factors.^{19,33}

Relaxation therapy

Evidence-based relaxation therapies, such as progressive muscle relaxation and guided imagery, can reduce anxiety before bed, or upon long awakenings throughout the night.^{5,19,34}

Like any new skill, it is important to practice relaxation therapy to become better at it. Patients should be encouraged to practice relaxation techniques during the day or evening to reduce levels of cognitive and physical arousal.^{5,19,34}

Pharmacological management

Medicines are not first-line treatment for insomnia, and when used, should only be used for as short a duration as possible.

Table 2 lists pharmacological treatment options for insomnia; however, »

CLASS	EXAMPLES
Benzodiazepines	Temazepam, oxazepam
Z-drugs	Zolpidem, zopiclone
Orexin receptor antagonists	Lemborexant, suvorexant
	Melatonin
H ₁ antagonists	Doxylamine, diphenhydramine
Complementary and alternative medicines	Valerian**



Table 2 – Pharmacological treatment options for insomnia in Australia

MECHANISM OF ACTION (MoA)	PRIMARY INDICATION/S	EXAMPLES OF COMMON ADVERSE EFFECTS (AEs)*	PRECAUTIONS AND CONTRAINDICATIONS	INTERACTIONS OF NOTE	NOTES
Increase effects of GABA	Short-term treatment of insomnia	Dependence, light-headedness, slurred speech, ataxia, vision impairment	Contraindications: myasthenia gravis, respiratory depression Precautions: elderly, hepatic impairment	Central nervous system (CNS) and respiratory depressant drugs	<ul style="list-style-type: none"> • Rapid tolerance develops • Dependence and withdrawal effects • Temazepam preferred due to short half-life
Increase effects of GABA	Short-term treatment of insomnia	Taste disturbance, dry mouth, diarrhoea	Contraindications: myasthenia gravis, acute stroke, sleep apnoea, pulmonary insufficiency, alcohol intake	Metabolised by CYP3A4 – administration with other medicines which affect this enzyme may alter therapeutic or adverse effects	<ul style="list-style-type: none"> • Similar MoA and AE profile to benzodiazepines, but may have less risk of dependence • Depression, psychosis, schizophrenia may worsen • Of note, reports of parasomnias/bizarre sleep behaviours led to reduced pack sizes for zolpidem
Bind to orexin receptors, blocking the wake-stimulating orexin A and B neuropeptides	Chronic insomnia (most useful for sleep maintenance insomnia)	Headache	Contraindications: narcolepsy Precautions: compromised respiratory function (e.g. sleep apnoea, COPD)	CYP3A4 inhibitors or inducers	<ul style="list-style-type: none"> • Take on an empty stomach for faster effect • May cause sleep paralysis and abnormal dreams • Patient should have a sleep of at least 7 hours planned given duration of action
Replaces endogenous melatonin; binds to MT ₁ and MT ₂ receptors in SCN/hypothalamus to regulate circadian rhythm	<ul style="list-style-type: none"> • Short-term use in primary insomnia • Insomnia in ASD or Smith-Magenis syndrome • Jet lag • Delayed sleep-wake phase disorder (strategically timed along with light therapy) 	Back pain, arthralgia, weakness	Precautions: Hepatic impairment	Fluvoxamine	<ul style="list-style-type: none"> • Does not appear to have any dependence or withdrawal effects • Small improvement in sleep parameters
Bind central H ₁ receptors, reducing effects of histamine to promote sleep	Short-term management of insomnia	Anticholinergic effects (e.g. increased risk of falls, confusion, dry mouth)	Precautions: GI obstruction, bladder outlet obstruction, risk factors for angle-closure glaucoma, elderly	CNS and anticholinergic drugs (increased AEs)	<ul style="list-style-type: none"> • Rapid tolerance develops • Not generally recommended for insomnia due to limited efficacy and safety data • Not recommended for older people
May bind to receptors implicated in circadian rhythm	Not generally recommended for insomnia due to limited evidence	Headache, diarrhoea, other GI complaints	Liver and pancreatic disease	Anaesthesia, haloperidol	<ul style="list-style-type: none"> • Liver damage and delirium may occur, but not common

* Note that excess drowsiness may occur with all treatment options and this may persist the following day.

**Information presented here relates to valerian, see specialised resources for further examples from this class.

References: TG⁵, AMH³⁶, MSKCC³⁷, Journal of Sleep Research³⁸, TGA³⁹, Sleep Health Foundation⁴⁵, MJA⁴⁶

it is not a comprehensive overview and other references and guidelines (e.g. *Australian Medicines Handbook* and the *Therapeutic Guidelines*) should be referred to for further information (e.g. doses, further interactions, safety in pregnancy and breastfeeding). The Sleep Health Foundation has a useful webpage about herbal medicines used for sleep – for most, evidence is low.³⁵

Knowledge to practice

Pharmacists have an important role to play in the management of insomnia, including recommending non-pharmacological management, providing advice and recommendations on pharmacological management and any potential contributing factors, and referring for further assessment and treatment when this is required.

KEY RESOURCES

- Sleep Health Foundation: www.sleephealthfoundation.org.au
- Refer to online CBTi programs: www.sleepprimarycareresources.org.au/insomnia/cbti/referral-to-digital-cbti-programs
- Australasian Sleep Association, primary care sleep health resources – Insomnia: www.sleepprimarycareresources.org.au/insomnia
- This Way Up online insomnia program. At: <https://thiswayup.org.au/programs/insomnia-program>

Conclusion

Insomnia is a multifactorial condition, and a thorough history should be taken. Non-pharmacological management should be encouraged, and pharmacological therapy is not first-line treatment. Pharmacists have a significant role to play, including providing advice about reducing the use of potentially addictive medicines for insomnia, counselling on healthy sleep behaviours, and encouraging and helping to facilitate the use of CBTi, which is the recommended first-line therapy for insomnia.



CASE SCENARIO CONTINUED

Actions and recommendations regarding insomnia

You recommend the following to the GP in your HMR:

- CBTi (as part of a Mental Health Treatment Plan to facilitate subsidised psychologist sessions if possible) as first-line management for Mrs Somnum's insomnia. If CBTi is ineffective, a trial of melatonin 2 mg CR at night 1–2 hours before bedtime for 3 weeks before review could be considered.
- Prednisolone and escitalopram should be taken in the morning to reduce any potential impact these medicines could have on the patient's ability to sleep.^{40–43} Prednisolone is best taken in the morning to avoid night-time insomnia, and it is recommended that selective serotonin reuptake inhibitors (SSRIs) such as escitalopram are taken in the morning to minimise any insomnia they may cause.^{40,41} Statins such as atorvastatin may cause sleep disturbances such as insomnia and nightmares; however, this patient has been using atorvastatin long-term and this effect is usually observed at treatment initiation and is clinically debated.^{42–44}
- You recommend a dose administration aid (DAA) to assist Mrs Somnum in taking medicines at appropriate times.
- Ceasing valerian, as evidence for this is low.³⁷

Patient information regarding insomnia


- You advise Mrs Somnum that insomnia is best managed with CBTi and encourage her to speak to her GP about this and direct her to available online resources in the interim.
- You provide stimulus control therapy instructions to reduce sleep onset insomnia, counsel on healthy sleep behaviours (including reducing her caffeine intake after midday) and provide resources to support these recommendations.

Outcomes

You follow up with Mrs Somnum in 6 months. She is now taking her medicines at appropriate times with a DAA from her local pharmacy, and after CBTi her sleep is much better. »

UP TO
1.5
CPD
CREDITS
GROUP 2

KEY POINTS

- Insomnia should be assessed with a sleep history.
- CBTi is the recommended first-line treatment of insomnia and includes promoting healthy sleep behaviours.
- GPs can arrange subsidised psychologist sessions through a Mental Health Treatment Plan, or CBTi can be accessed through self-guided online programs or suitably trained primary care clinicians when appropriate.
- Pharmacological management is not first line and should only be used for short periods when CBTi is ineffective or not acceptable to the patient, non-pharmacological options are impractical, or benefits of the medicine outweigh the risks. 

ASSESSMENT QUESTIONS

Each question has only one correct answer.

1 Which ONE of the following statements about Cognitive Behavioural Therapy for insomnia (CBTi) is **MOST** appropriate?

- A Sleep hygiene education is as effective as CBTi and can be used instead of this.
- B CBTi helps to challenge and overcome unhelpful thoughts and beliefs regarding sleep.
- C CBTi should be used only if prescribed medicines are not effective.
- D Bedtime restriction therapy is a quick process, requiring minimal commitment by the patient.

2 Which ONE of the following is a potential contributing factor to insomnia?

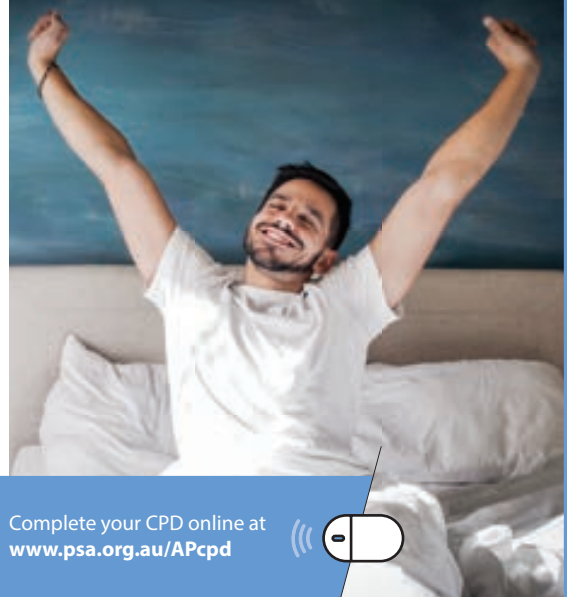
- A Socioeconomic advantage.
- B Cool room temperature.
- C Avoiding screens in the bedroom.
- D Genetic predisposition.

3 Which ONE of the following is the **MOST** appropriate regarding the pharmacological management of insomnia?

- A Pharmacological treatment is recommended to be trialled as the first step in the management of insomnia.
- B Zolpidem may have higher risk of dependence than oxazepam.
- C Tolerance does not occur with H₁ antagonists.
- D Most herbal medicines used for insomnia have low evidence for their use.

4 Mateo, 20, is a student completing an intensive university course. He is struggling to get to sleep at night and has presented to the pharmacy for advice. Mateo takes dexamfetamine for ADHD (started 6 weeks ago). Which ONE of the following is the **MOST** appropriate advice or recommendation for Mateo?

- A Suggest Mateo trial a 3-week course of melatonin, and supply this over the counter. You ask he return for review after completion of this for further advice.
- B Recommend having an extended lunchtime nap to help with sleep onset in the evening, and other healthy sleep behaviours.
- C Explain that the recent initiation of dexamfetamine may be contributing, discuss strategies to assist with this, and counsel on healthy sleep behaviours.
- D Encourage regular exercise and suggest that he leave the bedroom to do high-intensity exercise to tire himself out if he cannot sleep within 30 minutes of lying in bed.



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