
PharmaZzz
Non-Medication Therapy for Insomnia
TRAINING MANUAL

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ACRONYMS

- **BBTi:** Brief behavioural therapy for insomnia
- **CBT:** Cognitive behavioral therapy
- **CBTi:** Cognitive behavioural therapy for insomnia
- **DBAS:** Dysfunctional beliefs and attitudes about sleep
- **NMTi:** Non-medication therapy for insomnia
- **NSTs:** Negative Sleep Thoughts
- **REM:** Rapid eye movement
- **RLS:** Restless leg syndrome
- **SE:** Sleep efficiency
- **SL:** Sleep latency
- **SNRI:** Serotonin and norepinephrine reuptake inhibitors
- **SSRI:** Selective serotonin reuptake inhibitor
- **TIB Prescription:** Time in bed prescription
- **TIB:** Time in bed
- **TST:** Total sleep time
- **TTOB:** Total time out of bed
- **WASO:** Wake after sleep onset

RESOURCES FOR PATIENTS

Free Apps*:

- **Catch It** - https://www.nhs.uk/apps-library/catch-it/. Cognitive restructuring technique to help identify the cause of emotions and reassess these emotions
- **CBT-I Coach** - https://apps.apple.com/ca/app/cbt-i-coach/id655918660. A multifunctional tool including a sleep diary and graph, sleep habit guidelines, relaxation exercises, relapse prevention, sleep education
- **My Sleep Button** - https://mysleepbutton.com/home/. Guided imagery exercises
- **Best Meditation Apps -** https://www.healthline.com/health/mental-health/top-meditation-iphone-android-apps. – Review and links to a variety of meditation apps.

**Many other free guided imagery resources are available online.*

Books:

- *Say Good Night to Insomnia* by Gregg D Jacobs
- *The Insomnia Workbook* by Stephanie Silberman
- *Sink into Sleep: A Step-by-Step Workbook for Reversing Insomnia* by Judith Davidson

Part I: Understanding Non-Medication Therapy for Insomnia and its Appropriate Use in Practice

1.1 Introduction

This training manual was developed for pharmacists who wish to learn how to provide non-medication therapy as an alternative to hypnotic medication for patients with insomnia. Non-medication therapy for insomnia (NMTi) consists of several strategies that target behaviours and thought processes that may be negatively affecting sleep. These strategies have been proven to be as, if not more, effective than hypnotic medications and are now recommended as first line treatment for patients with chronic insomnia.[1,2] However, due to a variety of factors including lack of accessibility, cost and a lack of knowledge regarding its benefits, NMTi is currently underutilized.[3,4] Hypnotics remain the most common treatment for insomnia and are often used chronically although only officially indicated for short-term use.[5]

The goal of this program is to improve insomnia therapy and reduce long-term hypnotic use by training pharmacists to deliver NMTi. Pharmacists are one of the most accessible health care providers, giving them the opportunity to make this therapy more readily available to patients. Although pharmacists are not trained sleep specialists, many recent studies have demonstrated the ability of healthcare providers who are not experts in sleep therapy to effectively provide NMTi.[6-11] This training manual outlines a protocol for providing different levels of NMTi and some practical tips on how to integrate this service into pharmacy practice.

1.2 Background on Sleep

Sleep is a basic function of life and accounts for approximately one third of our lives. While the purpose of sleep is not entirely understood, it is thought to have restorative functions and to be important for the maintenance of a variety of physiological processes.[12] The amount of sleep required to feel fully restored in the morning varies among people. On average, between seven and eight hours a night is sufficient for most adults. However, some people require much less sleep while others require more. Thus, quality of sleep should not be based on the number of hours spent sleeping, but rather on feeling refreshed in the morning.[13]

Sleep Cycles

Throughout the night, our sleep cycles through a series of stages. The first three stages include the lighter stages of sleep, N1 and N2, as well as the deepest stage of sleep, N3. The last stage of sleep involves rapid eye movement (REM) and is the stage where dreaming occurs. An average adult enters REM sleep about 70-100 minutes after falling asleep. Once we have cycled through N1 -N3 and REM sleep, we briefly wake up before starting the cycle again.[12]

Factors Determining Sleep Needs

Our sleep needs are affected by a variety of individual and environmental factors. A major factor is our circadian rhythm or biological clock, which determines if we are naturally early or late risers. The rise and fall of our body temperature throughout the day is regulated by our biological clock and this influences how sleepy we feel, with a fall in temperature just before bed and a rise in temperature in the morning. The sun can also have a major effect on our biological clock.

Another factor affecting sleep needs is the process of aging. We often experience deeper and more satisfying sleep in our younger years but develop more shallow and fragmented sleep in our later years.[12]

Because we have individual sleep needs, many people begin to experience sleep problems when forced to sleep according to society's schedule. For example, if someone is naturally inclined to maintain a sleep-wake schedule of 12 AM to 8 AM but required to wake up at 6 AM for their job, they may have difficulties adjusting to the earlier sleep-wake schedule.

1.3 Background on Insomnia

Insomnia is a common health problem affecting an estimated 3.3 million Canadians.[14] Women are more often affected than men. Insomnia often presents with other medical conditions but it is difficult to determine whether the insomnia or the other condition(s) came first and whether they have a causal relationship. Recent research has shown that insomnia not only often persists after treatment of the primary condition, but is also an important risk factor for new onset or recurrence of mental and medical illnesses. Accordingly the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) has eliminated the primary and secondary definitions of insomnia and now lists "insomnia disorder" as a separate entity which may be co-morbid with other medical conditions or sleep disorders.[15] This is an important distinction as it indicates insomnia should be targeted for treatment as well as the co-morbid condition. A list of medical and psychiatric conditions often co-morbid with insomnia can be found in Tables 1 and 2, respectively.

Insomnia can be described in a number of ways but for our purposes it will be defined as follows: difficulty initiating sleep (**sleep-onset insomnia** – taking longer than 30 minutes to fall asleep) and/or difficulty staying asleep (**sleep-maintenance insomnia** – waking for longer than 30 minutes during the night) and feeling unrefreshed after waking (**non-restorative insomnia**).[15] To constitute insomnia, these definitions also require a complaint of impaired daytime functioning.[15]

Table 1: Common Co-Morbid Psychiatric Disorders[13]

Category	Example of Disorders
Mood disorders	Major depressive disorder, bipolar mood disorder, dysthmia
Anxiety disorders	Generalized anxiety disorder, panic disorder, posttraumatic stress disorder, obsessive compulsive disorder
Psychotic disorders	Schizophrenia, schizoaffective disorder
Amnestic disorders	Alzheimer's disease, other dementias
Disorders usually seen in childhood and adolescence	Attention deficit disorder
Other disorders and symptoms	Adjustment disorders, personality disorders, bereavement, stress

Table 2: Common Co-Morbid Medical Conditions [13]

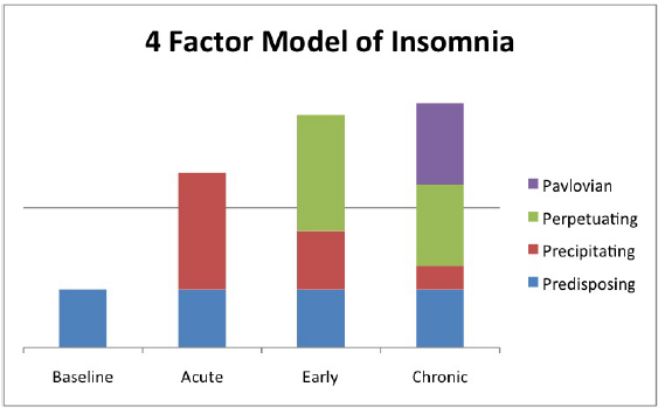
System	Examples of Symptoms, Conditions
Neurological	Stroke, dementia, Parkinson disease, seizure disorders, headache disorders, traumatic brain injury, peripheral neuropathy, chronic pain disorders, neuromuscular disorders
Cardiovascular	Angina, congestive heart failure, dyspnea, dysrhythmias
Pulmonary	Chronic obstructive pulmonary disorder, emphysema, asthma, laryngospasm
Digestive	Reflux, peptic ulcer disease, cholelithiasis, colitis, irritable bowel syndrome
Genitourinary	Incontinence, benign prostatic hypertrophy, nocturia, enuresis, interstitial cystitis
Endocrine	Hypothyroidism, hyperthyroidism, diabetes mellitus
Musculoskeletal	Rheumatoid arthritis, osteoarthritis, fibromyalgia
Reproductive	Pregnancy, menopause, menstrual cycle variations

The impairment of daytime functioning can include anything from irritability to dry mouth upon awakening.[2] People with chronic insomnia often feel **fatigued rather than sleepy** and report diminished concentration.[13] If a patient does not have a daytime complaint, provide education about the variability of individual sleep needs and assurance that sleep medications are not needed.

How Insomnia Evolves

In general, insomnia is considered to be chronic when it has persisted for at least three months (DSM-5 definition).[15] The 4P model of insomnia is built on the theory there are four factors responsible for the development of chronic insomnia: predisposing, precipitating, perpetuating, and Pavlovian factors.[17] Predisposing factors are characteristics that increase one's risk of insomnia, such as increasing age or being female. Precipitating factors are events that cause the initial bout of insomnia, such as an illness or new job. Perpetuating factors are the strategies we use to cope during an acute bout of insomnia, such as sleeping in later than usual. Pavlovian factors refer to the process of classical conditioning and include things that may promote an association of our bedroom with the feeling of wakefulness. These include stimulating activities in the bedroom, such as watching TV, and arousing emotions, such as anxiety. During the acute phase of insomnia, predisposing and precipitating factors are primarily responsible for the sleep disturbances.[14] However, as insomnia becomes chronic, perpetuating and Pavlovian factors are primarily responsible for the maintenance of sleep disturbances.[17] (Figure 1)

Figure 1: Insomnia Threshold[17]



* ***Upper horizontal line is the insomnia threshold***

1.4 Candidates for NMTi

As insomnia is often a co-morbid condition, it is important to determine which patients are candidates for NMTi. It has been proven through multiple studies that NMTi is effective for insomnia regardless of whether or not it is co-morbid with other medical conditions and may even be useful in helping patients manage depression and anxiety disorders.[1,10,11,18,19] However, there are certain situations in which NMTi is not appropriate and/or when referral or other action may be necessary.

When NMTi May Not Be Appropriate

Co-Morbid Disorders[17]

When insomnia is associated with an acute self-limiting illness, such as a patient suffering from a severe cold, NMTI is not indicated as the insomnia complaint is not likely the result of maladaptive behaviors. Additionally, patients with co-morbid illnesses that prevent the patient from participating in NMTi interventions are unlikely to benefit from therapy. An example of this is severe major depression, where the patient may not have the energy or motivation to adhere to therapy. Lastly, patients with co-morbid conditions that could be aggravated by certain components of NMTi should not be offered this therapy. These conditions include epilepsy, bipolar disorder, parasomnias and certain other sleep disorders. Patients with otherwise stable co-morbidities that will not interfere with or be worsened by NMTi are candidates for NMTi.

Sleep Apnea[22-24]

Sleep apnea is one of the most common sleep disorders and may present as central sleep apnea, obstructive sleep apnea or a combination of both. Central sleep apnea occurs when the body does not respond to respiratory signals resulting in the failure to inhale. In comparison, obstructive sleep apnea is caused by blockage of the upper airways that prevents air from entering the lungs. Both result in hypoxia which causes frequent sleep arousals.

Sleep apnea is associated with the symptoms of snoring, waking up gasping for air or choking, a sore or dry throat in the morning, and **sleepiness during the day.** In contrast, chronic insomnia patients generally report daytime fatigue rather than sleepiness. This can be measured using the Epworth Sleepiness Scale (https://eprovide.mapi-trust.org/instruments/epworth-sleepiness-scale-child-adolescent). Persons with scores > 10 should be assessed for sleep apnea.

Other risk factors for sleep apnea include increased body mass index, male sex, older age, snoring and frequent breathing pauses during sleep. Patients who report these symptoms along with risk factors for sleep apnea should be referred to a physician for further investigation. NMTi can be considered for patients using continuous positive airway pressure (CPAP) to treat sleep apnea providing they are compliant with therapy ($\geq$ 4 hours/night for at least 75 % of nights).

Restless Leg Syndrome[25]

Restless leg syndrome (RLS) is another common cause of sleep dysfunction. It is a neurologic disorder more common in women and those over the age of 65 but can present at any point in life. Common symptoms include a tingling feeling in the legs that is relieved by moving or stretching the legs, worsening upon rest and mainly occurring at night. The cause of RLS is unknown but factors that may contribute include iron deficiency, pregnancy, chronic renal insufficiency and certain medications. RLS should be ruled out before offering NMTi if a patient presents with these symptoms.

Medications/Drugs

Many substances have effects that can interfere with sleep. Therefore, before beginning NMTi a detailed medication and substance use history should be obtained, including details such as when medications were started, stopped or altered and if any of these changes coincided with the onset of the insomnia complaint. If a medication is suspected of causing sleep disturbances, interventions such as changing the dose and/or time of administration, or switching to an alternative agent that doesn't affect sleep, might be helpful. For example, if a patient is taking a medication with stimulant effects before going to bed, the time of administration could be switched to the morning. See Table 3 for a list of medications that may cause or contribute to insomnia.[26,27]

It should also be determined if sleep disturbances are due to withdrawal effects of medications/substances. Medications associated with withdrawal-induced insomnia include sedatives, hypnotics and glucocorticoids.[28] Compare the date of onset of insomnia with the date the suspect medication was discontinued. If the insomnia began prior to discontinuation it is less likely this is the cause of the sleep disturbances. Additionally, the higher the dose and the longer the duration of a medication, the greater the likelihood of withdrawal effects. If it is determined insomnia may be due to withdrawal effects of a medication, the medication may need to be tapered or tapered at a slower speed. If the patient is still experiencing sleep disturbances after the withdrawal effects should have subsided, it may be appropriate to enroll the patient in NMTi, as the patient has likely developed behaviors that are contributing to the insomnia.[17]

<u>Alcohol and Nicotine</u>[29-32]

Alcohol and nicotine are two commonly used substances that can impact the structure of sleep. Some people believe alcohol helps them sleep as they fall asleep more quickly. However, alcohol reduces REM sleep and causes more frequent awakenings during the second half of the night. Reducing REM sleep may result in daytime drowsiness and reduced concentration. Alcohol's effects on sleep are proportional to the quantity of alcohol consumed before bed. A small dose (1 -2 standard drinks) may have minimal effect, however moderate doses (2 -4 drinks) taken up to 6 hours before bedtime can significantly affect the structure of sleep.

The effects of alcohol on sleep differ between alcoholics and non-alcoholics. A non-alcoholic may fall asleep faster when they begin using alcohol for sleep, but with continued consumption, this effect gradually lessens while awakenings throughout the night increase. Alcoholics tend to experience increased sleep latencies, frequent awakenings and daytime fatigue. If they abruptly stop consuming alcohol, withdrawal symptoms may include increased insomnia. Once the withdrawal subsides, insomnia symptoms may improve, however, their sleep patterns may never return to normal.

Nicotine affects sleep structure by increasing sleep latency and decreasing the amount of time spent in deep sleep, total sleep time, and sleep efficiency. As nicotine is a stimulant, use before bedtime may make falling asleep more difficult (although some smokers argue it helps them sleep as they find it relaxing). Withdrawal effects during the night may also lead to increased awakenings. When nicotine use is stopped, a former smoker's sleep structure will become similar to that of a never-smoker.

Table 3: Medications That May Cause Insomnia[26,27]

Pharmacologic Category	Examples	Effect on Sleep
Selective serotonin reuptake inhibitors (SSRIs)*	fluoxetine paroxetine sertraline	Decrease total sleep time and increase awakenings, especially during initiation of treatment. Abrupt withdrawal may worsen insomnia.
Serotonin and norepinephrine reuptake inhibitors (SNRIs)	venlafaxine duloxetine	Decrease total sleep time and increase awakenings, especially during initiation of treatment. Abrupt withdrawal may worsen insomnia.
Aminoketones	bupropion	May alter REM activity and cause abnormal dreams.
Tricyclic and tetracyclic antidepressants	desipramine protriptyline trimipramine	Suppress REM sleep, increase wakefulness, decrease total sleep time, especially during initiation of treatment
Stimulants*	methylphenidate dextroamphetamine	Prolong sleep latency, reduce total sleep time, decrease deep (N3) sleep time
Anticonvulsants	lamotrigine* tiagabine* levetiracetam*	Increase wakefulness.
Beta-adrenergic antagonists	propranolol metoprolol atenolol	Suppress REM sleep
Methylxanthines	theophylline aminophylline	Prolong sleep latency, increase awakenings, decrease total sleep time
Glucocorticoids	dexamethasone prednisone prednisolone	Decrease total sleep time, may decrease deep (N3) sleep time
Decongestants	pseudoephedrine phenylephrine	Decrease total sleep time, increase awakenings
Opioid analgesics	morphine hydromorphone oxycodone	Increase night awakenings, decrease deep (N3) and REM sleep time
****Consider dosing in the morning***		

Lifestyle Factors

People with insomnia often have habits and lifestyle factors that contribute to the perpetuation of their insomnia.[17] While many of these habits are targets for NMTi, there are some that may be out of the patient's control or too complex for basic NMTi. Shift work is an example of a complicated lifestyle factor that may not be compatible with NMTi because

NMTi requires the patient to adhere to a regular sleep-wake schedule. This is not possible while working varying shifts.[17] Consistent jet lag creates similar issues with NMTi.[17] Advice can be provided on managing sleep in these situations, but NMTi is usually not be appropriate.

NMTi is also unlikely to be successful if the patient does not have the opportunity for adequate periods of uninterrupted sleep. For example, this may be a problem for parents of young infants who awake frequently during the night.

1.5 Hypnotic Therapy for Insomnia

A variety of medications is used to treat insomnia including benzodiazepines, non-benzodiazepine hypnotics, antidepressants, antipsychotics, antihistamines, melatonin and valerian.

Benzodiazepines[33-36]

Benzodiazepines are one of the most commonly prescribed medications for sleep. They are effective at reducing sleep latency and increasing total sleep time short-term. However, they increase stage N2 sleep while decreasing stage N3 (deep sleep) and REM sleep, resulting in decreased quality of sleep. Tolerance to their benefit may develop with as little as four weeks of regular use. Their long-term use is not recommended due to the risk of tolerance, withdrawal effects on discontinuation and numerous adverse effects that vary depending on the dose and the benzodiazepine being used. Anterograde amnesia, rebound insomnia, dizziness and/or drowsiness which increases risk of falls, and a hangover effect may be experienced with all benzodiazepines. It is usually necessary to taper when discontinuing benzodiazepines to avoid or minimize the risk of withdrawal effects (i.e. anxiety, rebound insomnia, agitation, seizures).

Non-Benzodiazepine Receptor Agonists (BZRAs)[35,36]

BZRAs representing the Z-drug category include zopiclone, zaleplon and most recently zolpidem, are used to treat insomnia and are preferred to the benzodiazepines. Although its pharmacology is similar to benzodiazepines, affecting the $GABA_A$ receptor to promote sleep, the binding is different. They do not affect REM sleep and either have no effect on, or may increase slow wave deep sleep (N3).[37] This may explain why Z-drugs do not appear to cause tolerance and dependence and have much lower risk for withdrawal.[32,37] Except for zaleplon, Z-drugs pharmacokinetic properties support its efficacy for all types of sleep problems (latency, awakenings and early arousal). Zaleplon's short half-life of one hour limits its use to managing sleep latency. Although the risk of withdrawal effects is much less, it is still recommended tapering off these medications if used long-term and at higher doses. The tapering duration however can be faster. Adverse effects are similar to other hypnotics and may include difficulty waking fully in the morning, dizziness, headache but also bitter taste and dry mouth.[31,38]

Antidepressants[35,36]

Some antidepressants have a sedating effect and are used off-label to treat sleep problems. Antidepressants have a lower tolerance potential than other drugs used as hypnotics and are sometimes used as an alternative for patients who should not be receiving benzodiazepines. However, with the exception of trazodone and doxepin, there is little evidence supporting the effectiveness of antidepressants for treating insomnia in patients who are not depressed. Due to the number of side effects (e.g., anticholinergic

activity, adrenergic blockade and cardiac conduction prolongation) that can occur when using antidepressants long-term, they are not recommended for long-term use.

Trazodone has dose dependent effects on the receptors. At higher doses used to manage depression and anxiety, it has mainly serotoninergic properties (5HT2A antagonism and 5HT reuptake). At lower doses of < 100 mg it maintains 5HT2A antagonist effects as well as H1 and α1 antagonism which are all associated with promoting sedation.[37] At the lower and once a day dosing, its half-life of 6-8 hours does not lead to daytime sedation. Trazodone may be useful in patients with SSRI and bupropion-induced insomnia.

Doxepin used as antidepressant and dosed from 150-300 mg daily leads to significant anticholinergic effects but it has long been known for its significant sleep promoting properties.[39] It has been reported that at low doses <25 mg day, doxepin has a high affinity to the H_1 receptor and low affinity for the muscarinic.[37] This leads to promoting sleep without annoying anticholinergic side effects. Its half-life of 8-15 hours also causes less daytime sedation. Doxepin is available in 1, 3 and 6 mg tablets.

Antipsychotics[35,36]

Antipsychotics are not approved by Health Canada for treating insomnia. However, due to their sedating effects, many doctors have begun prescribing certain antipsychotics off-label for insomnia. These medications may be useful for those patients who may also benefit from the other therapeutic effects of the medicine.

Quetiapine has emerged as a popular hypnotic agent. It has a complex pharmacological profile including antagonism of serotonin ($5HT_{2A}$) and dopamine (D2) and histamine (H1) receptors, which differs at different doses and oral formulations.[37] At the lower 50 mg dose it blocks the H_1 receptors within minutes leading to a quick onset for sleep.

However, there is a lack of evidence to support using these medications solely for insomnia. Adverse effects may include headache, drowsiness, dizziness, constipation, dry mouth, weight gain and metabolic syndrome.

Antihistamines[35,36]

First generation antihistamines for the treatment of mild insomnia may be effective and safe short-term. However, they are not recommended for routine use as tolerance is easily developed. They can also interfere with quality of sleep and have the disadvantage of anticholinergic side effects (such as dry mouth, constipation, heat intolerance). As such, their use is not recommended in the elderly.

Melatonin[36,40]

Melatonin is a hormone produced in our body responsible for regulating our circadian rhythm, or biological clock. Its effectiveness for insomnia for most people is questionable but it may be of benefit in elderly patients whose bodies produce decreased amounts of melatonin. Melatonin may also be useful for managing symptoms of jet leg when traveling eastward by at least five time zones. It has a good safety profile and may be tried with minimal risk. It is usually dosed at 0.5-5mg 2 to 5 hours before bedtime.

Valerian[36,41]

Valerian is an herb purported to have possible effectiveness for treating insomnia. As there are few studies testing the effectiveness of valerian, more research is required to prove its benefit. It is safe to use for up to 28 days but long-term effects are unknown. Valerian seems to be well tolerated but there have been reports of benzodiazepine-like withdrawal symptoms. Therefore, if used regularly it is recommended

to slowly reduce its use when discontinuing. Adverse effects may include headache, GI upset, mental dullness, dry mouth and morning drowsiness.

When Hypnotic Use May be Appropriate[35,36,42,43]

Most hypnotics are not recommended for long-term use due to concerns regarding residual sedative effects, memory impairment, respiratory depression, falls, rebound insomnia, medication abuse, tolerance and dependency. However, there are certain situations when hypnotic use may be beneficial to the patient. These include acute or transient insomnia, managing an exacerbation of previously controlled insomnia or preventing relapse. Hypnotics for acute purposes should not be used for more than seven consecutive nights. If treating an occasional bout of insomnia, hypnotics may be used on an as-needed basis (<3 times/week). To prevent relapse in a patient with chronic primary insomnia, it may be appropriate to use hypnotics on a scheduled basis (<3 times/week).[17]

Regardless of the reason for hypnotic use, the following measures are recommended to reduce the risk of adverse effects: Use the lowest dose possible for the shortest time period possible, use the drug every third or fourth night, advise patients of potential interactions with alcohol and other drugs, monitor use frequently and gradually terminate the therapy.

Tapering Hypnotics

As part of the NMTi program, patients using hypnotics will be expected to participate in a tapering schedule. If you have a patient who is unsure if they want to discontinue their hypnotic, the deprescribing.org brochure provides helpful information. Tapering is recommended before discontinuation for both non-benzodiazepine and benzodiazepine hypnotics to reduce the risk of withdrawal effects and rebound insomnia.

OTC sedative agents are unlikely to be an issue since tolerance to them occur quickly and therefore they are limited to short-term use. Antipsychotics such as quetiapine if prescribed only as a hypnotic are not expected to cause any withdrawal issues since the dosing is much lower than that required to manage psychosis. Antidepressant discontinuation syndrome (ADS) has been reported at higher antidepressant doses for more than 4 weeks, although symptoms are usually mild.[55] Similar to quetiapine, hypnotic doses are much lower and therefore withdrawal symptoms are not expected to occur. Therefore tapering of the above discussed sedative/hypnotic agents is usually not necessary.

With benzodiazepines, withdrawal effects (Table 4) can occur if the drug is stopped abruptly after four or more weeks of regular use and these may last for three to six weeks.[33,47] With non-benzodiazepine hypnotics, such as zopiclone, the risk of withdrawal symptoms in comparison to benzodiazepines is uncertain.[48] With both benzodiazepines and non-benzodiazepine hypnotics, the risk of withdrawal effects is increased with higher doses and longer durations of use. Therefore, a personal tapering schedule must be developed for each patient, as every situation is unique.[44-48]

The method and rate at which hypnotics are tapered depends on a number of factors including type of hypnotic, dose, duration of use, patients' readiness to discontinue, and the presence of withdrawal symptoms.[44-48] Because each of these factors differs between patients, there is no set guideline on how to taper hypnotics. A tapering schedule can be created using the following general guidelines

Table 4: High Dose Benzodiazepine Withdrawal Signs and Symptoms[33,47]

Minor Withdrawal	• Insomnia • Dizziness • Nausea/vomiting • Anxiety • Tremor of hands & fingers • Dilated pupils • Progressive weakness • Visual illusions • Weight loss • Orthostatic hypertension
Major Withdrawal	• Delirium • Confusion • Disorientation • Agitation • Tonic clonic seizures • Markedly elevated vital signs • Visual hallucinations

and adjusting them to the individual patient as needed. Typically patients who have been on higher doses for longer periods of time may require slower tapering schedules.

The first factor to consider when creating a tapering schedule is the type of hypnotic the patient is using. It is recommended to taper non-benzodiazepine hypnotics such as zopiclone or zolpidem if they have been used for more than four weeks.[48]

As there are no specific guidelines for how to taper these medications, general considerations can be used to determine the rate of taper. If the individual is relatively healthy and there is little concern regarding the taper, a 50% dose reduction/week can be used.[48] If there is greater apprehension regarding the taper and the individual is more complex, a dose reduction of 25%/week can be used.[48] The dose may then be reduced to every other day, then only as needed, and finally stopped completely.

The method and rate of benzodiazepine tapering is influenced by the dose and duration of use. Benzodiazepines that have been used for less than four weeks may be reduced over one to two weeks.[46] For patients who have been using high doses for more than four weeks or regular doses for more than twelve weeks, an option often recommended is to switch to an equivalent dose of a long-acting benzodiazepine such as diazepam (see Table 5). There are a number of tapering schedules that can then be applied.[46-50] Examples are provided in Table 6. However, be aware there is a lack of evidence supporting the efficacy of switching to long-acting agents.

Once the use of a hypnotic has been reduced to the smallest possible dose, drug-free nights may be gradually introduced at a rate comfortable to the patient until they are able to completely discontinue the drug. For some patients, as needed (PRN) use may be the final goal.

Table 5: Equivalent Benzodiazepine Doses [30]

Drug	Approximate Equivalent Dose (mg)
Diazepam	5
Alprazolam	0.5
Clonazepam	0.25
Flurazepam	15
Lorazepam	1
Nitrazepam	5
Oxazepam	15
Temazepam	10
Triazolam	0.25

When initiating a tapering regiment, first interview the patient and gather the history of their sleep medication use (*i.e.,* dose, duration) and their readiness to quit. Then work with the patient to develop a tapering regimen the patient feels they can comply with and contact their physician for authorization to make the required changes to their prescription. The tapering regimen may be initiated before or during NMTi. Ideally the hypnotic should be discontinued when therapy begins but this may not be realistic for some patients. If possible, try to avoid beginning the taper after the patient has gone through the NMTi program as this might reverse the gains of therapy.

Table 6: Examples of Tapering Options for Benzodiazepine Receptor Agonists [46-49]

1. Low-dose benzodiazepine use: taper at a rate of 20% every week
2. Direct taper: taper at a rate of 25% every week until 50% of the dosage remains. Then taper at a rate of 10% every week.
3. Switch to an equivalent dose of diazepam or clonazepam: Reduce by 25% every week for the first two weeks, then reduce by 12.5% every week for the following four weeks.
4. Switch to an equivalent dose of diazepam: Reduce by 10% every one to two weeks.
5. Switch to 50% of the daily equivalent dose of diazepam or clonazepam: Reduce by 1 0-20% daily, or 5-10% for high doses.
6. Taper by 10% every 1 to 2 weeks until 20% of original dose is reached. Then taper by 5% every 2 to 4 weeks.
7. Slower tapering: Reduce equivalent diazepam dose by 2mg every week or two until half the original dose is reached. Then reduce by 1 mg every week or two until discontinued.

1.6 Introduction to Non-Medication Therapy for Insomnia

Non-medication therapies which address and restructure dysfunctional behaviours and thoughts are used to treat a variety of conditions including anxiety, depression, chronic pain and insomnia.[50,51] As outlined previously, dysfunctional beliefs and behaviors are implicated in the etiology of chronic insomnia. A large body of evidence indicates behavioural and cognitive strategies targeting sleep are more effective and safer than sleep medications for the management of chronic insomnia.[1,2] These therapies are currently recommended as first-line treatment for insomnia[1,2,52] but are widely underutilized.[3,4] This has prompted the development of online programs, self-help books, and research into the provision of NMTi by non-sleep expert health care professionals.[6-13,53,54]

NMTi programs address behaviors and thoughts disruptive to sleep by providing education on good sleep habits, helping patients adopt regular sleep patterns and assessing false beliefs about sleep. The basic NMTi strategies are outlined in Table 7. Cognitive Behavioural Therapy for Insomnia (CBTi) utilizes both behavioural and cognitive strategies, typically delivered in a series of six to eight therapy sessions.[4] Traditionally, CBTi has been offered by psychologists and specialized sleep clinicians. These clinicians are relatively few in number and their services are not always covered by healthcare, making CBTi inaccessible for many patients.[4] Brief Behavioural Therapy for Insomnia (BBTi) focuses mainly on sleep restriction and stimulus control, often does not include cognitive strategies, and is typically delivered over one to four therapy sessions.[53,54] Table 8 summarizes the most recent recommendations from the American Academy of Sleep Medicine (AASM).

Table 7: Components of Non-medication Therapy for Insomnia[4,54]

Components	Description
Sleep hygiene	General measures that promote good sleep e.g. limiting stimulating drinks, avoiding naps, keeping the bedroom cool and dark
Behavioural • **Stimulus control**	Strengthens association between bed and sleep by eliminating nonsleep-related activities in the bedroom, not going to bed unless sleepy and getting out of bed when unable to sleep during the night
• **Sleep restriction**	Increases sleep drive by limiting time in bed to the estimated duration of actual sleep time
Cognitive	Identifies and addresses dysfunctional attitudes and beliefs about sleep and insomnia
Relaxation	Facilitates sleep onset through techniques that reduce muscular tension and mental stimulation e.g. progressive muscle relaxation, breathing exercises, guided imagery
CBTi	Combination of behavioural and cognitive components
BBTi	Combination of behavioural components +/- basic cognitive strategies

Table 8: AASM Recommendations [52]

Recommendation	Strength*
1. CBTi – MC**	Strong
2. BBTi – MC	Conditional
3. Stimulus control – SC***	Conditional
4. Sleep restriction – SC	Conditional
5. Relaxation – SC	Conditional
6. Sleep Hygiene – SC NOT recommended	Conditional

* Strong = recommended for almost all patients; Conditional = suggested for most patients; different choices may be appropriate for different patients
**MC = multicomponent
***SC = single component

Sleep Logs [17]

Sleep logs (diaries) are the primary tools used throughout therapy to assess patients' sleep patterns, track their progress, and assess adherence to therapy. The patient fills out a sleep log each morning detailing the previous night's sleep and a sleep hygiene log every evening detailing daily activities. This should take only about five minutes. The PharmaZzz program sleep log templates and instructions for use are presented in Appendix I. Several other formats are available including the RxFiles sleep diary. Smart phone apps such as the Consensus Sleep Diary are offered online as well.

The Night Sleep Log provides the therapist with the information needed for setting sleep restriction prescriptions and monitoring compliance with sleep restriction and stimulus control criteria. These include:

- **Sleep latency (SL) –** the amount of time it takes a person to fall asleep after going to bed. Patients should be instructed to estimate this value, as watching the clock interferes with sleep and creates more anxiety.

- **Wake after sleep onset (WASO)** is a measure of the amount of time a patient spends awake after initially falling asleep and before getting out of bed in the morning.

  For example, if a patient woke up twice during the night and was awake for 60 minutes each time and woke up 30 minutes before getting out bed in the morning, WASO would be 60 + 60 + 30 = 150 minutes. Note that WASO, like SL, should be an estimated number.

- **Time spent in bed (TIB)** is calculated as the time interval between when the patient goes to bed in the evening and when they get out of bed in the morning to start their day. This includes any time the patient spent in bed awake doing other activities such as reading or conversing.

  For example, if the patient had a bedtime of 10:30pm and arose from bed at 7:00am, their TIB would be 8.5 hours, or 510 minutes. Converting this value to minutes makes future calculations easier.

- **Total sleep time (TST)** is the time the patient is actually sleeping and is calculated by subtracting SL and WASO from TIB:

  TST = TIB – (SL + WASO)

  For example, if a patient had a TIB of 510 minutes, an SL of 50 minutes and WASO of 40 minutes the calculation of TST would be as follows:
  TST = 510 – (50 + 40) = 420 minutes

  Sleep efficiency (SE) is calculated by dividing the average TST by the average TIB.

  SE = TST / TIB

  For example, if the average nightly TST for the week was 330 minutes and the average TIB was 390 minutes, sleep efficiency would be calculated as follows:
  SE = TST/TIB = 330/390 = 0.85

  Total time out of bed (TTOB) measures the amount of time the patient is awake and out of bed during the night.

  For example, if a patient woke up at 2AM and watched TV for a half hour, the TTOB would be 30 minutes. TTOB can be used to assess adherence to stimulus control guidelines.

The Day sleep log includes questions about the patient's activities throughout the day and provides information that helps determine if any lifestyle factors are interfering with sleep. In combination, the sleep logs provide a profile of the patient's sleep status and their progress throughout the NMTi program.

1.7 Sleep Restriction Therapy[17,53]

A common problem for people with insomnia is a mismatch between the amount of time they spend in bed and the amount of time they actually spend sleeping in bed, i.e. reduced sleep efficiency. In an attempt to increase their opportunity for sleep, many people with insomnia go to bed early, sleep in later and / or take naps during the day. These activities not only often fail to result in more sleep, they can produce shallow and fragmented sleep. Sleep restriction aims to match total time spent in bed with time spent sleeping in bed. It is thought to exert its effect by preventing the patient from extending their sleep opportunity and by increasing the pressure for sleep through partial sleep deprivation. While the patient's daytime fatigue may be temporarily increased during the acute phase of treatment, consolidation of their sleep will result in better sleep quality. For some people, it may take up to 2-3 weeks of sleep restriction to see an improvement in their sleep.

Sleep restriction is somewhat of a misnomer. It is actually time in bed that is being restricted. The process involves limiting the amount of time spent in bed (TIB) to the average total sleep time (TST) as determined from the patient's sleep logs (see above). This is done by setting a TIB prescription to match the patient's average TST plus up to an additional 30 minutes to allow for normal SL and brief awakenings during the night (e.g., bathroom visits). The average TST is ideally calculated from two weeks of baseline data, however one week of data may be used if necessary. The patient is asked to set a standard wake time based on their preference or lifestyle. then the patient's time to bed is adjusted to reflect the TIB prescription.

After one to two weeks of sleep restriction, sleep efficiency (SE) is reassessed. Sleep efficiency is a measure of how well one is sleeping and is the major determinant for setting the TIB prescription for the following two weeks. This process continues until the patients reach a point where they are sleeping most of the time they are in bed (SL less than 30 minutes, WASO less than 30 minutes) AND are alert and experiencing little or no fatigue during the daytime.

Setting Time in Bed Prescriptions

The Night Sleep Log contains the key information needed for setting sleep restriction prescriptions and calculating sleep efficiency. Going over the entries and doing the calculations with patients is a good way to make sure they are doing them correctly and helps to involve them in therapy decisions.[17]

Once baseline sleep data (at least one week, preferably two) has been collected, the average TST can be calculated. The TIB prescription is set to match the average TST plus up to an additional 30 minutes. For example, if average TST is 390 minutes (6.5 hours), the TIB prescription would be 420 minutes (7 hours). Bedtime and wake time are set based on the TIB prescription and the time the patient wants or needs to get up in the morning. For example, if they have to be awake by 6:00am for work, bedtime (or earliest allowed time to go to bed) would be set to 11:00pm. The TIB prescription is assessed every one to two weeks and readjusted as necessary based on sleep efficiency values as described above. Appendix II illustrates setting and adjusting the TIB prescription using a hypothetical case.

Calculating Sleep Efficiency and Adjusting TIB Prescriptions[17]

A higher SE indicates the patient is spending more of the time in bed actually sleeping, while a lower SE indicates the patient is still awake for a large portion of their time in bed. Every one to two weeks, the average SE is calculated and the TIB prescription is adjusted as follows:

- **If SE is 0.90 or greater,** TIB can be increased by 15 minutes.
- **If SE is between 0.85 and 0.90**, continue with the same TIB prescription.
- **If SE is less than 0.85,** consider reducing the TIB prescription by 15 minutes.

Note TIB should not be set to less than five hours, as this core amount of sleep is required for basic functioning.[3]

1.8 Stimulus Control Therapy[17,53]

Many people with insomnia report feeling sleepy during the evening, but the moment they go to their bedroom they feel wide awake.[2] This common occurrence indicates many insomnia patients no longer associate their bedroom with sleep. This response may be a result of conditioning caused by performing stimulating activities in the bedroom, lying in bed awake for long periods of time and /or experiencing feelings of frustration, anger, or anxiety while trying to fall asleep.[13]

The aim of stimulus control therapy is to reconnect the bed and bedroom with feelings of relaxation and with sleep. Guidelines for stimulus control are set out in Table 9. By maximizing the amount of time in the bedroom spent asleep, reducing the amount of time spent awake, and maintaining a regular sleep-wake schedule, a patient can learn to associate the bedroom with sleep. This will help to induce more rapid onset of sleep in the future.

Table 9: Stimulus Control Guidelines[17,53]

- **Go to bed only if sleepy BUT do not allow yourself to go to sleep before the prescribed earliest to bed time.**
- **Use the bed or bedroom only for sleeping or sexual activity.**
- **If awake during the night and unable to fall back asleep, get up and go into another room. When you feel sleepy again, go back to bed.**
- **Get up at the same time every morning, regardless of how well you slept the night before.**
- **Avoid daytime napping**

Practicing stimulus control therapy may initially result in the patient getting even less sleep than previously. However, this sleep loss increases the pressure for sleep the following night and aids in producing shorter SL and WASO times. While stimulus control therapy is well tolerated by most people, there are a few situations in which caution should be used. These include patients with mania, epilepsy, parasomnias, and those at risk for falls. The initial sleep loss experienced while practicing stimulus control therapy may induce mania or reduce seizure threshold in susceptible patients. Additionally, sleep may be deeper which can increase the likelihood of parasomnias such as sleepwalking or night terrors.

Lastly, walking around in the middle of the night increases the chance for falls to occur. Therefore, appropriate measures should be taken to reduce this risk. Assess patients carefully to determine if stimulus control therapy is appropriate for them and advise them of the risks involved.

1.9 Sleep Hygiene /Bedroom Environment[13,17]

Sleep hygiene has not been proven effective as monotherapy but it is an important component of NMTi. It consists of a series of recommendations (Table 10) regarding behaviors that may influence sleep quality and quantity. These guidelines help the patient identify problematic habits and educate about sleep-promoting behaviours.

Napping

Napping, whether intentional or unintentional, is a common practice among people with insomnia. While the primary recommendation is to avoid napping while participating in NMTi, there may be situations where a patient feels a nap is absolutely necessary. In these situations it should be recommended that they nap for no longer than a half hour and not after 4:00pm. The aim is to avoid entering deep sleep, which could interfere with sleep quality later that night. Additionally, if a patient naps during the day they should prolong their wake time by the amount of time that they napped. For example, if a patient normally goes to bed at 12:00am but had a 30 minute nap during the day, they should wait until 12:30am to go to bed that night but still get up at the specified time in the morning.

Table 10: Sleep Hygiene Guidelines [13,17]

1. Limit the amount of time spent in bed to the amount you need to feel refreshed. Spending longer periods of time in bed results in more shallow and fragmented sleep.
2. Wake up at the same time every day. This will train your biological clock to have a steady sleep-wake cycle and make initiating sleep easier.
3. Exercise regularly. Exercise makes falling asleep easier and makes your sleep deeper. Avoid exercising within three hours of your bedtime.
4. Make sure your bedroom is comfortable and free from light and noise. This will reduce the likelihood of you waking up during the night.
5. Make sure your bedroom is a comfortable temperature during the night. An excessively warm or cold sleep environment may disturb sleep.
6. Eat regular meals and do not go to bed hungry. Hunger may disturb sleep. A light snack at bedtime (especially carbohydrates) may help sleep, but avoid greasy or "heavy" foods.
7. Avoid excessive liquids in the evening. Reducing liquid intake will minimize the need for nighttime trips to the bathroom.
8. Cut down on all caffeine products. Caffeinated beverages and foods can cause difficulty falling asleep, awakenings during the night, and shallow sleep. Even caffeine early in the day can disrupt nighttime sleep.
9. Avoid alcohol, especially in the evening. Although alcohol helps tense people fall asleep more easily, it causes awakenings later in the night.
10. Don't take your problems to bed. Plan some time earlier in the evening for working on your problems or planning the next day's activities. Worrying may interfere with initiating sleep and produce shallow sleep.
11. Smoking may disturb sleep. Nicotine is a stimulant. Try not to smoke during the night when you have trouble sleeping.
12. Do not try to force yourself to fall asleep. This only makes the problem worse. Instead, turn on the light, leave the bedroom, and do something different like reading a book. Don't engage in stimulating activity. Return to bed only when you are sleepy.
13. Put the clock under the bed or turn it so that you can't see it. Clock watching may lead to frustration, anger, and worry which interferes with sleep.
14. Avoid naps. Staying awake during the day helps you to fall asleep at night.

1.10 Cognitive Restructuring

Many patients will respond to behavioural therapy without the inclusion of cognitive therapy. However, it may be useful in some situations. Cognitive restructuring focuses on the patient's dysfunctional beliefs and thoughts and is based on the premise that one's feelings and behaviors are influenced by one's perception of events.[50,51] By bringing the patient's awareness to the inaccuracy of their perception, their feelings and behaviors can be altered to promote positive sleep thoughts and behaviors.[3,13,17] The goal of cognitive restructuring for insomnia is to eliminate disruptive thoughts during the night, engage the patient in realistic expectations for their sleep and daytime functioning, and correct false beliefs regarding sleep-promoting behaviors.[3,13,17] As an adjunct to sleep restriction and stimulus control therapy, cognitive interventions can be helpful for patients who are overly anxious and have unhealthy beliefs about sleep.

Negative Sleep Thoughts [3,13,17,44]

Negative sleep thoughts (NSTs) are any thoughts that promote negative emotions regarding sleep, bedtime and the effects of sleep loss. NSTs are a type of automatic thought which occurs subconsciously and contributes to the perpetuation of insomnia. Thinking negatively about sleep increases feelings of anxiety and frustration, which lead to hyperarousal and further sleep loss. The aim of cognitive restructuring is to be able to identify, reframe and restructure NSTs into more accurate and positive thoughts. Common NSTs are listed in Table 11.

Table 11: Examples of Negative Sleep Thoughts[2,10,14]

- **I know I won't sleep well tonight**
- **I'm going to toss and turn and be wide awake like I usually am**
- **It's going to take me forever to fall asleep tonight**
- **I'll be a wreck tomorrow if I don't sleep**
- **I must get eight hours of sleep**
- **I need a sleeping pill in order to sleep**

Underlying Fears[2,10,14]

NSTs are usually accompanied by an underlying fear.[2] This fear is the main source of feelings of anxiety, anger and frustration. Take this statement for example: "if I don't sleep tonight I will not be able to look after my children tomorrow". This NST may actually be associated with the underlying fear of being a bad parent. Identifying underlying fears is an important step in evaluating the accuracy of thoughts and understanding the origin of negative emotions.

Recognizing Negative Sleep Thoughts[2,10,14]

The first step in cognitive restructuring is being able to recognize NSTs. NSTs may present themselves as a variety of cognitive distortions. Common types of cognitive

Table 12: Common Cognitive Distortions[3,13,17]

Type of distortion	Examples
All-or-Nothing Thinking: Using words like "never," "always," and "every"	• I will never fall asleep tonight
Overgeneralization: Making irrational generalizations based on one isolated case	• "I failed a test today because I was tired. Now I am going to fail all my classes."
Catastrophic Thinking: Exaggerating the significance of an event and expecting the worst possible outcome	• "I can't fall asleep so I am probably going to crash my car on the way to work tomorrow"
Jumping to Conclusions: Involves predicting outcomes before sufficient evidence is present (*fortune-telling*) and assuming knowledge of other's thoughts (*mind-reading)*	• "I fell asleep at my desk today. My boss wants to see me in his office. He probably thinks I am irresponsible and wants to fire me."

distortions include all-or-nothing thinking, overgeneralization, catastrophic thinking, and jumping to conclusions (see Table 12). Once patients are aware of common types of cognitive distortions, it is easier for them to identify if NSTs are occurring. NSTs may also be detected by having patients observe their emotions. When emotions turn from positive to negative, it is likely there is a negative thought behind the shift in emotion.

Thought stopping is a technique that can be used by patients when they identify negative thoughts passing through their minds.[10] It involves saying the word "STOP" either out loud or in their head. By saying the word stop, it forces the mind to bring attention to the current thoughts they are having. At this point, it is also appropriate to use a technique called marveling, which involves appreciating the emotional tone of thoughts without buying into them.[10] Cognitive restructuring does not aim to suppress all negative emotions, but rather bring awareness to the inaccuracy of NSTs.[10] Therefore, marveling is a useful way to help patients understand how certain events make them feel without accepting their thoughts and emotions as absolute truth.

Reframing Negative Sleep Thoughts[3,13,17]

Once a negative thought has been identified, the next step is to reframe the thought by evaluating its accuracy. Writing the thought down is a crucial first step in reframing negative thoughts as it allows patients to visually see their thoughts in an objective manner. Once a thought is put into words, a number of techniques can be used to evaluate and reframe the thought into a more accurate thought. It should be noted that a clinician's role during cognitive restructuring is not to correct the patient's thoughts, but rather to guide them to discovering the inaccuracy of their thoughts. The following techniques can be used by a clinician to guide therapy or be assigned to patients as self-learning activities.

Evaluation by Asking Questions

The first technique for evaluating NSTs involves asking a series of questions regarding the accuracy and importance of the thoughts. By forcing a patient to think critically about their thoughts, their perceptions, and subsequently their feelings and beliefs about the initial concern may change. Examples of these questions can be found in Table 13.

The "Double Standard" Technique

Often times, people are much harder on themselves than others and apply unrealistic standards to themselves. The "double standard" technique involves asking the patients if they would say the same thing to a close friend or family member who was in a similar situation. For example, if the patient tells you they sometimes think that they are going to lose their job if they don't get a good night's rest, advise them to stop and ask if they would say the same thing to someone else. This technique helps to identify when people are expecting more from themselves than they would from other others.

Reflection

Another way to evaluate the accuracy of thoughts is by reflecting on past experiences. This can be done by asking if anything like this has ever happened before and what the outcome was. Often times it is found that the initial worry has never happened, or if it did, the situation was manageable. Brainstorming a list of solutions for the situation if it should occur may bring ease to some people.

The inaccuracy of thoughts can also be illustrated by calculating the perceived probability vs. actual occurrence of an event. The first step is to determine how many nights the patient has had insomnia. This can be done by multiplying the frequency of insomnia (nights per week) by the duration of insomnia.

Table 13: Evaluating NSTs [3,13,17]

What is the evidence for this thought?
What is the evidence against this thought?
Is this thought really true?
Am I over emphasizing a negative aspect of this event?
What is the worst thing that will happen?
Is there anything that might be positive about this situation?
Do my thoughts fall into any of the common negative thought categories? (Workbook, p14)
How do I know this situation will turn out this way?
Is there another way to look at this situation?
What difference will this make next week, month, or year?
If I had one month to live, how important would this be?

In the example in Table 14, the patient experiences bad nights an average of five times per week and has had insomnia for six months. This works out to 120 nights of insomnia. Next, calculate the perceived probability of the negative event by assessing the patient's belief in the thought. For example, if the patient is 80% certain the statement "I will lose my job if I don't get enough sleep" is true, the perceived probability of that event occurring would be 0.8 multiplied by the number of nights with insomnia. For this example, the perceived probability would be 0.8 multiplied by 120, which equals 96. That means that according to

Table 14: Example of Thought Evaluation Through Reflection[17]

Negative Thought: If I don't sleep tonight, I won't be able to function at work tomorrow and I will lose my job		
Perceived Certainty (%)	Perceived Probability	Actual Occurrence
80 %	0.8 X 120 = 96 times	0

the patient's perception, they should have lost their job 96 times over the last six months. The inaccuracy of the initial thought. While this method is more complicated than simply reflecting on past experiences, it may be useful to show some patients just how inaccurate their negative thoughts are.

CEO Thinking[3,13,17,50]

This involves patients imagining themselves as a Chief Executive Officer (CEO) who has to process incoming information from different divisions of a company. A CEO must be aware of different biases each division may possess and take these into consideration before making a decision that best serves the company. Patients may practice CEO thinking by actively listening to their thoughts, looking for any biases, and evaluating the thoughts for their accuracy and usefulness before making decisions. Marveling, that is, appreciating the emotional tone of thoughts without taking them at face value, while engaging in CEO thinking is also helpful. These techniques help to connect the links between specific thoughts and associated emotions.

Sleep-Related Dysfunctional Beliefs[3,13,17,50]

It is important for patients to be educated on sleep-related dysfunctional beliefs. Almost all insomnia patients will hold some dysfunctional beliefs about sleep and its consequences. The Dysfunctional Beliefs and Attitudes about Sleep questionnaire (DBAS-16) assesses sleep requirement expectations, perceived causes and consequences of insomnia, worry / helplessness about insomnia, and sleep medication. It should be administered when screening patients for PharmZzz therapy.

If a strong dysfunctional belief is identified, provide education (see examples in Table 15) and consider using the previously discussed techniques to demonstrate the inaccuracy of the belief. Patients with higher DBAS scores may not respond as well to behavioural therapy. If there is little or no progress within the first few sessions, patients should be referred for more formal cognitive therapy with a specialist.

Restructuring Negative Sleep Thoughts (NSTs)[3,13,17,50]

Once NSTs have been identified and evaluated for accuracy, the next step is to restructure them into more accurate and positive thoughts. A positive mantra can be created by removing negative words and replacing them with more positive words. For example, instead of saying "if I don't sleep tonight I will lose my job", replace it with "if I don't sleep tonight I will still do a good job". Some useful positive sleep thoughts are listed in Table 16.

With practice, recognizing, reframing and restructuring negative thoughts can become almost effortless. However, for the initial learning process, it is useful for patients to use cognitive restructuring worksheets. (See Patient Workbook.) When using the worksheets, patients may choose whichever technique works best for them.

Table 15: Debunking Dysfunctional Beliefs About Sleep[3,13,17,50]

I need 8 hours of sleep to feel refreshed and function well during the day. *Needing 8 hours of sleep is a myth. The amount of sleep required to feel refreshed varies between people. Some people require only 5-6 hours of sleep while others may require 9-10 hours.*
When I don't get the proper amount of sleep on a given night, I need to catch up the next day by napping or the next night by sleeping longer. *Taking naps, going to bed early and sleeping in may make you feel better for one night but will make falling asleep the next night more difficult. If you continue to compensate for a bad night of sleep by sleeping in, going to bed early or napping this will lead to the maintenance of your insomnia. Therefore, it is best to stick to a regular sleep-wake schedule.*
I am worried that I may lose control over my ability to sleep. *You will always have control over your ability to sleep as you can change your behaviors and attitudes. It may require effort but the opportunity is there if you are willing to try.*
A poor night's sleep will interfere with my activities the next day. *You may feel more fatigued the next day, however it is likely you are still able to function normally. Think of other occasions when you didn't sleep well and still made it through the next day just fine.*
To be alert and function well during the day, I believe I would be better off taking a sleeping pill rather than having a poor night's sleep. *Sleeping pills can cause you to feel groggy the next day and can actually decrease your daytime functioning. They also interfere with your quality of sleep during the night.*
When I feel irritable, depressed, or anxious during the day, it is mostly because I did not sleep well the night before. *Lack of sleep may contribute to your bad mood during the day. However, there are other factors that may also contribute to your mood. It may be specific events throughout the day or perhaps a mood disorder. Try not to hold your sleep disturbances solely accountable for your mood.*
When I feel tired, have no energy, or just seem not to function well during the day, it is generally because I did not sleep well the night before. *There are many factors that influence how we feel throughout the day. Your health, nutrition, stress level and even the weather can affect your daytime functioning. Try not to overemphasize the effects of sleep on your daytime functioning.*
When I sleep poorly one night, I know it will disturb my sleep schedule for the whole week. *This is not necessarily true. You may even sleep better the following night.*
I can't ever predict whether I'll have a good or poor night's sleep. *Using the sleep log can help you determine what may trigger a good or bad night of sleep. If you pay attention to your habits you will likely notice trends with your sleep.*
I believe insomnia is essentially the result of a chemical imbalance. *Research has shown that this is not true. Insomnia is usually the result of adapted behaviours, thoughts, stressors, and medical illnesses*.
Medication is probably the best solution to sleeplessness. *Cognitive behavioral therapy for insomnia is actually the primary recommendation to treat insomnia. However, it is widely underutilized as there is a lack of trained clinicians providing the service. Medications may be effective for short-term use but often become less effective over time.*
I avoid or cancel obligations (social, family) after a poor night's sleep. *Try not to let insomnia take control of your life. Spending time with friends and family will likely improve your sleep and reduce your stress and anxiety levels.*

Table 16: Positive SleepThoughts[3,13,17,50]

I'm probably getting more sleep than I think.
My daytime functioning does not depend only on my sleep.
Since I have survived nights of insomnia before, I can do it again.
If I didn't sleep well last night, I am more likely to sleep well tonight due to a biological pressure to recover my core sleep.
My daytime malfunctioning is due in part to my negative sleep thoughts.
Sleep requirements vary from person to person.
In most cases, the worst thing that may happen if I don't sleep well is that my mood will be impaired during the day.
It is normal to feel alert initially at the beginning or end of a dream; drowsiness will soon follow.
My sleep will be improving as I learn these behavioural techniques.
These techniques have worked for others and they will work for me.

1.11 Relaxation Techniques[13,17,50]

Relaxation training is not a mandatory component of CBTI but may be useful for patients who describe their insomnia as an inability to relax. These techniques may be used at any time of the day but require a quiet space where one will not be interrupted. Their purpose is to allow the body to be as comfortable as possible and promote relaxation while passively observing thoughts and emotions. They should not be used to try to suppress anxiety, as this is more likely to increase anxious arousal. It is a good idea to practice these techniques during the daytime before attempting to use them at nighttime, as failure to relax at nighttime may cause frustration, which can worsen insomnia. If relaxation techniques do not help after a couple weeks, it may be best to abandon them altogether. Three common relaxation techniques are breathing exercises, guided imagery and muscle relaxation. It is also appropriate for the patient to use any other technique they find relaxing.

Diaphragmatic Breathing

Breathing exercises include diaphragmatic breathing, which focuses on breathing with the diaphragm instead of the chest. Breathing from the diaphragm promotes relaxation and supplies more oxygen to the body through deeper breaths. The patient can practice diaphragmatic breathing by placing one hand on the abdomen and one hand on the chest. Breathing in through the nose and out through the mouth, the patient should be able to feel the diaphragm expanding on the inhale and collapsing on the exhale while the chest remains still.

Guided Imagery

Guided imagery is a relaxation technique that helps people to become relaxed and focused by imagining a place, event, or thing that elicits feelings of relaxation. It is based on the theory that the mind and body are connected, which is demonstrated by the body's response to the imagination. For example, when instructed to imagine a lemon using all of their senses, people often begin salivating. Guided imagery is beneficial as it can be done in short periods of time anywhere. It may be self-guided or facilitated by instructors, tapes and/or scripts.

Progressive Muscle Relaxation

Progressive muscle relaxation is a common technique used in cognitive behavioural therapy. It involves tightening then relaxing various muscles throughout the body. The goal is to have patients identify the feel of muscular tension and learn to let it go. Each muscle group is tightened for 5-7 seconds followed by release of tension for 15-20 seconds.[10] It is important to not rush the release of the tension phase as this is where one learns the feeling of relaxation. Each exercise is performed twice before moving on to the next muscle group. (See Table 17)

Table 17: Progressive Muscle Relaxation Techniques[13]

Feet and calves	Point toes downward
Shins	Flex feet upward
Thighs	Contract thigh muscles by extending legs forward and raising when tensing or squeezing
Buttocks	Tense and squeeze
Stomach	Pull in stomach as much as you can
Back	Arch your back while keeping your shoulder supported
Chest	Take a long deep breath, tighten your chest muscles and hold
Hands	Squeeze hands into fists
Biceps and triceps	Bring forearms up
Shoulders	Tighten and squeeze shoulders back
Neck	Turn head to the right, then the left, then down
Mouth	Open jaw as much as you can, then smile as wide as you can
Tongue	Touch tongue to the roof of your mouth, then the bottom
Eyes	Open eyes as wide as you can. Shut eyes tightly
Forehead	Raise your eyebrows as high as you can

Part II: Initiating and Implementing the PharmaZzz Program

2.1 Introduction

The PharmaZzz program was designed to be delivered by pharmacists in a community pharmacy setting. It involves an initial screening session, an in-person educational and treatment initiation session, and follow-up sessions every one or two weeks. It is important to note that the number of sessions and the interval between sessions can vary depending on the needs of the patient. The follow-up sessions can be provided in-person or over the phone. The following guide outlines the goals, important concepts and strategies for each session.

2.2 Session 1: Initial Interview and Screening

GOALS OF THIS SESSION:

1. **Identify potential participants**
2. **Provide basic information regarding the PharmaZzz program**
3. **Screen patient to determine if the program is appropriate for them**
4. **Decide with the patient if this is a good time to invest time and effort into the program**
5. **If using sleep medications, determine patient willingness to discontinue use**
6. **Provide and educate patient on keeping sleep logs**
7. **Wrap up: patient questions and concerns, schedule next session**

1. Identify Potential Participants

The ideal participant for this program meets the screening criteria for the program, is motivated to try non-medication therapy for insomnia and, if taking a hypnotic, wants to discontinue it. Depending on how the program is marketed, these patients may be referred by physicians or other healthcare professionals or self-referred. There are also opportunities for pharmacists to identify potential participants in their daily practice, for example, patients refilling hypnotics or asking about over-the-counter sleep aids.

2. Provide information regarding NMTI

The program can be introduced to potential participants by providing them with informational pamphlets about PharmaZzz and asking if they would like to learn more about the program. The patients most likely to be successful with the program are those who are genuinely interested in participating. It may be counterproductive to start the program with those who are not yet ready or not very interested.

3. Screening patients

Once a patient has expressed interest in participating in the program, schedule an interview to assess the patient to ensure PharmaZzz is appropriate. (See Appendix III, Screening Form) Ask patients to complete the ISI, GAD-7, PHQ-9 and DBAS questionnaires and bring them to the interview. If patients are not eligible for the program at this time, ensure their sleep concerns and any underlying medical conditions are being addressed by other measures.

4. Patient willingness to start therapy

If screening indicates PharmaZzz therapy is appropriate for a patient, the next step is to determine if the timing is right for the patient to start the program. The patient should be made aware of what will be expected from them, especially regarding sleep restriction and stimulus control therapy, and informed this will require effort on their part. With sleep restriction, the patient may experience more daytime fatigue and drowsiness for the first week or two of therapy before their sleep begins to improve.[14] It is also important to discuss the benefits of the program and the proven effectiveness of NMTi for managing chronic insomnia. Once the patient is aware of the challenges as well as the benefits of the program, they can decide if they have the time and willpower to start the program.

5. Sleep medications

Use of sleep medications should also be discussed during the initial session. For patients currently using hypnotics, an important component of therapy is helping them discontinue these medications. An appropriate tapering schedule should be developed based on the medication and dose being taken (pages 13 – 14). A patient is more likely to be adherent with the taper if they feel they have some control over the pace at which it is done. Therefore, it is important to involve the patient in these decisions, provide rationale for your decisions and provide support when necessary. Offer to contact the patient's doctor to get authorization for the tapering schedule or provide the patient with a written recommendation that they can take to their doctor themselves.

6. Providing sleep logs (diaries)

Before beginning therapy, at least one week (preferably two weeks) of baseline sleep data must be collected to determine patients' sleep patterns and calculate the time in bed (TIB) prescription for sleep restriction therapy. Explain the purpose and importance of the sleep logs for effective therapy in order to increase patient adherence. Not only are sleep logs used to determine TIB prescriptions, but they also function to track progress, assess adherence to therapy, and provide information regarding behaviors that may be affecting sleep.

Sleep logs should be provided during the initial interview with the patient so that therapy can begin immediately at the next session. Examples of sleep log templates and instructions for use are provided in Appendix II of this manual. It is a good idea to fill out an example sleep log with the patient. Key points to emphasize are:

- Sleep Latency (SL) and Wake After Sleep Onset (WASO) are estimations, not exact times
- Don't watch the clock
- Continue regular sleep routine to obtain accurate baseline data
- How to calculate time in bed (TIB) and total sleep time (TST) properly.

7. Wrap up

Before sending a patient home with their sleep logs, schedule an appointment for the next session in one or preferably two weeks' time. Patient questions and concerns should also be addressed at this point. Patients may ask about the accuracy of the sleep logs because some of the values are estimations. While true that compared to polysomnography and actigraphy measures, most patients tend to underestimate the amount that they sleep, their estimates are usually within 5-30 minutes of measured values and are consistently inaccurate.[17] Therefore patient-derived sleep log data provide useful information about general sleep patterns and patients' progress throughout therapy.

2.3 Session 2: Treatment Education and Initiation

GOALS OF THIS SESSION:

1. **Forming a Clinical Relationship**
2. **Educate the patient on sleep and insomnia**
3. **Review sleep logs**
4. **Introduce sleep restriction therapy, set Time In Bed (TIB) prescription**
5. **Introduce stimulus control**
6. **Introduce sleep hygiene**
7. **Discuss dealing with excessive daytime sleepiness**
8. **Initiate or monitor hypnotic medication taper**
9. **Wrap up: patient questions and concerns, arrange date for next session**

1. Forming a Clinical Relationship

There are no set guidelines on how to develop a good clinical relationship with your patients, however there are a set of characteristics that "good clinicians" are thought to possess. These include good listening skills, a good sense of empathy, respect for patient's autonomy and good persuasion skills.[17] A clinician should also view a patient as an equal and be open and honest in communications with the patient. To strengthen the relationship, it is important that the clinician is clear about expectations and outcomes. The clinician should also provide a rationale for every decision and make sure the patient understands why they are being asked to do something.

Throughout the program, the clinician needs to take on a leadership role as well as a follower role. In the beginning of therapy, the ability of the clinician to confidently lead and educate the patient through treatment initiation is important for instilling patient confidence in the therapy. As the program progresses, the clinician may take on more of an active listening role and help to guide the patient through their own self-directed therapy.

2. Educating on Sleep and Insomnia

An important component of NMTi is providing the patient with an understanding of their condition and the change process. This can be done with models such as the 4P model of insomnia to demonstrate how insomnia originates and is maintained (see page 7). Take time to help the patient identify behaviors and habits that may be responsible for perpetuating their insomnia. These may become more apparent as the patient learns about sleep hygiene and stimulus control. By identifying these behaviors, the patient can develop a vision of what changes need to be made throughout therapy.

The focus should not be only on the negative habits that need to be changed but also on the positive outcomes that may occur as a result of therapy. As such, it can be useful to have the patient identify goals of therapy for themselves.

The ultimate goal of CBTi is to help patients learn the skills they will need to eventually become an expert in their own treatment. This is important because insomnia is often a recurring condition. As a clinician, you can help the patient develop these skills by drawing links between their efforts and improvements.

3. Review Sleep Logs (Diaries)

Once the patient has a basic understanding of sleep and insomnia, treatment initiation can begin. The first step is to review the sleep logs the patient has completed. As our goal is to eventually have the patient take responsibility for their own therapy, this should be a collaborative process. The patient can be included by having them read the data aloud and going through the calculations with them. Average weekly values for sleep latency (SL), wake after sleep onset (WASO), time in bed (TIB), total sleep time (TST), total time out of bed (TTOB) and sleep efficiency (SE) should be calculated.

4. Introduce Sleep Restriction and set Time In Bed (TIB) Prescription

When reviewing the sleep logs it will often become clear there is a mismatch between TIB and TST. This is a good opportunity to educate the patient on the negative effects of attempting to extend sleep opportunity. Most patients believe that spending more time in bed will result in more sleep but the sleep logs will demonstrate this is not true. Spending more time in bed while awake maintains insomnia by increasing arousal through feelings of frustration and anxiety.[50] It also results in sleep being shallower and more fragmented.[17]

The aim of sleep restriction is to reduce the mismatch between TIB and TST by limiting the amount of time patients spend in bed. The TIB prescription is based on the patient's average TST and SE (see page 17.) Patients are asked to adhere to preset times to go to bed at night and get out of bed in the morning. The patient chooses a wake-up time that fits their schedule and bedtime is then determined by the TIB prescription. Throughout treatment, TST may not change substantially.[17] What should happen, if therapy is successful, is a reduction in the time it takes to fall asleep (SL) and/or the number of awakenings throughout the night (WASO). This will result in improved overall quality of sleep.[17]

Sleep restriction therapy usually requires the patient to go to bed later than they normally would. It is likely they will feel very tired by the end of the day and may have trouble staying up until the prescribed bedtime. Take time during this session to discuss activities the patients can do to keep themselves awake until their new bedtime. This can include activities they enjoy or perhaps a new hobby they have wanted to try. Caution patients to avoid things that may promote sleepiness like watching TV or cause excess stimulation like heavy exercise.[14]

As part of developing a good clinical relationship, it is important to be clear about expectations and outcomes. With sleep restriction therapy, remind the patient they may initially feel more fatigued and that it may take up to two weeks to start to see improvements. This may be discouraging to some patients. If this is the case, ask them to consider how long they have suffered from insomnia and remind them of the potential of this therapy to alleviate their insomnia in just a few weeks and eliminate their need for ongoing sleep medication. This may provide the necessary motivation for them to begin the program.

5. Introducing Stimulus Control

Introduce stimulus control by educating the patient on conditioned arousal and the bedroom. It is important to ensure the patient does not have any contraindications for stimulus control, including epilepsy, mania, parasomnias and risk of falls. If risk of falls is an issue, discuss measures for preventing falls, such as tacking down rugs, etc. Once they understand the rationale, provide instructions on how to practice stimulus control.

a) **Go to bed only when sleepy.** This is aimed at people who go to bed early, even when they are not tired, in an attempt to get a good night's rest. Trying to fall asleep when not tired will only increase frustration and contribute to conditioned arousal with the bedroom.

b) **Use the bed or bedroom only for sleeping and sexual activity.** This recommendation is also aimed at reducing conditioned arousal with the bedroom. By restricting the bedroom to sleep and sexual activity, the mind will begin to associate the bedroom with only these two activities, making it easier to fall asleep in the future.

c) **Leave the bedroom if awake for more than 15 minutes**. This applies both to people who cannot fall asleep initially after going to bed or who wake up in the middle of the night and cannot fall back asleep. Instead of lying in bed, becoming frustrated about not being able to sleep, recommend patients get up and leave the bedroom and only return when feeling sleepy again. Patients should be directed to estimate the amount of time that has passed and not clock-watch.[14] Some patients may worry about their ability to estimate when 15-20 minutes has passed. **As a rule of thumb, if they are putting effort into falling back to sleep they are better off leaving the bed.**

   Take some time during this session to discuss activities for the patient to do if they wake up in the middle of the night. Boring or monotonous activities that don't require bright light are best. These activities should not be related to work or increasing productivity, as this would give a function to the insomnia.[14] Using a computer or cellphone should be discouraged as they can be stimulating. Suggestions for activities include reading, listening to audio books, crossword puzzles, jigsaw puzzles, and listening to music. In addition, advise the patient to avoid eating food and smoking during this time as this may cause subsequent awakenings later.

d) **Get up at the same time every morning, regardless of how well you slept the night before**. This guideline stresses the importance of keeping a regular sleep-wake schedule. Sleeping-in may throw off the ability to fall asleep the next night. Waking up at the same time every day will build a consistent sleep-wake habit, making it easier to fall asleep and wake up at the same time in the future.

e) **Avoid daytime napping.** Similar to the above, this guideline is focused on maintaining a regular sleep-wake schedule. Napping during the day may make it more difficult to fall asleep that night. Avoiding naps during the day will increase your body's pressure for sleep the following night, making it easier to fall asleep.[14]

6. Sleep hygiene

This topic can be introduced by providing the patient with a handout of sleep hygiene guidelines (see page 19). The patient is then asked to read over the various points and identify any that apply to them. When going over the guidelines, it is important to focus on and provide rationale for the points that apply specifically to the patient. Showing that you comprehend a patient's individual circumstances increases the patient's confidence in your abilities and their likelihood to be adherent to these guidelines.

It is also important to discuss the rules from a critical and realistic perspective. For example, the guideline to "avoid caffeine" may be difficult for many people. It is more useful to provide advice on how to use caffeine in a way to reduce its impact on their sleep. In the case of smoking, continuing to use nicotine as

usual will be less disruptive at this point than changing the nicotine schedule.[17] Once the guidelines have been critically discussed, it may be useful to create a to-do list for any changes the patient needs to make to their daytime behaviors and add these to the suggested criteria on the Sleep Hygiene log. Ask the patient to fill this log out daily and bring it to the next session.

7. How to Deal with Excessive Daytime Sleepiness

Excessive daytime sleepiness is a valid concern for some patients and time should be taken to address this concern. Daytime fatigue is a potential side effect during the first few weeks of CBTi. If a patient believes they are at risk of an accident due to extreme sleepiness some alternative methods can be considered.

The first alternative is to have the patient begin sleep restriction therapy over a weekend, long weekend, or at a time when they don't have commitments.[14] The second alternative is to begin the initial sleep restriction during a vacation or time off work.[14]

If neither of these options is feasible, a third alternative is to replace sleep restriction therapy with sleep compression. Sleep compression maintains the same theory of sleep restriction, but gradually compresses TIB through a downward titration schedule. Each week either the bedtime is delayed or the wake time is advanced until TIB matches TST. The incremental reduction is determined by the average difference between TIB and TST divided by five.[14] For example, if on average, a patient had a TIB of 450 minutes and TST of 320 minutes, the incremental reduction would be: (TIB - TST) / 5 = (450-320)/5 = 26 minutes. This means TIB would be compressed by 26 minutes every week for five weeks in order to match TST. It should be noted there have been limited studies done using sleep compression as an alternative to sleep restriction therapy for insomnia.

The final alternative for dealing with excessive daytime sleepiness is to time the use of stimulating activities to increase arousal during the day without affecting sleep. Caffeine, nicotine, and exercise provide a stimulating effect and may even help patients fall asleep if timed properly. This may require some experimentation by the patient but in general caffeine should not be consumed within six hours of bedtime and exercise should be avoided within three hours of bedtime.[13]

8. Initiating / Monitoring Medication Taper

At this point in the program, consider introducing a tapering schedule for patients using hypnotics. Once a tapering schedule has been agreed upon by the patient, a goal should be set for the following week. The patient should be educated on potential withdrawal effects and how to manage them if they occur. Additionally, it may be useful to write the tapering directions on a calendar to help the patient adhere to the tapering schedule.

9. Wrap Up

Invite questions to ensure the patient understands the process and arrange a date for the next session in one or two weeks.

2.4 Follow-up Sessions: Monitoring and Adjusting Therapy

Goals of These Sessions:

1. **Review sleep logs and adjust TIB prescription**
2. **Review successes and difficulties with the previous week**
3. **Assess adherence**
4. **Identify patients not responding adequately to behavioural therapies and refer**
5. **Introduce cognitive restructuring and relaxation techniques as appropriate**
6. **Monitor sleep medication use**
7. **Wrap up: patient questions, arrange date for next session**

1. Reviewing Sleep Logs and Adjusting TIB Prescription

The first step of each follow-up session is review of the sleep logs and adjustment of the Time In Bed (TIB) prescription if indicated. When reviewing the sleep log data it is a good idea to make sure Total Sleep Time (TST) was calculated and not guessed. Once these values are determined to be correct, the weekly averages and SE can be calculated. As described previously, a SE > 0.90 warrants an increase in TIB by 15 minutes, a SE between 0.85-0.90 no change, and a SE < 0.85 may warrant a decrease in TIB by 15 minutes. If a patient has a SE less than 0.85, it is possible that they have not complied with treatment recommendations.[14] This should be investigated before adjusting TIB. If meeting weekly with the patient, consider allowing two weeks between adjustments as it may take this long for the full effect of sleep restriction to become apparent.

2. Reviewing Successes and Difficulties in the Previous Week

Before coming to any conclusions on the patient's adherence to the program, the successes and difficulties of the previous week's assignments should be discussed. This includes reviewing sleep hygiene issues, strategies for staying awake until bedtime, and the ability to carry out stimulus control procedures. Attention
should be drawn to any progress the patient has made, whether it is in their sleep, mood, or even completing the logs. Positive feedback provides the patient with motivation to with the therapy.

It is equally important to assess any difficulties the patient may have had throughout the week and provide solutions for problems. At this point you may find that a patient was non-adherent with treatment strategies and this would likely show in their SE. The reason for being non-adherent can fall into one of three categories:[14]

a) "Simply couldn't,"
b) "Wanted to but couldn't," and
c) "Didn't want to".

The strategies for dealing with non-adherence depend on which of the above categories applies to the patient.

3. Assessing Adherence

In addition to interviewing the patient, adherence can be checked using data from the sleep log. If a patient failed to complete their sleep logs, that in itself is a form of non-adherence. If the sleep logs were completed, the data can be used to verify if the patient complied with the prescribed bed and wake times. If the patient was adhering to stimulus

control guidelines, their Total Time Out of Bed

(TTOB) should be similar to Wake After Sleep Onset (WASO) time. Additionally, if the patient napped during the day it should be verified that the bedtime was adjusted to account for the length of the nap. Failure to adhere to these procedures and stimulus control practices is most likely to be the cause of a lack in treatment gains.[17] If this is the case, the next step is to determine why the patient was nonadherent.

a) "Simply couldn't"

Patients who "simply couldn't" adhere to the procedures have bought into the model of treating insomnia and want to participate in therapy but find themselves unable to.[14] They usually report they couldn't make themselves stay awake until the prescribed bedtime or arise from bed when awake during the night. To help these patients stay awake until the prescribed bedtime, various strategies may be used. These include avoiding recumbent positions a few hours before bedtime, scheduling physical activity in the evening, and applying cold compresses to the body.[14]

Strategies for helping a patient adhere to stimulus control guidelines are much more limited. It may be useful to ask the patient how they feel and what they are thinking when they lay awake in bed to determine if cognitive interventions are necessary.

If these patients continue to show no improvement and report an inability to stay awake, it is possible they have a sleep state misperception.[14] This occurs when a patient reports getting substantially less sleep than they actually do. In this case, restricting the patient's TIB to their perceived average TST would result in more sleep loss than the patient normally experiences, causing the patient to find it very hard to stay awake as prescribed for sleep restriction. To determine if a patient has sleep state misperception they must be referred to a sleep clinic.

b) "Wanted to but Couldn't"

Patients who "wanted to but couldn't" have also bought into the model of treating insomnia and want to participate in therapy. The difference between these patients and patients who "simply couldn't" is that dysfunctional cognition is usually responsible for the patient being unable to carry out the guidelines.[14] In these cases, cognitive interventions may be useful. There are various techniques that can be used for cognitive restructuring (see pages 22 - 25). It is proposed by some experts that "it's a bad thing to be awake when reason sleeps." This concept is based on the idea that thoughts and impulse control do not function properly during the night. According to polysomnography, the frontal lobe system, which is responsible for thoughts and impulse control, is the first system to "go to sleep."[14] This may make patients experience unreasonable thoughts during the night. By presenting non-adherence to the patient from a biological point of view, the patient should not have to feel that their non-adherence was completely their fault. This may give them more motivation to challenge their thoughts at night.

c) "Didn't Want to"

In this situation, the patient has not accepted the NMTi model of treating insomnia.[14] It is important to let the patient know that participating in treatment is their choice and if they are no longer interested that is fine. However, it may be useful to review the theory of "short-term pain for long-term gain." This may be demonstrated by asking the patient to review how many nights per week they have had insomnia and how long they have had insomnia. The number of nights they have had insomnia can be determined by multiplying the frequency by duration. For example, if a

patient has had insomnia five nights a week for one year (52 weeks), they have experienced approximately 260 nights of insomnia. By demonstrating to the patient that you are asking for a trade-off of 14-21 really bad nights to avoid 260 nights with insomnia, they may see the benefit of "short-term pain". However, if they are still uninterested in pursuing therapy, then CBTi may not be the best choice for them at this time.

Determining Patient's Category

When questioning a patient's adherence it is best to ask open-ended questions in a non-judgmental and collaborative manner.

If you receive answers such as "I was so exhausted I fell asleep on the couch" you can presume the patient belongs in the "simply couldn't" category and recommendations could include strategies on staying awake until the prescribed bedtime. If you receive answers such as "I wanted to get out of bed but I thought that would make me more tired" or "I didn't stay up until my prescribed bedtime because I was actually tired and didn't want to pass up the opportunity" then you can presume they fall into the "wanted to but couldn't" category. In these cases, cognitive interventions may be helpful.

If you can tell a patient is disinterested in the program and receive answers such as "I just don't think this will work for me" you can presume they fall into the "didn't want to" category.

Additional Reasons for Non-Response

In situations where there are no positive clinical gains but no signs of non-adherence are present, other factors may be responsible for the lack of treatment response, for example:

- Sleep state misperception
- More physiologic arousal present than typical with primary insomnia
- Circadian dysrhythmia
- Medical/mental illness that has not been detected
- Substance use or abuse that has not been detected.

4. Identify patients not responding adequately to behavioural therapies and refer to a sleep specialist

Patients who do not experience significant improvement in their sleep within 4 weeks of sleep restriction and stimulus control should be referred to a sleep specialist. It is important not to characterize this as a failure of therapy but rather as the next step in the continuum of insomnia management.

In Saskatchewan, patients cannot be referred directly to specialists. Pharmacists can either offer to contact the patient's family physician to recommend a referral or direct the patient to visit their family physician to request the referral. In either case, the pharmacist should provide a summary of the therapy received by the patient and any issues identified during therapy.

5. Introducing Cognitive Restructuring and Relaxation Techniques

Cognitive restructuring and relaxation techniques may be introduced into therapy during the follow-up sessions as appropriate. Cognitive restructuring is a useful part of therapy that all patients can be invited to participate in to some extent. Alternatively, relaxation techniques may only be necessary for those who report being unable to relax.[17]

Depending on the individual patient and time limitations, rather than the clinician introducing cognitive restructuring in person, the patient could be instructed to complete a homework reading on cognitive restructuring

in their patient workbook. During the next follow-up session, the patient's discoveries about their cognitions can be discussed. This may include identifying any common cognitive distortions that pertain to the patient, negative sleep thoughts, and dysfunctional beliefs about sleep.

If the patient was unable to identify any type of cognitive distortions or common negative sleep thoughts, it may be useful to role-play what they are feeling and thinking when they go to bed. Once a Negative Sleep Thought (NST) has been identified, the patient may need help understanding the underlying fear associated with their thought (see Table 9 – page 20)

It is also beneficial to review any dysfunctional beliefs about sleep identified by the patient. Some time should be spent discussing what the patient has learned and if they still believe the dysfunctional thoughts. If there is still concern about dysfunctional beliefs, it may be useful to go through some exercises to validate the accuracy of these beliefs. (See page 22)

Once you have discussed the NSTs and dysfunctional beliefs identified, you can question the patient on their use of different techniques to evaluate the accuracy of the thoughts and restructure negative thoughts into positive thoughts. It is important to encourage writing down NSTs and using the cognitive distortions worksheets, as these are very beneficial for patients at this stage. For patients who require guidance when attempting cognitive restructuring, it may be beneficial to walk them through some of the restructuring techniques and help them in creating positive mantras. Over time, the patient should learn what works for them and view you as a collaborator rather than facilitator.

Similar to introducing cognitive restructuring, patients who would benefit from relaxation therapy can be instructed to read the relaxation section in their patient workbook. They may also be instructed to explore other activities they find relaxing. Patients should be advised to practice their relaxation technique during the day before using it to try to fall asleep, as the latter may increase frustration and anxiety at bedtime if it does not work.[2] If the technique does not help within a few weeks, recommend discontinuing it and trying something new.

5. Monitoring Sleep Medication Use

Every week sleep medication use should be monitored to assess how the tapering schedule is going. If a patient has no complaints, the tapering schedule may be continued as planned with a new goal set for each following week. If a patient complains of withdrawal effects, advice should be given on how to manage these effects and the taper may need to be slowed down. If difficulties are encountered it is recommended to maintain the same dose for a few weeks.[38] Increasing the dose or using the medication "as needed" is not recommended and should remain a last resort.[38]

6. Wrapping up the Session

Before concluding the session, ensure all the patient's concerns and questions have been addressed. The patient should have a clear understanding of expectations for their assignments between sessions, be aware of their TIB prescription and have a scheduled time for the next session.

2.5 Final Session/Relapse Prevention

Goals of the Session:

1. Review sleep logs and adjust Time In Bed (TIB) prescription
2. Review successes and difficulties
3. Monitor sleep medication use
4. Discuss relapse prevention
5. Treatment of recurrence
6. Address patient questions and concerns

1. Review sleep logs and adjust TIB prescription

As with the previous sessions, the final session begins with a review of the sleep logs and adjustment of the TIB prescription if needed. Increases in the TIB prescription should stop when the patient is falling asleep quickly, sleeping soundly throughout the night and no longer has a complaint of daytime functioning impairment.[17] At this point, the patient can establish regular bed and wake times and use these as a guideline for the amount of time spent in bed. If the patient's Sleep Efficiency (SE) begins to decrease, this may mean that the TIB prescription is allowing too much time in bed and it should be decreased again.[17] By the end of the program, patients should have a good understanding of their sleep logs and how to perform sleep restriction on their own.

2. Review successes and difficulties

During the final session, successes and difficulties from the previous week's assignments should be discussed as before. In this session however, a greater focus should be placed on improvements from baseline data. This can be done by discussing specific parameters, such as reduced Sleep Latency (SL) and Wake After Sleep Onset (WASO), and improved mood and daytime functioning. As previously mentioned, there may not be a large increase in Total Sleep Time (TST). TST is not a measure of the effectiveness of therapy but rather represents a person's average sleep capacity.[17] However, it is common for TST to increase somewhat over the course of therapy.[17]

3. Monitoring Sleep Medication Use

At this point in the program some patients may have completely discontinued their hypnotic while others may still be using it regularly. If the patient has not had much success tapering their hypnotic it is important to discuss what factors may have interfered with the process. This is also a cue that more cognitive interventions may be necessary regarding the patient's views towards hypnotics. For these patients, it may be necessary to slow the taper down and set new goals for the following weeks. As their pharmacist, you may continue to monitor their taper even after the NMTi program is complete.

For patients who have successfully discontinued their hypnotic, key points to reinforce include not relying on hypnotics after a bad night and only using them on planned nights (if necessary).[3] Instead, focus should be placed on the skills learned in this program to manage a bad night of sleep.

4. Relapse Prevention

A key part of the final session is discussing relapse prevention. The patient should be

informed it is normal for everyone to have restless nights now and then as insomnia is a natural response to life stressors. With proper relapse prevention techniques, the patient can ensure that these nights do not develop into a chronic case of insomnia.

A good way to open the discussion of relapse prevention is by asking the patient to explain the 4P model of insomnia (see page 7) to you. Demonstrating they know how predisposing, precipitating, perpetuating and Pavlovian factors contribute to chronic insomnia and identifying specific factors that apply to their specific situation indicates the patient has a good understanding of their condition and the potential triggers that might cause a relapse and therefore stands a much better chance of maintaining long-term treatment gains.

<u>Maintain Therapeutic Gains</u>

One of the challenges of ending formal therapy is determining which interventions can be discontinued and which should become long-term practices. This may vary from patient to patient and depends on the severity of their insomnia. Many patients will be able to discontinue some of the stimulus control strategies, such as limiting the bedroom to sleep and sex only.[14] Additionally, if a patient has identified the ideal amount of time they need to spend in bed (TIB), they can discontinue sleep logs and set a standard bed and wake time to follow on a regular basis.[14] There may be some flexibility with the bed and wake times, however a few guidelines should be followed in regards to altering the schedule:

- Sleeping in should only occur on predetermined days and not exceed 60 minutes past the regular wake time.[14] As long as sleeping in does not occur

- more than two nights a week and a regular sleep-wake schedule is followed for the rest of the week, the patient's sleep homeostat should be able to recover.[14]

- Never sleep in after a bad night as this may result in an acute bout of insomnia.[14]

Along with keeping a regular sleep-wake schedule, sleep hygiene practices should be followed as necessary. Cognitive restructuring and relaxation techniques may also be used if the patient finds them helpful.

5. Treatment of Recurrence

Time should be taken to discuss with the patient what to do when insomnia recurs. There is also a guideline in the patient workbook for them to refer to later. When presented with an acute bout of insomnia it may be useful to try to determine what triggered the sleep disturbance. By understanding what initially caused the insomnia, treating and preventing future occurrences will be easier.

When insomnia presents, the first and perhaps most important recommendation is not to compensate for sleep loss by napping, going to bed early, or waking up later.[14] While these strategies may make the patient feel better for one night, they will likely have trouble sleeping the next night, resulting in perpetuation of insomnia. Additionally, stimulus control procedures should be implemented immediately.[14] If the insomnia has not

improved within a few days of using these techniques, it may be necessary to initiate sleep restriction therapy again. Encourage a patient to contact yourself or their physician if the insomnia does not resolve within a week

6. Wrap up the Session

As always, any patient questions and concerns should be addressed before the end of the session. It is important to congratulate the patient on all they have accomplished over the last few weeks and make yourself available for further support if concerns arise down the road.

PART III: Additional Information

1. **Transferring Skills from PharmaZzz Sessions to Real Life**
2. **Acute Insomnia**
3. **Jet Lag**
4. **Shift Work**

3.1 Transferring PharmaZzz Skills to Real Life

Taking what has been learned in PharmaZzz sessions and transferring it to the real world can be a challenging task for many patients. The patient workbook was developed as a guide for pharmacists to use during the sessions and a tool to help patients practice what they have learned at home. Readings and assignments from the workbook assist patients to apply the NMTi skills they are learning to the real world and to become experts in their own therapy.

Another way to promote the transfer of skills is by including cues from the patient's world into the sessions. This can be done through role-plays, review of homework assignments, and the induction of emotion.[17] When implementing a new therapy, questions that may be asked to help the patient imagine how they will implement it into their life include:

- When will you do it?
- How will you be feeling at that time?
- What might you be thinking?
- How will you remember to do the intervention?
- What will make it harder?
- What might make it easier?

It may also be useful to have a patient walk you through what their bedtime routine that night is going to look and feel like. By addressing some of the initial anxieties in session, coping with the actual act in real life may be easier.[17]

3.2 How to Manage Acute Insomnia

When a patient presents with an acute episode of insomnia, the first step is to assess and determine what predisposing, precipitating and perpetuating factors are present.[36] This may be done through observation and questioning the patient. Common predisposing factors include being older, female, and a family history of insomnia.[17] The tendency to worry or be anxious may also predispose one to developing insomnia.[17] The more predisposing factors a patient has, the easier it may be to trigger a case of insomnia.

If the trigger is another medical condition, it may be necessary to treat that condition in order to relieve the insomnia. Other sleep disorders should be considered and can be assessed with the appropriate questions. Stressful life events may also trigger insomnia. Often insomnia will resolve after the stress is reduced.[36] Some patients may not be able to identify a specific trigger. In either case, the next step is to determine if any perpetuating habits are being developed.

The easiest way to assess if a patient is developing any perpetuating sleep habits is by asking them questions about their bedtime routine, napping, and how they cope with a bad night of sleep. At this point you may identify habits that need to be changed in order to prevent progression to chronic insomnia.

General sleep hygiene guidelines may also be provided to the patient. In some cases it may be appropriate to recommend a hypnotic agent for short-term therapy, as long as the patient is provided with proper education regarding

its use. There is some preliminary evidence that intensive one-session NMTI may be effective for acute insomnia but more research is needed.

3.3 How to Manage Shift Work

Shift work is a lifestyle factor that often causes sleep disturbances due to the irregular sleep-wake schedule that forces people to function against their natural circadian rhythm.[2] Some tips to help manage shift work can be found in Table 16.

3.4 How to Manage Jet Lag

Jet lag is another situation that can lead to acute sleep disturbances due to the change in time zones. Advise patients preparing for travel that it may be useful to slowly adjust their sleep-wake schedule to match that of their destination before they leave.[2] When arriving at their destination, they should change their sleep-wake schedule immediately and not go to bed until it's appropriate for the local time.[2] Recommend patients give themselves a couple days if possible to adjust to the new time zone to improve their daytime functioning before attending any important events.[2]

Table 16: Tips for Shift Work[2]

- **Wear sunglasses when leaving work in the morning.**
- **Allow time to wind down after work instead of heading straight to bed.**
- **Make sure your room is dark and free from interruptions. You may use blinds or nightshades to block light and ear plugs to reduce noise.**
- **Suggest using bright lights at work to increase alertness.**
- **Take a couple of days or up to a week to slowly adjust to a major change in your sleep schedule.**

Key Summary Points

Part I: Understanding Non-Medication Therapy for Insomnia and Appropriate Use in Practice

Background on Insomnia

- 4P theory of insomnia: predisposing, precipitating, perpetuating and Pavlovian factors are responsible for the development of chronic insomnia. Predisposing and precipitating factors are more prominent during the acute phase while perpetuating and Pavlovian factors are more prominent during the chronic phase.

Candidates for NMTI

- Rule out other medical conditions, uncontrolled mental illnesses, other sleep disorders, medications/drugs and complicated lifestyle factors as the cause of insomnia. *(For other sleep disorders, focus on sleep apnea and restless leg syndrome.)*
- Use with caution in patients at high risk of falling.
- Relative contraindication in patients with mania, epilepsy, parasomnias.

Hypnotic Tapering

- Discontinuing hypnotic use is an important goal of therapy.
- Recommend a tapering schedule based on type, dose and duration of hypnotic use and patient preference for the rate of taper. (See Table 6, page 14)
- For additional information, see deprescribing.org Benzodiazepine & Z-Drug Deprescribing algorithm (https://deprescribing.org/wp-content/uploads/2019/03/deprescribing_algorithms2019_BZRA_vf-locked.pdf).

Sleep Restriction Therapy

- Goal is to match time spent in bed to sleep time (*consolidate and improve quality of sleep)*
- **Sleep Restriction Parameters:**
  - **TIB** – Time in bed: the amount of time that has elapsed from the time the person went to bed to the time they wake up in the morning.
  - **TST** – Total sleep time: the total amount of time actually spent sleeping during the night.
  - **TIB Prescription** – The allotted amount of time that the patient is allowed to spend in bed. Set to match the calculated TST + up to an additional 30 minutes at therapist's discretion.
  - **SE** – Sleep efficiency = TST/TIB. A measure of how well the patient is sleeping, with a higher sleep efficiency representing more consolidated sleep.
  - **SL** – Sleep latency: a measure of how long it takes to fall asleep. Should be estimated by patient.
  - **WASO** – Wake after sleep onset: a measure of how long the patient was awake after initially falling asleep. Should be estimated by patient.
  - **TTOB** – Total time out of bed: the amount of time spent awake and out of bed during the night.

- **Sleep Log Calculations**
  - **TST = TIB – (SL + WASO)**
  - **SE = TST/TIB**

- **<u>Sleep Restriction Procedure</u>**
    1. Calculate TST from the patient's sleep log.
    2. Set a TIB prescription to match the TST + ≤ 30 minutes.
    3. Set bedtime and wake time to reflect the TIB prescription.
    4. After 1 - 2 weeks, recalculate the patient's SE from the sleep logs.
    5. If the SE is >0.90, increase the TIB prescription by 15 minutes. If the SE is between 0.85-0.90, the TIB prescription remains the same. If the SE is <0.85, consider decreasing the TIB prescription by 15 minutes.

Stimulus Control Therapy

- Goal is to re-associate the bed and bedroom with feelings of relaxation and sleep.
- Regular scheduled bedtime and wake time.
- Limit activity in bedroom to sleep or sexual activity.
- Do not stay in bed for more than 15 minutes if not sleeping.
- Avoid daytime napping. *If napping occurs, instruct patient to nap for no longer than a half hour and to not nap after 4:00 pm. Additionally, postpone bedtime that evening by the amount of time that they napped.*

Cognitive Restructuring

- Goal is to bring patient awareness to the inaccuracy of their negative thoughts and dysfunctional beliefs and alter these thoughts to promote positive sleep habits and decrease worry/anxiety.

- Cognitive Restructuring Process:
    - Recognize negative sleep thoughts (NSTs)
        - Being aware of common types of cognitive distortions helps identify negative thoughts: all-or nothing thinking, overgeneralization, catastrophic thinking, jumping to conclusions.
        - Thought stopping, e.g., saying the word "STOP" when you detect a negative thought.
        - Marveling, e.g., appreciating the emotional tone of your thoughts without buying into them.

    - Reframe negative sleep thoughts (NSTs)
        - Write thought down.
        - Determine if an underlying fear is present.
        - Accuracy of negative thoughts can be evaluated using a number of techniques: questioning thoughts, "double standard" technique, reflection, CEO thinking.

Part II: Initiating and Implementing Treatment

Session 1: Initial contact and screening

- Determine patient eligibility for program.
- Discuss sleep medication use and patient willingness to discontinue use.
- Provide patient with sleep logs and educate on their use.
    - Emphasize that Sleep Latency (SL) and Wake After Sleep Onset (WASO) times are to be estimated and not to watch the clock.
    - Ensure patient understands how to calculate Time in Bed (TIB) and Total Sleep Time (TST) properly.

Session 2: Treatment Education and Initiation of Therapy

- Educate the patient on sleep and insomnia: Introduce the 4P model of insomnia.
- Introduce sleep restriction therapy, review sleep logs and set TIB prescription.
    - Point out the mismatch between TIB and TST and educate on the effects of extending sleep opportunity.
    - Set TIB prescription, wake time and bedtime.
    - Remind patient of potential for increased fatigue initially and that it may take a couple weeks to see results from therapy.
- Introduce stimulus control and sleep hygiene.
    - Bedroom reserved for sleep and sexual activities only.
    - If lying awake in bed for more than 15 minutes, either before falling asleep initially or after waking during the night, get up and leave the bedroom. Instruct patient to estimate the amount of time that has passed and not clock watch.
- Pick activities to do while awaiting bedtime and during the night when practicing stimulus control.
- Initiate or monitor medication taper.
    - Set a goal for the following week.
    - Educate on potential withdrawal effects and how to manage them if they occur.

Follow-up Sessions: Therapy Adjustments and Monitoring

- Review sleep logs and adjust TIB prescription as appropriate.
    - Make sure TST was calculated and not guessed.
- Review successes and difficulties with the previous week
    - Sleep hygiene issues, strategies for staying awake until bedtime, and ability to carry out stimulus control procedures.
    - Draw attention to any progress the patient has made that week.
    - Brainstorm solutions for any problems the patient encountered.
- Assess adherence
    - Look for complete sleep logs, adherence to bed and wake times and adjustments for naps.
    - Compare Total Time Out of Bed (TTOB) to Wake after Sleep Onset (WASO) time to assess if patient is following stimulus control guidelines.
    - If patient appears to be nonadherent, determine if patient falls into “simply couldn’t,” “wanted to but couldn’t,” or “didn’t want to” category.
        - "simply couldn't" - avoid recumbent positions a few hours before bedtime, schedule physical activity in the evening, and apply cold compresses to the body.
        - "wanted to but couldn't" - cognitive interventions to assess disruptive thoughts.
        - "didn't want to" - reassess if patient still wants to continue therapy.
- Introduce cognitive restructuring and relaxation techniques if necessary.

    - Review dysfunctional beliefs.
- Monitor sleep medication use.
    - If no issues, set a new goal for the following week.
    - If complaints of withdrawal effects, give advice on how to manage these effects and slow the taper down.
    - Do not increase the dose or suggest PRN dosing.

Final Session: Maintenance and Relapse Prevention`

- Review sleep logs and assess TIB prescription.
    - At this point, the patient should feel comfortable managing their own sleep therapy.
- Review successes and difficulties.
    - Place focus on improvements from baseline data.
- Monitor sleep medication use.
    - If the patient has not been successful with taper, discuss what factors have interfered with the process and offer ongoing support to the patient.
    - For patients who have discontinued their hypnotic, emphasize not relying on hypnotics after a bad night and using only on planned nights (if necessary).
- Discuss relapse prevention.
    - Emphasize that is normal for everyone to have occasional restless nights.
    - Have patient explain the 4P model of insomnia and identify predisposing, precipitating, perpetuating and Pavlovian factors that apply to them.
    - Determine which interventions should be discontinued and which should become long-term practices.
        - Only sleep in on predetermined days (max twice a week) for no longer than 60 minutes past the regular wake time.
        - Never sleep in after a bad night.
    - Discuss what to do when insomnia recurs.
        - Try to determine what caused the initial sleep disturbance.
        - Do not compensate for sleep loss by napping, going to bed early or waking up later
        - Implement stimulus control procedures.
        - If insomnia not resolved within a week, may initiate sleep restriction therapy again.

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Appendix 1: Sleep Logs

- Day Log
- Night Log
- How to use your sleep logs

DAY LOG

DATE/DAY *(Fill in each evening just before going to bed)*										AVERAGE
Caffeinated drinks? How many?	Before 5PM									
	After 5 PM									
Alcoholic drinks? How many?	Before 5PM									
	After 5 PM									
Nicotine use? How many cigarettes, other forms?	Before 5PM									
	After 5 PM									
Exercise?	Before 5PM									
	After 5 PM									
Naps?	Time of day									
	How long?									
Stress during your day?	*Y / N*									
Feel sleepy during the day?	*Y / N*									
Mood in general during day?	*1=poor; 2=fair; 3=good; 4=excellent*									
Overall function during day?	*1=poor; 2=fair; 3=good; 4=excellent*									
Additional items to track: (list)										

NIGHT LOG

PharmaZzz
Non-Medication Therapy for Insomnia

DATE/DAY *Fill in each morning immediately after getting out of bed*									
1. What time did you go to bed last night?									
2. How long did it take you to fall asleep?									
3. How many times did you wake up during the night?									
4. For how long in total were you awake during the night?									
5. How much time did you spend out of bed during the night?									
6. What time did you wake up this morning?									
7. What time did you get out of bed this morning?									
8. Did you take a sleeping pill last night? (Y?N)									
9. Generally speaking, how well do you feel this morning? ***(1=Not well; 2=Just OK; 3=Fine; 4=Very well)***									
10. How enjoyable was your sleep last night? ***(1=Not good; 2=Just OK; 3 Good; 4=Very good)***									
11. TIME IN BED (TIB) = time between # 1 and # 7									
12. WAKE AFTER SLEEP ONSET (WASO) – Time awake after first falling asleep and before getting out of bed in the morning = #4 + (time between #6 and #7)									
13. TOTAL SLEEP TIME (TST) = #11 – (#2 + #12)									
14. SLEEP EFFICIENCY = TST (#13) / TIB (#11)									

How to Use Your Sleep Logs

Sleep logs are a very important part of your sleep therapy program. They provide us with information about your sleep patterns and allow us to monitor your progress throughout the program. Each day you will be asked to fill in two sleep logs: one in the morning and one in the evening. This will only take a couple minutes of your day. Included is an example of how to fill out your sleep logs.

Night Sleep Log

The night sleep log asks questions about your sleep the previous night and provides us with the information we need to initiate therapy. It is very important to complete these sleep logs for at least one week, preferably two weeks, before your first session so that we have enough information to begin therapy. Some questions on this sleep log include:

1) What time did you go to bed last night?

This includes any time you spent reading, watching tv, or conversing, etc. before going to sleep.

2) How long did it take you to fall asleep?

This is an estimation of the amount of time it took you to fall asleep after shutting off your lights with the intention of going to sleep, also known as sleep latency or SL Do not watch the clock as this can make falling asleep more difficult.

3) How many times did you wake up during the night and for how long in total?

Count any time you were awake enough to be fully aware. If you are not sure if you were awake, do not count it.

4) For how long in total were you awake during the night?

Estimate the amount of time you were awake. Do not watch the clock.

6) What time did you wake up this morning?

This is the last time you woke up and became fully alert without going back to sleep again.

7) What time did you get out of bed this morning?

This is the time that you arose from bed to start your day. This may be different from your final awakening time (question 6).

11) TIME IN BED

How many hours passed between the time you went to bed and woke up to start the day? This value, also know as TIB, is the amount of time that passed between question one and seven. For example, if you went to bed at 12:00am and woke up at 7:00am, your TIB would be seven hours or 420 minutes.

12) WAKE AFTER SLEEP ONSET

This value, also known as WASO, is the amount of time that you were awake after first falling asleep last night and before getting out of bed this morning. Add question four and the difference between question 6 and question 7 together. For example, if you woke up once during the night for 30 minutes and were awake for 50 minutes in the morning before getting out of bed, WASO would be 80 minutes.

WASO = Question 4 + (time between Question 6 and Question 7)

13) TOTAL SLEEP TIME

How many hours total did you sleep last night? This value, also known as TST, includes only the amount of time you were actually sleeping. To calculate this value, WASO (question 12) subtract from TIB (question 11). For example, we determined the TIB to be 420 minutes, so subtracting 80 from 420 gives us 340 minutes. This means that you actually slept for 340 minutes.

TST = Question 11 – Question 12

14) SLEEP EFFICIENCY

Your sleep efficiency is a measure of how well you are sleeping and is used as a guideline for your sleep therapy. It is calculated by dividing your TST (question 13) by your TIB (question 11). For example, if your TST is 340 minutes and your TIB is 420 minutes, your sleep efficiency would = 340/420 = 0.80 = 80 %

Day Sleep Log

This log asks questions about your activities during the day. This information helps us to identify any habits that may be interfering with your sleep. Some habits asked about include:

- Caffeine consumption throughout the day: Caffeine is a stimulant and is found in many common products including coffee, tea, pop, energy drinks and chocolate.
- Alcohol consumption throughout the day: Measure alcohol by ounces (oz). One ounce (one shot) of hard liquor is about equal to a glass of wine or a can of beer. Don't get too caught up in calculating the exact amount of alcohol consumed.
- Nicotine use: Write down how much nicotine was used, e.g. 3 cigarettes.
- Exercise throughout the day: Write down what kind of exercise you did and for how long.
- Naps: Write down how many naps you took during the day, what time and an estimate of the length of time you napped.

Appendix II: Case Study - Setting and Adjusting Time in Bed (TIB) Prescription

Setting and Adjusting TIB Example Calculations

This example is based on the average values calculated from hypothetical evening sleep log data recorded prior to therapy and after two weeks of sleep restriction (Sidebar).

Total sleep time (TST) = TIB – (SL + WASO)
= 540 - (60 + 120 +30 minutes) = **330 minutes**

Sleep efficiency (SE) = TST/TIB
= 330 min/540min = **0. 61 (61 %)**

The TIB prescription is calculated as TIB (330 minutes + up to an additional 30 minutes **= 360 minutes (6 hours).** The patient chooses the time they want to get out of bed in the morning, then bedtime is set to match the TIB prescription. For example, if this patient wants to get up at 7:00 AM, his bedtime would be set for 1:00 AM.

Adjusting TIB Rx Based on SE

The sleep log for the second week of sleep restriction (SR) indicates the patient is on average adhering to the prescribed bed and arise times. Going to bed later, the patient fell asleep more rapidly (SL = 10 minutes) but continued to experience one or two awakenings during the night Although total sleep time has decreased slightly, sleep efficiency has improved to 89 %. The patient may complain of more daytime drowsiness and fatigue. Since sleep efficiency is between 85 and 90 %, the TIB Rx remains the same (6 hours) for the next two weeks. If SE had increased to ≥90 %, the TIB Rx would have been increased by 15 minutes (375 minutes, bedtime 12:45 AM) for the next 7 to 14 days. If, on the other hand, SE was less than 85 %, the TIB Rx would have been decreased by 15 minutes (345 minutes, bedtime 1:15 AM).

Sleep Log Items	Weekly Average	
	Pre-therapy	Week 2 of SR
1. What time did you go to bed last night?	10:00 PM	1:00 AM
2. How long did it take you to fall asleep? (SL)	60 min.	10 min
3. How many times did you wake up during the night?	2	1 or 2
4. For how long were you awake during the night?	120 min.	30 min
5. How much time did you spend out of bed during the night? (TTOB)	0	20 min
6. What time did you wake up this morning?	6:30 AM	7:00 AM
7. What time did you get out of bed this morning?	7:00 AM	7:00 AM
11. TIME IN BED (TIB) *time between #1 & #7*	9 hours (540 min.)	6 hours (360 min.)
12. WAKE AFTER SLEEP ONSET (WASO) *#4 + (time between #6 & #7)*	150 min	30 min
8. How many hours total did you sleep last night? (TST) *#11 – (#2 +#12)*	540 – (60 + 150) = 330 min (5.5 hours)	360 - (10 + 30) = 320 min (5.3 hours)
Sleep Efficiency (SE)	330/540 = .61 (61%)	320/360 = .89 (89%)

Appendix III: Screening Form

Screening Form

PharmaZzz
Non-Medication Therapy for Insomnia

Patient information:		
Name:	HSN:	
Address:	Gender: ☐Male ☐Female ☐Other	☐Pregnant ☐Breastfeeding
Telephone:	DOB:	

Alcohol use
☐ No ☐ Yes (how often, how much, when)
_____

Tobacco use
☐ No ☐ Yes (how often, how much, when)
_____

Shift work
☐ No → continue ☐ Yes → refer, PharmaZzz therapy unlikely to be effective

Medical History:

Co-morbid condition contra-indication to PharmaZzz (e.g. severe depression, seizure disorder, bipolar disorder)?
☐ No → continue ☐Yes → refer

Symptoms or diagnosis of sleep disorder other than chronic insomnia untreated sleep apnea, RLS, narcolepsy, etc.)?
☐ No → continue ☐ Yes → PharmaZzz therapy may not be appropriate, refer

Chronic condition(s) that may cause or contribute to sleep disturbances? *(Tables 1 and 2 in Training Manual)*
☐ No → continue ☐ Yes → what condition(s) _____
Assess, treat, refer if indicated. PharmaZzz therapy may still be appropriate

Acute condition which may be disturbing sleep (e.g. nasal congestion, acute pain)
☐ No → continue ☐ Yes → insomnia will likely improve as condition resolves, educate & monitor.
PharmaZzz therapy not indicated

Medication History

Currently using a medication that may be responsible for or contributing to sleep disorder?
☐ No → continue ☐ Yes → recommend stopping or changing medication if appropriate and/or refer.

Recent discontinuation of a medication or other substance associated with withdrawal effects that include sleep disturbances?
☐ No → continue ☐ Yes → assess and/or refer

Currently using a medication for sleep?
☐ No → continue ☐ Yes → list medication(s), dose, duration: _____
_____

If using sleep medication, does the patient wish to discontinue the medication?
☐ Yes → continue ☐ No → continue but inform patient this is an eventual goal of therapy

P.1

Review of Symptoms:

☐ **Sleep** Insomnia Severity Index (ISI) Score_____

- ☐ 0 – 7 = No clinically significant insomnia → sleep education
- ☐ 8–14 = Subthreshold insomnia → sleep education + sleep hygiene
- ☐ 15–21 = Clinical insomnia (moderate severity) → offer PharmaZzz therapy
- ☐ 22–28 = Clinical insomnia (severe) → offer PharmaZzz therapy

☐ **Dysfunctional Beliefs and Attitudes about Sleep** (DBAS-16) Score_____

- ☐ ≥ 4 average (total score/16), ≥ 6 any individual item → monitor, PharmaZzz still appropriate but may be less successful; refer to physician if no or slow response to therapy (See manual)

☐ **Depression** PHQ-9 Score _____

- ☐ If 10 or higher →consider referral to physician
  PharmaZzz therapy may still be appropriate

☐ **Anxiety** GAD-7 Score _____

- ☐ If 10 or higher → consider referral to physician
  PharmaZzz therapy may still be appropriate

Duration of sleep disturbance?

☐ Less than 1 month → educate on management of acute insomnia, monitor

☐ 1 – 3 months → consider PharmaZzz therapy (e.g., if ongoing hypnotic use is a concern)

☐ More than 3 months → offer PharmaZzz therapy

Other signs / symptom(s) of concern (systemic or mental health)?

☐ Yes → List: _____

Enrollment in PharmaZzz program

Describe rationale for enrolling patient:

Provided patient with sleep logs and instructions on use?

☐Yes ☐ No → Therapy cannot begin without at least one week of sleep log data (two weeks preferred)

If taking a hypnotic, arrangements made to contact prescriber in regards to tapering the medication?

☐ Yes → Pharmacist will communicate with prescriber.
Name of prescriber: _____

☐ No → Patient does not wish to reduce hypnotic use at this time

Next appointment: Date: _____ Time: _____ Venue: _____

Pharmacist Completing the Assessment:

Name:

Pharmacy:
Tel: Fax: Email:

Signature Date: P.2