

**BEHAVIORAL MANAGEMENT APPROACHES TO INSOMNIA IN  
PRIMARY CARE**

**by**

**Friederike von Aweyden**

**A Practicum Project  
Submitted to the Faculty of Graduate Studies  
In Partial Fulfillment of the Requirements  
For the Degree of**

**Master of Nursing**

**Faculty of Nursing  
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**A Thesis/Practicum submitted to the Faculty of Graduate Studies of The University  
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**MASTER OF NURSING**

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## ABSTRACT

Despite the fact that sleep is an integral part of our health and well being approximately one third of the North American population experiences insomnia on a regular basis (Ohayon, 2002). Insomnia is a condition frequently encountered in primary care, however, it is not always appropriately managed (Sateira, Dogrhamji, Hauri, & Morin, 2000). Treatment approaches for insomnia mainly consist of pharmacological and behavioral methods. Research suggests that primary care providers lack training and familiarity with using behavioral techniques, even though these techniques have greater long-term effectiveness and fewer undesirable side effects than pharmacological methods (Morin et al., 1999). The goal of this project was to enhance the use of effective behavioral treatment approaches for insomnia in primary care by designing a management tool, which guides practitioners' selection of effective behavioral treatment options. A comprehensive review of the literature was conducted on the effectiveness of several behavioral strategies. Three techniques were selected based on their level of evidence for efficacy and include stimulus control, sleep restriction and progressive muscle relaxation. This data was then incorporated into a management tool that could be used as a desk reference in clinical practice. The tool was presented and evaluated by practitioners at a primary care clinic and revisions were made accordingly. Ultimately, it is hoped that this tool will facilitate primary care providers' use of appropriate behavioral management techniques for insomnia in the future.

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## CHAPTER ONE

### STATEMENT OF THE PROBLEM

#### *Background*

Sleep is an integral part of our wellbeing and is one of the fundamental conditions for quality of life. It is defined as a state of perceptual disengagement from the environment and is characterized by reduced consciousness during which various complex physiological processes occur (Caskadon & Dement, 2000). With the advent of the industrial revolution, the significance of human sleep has become more important and undeniably altered (Elliot, 2001). The recent Omnibus Sleep in America Poll suggests that only one third of adults (37%) get sufficient sleep at night (American Association of Sleep Disorders, 2001). Sleep loss has become increasingly common in today's society and frequently occurs because of insomnia.

Insomnia is defined as difficulty initiating or maintaining sleep at least three times per week in the presence of functional daytime impairment (Smith et al., 2002). Approximately 24% of the Canadian adult population report suffering from symptoms of insomnia (Sutton, Moldofsky, & Badley, 2001). It can result from underlying medical conditions or, if no underlying cause can be identified, it is termed primary insomnia. Often primary insomnia is associated with lifestyle behaviors, such as napping during the day and increased caffeine intake that are incompatible with sleep.

#### *Significance of Sleep*

Sleep has many beneficial health benefits and the potential consequences of insomnia on quality of life, social, and economical functioning are serious. Epidemiological studies have shown that insomnia is associated with higher rates of morbidity, due to its

detrimental effects on mental, cardiovascular and endocrine health (Bliwise, 2000). As a result insomnia has also been associated with increased use of health care services. (Kapur, et al., 2002). In addition, insomnia may lead to accident-related loss of life, problems with self-esteem and decreased concentration abilities. Thus, insomnia may undermine the healthy functioning of society by contributing to mood and social adjustment disturbances, and dysfunctional interactions in families (Elliot, 2001).

### *Clinical Dilemma*

Various approaches for the management of insomnia are available. The traditional mainstay of insomnia treatment has been the prescription of hypnotic medication. More recently, behavioral factors have been recognized to have an important mediating role in insomnia (Morin et al., 1999). This awareness has led to the development and evaluation of behavioral interventions for the management of insomnia (Holbrook, Crowther, Lotter, Cheng, & King, 2000). Behavioral management strategies consist of several different techniques, such as stimulus control or sleep restriction and each technique has its own distinct level of efficacy (Morin et al., 1999). Recent sleep research indicates that certain behavioral management strategies have been shown to work as well as hypnotic medication in relieving insomnia symptoms and tend to have better long-term outcomes (Morin et al., 1999; Smith et al. 2002; Pallesen, Nordhus, & Kvale, 1998).

Given that about one in four Canadians suffer from insomnia, it is a common symptom reported to primary care providers (Sutton et al., 2001). Because the capacity to sleep is shaped by complex genetic and lifestyle factors, the evaluation of patients with insomnia can be difficult and overwhelming in clinical practice (Hublin, Kaprio, Partinen & Koskenvuo, 2001). Physician training in the recognition and management of sleep

disorders continues to be minimal; therefore sleep disorders remain largely undiagnosed and under-treated (Sateia et al., 2000).

Specifically behavioral treatment methods are not well known by practitioners.

Vincent and Lionberg (2001) have shown that the type of treatment a patient receives for insomnia often depends on the practitioner's awareness of treatment options rather than on efficacy, patient preference and suitability of the given intervention. The lack of awareness of the availability and efficacy of behavioral methods and the assumption that most patients desire pharmacological treatment has left these behavioral strategies largely under-utilized (Morin et al., 1999).

### ***Purpose of the Project***

Appropriate management of insomnia in primary care requires that the practitioner be familiar with the effectiveness and appropriateness of each technique. Sateia et al. (2000) suggest that educational efforts be oriented toward providing practitioners with simplified practical approaches that are useful and applicable to primary care. This knowledge may assist practitioners to shift their focus from providing unnecessary pharmacological interventions to designing a treatment plan of specific and effective behavioral management strategies.

This project recognizes that the use of appropriate behavioral management strategies for insomnia is desirable. The project's intended contribution towards this goal is to provide a management tool for practitioners, which guides them in their selection of effective behavioral treatment options for insomnia. The proposed intervention consists of the following four components: The literature is reviewed regarding available evidence to support the use of specific behavioral techniques. Technique selection is based on

suitability for primary care and the tool development is guided by principles of adult education and evidence-based practice. The tool is then introduced to practitioners at the practicum site and evaluated for content, format and applicability. The collected feedback is used to revise the tool and a framework for the future evaluation and dissemination of the tool is proposed.

It is assumed that sufficient evidence is available to support the construction of such a tool. The investigator recognizes that time constraints of the project confine the evaluation of the tool to only one practice site with a relatively small number of practitioners and that the development of the tool is only one of several steps necessary to affect change in clinical practice.



## CHAPTER TWO

### LITERATURE REVIEW

The following section is intended to provide the reader with basic concepts of sleep, an understanding of which is fundamental to principles of insomnia management. It also highlights factors that affect sleep, and describes both, pharmacological and behavioral interventions for insomnia. Following this, determinants of treatment modalities and the role of the primary care providers in the management of insomnia are discussed.

#### Definitions and Terms

Sleep terminology is often used inconsistently across the sleep literature. For the purpose of this project the following definitions will be utilized.

*Insomnia:* Difficulty initiating or maintaining sleep at least three times per week in the presence of functional daytime impairment (Smith et al., 2002).

*Primary Insomnia:* Primary insomnia is defined by the exclusion of an underlying medical condition, a mental health or sleep disorder (Morin et al., 1999). True primary insomnia is not associated with another disease (Grunstein, 2002). Often, primary insomnia results from environmental or behavioral patterns that are incompatible with sleep.

*Secondary Insomnia:* Insomnia related to an underlying condition, such as a medical, psychiatric or neurological disorder (Petit, Aza, Byszewski, Sarazan & Power, 2003).

*Rebound Insomnia:* A brief exacerbation of the original insomnia symptoms after sleep medication, such as benzodiazepines is discontinued (Roehrs & Roth, 2000).

*Sleep onset latency (SOL):* Frequently stated as *delayed sleep onset*. Difficulty falling asleep within 30 minutes or more of trying to obtain sleep (Hauri, 2000).

*Wakening after sleep onset (WASO):* Also termed maintenance insomnia. Difficulty staying asleep with prolonged nocturnal awakenings (Hauri, 2000). Often this form of insomnia is experienced concomitantly with SOL and patients may experience difficulties falling asleep and maintaining sleep within the same night.

*Sleep efficiency:* The total amount of time slept in relation to the amount of time attempted to sleep (e.g. time spent in bed). It is calculated as a ratio of time asleep to time spent in bed. Sleep efficiency is considered poor if it is less than 85 % on three or more nights per week (Zorick & Walsh, 2000).

*Sleep state misperception:* Discrepancy between a person's sleep perception and actual amount and quality of sleep obtained. This condition can be detected in sleep laboratories. Occasionally, a person's bed partner can also provide valuable insight into the sleep pattern of a patient. Generally this presentation is not accompanied by true daytime impairment (Zorick & Walsh, 2000).

*Polysomnography:* Method of recording of electrical brain activity, eye movement, muscle, heart and respiratory activity during sleep in special laboratories (Cascardon & Rechtschaffen, 2000).

*Primary care provider (PCP):* Professional who provides primary health care services, such as a family physician or nurse practitioner. The terms primary care provider and practitioner will be used interchangeably throughout this project.

### ***Basic Overview of Sleep Stages***

During sleep, a person progresses systematically through a predictable cycle of sleep stages. Each stage can be identified by a distinct wave pattern by polysomnography in sleep laboratories. Sleep stages vary in depth and functional significance and can be broadly categorized into non-rapid eye movement (NREM) and rapid eye movement (REM) sleep. Sleep staging has been useful for determining specific sleep pathologies. Also, any sleep disruption results in a temporary disturbance of the sleep stage sequence, which potentially deprives a person of crucial components of sleep (Cascardon & Rechtschaffen, 2000). A more detailed overview of these stages can be viewed in Appendix A.

### ***Consequences of Insufficient Sleep***

Lack of sleep is associated with a variety of detrimental health effects. Insomnia is known to impair cognitive functions, including concentration and memory. For example, reaction times of individuals with six or less hours of sleep per night are comparable to reaction times of those with legal alcohol impairment (Williamson & Feyer, 2000). Insomnia has an exceptionally close association with mental health conditions, such as anxiety and mood disorders. Insomnia and depression appear to be so closely inter-related, that it is often difficult to determine whether insomnia is the original symptom or a contributing factor (Mc Call & Reynolds, 2000).

Decreased host defense, increased inflammatory response and pain threshold has been associated with sleep loss (Spiegel, Leproult & Van Cauter, 1999). Insomnia affects endocrine function by decreasing insulin sensitivity and contributes to cardiovascular disease by increasing blood pressure. Individuals who suffer from

insomnia are more likely to develop chronic conditions, such as obesity, diabetes, and hypertension (Spiegel et al., 1999).

### **Factors affecting Sleep**

A wide variety of factors play a role in how an individual sleeps. These include circadian rhythm, environmental influences, age and ingestion of substances.

#### ***Circadian Rhythm***

Circadian rhythm refers to an individual's pattern of cyclical behavior within a 24-hour interval. This rhythm resembles a clock-like mechanism, which acts as a pacemaker for various physiological activities. The circadian rhythm also indirectly signals the organism when it is time to sleep. Normally, periods of sleepiness occur twice within 24 hours; once, approximately eight hours after nocturnal sleep (e.g. in the early afternoon) and then again 14-16 hours later (Misteleberger & Rusak, 2000). This rhythm can be affected and shifted by several factors. Understanding how these factors influence the circadian rhythm is important for the evaluation and management of insomnia:

Napping, for instance can shift the circadian rhythm, however, this depends on the timing and duration of the nap. If a person naps for more than 10-15 minutes or 10-12 hours after nocturnal sleep, the circadian rhythm is likely to change, resulting in delayed sleep onset (Zarcone, 2000). In the absence of napping, small bedtime changes of an hour or two can de-synchronize the circadian rhythm sufficiently enough to affect daytime functioning, even if the total sleep time has remained unchanged. This is the rationale for encouraging insomniacs to maintain a fixed bed/wake-up time and to avoid napping during the day (Zarcone, 2000).

### *Environmental Influences*

The circadian rhythm is also responsive to external environmental stimuli, such as light, noise and temperature (Mistlberger & Rusak, 2000). The effect of light on sleep may be observed during the change of seasons. When bright light is presented at the beginning of the night (i.e. evening) it delays sleep onset and the entire sleep phase. Conversely, when light exposure occurs at the end of the night (i.e. early morning), it results in earlier awaking. Light pulses during mid-day exert relatively little effect on sleep phase. Administration of bright light through artificial light boxes has been used to synchronize disturbed sleep in travelers and the elderly. However, no controlled trials are yet available to recommend bright light therapy as effective treatment for insomnia (Montgomery, 2003).

Environmental temperature may also affect the circadian rhythm although its mechanism is less clearly understood. It is speculated that this effect is brought about by neuronal and endocrine mechanisms, which in turn influence behavioral states (Mistlberger & Rusak, 2000). Extreme heat or cold is not conducive to sleep although a slight rise in body temperature before bed, induced by a warm bath or a hot beverage, has been associated with decreased SOL (Zarcone, 2000).

Activities, such as exercise, social arousal and eating can also significantly shift an established sleep pattern. Exercise activates the sympathetic nervous system and has an immediate arousing effect and is not recommended within two to three hours of bedtime. Yet regular daily exercise, preferably during the first half of the day, is thought to enhance sleep by producing physical fatigue (Zarcone, 2000).

Social cues affect sleep, but depend on the degree of arousal produced and time of presentation. Arousing social stimulation, such as anxiety-provoking activities presented late in the day can significantly delay sleep onset. Conversely, arousal in the early portion of the day can lead to earlier sleep onset in the evening (Mistlberger & Rusak, 2000). An overall active lifestyle during the day and a calming bedtime ritual can be advised to enhance sleep. Similarly, presence of hunger or consumption of a large meal just before bedtime is assumed to interfere with sleep. While, this has not been scientifically proven, it has generally led to recommending only a light snack within two hours of bedtime (Zarcone, 2000).

It should be stated that each individual has their own distinct response to each of the above-discussed factors. Also, it is thought that certain combinations of these factors can either produce synergistic or inhibitory effects on sleep. The interaction between these factors is very complex and so far has not been fully understood.

### *Age Related Changes*

Much controversy exists regarding the effect of age on circadian rhythm. It is a common belief that sleep disturbances are an inevitable part of aging. However, this has not been fully substantiated by research, although it has been shown that the prevalence of sleep problems increases with age (Morin et al., 1999).

Research in sleep laboratories has shown that deep sleep is decreased in the aged. Perhaps the age related overall decline in hormone levels (cortisol, thyroid stimulating hormone), body temperature and mobility further contribute to alterations in sleep patterns (Mistlberger & Rusak, 2000). However, the extent to which these changes occur varies among individuals. Studies of successful aging in the absence of chronic

conditions have shown that elderly people, even well into their 80s, may incur no insomnia at all (Bliwise, 2000). One could speculate whether the presence of insomnia is less associated with aging but depends on coexisting medical conditions.

Daytime napping and early morning awakening is commonly observed in the elderly population. However, daytime sleep may be a result of social isolation, medication side effects and limitations in mobility, hearing and vision (Pallesen et al., 1998). Therefore, the question of whether age truly contributes to a deterioration of circadian rhythm and whether older adults need less sleep or simply cannot get more sleep has not been answered (Montgomery, 2003).

### *Substances*

Consumption of social drugs, such as caffeine, nicotine and alcohol, is quite prevalent in our society. While these substances are often used to induce a state of sleepiness or arousal, many individuals lack awareness of how caffeine, nicotine and alcohol ultimately influence their capacity to sleep.

It is well known that consumption of caffeine interferes with the ability to sleep by causing increased SOL, increased number of awakenings during the night and shortened total sleep time (Zarcone, 2000). The effects of caffeine last eight to 14 hours. The earlier in the day caffeine is consumed the less likely it interferes with an individual's sleep. The degree of sensitivity to caffeine varies significantly among individuals. A person, who suffers from insomnia and consumes the equivalent of three to four cups of coffee per day should be encouraged to decrease or preferably discontinue caffeine intake for six to ten weeks to assess the effect this has on subsequent sleep (Zarcone, 2000). It is important to ensure that patients understand which products contain caffeine as they may

not know that soft drinks, chocolate, tea and many over the counter (OTC) preparations are also caffeinated. In addition, patient motivation to curtail caffeine consumption may be enhanced if the practitioner makes patients aware of the other positive health consequences associated with minimizing caffeine intake (e.g. increased calcium and iron absorption, decreased anxiety).

Alcohol is often one of the first self-administered substances used by insomniacs. Initially alcohol has indeed some sleep-inducing properties but two to three hours later it disturbs sleep by reducing REM and deep sleep. This results in sleep maintenance difficulties from diuresis, nocturia and intense dreaming activity (Roehrs, Hollebeek, Drake, & Roth, 2002). With this paradoxical effect on sleep, it is common for patients to increase their alcohol consumption at bedtime only to find that they are perpetuating the initial symptoms.

Sleep lab studies indicate that nicotine and caffeine share similar effects on nocturnal sleep and daytime functioning (Zarcone, 2000). But unlike caffeine, nicotine has a biphasic effect, in that low concentrations induce mild sedation and higher concentrations produce arousal. As a result smoking before or during the sleep period can result in arousal (Zarcone, 2000).

Insomnia is also a common side effect of numerous medications. It is beyond the scope of this paper to list these medications and their effect on sleep. It should be stated however that a detailed inquiry into the patient's medication profile is an integral part of the assessment and management of insomnia.



### **Pharmacological Interventions**

A variety of sedative pharmacological agents have been used to promote sleep. These consist of herbal products, OTC preparations, and prescription products. While it is beyond the purpose of this project to discuss specific details of these sleep enhancing medications, the following section will briefly describe the efficacy and side effects of the most commonly used prescription agents.

It has been shown that insomnia and depression share certain changes in sleep structure (Bliwise, 2000). Hence, treatment of insomnia with antidepressants may treat both symptom and underlying cause. Consequently the use of antidepressants for the symptomatic treatment of insomnia has grown substantially over recent years (Saletu-Zyhlarz et al., 2002). Tricyclic antidepressants produce sedative effects, but also cause daytime sedation and undesirable cholinergic side effects, such as dry mouth and blurred vision (Hajak et al., 2001). Newer drugs, such as trazodone, mirtazapine and nefazodone have fewer undesirable side effects than tricyclic antidepressants (Winokur et al., 2000).

Barbituates were formerly the mainstay of sedative medication. Today, this drug class is no longer a first line agent in the management of insomnia because of potential problems with tolerance, dosing escalation, psychological addiction and physical dependence (Hirst & Sloan, 2003).

Benzodiazepines represent the most commonly used pharmacological treatment modality for insomnia (Roehrs et al., 2002). Benzodiazepines produce central nervous system depression, causing sedating, anxiolytic, myorelaxing effects and often impart a sense of refreshing sleep (Roehrs & Roth, 2000). Adverse effects associated with benzodiazepine use consist of impaired psychomotor performance, amnesia, respiratory

depression, bradycardia, hypotension, vertigo, hepatic dysfunction and rebound insomnia (Roehrs & Roth, 2000). In the elderly this medication has been associated with drowsiness, confusion and increased risk of falls (Busto, Sproule, Knight, & Herrmann, 2001). In addition, prolonged use of benzodiazepines leads to dependence, such that sudden discontinuation results in withdrawal symptoms, like anxiety, perceptual disturbances and convulsions (Roehrs & Roth, 2000). Therefore, benzodiazepines are only considered useful in the short term.

A new class of medication, collectively known as pyrazolopyrimidine hypnotics or benzodiazepine receptor agonists, produce minimal next-day residual effects, withdrawal symptoms and rebound insomnia and can be administered on an "as needed" basis. The most commonly described side effects of this drug consist of a bitter taste alteration, daytime agitation, anxiety and restlessness (Doghramji, 2001). Long-term experience with benzodiazepine receptor agonists is still limited (Hajak & Bandelow, 1998).

Smith et al. (2000) conducted a meta-analysis comparing the effectiveness of pharmacological and behavioral treatment approaches and concluded that both have comparable efficacy. Medication has the advantage of being immediately effective in relieving symptoms of insomnia. In general, medication is easily prescribed, does not require counseling by a practitioner and patients do not need to engage in the challenging task of changing their behavior. However, hypnotic medication has only a limited duration of efficacy (two to four weeks) and is associated with significant side effects, dependence, potential for drug interaction, and financial cost. Sleep experts continue to recommend that treatment of insomnia be tailored to resolve the underlying cause of insomnia and that routine prescription for any hypnotic agent is not appropriate (Scharf,

2001). For this reason, pharmacological treatment modalities do not automatically provide an advantage over behavioral strategies and clinical decisions regarding the use of medication for insomnia must carefully take the overall risk/benefit ratio and impact on quality of life into consideration.

### **Behavioral Strategies**

Behavioral treatment strategies attempt to establish a healthy sleep pattern by focusing on lifestyle practices that are thought to contribute to chronic insomnia (Morin et al., 1999). In contrast to pharmacological management, behavioral interventions are free of undesirable side effects, do not incur expenses beyond the cost of the clinic visit and -once established- have longer lasting effects (Smith et al., 2002). Behavioral interventions have the additional advantage of lowering risk factors for chronic diseases, such as heart disease and osteoporosis, because they incorporate healthful behaviors like physical activity, stress reduction or moderation in substance use. Another important, often underestimated advantage of behavioral interventions is that they provide the patient with a sense of control over their sleep habits again.

However, behavioral management approaches require a high degree of patient motivation. For practitioners it may be easy to underestimate how demanding these behavioral changes can be on patients (Elliot, 2001). Counseling patients about behavioral techniques demands extra effort and time from the practitioner as well. Furthermore, behavioral methods take longer to establish and symptoms fade more gradually over time (Smith et al., 2002). The elderly experience treatment effects to the same extent but later in the therapeutic process than younger adults (Pallesen et al., 1998).

In the following section, five selected strategies are discussed based on the findings of the meta-analyses by Morin et al. (1999). In addition, two other meta-analyses were reviewed for this project. Smith et al. (2002) compared pharmacotherapy with behavior therapy and Pallesen, Hilde Nordhus and Kvale (1998) investigated the efficacy of non-pharmacological treatment methods in older adults. Results of all three meta-analyses were congruent in that behavioral treatment approaches were shown to be as effective as pharmacological interventions. This project predominantly incorporates the findings of Morin et al.'s meta-analysis (1999), because this meta-analysis provides insight into the effectiveness of individual techniques, their respective levels of evidence and strength of recommendations. The evidence for efficacy of each method is graded according to the American Academy of Sleep Medicine as explained in chapter three (Chesson et al., 1999). As there is a blurred distinction between the various techniques within the literature, the strategies discussed in this paper are largely consistent with those used by Morin et al. (1999).

### ***Stimulus Control (SC)***

Developed by Nicassio and Bootzin in 1972, this technique is based on the premise that sleep is a conditioned response to timing and environmental cues, such as a dark and quiet bedroom. A common response to delayed sleep onset is to spend more time in bed in order to increase the likelihood of falling asleep. However, spending sleepless time in bed may only further induce anxiety over sleep loss and its daytime consequences.

SC teaches the patient to be in the bedroom only when drowsy or asleep and a positive association between the bedroom and sleep is created (Stepanski, 2000). Hence, reading, eating, working, watching television or having a clockface within sight while in

bed is not advised. The patient is to go to bed only when feeling sleepy. If unable to sleep after 15- 20 minutes in bed, the patient is to go to another room, engage in a calming activity with dim light and not return to bed until feeling sleepy. This may be repeated until the patient is able to fall asleep. At the end of the night the patient is to rise at the same time each day, regardless of how much sleep was obtained during the previous night. SC instructions for patients can be viewed in Appendix B.

Morin et al. (1999) reviewed 12 studies evaluating SC therapy as a single treatment modality. All 12 studies demonstrated that SC improved SOL (by 31 minutes) and WASO (by 40 minutes) and was superior to placebo and to other behavioral modalities. Apart from some degree of initial daytime drowsiness there were no known negative effects associated with this technique. Chesson et al. (1999) declare SC a grade B recommendation for the treatment of insomnia, which is supported by level II evidence from randomized studies (For further details on the levels of evidence quoted in this paper the reader is referred to chapter three).

### ***Sleep Restriction (SR)***

Developed by Spielman, Saskin and Thorpy (1987), the goal of this technique is to increase the desire and drive for sleep by temporarily creating a mild degree of sleep deprivation (Stepansky, 2000). Based on prior collection of data from sleep logs, patients are instructed to reduce their time in bed to the average amount of sleep during the previous nights. For example, if a person reports sleeping an average of six hours per night while spending eight hours in bed, the initial prescribed sleep duration is six hours. Less than five hours of sleep is never prescribed in order to avoid excessive daytime impairment. Clearly, daytime naps are not permitted. If the patient is able to sleep these

six hours, the bedtime is then advanced by 15 minutes and the wake up time remains unchanged. This incremental increase in sleep continues until the time spent in bed matches the time asleep by 80-90 % (or 80-85 % for the elderly). Small adjustments are made periodically until an optimal duration of sleep is obtained. An instructional handout of this technique for patients and practitioners can be viewed in Appendix C.

SR decreases awakening after sleep onset more effectively (by 80 minutes compared to 40 and 30 minutes of SC and progressive muscle relaxation respectively) than any other behavioral techniques (Chesson et al., 1999). Although SR is a powerful intervention, it is complex to teach and requires great discipline from the patient. Furthermore, it is often relatively unappealing to patients, as it does not immediately relieve daytime fatigue (Vincent & Lionberg, 2001). Therefore, presenting this technique with emphasis on the long-term effectiveness and preparing the patient mentally for the required commitment may enhance compliance.

Six multi-component studies from Morin et al.'s meta- analysis, which included SR, showed significant improvements of sleep parameters, but unfortunately it was impossible to determine the specific contributions of SR (Chesson et al., 1999). Morin et al. (1999) also examined two studies that evaluated SR as single treatment modality. SOL was reduced by 29 minutes; WASO was dramatically reduced by 80 minutes and sleep efficiency improved by 20 %. Therefore Chesson et al. (1999) endorse SR as effective therapy in the treatment of chronic insomnia, based on level II, III and V evidence with a grade B-C recommendation. The variability in evidence is likely a reflection of the small number of studies available which investigate SR as a single treatment modality.

### ***Progressive Muscle Relaxation (PMR)***

Many different types of relaxation techniques exist. For the purpose of this project, only progressive muscle relaxation (PMR) will be discussed, as this method appears to be most suitable for use within primary care. PMR consists of an exercise that involves systematic tensing and relaxing of the major muscle groups. It provides the patient with practice in the recognition and control of involuntary muscle tension. PMR can either be self-taught or the patient can learn this technique in a training session in the office. Sample instructions for this intervention are provided in Appendix D. The most important aspect of this technique is that patients must practice once during the day and once before bedtime until they can reliably produce the desired change in muscle tone. It has been shown that effectiveness of PMR is increased when feedback is provided by a practitioner (Petit et al., 2003).

A guided imagery component can be added to PMR for those patients, who experience racing thoughts or worrying at bedtime. Guided imagery provides a neutral target on which to focus thought processes. The patient visualizes a specific scene that is associated with a calm and relaxed state. As cognitive arousal produces physiological tension, guided imagery and PMR training is often combined in practice (Stepanski, 2000). However, three multi-component studies, which reviewed the efficacy of this technique showed conflicting results and there was no clear evidence to recommend the use of guided imagery for patients with insomnia (Chesson et al., 1999).

Morin et al. (1999) investigated the efficacy of PMR in 17 studies. With one exception, it was shown to be superior to placebo. PMR reduced both SOL and WASO by an average of 20- 30 minutes. These studies also showed that PMR significantly

improved patients' perception of sleep quality. However, it was shown that older adults were less responsive to this technique.

In spite of clear evidence that PMR is effective, it was shown that PMR had slightly less treatment effect than either SR or SC. Instead of reducing SOL by 40 minutes, PMR reduced SOL by 30 minutes (Morin et al., 1999). Given the time commitment to teach and practice PMR on a regular basis, the practitioner may prefer to use techniques with better treatment effect. Yet PMR may still be appropriate for patients who complain of poor sleep quality and can benefit from PMR's self-calming effects. Chesson et al. (1999) conclude that PMR can be supported by level II and III evidence and is a grade B-C recommendation.

### ***Health Practices (HP)/ Sleep Hygiene***

In the literature the term "sleep hygiene" is used with surprising incongruity of definitions and components. For example, Zarcone (2000) uses sleep hygiene as an umbrella term for a variety of behavioral interventions, which overlap with SC and SR. In contrast, Elliot (2001) includes only nine sleep hygiene instructions, which can be viewed in Appendix E. In order to avoid confusion of terms, what Morin et al. (1999) refer to as sleep hygiene is referred to as "health practices" (HP) for the remainder of the project.

HP are frequently used as a first line behavioral strategy in the management of insomnia in primary care. In essence HP consist of a group of instructions which target maladaptive health practices that are thought to interfere with sleep (Zarcone, 2000). Morin et al. (1999) list diet, exercise, substance use, light, noise and temperature as characteristics that may potentially be detrimental to sleep. The authors explain that these behavioral factors are rarely severe enough to be the primary cause of chronic insomnia.



However, these practices may hinder treatment progress or complicate an existing sleep problem (Hauri, 1997).

HP are often integrated into multi-component approaches. Morin et al. (1999) reviewed three studies that evaluated the benefits of HP in isolation from other techniques. Interestingly, the authors found that HP alone have limited benefit in the treatment of insomnia. It remains uncertain whether the lack of efficacy is a result of the patient's inability to comply with the instructions or whether successful changes in HP have relatively little effect on sleep propensity. However, in ten studies using HP in combination with other behavioral techniques, HP were associated with a reduction of insomnia symptoms (Morin et al., 1999).

Consequently Chesson et al. (1999) identify that insufficient evidence is available for HP to be recommended as a single therapy. Given that no negative effects were associated with its use and that health practice behaviors also have considerable other health benefits (such as moderation of alcohol, caffeine and nicotine use), the practitioner may consider incorporating HP with other insomnia interventions. On the other hand, this may dilute the overall treatment effect of more powerful interventions. Therefore, the practitioner must carefully consider the implications of insufficient evidence for this technique and use clinical judgement to select interventions that best suit the symptom profile of the individual patient.

### ***Cognitive Therapy (CT)***

Cognitive therapy has been used for the treatment of psychological disorders, such as anxiety and depression and was adapted for insomnia by sleep specialists (Stepanski,

2000). CT is aimed at changing unrealistic beliefs and irrational fears surrounding sleep. These beliefs often cause sufficient emotional distress and thereby further exacerbate sleep disturbances. CT provides patients with insight into their beliefs and behaviors and uses de-catastrophizing and reappraising techniques to challenge these faulty beliefs (Stefanski, 2000).

Facilitating cognitive therapy requires in-depth training, which PCPs do not have. However, practitioners often use this technique in daily practice by challenging patient's most obvious false beliefs, such as advising a patient who wishes to sleep in excess of ten hours without interruption that this may not be a realistic expectation. However, those patients, who present with significant anxieties about their sleep or with deep-rooted unrealistic expectations should be referred to a well-trained specialist in CT.

In the review by Morin et al. (1999), controlled studies of formal CT for insomnia could not be found. Hence insufficient evidence is available to recommend CT as a single treatment modality (Chesson et al., 1999). However, out of six studies with multi-component therapy that included CT strategies, all showed efficacy in the treatment of insomnia. While it remains unclear how effective CT is in the general management of insomnia, clinical reasoning suggests that this treatment modality is particularly useful in patients with faulty beliefs and dysfunctional attitudes about sleep. In summary of the above described behavioral interventions, a table including each technique, its' efficacy and assigned level of evidence is provided in Appendix F.

### **Using Sleep Logs as a Therapeutic Intervention**

As sleep can be affected by virtually all aspects of a person's activities of daily living, gaining insight into how these behaviors affect sleep can be challenging for patients and practitioners alike. One of the best ways to obtain an initial overview of insomnia symptoms is to have the patient complete a sleep log over a period of two weeks. An example of a sleep log format can be viewed in Appendix G.

Completion of sleep logs actively involves patients in the management of their condition. In accordance with principles of adult learning, sleep logs enhance patients learning by providing them with an opportunity to discover how their behaviors affect their sleep pattern. The act of logging information on a nightly basis is a task-oriented learning activity, which enhances adult learning and facilitates patient-generated action plans. In addition, it also functions as a pre-treatment baseline of insomnia.

### **Combined Approaches**

Many studies used in the meta-analyses by Morin et al. (1999) and Smith et al. (2002) consist of multi-component behavioral strategies. A logical question for the practitioner to pose is whether combinations of certain behavioral techniques create a synergistic effect or actually dilute the treatment effect. At this time, little research has been done to answer this question (Chesson et al., 1999). Since behavioral techniques have few undesirable side effects, practitioners may feel tempted to use several techniques simultaneously. However, provided that behavioral lifestyle changes are generally difficult to implement, the practitioner may choose to use fewer but more effective techniques to avoid overwhelming the patient.

The practitioner may also consider blending pharmacological with behavioral methods. As pharmacological treatment produces immediate effects with limited duration, and behavioral methods take more time to implement but have better long-term effectiveness, it would appear that both approaches complement each other well. Yet, research suggests that behavioral methods alone have better long-term effectiveness than combined methods (Hauri, 1997). Since medication relieves insomnia symptoms almost immediately, one could speculate that patients are less motivated to practice behavioral techniques when combined methods are used. Consequently using behavioral and pharmacological methods together compromises adult learning and is associated with a loss of therapeutic benefits.

In conclusion, various pharmacological and behavioral treatment modalities have been used in the treatment of insomnia. Five distinct behavioral techniques and their levels of evidence for efficacy have been described and selected for the management tool. Because certain behavioral interventions have clearly been shown to be as effective as pharmacological agents, but have fewer side effects and better long-term effectiveness, behavioral approaches should clearly be first line interventions

### **Determinants of Treatment Modalities**

Given that behavioral techniques have many advantages and are effective in treating insomnia, the question emerges why these approaches are not used more frequently in practice. The intent of research utilization is to provide a link between theory and practice to ensure practice based on the best available evidence is achieved. Ideally this involves an examination of barriers to implementation, such as clinical factors, social and organizational context. According to Vincent and Lionberg (2001),

common obstacles to using behavioral interventions include lack of practitioner familiarity with these techniques and practitioner's assumptions that medication is more effective in reducing insomnia symptoms. Smith et al. (2002) also identify lack of reimbursement for patient education and the assumption that patients prefer pharmacological interventions as potential barriers to using behavioral interventions. The latter assumption has been shown to be incorrect by Vincent and Lionberg (2001), whose study found that most adults with chronic insomnia viewed medication as potentially harmful and preferred behavioral treatment options.

### **The Role of the Primary Care Provider**

Facilitating behavioral change is a challenging but frequently encountered task in primary care. Successful behavioral management of insomnia requires not only that practitioners are knowledgeable about effective treatment options but also that practitioners interact with patients in a manner that enhances patient adherence to these techniques. There is a large body of literature investigating specific counseling approaches that facilitate behavioral change in patients, and a certain degree of overlap between these approaches and adult learning principles (described in chapter three) exist. The following section lists three key principles for promoting behavioral change.

Firstly, treatment preference plays a key role in compliance with behavioral interventions. Only those treatment strategies that are viewed favorably by the patient will be practiced and maintained over time. Regardless of how effective a certain method may be it must be acceptable to the patient in order to be clinically useful. Therefore opinions about treatment options must be carefully explored and considered when selecting a suitable intervention (Morin, Gaulier, Barry, & Kowatch, 1992).

Secondly, internal motivation has a strong predictive value for successful implementation of health behaviors (Kelly, Zyzanski, & Alemagno, 1991). Patients must believe that the intervention is effective and the outcome of the intervention is of personal benefit. In addition, simple behavioral tasks have a stronger predictive value for successful intervention than complex ones (Kelly, Zyzanski & Alemagno, 1991). This suggests that the introduction of only one technique at a time may be more effective than introducing multi-component strategies at once. If complex techniques are used, such as SR, the patient may benefit from implementing only one step at a time.

Thirdly, it appears that the practitioner's interpersonal style is a key element influencing patient compliance. A patient-centered approach is thought to nurture the therapeutic alliance between the patient and practitioner and is assumed to facilitate patients' active involvement in their care. In fact it has been shown that clinical outcomes are improved if patients generate their own action plans rather than being provided with generic recommendations. The common practice of simply giving the patient a pamphlet without further discussion about implementation strategies is not sufficient (Bodenheimer, Lorig, Holman, & Grumbach, 2002).

Communication of caring and empathizing with the individual's symptom experience predicts patient satisfaction, but ultimately has not been shown to affect compliance (Kelly et al., 1991). Similarly, support from family and others has not been linked to increased patient motivation (Edinger & Sampson, 2003).

Also, it has been shown that patients' own beliefs in their ability to implement the desired behavior increases the likelihood of succeeding. For this reason the plan should

be realistic. Furthermore it must be specific, and determine a distinct period of time before a reassessment takes place.

In summary, the three characteristics that are associated with successful behavioral changes consist of considering the patient's treatment preferences, assisting the patient with designing a suitable action plan, and interacting with the patient in a manner that is conducive to enhancing the patients' confidence in succeeding with the desired behavior. Familiarizing PCPs with effective behavioral management strategies for insomnia and combining this education with patient-centered behavioral counseling strategies may lead to improved management of insomnia. If achieved, the overall outcome of freedom from sleep-related daytime impairment may contribute to a decreased risk for depression, anxiety and other medical disorders, resulting in less frequent use of the health care system. Considering the social cost and human suffering associated with insomnia, appropriately managed sleep disorders are expected to contribute to increased productivity, fewer accidental injuries and more functional interpersonal relationships within families and society.

## CHAPTER THREE

### CONCEPTUAL FRAMEWORK

The design and implementation of this project is guided by two conceptual principles. Firstly, principles of adult learning take the role of a catalyst in the behavioral management approach of insomnia. The nature of this project is such that adult learning principles are applied to two target groups: They guide the process of educating the patient and are also employed in the process of familiarizing practitioners with new aspects of management approaches. A brief discussion on how these principles are integrated into this project is provided in chapter three. The following section is a list of the principles that are thought to be relevant in the educational process of adults:

Learning is enhanced:

- ❑ when the learning climate fosters self-esteem and teacher-learner collaboration.
- ❑ when individuals expect that the learning outcome will have meaning for them and their lives.
- ❑ when individuals are actively involved in decision making and planning and when responsibility for learning is shared.
- ❑ when learning activities are task-, problem- or growth-centered.
- ❑ when activities are used that promote the learners' discovery of ideas.
- ❑ when newly acquired knowledge is followed by the implementation of concrete actions.
- ❑ when individuals evaluate their own learning outcomes, skills and needs for more learning.

(adapted from Brundage & MacKeracher, 1980)



The second principle that guides this project is evidence-based (EB) practice. EB practice has redefined health care within the past decade, as more research, easier access to study reports and newly developed methods for systematically appraising the validity of research findings have become available. EB practice consists of systematically finding, appraising, and using contemporary research findings as the basis for clinical decisions (Thomas, 1999). Unlike experience and personal opinions, these systematically appraised studies provide an objective rationale for choosing one treatment approach over another, contribute to the elimination of ineffective practice and lead to better health outcomes (Brown, 1999).

Different forms of evidence have been characterized in a hierarchy or continuum, based on the methodology used to generate them. The following table reflects the levels of evidence applied to the above-described behavioral management techniques as used by Chesson et al. (1999).

American Association of Sleep Medicine Classification of Evidence

| <u>Recommendation</u><br><u>Grades</u> | <u>Evidence</u><br><u>Levels</u> | <u>Study</u><br><u>Design</u>                                       |
|--|----------------------------------|---|
| A                                      | I                                | Randomized well-designed trials with low alpha* & low beta** errors |
| B                                      | II                               | Randomized trials with high beta errors                             |
| C                                      | III                              | Nonrandomized controlled or concurrent cohort studies               |
| C                                      | IV                               | Nonrandomized historical cohort studies                             |
| C                                      | V                                | Case series   |

\* alpha error refers to the probability that a significant result is the correct conclusion of the study

\*\* beta error refers to the probability that a non-significant result is the correct conclusion of the study.

## CHAPTER FOUR

### METHODOLOGY

The following chapter will provide a brief description of the methods used as they relate to each of the project components, namely the literature review, content selection and tool development, tool testing and evaluation.

#### *Literature Review*

A literature search in MEDLINE, CINAHL and the Cochrane Library was implemented to locate the most current information on behavioral management of insomnia. Key words used in the search included sleep, insomnia, primary insomnia, cognitive-behavioral therapy, non-pharmacological treatment and primary care. An evidence based management tool for the treatment of insomnia could not be identified in this search. Valuable research data regarding behavioral treatment approaches for insomnia is generally published in full text format. Similarly, Hamer (1999) observes that important research data often does not get translated into a design that is appropriate for clinical practice. Recognition of this dilemma led to the plan of integrating the scientific evidence for behavioral management techniques into a simple management tool for insomnia. This tool is intended to provide practitioners with a quick overview of effective techniques and guide them in their selection process of appropriate management strategies.

#### *Content Selection and Tool Development*

Clinically relevant and evidence-based data was extracted from the literature for incorporation into the management tool. Each behavioral technique was indexed with its respective level of evidence. It was important to keep the content of the tool simple and

only relevant to clinical decision-making. Specific details were avoided to allow for clinical flexibility. A design of textboxes was chosen to arrange the information in readily visible and logical segments. To allow access to more detailed information about each technique, a table of behavioral interventions was provided as a supplement (Appendix F) and the main references were provided with the tool.

Principles of adult learning were applied to the development of the tool in that it provides building blocks for management strategies and offers flexibility regarding which and how many techniques are used at one time. It was thought to be important that the practitioner and patient tailor the treatment strategy to the specific needs of the patient, as the treatment plan must be congruent with the patient's expectations. The decision to use a sleep log as a treatment component was made because adult learning is enhanced when patients adopt an active role in their care. While patients are given the responsibility for recording their own sleep pattern, this direct involvement in the treatment process often leads to increased patient awareness of how lifestyle behaviors affect sleep symptoms and also to a sense of ownership, where the patient becomes part of the solution.

Three techniques without clear evidence for efficacy were considered clinically important for inclusion into the tool because absence of research studies to support their use was mainly related to a lack of controlled studies for these techniques (CT, Sleep log). For HP, only a small number of studies were available that investigated this technique as a single method. Therefore, it was thought to be important for the practitioner to consider this technique for patients with lifestyle behaviors that interfere with sleep. Hence the practitioner must be aware that the use of techniques without

evidence may still have significant clinical value and conversely that indication of evidence does not replace clinical judgement.

The management tool was developed for use as a desk reference by a variety of health professionals in primary care or community health settings. It is assumed that these professionals have proficiency in promoting behavioral changes (as discussed in chapter two). For this reason the tool does not provide specific guidance on patient education and counseling techniques.

### ***Tool Testing***

As PCPs may lack familiarity with behavioral management techniques, a semi-formal presentation was arranged to introduce the components of the management tool to the practitioners at the clinical site on July 4<sup>th</sup> 2003. This session was scheduled to take place as a part of routine clinical rounds discussion at the clinical practicum site, the Family Medical Centre. This clinic also functions as a training facility for residents in family medicine. The presentation was announced on the printed clinic schedule one week before the session. Eleven participants made up a convenience sample composed of three family physicians, six residents in family medicine, a clinical nurse specialist, a chaplain and a nutritionist. While residents and physicians are expected to attend rounds discussion, participation in the evaluation process was voluntary. The session consisted of a 20-minute animated power point presentation followed by a brief general discussion on how to improve the tool. Participants completed the evaluation form in the remaining 10 minutes.

As adult learning is enhanced when individuals expect that learning outcomes will have meaning for them, the content of the presentation focussed only on aspects that were

considered relevant to clinical decision making of practitioners (Brundance & MacKeracher, 1980). The management tool was introduced in three sequential steps and practitioners were provided with a one-page handout of the tool (Appendix H). In addition, supplemental patient and practitioner resources were enclosed with the tool to foster practitioner learning and provide assistance for patient education. Because adults generally do not learn well when they feel overwhelmed by excessive quantity of information, the investigator based the selection of patient resources on brevity, clarity, readability and organization (Brundance & MacKeracher, 1980).

### *Evaluation*

Immediately after the presentation practitioners were invited to engage in a discussion to evaluate the tool and their own learning. This activity of evaluating information and assessing its' significance in the context of clinical practice is also supported by adult learning principles.

Ethical approval for this project was obtained by the Education/ Nursing Ethics Board and all participating individuals were asked to sign a waiver explaining that participation was anonymous and voluntary (see Appendix I and J). Verbal and written feedback regarding the format, content and applicability of the tool was invited from all attending participants. Verbal feedback was recorded as field notes, written feedback was collected on an evaluation form (Appendix K). Both verbal and written feedback was sought because feedback from particularly outspoken individuals or key players may affect responses from other group members. Therefore collection of anonymously written responses in addition to the group participation provided an opportunity to comment without concern over peer influence. The evaluation form consisted of four components.

The first three sections provided closed-ended questions regarding content, format and applicability. Each question offered three or four choices on a rating scale. The last portion of the evaluation form consisted of open-ended questions regarding general and specific suggestions for tool improvement. The collection of both qualitative and quantitative information likely increased the validity of the data collection. The investigator's committee members reviewed the evaluation form for construct validity, but reliability and inter-rater variability was not tested. The investigator reviewed the written evaluations and calculated results for the closed-ended questions in percentages. Responses to the open-ended questions were simply grouped into themes and are listed in chapter five. The results of this tool evaluation were used to make final revisions in the format and content of the tool.

In summary, the presentation introducing the tool and collection of feedback from practitioners regarding its content, format and applicability was thought to be a logical first step in the evaluation and dissemination process. A complete evaluation of this management tool would include further evaluation efforts within the practice environment. As these steps are beyond the scope of the project, a proposed evaluation framework is described in chapter six.

## CHAPTER FIVE

### RESULTS

This chapter will highlight, summarize and discuss the results of the tool evaluation.

#### *Verbal Feedback.*

Only one participant offered verbal feedback suggesting a change in the layout of the tool to improve the logical flow. She suggested a vertical format in which the right portion of the page, containing health practices, cognitive therapy and patient reassurance (Appendix H) would be moved below the section of stimulus control, sleep restriction and progressive muscle relaxation. From the verbal and non-verbal cues of other participants it appeared that they agreed and found the flow of the schematic unclear.

#### *Evaluation Forms*

All 11 evaluation forms were completed and returned to the presenter. The following section summarizes the responses:

Table 1. Evaluation of Content

|                             |              |                      |                     |
|-----------------------------|--------------|----------------------|---------------------|
| <b>Accurate</b>             | Agree: 11    | Partially agree: 0   | Disagree: 0         |
| <b>Useful</b>               | Useful: 9    | Somewhat useful: 2   | Not at all useful:0 |
| <b>Relevant to practice</b> | Relevant: 10 | Partially relevant:0 | Irrelevant: 0       |

All subjects perceived the content of the tool as accurate and all but one (indicated as not applicable) thought the content was relevant to their clinical practice. Eighty-one percent of practitioners thought the tool was useful, while 18 % considered it somewhat useful. Hence the overall content of the tool was generally perceived as accurate, useful and relevant to practice.

Table 2. Evaluation of Format

|               |              |                |               |         |
|---------------|--------------|----------------|---------------|---------|
| <b>Layout</b> | Excellent: 2 | Good: 6        | Fair: 3       | Poor: 0 |
| <b>Detail</b> | Too much:1   | About right: 8 | Too little: 2 |         |

In contrast to content related responses, evaluation of the tool format was more varied, with 54 % of respondents viewing the layout as good and 72 % viewing the detail provided as about right. These responses are congruent with other comments in the suggestion section and clearly indicate that the layout of the tool needed to be improved.

Table 3. Applicability

|  | Strongly agree | Agree | Partially disagree | Disagree |
|--|----------------|-------|--------------------|----------|
| Does this tool present <b>new information</b> ?                              | 1              | 9.5   | 0.5*               |          |
| Does awareness of this tool <b>change how you currently manage</b> insomnia? | 3              | 5.5   | 1.5                |          |
| Could you see yourself <b>using this tool</b> in practice?                   | 2              | 7     | 1                  |          |

\* one participant marked the line between agree and partially disagree

The majority (95%) of respondents indicated that the tool presented some degree of new information. Seventy-seven percent of respondents thought this tool would change the way they manage insomnia and 81 % could see themselves using the tool in the future. Overall, the participants viewed the applicability of the tool as favorable. The responses further indicated that most practitioners had some degree of familiarity with behavioral techniques, but generally were not familiar with all of the information presented.

### ***Suggestions***

The evaluation form allowed participants to elaborate on any changes or suggestions to improve the tool. Three respondents did not have any specific suggestions, two had



general encouraging comments, such as "well done" or "excellent summary", while six respondents offered the following suggestions:

- "If it is a management tool, try not to confuse with diagnosis."
- "Some more information will be helpful about evaluating and assessing patients for insomnia, if that could be included in the tool."
- "What is the recommendation to start any particular treatment approach first?"
- "I would like to see the tool refined to show the decision points where it would lead us towards one decision versus another."
- "Improve the layout to make it less cramped."

Based on the overall results of responses it became clear that the content and applicability of the tool was valuable and appropriate for primary care, however, the format of the tool appeared to have some shortcomings. Firstly, the layout of the tool resembled an algorithm for the treatment of insomnia, but the content of the research data did not support such a format. Secondly, the nature of the information did not allow a logical, clear flow of information that could be molded into an orderly decision tree. Thirdly, the information provided was too compressed. Clarification was needed that the tool focussed not on assessment but on management only and that it was not intended to be an algorithm. Hence most arrows between textboxes were removed. In order to simplify the design the page was separated into two sections. The three most effective techniques were displayed on the first portion and the bottom section showed supplemental but not EB strategies. The diagnostic tool was identified as an intervention strategy only. The original and the revised management tool can be viewed in Appendix H and L.

Overall, the results indicated that the content of the tool was valuable and applicable to primary care. Evaluation of the format and layout however suggested that

changes be made to provide a less crowded design. This was accomplished by rearranging the content and components of the tool.

## CHAPTER SIX

### DISCUSSION

This final chapter provides the reader with a brief account of the investigator's view of the project, addresses research limitations, presents a proposed evaluation framework and suggestions for future research.

#### Observations

Interestingly, the evaluation of the tool presents conflicting results regarding its content. Quantitative results indicate that the tool content is rated as accurate, useful and relevant to practice by at least 81 % of participants. In contrast the suggestion section of the evaluation form prompted several recommendations proposing a change in tool content (inclusion of clear decision points, confusion with diagnostic tool). Given the small sample size of the project, participants' qualitative responses may carry greater significance than the quantitative responses. This recognition ultimately influenced the revision of the tool.

Overall, the feedback provided by practitioners indicated that behavioral management for the treatment of insomnia is indeed valuable and relevant to primary care. The writer's initial assumption that PCPs are somewhat familiar with behavioral techniques, but are not well versed with the entire content presented in the tool was validated by the feedback.

At the outset of this project the investigator expected to find evidence in the literature that certain symptom profiles of insomnia responded better to specific management techniques. It was thought, for example, that a patient with SOL would experience a greater benefit from PMR than from any other technique. However, after

reviewing the literature it became apparent that there was no evidence for such a "cookbook" approach. Perhaps the original desire to produce a symptom-specific tool led the investigator to arrange the initial tool (Appendix H) in a format that resembled an algorithm. Thanks to practitioner feedback at the Family Medical Centre this mismatch between tool content and format was recognized and appropriate changes were undertaken.

It is important to recognize that in the process of modifying the tool, the revisions essentially led to a summary of various behavioral techniques and no longer consisted of a "tool" in the traditional sense. The reason for this transformation from tool to summary was thought to be twofold. Firstly, insomnia often presents as a combination of symptoms in that a disturbed sleep pattern generally results in SOL, WASO, decreased sleep efficiency and poor perceived sleep quality occurring concomitantly within the same night (Zorick & Walsh, 2000). Secondly, sleep research of non-pharmacological interventions is costly and given that drug companies have little interest in sponsoring this type of research, independent funding for research on behavioral interventions may be difficult to obtain. However, there is certainly room for future research to explore symptom specific treatment approaches for insomnia. In the meantime, the revised management tool, or summary of behavioral interventions is nevertheless thought to be of clinical value to the practitioner as it provides an overview of the suitability and efficacy of the available treatment options.

Effective management of insomnia not only requires that practitioners are familiar with appropriate treatment strategies, but also that they are able to provide a systematic assessment of the presenting complaints. Ideally, a comprehensive clinical tool would

also include an approach for the assessment of insomnia, as was suggested by two practitioners (see chapter 5). However, it was recognized that incorporation of an assessment approach would require an additional literature review and the evaluation of practitioners' existing assessment skills and therefore would constitute an entirely separate project.

Another significant finding from the literature review was that there was no evidence available for the use of the health practices (HP), also known as sleep hygiene. In the investigator's clinical experience, this technique is most frequently advised as a first-line behavioral intervention. However, it is important that the practitioner be aware that the list of HP instructions is comprehensive and that patients may find it difficult to comply with the many components of this technique. Having patients complete a sleep log before discussing HP may enhance learning and compliance, as the sleep log facilitates patients' discovery of those behaviors that exacerbate insomnia. In using HP the practitioner applies adult learning strategies by simplifying and limiting the list of HP instructions to those that are most relevant. Future research into patients' compliance with HP instructions may shed light on reasons why this technique has not been shown as effective. At this time, practitioner awareness of the limitation of this technique is important when designing a management plan.

In retrospect, it was thought to be valuable that the tool introduction was followed by the tool evaluation. It is speculated that this sequence contributed to the excellent return rate of evaluation forms and incorporated adult learning principles in that practitioners were able to assess their own learning and also had to reflect on the information presented. Another way of integrating adult learning principles would have

been to conduct a learning needs assessment prior to planning and implementation of the project. While this assessment was not implemented due to time constraints, it would have contributed to the overall learning process by allowing practitioners to express what content areas they perceived as meaningful and relevant to their practice. In addition, using a learning needs assessment would offer practitioners an opportunity to become directly involved with the development of the project. Such involvement may further endorse their learning with regards to behavioral management of insomnia and their use of these techniques in the future. To further reinforce the same adult learning principles the investigator would allow more time and rhetorical prompts for the verbal feedback session. In addition to collecting useful feedback, this opportunity would potentially initiate a stimulating group discussion that would promote the dissemination of the tool.

Overall, the participants' openness to learning and willingness to provide feedback was very much appreciated. Perhaps this was a result of delivering a presentation that avoided a lecturing approach and incorporated adult learning principles by providing a climate that fosters teacher-learner collaboration. There were many informal positive comments from practitioners throughout the day of the session, indicating perhaps that practitioners enjoyed the information conveyed and did not feel criticized in their existing approaches to insomnia.

### **Limitations**

The development of this management tool has several limitations, which are related to the type of research available, contradictions of techniques, and to certain aspects of the methodology of the project.

**Research.** Many studies in the sleep literature measure insomnia by patient report only. Research has shown that significant incongruencies exist between patients' perception of sleep, and objective measurements in sleep laboratories (Zorick & Walsh, 2000). The reader must be aware that studies with such limitations were used in the development of this project. As discussed previously, definition and content of various behavioral techniques are used consistently in the meta-analysis by Morin et al. (1999), but are not always used consistently in the remainder of literature. This variability of terms may compromise the validity of the studies used in literature review. Unfortunately only the meta-analysis by Morin et al. (1999) was used as a base for the tool development. This occurred because the other meta-analyses were either dated or did not focus on the effectiveness of individual techniques. In addition, most behavioral techniques have been studied as multi-component strategies, using combinations of behavioral techniques. At this time little is known about how these techniques interact. Therefore, it must be recognized that this overlap of interventions confounds the validity and reliability of the study results.

**Techniques.** A contradiction in instructions between SC and HP was noted. In SC patients are instructed to get out of bed if unable to fall asleep within 10-15 minutes. HP guidelines however discourage patients from having a clock-face within sight, as this can cause anxiety about SOL (Zarcone, 2000). As a result it may be difficult for patients to determine a 15-minute time interval in bed without the use of a clock.

With SC, there is controversy about how to instruct patients regarding sexual activity at bedtime, as the bedroom is to be used for sleep and sex only. For some patients sex at bedtime can exacerbate insomnia, while it can have a sedative effect on

others. Zarcone (2000) recommends that sex, if it interferes with sleep, can occur either in a different setting or at a different time. Similarly other activities, such as reading before bed, can either be part of a calming bedtime ritual or interfere with sleep. Therefore the investigator recommends that SC instructions be tailored to individual patient responses.

***Methodology.*** Regrettably, a methodological pitfall occurred during the presentation and evaluation process. Participants were advised that provision of feedback was optional and anonymous. Consent forms with participants' signatures were stapled to the evaluation form. Unfortunately, the presenter omitted to mention that these two pages were to be separated before submitting them. As a result it was theoretically possible to link feedback to individual participants. This may have affected the validity of the feedback; however, most of the signatures were illegible and did not permit identification of the evaluator. In addition, the atmosphere at the Family Medical Centre as a teaching facility is such that critique is an integral part of learning and professional growth, and generally practitioners are comfortable providing honest and open feedback.

Even though attendance of the presentation included most of the practitioners at the clinic and there was a 100% response rate to the evaluations, the small sample size and the fact that the tool was only introduced at one clinical site significantly limits the validity of the tool evaluation. If the project had not been limited by time constraints, several presentations could have been held at various primary care sites.

### **Proposed Dissemination and Evaluation Framework**

Program evaluation is becoming increasingly important in modern health care as economic resources are shrinking and impact of existing programs are questioned



(Lepper & Titler, 1997). Effective and evidence based management of insomnia has the potential to save costly referrals to sleep specialists and to decrease the health care costs of treating conditions like depression, which are associated with sleep loss. Therefore, it would be of value to assess the overall impact of this management tool on practitioners and patients.

Formative evaluation allows us to view the best method of care within a particular environment and is intended to monitor the progress of implementing a clinical program. Lepper and Titler (1997) state that a well-planned formative evaluation ensures that the program goals are realistic and that the variables of interest are measurable. An essential step in the formative evaluation of the insomnia management tool consists of the practitioners' evaluation of the revised tool in theory and in practice. This step was not implemented due to time constraints of the project. Ideally, practitioners would engage in an informal group discussion regarding the suitability and practicality of the methods and the tool, after the tool was pilot tested in practice for approximately two weeks. This process incorporates two adult learning strategies: Newly acquired knowledge is followed by implementation of concrete actions (pilot testing) and active involvement in the group discussion process creates a sense of ownership in the development of the tool.

Kanouse, Kallich and Kahan (1995) suggest that the introduction and availability of new research data will not automatically lead to successful dissemination of the data and advise that additional efforts to motivate, facilitate and reinforce change is required. Research has shown that contact with peers and opinion leaders, active involvement of the learner and provision of supportive materials for later use are especially effective in achieving behavior change in practitioners (Kanouse et al., 1995). These elements were

employed with an educational session, the provision of supplemental resources and participant involvement in the evaluation process and interviews. The attendance of the educational session by a sleep expert would further enhance the dissemination process.

Once the changes in accordance with the formative evaluation have been made, a summative evaluation, which focuses on whether the clinical program has reached the intended goal (Lepper & Titler, 1997) follows. The ultimate goal of this project is to improve management of insomnia in primary care as evidenced by a) increased use of behavioral techniques for primary insomnia and b) decreased first-line use of sedative medication in primary insomnia. Quantitative data of these two dependent variables would be obtained through a chart review over 12 weeks. Chart reviews would serve to collect data regarding the documented use of effective behavioral techniques and use of sedative medication for primary insomnia. This would be compared to a baseline of the same variables and practitioners two months prior to the project. Care must be taken to conduct data collection approximately during similar seasons, because variations in daylight can alter sleeping patterns. This simple "one-group pretest-posttest design" is practical and easy to implement, but does not offer a high degree of scientific rigor (Thomas, 1999).

Ideally data triangulation, or collection of more than one type of data should be used in order to determine the success of a clinical program (Lepper & Titler, 1997). The addition of qualitative data in the form of patient perspectives would certainly enhance the validity of this evaluation design. For example, patients could be interviewed regarding their experience and satisfaction with the management strategies for insomnia. Similarly, focus group interviews with practitioners could be conducted to determine the

tools' impact on their practice habits. While conduction of interviews is beyond the skills of the investigator and the scope of the project, this data could provide a different perspective on how the introduction of the tool affects insomnia management in the clinic.

Even though this proposed evaluation strategy does not include a true experimental design and likely involves only a small number of practitioners and patients, it may provide some degree of insight into how the introduction of a management tool affects treatment strategies of insomnia in primary care.

### **Suggestions for Future Research.**

Over the past decades, sleep research has made extraordinary advances in the discovery of various treatment approaches for insomnia. While funding for research of pharmacological treatment appears to be more readily available, many aspects of behavioral interventions have not been fully studied. For example, research of the interactive effects of combined techniques would provide us with valuable insight into optimal management of insomnia. Also, little is known about the key components of various techniques and their mechanism of action. Furthermore, studies investigating whether certain techniques are more effective for specific symptom profiles would be useful for refining our current treatment approaches.

In summary, the goal of this project was met by providing practitioners with clinically relevant information regarding the use and effectiveness of behavioral management strategies for insomnia as a part of introducing an evidence-based management tool. The purpose of evaluating the tool was to increase its' validity and to adapt it in a manner that would be conducive for practice. It is hoped that this project will

assist practitioners in the use of effective behavioral treatment approaches for insomnia.

Reducing the symptoms of insomnia and the adverse effects of insufficient sleep has far-reaching positive effects on the health and wellbeing of individuals, families and society.

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## APPENDIX A

## STAGES OF SLEEP

(adapted from Cascardon and Rechtschaffen, 2000)

| Stage        |                       | EEG   | EOG/EMG*  |
|--------------|-----------------------|---|---|
|              | Relaxed wakefulness   | Low voltage-eyes open<br>Rhythmic alpha- eyes closed                                | Voluntary eye movement control, some REM*s, SEM*s when drowsy |
| <b>NREM*</b> |                       |   |   |
| I            | Falling asleep        | Low voltage, mixed frequency, some theta  | SEM*s, tonic activity   |
| II           | Light sleep           | Low voltage, mixed frequency, characterized by sleep spindles and K complexes       | SEM*s at sleep onset only, tonic activity                     |
| III          | Moderately deep sleep | ≥ 20 # 50 % high amplitude delta waves, spindles and K complexes may be occur       | No eye movements, tonic activity                              |
| IV           | Deep sleep            | ≥ 50 % high amplitude delta waves, spindles and K complexes may be occur            | No eye movements, tonic activity                              |
| <b>REM*</b>  |                       | Relatively low voltage, mixed frequency, sawtooth waves, theta activity, slow alpha | Phasic REM*s, tonic suppression, phasic twitches              |

\* Abbreviations:

EOM- electro-oculogram

EMG- electromyogram

REM- rapid eye movement

SEM - slow eye movement

NREM- non rapid eye movement

## APPENDIX B

### STIMULUS CONTROL

- ❑ Go to bed only when sleepy
- ❑ Do not read, eat, work or watch television in bed. Use the bed and bedroom only for sleep and sex.
- ❑ Whenever unable to fall asleep or return to sleep within 15-20 minutes get out of bed and go into another room with a dim light. Do not watch television or use a computer because the full-spectrum light produces an arousing effect. Return to bed only when sleepy again.
- ❑ Get out of bed at the same time each day, regardless of the total hours of sleep obtained during the previous night.
- ❑ Avoid daytime napping. If necessary, a brief early-afternoon nap may be taken.

(adapted from Elliot, 2001 and Morin et al., 1999)

## APPENDIX C

### SLEEP RESTRICTION

(adapted from Elliot, 2001 and Morin et al., 1999)

Sleep restriction is a powerful technique that has been shown to help people with sleep disturbances. Your care provider will give you detailed instructions on how you should use this technique. The plan below tells you exactly when to go to bed and when to wake up. You should also avoid naps during the day. It is important that you keep the prescribed bedtime and wake-up time regardless of how tired you may feel. It is normal to feel tired at first, but this will gradually improve within a few weeks.

#### Sample Plan

|                                | Wake up time | Bedtime             | <u>Time in bed</u><br>Sleep duration |
|--------------------------------|--------------|---------------------|--------------------------------------|
| Week 1<br>Sleep time:    hours |              |                     |                                      |
| Week 2<br>Sleep time:    hours |              | ↑ by 10- 15 minutes |                                      |
| Week 3<br>Sleep time:    hours |              | by    minutes       |                                      |
| Week 4<br>Sleep time:    hours |              | by    minutes       | 85-95% efficiency                    |

#### Instructions for the Practitioner:

1. Ask your patient to complete a sleep log for two weeks.
2. From the sleep log calculate the average amount of sleep obtained within 24 hours. This is the initial "sleep time". Never use less than 5 hours of total sleep time in order to avoid excessive daytime impairment.
3. Then determine the patient's desired wake-up time.
4. Subtract the "sleep time" from the wake-up time, which will be the patient's bedtime for the first week. For example, if the patient wishes to rise at 7 am and the average amount of sleep per day is 6 hours, the bedtime for the first week will be 1 am.
5. If the patient sleeps most of the allotted sleep time during the first week, advance the bedtime by 15 minutes for the second week (i.e. patient goes to bed 15 minutes earlier but continues to rise at the same time every morning).
6. Incrementally advance the bedtime by 15 minutes each week until the patient experiences difficulties falling asleep or waking up during the night again. Then delay the bedtime by 10-15 minutes.
7. Continue adjusting the bedtime until the patient has achieved at least 85% sleep efficiency without experiencing daytime impairment.

## APPENDIX D

### PROGRESSIVE MUSCLE RELAXATION

**To learn this technique, it is important that you establish a regular routine of practice. Ideally, you should practice once during the day and once at bedtime for about 10 -15 minutes in a quiet, place without distractions. After practicing twice daily for about two weeks, you can start using it only once a day as part of your bedtime ritual.**

Sit quietly in a comfortable position.

Take a deep, slow breath.

Hold the breath for several seconds.

Slowly exhale.

Take another deep, slow breath.

Hold the breath and pull your toes tightly towards your head, tightening your leg and calf muscles.

Hold the tension and feel your legs tremble with it.

Breathe out and let go completely.

Take another deep, slow breath.

Hold the breath and make a fist with both hands, tightening your arm and shoulder muscles.

Hold the tension and feel your arm begin to tremble with it.

Breathe out and let go completely.

Take another deep, slow breath.

Hold the breath and bite down as hard as you can, tightening your jaw muscles.

Also tighten all of the other muscles in your face including your eyes.

Feel the tension.

Breathe out and let go completely.

Take another deep slow breath.

Hold the breath while tightening your stomach, buttocks and chest muscles.

Feel the tension.

Breathe out and let all these muscles go limp.

Take another deep, slow breath.

Hold the breath while tightening the muscles of your head and upper back.

Move your head from side to side.

Feel the tension in your neck and upper back.

Breathe out and let your muscles go limp.

Take another deep, slow breath.

Hold the breath and tighten every muscle in your body until you feel your whole body start to tremble with the tension.

Hold that tension.

Now breathe out and let all your muscles in your body go.

Become aware of any remaining tension in your body and relax those muscles.

Take another deep slow breath.

Breathe out and let go to relax completely.

(adapted from Chaitow, 1983. *Relaxation and Meditation Techniques*. New York)

## APPENDIX E

### HEALTH PRACTICES

- ❑ Avoid caffeine in coffee, tea, chocolate and soft drinks after noon, and limit to no more than the equivalent of two cups per day or eliminate caffeine completely.
- ❑ Do not drink alcoholic beverages in the evening.
- ❑ Do not smoke just before bedtime or during the night.
- ❑ Exercise regularly every day, but not within three hours of going to bed.
- ❑ Maintain a regular bedtime and wake up time.
- ❑ Do not nap during the day.
- ❑ Keep your bedroom dark, quiet and at a comfortable temperature. Avoid having a clock within sight.
- ❑ Establish a relaxing routine in preparation for sleep.

(adapted from Elliot, 2001 and Morin et al., 1999)



## APPENDIX F

TABLE OF BEHAVIORAL INTERVENTIONS

| <u>Technique</u>   | <u>Suitability</u>   | <u>Evidence Level<br/>&amp;<br/>Recommendation</u>                              |
|--|--|---|
| <b>Stimulus Control</b><br>(SC)<br>(empirically validated)               | <ul style="list-style-type: none"> <li>▪ ↓ SOL* by 31 min</li> <li>▪ ↓ WASO* by 40 min.</li> </ul>   | II B<br>(12 studies)  |
| <b>Sleep Restriction</b><br>(SR)<br>(probably efficacious)               | <ul style="list-style-type: none"> <li>▪ ↓ SOL by 29 min.</li> <li>▪ ↓ WASO by 80 min.</li> <li>▪ ↑ Sleep efficiency by 20 %</li> <li>▪ Not well liked by patients</li> </ul>  | II, III & V<br>B - C<br>(2 studies)   |
| <b>Progressive Muscle Relaxation</b><br>(PMR)<br>(empirically validated) | <ul style="list-style-type: none"> <li>▪ ↓ SOL by 20-30 min.</li> <li>▪ ↓ WASO by 20-30 min.</li> <li>▪ Less treatment effect than other methods</li> <li>▪ Improves perceived sleep quality</li> <li>▪ Patients must practice regularly</li> <li>▪ Less effective in the elderly</li> </ul> | II & III<br>B - C<br>(17 studies)   |
| <b>Health Practices (HP)</b><br>= Sleep Hygiene (SH)<br>(experimental)   | <ul style="list-style-type: none"> <li>▪ Limited benefit when used alone</li> </ul>  | Insufficient evidence<br>as single therapy<br>(3 studies)                       |
| <b>Cognitive Therapy</b><br>(CT)<br>(probably efficacious)               | <ul style="list-style-type: none"> <li>▪ Positive results when used in multifaceted approach</li> <li>▪ Suitable for altering dysfunctional beliefs about sleep</li> </ul>   | Insufficient evidence<br>as single therapy<br>(no controlled studies available) |

\* Abbreviations:

SOL = sleep onset latency

WASO = waking after sleep onset

## References:

Chesson, A., McDowell Anderson, W., Littner, M., Davila, D., Hartse, K., Johnson, S., Wise, M., & Rafecas, J. (1999). Practice parameters for the nonpharmacological treatment of chronic insomnia. *Sleep*, 22( 8), 1128-1133.

Morin, C., Hauri, P., Espie, C., Spielman, A., Buysse, D., & Bootzin, R. (1999). Nonpharmacologic treatment of chronic insomnia. *Sleep*, 22 (8), 347-53.

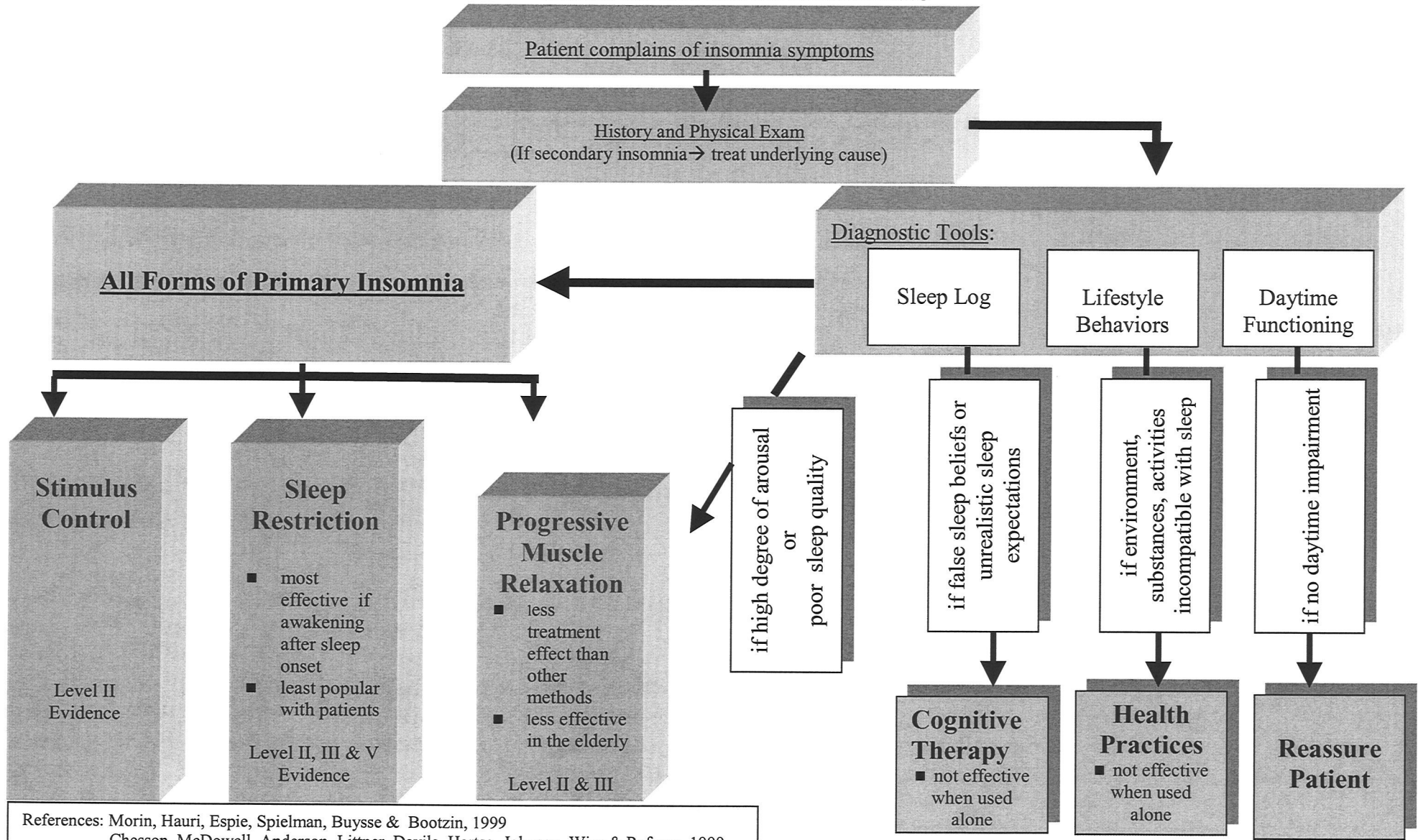
| Recommendation Grade  | Evidence Level | Study Design  |
|---|----------------|---|
| A   | I              | Randomized well-designed trials with low $\alpha$ and $\beta$ errors* |
| B   | II             | Randomized trials with high $\beta$ errors                            |
| C   | III            | Nonrandomized controlled or concurrent cohort studies                 |
| C   | IV             | Nonrandomized historical cohort studies                               |
| C   | V              | Case series   |
| *alpha errors refers to the probability that a significant result is the correct conclusion of the study.<br>beta errors refers to the probability that a nonsignificant result is the correct conclusion of the study. |                |   |

## APPENDIX G

## SLEEP LOG

|   |  |  |  |
|---|--|--|--|
| <b>Date</b>   |  |  |  |
| <b>Time to bed</b>  |  |  |  |
| <b>Time to fall asleep</b>  |  |  |  |
| <b>Number of night awakenings</b>   |  |  |  |
| <b>Time of morning awakening</b>  |  |  |  |
| <b>Time out of bed</b>  |  |  |  |
| <b>Rating of daytime functioning:</b>   |  |  |  |
| Feeling alert and wide awake  |  |  |  |
| Awake but not fully alert   |  |  |  |
| A little foggy, not at peak   |  |  |  |
| Could easily fall asleep  |  |  |  |
| Struggling to stay awake  |  |  |  |
| <b>Rating of sleep quality:</b><br>good-fair-poor   |  |  |  |
| <b>Sleep environment</b><br>i.e. light, noise, temperature                                    |  |  |  |
| <b>Observations of bed-partner</b><br>if different from own perception                        |  |  |  |
| <b>Naps</b><br>number, duration and time  |  |  |  |
| <b>Exercise</b><br>number, duration and time  |  |  |  |
| <b>Caffeine</b> (cola products, chocolate, tea)<br>number of servings and time of consumption |  |  |  |
| <b>Alcohol</b><br>number of servings and time of consumption                                  |  |  |  |
| <b>Nicotine</b><br>number of cigarettes and time of last cigarette<br>in the day or night     |  |  |  |
| <b>Medication/drugs</b><br>list type and time taken   |  |  |  |
| <b>Other comments</b>   |  |  |  |

## APPENDIX H ORIGINAL INSOMNIA SCHEMATIC



References: Morin, Hauri, Espie, Spielman, Buysse & Bootzin, 1999  
 Chesson, McDowell, Anderson, Littner, Davila, Hartse, Johnson, Wise & Rafecas, 1999

## APPENDIX I

## APPROVAL CERTIFICATE

23 May 2003

**TO:** **Friederike von Aweyden** (Advisor D. Fraser Askin)  
Principal Investigator

**FROM:** **Stan Straw, Chair**  
Education/Nursing Research Ethics Board (ENREB)

**Re:** **Protocol #E2003:042**  
**“Non-pharmacological Management Strategies of Primary Insomnia  
for General Practitioners”**

---

Please be advised that your above-referenced protocol has received human ethics approval by the **Education/Nursing Research Ethics Board**, which is organized and operates according to the Tri-Council Policy Statement. This approval is valid for one year only.

Any significant changes of the protocol and/or informed consent form should be reported to the Human Ethics Secretariat in advance of implementation of such changes.

**Please note that, if you have received multi-year funding for this research, responsibility lies with you to apply for and obtain Renewal Approval at the Expiry of the initial one-year approval; otherwise the account will be locked.**

## APPENDIX J

**INFORMED CONSENT**

Project title:

Behavioral management strategies of primary insomnia in general practice.

Investigator: Friederike von Aweyden

Preceptor: Dr Alan Katz

This consent form, a copy of which will be left with you for your records and reference, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

The purpose of this investigation is to improve the clinical management of primary insomnia. As part of my practicum I have developed a tool with five behavioral interventions for insomnia. This tool will be presented to you and you will be asked to offer any verbal or written feedback regarding the format and usefulness of the instrument. Please note that attendance of the session and provision of feedback is entirely voluntary. Your written response will remain anonymous and confidential. There will be no auditory recording device used during the session. Only my practicum committee members and myself will have access to your feedback. Your attendance of the session will take approximately 30 minutes of your time, but it may offer you valuable insight into management strategies of insomnia. Your feedback will be used to improve this tool and you will receive a revised copy.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the practicum project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigator or involved institutions from their legal and professional responsibilities. You are free to withdraw from the discussion at any time, and/or refrain from answering any questions you prefer to omit, without prejudice or consequence. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation.

This research has been approved by the Education/Nursing Research Ethics Board. If you have any concerns or complaints about this project you may contact any of the above- named persons or Human Ethics Secretariat at 474-7122. A copy of this consent form has been given to you for your records and reference.

\_\_\_\_\_  
Participant's Signature\_\_\_\_\_  
Date\_\_\_\_\_  
Researcher's Signature\_\_\_\_\_  
Date

## APPENDIX K

## EVALUATION FORM

The completion of this questionnaire is voluntary and individual responses will remain confidential. Your honest response will be a valuable contribution towards improving this tool and the future management of patients with insomnia.

1. Content

Do you perceive the information presented in this tool as:

- Accurate:** ☐ agree ☐ partially disagree ☐ disagree  
**Useful:** ☐ useful ☐ somewhat useful ☐ not at all useful  
**Relevant to your practice:** ☐ relevant ☐ partially relevant ☐ irrelevant

2. Format

Please rate the following:

- Layout:** ☐ excellent ☐ good ☐ fair ☐ poor  
**Amount of detail:** ☐ too much ☐ about right ☐ too little

3. Applicability

|  | strongly<br>agree | agree | partially<br>disagree | Disagree |
|--|-------------------|-------|-----------------------|----------|
| Does this management tool present new information?                                 |                   |       |                       |          |
| Do you think awareness of this tool changes the way you currently manage insomnia? |                   |       |                       |          |
| Could you see yourself using this tool in your practice?                           |                   |       |                       |          |

4. Suggestions

What changes would you recommend to improve this tool? \_\_\_\_\_

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Please feel free to write down any other suggestions you may have: \_\_\_\_\_

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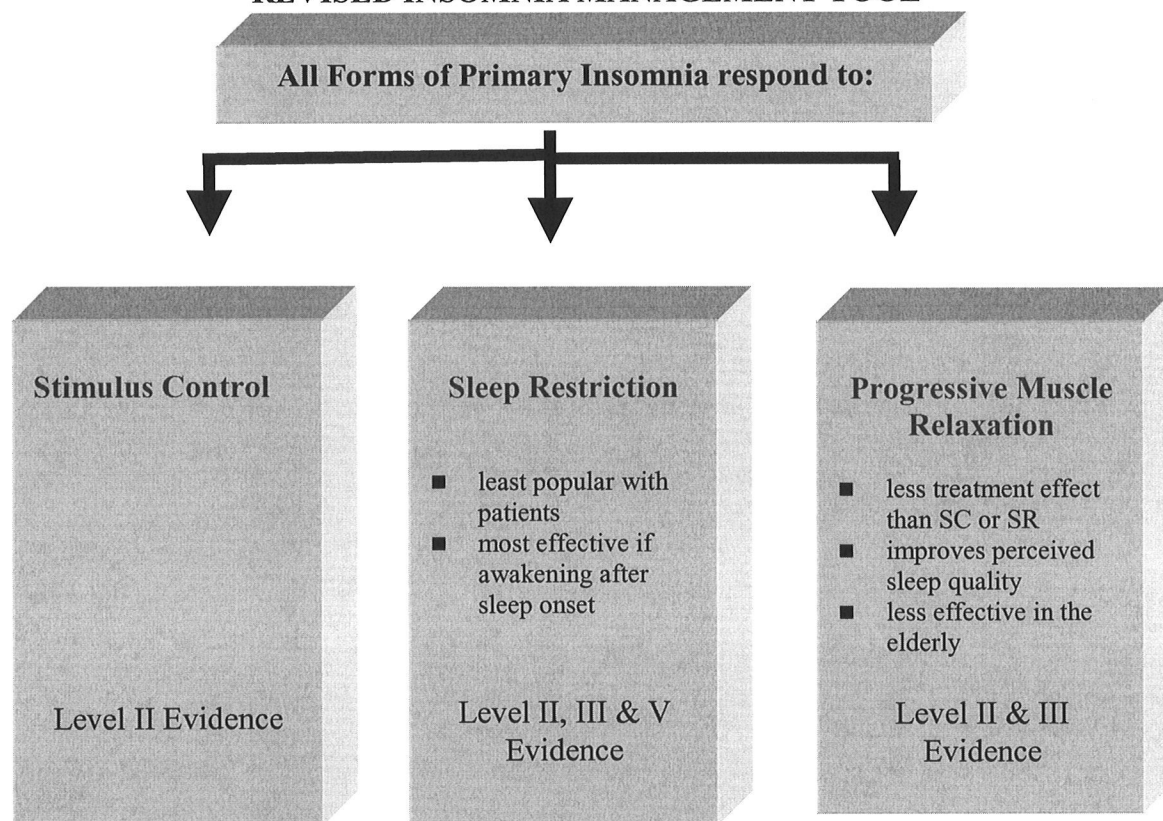


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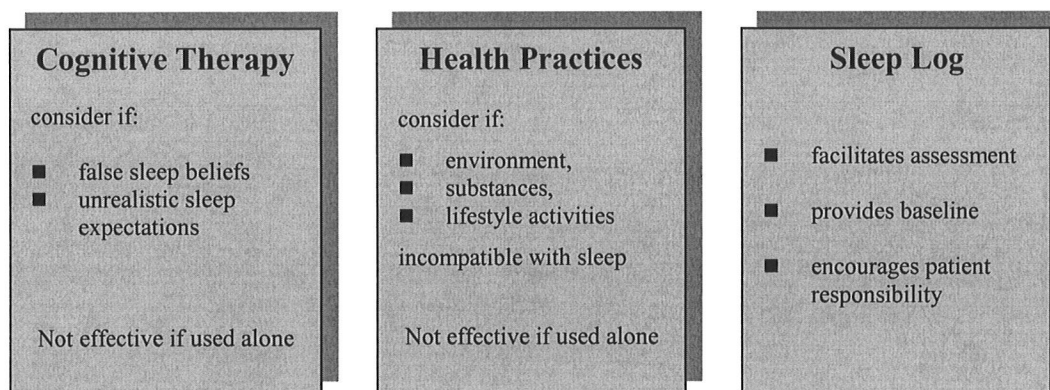
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## APPENDIX L REVISED INSOMNIA MANAGEMENT TOOL



### Supplemental Techniques

**No evidence available to support use**



References: Morin, Hauri, Espie, Spielman, Buysse & Bootzin, 1999  
 Chesson, McDowell, Anderson, Littner, Davila, Hartse, Johnson, Wise & Rafecas, 1999