

# Psychological And Behavioral Treatment Of Insomnia: Update Of The Recent Evidence (1998-2004)

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**Background:** Recognition that psychological and behavioral factors play an important role in insomnia has led to increased interest in therapies targeting these factors. A review paper published in 1999 summarized the evidence regarding the efficacy of psychological and behavioral treatments for persistent insomnia. The present review provides an update of the evidence published since the original paper. As with the original paper, this review was conducted by a task force commissioned by the American Academy of Sleep Medicine in order to update its practice parameters on psychological and behavioral therapies for insomnia.

**Methods:** A systematic review was conducted on 37 treatment studies (N = 2246 subjects/patients) published between 1998 and 2004 inclusively and identified through PsycInfo and Medline searches. Each study was systematically reviewed with a standard coding sheet and the following information was extracted: Study design, sample (number of participants, age, gender), diagnosis, type of treatments and controls, primary and secondary outcome measures, and main findings. Criteria for inclusion of a study were as follows: (a) the main sleep diagnosis was insomnia (primary or comorbid), (b) at least 1 treatment condition was psychological or behavioral in content, (c) the study design was a randomized controlled trial, a nonrandomized group design, a clinical case series or a single subject experimental design with a minimum of 10 subjects, and (d) the study included at least 1 of the following as dependent variables: sleep onset latency, number and/or duration of awakenings, total sleep time, sleep efficiency, or sleep quality.

**Results:** Psychological and behavioral therapies produced reliable changes in several sleep parameters of individuals with either primary insomnia

or insomnia associated with medical and psychiatric disorders. Nine studies documented the benefits of insomnia treatment in older adults or for facilitating discontinuation of medication among chronic hypnotic users. Sleep improvements achieved with treatment were well sustained over time; however, with the exception of reduced psychological symptoms/distress, there was limited evidence that improved sleep led to clinically meaningful changes in other indices of morbidity (e.g., daytime fatigue). Five treatments met criteria for empirically-supported psychological treatments for insomnia: Stimulus control therapy, relaxation, paradoxical intention, sleep restriction, and cognitive-behavior therapy.

**Discussion:** These updated findings provide additional evidence in support of the original review's conclusions as to the efficacy and generalizability of psychological and behavioral therapies for persistent insomnia. Nonetheless, further research is needed to develop therapies that would optimize outcomes and reduce morbidity, as would studies of treatment mechanisms, mediators, and moderators of outcomes. Effectiveness studies are also needed to validate those therapies when implemented in clinical settings (primary care), by non-sleep specialists. There is also a need to disseminate more effectively the available evidence in support of psychological and behavioral interventions to health-care practitioners working on the front line.

**Keywords:** Insomnia, treatment, behavioral, psychological, non pharmacological

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## 1.0 INTRODUCTION

INSOMNIA IS A PREVALENT COMPLAINT BOTH IN THE GENERAL POPULATION AND IN CLINICAL PRACTICE. IT MAY PRESENT AS THE PRIMARY COMPLAINT or in asso-

### Disclosure Statement

This was not an industry supported study. Dr. Morin has received research support from Sanofi-Aventis; has provided consulting services to Sepracor, Pfizer, Neurocrine, Takeda, and Shire Biochem; and has participated in speaking engagements supported by Takeda, Sanofi-Aventis, and Merck. Dr. Buysse is a consultant for Actelion, Cephalon, Eli Lilly, GlaxoSmithKline, Merck, Neurocrine, Pfizer, Respironics, Sanofi-Aventis, Servier, Sepracor, and Takeda. Dr. Edinger has received research support from Respironics; and has received fees for manuscript preparation from Sepracor. Dr. Lichstein is a consultant for Lilly and Takeda; has received research support from Respironics; and has participated in a speaking engagement supported by Sanofi-Aventis. Drs. Bootzin and Espie have indicated no financial conflicts of interest.

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ciation with another physical or mental-health problem. Prevalence estimates indicate that about one third of the adult population reports insomnia symptoms, 9%-12% experience additional daytime consequences, and approximately 6% meet formal criteria for an insomnia diagnosis.<sup>1</sup> Insomnia is more common among women, middle-aged and older adults, shift workers, and patients with medical or psychiatric disorders. Persistent insomnia can produce an important burden for the individual and for society, as evidenced by reduced quality of life, impaired daytime functioning and increased absenteeism at work, and higher health-care costs. Persistent insomnia is also associated with increased risks of depression and chronic use of hypnotics.<sup>2-5</sup>

The diagnosis of insomnia is based on a subjective complaint of difficulties falling or staying asleep, or nonrestorative sleep, that is associated with marked distress or significant daytime impairments.<sup>6,7</sup> Several indicators are useful to quantify the severity and clinical significance of insomnia. These markers may include the intensity (e.g., time to fall asleep, duration of awakenings, total sleep time), frequency, and duration of sleep difficulties. In the case of duration, a distinction is made between adjustment insomnia, a condition lasting a few days or weeks and often associated with stressful life events or changes in schedules and environment, and persistent insomnia, a condition lasting more than 1

**Table 1**—Psychological and Behavioral Treatments for Insomnia

| Therapy                    | Description   |
|----------------------------|---|
| Stimulus control therapy   | A set of instructions designed to reassociate the bed/bedroom with sleep and to re-establish a consistent sleep-wake schedule: (1) Go to bed only when sleepy; (2) get out of bed when unable to sleep; (3) use the bed/bedroom for sleep only (no reading, watching TV, etc); (4) arise at the same time every morning; (5) no napping.  |
| Sleep restriction therapy  | A method designed to curtail time in bed to the actual amount of sleep time. For example, if a patient reports sleeping an average of 6 hours per night, out of 8 hours spend in bed, the initial recommended sleep window (from lights out to final arising time) would be restricted to 6 hours. Periodic adjustments to this sleep window are made contingent upon sleep efficiency, until an optimal sleep duration is reached. |
| Relaxation training        | Clinical procedures aimed at reducing somatic tension (e.g., progressive muscle relaxation, autogenic training) or intrusive thoughts at bedtime (e.g., imagery training, meditation) interfering with sleep.   |
| Cognitive therapy          | Psychological methods aimed at challenging and changing misconceptions about sleep and faulty beliefs about insomnia and its perceived daytime consequences. Other cognitive procedures may include paradoxical intention or methods aimed at reducing or preventing excessive monitoring of and worrying about insomnia and its correlates/consequences.   |
| Sleep hygiene education    | General guidelines about health practices (e.g., diet, exercise, substance use) and environmental factors (e.g., light, noise, temperature) that may promote or interfere with sleep. This may also include some basic information about normal sleep and changes in sleep patterns with aging.   |
| Cognitive-behavior therapy | A combination of any of the above behavioral (e.g., stimulus control, sleep restriction, relaxation) and cognitive procedures.  |

month and often several years. Insomnia complaints are typically associated with reports of daytime fatigue, problems with memory and concentration, and mood disturbances, impairments that may be the primary concerns prompting patients to seek treatment. Insomnia can be a symptom of several other conditions including medical, psychiatric, substance abuse or another sleep disorder; or, it can be a disorder in itself as in primary insomnia.<sup>6-8</sup>

There are several treatment options available for insomnia, including psychological/ behavioral approaches, various classes of medications, and a host of complementary and alternative therapies (e.g., herbal/dietary supplement, acupuncture). The present paper focuses on psychological and behavioral approaches to treating insomnia. These procedures have received increasing research attention in the past 2 decades, and were noted as effective therapies at a recent National Institutes of Health State-of-the-Science Conference<sup>9</sup> on the manifestations and management of chronic insomnia. These methods include stimulus control therapy, sleep restriction, relaxation-based interventions, paradoxical intention, cognitive therapy, and combined cognitive-behavioral therapy. A brief summary of the nature of these interventions is presented in Table 1; more extensive descriptions are available in other sources.<sup>10,11</sup>

## 2.0 PURPOSE

The objective of this paper is to provide an update of the evidence regarding the efficacy, effectiveness, durability, and generalizability of psychological and behavioral interventions for persistent insomnia. The evidence is reviewed for the treatment of both primary insomnia and insomnia associated with other medical, psychiatric, or substance abuse disorders. As with the initial review paper<sup>12</sup> this updated review was commissioned by the Standards of Practice Committee of the American Academy of Sleep Medicine.

## 3.0 METHODS

### 3.1 Search Methods, Keywords, and Databases

Treatment studies selected for review in this paper were identified through PsycInfo and Medline searches for research conducted from 1998 through 2004 inclusively. The following key words were used: nonpharmacologic, behavior therapy, cognitive therapy, psychotherapy, alternative medicine, stimulus control, progressive relaxation therapy or progressive muscle relaxation, paradoxical techniques or paradoxical intention, behavior modification, cognitive behavior therapy, psychological therapy, treatment, intervention, behavioral intervention, treatment, cognitive treatment, alternative treatment, therapy, biofeedback, sleep restriction, sleep deprivation, complementary therapies, mind-body and relaxation techniques, aromatherapy, biofeedback, hypnosis, imagery, or meditation, relaxation, relaxation techniques, yoga, massage. These terms were combined with sleep disorders or sleep initiation and maintenance disorders, or insomnia, or dys-somnia. The search was limited to humans, adults (18 and older), English or French language.

### 3.2 Selection Criteria of Treatment Studies

The initial PsycInfo and Medline searches yielded a total of 312 titles of potential interest; an additional 34 titles were identified by members of the task force through their own reading of the literature, for a total of 346 titles of potential interest. Of these, 102 abstracts were read by the task force chair for initial screening and 53 articles were selected for full review by 2 independent members of the task force. Only peer-reviewed published articles were retained at this phase. Each rater used a standard extraction sheet to summarize information about the study including experimental design, sample (number of participants, age, gender), diagnosis, type of treatments and controls, primary and secondary outcome measures, and main findings. Data extraction was completed independently and discrepancies between 2 members of a pair of raters were resolved through discussion with the chair and other members of the task force. The criteria for inclusion of a study were: (a) the main sleep diagnosis was insomnia (primary or comorbid), (b) at least 1 treatment condition was psychological or behavioral in content, (c) the study design was a randomized controlled trial, a nonrandomized group design, a clinical case series or a single subject experimental design with a minimum of 10 subjects, (d) the dependent measure included 1 or more of the following variables (as measured by daily sleep diaries, polysomnography (PSG), or actigraphy): Sleep onset latency (SOL), number of awakenings (NA), time awake after sleep onset (WASO), total sleep time (TST), sleep efficiency (SE), or sleep quality

(SQ). Studies using global measures of treatment outcome were included if those measures had been validated. Studies of circadian disorders (e.g., phase delay or phase advance syndromes) and those using other nonpharmacological therapies (e.g., light therapy, electro-sleep therapy) or complementary and alternative therapies (e.g., acupuncture) were excluded from this review.

The majority of the initial 346 titles of potential interest were excluded either because they were not treatment studies for insomnia or because the main intervention was pharmacological. Of the 53 full articles reviewed and rated, 16 were rejected. The main reasons for article rejection were: no documentation of an insomnia diagnosis, sample size smaller than 10, results were secondary analyses of other databases (e.g., predictors of treatment response) and used global and non-validated measures of outcome. A list of excluded studies with reasons for exclusion is provided in an Appendix A. The 37 studies that met inclusion criteria are listed in Table 2. For each study, we report the study design and the evidence level (using the Sackett System, 1993), the sample size (enrolled/completed), age, gender, insomnia diagnosis (primary or secondary), types of treatment and control conditions, therapy dosage, format, setting, therapist training, treatment duration and longest follow-up, primary and secondary outcome measures, and summary of main findings. Although some studies not meeting inclusion criteria are discussed in the text they are not included in the evidence table. Based on the Sackett system,<sup>13</sup> the criteria for grading evidence level of each study were: Randomized well-designed trials with low alpha and beta error (Grade I), randomized trials with high alpha and beta error (Grade II), nonrandomized concurrently controlled studies (Grade III), nonrandomized historically controlled studies (Grade IV), case series (Grade V).

## 4.0 RESULTS

### 4.1 Descriptive Features of the Studies and Samples

Table 2 summarizes the main features of the 37 studies selected for this review paper. The number of studies meeting Sackett System standards for grading evidence levels<sup>13</sup> was as follows: 11 studies were graded I, 13 studies graded II, 2 studies graded III, 5 studies graded IV, and 6 studies graded V. A total of 2246 patients with insomnia were enrolled in the 37 studies and approximately 2029 of those completed treatment, for an attrition rate of less than 10% overall. With a few exceptions (studies of Veterans, substance abusers, internet-based treatment), there was a larger representation of women than men enrolled in most studies, with a typical ratio of 2:1, which is representative of insomnia prevalence estimates.<sup>1</sup> Nine of the 37 studies focused specifically on older adults (average age > 60 years old).

The main sleep diagnoses of patients enrolled in the studies were primary or psychophysiological insomnia (28 studies), insomnia associated with medical (4 studies) or psychiatric disorders (3 studies) or a mix of both conditions (6 studies), and hypnotic-dependent insomnia (5 studies). Eight studies examined treatment efficacy in patients with different subgroups of insomnia diagnoses, leading to a total number of studies greater than 37 studies.

The majority of reviewed studies (n = 33) relied on prospective daily sleep diaries to document treatment outcome. Participants

were typically required to complete a daily diary for a minimum of a 1 or 2 week baseline period, for the duration of treatment, and for an additional 1 or 2 week period at post treatment and follow-ups. We retained 3 studies using the Pittsburgh Sleep Quality Index (PSQI) as the primary outcome.<sup>14-16</sup> A few studies have also included polysomnography (n = 7)<sup>17-23</sup> and actigraphy (n = 6)<sup>18,19,24-27</sup> to complement subjective reports from daily sleep diaries. Those studies are identified in Table 2 and in the appropriate subsections of the results. Primary dependent variables derived from these assessment methods were sleep onset latency (SOL), wake time after sleep onset (WASO), total sleep time (TST), sleep efficiency (SE), and sleep quality (SQ). Secondary outcomes included measures of insomnia severity (Insomnia Severity Index; ISI,<sup>28</sup> sleep quality (PSQI),<sup>29</sup> psychological symptoms (Beck Depression Inventory, BDI,<sup>30</sup> State-Trait Anxiety Inventory STAI<sup>31</sup>, and fatigue (Multidimensional Fatigue Inventory, MFI<sup>32</sup>).

The following sections summarize the evidence regarding the efficacy of treatment for primary insomnia, the generalizability of the evidence to different forms of insomnia (primary, secondary, hypnotic-dependent), insomnia in older adults, and the clinical significance and durability of sleep improvements over time. Comparative findings of single and multifaceted therapies and of different treatment implementation models are also summarized.

### 4.2 Treatment of Primary Insomnia

Seventeen studies evaluated the effects of treatment for primary insomnia (see Table 2). Five of those studies were randomized clinical trials (RCT; with grade I,<sup>17,20,21,33,34</sup> 4 of which used CBT as the main intervention. In a comparative study of CBT (without relaxation), relaxation, and a psychological placebo (i.e., quasi-desensitization) with a sample of 75 primary insomniacs,<sup>17</sup> CBT produced greater improvements on the main diary and PSG-defined sleep measures (e.g., SE, WASO) relative to relaxation and control. More CBT patients (64%) achieved clinically significant outcomes compared to relaxation (12%) and placebo (8%). In an effectiveness trial<sup>33</sup> conducted in primary care that evaluated CBT against a wait-list control group, active treatment was found superior to the control condition on most primary and secondary outcome measures. SOL was reduced from 61 to 28 min following active treatment compared to a change from 74 to 70 min for the control condition.<sup>a</sup> Smaller improvements were noted on WASO. There was no significant change on TST during treatment, but an increase of about one-half hour over baseline was obtained at follow up. Of those patients using hypnotic medications at baseline, 76% were medication-free at the end of treatment and 80% at the 12-month follow up. In a comparative study<sup>21</sup> of CBT, medication (temazepam), and combined CBT plus medication, all 3 active treatments improved more than pill placebo on the main outcomes of WASO and SE, with a trend for the combined intervention to yield the greatest benefits. PSG data produced similar outcomes, although of smaller magnitude, but only the combined condition was significantly superior to placebo on the main outcome variables. According to PSG, more patients in the CBT (56%) and combined (68%) conditions achieved clinically significant changes (i.e., SE > 85%) relative to medication alone (47%) or placebo groups (22%). In another clinical trial of primary insomnia in older adults,<sup>20</sup> sleep restriction and relaxation were more effective than placebo on sleep diary variables but not on PSG measures. Sleep restriction produced the best outcome

<sup>a</sup>Unless otherwise stated, reported outcomes are based on daily sleep diaries.

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| Davidson et al. (2001), <sup>42</sup>      | Non RCT; IV | 14/11; 91%; 54.7;<br>Insomnia associated with a medical condition (cancer)  | Multi-component (SC, Rel, SHE)  | 8 wk; No FU  | Sleep diaries; ISI, Hospital Anxiety and Depression Scale; QoL                                     | Significant improvements in SOL (42 to 6 min), NA (1.7 to 1.0), WASO (42 to 11 min), SE (73 to 89%), TST (376 to 411 min), sleep quality and impairments ratings. All patients (n = 9) with baseline SOL or WASO > 30 min and SE < 85% no longer met these criteria after treatment. Significant improvements on QoL for role functioning and fatigue.   |
| Dopke et al. (2004), <sup>45</sup>         | NonRCT; IV  | 11/10; 60%; 45.6;<br>Insomnia associated with psychological disorders   | Multicomponent (SH+SC+SR+ Rel)  | 10 wk; No FU | Sleep diaries; ISI   | No significant improvement on SOL or WASO, but significant reductions of ISI scores.   |
| Edinger et al. (2001), <sup>17</sup>       | RCT; I      | 75/70; 46.7%; 55.3;<br>Persistent primary insomnia  | CBT;<br>Rel;<br>Placebo (psychological)   | 6 wk; 6 mo   | Sleep diaries; PSG; BDI, Insomnia Symptom Questionnaire, Self-efficacy Scale                       | CBT produced greater improvements on most sleep measures, with higher PSG and diary SE (86% and 84% respectively) and lower diary WASO (28 min) than relaxation (PSG SE: 78%, diary SE: 78%; WASO: 44 min), and placebo (PSG SE: 76%, diary SE: 76%, diary WASO: 47 min). More CBT patients (64%) achieved clinically significant outcomes compared to relaxation (12%) and placebo (8%). Greater improvements of self-efficacy in CBT and larger reductions of depressive symptoms in relaxation relative to placebo. |
| Edinger & Sampson (2003), <sup>35</sup>    | RCT; II     | 20/19; 10%; 51.0;<br>Primary insomnia   | Multi-component (SC, SR, SHE);<br>Control (SHE only)  | 2 wk; 3 mo   | Sleep diaries;<br>Insomnia Symptoms Questionnaire; Self-efficacy Scale, DBAS                       | Significantly greater reductions in WASO (97 to 54 min) and SOL (39 to 31 min), and greater increases in SE (71 to 80%) and sleep quality in CBT patients relative to sleep hygiene education controls. These results were maintained at FU. Larger FU changes in CBT patients relative to controls on measures of restlessness, insomnia symptoms, control over sleep and sleep-related cognitions.   |
| Espie et al. (2001), <sup>33</sup>         | RCT; I      | 161/138; 68%; 51.4;<br>Persistent sleep-onset and/maintenance insomnia (probable mix of primary and secondary insomnia) | CBT (with Rel);<br>Wait list control  | 6 wk; 12 mo  | Sleep diaries; PSQI, BDI, STAI, Penn State Worry Questionnaire                                     | SOL reduced from 61 to 28 min following CBT compared to 74 to 70 min for controls; results maintained at FU. Mean reduction of WASO from 78 to 47 min at posttreatment and partially maintained (53 min.) at FU. No change in TST during treatment, but increase of 30 min at FU. Of the 74 patients using medications, 56 had discontinued hypnotic usage at posttreatment and 50 were still medication free at FU.   |
| Friedman et al. (2000), <sup>18</sup>      | RCT; II     | 39/35; 69%; 64.2;<br>Psychophysiological (n =28), inadequate sleep hygiene (n=9), insufficient sleep (n= 2)             | SR + SHE;<br>SR (with optional nap) + SHE;<br>SHE   | 4 wk; 3 mo   | Sleep diaries; PSG; Actigraphy; MSLT, Stanford Sleepiness Scale                                    | Sleep diaries: Higher SE and reduced time in bed for the two sleep restriction conditions at posttreatment. Slower but comparable improvement for the sleep hygiene only condition at FU. Actigraphy: reductions of TST at posttreatment and return towards baseline at follow-up for the two sleep restriction conditions. No group differences on any actigraphy measure. PSG (n=16) data not formally analyzed but descriptive data suggest similar pattern of results as those observed on actigraphy.             |
| Guilleminault et al. (2002), <sup>19</sup> | RCT; II     | 130/126; 100%; 62.4;<br>Chronic insomnia  | CBT; Control (SHE);<br>Sleep disordered breathing (SDB) treatment (Nasal CPAP or ENT nasal treatment) | 6 mo; no FU  | PSG; Actigraphy; Visual Analogue Scales (sleep quality, daytime fatigue); Epworth Sleepiness Scale | PSG-defined SOL reduced by 12 min in CBT groups (with or w/o sleep-disordered breathing). WASO was reduced in all groups. TST significantly increased in CBT group (without sleep-disordered breathing). No significant change in actigraphy-defined measures of SOL and WASO, but all groups improved quantity and quality of sleep at FU. No change on measure of sleepiness; fatigue ratings decreased for the sleep disordered breathing group.  |

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| Hryshko-Mullen (2000), <sup>40</sup>   | Case replication series; V | 42/42; 52%; 53.6; Primary insomnia   | CBT (with Rel)   | 10 wk; 1 mo | Sleep diaries  | CBT produced significant improvements in most sleep parameters. For patients with sleep onset insomnia, SOL was reduced from 69.4 to 32.9 min and SE increased from 59.3% to 75.6%; for those with sleep-maintenance insomnia, WASO was decreased from 65 to 41.5 min, SE increased from 62.1% to 75.9%, and TST increased from 298 to 333 min.   |
| Jacobs et al. (2004), <sup>34</sup>    | RCT; I                     | 63/54; 70%; 47.1; Primary insomnia   | CBT (with Rel); SHE + zolpidem; CBT + zolpidem; Pill placebo                         | 8 wk; 12 mo | Sleep diaries; BDI, Profile of Moods State scale   | SE increased by 14% and SOL decreased by 34 min in CBT group. TST increased in all 4 groups, with largest gain (78 min) in the medication only group. No differences on mood measures. Gains maintained at 12-month FU for CBT and CBT + zolpidem conditions. No information for medication only groups. More CBT patients achieved clinically significant changes on SOL and SE measures.  |
| Lichstein et al. (1999), <sup>50</sup> | NonRCT; III                | 40/40; 58%; 52; Psychophysiological insomnia and Hypnotic dependent insomnia | Rel with medication withdrawal; Medication withdrawal alone; Rel alone; No treatment | 6 wk; 2 mo  | Sleep diaries; Epworth Sleepiness Scale, BDI, STAI.  | Relaxation increased SE in both medicated (from 75.7% to 79.6%) and nonmedicated insomniacs (from 67.0% to 78.8%). Worsening of all other sleep measures during medication withdrawal; relaxation did not attenuate this effect. Only medicated participants receiving relaxation reported improved sleep quality. Relaxation associated with fewer withdrawal symptoms than no relaxation. Medicated participants (with or without relaxation) reduced medication use by 78% at FU. Significant reductions of anxiety and depressive symptoms but no change in sleepiness. |
| Lichstein et al. (2000), <sup>43</sup> | RCT; I                     | 49/44; 48%; 68.6; Insomnia secondary to medical/ psychiatric conditions      | Multicomponent (SC, Rel, SHE); Wait list control                                     | 4 wk; 3 mo  | Sleep diaries; STAI, Geriatric Depression Scale, Insomnia Impact Scale                               | No difference in outcome between insomnia secondary to medical or psychiatric disorders. Greater improvements for treated patients relative to controls with WASO reductions from 87min (baseline) to 61 min (posttreatment) to 56 min (follow-up) and SE increases from 67% (baseline) to 78% (posttreatment) to 78% (follow-up). SOL reduced and TST increased in both conditions at post-treatment. 57% of treated patients achieved clinical improvement in SE compared with 19% of control patients. None of the secondary measures were significant.                  |
| Lichstein et al. (2001), <sup>20</sup> | RCT; I                     | 89/72; 74%; 68.03; Psychophysiological insomnia                              | Rel; SR; Placebo (psychological)   | 6 wk; 12 mo | Sleep diaries; PSG; Epworth Sleepiness Scale, DBAS; Insomnia Impact Scale, Fatigue Severity Scale    | Sleep Restriction and Relaxation more effective than Placebo on sleep continuity variables at post and FU. WASO reduced from 67 min (baseline) to 43 (post) to 38 (FU) in Sleep Restriction, compared to 67 min (baseline), 43 (post), and 52 (FU) for Relaxation. No significant gains in daytime functioning. Sleep restriction produced best outcomes at FU. No significant change on PSG measures. All groups (including placebo) improved on the secondary variables.  |
| Means et al. (2000), <sup>37</sup>     | RCT; I                     | NS/57; 68.5%; 21.2 Primary insomnia  | Rel; Wait list control   | 3 wk; 5 wk  | Sleep diaries; DBAS, Fatigue Severity and; Epworth Sleepiness Scales, Penn State Worry Questionnaire | Relaxation produced more improvement than no treatment on diary measures of WASO, SE, sleep quality, but not SOL. The magnitude of improvement was small. For example, WASO for treated insomniacs went from 22 min (baseline) to 13 min (posttreatment) and SE went from 84.8% (baseline) to 88.4% (posttreatment). No group differences for daytime measures.   |

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| Mimeault & Morin (1999), <sup>38</sup> | RCT; I      | 58/54; 59%; 50.8;<br>Primary insomnia                                  | Self-help CBT with telephone contact;<br>Self-help CBT only;<br>Wait list control | 6 wk; 3 mo   | Sleep diaries; PSQI, ISI, DBAS, BAI  | The addition of telephone consultations to a self-help treatment slightly enhanced outcome on TWT (- 82 min vs. - 62 min) and SE (+ 15% vs. + 11%) at posttreatment, but both treated groups were comparable at follow-up and remained more improved than controls. 59% (17/29) of treated patients had SE > 80% at follow up. Improvements were also obtained on secondary measures of PSQI, ISI, DBAS and BDI. Hypnotic use decreased in all three groups.  |
| Morgan et al. (2003), <sup>15</sup>    | RCT; I      | 209/123; 67.5%; 65.5;<br>chronic insomnia and chronic use of hypnotics | CBT (with Rel) and medication withdrawal;<br>No treatment control                 | 3 mo; 6 mo   | PSQI (TST, SOL, SE, global score), SF-36, use of hypnotic medication, treatment costs          | CBT patients showed significant improvements in PSQI scores (global, sleep latency, sleep efficiency) and reductions of hypnotic use at 3- and 6-month follow-ups. Greater percentages of the CBT group (39%) than controls (11%) achieved low hypnotic (< 50% of baseline) or no hypnotic use at 6-month follow-up. Lower SF-36 vitality scale at the three month follow-up in CBT than in control group. Greater costs for CBT initially but evidence of longer term cost offsets due to reduction of sleep medication usage.   |
| Morin et al. (1999), <sup>12</sup>     | RCT; I      | 78/72; 65%; 65.0;<br>Primary insomnia                                  | CBT;<br>Med (temazepam);<br>Combined CBT+Med;<br>Placebo                          | 8 wk; 24 mo  | Sleep diaries; PSG; ISI  | All three treatments improved significantly more than placebo, with a trend for the combined condition to yield greatest benefits. CBT reduced diary measures of WASO from 50 to 22 min, Med 55 to 29 min and combined 57 to 21 min compared with 62 to 52 min for placebo. SE increased by 17% (CBT), 11% (PCT), 21% (CBT+Med), and 4% (Placebo). PSG data showed that all three treated groups spent less time awake after sleep-onset than placebo, but only the combined approach was superior to placebo. CBT patients best sustained sleep improvements over time, whereas Medication a lone group did not, and the combined condition showed more variable long-term outcomes. |
| Morin et al. (2004), <sup>22</sup>     | RCT; I      | 76/69; 50%; 62.5;<br>Hypnotic-dependent insomnia                       | CBT;<br>Medication taper;<br>Combined CBT + medication taper                      | 10 wk; 12 mo | Sleep diaries; PSG; ISI, BAI, BDI, benzodiazepine use.   | All three groups reduced both the quantity (90%) and frequency (80%) of benzodiazepine use, but more participants receiving the combined intervention were drug-free at post treatment. Modest changes in sleep during initial withdrawal but participants receiving CBT, alone or combined with medication taper, reported greater sleep improvements relative to patients receiving medication taper alone. Improvements reported on secondary variables (ISI, BAI BDI) in all three groups, with gains maintained through FU.  |
| Pallesen et al. (2003), <sup>49</sup>  | NonRCT; III | 66/55; 84%; 69.8;<br>Primary and secondary insomnia                    | Rel + SHE;<br>SC + SHE;<br>Wait list control                                      | 4 wk; 6 mo   | Sleep diaries; ISI, rating of daytime alertness, use of hypnotic medication, life satisfaction | SHE+SC reduced SOL from 87 to 56 min and WASO from 55 to 42 min. SHE+Rel reduced SOL from 71 to 51 min and WASO from 47 to 33 min. No significant group differences between treatments. Effect sizes were of medium size and greater for sleep than daytime measures. Treatment effects maintained in both treatment groups. Controls showed no improvement on any variable.  |

|                                     |                            |  |  |              |  |  |
|-------------------------------------|----------------------------|--|--|--------------|--|--|
| Perlis et al. (2000), <sup>47</sup> | Case replication series; V | 85/47; 64%; 43;<br>Mix of primary insomnia and insomnia associated with medical or psychiatric disorders | CBT  | 4-9 wk; NS   | Sleep diaries  | 61% completing adequate treatment trial showed significant improvement, with averaged SOL reduction of 48 min (65%; effect size = 1.25), WASO reduction of 61 min (48%; effect size = 1.42), and TST increase of 34 min (13%; effect size = .41).  |
| Perlis et al. (2001), <sup>46</sup> | Case replication series; V | 89/28; 64%; 46.5;<br>Mix of primary and secondary insomnia   | CBT  | 4-9 wk; NS   | Sleep diaries  | Subjects completing a minimum adequate trial reduced their SOL (55 to 21 min: effect size = .85), WASO (83 to 28 min: effect size = 1.14), number of awakenings (effect size = .54), and increased TST (291 to 341 min: effect size = .54). Outcomes did not vary relative to medical or psychiatric morbidity.  |
| Perlis et al. (2004), <sup>54</sup> | RCT; II                    | 30/27; 70%; 41.3;<br>Psychophysiological insomnia  | CBT + placebo drug;<br>CBT+ modafinil 100 mg;<br>Contact control + modafinil 100 mg  | 8 wk; No FU  | Sleep diaries; Epworth Sleepiness Scale  | Average SOL reduction of 17 min and WASO of 28 min among CBT patients. Trends suggesting lower Epworth Sleepiness Scale scores and higher adherence to prescribed bedtime during CBT among participants receiving modafinil.   |
| Riedel et al. (1998), <sup>51</sup> | RCT; II                    | 45/41; 54%; 56.6;<br>Hypnotic-dependent insomnia, primary insomnia                                       | SC + med withdrawal;<br>SC alone;<br>Med withdrawal alone;<br>Wait list control      | 4-6 wk; 2 mo | Sleep diaries; Use of hypnotic medication, Epworth Sleepiness Scale, BDI, STAI   | Significant improvements on most sleep parameters over time among stimulus control subjects but not in controls. Lower daytime sleepiness in treated subjects relative to controls at post-treatment and follow-up. No significant differences in outcomes between medicated an unmedicated patients. BDI and STAI showed no significant changes over time.  |
| Rosen et al. (2000); 55             | RCT; II                    | 41/32; 66%; 47.2;<br>Psychophysiological insomnia  | Med (estazolam) + relaxation;<br>Med (estazolam) + imagery;<br>Med (estazolam) + SHE | 4 wk; 6 mo   | Sleep diaries; BDI, Pre-Sleep Arousal Scale, Sleep Efficacy Scale, Sleep Hygiene Practice and Knowledge Scale, Taylor Manifest Anxiety Scale | All three groups showed significant increase of TST (Med + Rel = + 65 min; Med + Imagery = + 40 min; Med + SHE = + 34 min). Only the relaxation and imagery groups showed significant pre to post changes in WASO (- 17 min and - 33 min, respectively) and SE (+ 9.7%, + 7.4%). Significant improvements in all groups at FU relative to baseline sleep. Significant improvements across groups for the Pre-Sleep Arousal Scale, Sleep Efficacy Scale, and BDI (but not anxiety) from baseline to 6-month follow-up, but no group differences.  |
| Rybarczyk et al. (2002); 27         | RCT; II                    | 51/38; 58%; 67.8;<br>Insomnia secondary to medical illness   | CBT (with Rel);<br>Rel;<br>Wait list control   | 8 wk; 4 mo   | Sleep diaries, Actigraphy; PSQI, DBAS, GDS, BAI, SF-36, McGill Pain Questionnaire, Life satisfaction   | CBT more effective than control at posttreatment and FU on measures of SE, WASO, PSQI, and DBAS. Relaxation produced greater change in TST than CBT at posttreatment, greater change than control in TST and PSQI at posttreatment, and greater change than control in SE, WASO, and PSQI at FU. More CBT than control patients achieved clinically significant improvement at posttreatment and FU, and a higher proportion of Relaxation than controls had clinically significant improvement at posttreatment. No group differences on actigraphy, medication use, or secondary outcomes. |

|  |                                  |   |  |              |   |  |
|--|----------------------------------|---|--|--------------|---|--|
| Simeit et al. (2004); 16               | NonRCT; IV                       | NS/229; 75%; 58;<br>Insomnia secondary to cancer  | CBT + Progressive muscle relaxation;<br>CBT + Autogenic training Standard treatment  | 3-4 wk; 6 mo | PSQI, Cancer Quality of Life Questionnaire  | Significant improvement from baseline to FU on SOL, TST, SE for all groups; no group differences. On sleep quality, daytime energy, daytime dysfunction and most other quality of life measures, improvement occurred in all groups. Sleep medication use decreased among participants receiving CBT only.   |
| Strom et al. (2004); 39                | RCT; II                          | 109/81; 65%; 44.1;<br>Primary insomnia  | Internet CBT (with Rel);<br>Wait list control  | 5 wk; 9 mo   | Sleep diaries;<br>DBAS, Medication Index  | Greater improvements observed on TWT (- 55 min), TST (+ 34 min), and SE (+ 10%) in treated relative to controls. Greater reductions of hypnotic use and improvements of DBAS scores in CBT relative to controls. Improvements noted on other sleep measures in both treated and control conditions. Attrition rate of 24%.   |
| Verbeek et al. (1999); 48              | Case replication series; V       | 127/86; 65%; 46;<br>54 psychophysiological, 5 hypnotic dependent, 14 secondary (9 affective, 4 neurological, 1 medical) | CBT (with Rel) and medication withdrawal   | 6 wk; NS     | Sleep diaries; Global improvement   | Significant improvements on SOL (79 vs. 45 min), WASO (137 vs. 74 min), SE (56 vs. 71%). Overall treatment effect rated as "good" in 49%, "reasonable" in 37%, "no change" in 14%; no difference between hypnotic users and non-users. 37% of hypnotic users discontinued medication and 39% reduced their use. No difference between responders and non-responders on baseline measures of sleep, depression, or anxiety. |
| Viens et al. (2003); 23                | RCT; II                          | 23/20; 70%; 36.0;<br>Sleep onset insomnia   | Anxiety Management Training;<br>Rel  | 9 wk; No FU  | PSG;<br>STAI, BDI, MMPI, Sleep onset monitor, sleep satisfaction  | Self-reported SOL significantly decreased and sleep satisfaction improved significantly. SOL measured by behavioral device improved significantly for both treatments (68 and 81 min at baseline vs. 43 and 46 min. at posttreatment). No significant effects for PSG measures of sleep continuity. Secondary measures of depression and anxiety improved with treatment.  |
| Vincent & Hameed (2003); <sup>41</sup> | Case replication series; V       | 50; 66%; 51.4;<br>Primary insomnia  | CBT (with Rel) combined with hypnotic withdrawal and stress management   | 7 wk; No FU  | Sleep diaries;PSQI, DBAS, ISI, BDI  | Significant improvements for SOL (46 vs. 26 min), TST (5.3 vs. 6.2 hrs.), SE (80 vs. 86%), but not for WASO. Significant effect also found for PSQI, ISI, and DBAS. Better treatment compliance associated with better outcomes on DBAS, ISI, and PSQI but not with SOL, TST, SE.  |
| Waters et al. (2003); <sup>52</sup>    | RCT; II                          | 53/53; 70%; 44.1;<br>Psychophysiological insomnia   | Rel;<br>SR + SC;<br>Med (flurazepam);<br>SHE   | 4 wk; No FU  | Sleep diaries   | Rel treatment had greater effect on sleep onset than SR/SC and SHE, whereas SR/SC had greater effect than Rel on sleep maintenance variables (WASO, NA). Medication produced largest changes in all sleep measures.  |
| <b>Abbreviations</b>                   | RCT: Randomized controlled trial |   | CBT: Cognitive-behavior therapy;<br>Rel: Relaxation;<br>SR: Sleep restriction;<br>SC: Stimulus control;<br>SHE: sleep hygiene education;<br>Med: Medication; |              | PSC: Polysomnography;<br>PSQI: Pittsburgh Sleep Quality Index; ISI: Insomnia Severity Index;<br>DBAS: Dysfunctional Belief and Attitudes about Sleep Scale;<br>BDI: Beck Depression Inventory; BAI: Beck Anxiety Inventory; STAI: State-Trait Anxiety Inventory | SOL: Sleep onset latency; WASO: Wake time after sleep onset; TST: Total sleep time; SE: Sleep efficiency   |

on sleep efficiency but there was no evidence of improvements on secondary measures of daytime functioning. In a study that focused specifically on sleep onset insomnia,<sup>34</sup> CBT (with relaxation) decreased SOL by a mean of 34 min with a corresponding 14% increase of SE. Sleep improvements, which had limited impact on secondary mood measures, were well maintained at follow up. Several additional studies, including both controlled and uncontrolled studies, have documented treatment efficacy for insomnia in the context of primary care settings,<sup>14,35,36</sup> in comparisons of different interventions<sup>23,37</sup> or treatment implementation models,<sup>38,39</sup> or as part of case series.<sup>40,41</sup> Some of these studies will be discussed in later sections of this paper.

### 4.3 Treatment of Insomnia Associated with other Medical or Psychiatric Disorders

Twelve investigations have evaluated the efficacy of psychological and behavioral treatments for insomnia associated with another medical or psychiatric disorder. These studies have focused, for example, on patients with chronic pain,<sup>25</sup> cancer,<sup>16,42</sup> alcohol dependence<sup>26</sup> and older adults with various medical illnesses.<sup>27,43</sup> Only 4 of those 12 studies were RCT (Grade I or II)<sup>25-27,43</sup> and the remaining were nonrandomized studies or clinical replication series.

In a study of 60 patients with insomnia associated with chronic pain,<sup>25</sup> CBT was significantly more effective than control on measures of SOL, WASO, and SE, but not on number of awakenings and TST. SOL was reduced from 55 min to 28 min and SE increased from 72% to 85%. Nocturnal motor activity (as measured by actigraphy) was reduced in the treated group but not in the control group; there were no group differences on pain ratings, depressive symptoms, or medication use. In a study of 51 older adults with insomnia associated with medical illness,<sup>27</sup> CBT and relaxation conditions were more effective than control on diary measures of WASO and SE, as well as on a measure of overall sleep quality (PSQI); the relaxation group had a greater increase in TST than CBT and controls. A higher proportion of treated patients relative to controls achieved clinically significant improvements. There were no differential group effects on actigraphy, medication use, or other secondary measures of anxiety, depression, and quality of life. In a study of 49 older adults with insomnia associated with medical and psychiatric conditions,<sup>43</sup> a combined intervention of stimulus control, relaxation, and education reduced WASO 25 min and increased SE 11% at post treatment. Fifty-seven percent (57%) of treated patients achieved clinically significant improvements on SE relative to 19% of control patients; there was no significant change on secondary measures of anxiety, depression, and impact of insomnia. Outcomes were similar for individuals with insomnia associated with a medical condition and those with insomnia related to a psychiatric disorder. A controlled study conducted with recovered alcoholics<sup>26</sup> showed modest but significant improvements of SOL (- 18 min) and SE (+10%) among insomnia-treated patients. At the 6 month follow-up, 15% of treated participants had relapses with alcohol and this proportion was not different between treated and control patients.

Several additional studies (clinical replication series or uncontrolled group studies) have also provided evidence showing that patients with medical and psychiatric disorders could also benefit from sleep/insomnia specific interventions. Two investigations

with cancer patients<sup>16,42</sup> showed that CBT was associated with improvements of sleep and of daytime functioning (e.g., fatigue, energy). One case series study of 67 patients with psychiatric disorders and insomnia<sup>44</sup> reported significant improvements of sleep, mood, fatigue, and reduced use of sleep medication, while a smaller study<sup>45</sup> found no change on specific sleep parameters (SOL and WASO) but reported significant reductions of global insomnia severity as measured by the ISI. Additional evidence supporting the efficacy of CBT was reported in 3 clinical replications series<sup>46-48</sup> conducted with heterogeneous samples of patients presenting to sleep disorders clinics with a variety of primary and secondary insomnia diagnoses. Although conclusions drawn from these uncontrolled studies should be treated with caution because of the studies' high attrition rate, the evidence suggests that among those who received an adequate treatment exposure (average of 6 - 8 therapy sessions) outcomes were comparable to those patients with primary insomnia enrolled in controlled clinical trials. Furthermore, treatment response appeared comparable between patients with medical or psychiatric comorbidity and those with primary insomnia in one study. Baseline anxiety, depression, and insomnia severity did not differ among treatment responders and nonresponders.<sup>48</sup>

### 4.4 Treatment of Insomnia in Older Adults

Nearly 25% (9 studies out of 37) of reviewed studies were conducted with older adults (average age > 60 years old). This is in sharp contrast to our previous review<sup>12</sup> that included only a handful of studies with older subjects. Three studies focused on older adults with primary insomnia,<sup>18,20,21</sup> 2 on insomnia associated with medical or psychiatric illnesses,<sup>27,43</sup> 1 included a mix of patients with primary and comorbid insomnia,<sup>49</sup> 2 evaluated the impact of psychological and behavioral interventions specifically in older adults who were chronic users of hypnotic medications,<sup>15,22</sup> and 1 study<sup>19</sup> examined the moderating role of upper airway resistance syndrome in the treatment of postmenopausal insomnia. With the exception of the study conducted by Pallesen et al,<sup>49</sup> all these investigations were RCT.

In a study of 89 older adults with primary insomnia,<sup>20</sup> sleep restriction and relaxation were both more effective than a psychological placebo for reducing WASO; changes were identical (67 min to 43 min) for the 2 treatment groups at the end of the 6-week treatment phase, but sleep restriction produced the best outcome at the 1-year follow up. No significant changes were obtained on PSG measures. All 3 conditions, including placebo control, showed improvements on secondary measures of fatigue and a measure of insomnia impact. In another placebo-controlled study,<sup>21</sup> 76 older adults treated with CBT, medication (temazepam), or combined CBT + medication improved more than those receiving placebo on the main outcome measures of WASO and SE. PSG comparisons yielded improvements in the same direction, albeit of smaller magnitude, than those reported on sleep diaries. A greater proportion of patients treated with CBT, alone or combined with medication, achieved clinically significant improvements (i.e., SE > 85%) compared to those receiving medication alone or placebo.

In a comparison of sleep restriction, with and without an optional daytime nap, to sleep education alone,<sup>18</sup> both sleep restriction conditions produced greater SE increase, with reduced time spent in bed, relative to the control condition. There was no sig-

nificant group difference on actigraphy or PSG measures; TST was reduced for the sleep restriction conditions at post treatment and returned towards baseline values at the 3-month follow-up. There was a mild increase of physiological sleepiness (as measured by the MSLT) but no change on subjective sleepiness. In another investigation,<sup>49</sup> a combination of sleep education plus stimulus control was as effective as sleep education plus relaxation, and more effective than a wait-list control, in older adults with mixed primary and secondary insomnia; there were modest improvements of daytime measures for both active conditions. Two additional studies (reviewed in section 4.3) provided evidence that older adults with insomnia and comorbid medical disorders also benefitted from sleep-specific interventions.<sup>20,27</sup>

#### 4.5 Treatment of Insomnia Among Chronic Hypnotic Users

Four investigations examined the efficacy of psychological and behavioral interventions for insomnia in the context of chronic hypnotic usage, including 2 that were conducted with older adults.<sup>15,22</sup> In a study of 209 chronic hypnotic users,<sup>15</sup> CBT (with an optional medication taper) was associated with improved PSQI scores and reductions of hypnotic use at 3- and 6-month follow ups. A greater percentage of patients treated with CBT for insomnia (39%) relative to no treatment controls (11%) achieved at least a 50% reduction of hypnotic use relative to baseline at the 6-month follow up. A cost-offset analysis revealed that while CBT added to the initial treatment cost, there was a significant cost offset at follow up resulting from a reduction of sleep medication usage. In another study comparing a supervised medication withdrawal program, alone and combined with CBT for insomnia, to CBT alone,<sup>22</sup> all 3 interventions produced significant reductions in both the quantity (90%) and the frequency (80%) of benzodiazepine use, and more patients in the combined approach (85%) were medication free at post-treatment than for those receiving the taper schedule alone (48%) or CBT alone (54%). There were modest changes in sleep patterns during the initial 10-week withdrawal phase, but CBT-treated patients reported greater sleep improvements relative to those receiving the medication withdrawal alone. Several improvements were also reported on secondary measures of insomnia severity (ISI), anxiety (BAI) and depressive (BDI) symptoms.

Two additional studies have examined the impact of chronic hypnotic use on outcome with middle-aged adults. One study<sup>50</sup> found a significant worsening of sleep parameters during medication withdrawal and the addition of relaxation therapy did not attenuate this effect. In a similar study using stimulus control as the main behavioral intervention,<sup>51</sup> stimulus control produced significant improvements on most sleep parameters relative to no additional treatment. There was no difference in sleep outcomes between medicated and nonmedicated patients.

#### 4.6 Validation and Comparative Efficacy of Single and Multifaceted Therapies

Although there are several distinct psychological and behavioral therapies for insomnia, there was a clear trend/preference for investigators to combine 2 or more of these methods when treating insomnia. The most common combination involves an educational (sleep hygiene), behavioral (stimulus control, sleep restriction, relaxation), and a cognitive therapy component, usually referred to as cognitive-behavior therapy. Indeed, 21 stud-

ies have evaluated the efficacy of CBT, either with (12 studies) or without relaxation (9 studies), and 5 more studies have used a similar multi-component interventions but without cognitive therapy (see Table 2).

There has been no complete dismantling of CBT to isolate the relative efficacy of each component within the same study. However, comparisons of some components revealed that CBT was superior to relaxation alone in 1 study of primary insomnia<sup>17</sup> and sleep restriction was superior to relaxation at follow-up in another study with older adults.<sup>20</sup> In another study,<sup>52</sup> relaxation was more effective for sleep initiation problems relative to sleep hygiene education alone and a combination of stimulus control plus sleep restriction, whereas the latter combination had greater effects on sleep maintenance variables.

Twelve studies have isolated in a controlled trial at least 1 therapy component such as relaxation, sleep restriction, stimulus control, or paradoxical intention. All 6 studies contrasting relaxation-based interventions (either progressive muscle relaxation or similar procedures) to a control condition, have reported that this single therapy was more effective than wait-list,<sup>27</sup> placebo,<sup>17,20</sup> no treatment,<sup>37,50</sup> and minimal sleep hygiene education control.<sup>52</sup> Two studies showed that sleep restriction was superior to either placebo<sup>20</sup> or sleep hygiene education alone,<sup>18</sup> 1 study found that stimulus control was more effective than a wait-list control,<sup>51</sup> and 1 additional investigation reported that paradoxical intention was superior to a wait-list control for sleep onset insomnia.<sup>24</sup> In spite of the inclusion of a cognitive therapy component in numerous studies, no study has yet evaluated its unique contribution to outcomes.

As in the earlier review paper,<sup>12</sup> criteria developed by the American Psychological Association<sup>53</sup> for defining empirically-validated psychological treatments, were used to determine whether additional evidence was available for each psychological and behavioral interventions (See Table 3). Based on the criteria outlined in our previous review,<sup>12</sup> stimulus control therapy, relaxation training, and paradoxical intention met criteria for well-established psychological treatment for insomnia. With the additional evidence from the present review (indicated by studies in boldface in Table 3), sleep restriction<sup>18,20</sup> and CBT<sup>17,21</sup> would also meet criteria for well-established treatments. Furthermore, additional studies strengthened the level of evidence supporting stimulus control,<sup>51</sup> relaxation,<sup>17,20,27,37</sup> and paradoxical intention.<sup>24</sup>

#### 4.7 Comparisons of Psychological/Behavioral Therapies and Medication

Five controlled studies conducted with primary/psychophysiological insomnia patients have evaluated the impact of psychological/behavioral interventions in comparison to or as an adjunct to hypnotic medications. Two studies evaluated the efficacy of CBT, singly and combined with medication,<sup>21,34</sup> 1 used a medication alone condition as a comparator to psychological treatments,<sup>52</sup> and 2 examined the incremental benefits of adding 1 treatment to the other.<sup>54,55</sup>

In a placebo-controlled comparison of CBT and medication (temazepam) singly and combined<sup>21</sup> (study described in Sections 4.2 and 4.4), all 3 active treatments were more effective than placebo on sleep continuity variables, with a trend for the combined approach to yield better outcomes. These results were corroborated with PSG measures, although the magnitudes of sleep improve-

**Table 3**—Key Studies Supporting Efficacy Of Psychological And Behavioral Treatments Of Insomnia

| Treatment              | Study reference                                  | Evidence                         |
|------------------------|--|----------------------------------|
| Stimulus control*      | Espie et al. (1989) <sup>69</sup>                | SC > Pla & Rel                   |
|                        | Lacks et al. (1983) <sup>70</sup>                | SC > Pla                         |
|                        | Lacks et al. (1983) <sup>71</sup>                | SC > Pla                         |
|                        | Morin & Azrin (1987;1988) <sup>72,73</sup>       | SC > IT                          |
|                        | Turner & Asher (1979) <sup>74</sup>              | SC > Pla                         |
| Relaxation*            | <b>Riedel et al. (1998)<sup>51</sup></b>         | <b>SC &gt; WL</b>                |
|                        | <b>Edinger et al. (2001)<sup>17a</sup></b>       | <b>Rel &gt; Pla</b>              |
|                        | <b>Lichstein et al. (2001)<sup>20b</sup></b>     | <b>Rel &gt; Pla</b>              |
|                        | Lick & Heffler (1977) <sup>75</sup>              | Rel > Pla                        |
|                        | Nicassio et al. (1982) <sup>76</sup>             | Rel > No treatment               |
|                        | Turner & Asher (1979) <sup>74</sup>              | Rel > Pla                        |
|                        | Woolfolk & McNulty (1983) <sup>77</sup>          | Rel > WL                         |
| Paradoxical Intention* | <b>Means et al. (2000)<sup>37</sup></b>          | <b>Rel &gt; No treatment</b>     |
|                        | <b>Rybarczyk et al. (2002)<sup>27c</sup></b>     | <b>Rel &gt; WL</b>               |
|                        | Espie et al. (1989) <sup>69</sup>                | PI > Pla                         |
| Sleep restriction*     | Turner & Asher (1979) <sup>74</sup>              | PI > Pla                         |
|                        | <b>Broomfield et al. (2003)<sup>24</sup></b>     | <b>PI &gt; WL</b>                |
| EMG biofeedback†       | Friedman et al. (1991) <sup>78</sup>             | SR > Pla                         |
|                        | <b>Friedman et al. (2000)<sup>18</sup></b>       | <b>SR + SHE &gt; SHE</b>         |
|                        | <b>Lichstein et al. (2001)<sup>20b</sup></b>     | <b>SR &gt; Pla</b>               |
| CBT*                   | Nicassio et al. (1982) <sup>76</sup>             | BF > No treatment                |
|                        | Sanavio et al. (1990) <sup>79</sup>              | BF > WL                          |
|                        | VanderPlate & Eno (1983) <sup>80</sup>           | BF > WL                          |
|                        | Freedman & Papsdorf (1976) <sup>81</sup>         | BF > Pla                         |
|                        | <b>Edinger et al. (2001)<sup>17a</sup></b>       | <b>CBT &gt; Rel &gt; Pla</b>     |
| CBT (with Rel)*        | <b>Mimeault &amp; Morin (1999)<sup>38</sup></b>  | <b>CBT &gt; WL</b>               |
|                        | Morin et al. (1993) <sup>82</sup>                | CBT > WL                         |
|                        | <b>Morin et al. (1999)<sup>21</sup></b>          | <b>CBT &gt; Pla</b>              |
|                        | <b>Morin et al. (2004)<sup>22</sup></b>          | <b>CBT &gt; Medication taper</b> |
|                        | <b>Perlis et al. (2004)<sup>54</sup></b>         | <b>CBT &gt; Contact control</b>  |
|                        | <b>Currie et al. (2000)<sup>25</sup></b>         | <b>CBT &gt; WL</b>               |
|                        | <b>Currie et al. (2004)<sup>26</sup></b>         | <b>CBT &gt; WL</b>               |
| Multi-component†       | <b>Espie et al. (2001)<sup>33</sup></b>          | <b>CBT &gt; WL</b>               |
|                        | <b>Jacobs et al. (2004)<sup>34</sup></b>         | <b>CBT &gt; Pla</b>              |
|                        | <b>Morgan et al. (2003)<sup>15</sup></b>         | <b>CBT &gt; No treatment</b>     |
|                        | <b>Rybarczyk et al. (2002)<sup>27c</sup></b>     | <b>CBT &gt; WL</b>               |
|                        | <b>Edinger &amp; Sampson (2003)<sup>35</sup></b> | <b>MC &gt; SHE</b>               |
|                        | <b>Lichstein et al. (2000)<sup>43</sup></b>      | <b>MC &gt; WL</b>                |
|                        | <b>Waters et al. (2003)<sup>52</sup></b>         | <b>MC &gt; SHE</b>               |

Note: Citations in boldface are for studies published between 1998 and 2004; all other studies were published prior to this period.

BF = EMG Biofeedback; CBT = Cognitive Behavior Therapy; IT = Imagery Training; PI = Paradoxical Intention; Pla = Placebo; Rel = Relaxation; SC = Stimulus Control; SR = Sleep Restriction; SHE = Sleep Hygiene Education; WL = Wait-List Control; MC = Multicomponent.

<sup>a,b,c</sup>These studies provided evidence supporting more than 1 treatment.

\*Well established treatments according to APA criteria for empirically supported treatments. Criteria for well-established treatments require at least 2 between-group design studies demonstrating efficacy in 1 or more of the following ways: I. superior to pill or psychological placebo or to another treatment; or equivalent to an already established treatment in a study with adequate statistical power; II. a large series of single case design experiments (n > 9) demonstrating efficacy as in I; III. the studies must be conducted with treatment manuals; IV. the characteristics of the sample must be well-described; V. the effects must have been demonstrated by at least 2 different investigators or investigatory teams.

†Probably efficacious treatments according to APA criteria for empirically supported treatments. Criteria for probably efficacious treatments are: I. 2 studies showing the treatment is more effective than a waiting-list control group, or II. 1 or more studies meeting the well-established treatment criteria I, III, and IV, but not V, or III. a small series of single case design studies (n > 3) otherwise meeting well-established treatment criteria II, III, and IV.

ments were smaller on PSG than on diary measures. Long-term follow-up data showed that subjects treated with CBT sustained their clinical gains over time, whereas those treated with medication alone did not. The combined approach showed some loss of therapeutic benefits over the follow-up periods, although there was more variability across subjects in that condition. In a similar study design with 63 young and middle-aged adults with sleep onset insomnia<sup>34</sup> (study described in Section 4.2), CBT was shown more effective than medication (zolpidem) and placebo on measures of SOL and SE. All 4 conditions, including placebo, increased their TST, with medication yielding the largest increase in TST (69 min), though this finding was not significantly different from the other groups. There was no significant difference between CBT alone and CBT combined with medication. Sleep changes were well maintained at the 12-month follow up for patients treated with CBT, singly or combined with medication, but no follow up data was available for those treated with medication alone. Data obtained from a Nightcap device showed sleep changes in the same direction as those from diaries, except that no improvement was obtained on any of the measures for the placebo condition.

An investigation of 41 patients treated with estazolam examined the added benefits of muscle relaxation, imagery training, and sleep hygiene education to medication.<sup>55</sup> There was no group difference on any outcome. Significant improvements from baseline to post treatment were obtained on WASO and SE for the relaxation (-17 min and + 9.7% respectively) and imagery training groups (- 33 min and + 7.4%). TST was increased by 34 min (education), 40 min (imagery), and 65 min (muscle relaxation) for the same period but there was no significant group difference. SOL was not changed in any of the groups. Significant changes were obtained from baseline to follow up in all 3 groups on sleep measures and on secondary measures of arousal, self-efficacy, and depressive (but not anxiety) symptoms.

Another study of 30 patients<sup>54</sup> examined the added benefits of modafinil when combined with CBT in the management of primary insomnia. Although there was no significant gain from modafinil in terms of sleep continuity parameters, there were trends suggesting that the addition of modafinil to CBT reduced daytime sleepiness and enhanced compliance with prescribed bedtime. Finally, data from 53 patients with primary insomnia<sup>52</sup> showed that while relaxation was more effective for sleep onset problems and a combination of stimulus control plus sleep restriction had more benefits for sleep maintenance variables, medication (flurazepam) produced the largest improvements on all sleep variables during the initial 2-week intervention.

#### 4.8 Treatment Implementation Methods: Individual, Group, and Self-Help

Treatment was implemented on an individual basis in 22 studies (54%), in a group format in 11 studies (29.7%), and a few additional studies relied on self-help materials with or without additional telephone consultations. An average of 5.7 consultation visits was conducted over a mean treatment period of 6.5 weeks. 1 study directly compared the relative efficacy of CBT implemented in group or individual sessions, or through self-help written materials combined with brief telephone consultations.<sup>56</sup> All 3 groups produced significant improvements of sleep and secondary measures and there was no between group difference on any

measure. A similar study of insomnia in recovered alcoholics also found equivalent outcome between individual CBT and self-help CBT plus telephone consultation.<sup>26</sup> In contrast, 1 study<sup>38</sup> found that the addition of telephone consultation to self-help written material enhanced outcomes at post treatment, but those initial gains tended to disappear at follow up. An internet-based intervention produced greater improvement in several sleep parameters relative to controls,<sup>39</sup> but the attrition rate (24%) was higher than in studies using face-to-face consultation visits. While the majority of reviewed studies have used psychologists or psychology trainees as therapist (with treatment manual), 2 studies examined treatment efficacy as implemented by primary care physicians<sup>36</sup> or by nurse practitioners<sup>33</sup> who had also been trained before the studies; treatment benefits were generally equivalent to those obtained with therapists who had mental-health training.

#### 4.9 Durability of Sleep Improvements

Twenty-six of the 37 reviewed studies reported follow up data of at least 1 month duration after completing treatment (mean duration = 7.7 months; range 1-36 months). The remaining 11 studies reported no follow-up data. As was the case in the initial review, a very robust finding across studies is that treatment-produced changes in sleep parameters are well maintained at short (1-3 month), intermediate (6-month), and long-term (> 12 months) follow-ups. One interesting finding from studies using sleep restriction is that total sleep time may be reduced during the initial intervention, but it is significantly increased at follow up evaluation.<sup>20</sup> Despite fairly robust long-term outcomes, follow-up data must be interpreted cautiously as there are relatively few studies reporting long-term (> 1 year) follow-ups (see Table 2) and, among those that do, attrition rates increase substantially over time.

#### 5.0 CONCLUSIONS

This updated review of treatment studies conducted between 1998 and 2004 provides additional evidence that psychological and behavioral interventions represent an effective treatment option for the management of persistent insomnia. In addition to studies further documenting treatment efficacy for primary insomnia, recent studies indicate that treatment is also effective for insomnia associated with some medical conditions and, to a lesser extent, with psychiatric conditions. Treatment benefits are well sustained over time. There is still limited evidence of clinically meaningful changes beyond reductions of insomnia symptoms (i.e., improved daytime functioning, quality of life).

These findings are consistent with our previous systematic review<sup>12</sup> as well as with other meta-analyses of the efficacy of psychological and behavioral interventions for insomnia.<sup>57-59</sup> For instance, of the 17 most recent treatment studies of primary insomnia, 5 were randomized controlled trials,<sup>17,20,21,33,34</sup> and all 5 yielded additional evidence of significant sleep improvements with psychological and behavioral interventions. Although most of this additional evidence is based on daily sleep diaries, 3 of the 5 key studies included PSG measures and 2 of them reported outcomes that paralleled findings from diary measures. Actigraphy, on the other hand, was not very sensitive for detecting changes in sleep/wake variables in the few studies using this device.

The treatment of comorbid insomnia has received limited attention until recently, perhaps owing to the traditional notion that

it would not respond to treatment unless the associated condition was treated first. The present review, as well as recent findings,<sup>60-62</sup> challenge this traditional notion and indicate that insomnia-specific treatment is of benefit even among those whose insomnia is associated with comorbid conditions such as cancer, pain, alcohol abuse, and some psychiatric conditions. Nonetheless, there is a need for additional prospective and randomized controlled studies of comorbid insomnia contrasting outcomes when sleep is or is not directly targeted in treatment.

The treatment of insomnia in older adults is another area previously neglected and for which there was limited evidence to guide practitioners. Nearly 25% of the studies reviewed in this paper focused on older adults. The findings from those studies indicate that older adults with primary insomnia respond to treatment as well as younger and middle-aged adults, although the presence of comorbid medical or psychiatric condition may moderate outcomes.<sup>27,43</sup> A recent meta-analysis<sup>63</sup> also confirmed that treatment effect sizes are comparable for middle-aged and older adults. There is additional evidence that psychological treatment can facilitate hypnotic discontinuation in older adults who are chronic users of hypnotics.<sup>15,22</sup> This is an important finding as older adults are more likely to be long-term hypnotic users which, in some cases, may perpetuate sleep disturbances. Thus, although heterogeneity in diagnosis makes it more difficult to compare studies,<sup>64</sup> such heterogeneity of insomnia samples also enhances generalizability of outcomes.

This review highlights an emerging trend among investigators for combining multiple treatments, which contrasts with the earlier review describing numerous studies comparing treatment efficacy among 2 or more single therapies. Indeed, 26 of the 37 reviewed studies evaluated the efficacy a multi component approaches, including 21 studies using multicomponent therapy, with or without relaxation, and 5 more combining behavioral interventions (e.g., stimulus control and sleep restriction) but without cognitive therapy. Although the reason for this shift in paradigm is not entirely clear, the use of multi-component approaches is more likely, at least on a clinical basis, to address the different facets/perpetuating factors of insomnia.<sup>11</sup>

Whether CBT produces outcome that is superior to single therapies remains largely unexplored. The few comparative studies available show that outcome is superior for CBT, stimulus control, and for sleep restriction relative to relaxation alone,<sup>17,20,27,49</sup> however, there has been no complete dismantling of CBT to isolate the relative efficacy of each component. Furthermore, although some findings<sup>65</sup> suggest that change in beliefs and attitudes is an important mediator of long-term outcomes, there has been no direct controlled evaluation to isolate the relative contribution of cognitive therapy.

Our previous review had identified 3 treatments as well-validated and 2 more as probably efficacious according to criteria set by the American Psychological Association.<sup>53</sup> This updated review provides further evidence supporting stimulus control, relaxation, paradoxical intention as well validated therapies, and new evidence to upgrade sleep restriction and CBT from probably efficacious to well-established treatments.

Although there is evidence supporting the efficacy of psychological and behavioral treatment for insomnia, there is still little information about the specificity of this treatment modality and the active therapeutic mechanisms responsible for sleep improve-

ments. With a few notable exceptions using attention-placebo conditions,<sup>17,20</sup> most CBT trials have used wait-list control groups, precluding the unequivocal attribution of treatment effects to any specific ingredient of psychological and behavioral treatment. The lack of a pill-placebo control equivalent in psychological outcome research makes it difficult to determine what percentage of the variance in outcomes is due to specific therapeutic ingredients (i.e., restriction of time in bed, cognitive restructuring), the measurement process (i.e., self-monitoring), or to non-specific factors (e.g., therapist attention, patients' expectations).

An important limitation noted in the previous review that is still evident in recent studies is the limited evidence documenting the clinical significance of outcomes beyond insomnia symptom reductions (i.e., reduced morbidity, improved quality of life). There is a need for broadening the scope of outcome measures<sup>66</sup> and for standardizing assessment methodology in insomnia research,<sup>64,67</sup> Furthermore, even for patients meeting criteria for what might be considered a clinically meaningful change, many such treatment responders reach a plateau and continue showing residual sleep disturbances after treatment and may remain at risk for relapse. There is a need to develop and validate more potent interventions that would increase the rate of patients reaching full remission.<sup>9</sup> Ongoing studies are currently examining optimal treatment dosage, treatment combination involving medication, and maintenance therapies.

A related issue is that most of the outcome evidence currently available is about improving sleep initiation and sleep continuity parameters, with essentially no information about the impact of treatment on more qualitative aspects of sleep, i.e., non-restorative sleep. Although this qualitative feature is part of the standard insomnia definition, no study has of yet examined the impact of psychological treatment on this variable.

Proper implementation of psychological and behavioral therapies usually requires more time than prescribing a hypnotic medication, which may represent an important barrier to using such interventions in clinical practice. Nonetheless, several studies have documented the benefits of cost-effective implementation models using nurse practitioners, group therapy, or self-help materials to complement therapist-guided intervention. Whereas such implementation models are likely to make treatment more readily available, adequate therapist training remains an important consideration in using CBT effectively to optimize outcome. Additional studies examining the relative cost-effectiveness of different insomnia interventions would be warranted<sup>68</sup>

In summary, this updated review provides additional evidence supporting the use of psychological and behavioral interventions for primary insomnia, for insomnia associated with medical or psychiatric conditions, and for insomnia in older adults. Additional research is still needed to develop and validate treatment algorithms that would optimize outcomes and reduce morbidity; clinical research that would examine treatment mechanisms, mediators and moderators of outcomes is also warranted; and, additional effectiveness trials are particularly needed to document outcomes in unselected patients seeking treatment in various clinical settings (e.g., primary care). Finally, an important challenge for the future will be to disseminate more efficiently the available evidence to health-care providers and translate that evidence into meaningful clinical guidelines in order to ensure a more widespread use of validated therapies.

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**Appendix A.**  
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